DRAFT REGISTRATION REPORT
Part A

Risk Management

Product name: Kumar

Product code: ACH-07547-F-0-SP

Active Substance: Potassium hydrogen carbonate 850 g/kg

COUNTRY: Germany

Central Zone

Zonal Rapporteur Member State: Germany

NATIONAL ASSESSMENT

Applicant: Spiess-Urania Chemicals GmbH

Submission date: 02.10.2015

Finalisation date: 08.11.2017

Table of Contents

PART A – Risk Management

This document describes the acceptable use conditions required for the extension of registration of ACH-07547-F-0-SP (Kumar) containing potassium hydrogen carbonate in Germany. This evaluation is required subsequent to the inclusion of potassium hydrogen carbonate on Annex 1.

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 1-7 and Part C and where appropriate the addendum for Germany. The information, data and assessments provided in Registration Report, Parts B includes assessment of further data or information as required at national registration by the EU review. It also includes assessment of data and information relating to ACH-07547-F-0-SP (Kumar) where that data has not been considered in the EU review. Otherwise assessments for the safe use of ACH-07547-F-0-SP (Kumar) have been made using endpoints agreed in the EU review of potassium hydrogen carbonate.

This document describes the specific conditions of use and labelling required for Germany for the registration of ACH-07547-F-0-SP (Kumar).

Appendix 1 should include the authorisation of the final product in Germany. Due to technical reasons, the authorisation of the final product in Germany is inserted under Appendix 4.

Appendix 2: The submitted draft product label has been checked by the competent authority. The applicant is requested to amend the product label in accordance with the decisions made by the competent authority. The final version of the label has to fulfil the requirements according to Article 31 of Regulation (EC) No 1107/2009.

Appendix 3: Letter(s) of access is/are classified as confidential and, thus, are not attached to this document.

Appendix 4 of this document provides a copy of the final product authorisation Germany. It will be inserted in the final version.

1 Details of the application

1.1 Application background

This application was submitted by DHD-Consulting GmbH on behalf of Spiess-Urania Chemicals GmbH on 2 October 2015.

The application was for approval of ACH-07547-F-0-SP (Kumar), a water soluble powder containing 850 g/kg potassium hydrogen carbonate for use as a fungicide in viticulture.

1.2 Annex I inclusion

Potassium hydrogen carbonate was included on Annex I of Directive 91/414/EEC on 1 September 2009 under Inclusion Directive **2008/127/EC** amended by the Commission implementing Regulation (EU) No 735/2012 on 14 August 2012.

The Annex I Inclusion Directive for Potassium hydrogen carbonate provides specific provisions under Part B which need to be considered by the applicant in the preparation of their submission and by the MS prior to granting an authorisation.

For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on potassium hydrogen carbonate (SANCO/2625/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 13 July 2012 shall be taken into account. In this overall assessment:

Member States shall pay particular attention to the:

- risk to honeybees. Conditions of use shall include, where appropriate, risk mitigation measures.'

EFSA (2012[1]) identified the following data gap for the section Environment:
"The background level of K^+ in natural soils and surface waters needs to be reported from a study or a peer reviewed scientific reference (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 4).

These concerns were all addressed in the submission.

1.3 Regulatory approach

To obtain authorisation the product ACH-07547-F-0-SP (Kumar) must meet the conditions of Annex I inclusion /approval and be supported by dossiers satisfying the requirements of Annex II and Annex III, with an assessment to Uniform Principles, using Annex I agreed / approved end-points.

Kumar has already been approved by the German competent authorities for the use in apple (ZV1 007547-00/00) in accordance with the above.

This application was submitted in order to allow the use extension of this product in Germany to grapevine.

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of Kumar, it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B, sections 1, 5, 6 and 7.

1.5 Letters of Access

Not necessary. The applicant addressed all data requirements by own data or made reference to data out of protection, respectively.

2 Details of the authorisation

2.1 Product identity

Product Name	Kumar (Armicarb 85SP
Authorization Number (for re-registration)	007547-10
Function	fungicide
Applicant	Spiess-Urania Chemicals GmbH
Composition	850 g/kg potassium hydrogen carbonate
Formulation type	Water soluble powder (Code: SP)
Packaging	5 kg kraft PE bag with polyethylene lining

2.2 Classification and labelling

2.2.1 Classification and labelling under Directive 99/45/EC

Not proposed.

2.2.2 Classification and labelling under Regulation (EC) No 1272/2008

The following labelling is proposed in accordance with Regulation (EC) No 1272/2008:

Hazard classes and categories:	
None	
Hazard pictograms:	
None	
Signal word:	
None	
Hazard statements:	
None	
Precautionary statemtents:	
None	

Special rule for labelling of PPP:	
EUH401	To avoid risks to man and the environment, comply with the instructions for use.
Further labelling statements under Regulation (EC) No 1272/2008:	
None	

2.2.3 Standard phrases under Regulation (EC) No 547/2011

None

2.3 Other phrases notified under Regulation (EC) No 547/2011

2.3.1 Restrictions linked to the PPP

The authorization of the PPP is linked to the following conditions (mandatory labelling):

Human health protection	
SB001	Avoid any unnecessary contact with the product. Misuse can lead to health damage.
SB010	Keep out of the reach of children.
SF245-01	Treated areas/crops may not be entered until the spray coating has dried.
Integrated pest management (IPM)/sustainable use	
NN3001	The product is classified as harmful for populations of relevant beneficial insects.
NN3002	The product is classified as harmful for populations of relevant predatory mites and spiders.
WMFUN	Mode of action (FRAC-group): unknown (for potassium hydrogen carbonate)
Ecosystem protection	
EB001-1	SP 1: Do not contaminate water with the product or its container.

The authorization of the PPP is linked to the following conditions (voluntary labelling):

Integrated pest management (IPM)/sustainable use	
NB6641	The product is classified as non-hazardous to bees, even when the maximum application rate, or concentration if no application rate is stipulated, as stated for authorisation is applied. (B4)

2.3.2 Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions (mandatory labelling):
See 2.4 (Product uses)

Integrated pest management (IPM)/sustainable use	
NN334 for uses -001 and -002	The product is classified as harmful for populations of the species Typhlodromus pyri (predatory mite).
Ecosystem protection	
NW 642-1	The product may not be applied in or in the immediate vicinity of surface or coastal waters. Irrespective of this, the minimum buffer zone from surface waters stipulated by state law must be observed. Violations may be punished by fines of up to 50 000 EUR

2.4 Product uses

GAP-Table of intended uses for Germany

GAP rev. 1, date: 2016-May-24

PPP (product name/code):	Kumar
Active substance 1:	Potassium hydrogen carbonate
Applicant:	Spiess-Urania Chemicals GmbH
Zone(s):	central [d]
Verified by MS:	yes
Formulation type:	Water soluble powder (SP) [a, b]
Conc. of as 1:	850,00 g/kg [c]
Professional use:	☒
Non professional use:	☐
Field of use:	herbicide, fungicide, insecticide etc

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f]
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	DE	Grape VITVI (utilisation as table and wine grape)	F	grey mould *Botrytis cinerea* BOTRCI	spraying or fine spraying (low volume spraying)	in case of danger of infection and/or after warning service appeal BBCH 75-89	a) 4 b) 6	8-30 days	a) 5.00 kg/ha b) 30.00 kg/ha	a) 4.25 kg as/ha b) 25.50 kg as/ha	800-1600	1	
2	DE	Grape VITVI (utilisation as table and wine grape)	F	powdery mildew of grape *Uncinula necator* UNCINE	spraying or fine spraying (low volume spraying)	in case of danger of infection and/or after warning service appeal BBCH 57-85	a) 6 b) 6	7-10 days	a) 5.00 kg/ha b) 30.00 kg/ha	a) 4.25 kg as/ha b) 25.50 kg as/ha [2]	200-1600	1	Dose rates staggered according to BBCH: basic application rate: 1.25 kg/ha in 200-400 L/ha Water BBCH 61: 2.50 kg/ha in 400-800 L/ha Water

													BBCH 71: 3.75 kg/ha in 600-1200 L/ha Water BBCH 75: 5.00 kg/ha in 800-1600 L/ha Water

Remarks table heading:

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008
(c) g/kg or g/l
(d) Select relevant
(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
(f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

Remarks columns:

1 Numeration necessary to allow references
2 Use official codes/nomenclatures of EU Member States
3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)
4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application
5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.
6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.
7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
8 The maximum number of application possible under practical conditions of use must be provided.
9 Minimum interval (in days) between applications of the same product
10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".
13 PHI - minimum pre-harvest interval
14 Remarks may include: Extent of use/economic importance/restrictions

3 Risk management

3.1 Reasoned statement of the overall conclusions taken in accordance with the Uniform Principles

3.1.1 Physical and chemical properties (Part B, Section 1, Points 2 and 4)

Overall Summary:
The product Kumar is a water soluble powder. Most studies have been performed in accordance with the current requirements, the critical GAP and the results are deemed to be acceptable. The appearance of the product is that of white odourless powder. It is not explosive, not highly flammable and has no oxidising properties. In aqueous solution, it has a pH value around 8.3. The stability data provisionally indicate a shelf life of at least 2 years in LDPE and plastic sachets at ambient temperature.
The technical characteristics are acceptable for a water soluble powder formulation. Due to its chemical nature (salts), Kumar is hygroscopic under ambient conditions with humidity and aggregates tend to form during storage. However specific test on aggregates show that the dissolution degree and stability is acceptable, including after accelerated stability storage.

Implications for labelling: none

Compliance with FAO guidelines:
The product Kumar complies with the general requirements for SP formulations according to the FAO/WHO manual 2010.

Compatibility of mixtures:
No tank mixtures are recommended.

Nature and characteristics of the packaging:
Information with regard to type, dimensions, capacity, size of opening, type of closure, strength, leakproofness, resistance to normal transport & handling, resistance to & compatibility with the contents of the packaging, have been submitted, evaluated and is considered to be acceptable.

Nature and characteristics of the protective clothing and equipment:
Information regarding the required protective clothing and equipment for the safe handling of Kumar has been provided and is considered to be acceptable.

3.1.2 Methods of analysis (Part B, Section 2, Point 5)

3.1.2.1 Analytical method for the formulation (Part B, Section 2, Point 5.2)

Kumar was a representative formulation in the EU review of potassium hydrogen carbonate. Analytical methods for determination of potassium hydrogen carbonate, impurities and relevance of CIPAC methods in Kumar were evaluated as part of the EU review of potassium hydrogen carbonate.
A method for the determination of the relevant impurities lead and arsenic is under development and should be available in October 2017.

3.1.2.2 Analytical methods for residues (Part B, Section 2, Points 5.3 – 5.8)

In the EU review it was concluded that residue analytical methods are not required due to the nature of the compound.

3.1.3 Mammalian Toxicology

The PPP is already registered in Germany according to Directive 91/414/EEC.
If used properly and according to the intended conditions of use, adverse health effects for operators, workers, bystanders and residents will not be expected.Residues and Consumer Exposure

3.1.3.1 Residues

Residue studies were not considered relevant for evaluation nor were they considered necessary for Annex I inclusion (Commission Directive 2008/127/EC) due to the nature and properties of the active substance. As no MRLs are required; the substance was included in annex IV to Regulation (EC) No 396/2005.

3.1.3.2 Consumer exposure

No risk assessment is necessary due to the intrinsic properties of the active ingredient. Chronic as well as short-term intake of potassium hydrogen carbonate residues is unlikely to present a public health concern. Environmental fate and behaviour (Part B, Section 5, Point 9)

No new studies are presented; all data were reviewed in the EU review (potassium hydrogen carbonate). Appropriate endpoints from the EU review were used to calculate PECs in the core assessment for potassium hydrogen carbonate in soil, surface water, ground water and air for the intended use patterns.
The rate of degradation in soil of potassium hydrogen carbonate was evaluated during the Annex I Inclusion. No additional studies have been performed. No degradation endpoints have been derived. Instead a description of the behaviour of the compound in soil is presented in the DAR.

3.1.3.3 Predicted Environmental Concentration in Soil (PECsoil) (Part B, Section 5, Points 9.4 and 9.5)

The PEC of potassium hydrogen carbonate in soil has been assessed assuming no breakdown between the applications.

The PECsoil values are presented in the core assessment and national addenda.

The results for PEC soil for the active substance and its metabolites were used for the eco-toxicological risk assessment.

3.1.3.4 Predicted Environmental Concentration in Ground Water (PECGW) (Part B, Section 5, Point 9.6)

The PEC of potassium hydrogen carbonate in ground water has been assessed during the EU review.

Potassium bicarbonate spontaneously dissociates in water to give potassium and bicarbonate ions. The potassium ion is stable and does not degrade. Bicarbonate on the other hand will equilibrate with carbonate and carbonic acid to yield carbon dioxide and water. The potassium and bicarbonate ions potentially leach through the soil to groundwater resources. However, these ions are not of toxicological relevance. In the event of reaching groundwater it would be impossible to distinguish these ions by analytical means from natural sources of these ions. Given the nature of potassium bicarbonate it is considered inappropriate to use the FOCUS groundwater tools.

3.1.3.5 Predicted Environmental Concentration in Surface Water (PECSW) (Part B, Section 5, Points 9.7 and 9.8)

The results for PEC surface water for the active substance were used for the eco-toxicological risk assessment.

3.1.3.6 Predicted Environmental Concentration in Air (PECAir) (Part B, Section 5, Point 9.9)

The PEC of potassium hydrogen carbonate in surface water (PECsw and PECsed) has been assessed assuming no breakdown between the applications and overspray based on data established in the EU review. For the results please refer to the core assessment or the national addenda.

Implications for labelling resulting from environmental fate assessment:

None

3.1.6 Ecotoxicology (Part B, Section 6, Point 10)

No new studies are presented; all data were reviewed in the EU review (potassium hydrogen carbonate). Appropriate endpoints from the EU review were used

3.1.6.1 Effects on Terrestrial Vertebrates (Part B, Section 6, Points 10.1 and 10.3)

Birds

The effects on birds of potassium hydrogen carbonate were evaluated during the Annex I Inclusion. No additional studies have been performed. According to the DAR (2008)1 studies to address the acute or long-term toxicity of Potassium hydrogen carbonate on birds are not required.
Therefore, a risk assessment considering the risk of Potassium hydrogen carbonate to birds is not considered necessary.

Terrestrial vertebrates (other than birds)

Effects on mammals for the product Kumar were not evaluated as part of the Draft Assessment Report of the active substance Potassium hydrogen carbonate. According to the DAR (2008) studies to address the acute or long-term toxicity of Potassium hydrogen carbonate on mammals are not required.
Therefore, a risk assessment considering the risk of Potassium hydrogen carbonate to mammals is not considered necessary.

3.1.6.2 Effects on Aquatic Species (Part B, Section 6, Point 10.2)

The results of the assessment indicate an acceptable risk for aquatic organisms due to the intended use of Kumar according to the label.

[1] RMS UK, Draft Assessment Report on the existing active substance Potassium hydrogen carbonate,(2008), Vol. 3, Annex B, part 5, B.9

Only labeling with SP1 and the national phrase NW642-1 is considered necessary.

Code	Phrase
SP1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water./Avoid contamination via drains from farmyards and roads).
NW642-1	The product may not be applied in or in the immediate vicinity of surface or coastal waters. Irrespective of this, the minimum buffer zone from surface waters stipulated by state law must be observed. Violations may be punished by fines of up to 50 000 EUR.

3.1.6.3 Effects on Bees and Other Arthropod Species (Part B, Section 6, Points 10.4 and 10.5)

Bees

Effects on bees for Kumar were not evaluated as part of the EU review of potassium hydrogen carbonate.. Risk assessments for Kumar with the proposed use pattern were provided and are considered adequate.

Active substance	Endpoints used in risk assessment[1]
$KHCO_3$	Oral LD_{50} : > 100 µg as/bee Contact LD_{50}: > 100 µg as/bee

[1] Since Annex I inclusion new studies on the formulated product have been performed and as a result, new end-points are used in the risk assessment.

The acute risk of Kumar to honey-bees was assessed from hazard quotients between toxicity endpoints, estimated from acute oral and contact studies with active ingredient and the maximum single application rate of 5.0 kg/ha (equivalent to 4250 g ai/ha). The hazard quotients were calculated as follows:

$$Hazard\ Quotient = \frac{Maximum\ application\ rate\ (g\ formulation/ha)}{Acute\ LD_{50}\ (\mu g\ formulation/bee)}$$

Test substance	Application rate (g as/ha)	LD_{50} (µg/bee)	Hazard quotient
$KHCO_3$	4250	Contact > 100 µg as/bee	<42.5
		Oral > 100 µg as/bee	<42.5

All the hazard quotients are less than 50, indicating that the active ingredient poses a low risk to bees. Therefore, a low risk to bees is expected from the application of Kumar according to the recommended use pattern.

Other non-target arthropods

For the intended uses 00-001 (17 kg a.s./ha max total rate per season) and 00-002 (25.5 kg a.s./ha max total rate per season), no risk mitigation measures are needed.

3.1.6.4 Effects on Earthworms and Other Soil Macro-organisms (Part B, Section 6, Point 10.6)

No studies with Potassium hydrogen carbonate on earthworms were conducted. A risk assessment considering the toxicity of Kumar to earthworms and other soil non-target macroorganisms is not considered necessary.

3.1.6.5 Effects on organic matter breakdown (Part B, Section 6, Point 10.6)

No risk assessment necessary.

3.1.6.6 Effects on Soil Non-target Micro-organisms (Part B, Section 6, Point 10.7)

No studies with Potassium hydrogen carbonate on soil microbial activity have been conducted.
Adverse effects on soil microorganisms from the application of Kumar are extremely unlikely and thus, no further risk assessment is considered necessary.

3.1.6.7 Assessment of Potential for Effects on Other Non-target Organisms (Flora and Fauna) (Part B, Section 6, Point 10.8)

No studies with Potassium hydrogen carbonate on terrestrial vascular plants were conducted. Adverse effects on terrestrial vascular plants from the application of Kumar are extremely unlikely and thus, no further risk assessment is considered necessary.

Implications for labelling resulting from ecotoxicological assessment:

Code	Phrase
SP1	SP1: Do not contaminate water with the product or its container (Do not clean application equipment near surface water./Avoid contamination via drains from farmyards and roads).
NW642-1	The product may not be applied in or in the immediate vicinity of surface or coastal waters. Irrespective of this, the minimum buffer zone from surface waters stipulated by state law must be observed. Violations may be punished by fines of up to 50 000 EUR.

No further labelling under Regulation (EC) No 1272/2008 is necessary.

3.1.7 Efficacy (Part B, Section 7, Point 8)

Preliminary trials are not considered to be required since potassium bicarbonate-based products are well known for their fungicidal use and have been on the market for a number of years.

The presented dose justification demonstrates that the dose rate applied for represents the minimum effective dose rate to achieve sufficient efficacy against the target pests, both on grape bunches as well as on leaves.

Good efficacy of Kumar against grey mould and powdery mildew is achieved when the product is applied according to the envisaged GAP use.

The yield was increased and the wine quality of plots treated with Kumar was not influenced negatively compared to the untreated control and the reference standards. No negative effects regarding the quality of harvested vine grapes, the wine making process and the wine as the processed product were observed.

Kumar can be regarded as safe for the crop grapevine when applied according to the envisaged GAP use, no phytotoxicity was observed.

Adverse effects on beneficial organisms (other than bees) were observed in laboratory trials. NN3001 and NN3002 are assigned to the label.

No negative impact of Kumar is expected on succeeding crops. The risks to non-target plants following the use of potassium bicarbonate are considered to be very low.

The overall risk for potassium bicarbonate combining the fungicide risk, the pathogen risk and the agronomic risk is considered to be low for the envisaged GAP use assuming that the general measures of good agricultural practice and integrated pest management are considered.

All the data regarding the efficacy of the product have been submitted. These data demonstrate that Kumar fulfils all criteria for the authorization of preparations described in Directive 97/57/EC (Uniform Principles, Annex VI to Directive 91/414/EEC). No phytotoxicity, effects on neighbouring or following crops were observed.

3.2 Conclusions

Kumar showed a sufficient effect against the diseases for all uses applied for and no unacceptable effects on the plants or plant products occur.
All uses applied for can be authorised.

With regard to identity, physical, chemical and technical properties, further information and analytical methods (product and residues) an authorisation can be granted.

With respect to fate and ecotoxicology assessment, an authorisation can be granted. Considering an application in accordance with the evaluated use pattern and good agricultural practice as well as strict observance of the conditions of use no harmful effects on groundwater or adverse effects on the ecosystem are to be apprehended.

The intended uses are not relevant in terms of consumer health protection. The submission of supervised residue trials is not necessary. There is no special risk mitigation necessary which deviate from the existing registration. With respect to toxicology, residues and consumer protection an authorisation can be granted.

An authorisation can be granted.

3.3 Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorisation

No further information is required.

Appendix 1 – Copy of the product authorisation (see Appendix 4)

Appendix 2 – Copy of the product label

The submitted draft product label has been checked by the competent authority. The applicant is requested to amend the product label in accordance with the decisions made by the competent authority. The final version of the label has to fulfil the requirements according to Article 31 of Regulation (EU) No 1107/2009.

Appendix 3 – Letter of Access

Letter(s) of access is/are classified as confidential and, thus, are not attached to this document.

Appendix 4 – Copy of the product authorisation

Will be inserted in the final version.

Bundesamt für
Verbraucherschutz und
Lebensmittelsicherheit

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IHR ZEICHEN
IHRE NACHRICHT VOM

AKTENZEICHEN 200.22100.007547-00/10.135282
(bitte bei Antwort angeben)

DATUM 8. November 2017

ZV1 007547-00/10

Kumar

Zulassungsverfahren für Pflanzenschutzmittel

Ergänzungsbescheid

Die Zulassung des oben genannten Pflanzenschutzmittels

mit dem Wirkstoff: 850 g/kg Kaliumhydrogencarbonat

Zulassungsnummer: 007547-00

Versuchsbezeichnungen: SPU-07547-F-0-SP

Antrag vom: 2. Oktober 2015

ändere ich wie folgt:

Zusätzliche Anwendungsgebiete bzw. Anwendungen

Die Zulassung wird um folgende Anwendungsgebiete bzw. Anwendungen erweitert (siehe Anlage 1):

Anwendungs-nummer	Schadorganismus/ Zweckbestimmung	Pflanzen/-erzeugnisse/ Objekte	Verwendungszweck
007547-00/10-001	Botrytis cinerea	Weinrebe	Nutzung als Tafel- und Keltertraube

BVL_FO_05_2476_200_V1.6

Anwendungs-nummer	Schadorganismus/ Zweckbestimmung	Pflanzen/-erzeugnisse/ Objekte	Verwendungszweck
007547-00/10-002	Echter Mehltau (Uncinula necator)	Weinrebe	Nutzung als Tafel- und Keltertraube

Festgesetzte Anwendungsbestimmungen

Es werden folgende Anwendungsbestimmungen gemäß § 36 Abs. 1 S. 1 des Gesetzes zum Schutz der Kulturpflanzen (Pflanzenschutzgesetz - PflSchG) vom 6. Februar 2012 (BGBl. I S. 148, 1281), zuletzt geändert durch Artikel 4 Absatz 84 des Gesetzes vom 18. Juli 2016 (BGBl. I S. 1666), festgesetzt:

Siehe anwendungsbezogene Anwendungsbestimmungen in Anlage 1, jeweils unter Nr. 3.

Auflagen

Die Zulassung wird mit folgenden Auflagen gemäß § 36 Abs. 3 S. 1 PflSchG verbunden:

Siehe Anlage 1, jeweils unter Nr. 2.

Vorbehalt

Dieser Bescheid wird mit dem Vorbehalt der nachträglichen Aufnahme, Änderung oder Ergänzung von Anwendungsbestimmungen und Auflagen verbunden.

Abgelehnte Anwendungsgebiete bzw. Anwendungen

Für folgende Anwendungsgebiete bzw. Anwendungen lehne ich Ihren Antrag ab (siehe Anlage 2):
- keine -

Hinsichtlich der Gebühren erhalten Sie einen gesonderten Bescheid.

Rechtsbehelfsbelehrung

Gegen diesen Bescheid kann innerhalb eines Monats nach Bekanntgabe Widerspruch erhoben werden. Der Widerspruch ist bei dem Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, Messeweg 11/12, 38104 Braunschweig, schriftlich oder zur Niederschrift einzulegen.

Mit freundlichen Grüßen
im Auftrag

gez. Dr. Martin Streloke
Abteilungsleiter

Dieses Schreiben wurde maschinell erstellt und ist daher ohne Unterschrift gültig.

Anlage

Anlage 1 zugelassene Anwendung: 007547-00/10-001

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung:	Botrytis cinerea
Pflanzen/-erzeugnisse/Objekte:	Weinrebe
Verwendungszweck:	Nutzung als Tafel- und Keltertraube

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Weinbau
Anwendungsbereich:	Freiland
Anwendung im Haus- und Kleingartenbereich:	Nein
Stadium der Kultur:	75 bis 89
Anwendungszeitpunkt:	Bei Infektionsgefahr bzw. ab Warndiensthinweis
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	4
- für die Kultur bzw. je Jahr:	6
- Abstand:	8 bis 30 Tage
Anwendungstechnik:	spritzen oder sprühen
Aufwand:	
-	5 kg/ha in 800 bis 1600 l Wasser/ha

2.2 Sonstige Kennzeichnungsauflagen

(NW642-1)
Die Anwendung des Mittels in oder unmittelbar an oberirdischen Gewässern oder Küstengewässern ist nicht zulässig. Unabhängig davon ist der gemäß Länderrecht verbindlich vorgegebene Mindestabstand zu Oberflächengewässern einzuhalten. Zuwiderhandlungen können mit einem Bußgeld bis zu einer Höhe von 50.000 Euro geahndet werden.

2.3 Wartezeiten

1 Tag	Freiland: Weinrebe (Tafel- und Keltertrauben)

3 Anwendungsbezogene Anwendungsbestimmungen

- keine -

Anlage 1 zugelassene Anwendung: 007547-00/10-002

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung:	Echter Mehltau (Uncinula necator)
Pflanzen/-erzeugnisse/Objekte:	Weinrebe
Verwendungszweck:	Nutzung als Tafel- und Keltertraube

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Weinbau
Anwendungsbereich:	Freiland
Anwendung im Haus- und Kleingartenbereich:	Nein
Stadium der Kultur:	57 bis 85
Anwendungszeitpunkt:	Bei Infektionsgefahr bzw. ab Warndiensthinweis
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	6
- für die Kultur bzw. je Jahr:	6
- Abstand:	7 bis 10 Tage
Anwendungstechnik:	spritzen oder sprühen
Aufwand:	
- Basisaufwand:	1,25 kg/ha in 200 bis 400 l Wasser/ha
- ES 61:	2,5 kg/ha in 400 bis 800 l Wasser/ha
- ES 71:	3,75 kg/ha in 600 bis 1200 l Wasser/ha
- ES 75:	5 kg/ha in 800 bis 1600 l Wasser/ha

2.2 Sonstige Kennzeichnungsauflagen

(NW642-1)
Die Anwendung des Mittels in oder unmittelbar an oberirdischen Gewässern oder Küstengewässern ist nicht zulässig. Unabhängig davon ist der gemäß Länderrecht verbindlich vorgegebene Mindestabstand zu Oberflächengewässern einzuhalten. Zuwiderhandlungen können mit einem Bußgeld bis zu einer Höhe von 50.000 Euro geahndet werden.

2.3 Wartezeiten

1 Tag	Freiland: Weinrebe (Tafel- und Keltertrauben)

3 Anwendungsbezogene Anwendungsbestimmungen

- keine -

REGISTRATION REPORT
Part B

Section 5 Environmental Fate
Detailed summary of the risk assessment

Product code:	**Kumar**
Active Substance:	**potassium hydrogen carbonate 850 g/kg**

Central Zone
Zonal Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant: Spiess-Urania Chemicals GmbH
Date: 08.09.2017

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Sec 5 FATE AND BEHAVIOUR IN THE ENVIRONMENT (KIIIA 9)

The product Kumar (= ARMICARB 85 SP) containing 850 g/kg potassium hydrogen carbonate was already evaluated by the Netherlands as zRMS and by Germany as cMS for registration in the Central Zone for the use in apples (8 x 4250 g ai/ha). Authorization in Germany was granted in June 2013 (007547-00/00).
This document is related to an application for label extension for the product Kumar according to article 29 of Regulation (EC) No 1107/2009 for the use in grape against *Botryotinia fuckeliana* and *Erysiphe necator*.

This document reviews the environmental fate studies and modelling for the product Kumar containing potassium hydrogen carbonate which was included into Annex I of Directive 91/414 (2008/127/EC). A full risk assessment according to Uniform Principles is provided which demonstrates that the product is safe for the environment.

Where appropriate this document refers to the conclusions of the EU review of potassium hydrogen carbonate. This will be where:

- the active substance data is relied upon in the risk assessment of the formulation.
- the EU review concluded that additional data/information should be considered at national re-registration.

Note: this Part B document only reviews data (Annex II or Annex III) and additional information that has not previously been considered within the EU review process, as part of the Annex I inclusion decision. New annex II data must only be included if they are considered essential for the evaluation and in this case a full study summary must be provided. In the case where the formulation has been previously evaluated, at European level, detailed summaries have not been provided.

The product Kumar (syn. Armicarb 85 SP) was the representative formulation during the EU review. The product has been previously evaluated in the central zone according to the Uniform Principles under Regulation 1107/2009; also for the use in viticulture.

The SANCO report for potassium hydrogen carbonate (SANCO/2625/08 – 04/07/2008) and the EFSA conclusion for potassium hydrogen carbonate (EFSA Scientific Report (2012) 10(1):2524) are considered to provide the relevant review information or a reference to where such information can be found.

EFSA (2012[1]) identified the following data gap for the section Environment:
"The background level of K^+ in natural soils and surface waters needs to be reported from a study or a peer reviewed scientific reference (relevant for all representative uses evaluated; submission date proposed by the notifier: unknown; see section 4)."

These concerns have been addressed within the current submission.

[1] European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance potassium hydrogen carbonate. EFSA Journal 2012;10(1):2524. [36 pp.] doi:10.2903/j.efsa.2012.2524.

Introduction

Concentrations of Kumar in various environmental compartments are predicted following the proposed use pattern. The predicted environmental concentrations (PEC values) in soil, surface water, sediment, groundwater and air are provided. The long-term concentrations are based on results obtained for the active substance contained in the formulation.

5.1 Proposed use pattern

The critical use patterns used for exposure assessment are presented in Table 5.1-1:. They have been selected from the individual GAPs in the zone for orchards.

Table 5.1-1: Critical use pattern of Kumar

Use	Application rate (g ai/ha)	Application method	Number of applications	Minimum application interval (days)	Application timing
Grape	4250	spraying on crop	6	7-10	BBCH 57-85

The impact of formulants is limited to short-term effects such as formation of stable spray dispersions or to facilitate uptake by target organisms, while their influence on long-term processes, such as degradation and distribution is negligible. Therefore, for the purposes of this risk assessment it is assumed that formulants do not influence the fate and behaviour of an active substance in the environment and are not considered further.

No residue definitions have been proposed for potassium hydrogen carbonate ($KHCO_3$) for all environmental compartments, as both K^+ and HCO_3^- (plus CO_3^{2-} and H_2CO_3) are naturally occurring in the environment.

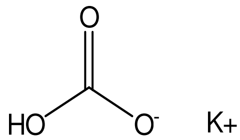
5.2 Information on the active substance

5.2.1 Potassium hydrogen carbonate

5.2.1.1 Identity, further information of potassium hydrogen carbonate

Table 5.2-1: Identity, further information on potassium hydrogen carbonate

Active substance (ISO common name)	Potassium hydrogen carbonate
IUPAC	Potassium hydrogen carbonate
Function (e.g. fungicide)	Fungicide
Status under Reg. (EC) No 1107/2009	Approved
Date of approval	01/09/2009
Conditions of approval	Conditions of use shall include, where appropriate, risk mitigation measures
Confirmatory data	

RMS	IE
Minimum purity of the active substance as manufactured (g/kg)	> 99.5
Molecular formula	$KHCO_3$
Molecular mass	100.12
Structural formula	

5.3.1.2 Physical and chemical properties of potassium hydrogen carbonate

Physical and chemical properties of potassium hydrogen carbonate as agreed at EU level (see SANCO/2625/08-rev 1 from the 04/07/2008) and considered relevant for the exposure assessment are listed in Table 5.2-2.

Table 5.2-2: EU agreed physical chemical properties of potassium hydrogen carbonate relevant for exposure assessment

	Value	**Reference**
Vapour pressure (at 20 °C) (Pa)	Not applicable	SANCO/2625/08-rev 1 - 04/07/2008
Henry's law constant (Pa × m³ × mol⁻¹)	No Henry's law constant	
Solubility in water (at 20 °C in g/L)	332	
Partition co-efficient (at 25 °), log P_{OW}	No information provided. Not considered relevant.	
Dissociation constant, pKa	Not applicable. Potassium hydrogen carbonate completely dissociates to its respective ions when dissolved in water: $KHCO_3 \rightarrow K^+ + HCO_3^-$ HCO_3^- is amphoteric and will then naturally participate in natural carbonic acid equilibria: $CO_3^{2-} + 2H^+ \leftrightharpoons HCO_3^- + H^+$ (pKa1 = 10.377) $HCO_3^- + H^+ \leftrightharpoons H_2CO_3$ (pKa2 = 6.381) $H_2CO_3 \leftrightharpoons CO_2 + H_2O$	
Hydrolytic degradation	Not applicable: Potassium hydrogen carbonate completely dissociates to potassium and bicarbonate ions in the presence of water.	
Photolytic degradation	Not applicable	

Quantum yield of direct phototransformation in water > 290 nm	Not applicable	
Photochemical oxidative degradation in air (calculation according to Atkinson)	Not applicable	

5.3.1.3 Metabolites of potassium hydrogen carbonate

Potassium hydrogen carbonate dissociates in the presence of water to produce K^+ and HCO_3^-. These ions are not considered as metabolites according to the EFSA guidance document Sanco/221/200-rev.10-final (2003) [2].

5.3 Summary on Input parameter for environmental exposure assessment

Potassium hydrogen carbonate is a naturally occurring inorganic compound that completely dissociates to K+ and HCO_3^- in the presence of water.

$KHCO_3 \leftrightarrow K^+ + HCO_3^-$

Depending upon soil type and soil pH, bicarbonate will either remain intact or transform to carbonate.

$HCO_3^- \leftrightarrow H^+_{(aq)} + CO_3^{2-}$

At low pH values bicarbonate anions will be reduced by free hydrogen ions that ultimately produce water and carbon dioxide that in turn will form carbonic acid. The further dissociation of carbonic acid will in turn release more bicarbonate.

$HCO_3^- + H^+_{(aq)} \leftrightarrow H_2O + CO_2$

$CO_2 + H_2O \rightarrow H_2CO_3$

$H_2CO_3 \leftrightarrow H^+_{(aq)} + HCO_3^-$

In alkaline soils, bicarbonate anion can remain as the anion or loosely associated with free cations like calcium, magnesium or potassium and thus form rocks such as limestone.

$Ca^{2+} + 2HCO_3^- \leftrightarrow Ca(HCO_3)_2$

Bicarbonate:
Overall, bicarbonate anions form part of the natural buffering system in soils through the carbonate equilibria mechanism and, hence, influence the soil pH. Bicarbonate anions become part of the natural carbon cycle and depending on the pH will form limestone ($Ca(HCO_3)_2$) as long as Ca^{2+} cations are in excess.

Potassium:
According to the data gap identified on the background level of K^+ in natural soils (EFSA, 2012), additional information were supplied by the notifier.

Potassium ions are strongly bound in soil and a rapid equilibrium is observed between soluble and exchangeable forms. The levels of potassium ions added to soil from the application of the formulated

[2] Guidance Document on the assessment of the relevance of metabolites in groundwater of substances regulated under council directive 91/414/EEC (SANCO/221/2000 –rev.10- final - 25 February 2003)

product KUMAR will be within naturally occurring levels of potassium in mineral soils (0.4-30 g/kg, according to Sparks, 1987[3]).

According to Sparks (2001)[4] (KIIIA 9.4/01), "the quantity of potassium in the soil solution varies from 2 to 5 mg K.L^{-1} for normal agricultural soils of humid regions and is an order of magnitude higher in arid region soils. Levels of K in solution are affected by the equilibrium and kinetic reactions that occur between the forms of soil K, the soil moisture content, and the concentrations of bivalent cations in solution and on the exchanger phase." The following table presents raw data from the publication:

Table 1. Potassium status of selected soils.

Origin of Soil	*Exchangeable K* (cmol kg^{-1})	*Nonexchangeable K* (cmol kg^{-1})	*Total K* (cmol kg^{-1})	*Source*
Alfisols				
Nebraska, USA	0.40	--	--	*Soil Taxonomy* (1975)
West Africa	0.46	--	3.07	Juo (1981)
Inceptisols				
California, USA	0.40	--	--	*Soil Taxonomy* (1975)
Maryland, USA	0.20	--	--	*Soil Taxonomy* (1975)
Mollisols				
Iowa, USA	0.27	--	--	*Soil Taxonomy* (1975)
Nebraska, USA	0.40	--	--	
Ultisols				
Delaware, USA	0.33	0.49	22.5	Parker *et al.* (1989)
Florida, USA	0.14	0.25	2.71	Yuan *et al.* (1976)
Virginia, USA	0.11	0.17	6.5	Sparks *et al.* (1980)
West Africa	0.24	--	8.06	Juo (1981)

a Data are for surface soils (0-20 cm depth).

In the study of Martin and Sparks (1985) (KIIIA 9.4/02) it is mentioned that soil contains an average of 1.7% of potassium (17,000 mg/kg); assuming a bioavailable content of 2% (sum of soil solution and exchangeable phase), this corresponds to 340 mg/kg.

In addition to literary reviews, levels of potassium in soils may be estimated from soils database. At European level, the Geochemical Atlas of Europe maintains an extensive database of soil, sediment and water samples randomly collected across Europe. Total potassium (expressed as K_2O) was extracted by the fused bead technique or strong acidic digestion, then analysed by X-ray fluorescence spectrometry or ICP-MS. The results are shown in Figure 9.1- 1.

[3] Study presented and accepted in the EFSA journal on potassium phosphonate (2012)
[4] Dynamics of K in Soils and Their Role in Management of K Nutrition, Potassium in Soils - The International Potash Institute, Sparks, 2001, Event: IPI PRII K in nutrient management for sustainable crop production in India, New Delhi, India

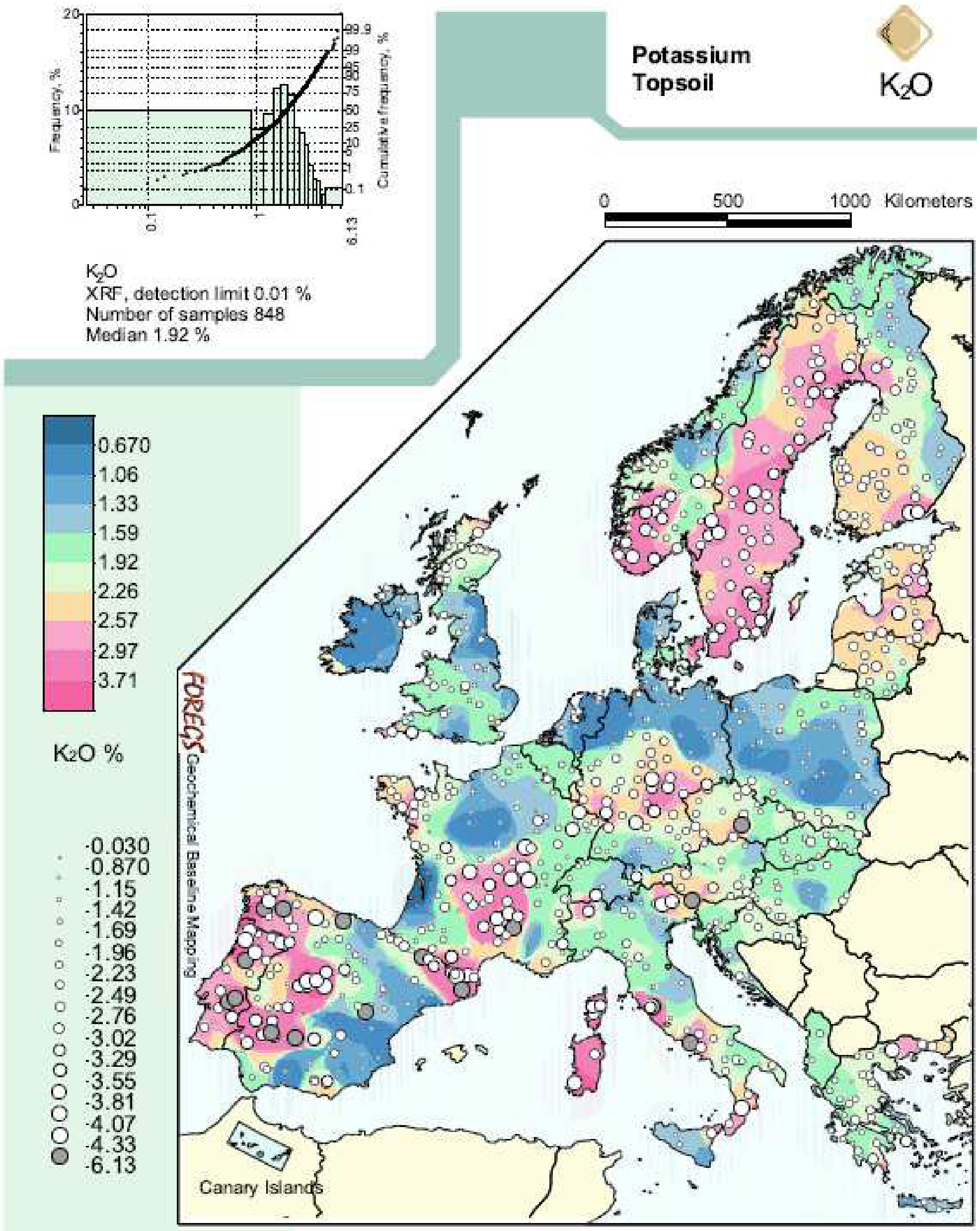


Figure 9.1- 1 Total potassium content in topsoil (%K_2O)[5]

Samples results vary between 0.67% and 3.71% K_2O, which corresponds to 5.5 to 30.4 g/kg of potassium. The median of all samples (848 samples) is 1.92% corresponding to 19.2 g/kg of potassium oxide and 15.7 g/kg of total potassium.

From the literature review, the background level of potassium in soil varies from 0.4 to 30 g/kg.

[5] On line Geochemical Atlas of Europe: http://weppi.gtk.fi/publ/foregsatlas/

5.3.1 Degradation in soil

The rate of degradation in soil of potassium hydrogen carbonate was evaluated during the Annex I Inclusion. No additional soil degradation studies have been supplied by the notifier.
Please refer to Point 5.3.

5.3.2 Adsorption/desorption

Please refer to Point 5.3.

5.3.3 Rate of degradation in water

Please refer to Point 5.3.

5.4 Estimation of concentrations in soil (PECsoil) (KIIIA1 9.4)

Kumar is intended for a label extension for two uses in grape as a fungicide. The maximum number of applications is limited to 6. The maximum single application rate is 5.0 kg Kumar / ha (4.25 kg ai/ha). The minimum interval between the applications is 7 days.

The active substance potassium hydrogen carbonate is soluble in water and will rapidly dissociate to K^+ and HCO_3^-. The initial predicted environmental concentration of potassium and bicarbonate arising in soil from the use of Kumar was calculated using the highest rate of application and the input parameters summarised in table 5.4-1. The potassium ion does not degrade, whilst the bicarbonate ion can transform into other common natural products such as carbon dioxide, carbonates and water, which are of no known toxicological, ecotoxicological or environmental significance. Potassium ions are strongly bound in soil.

The predicted concentration of a plant protection product resp. its active ingredient in soil is calculated by assuming homogenous distribution of the maximal application rate over a soil horizon of 5 cm and a standard soil dry weight of 1.5 g/cm³. The crop interception was set to 60% as worst case leading to the highest soil load at representative application stage [6]. Calculations were based on a lumped application of 25500 g active substance / ha corresponding to the maximum number of recommended doses and the highest rate of application in a season (**4250 g active substance/ha applied at a maximum of 6 time points**). No degradation between applications was considered for PEC_{soil} calculations.

Table 5.4-1 Overview on input parameters used for PEC_{soil} calculations

Crop	Grape		
Depth of soil layer	5 cm		
Soil bulk density	1.5 kg/l		
% plant interception	60		
Number of applications	6		
Interval (d)	7		
	$KHCO_3$	**K^+**	**HCO_3^-**
% content of active substance	**100 %**	**39%**	**61%**
Application rate per treatment (g a.i./ha)	**4250**	**1658**	**2593**
Application rate per season (g a.i./ha), used for calculations	**25500**	**9945**	**15555**

No short-term and long-term actual concentrations ($PEC_{soil,}$ actual) and the time weighted average concentrations (PEC_{soil}, twa) were calculated since the active substance potassium hydrogen carbonate doesn't degrade in soil but dissociates to potassium and bicarbonate ions in the presence of water instead.

PEC_{soil} calculations

[6] EFSA Journal 2014; 12(5):3662: Interception (%) for vines is 60% at BBCH stage 53-69 and 75% at BBCH stage 71-89

PEC_s immediately after the first application were calculated using FOCUS guidance[7] with the following equation:

$PEC_{soil, initial}$ = A * (1-f_{int}) / d* bd_{soil} * %AR metabolite * mol. weight metabolite / mol. weight parent

$PEC_{soil, initial}$:	initial concentration in soil [mg a.i./kg dw soil]
AR:	application rate [g a.s./ha]
f_{int}:	fraction intercepted by plant cover [-]
D:	depth of soil layer [cm]
bd_{soil}:	soil bulk density [g/cm³]

In case of one application, the $PEC_{soil,initial}$ equals $PEC_{soil,max}$.

Results are presented in the table below.

Table 5.4-2 **Initial/actual PEC_{soil} values for the active substance and potassium and bicarbonate ions**

	$KHCO_3$	**K^+**	**HCO_3^-**
$PEC_{S, actual}$ mg/kg soil	**13.600**	**5.304**	**8.296**

The initial worst case PECs are negligible in comparison with natural background level of potassium and bicarbonate in soil:

Potassium:
In general, agricultural soils are classified as shown below with respect to the concentration of extractable (based on extraction using ammonium acetate) and therefore bioavailable potassium (Marx et al, 1999 – KIIIA 9.4/03):

Low	<150 mg/kg
Medium	150 – 250 mg/kg
High	250 – 800 mg/kg

In other literature (Sparks, 2001. KIIIA 9.4/01), Sparks mentions that mineral soils generally range between 0.04 and 3% K (400 – 30,000 mg/kg), from which 2% is in soil solution and exchangeable phases (80 – 6000 mg/kg) (see Martin and Sparks 1985, KIIIA 9.4/02).

Bicarbonate:
The bicarbonate concentration of the soil varies a lot and is directly linked with the moisture and the pH of the soil, the carbonate and calcium content (see IIIA 9.1). The CO_2 producing capacity of plant roots also influences soil bicarbonate concentration.

[7] FOCUS (1997) Soil persistence models and EU Registration - The Final Report of the Soil Modelling Workgroup of FOCUS (Forum for the Co-ordination of Pesticide Fate Models and their Use) – 29 February 1997. AND FOCUS (2006) "Guidance Document on Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration" Report of the FOCUS Work Group on Degradation Kinetics, EC Document Reference Sanco/10058/2005 version 2.0, 434 pp

PEC_{soil} calculation for the formulation Kumar

Table 5.4-3 Overview on input parameters and results of PEC_{soil} calculation for the formulation Kumar

Number of applications	6
Single application rate [g product /ha]	5000
Application rate [g product/ha]	**30000**
Interception by plants [%]	60
Soil depth [cm]	5
Dry soil bulk density [g/cm³]	1.5
$PEC_{soil\ initial}$ [mg product/kg soil)	**16**

5.5 Estimation of concentrations in surface water and sediment (PECsw/PECsed) (KIIIA1 9.7)

The PEC_{SW} was evaluated during the Annex I Inclusion. No additional studies have been performed. Here, a label extension on grapes as a fungicide is intended for Kumar. The maximum number of applications is limited to 6. The maximum single application rate is 5.0 kg Kumar / ha (4.25 kg ai/ha). The minimum interval between the applications is 7 days.

Potassium hydrogen carbonate is soluble in water and will rapidly dissociate to K^+ and HCO_3^-. Given the nature of the active substance it is not considered appropriate to use the FOCUS model to determine PEC_{SW}. Instead, an estimation based on spray drift with no degradation between applications is considered adequate. This approach was accepted during the EU inclusion of potassium hydrogen carbonate. The initial PEC_{sw} values for entry via spray drift were calculated for a worst case scenario with a lumped application of 25500 g active substance / ha corresponding to the maximum number of recommended doses and the highest rate of application in a season (**4250 g active substance/ha applied at a maximum of 6 time points**). No degradation and no volatilization were assumed.

The surface water was assumed to be 30cm depth. Therefore, a 300L water volume is contaminated for 1 sprayed square meter. Calculations were performed with a basic drift value of 8.02% for one application in % of the application rate (90th percentiles) for grapes (late application) and a buffer zone of 3 m according to Rautmann, 2001[8]. Input parameters are presented in the table below.

Table 5.5-1 Summary of input parameters of potassimum hydrogen carbonate for PECsw calculations

active substance/product:	**$KHCO_3$**	**K^+**	**HCO_3^-**
intended use:	Grape	Grape	Grape

[8] Rautmann, D.; Streloke, M.; Winkler, R.: "New basic drift values in the authorization procedure for plant protection products" Mitteilungen aus der Biologischen Bundesanstalt für Land- und Forstwirtschaft 383, 133-141 (2001).

Buffer zone	3m	3m	3m
Basic drift value (90th percentiles) for grapes (late application), Rautmann, 2001	8.02%	8.02%	8.02%
application parameters:	1 x 25500 g/ha (= 6 x 4250 g/ha)	1 x 9945 g/ha (= 6 x 1658 g/ha, 39% content of a.s.)	1 x 15555 g/ha (= 6 x 2593 g/ha, 61% content of a.s.)

Initial PEC_{sw} are shown in **Fehler! Verweisquelle konnte nicht gefunden werden.**.

Table 5.5-2 Initial PECsw for the use of Kumar in grapes (3m buffer zone)

Crop	Buffer Zone (m)	% spray drift	PECsw µg/L		
			$KHCO_3$	Potassium K^+	Bicarbonate HCO_3^-
Grapes	**3**	**8.02***	681.700	265.863	415.837

*Rautmann (2001)

Natural background concentrations of bicarbonate and potassium in surface waters

Bicarbonate is generally the most important anion in rivers. Typical levels of bicarbonate in surface waters in Europe ranged from 12 mg/L (Norwegian rivers) to 190 mg/L (Danube)[9].

According to the data gap identified on the background level of K^+ in natural surface water (EFSA, 2012), additional information were supplied by the notifier.

According to the EFSA journal on potassium phosphonate (2012), "Potassium ions in the solution sprayed have the potential to reach surface water *via* spray drift. The resulting concentrations will be within naturally occurring levels of potassium in surface waters (streams, 0.01-36.6 mg/L, De Vos *et al.*, 2006).

According to the UN GEMS/water programme (http://www.unep.org/gemswater/), in natural surface waters potassium concentrations are typically <5 mg/L. In the study of Meybeck (1979) (KIIIA 9.7/01), an average concentration of 1.3 mg/L and 52 mg/L for potassium and bicarbonate respectively based on extensive surveys in river waters around the world were specified. Several primary sources of published literature data are compiled in a UNESCO workshop report by Burton (1988) (KIIIA 9.7/02) which mentions similar concentrations.

At European level, the Geochemical Atlas of Europe maintains an extensive database of soil, sediment and water samples randomly collected across Europe. The results for bicarbonate concentration in stream water are shown in Figure 9.7- 1. The median value over 808 water samplings is 130 mg/L.

[9] Berner, E.K., Berner R.A., 1996. Global Environment: Water, Air, and Geochemical Cycles. Robert A. McConnin. New Jersey: Prentice-Hall Inc.

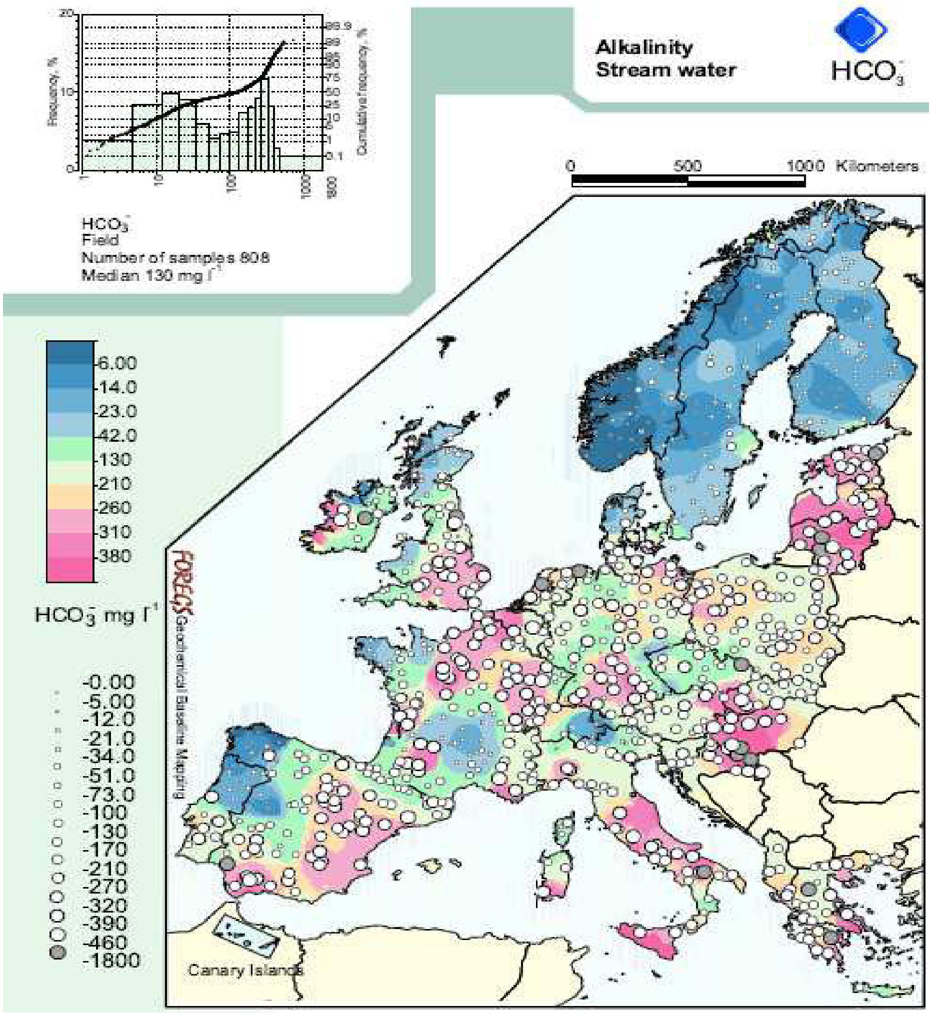


Figure 9.7- 1 Bicarbonate concentration in stream water (HCO_3^- mg/L)[10]

Comparison of the worst case PEC_{sw} with typical natural levels demonstrates that the use of Kumar is very unlikely to cause any significant increases in the concentrations of potassium or bicarbonate. Please refer to the DAR for more details.

A waiver is requested for calculation of PEC in sediments. If required, absolute worst-case initial concentrations could be calculated by assuming 100% partitioning from water to sediment. However, such calculations would not be representative of the behaviour of this highly water-soluble substance. If potassium hydrogen carbonate is present in aquatic systems it is likely to be predominantly in the water column or in the pore-water of the sediment.

[10] On line Geochemical Atlas of Europe: http://weppi.gtk.fi/publ/foregsatlas/

PEC_{SW} calculation for the formulation Kumar

Table 5.5-3 Overview on input parameters used for PEC_{SW} calculation for the product

active substance/product:	**Kumar**
intended use:	Grape
application parameters:	1 x 30000 g/ha (= 6 x 5000 g/ha)
Buffer zone	3m
Basic drift value (90th percentiles) for grapes (late application), Rautmann, 2001	8.02%

Table 5.5-4 PEC in aquatic environment - water (µg/L) for Kumar

Crop	Buffer Zone (m)	% spray drift	PEC_{SW} µg/L
Grapes	**3**	**8.02***	802.000

*Rautmann (2001)

The initial/actual PEC_{SW} for the plant protection product Kumar is 802.000 µg/L.

5.6 Risk assessment ground water (KIIIA1 9.6)

5.7.1 Predicted environmental concentration in groundwater (PEC_{GW}) calculation for the active substance (Tier 1 and 2)

The PEC_{GW} was evaluated during the Annex I Inclusion. No additional studies have been performed. Given the nature of potassium bicarbonate it is considered inappropriate to use the FOCUS groundwater tools and this was accepted by The Netherlands as the zRMS for the Central zone and by EU authorities during the EU inclusion of potassium hydrogen carbonate [11].

Potassium bicarbonate spontaneously dissociates in water to give potassium and bicarbonate ions. The potassium ion is stable and does not degrade but it is taken by plant and microbials. In fact, potassium is often applied to soil as a supplement in fertilizers in order to improve the plant growth. Bicarbonate on the other hand will equilibrate with carbonate and carbonic acid to yield carbon dioxide and water. The potassium and bicarbonate ions can potentially leach through the soil to groundwater resources.

[11] EFSA Journal 2012;10(1):2524: EFSA's reading of the Council Directive 98/83/EC[16] on the quality of drinking water intended for human consumption is that, as an inorganic fungicide, potassium hydrogen carbonate or the relevant ions that are formed from it, are not considered a pesticide under this directive, so the parametric drinking water limit of 0.1µg/L for pesticides, usually used as a decision making criteria regarding groundwater exposure, does not apply. 'Chemical parameters' or 'indicator parameters' levels (as defined in this directive) have not been prescribed for potassium or carbonate ions.

However, these ions are not of toxicological relevance and background levels are significantly higher than those likely to arise from the use of Kumar. In the event of reaching groundwater it would be impossible to distinguish these ions by analytical means from natural sources of these ions. In addition, the drinking water limit for potassium is 12 mg/L. The trigger of 0.1 µg/L valid for organic pesticides is not applicable for potassium hydrogen carbonate.

Thus, following the argumentation, no risk of groundwater contamination is expected from the use of Kumar and PEC_{GW} calculations are not considered necessary.

5.7 Potential of active substance for aerial transport

Potassium hydrogen carbonate is not volatile. It is naturally occurring in the environment and will dissociate to K^+ and HCO_3^- in water droplets. HCO_3^- will enter the natural carbon cycle and dissociate further to H_2O and CO_2. K^+ will get deposited again during precipitation events. Thus, there is no potential for long range transport of K^+.

Appendix 1 List of data submitted in support of the evaluation

Table A 1: List of data submitted in support of the evaluation

Annex point/reference No	Author(s)	Year	Title Source (where different from company) Report-No. GLP or GEP status (where relevant), Published or not Authority registration No	Data protection claimed	Owner	How considered in dRR Study-Status/Usage*
-/-	-/-	-/-	-/-	-/-	-/-	-/-

*

1) accepted (study valid and considered for evaluation)
2) not accepted (study not valid and not considered for evaluation)
3) not considered (study not relevant for evaluation)
4) not submitted but necessary (study not submitted by applicant but necessary for evaluation)
5) supplemental (additional information, alone not sufficient to fulfil a data requirement, considered for evaluation)

Appendix 2 Detailed evaluation of studies relied upon

Since EU approval, no new studies on the environmental fate of the active substance potassium hydrogen carbonate have been submitted. For a detailed evaluation of the study data, please refer to the Review Report SANCO/2625/08- rev 1 from the 4th of July 2008.

Appendix 3 Table of Intended Uses justification and GAP tables

PPP (product name/code)	**Kumar**	**Formulation type:**	**SP**
active substance	**Potassium bicarbonate**	**Conc. of as:**	**850 g/kg**
Applicant:	**Spiess Urania Chemicals GmbH**	**professional use**	☒
Zone(s):	**Central EU**	**non professional use**	☐

1	2	3	4	5	6	7	8	10	11	12	13	14
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**			**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	kg, L product / ha a) max. rate per appl. b) max. total rate per crop/season	g, kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
1	DE	Grape vine	F	*Botryotinia fuckeliana* BOTRYCI	spraying	BBCH 75 -89	a) 4 (8-30) b) 4 (8-30)	a) 5 kg/ha b) 20 kg/ha	a) 4.25 kg/ha b) 17 kg/ha	800 -1,600	1 day	1.25 kg product basis in 200-400 L water
2	DE	Grape vine	F	*Erysiphe necator* UNCINE	spraying	BBCH 57-85	a) 6 (7-10) b) 6 (7-10)	a) 5 kg/ha b) 30 kg/ha	a) 4.25 kg/ha b) 25.5 kg/ha	200-1,600	1 day	1.25 kg product basis in 200-400 L water BBCH 57: 1.25 kg/ha BBCH 61: 2.5 kg/ha BBCH 71: 3.75 kg/ha BBCH 75: 5 kg/ha

Remarks:
(a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds
(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(i) g/kg or g/l
(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) The minimum and maximum number of application possible under practical conditions of use must be provided
(l) PHI - minimum pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions

REGISTRATION REPORT
Part B

Section 5 Environmental Fate
Detailed summary of the risk assessment

Product code: **Kumar**

Active Substance(s): **Potassium hydrogen carbonate 850 g/kg**

Central Zone
Zonal Rapporteur Member State: Germany

NATIONAL ADDENDUM – Germany

Applicant: **Spiess-Urania Chemicals GmbH**

Date: **08.09.2017**

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Sec 5 FATE AND BEHAVIOUR IN THE ENVIRONMENT (KIIIA 9)

The product Kumar (= ARMICARB 85 SP) containing 850 g/kg potassium hydrogen carbonate was already evaluated by the Netherlands as zRMS and by Germany as cMS for registration in the Central Zone for the use in apples (8 x 4250 g ai/ha). Authorization in Germany was granted in June 2013 (007547-00/00).
This document is related to an application for label extension for the product Kumar according to article 29 of Regulation (EC) No 1107/2009 for the use in grape against *Botryotinia fuckeliana* and *Erysiphe necator*.

The exposure assessment of the plant protection product Kumar in its intended uses in grapes is documented in detail in the core assessment of the plant protection product Kumar. The environmental fate section according to Germany requirements has been previously evaluated for the same formulation but for a different use (apple). For the use in apples, authorization in Germany was granted in June 2013 (reg. number 007547-00).

5.1 General Information on the formulation

Table 5.1-1: General information on the formulation Kumar

Code	-
plant protection product	Kumar
applicant	Agchem Project Consulting
Submission date	September 2015
Formulation type (WP, EC, SC, …; density)	SP
active substance (as)	Potassium hydrogen carbonate
Concentration of as	850 g/kg

Data pool/task force	None
letter of access/cross reference	None
existing authorisations in DE	None

5.2 Proposed use pattern

This document comprises the risk assessment for groundwater and the exposure assessment of surface water and soil for authorization of the plant protection product Kumar in Germany according to the use listed in Appendix 2 and in table below.

Table 5.2-1: Critical use pattern of Kumar

Use	Application rate (g ai/ha)	Application method	Number of applications	Minimum application interval (days)	Application timing
Grape vine (00-002)	4.25 kg / ha	spraying on crop	6	7-10	BBCH 57-85

For further details, please refer to the core assessment, part B, section 5 for the label extension of the plant protection product Kumar in grape.

5.3 Information on the active substances

5.3.1 Potassium hydrogen carbonate

Please refer to the core assessment, part B, section 5 of the plant protection product Kumar.

5.4 Summary on input parameters for environmental exposure assessment

5.4.1 Rate of degradation in soil

Potassium hydrogen carbonate

Please refer to the core assessment, part B, section 5 of the plant protection product Kumar.

5.4.2 Adsorption/desorption

Potassium hydrogen carbonate

Please refer to the core assessment, part B, section 5 of the plant protection product Kumar.

5.4.3 Rate of degradation in water

Potassium hydrogen carbonate

Please refer to the core assessment, part B, section 5 of the plant protection product Kumar.

5.5 Estimation of concentrations in soil (KIIIA1 9.4)

A label extension for two uses in grape as a fungicide is intended for Kumar. The maximum number of applications is limited to 6. The maximum single application rate is 5.0 kg Kumar / ha (4.25 kg ai/ha). The minimum interval between the applications is 7 days.

The active substance potassium hydrogen carbonate is soluble in water and will rapidly dissociate to K^+ and HCO_3^-. The initial predicted environmental concentration of potassium and bicarbonate arising in soil from the use of Kumar was calculated using the highest rate of application and the input parameters summarised in **Fehler! Verweisquelle konnte nicht gefunden werden.**. The potassium ion does not degrade, whilst the bicarbonate ion can transform into other common natural products such as carbon dioxide, carbonates and water, which are of no known toxicological, ecotoxicological or environmental significance. Potassium ions are strongly bound in soil.

The predicted concentration of a plant protection product resp. its active ingredient in soil is calculated by assuming homogenous distribution of the maximal application rate over a soil horizon of 2.5 cm / 1 cm[1] according to German requirements and a standard soil dry weight of 1.5 g/cm³. The crop interception was set to 60% as worst case leading to the highest soil load at representative application stage [2]. Calculations were based on a lumped application of 25500 g active substance / ha corresponding to the maximum number of recommended doses and the highest rate of application in a season (**4250 g active substance/ha applied at a maximum of 6 time points**). No degradation between applications was considered for the PEC_{soil} calculations.

Table 5.5-1: Overview on input parameters used for PEC_{soil} calculations

Crop	Grape		
Depth of soil layer	2.5 cm / 1 cm		
Soil bulk density	1.5 kg/l		
% plant interception	60		
Number of applications	6		
Interval (d)	7		
	$KHCO_3$	**K^+**	**HCO_3^-**
% content of active substance	**100 %**	**39%**	**61%**
Application rate per treatment (g a.i./ha)	**4250**	**1658**	**2593**
Application rate per season (g a.i./ha), used for calculations	**25500**	**9945**	**15555**

Calculations of initial PEC_{soil} values were performed with Escape version 2. No short-term and long-term actual concentrations ($PEC_{soil,}$ actual) and the time weighted average concentrations (PEC_{soil}, twa) were calculated since the active substance potassium hydrogen carbonate doesn't degrade in soil but dissociates to potassium and bicarbonate ions in the presence of water instead. Taken into account the properties of the active substance and that only initial PEC_{soil} calculations are reasonable, the use of the input decision sheet, as required by Germany, was not appropriate in this case.

<u>PEC_{soil} calculations</u>

PEC_s immediately after the first application were calculated using FOCUS guidance[3] with the following equation:

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[1] According to the German requirements the following soil depth has to be chosen: 2.5 cm if $K_{f,oc}$ < 500 or 1 cm if $K_{f,oc}$ > 500. Taken into account that potassium is strongly bound in soil, indicating a low mobility, a soil depth of 1 cm was calculated additionally.

[2] EFSA Journal 2014; 12(5):3662: Interception (%) for vines is 60% at BBCH stage 53-69 and 75% at BBCH stage 71-89

[3] FOCUS (1997) Soil persistence models and EU Registration - The Final Report of the Soil Modelling Workgroup of FOCUS (Forum for the Co-ordination of Pesticide Fate Models and their Use) – 29 February 1997. <u>AND</u> FOCUS (2006) "Guidance Document on Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in

$PEC_{soil, initial}$ = A * (1-f_{int}) / d* bd_{soil} * %AR metabolite * mol. weight metabolite / mol. weight parent

$PEC_{soil, initial}$:	initial concentration in soil [mg a.i./kg dw soil]
AR:	application rate [g a.s./ha]
f_{int}:	fraction intercepted by plant cover [-]
D:	depth of soil layer [cm]
bd_{soil}:	soil bulk density [g/cm³]

In case of one application, the $PEC_{soil,initial}$ equals $PEC_{soil,max}$.
Results are presented in the table below.

Table 5.5-2: **Initial/actual PEC_{soil} values for the active substance and potassium and bicarbonate ions**

	$KHCO_3$	**K^+**	**HCO_3^-**
2.5 cm soil depth $PEC_{S, actual}$ mg/kg soil	**27.200**	**10.608**	**16.592**
1 cm soil depth $PEC_{S, actual}$ mg/kg soil	**68.000**	**26.520**	**41.480**

The initial worst case PECs are negligible in comparison with natural background level of potassium and bicarbonate in soil. For further information on the natural background level please refer to the core assessment, part B, section 5.

Please note that results of PEC_{soil} calculation for Kumar according to EU assessment considering 5 cm soil depth are given in the core assessment, part B, section 5 for the label extension of the plant protection product Kumar in grape.

PEC_{soil} calculation for the formulation Kumar

Table 9.4- 1 Overview on input parameters and results of PEC_{soil} calculation for the formulation Kumar

Number of applications	6
Single application rate [g product /ha]	5000
Application rate [g product/ha]	**30000**
Interception by plants [%]	60
Soil depth [cm]	2.5 / 1
Dry soil bulk density [g/cm³]	1.5
Soil depth of 2.5 cm: $PEC_{soil\ initial}$ [mg product/kg soil)	**32.00**

EU Registration" Report of the FOCUS Work Group on Degradation Kinetics, EC Document Reference Sanco/10058/2005 version 2.0, 434 pp

Soil depth of 1 cm: $PEC_{soil\ initial}$ [mg product/kg soil)	**80.00**

5.6 Estimation of concentrations in surface water and sediment (KIIIA1 9.7)

The PEC_{SW} was evaluated during the Annex I Inclusion. No additional studies have been performed. A label extension on grapes as a fungicide is intended for Kumar. The maximum number of applications is limited to 6. The maximum single application rate is 5.0 kg Kumar / ha (4.25 kg ai/ha). The minimum interval between the applications is 7 days.

Potassium hydrogen carbonate is soluble in water and will rapidly dissociate to K^+ and HCO_3^-. Given the nature of the active substance it is not considered appropriate to use the FOCUS model to determine PEC_{SW}. Instead, an estimation based on spray drift with no degradation between applications is considered adequate. This approach was accepted during the EU inclusion of potassium hydrogen carbonate

In general, for authorization in Germany, exposure assessment of surface water considers the two routes of entry

(i) spray drift and volatilisation with subsequent deposition, calculated with EVA 3.0 and

(ii) run-off, drainage separately in order to allow risk mitigation measures separately for each entry

route (calculated with EXPOSIT 3.01)

However, since potassium hydrogen carbonate is not volatile and immediately dissociates to K^+ and HCO_3^- in the presence of water, only entry via spray drift is considered likely for Kumar and the intended use. Thus, the initial PEC_{sw} values calculated for entry via spray drift using drift values according to Rautmann, 2001[4] and the calculation tool EVA 3 - Exposure Via Air, rev. 1h of 16.12.2013- are considered sufficient for risk assessment in Germany.

Calculations were based on a lumped application of 25500 g active substance / ha corresponding to the maximum number of recommended doses and the highest rate of application in a season (**4250 g active substance/ha applied at a maximum of 6 time points**). The vine drift scenario was used for the modelling with EVA 3. No degradation and no volatilization were assumed.

Results are presented in the following tables.

Table 5.6-1 Summary of input parameters of potassium hydrogen carbonate for PECsw calculations with EVA 3

active substance/product :	**$KHCO_3$**	**K^+**	**HCO_3^-**
intended use:	Grape	Grape	Grape

[4] Rautmann, D.; Streloke, M.; Winkler, R.: "New basic drift values in the authorization procedure for plant protection products" Mitteilungen aus der Biologischen Bundesanstalt für Land- und Forstwirtschaft 383, 133-141 (2001).

application parameters:	1 x 25500 g/ha (= 6 x 4250 g/ha)	1 x 9945 g/ha (= 6 x 1658 g/ha, 39% content)	1 x 15555 g/ha (= 6 x 2593 g/ha, 61% content)
DisT50 water phase (SFO):	*Not applicable - no breakdown between the applications assumed*		
scenario, drift percentile:	vines, 90. percentile	vines, 90. percentile	vines, 90. percentile
PEC type:	PECini/PECact	PECini/PECact	PECini/PECact

Table 5.6-2 PEC in aquatic environment - water (µg/L) for $KHCO_3$ (calculated with EVA 3)

dist. (m)	(final) drift-%	drift only	No drift reduction	50% drift reduction	75% drift reduction	90% drift reduction
3	8.02%	681.700	681.700	340.850	170.425	68.170
5	3.62%	307.700	307.700	153.850	76.925	30.770
10	1.23%	104.550	104.550	52.275	26.138	10.455
15	0.65%	55.250	55.250	27.625	13.813	5.525
20	0.42%	35.700	35.700	17.850	8.925	3.570

Table 5.6-3 PEC in aquatic environment - water (µg/L) for K+ (calculated with EVA 3)

dist. (m)	(final) drift-%	drift only	No drift reduction	50% drift reduction	75% drift reduction	90% drift reduction
3	8.02%	265.863	265.863	132.932	66.466	26.586
5	3.62%	120.003	120.003	60.002	30.001	12.000
10	1.23%	40.775	40.775	20.387	10.194	4.077
15	0.65%	21.548	21.548	10.774	5.387	2.155
20	0.42%	13.923	13.923	6.962	3.481	1.392

Table 5.6-4 PEC in aquatic environment - water (µg/L) for HCO3- (calculated with EVA 3)

dist. (m)	(final) drift-%	drift only	No drift reduction	50% drift reduction	75% drift reduction	90% drift reduction
3	8.02%	415.837	415.837	207.919	103.959	41.584
5	3.62%	187.697	187.697	93.849	46.924	18.770
10	1.23%	63.776	63.776	31.888	15.944	6.378
15	0.65%	33.703	33.703	16.851	8.426	3.370
20	0.42%	21.777	21.777	10.889	5.444	2.178

Table 5.6-5 Initial/actual PECSW values for the active substance and potassium and bicarbonate ions

	$KHCO_3$	**K^+**	**HCO_3^-**
PEC_{SW} µg/L*	681.700	265.863	415.837

* Vine drift scenario (EVA 3, 90. Percentile, with 3 m buffer zone, drift only, application rate of 1 x 25500 g as/ha (= 6 x 4250 g as/ha))

Information on the Natural background concentrations of bicarbonate and potassium in surface waters can be found in the core assessment, part B, section 5 for the label extension of the plant protection product Kumar in grape.

The PEC sediment was not considered relevant because if potassium hydrogen carbonate is present in aquatic systems it is likely to be predominantly in the water column or in the pore-water of the sediment. The results for PEC surface water for the active substance were used for the eco-toxicological risk assessment.

PEC$_{SW}$ calculation for the formulation Kumar

Table 5.6-6 Parameters used for PEC$_{SW}$ calculation for the product with EVA 3

active substance/product:	**Kumar**
intended use:	Grape
application parameters:	1 x 30000 g product/ha (= 6 x 5000 g product/ha)
scenario, drift percentile:	vines, 90. percentile
PEC type:	PECini/PECact

Table 5.6-7 PEC in aquatic environment - water (µg/L) for Kumar (calculated with EVA 3)

dist. (m)	(final) drift-%	drift only	No drift reduction	50% drift reduction	75% drift reduction	90% drift reduction
3	8.02%	802.000	802.000	401.000	200.500	80.200
5	3.62%	362.000	362.000	181.000	90.500	36.200
10	1.23%	123.000	123.000	61.500	30.750	12.300
15	0.65%	65.000	65.000	32.500	16.250	6.500
20	0.42%	42.000	42.000	21.000	10.500	4.200

Table 5.6-8 PEC in aquatic environment - water (µg a.s./L) for potassium hydrogen carbonate (calculated with EVA 3)

dist. (m)	(final) drift-%	drift only	No drift reduction	50% drift reduction	75% drift reduction	90% drift reduction
3	8.02%	681.700	681.700	340.850	170.425	68.170
5	3.62%	307.700	307.700	153.850	76.925	30.770
10	1.23%	104.550	104.550	52.275	26.138	10.455
15	0.65%	55.250	55.250	27.625	13.813	5.525
20	0.42%	35.700	35.700	17.850	8.925	3.570

The initial/actual PEC$_{SW}$ for the plant protection product Kumar is 802.000 µg/L, **equivalent to 681.7 µg a.s./L.**

5.7 Risk assessment for groundwater (KIIIA1 9.6)

The PEC_{GW} was evaluated during the Annex I Inclusion. No additional studies have been performed. Given the nature of potassium bicarbonate it is considered inappropriate to use the FOCUS groundwater tools and this was accepted by The Netherlands as the zRMS for the Central zone and by EU authorities during the EU inclusion of potassium hydrogen carbonate [5].

Generally, for authorization in Germany, risk assessment for groundwater considers two pathways,

(i) direct leaching of the active substance into the groundwater after soil passage and

(ii) surface run-off and drainage of the active substance into an adjacent ditch with subsequent bank filtration into the groundwater.

However, potassium hydrogen carbonate spontaneously dissociates in water to give potassium and bicarbonate ions. The potassium ion is stable and does not degrade but it is taken by plant and microbials. In fact, potassium is often applied to soil as a supplement in fertilizers in order to improve the plant growth. Bicarbonate on the other hand will equilibrate with carbonate and carbonic acid to yield carbon dioxide and water. The potassium and bicarbonate ions can potentially leach through the soil to groundwater resources. However, these ions are not of toxicological relevance and background levels are significantly higher than those likely to arise from the use of Kumar. In the event of reaching groundwater it would be impossible to distinguish these ions by analytical means from natural sources of these ions. In addition, the drinking water limit for potassium is 12 mg/L. The trigger of 0.1 µg/L valid for organic pesticides is not applicable for potassium hydrogen carbonate.

Thus, following the argumentation in the core assessment, no risk of groundwater contamination is expected from the use of Kumar and PEC_{GW} calculations are not considered necessary.

For further information, refer to the core assessment, part B, section 5 for the label extension of the plant protection product Kumar in grape.

[5] EFSA Journal 2012;10(1):2524: EFSA's reading of the Council Directive 98/83/EC[16] on the quality of drinking water intended for human consumption is that, as an inorganic fungicide, potassium hydrogen carbonate or the relevant ions that are formed from it, are not considered a pesticide under this directive, so the parametric drinking water limit of 0.1µg/L for pesticides, usually used as a decision making criteria regarding groundwater exposure, does not apply. 'Chemical parameters' or 'indicator parameters' levels (as defined in this directive) have not been prescribed for potassium or carbonate ions.

Appendix 1 List of data submitted in support of the evaluation

No additional data for national assessment submitted.

Appendix 2 Table of Intended Uses in Germany (according to BVL, date: 2016-May-24)

PPP (product name/code):	Kumar	Formulation type:	Water soluble powder (SP) [a, b]
Active substance 1:	Potassium hydrogen carbonate	Conc. of as 1:	850,00 g/kg [c]
Applicant:	Spiess-Urania Chemicals GmbH	Professional use:	☒
Zone(s):	central [d]	Non professional use:	☐
Verified by MS:	yes		

Field of use: herbicide, fungicide, insecticide etc

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f]
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	DE	Grape VITVI (utilisation as table and wine grape)	F	grey mould *Botrytis cinerea* BOTRCI	spraying or fine spraying (low volume spraying)	in case of danger of infection and/or after warning service appeal BBCH 75-89	a) 4 b) 6	8-30 days	a) 5.00 kg/ha b) 30.00 kg/ha	a) 4.25 kg as/ha b) 25.50 kg as/ha	800-1600	1	
2	DE	Grape VITVI (utilisation as table and wine grape)	F	powdery mildew of grape *Uncinula necator* UNCINE	spraying or fine spraying (low volume spraying)	in case of danger of infection and/or after warning service appeal BBCH 57-85	a) 6 b) 6	7-10 days	a) 5.00 kg/ha b) 30.00 kg/ha	a) 4.25 kg as/ha b) 25.50 kg as/ha [2]	200-1600	1	Dose rates staggered according to BBCH: basic application rate: 1.25 kg/ha in 200-400 L/ha Water BBCH 61: 2.50 kg/ha in 400-800 L/ha Water

													BBCH 71: 3.75 kg/ha in 600-1200 L/ha Water BBCH 75: 5.00 kg/ha in 800-1600 L/ha Water

Remarks table heading:

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008
(c) g/kg or g/l
(d) Select relevant
(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
(f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

Remarks columns:

1 Numeration necessary to allow references
2 Use official codes/nomenclatures of EU Member States
3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)
4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application
5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.
6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.
7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
8 The maximum number of application possible under practical conditions of use must be provided.
9 Minimum interval (in days) between applications of the same product
10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
13 PHI - minimum pre-harvest interval
14 Remarks may include: Extent of use/economic importance/restrictions

REGISTRATION REPORT
Part B

Section 6 Ecotoxicological Studies
Detailed summary of the risk assessment

Product name: **Kumar**

Active Substance: **potassium hydrogen carbonate 850 g/kg**

Central Zone
Zonal Rapporteur Member State: Germany (DE)

CORE ASSESSMENT
Label extension for grapes

Applicant: **Spiess-Urania Chemicals GmbH**

Date: **08.09.2017**

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Sec 6 ECOTOXICOLOGICAL STUDIES

The product Kumar (= ARMICARB 85 SP) containing 850 g/kg potassium hydrogen carbonate was already evaluated by the Netherlands as zRMS and by Germany as cMS for registration in the Central Zone for the use in apples (8 x 4250 g ai/ha). Authorization in Germany was granted in June 2013 (007547-00/00).
This document is related to an application for label extension for the product Kumar according to article 29 of Regulation (EC) No 1107/2009 for the use in grape against *Botryotinia fuckeliana* and *Erysiphe necator*.

This document reviews the eco-toxicological studies for the product Kumar containing potassium hydrogen carbonate which was included into Annex I of Directive 91/414 (2008/127/EC). A full risk assessment according to Uniform Principles is provided which demonstrates that the product is safe for the environment.

Where appropriate this document refers to the conclusions of the EU review of potassium hydrogen carbonate. This will be where:

- the active substance data is relied upon in the risk assessment of the formulation.
- the EU review concluded that additional data/information should be considered at national re-registration.

Note: this Part B document only reviews data (Annex II or Annex III) and additional information that has not previously been considered within the EU review process, as part of the Annex I inclusion decision.

The product Kumar (syn. Armicarb 85 SP) was the representative formulation during EU-review. This product has previously been evaluated according to the Uniform Principles under Regulation 1107/2009, also for the use in viticulture.

The SANCO report for potassium hydrogen carbonate (SANCO/2625/08 – 04/07/2008) and the EFSA conclusion for potassium hydrogen carbonate (EFSA Scientific Report (2012) 10(1):2524) are considered to provide the relevant review information or a reference to where such information can be found.

In 2012, EFSA identified the following concerns in their conclusions on the peer-review:

1. The environmental risk assessment for soil and water can not be finalised until the naturally occurring background levels assumed for potassium are confirmed by studies or peer reviewed scientific literature. Consequently, the long-term risk assessment for aquatic organisms, and the risk assessments for non-target arthropods, soil non-target organisms and terrestrial non-target plants could not be finalised.

2. There were some indications that the representative formulation is more toxic to aquatic organisms than the active substance. Therefore further data and assessments are necessary to finalise the risk assessments.

3. Further data and assessments are necessary to finalise the risk assessment for bees.

These concerns have been addressed within the current submission.

Appendix 1 of this document contains the list of references included in this document for support of the evaluation.

Appendix 2 of this document is the table of intended uses for Kumar.

Introduction

This section of the submission summarises the ecotoxicological effects of the formulation and evaluates the potential risk to various representatives of terrestrial, aquatic and soil organisms. The risk assessment was previously evaluated for an application to apples. A label extension has now been requested for applications to grapes.

6.1 Proposed use pattern and considered metabolites

Introduction

Section 6 of the submission summarises the ecotoxicological effects of the formulation Kumar containing the active substance potassium hydrogen carbonate and evaluates the potential risk to various representatives of terrestrial, aquatic and soil organisms. Full details or the proposed use patterns that will be assessed are shown in Appendix 3 of this document and summarized below. Moreover, an overview of the metabolites of potassium hydrogen carbonate that will be addressed in the risk assessment is given below.

6.1.1 Proposed use pattern

The critical use patterns used for exposure assessment are presented in Table 6.1-1. They have been selected from the individual GAPs in the zone for orchards. A complete list of all intended uses within the zone is given in Appendix 3.

Table 6.1-1: Critical use pattern of Kumar

Use	Application rate (g ai/ha)	Application method	Number of applications	Minimum application interval (days)	Application timing
Grape	4250	spraying on crop	6	7-10	BBCH 57-85

6.1.2 Consideration of metabolites

There are no relevant metabolites. Potassium hydrogen carbonate spontaneously dissociates to potassium and bicarbonate in moist soils. Potassium and bicarbonate do not accumulate in soil since potassium is taken by the plants and microbial organisms while bicarbonate is associated to cations (alkaline soils) or is reduced to form water and carbon dioxide (acidic soils).

6.2 Effects on Birds

6.2.1 Overview and summary

Effects on birds of Kumar were not evaluated as part of the EU review of potassium hydrogen carbonate. However, the provision of further data on the formulation Kumar is not considered essential as the available data are deemed to be sufficient to assess the risk of birds exposed to Kumar.

6.2.1.1 Toxicity

According to the DAR (2008) four different studies including feeding sodium bicarbonate to chickens were reviewed. It was concluded that the intake of Potassium hydrogen carbonate does not present any significant hazard to birds and therefore, no further considerations regarding a risk assessment to birds was made.

6.2.1.2 *Exposure*

Kumar is intended for field/glasshouse use as a foliar spray in orchards.

6.2.1.3 *Risk Assessment –overall conclusions*

The effects on birds of potassium hydrogen carbonate were evaluated during the Annex I Inclusion. No additional studies have been performed. According to the DAR (2008)[1] studies to address the acute or long-term toxicity of Potassium hydrogen carbonate on birds are not required due to the following reasons:

- Potassium and bicarbonate are extremely common in all natural systems, including water, soil, plant and animal tissues
- Potassium bicarbonate has extremely low toxicities in mammals
- Poultry are often fed bicarbonates (usually sodium bicarbonate) as a supplement at 0.2% (2000 mg/kg) but it has been shown to have no negative effects at rates up to 1% (10000 mg/kg) in the diet
- Bicarbonate is not harmful to animals unless consumed in extremely high quantities and is widely used as a buffering agent to reduce stomach acidity
- Potassium is an essential plant nutrient and is often applied to crops as both a soil and/or foliar fertilizer
- Potassium bicarbonate is an approved food additive in the EU (E501) and is also listed as a food additive by CODEX Alimentarius
- Potassium bicarbonate is generally regarded as safe (GRAS) by the US FDA
- The recommended daily allowance for potassium is usually considered as being 3.5 g/d in humans
- According to the DAR (2008)[1] the intake of potassium bicarbonate over long periods of time is assumed to be 2,500 mg/kg bw/d, based on a body weight of 250 g and a concentration of 10,000 mg/kg diet.

6.2.1.4 *Short -term toxicity exposure ratio (TER_{ST})*

There is no requirement for the calculation of TER_{ST} for birds under the EFSA birds and mammals guidance document (EFSA Journal 2009; 7(12): 1438) and, consequently, a risk assessment for short-term toxicity will not be conducted.

6.2.1.5 *Long-term toxicity exposure ratio (TER_{LT})*

Please refer to Point 6.2.1.3

6.2.2 Drinking water exposure

Please refer to Point 6.2.1.3

[1] RMS UK, Draft Assessment Report on the existing active substance Potassium hydrogen carbonate,(2008), Vol. 3, Annex B, part 5, B.9

6.2.3 Details on formulation type in proportion per item

6.2.3.1 Baits: Concentration of active substance in bait in mg/kg

Kumar is not formulated as bait. The formulation is intended for use as a foliar spray, and therefore this information is not required.

6.2.3.2 Pellets, granules, prills or treated seed

Kumar is not formulated as pellets, granules, pills or treated seeds. Kumar is intended for use as a foliar spray, and therefore this information is not required.

Amount of active substance in or on each item

Not applicable.

Proportion of active substance LD_{50} per 100 items and per gram of items

Not applicable.

Size and shape of pellet, granule or prill

Not applicable.

6.2.4 Acute toxicity of the formulation

Avian toxicity tests with the formulation were not performed and are not considered necessary.

6.2.5 Metabolites

There are no relevant metabolites.

6.2.6 Supervised cage or field trials

The risk assessment above has demonstrated that the proposed uses of Kumar pose no unacceptable acute or long-term risks to birds, and therefore further studies are not considered necessary.

6.2.7 Acceptance of bait, granules or treated seeds (palatability testing)

Kumar is intended for use as a foliar spray, and therefore this information is not required.

6.2.8 Effects of secondary poisoning

According to the EFSA birds and mammals guidance document (EFSA Journal 2009; 7(12): 1438), substances with a log P_{OW} greater than 3 have potential for bioaccumulation and should be assessed for the risk of biomagnification in terrestrial food chains. For the active substance Potassium hydrogen carbonate the log P_{OW} is not relevant because Potassium and bicarbonate are widely occurring natural inorganic ions present in soils, sediments and water bodies. Therefore no further assessment of effects of secondary poisoning are considered necessary.

6.3 Effects on Terrestrial Vertebrates Other Than Birds

6.3.1 Overview and summary

6.3.1.1 Toxicity

Table 6.3-1: Toxicity of potassium hydrogen carbonate to mammals with reference to agreed endpoints

Species	Substance	Exposition Duration System	Results Toxicity	Reference Author Date Report No.	ICS-No.
Rat	potassium hydrogen carbonate	Acute oral toxicity	LD_{50} >2064 mg a.i./kg bw/d (female) [1)]	-	-

1) EFSA conclusion (2012), doi:10.2903/j.efsa.2012.2524)

6.3.1.2 Exposure

Exposure to standard generic indicator species was estimated according to the 'EC Guidance Document on Risk Assessment for Birds and Mammals Council (EFSA/2009/1438).

6.3.1.3 Risk assessment –overall conclusions

Effects on mammals for the product Kumar were not evaluated as part of the Draft Assessment Report of the active substance Potassium hydrogen carbonate. According to the DAR (2008) studies to address the acute or long-term toxicity of Potassium hydrogen carbonate on mammals are not required due to the following reasons:

- Potassium and bicarbonate are extremely common in all natural systems, including water, soil, plant and animal tissues
- Potassium bicarbonate has extremely low toxicities in mammals with the lowest acute oral LD_{50} being 2064 mg/kg in female rats
- Bicarbonate is not harmful to animals unless consumed in extremely high quantities and is widely used as a buffering agent to reduce stomach acidity
- Potassium is an essential plant nutrient and is often applied to crops as both a soil and/or foliar fertiliser
- Potassium bicarbonate is an approved food additive in the EU (E501) and is also listed as a food additive by CODEX Alimentarius
- Potassium bicarbonate is Generally Regarded As Safe (GRAS) by the US FDA
- The recommended daily allowance for potassium is usually considered as being 3.5 g/d in humans

Therefore, a risk assessment considering the risk of Potassium hydrogen carbonate to mammals is not considered necessary.

6.3.2 Toxicity exposure ratio

6.3.2.1 Acute toxicity exposure ratio (TER_A)

Please refer to Point 6.2.1.3

6.3.2.2 Short-term toxicity exposure ratio (TER_{ST})

There is no requirement for the calculation of TER_{ST} for mammals under the EFSA birds and mammals guidance document (EFSA Journal 2009; 7(12): 1438) and, consequently, a risk assessment for short-term toxicity has not been performed.

6.3.2.3 Long-term toxicity exposure ratio (TER_{LT})

Please refer to Point 6.3.1.3

6.3.3 Drinking water exposure

Please refer to Point 6.3.1.3

6.3.4 Details on formulation type in proportion per item

Please refer to section 6.2.3 for details on the formulation type of Kumar.

6.3.4.1 Baits: Concentration of active substance in bait in mg/kg

Please refer to section 6.2.3.

6.3.4.2 Pellets, granules, prills or treated seed

Please refer to section 6.2.3.

Amount of active substance in or on each item

Please refer to section 6.2.3.

Proportion of active substance LD50 per 100 items and per gram of items

Please refer to section 6.2.3.

Size and shape of pellet, granule or prill

Please refer to section 6.2.3.

6.3.5 Acute toxicity of the formulation

Mammal toxicity tests with the formulation were not performed and are not considered necessary.

6.3.6 Metabolites

There are no relevant metabolites.

6.3.7 Supervised cage or field trials

The risk assessment above has demonstrated that the proposed uses of Kumar pose no unacceptable acute or long-term risks to mammals, and therefore further studies are not considered necessary.

6.3.8 Acceptance of bait, granules or treated seeds (palatability testing)

Kumar is intended for use as a foliar spray, and therefore this information is not required.

6.3.9 Effects of secondary poisoning

According to the EFSA birds and mammals guidance document (EFSA Journal 2009; 7(12): 1438), substances with a log P_{OW} greater than 3 have potential for bioaccumulation and should be assessed for the risk of biomagnification in terrestrial food chains. For the active substance Potassium hydrogen carbonate the log P_{OW} is not relevant because Potassium and bicarbonate are widely occurring natural inorganic ions present in soils, sediments and water bodies. Therefore no further assessment of effects of secondary poisoning are considered necessary.

6.4 Effects on Aquatic Organisms

6.4.1 Overview and summary

The following EU agreed endpoints for aquatic organisms exposed to the active substances potassium hydrogen carbonate are reported in the lists of endpoints of the Conclusion on the Peer review of potassium hydrogen carbonate (EFSA Journal 2012;10(1):2524) (see table below).

A data gap was identified concerning data and risk assessment not available for algae for active substance at European level. The study for algae provided in the present dossier with the formulation Kumar (Armicarb 85 SP) is considered as sufficient to address the risk since the formulation contains 85 % of potassium hydrogen carbonate.

No chronic data and long-term risk assessments were available. However, according to the EFSA conclusion on peer-review (2012), it is noted that the background concentrations of the dissociation products of potassium hydrogen carbonate in natural aquatic systems was assumed to be relatively high compared to the predicted concentrations arising from the application of the active substance, although there is a data gap identified for data to support the high background concentrations of K^+.
As specified in the section 5, the natural background level of potassium in surface waters is 0.01-36.6 mg/L (data available in the EFSA journal on potassium phosphonate, streams, according to De Vos *et al*. 2006). According to the UN GEMS/water programme, in natural surface waters potassium concentration are typically < 5 mg/L. In the study of Meybeck (1979), an average concentration of 1.3 mg/L based on extensive surveys in river waters around the world was specified.

Therefore, for potassium, the worst case PEC value calculated assuming no dissipation between applications (265.863 µg K^+/L for the use in grape) can be considered lower in comparison with the natural background level of potassium in water.

Bicarbonate is generally the most important anion in rivers. According to the section 5, typical levels of bicarbonate in surface waters in Europe are between 12 mg/L (Norwegian rivers) and 190 mg/L (Danube)[2]. In the study of Meybeck (1979), an average concentration of 52 mg/L based on extensive surveys in river waters around the world was specified. At European level, the Geochemical Atlas of Europe maintains an extensive database of soil, sediment and water samples randomly collected across Europe. The median value over 808 water samplings for bicarbonate is 130 mg/L.
Therefore, for bicarbonate, the worst case PEC value calculated (415.837 µg HCO_3^- /L for the use in grape) can be considered negligible in comparison with the natural background level of bicarbonate in water.

Moreover, both potassium and bicarbonate are essential constituents of living organisms and essential nutrients of plants, including algae. Potassium bicarbonate has a very low acute toxicity to fish and *Daphnia magna* and potassium bicarbonate is highly soluble in water and has very limited potential for bio-accumulation in aquatic organisms.

Therefore, chronic toxicity data for fish and daphnia are considered not necessary by zRMS.

Metabolites

[2] Berner, E.K., Berner R.A., 1996. Global Environment: Water, Air, and Geochemical Cycles. Robert A. McConnin. New Jersey: Prentice-Hall Inc.

As discussed in the EU review, potassium hydrogen carbonate dissociates into potassium and bicarbonate ions in water. Potassium cannot degrade any further but bicarbonate can form carbon dioxide, water, carbonate and carbonic acid. All of these compounds are commonly found in natural water where they usually occur at levels much higher than those that might result from the use of Kumar. Therefore as agreed at EU level no additional tests with metabolites are required.

6.4.1.1 Toxicity

The endpoints for aquatic organisms relevant for the risk assessment are indicated in the following table.

Table 6.4-1: Ecotoxicological endpoints for aquatic species exposed to potassium hydrogen carbonate with indication to agreed endpoints

Species	Substance	Exposition Duration System	Results Toxicity	Reference Date author Report No.	ICS-No.
Acute toxicity to fish					
O.mykiss	potassium hydrogen carbonate	Acute	LC_{50} (96 h) = 1400 mg a.s./L[1]	[redacted] 1993a [2]	-
Lepomis macrochirus	potassium hydrogen carbonate	Acute	LC_{50} (96 h) = 1500 mg a.s./L[1]	[redacted] 1993b [2]	-
Acute toxicity to aquatic invertebrates					
Daphnia magna	potassium hydrogen carbonate	Acute	EC_{50} (48 h) = 1200 mg a.s./L[1] (flow-through, measured)	Putt, A.E. 1993 [2]	-
Algae					
Pseudokirchneriella subcapitata	Armicarb 85 SP (= Kumar)		72 hr EC50 (growth rate): ->85.75 mg a.s./L 72 hr EC50 (yield): >85.75 mg a.s./L	Ythier, 2010	81450

1) EFSA conclusion (yyyy) e.g. doi:11.1111/j.efsa.2010.1111)

2) DAR on potassium hydrogen carbonate (April 2006)

6.4.1.2 Exposure

Please refer to Point 5.5 in section 5 (Environmental Fate) for more details.

6.4.1.3 Risk assessment –overall conclusions

Based on the worst case $PEC_{sw, ini}$ values presented above, the aquatic TER values for potassium hydrogen carbonate are well above the trigger of 100 and 10, indicating a low and acceptable acute and chronic risk for aquatic organisms from potassium hydrogen carbonate and its water metabolites following application of Kumar at the proposed application rates.

A summary of the toxicity exposure ratios for potassium hydrogen carbonate following the proposed use on grape is shown below.

Table 6.4-2: Aquatic TER values for potassium hydrogen carbonate after applications of Kumar.

Test substance	Organism	Endpoint type	Toxicity endpoint (mg as /L)	PEC (mg a.s./L)	RAC (mg a.s./L)	PEC≤ RAC: low risk
$KHCO_3$	*Oncorhynchus mykiss*	acute	>1400	0.6817	Acute: >14.00	ok
$KHCO_3$	*Daphnia magna*	acute	>1200	0.6817	Acute: >12.00	ok
Armicarb 85 SP*	*Pseudokirchneriella subcapitata*	Long term (population growth)	> 85.75 (yield and growth rate)	0.6817	Chronic: >8.575	ok

*syn. Kumar

6.4.2 Toxicity to Exposure ratio

The results of the assessment indicate an acceptable risk for aquatic organisms due to the intended use of Kumar according to the label.

6.4.3 Acute toxicity and chronic toxicity of the formulation

For fish and daphnia, no additional tests were carried out with the formulation. The acute toxicity can be extrapolated from the active substance. Indeed, the toxicity obtained for the active substance can be extrapolated to the preparation as it comprises 85% w/w of the preparation and the co-formulants are not of ecotoxicological concern for classification purposes. For algae, an acute toxicity limit test was carried out on the green algae with the formulation Armicarb 85 SP (syn. Kumar) and is summarised below.

6.4.4 Metabolites of potassium hydrogen carbonate

There are no relevant metabolites of potassium hydrogen carbonate occurring in surface water or sediment. Potassium hydrogen carbonate spontaneously dissociate to potassium and bicarbonate in water to give potassium and bicarbonate ions. Potassium cannot degrade any further but bicarbonate can form carbon dioxide, water, carbonate and carbonic acid. All of these compounds are commonly found in natural waters where they usually occur at levels much higher than those might result from the use of Kumar. Thus, no risk assessment is considered necessary.

6.4.5 Accumulation in aquatic non-target organisms

Potassium bicarbonate is highly soluble in water and as a result has a very limited potential for bio-concentration. Bioaccumulation of the active substance under natural conditions is not expected to occur and specific tests to evaluate bio-concentration potential are therefore considered unnecessary.

6.5 Effects on Bees

In the honey bee risk assessment for the main application it was concluded that the risk to bees is acceptable when Kumar is used up to 7.5 kg/ha in bee attractive crops. Since the recommended application rate does not exceed this rate no further risk assessment is required.

6.5.1 Risk assessment for Arthropods other than Bees

Effects on arthropods other than bees of Armicarb 85 SP (syn. Kumar) were not evaluated as part of the EU review and were identified as a data gap in the EFSA review 2012. New studies on the formulated product and risk assessments are provided with this application which fulfils the data gap.

EU Endpoints: Effects on Arthropods
Ecotoxicological endpoints for Arthropods

Formulation	EU agreed endpoints EFSA conclusion (2012)	Endpoints used in risk assessment[1]
Acute		
Armicarb 85 SP	No data – data gap	*Aphidius rhopalosiphi* extended laboratory limit test LR_{50} > 7438 g as/ha
Armicarb 85 SP	No data – data gap	*Typhlodromus pyri* extended laboratory multi-dose test LR_{50} = 5519 g as/ha
Sub-lethal		
Armicarb 85 SP	No data – data gap	*Aphidius rhopalosiphi* extended laboratory limit test Reproduction reduction: 11.57% No repellent effect
Armicarb 85 SP	No data – data gap	*Typhlodromus pyri* extended laboratory multi-dose test Reproduction reduction: 48% at 2688 kg as/ha
Armicarb 85 SP	No data – data gap	*Orius laevigatus* extended laboratory multi-dose test <50% mortality at 6.54 kg a.s./ha (LR_{50} = 8.70 kg a.s./ha) <50% effects on reproduction at 17.4 kg a.s./ha (ER_{50} > 17.4 kg a.s./ha)
Armicarb 85 SP	No data – data gap	*Typhlodromus pyri* aged residue study (up to 28 days aging following application of either 6.37 or 13.1 kg a.s./ha) <50% mortality at ≥0 days after application (DAA) of both 6.37 and 13.1 kg a.s./ha <50% effects on reproduction at 0 DAA of 6.37 kg a.s./ha <50% effects on reproduction at 7 DAA of 13.1 kg a.s./ha

[1] Since Annex I inclusion new studies on the formulated product have been performed and as a result there are new end-points which are used in the risk assessment.

Summary
Effects on arthropods other than bees of Armicarb 85 SP (syn. Kumar) were not evaluated as part of the EU review of potassium hydrogen carbonate as a general waiver for studies and risk assessment was accepted and no data was required that time.

The intended use pattern for registration in the Central zone is within the use pattern considered for EU review. A waiver is based on the following:

- There are no recorded issues of adverse effects of Kumar on beneficials arthropods despite several years of usage in the USA, mostly in IPM and organic farming situations.
- Potassium and bicarbonate are extremely common in all natural systems, including water, soil, plant and animal tissues.
- Potassium hydrogen carbonate has been listed on Annex II of EC Regulation 2092/91 on organic production of agricultural products since 2008

Despite the waiver above which is deemed relevant in the Central zone, new data and assessments are provided here.

2012 EFSA identified a data gap for non-target arthropods, however. They stated in the conclusion: "*No data or risk assessments were available for non-target arthropods, earthworms, soil macro- and micro-organisms or for terrestrial non-target plants. It is noted that the background concentrations of the dissociation products of potassium hydrogen carbonate in soil was assumed to be relatively high compared to the predicted concentrations arising from the application of the active substance, although there is a data gap identified for data to support the high background concentrations of* K^+ *(see section 4). If the background levels are confirmed to be higher than the exposure from the representative uses then the risk could be considered as low, however, a data gap to re-consider the risk assessments has been identified pending the availability of the necessary data in section 4*."

The new toxicity studies and also the information on background concentrations are considered to address this concern in the EFSA conclusion.

Although in-field HQ for *A. rhopalosophi* is more than the trigger of 1 for extended studies, no significant realistic risk to non-target arthropod populations is expected. This is since the exposure considered is very worst case and does not take into account the binding and buffering of the resultant potassium and bicarbonate ions on leaves and soil and movement due to high solubility in water. Additionally less than 6 applications are likely in reality and the *A. rhopalosophi* endpoint is from a limit dose test and thus an actual LR_{50} is not known. In addition, based on a new higher tier study (aged residue study with the predatory mite), it was concluded during evaluation of the product dossier for the use in apples that populations of arthropods would be able to recover within the one year time-frame stated in ESCORT 2. No specific mitigation measure is required for apple and the intended use in grape.

Risk assessment

Toxicity

The toxicity of Kumar to non-target arthropods has been investigated. The testing and risk assessment strategy used here follow the approach recommended in the *ESCORT 2 guidance document* (*Candolfi et al. 2001*)[3] and the *EC Guidance Document on Terrestrial Ecotoxicology*[4].

The toxicity of Kumar to non-target arthropods has been investigated by carrying out Tier II tests on *Aphidius rhopalosiphi* and on *Typhlodromus pyri*. These two species are tested, in accordance with ESCORT 2, as representative non-target arthropods since they have been found to be particularly sensitive species, and therefore can be considered as indicators of potential effects to the most sensitive arthropods in the field. Two further Tier II studies have also been performed: an extended laboratory study on *Orius laevigatus* and an aged residue study on *T. pyri*. For convenience, the results of these studies are summarised in Table 10.5-2. Study summaries are provided below (data point IIIA 10.5.2).

[3] Candolfi MP, Barrett KL, Campbell PJ, Forster R, Grandy N, Huet M-C, Lewis G, Oomen PA, Schmuck R, Vogt H (2000) 'Guidance Document on regulatory testing procedures for plant protection products with non-target arthropods' From the workshop, European Standard Characteristics of Non-target Arthropod Regulatory Testing (ESCORT 2) 21-23 March 2000.

[4] EC Guidance Document on Terrestrial Ecotoxicology Under Council Directive 91/414/EEC, SANCO/10329, 17 October 2002.

Table 10.5-1 Kumar (syn. Armicarb 85 SP) - Toxicity to non-target arthropods

Test substance	Species	Exposed life stage	Study type	LR_{50} (g product/ha)	Sub-lethal effects	Reference
Armicarb 85 SP	*Aphidius rhopalosiphi*	Adult	Extended laboratory study on barley seedlings (limit test)	LR_{50} > 8750 (equivalent to > 7438 g as/ha)	No repellent effect Reduction of reproduction: 11.57% ER_{50} >8750 g product/ha (equivalent to > 7438 g as/ha)	*Juan, D (2011) KIIIA 10.5.2/01*
Armicarb 85 SP	*Typhlodromus pyri*	Protonymph	Extended laboratory study on bean leaf discs (multi dose test)	LR_{50} = 6493 (equivalent to 5519 g as/ha)	Reduction of reproduction: 42% (1000 g/ha) 30% (1778 g/ha) 48% (3162 g/ha) Not significant reduction at 1778 g/ha ER_{50} >3162 g product/ha (equivalent to > 2688 g as/ha)	*Juan, D (2011) KIIIA 10.5.2/02*
Armicarb 85 SP	***Orius laevigatus***	**2nd instar nymph**	**Extended laboratory study on detached apple leaves (multi dose test)**	**LR_{50} = 9.978 (equivalent to 8703 g as/ha)**	**ER_{50} > 7.5 (equivalent to > 6540 g as/ha) (2.6% reduction observed at 7.5 kg PP/ha)**	***Martinez, F.L. (2013) KIIIA 10.5.2/03***
Armicarb 85 SP	***Typhlodromus pyri***	**Protonymph**	**Aged residue study (up to 28 days aging following application of either 6.37 or 13.1 kg a.s./ha)**	**<50% mortality at ≥0 days after application (DAA) of both 6.37 and 13.1 kg a.s./ha**	**<50% effects on reproduction at 0 DAA of 6.37 kg a.s./ha <50% effects on reproduction at 7 DAA of 13.1 kg a.s./ha**	***Luna, F (2013) KIIIA 10.5.2/04***

New studies provided with this application are indicated in bold.

Exposure

<u>In-field</u>

Non-target arthropods living in the crop can be exposed to residues from Kumar by direct contact either as a result of overspray or through contact with residues on plants and soil or in food items. Kumar is applied at a maximum rate of 6 x 4.25 kg as/ha. The maximum in-field exposure (Predicted Environmental Rate, PER) to foliar-dwelling or soil-dwelling organisms is therefore 13.600 kg as/ha, assuming the worst-case (contradiction) of 100% crop interception and 0% crop interception, respectively.

The in-field exposure (predicted environmental residue, PER) is calculated according to ESCORT 2 using the following equation:

$$PER_{in-field} = \text{Application rate (g ai/ha)} \times \text{MAF}$$

The MAF is a generic multiple application factor, which is used to take into account the potential build-up of applied substances between applications based on the application interval, DT_{50} value and number of applications. Default foliar and soil MAF values following six applications are given in the ESCORT 2 Guidance Document. Kumar is applied six times per season and the foliar multiple application factor MAF is therefore 3.2 and for soil is 4.6. The applicant calculated the risks to *T.pyri* and *A.rhopalosiphi* from both foliar and soil exposure. However, the soil route is considered not relevant, since only foliar dwelling species are concerned (see also the note under the MAF table in ESCORT 2). Therefore, the soil exposure route has been removed.

The maximum predicted environmental residues (PER) occurring within the field after application of Kumar at the maximum application rate are presented in Table 10.5-2.

Table 10.5-2 In-field PER values for application of Kumar

Substance	Application rate	PER (foliar)
Potassium hydrogen carbonate	6 x 4250 g/ha	13600 g/ha

<u>Off-field</u>

Risk assessment of areas immediately surrounding the crop is considered important since these areas represent a natural reservoir for immigration, emigration and reproduction of arthropod populations and provide increased species diversity. Exposure of non-target arthropods living in off-field areas to Kumar will mainly be due to spray drift from field applications. Again, evaluation of exposure *via* soil residues in off-field areas was not considered. Off-field foliar PER values were calculated from in-field foliar PERs in conjunction with drift values according to Rautmann, 2001[5] as shown in the following equation:

$$\text{Off-field foliar PER} = \frac{\text{Maximum in-field foliar PER x (\% drift/100)}}{\text{vegetation distribution factor}}$$

<u>Vegetation distribution factor</u>: The model used to estimate spray drift was developed for drift onto a two-dimensional water surface and, as such, does not account for interception and dilution by three-dimensional vegetation in off-crop areas. Therefore, a vegetation distribution or dilution factor is incorporated into the equation when calculating PERs to be used in conjunction with toxicity endpoints derived from two-

[5] Rautmann, D.; Streloke, M.; Winkler, R.: "New basic drift values in the authorization procedure for plant protection products" Mitteilungen aus der Biologischen Bundesanstalt für Land- und Forstwirtschaft 383, 133-141 (2001).

dimensional (glass plate or leaf disc) studies. A dilution factor of 10 is recommended by ESCORT 2. For 3-dimensional studies, i.e. where spray treatment is applied onto whole plants, the dilution factor of 10 is not used, as any dilution over the 3-dimensional vegetation surface is accounted for in the study design.

The drift value at 3 m distance is 8.02% of the application rate (90th percentile drift, grapevine, late application). The drift factor (% drift/100) is therefore 8.02/100 = 0.0802.

The resulting PERoff-field values are shown in Table 10.5-3.

Table 10.5-3 Off-field foliar Predicted Environmental Rates (PER) (grapes, 6 applications)

Study type	Maximum in-field foliar PER [a] (g as/ha)	drift factor (% drift/100)	Vegetation distribution factor	Off-field foliar PER (g as/ha)
A. rhopalosiphi whole plant 3D	13600	0.0802	Not applicable	1090.72
T. pyri leaf disc 2D	13600	0.0802	10	109.072
O. laevigatus leaves 2D	13600	0.0802	10	109.072

[a] See Table 10.5-2

Risk assessment - Hazard quotients

The risk to non-target arthropods is assessed using the approach recommended in the published *ESCORT 2 document (Candolfi et al. 2001)*[6] and the *EC Guidance Document on Terrestrial Ecotoxicology* [7].

In-field

The potential risk of Kumar to in-field non-target arthropods was assessed by calculation of the hazard quotient (HQ = exposure/toxicity) with the predicted environmental rate (PER) and the lowest lethal rate (LR_{50}) values according to the following formula:

$$\text{In field HQ} = \frac{\text{In - field PER}}{LR_{50}}$$

The HQ trigger for Tier I laboratory and Tier II extended laboratory studies is 2 and 1, respectively. The resulting $HQ_{in\text{-}field}$ values are presented, quoted to 2 significant figures, in Table 10.5-4.

[6] Candolfi MP, Barrett KL, Campbell PJ, Forster R, Grandy N, Huet M-C, Lewis G, Oomen PA, Schmuck R, Vogt H (2000) 'Guidance Document on regulatory testing procedures for plant protection products with non-target arthropods' From the workshop, European Standard Characteristics of Non-target Arthropod Regulatory Testing (ESCORT 2) 21-23 March 2000.

[7] EC Guidance Document on Terrestrial Ecotoxicology Under Council Directive 91/414/EEC, SANCO/10329, 17 October 2002.

Table 10.5-4 In-field HQs for non-target arthropods assuming 6 applications

Species	L/ER_{50} (g as/ha)	In-field foliar		Trigger value
		PER (g as/ha)	HQ	
Typhlodromus pyri Tier II, 2D exposure scenario	LR50 : 5519 ER50 : 2688	13600	**2.46** **5.06**	1
Aphidius rhopalosiphi Tier II,3D exposure scenario	>7438		>1.83	1
Orius laevigatus Tier II, 2D exposure scenario	8700		**1.56**	1

The in-field HQ values indicate that Kumar poses a theoretical risk to in-field non-target athropods following application according to the proposed use patterns. However given the multiplication of very conservative factors, no refinement is considered necessary and the risk is considered acceptable. In particular it should be noted that:

Realistic exposure will be less than estimated as availability of the potassium and bicarbonate ions will be reduced by buffering and binding in the foliar and soil environments.

- in practice, less than 6 applications will be applied in the field programme as farmers will alternate the product
- in practice, Kumar may be applied with a reduced dose (less applications)
- Worst case residues for foliar organisms assumed
- toxicity endpoints represent a very worst case under laboratory conditions: in the field, Kumar will be washed off between applications by wind and rain because of the nature of the product and the active substance

Assuming that significant buffering and binding of the ions will occur in the natural environment, it is considered relevant to consider the risk from a single application as shown below:

Table 10.5-5 In-field HQs for non-target arthropods from a single application

Species	L/ER50 (g as/ha)	In-field foliar		Trigger value
		PER (g as/ha)	HQ	
Typhlodromus pyri Tier II, 2D exposure scenario	LR50 : 5519 ER50 : 2688	4250	0.77 **1.58**	1
Aphidius rhopalosiphi Tier II,3D exposure scenario	>7438		<0.57	1
Orius laevigatus Tier II, 2D exposure scenario	8700		0.49	1

The above illustration clearly shows that there should be no unacceptable risk to non-target arthropods in either the foliar or soil environment following a single application. Since buffering and binding of ions will occur rapidly especially in the case of soil inbetween applications this illustration is considered to represent a more realistic assessment of the in-field risk to non-target arthropods.

Based on the study with *T.pyri*, in-field effects on reproduction cannot be excluded, even when only one application is considered. However, since no effects on mortality are expected and the off-field risk is acceptable (see below), it is considered that the in-field population will be able to recover within a relevant period by recolonisation from out of the off-field area.

This conclusion is further supported by new data provided since the last core assessment in the central zone as explained hereafter for the use of Kumar in grapes (6 x 4250 kg /ha, PER = 13.6 kg a.s./ha (in-field)):

An aged residue study has been performed using the most sensitive species tested, *T. pyri*. The results of the aged residue study indicate that there is potential for recolonisation from off-field populations into affected treated areas in-field. Apple trees were treated with Kumar at one of two rates (6.37 or 13.1 kg a.s./ha) and residues allowed to age for up to 28 days under realistic outdoor conditions. Protonymphs of *T. pyri* were then exposed to these aged residues in the laboratory. Less than 50% effects on mortality were observed following exposure to freshly dried residues i.e. 0 DAA. Less than 50% effects on reproduction were observed at 0 DAA for 6.37 kg a.s./ha, and at 7 DAA for 13.1 kg a.s./ha. The predicted exposure rates (PERs) for the proposed use of Kumar on grapes are 13.6 kg a.s./ha (in-field) and 0.218 kg a.s./ha (off-field). The PERs are within the rates tested in the aged residue study. The effects (lethal and sublethal) on *T. pyri* were less than 50% after residues had been aged for 0-7 days. Therefore, it is expected that *T. pyri* would successfully recolonize a treated area in much less than a year, which is the criteria under ESCORT II. As such, the risks from in-field exposure of *T. pyri* are considered to be acceptable.

Therefore it is concluded that populations of arthropods would be able to recover within the one year time-frame stated in ESCORT 2.

Off-field

In order to assess the potential risk of Kumar to off-field non-target arthropods, the predicted environmental rate (Table 10.5-3) is compared with the toxicity endpoints according to the following formula:

$$\text{Off-field HQ} = \frac{PER_{off-field}\ (g/ha)}{LR_{50}\ (g/ha)} \times \text{Correction factor}$$

The HQ trigger for Tier I laboratory and Tier II extended laboratory studies is 2 and 1, respectively.

Correction factor: ESCORT 2 recommends that a correction factor of 5 be used when assessing Tier II data, or 10 for Tier I data, to account for extrapolation from testing just 2 representative species, to the species diversity expected in off-crop areas.

$HQ_{off-field}$ values are given, quoted to 2 significant figures, in Table 10.5-6.

Table 10.5-6 Off-field HQ values for non-target arthropods assuming 6 applications

Species	L/ER_{50} (g as/ha)	Off-field foliar PER (g as/ha)	Correction factor	Off-field foliar HQ	Trigger value
Typhlodromus pyri Tier II, 2D exposure scenario	LR50 : 5519 ER50 : 2688	109.072	5	mortality : 0.10 reproduction : 0.20	1
Aphidius rhopalosiphi Tier II, 3D exposure scenario	>7493	1090.72	5	**<0.73**	1
Orius laevigatus Tier II, 2D exposure scenario	8700	109.072	5	0.06	1

The off-field HQ values for indicator species fall below the trigger values, indicating that Kumar does not pose an unacceptable risk to non-target arthropods in off-field areas.

Please note: Given the new data (aged residue study) provided on the most sensitive species, it is concluded by the zRMS that populations of arthropods would be able to recover within the one year time-frame stated in ESCORT 2 (please refer to the in-field HQ paragraph above).

zRMS conclusions: Extended laboratory studies are available for the two standard species *Aphidius rhopalosiphi* and *Typhlodromus pyri* with the formulation ARMICARB 85 SP (syn. Kumar). An extended laboratory study using an additional species, *Orius laevigatus*, is also available with the formulation ARMICARB 85 SP. As recommended in the ESCORT 2 guidance document, the risk for non-target arthropods other than bees at Tier-1 is assessed by calculating Hazard Quotients (HQ).

For the standard species, the in-field HQ values indicate that ARMICARB 85 SP poses a theoretical risk to in-field non-target athropods following application according to the proposed use patterns.
However, for *Aphidius rhopalosiphi*, since only 10.71 % of mortality and 11.57 % of reduction of reproduction were observed at 7438 g as/ha, and by considering the natural occurring of potassium and bicarbonate in the environment, the in-field HQ value of < 2 is considered sufficiently protective.
Moreover, based on an aged residue study with *T. pyri*, it is concluded that populations of arthropods would be able to recover within the one year time-frame stated in ESCORT 2.

The off-field HQ values for the indicator species *T. pyri* and *A. rhopalosiphi* and the additional species *O. laevigatus* are within the trigger value of 1 indicating no unacceptable risk to off-field populations of non-target arthropods.

The available data are sufficient to conclude to an acceptable risk in-field with recovery and off-field at 3 meters. Then no mitigation measures are required. This conclusion (no mitigation measure) is also reliable for uses previously assessed. Indeed, considering the results from the additional studies provided in this dossier, the prescription of appropriate warning sentences by Member States indicated in the conclusions of the previous Registration Report is not considered anymore required.

6.6 Effects on Earthworms, other Non-target Soil Organisms and Organic Matter Breakdown

6.6.1 Overview and summary

No studies with Potassium hydrogen carbonate on earthworms were conducted for the following reasons:

- Potassium and bicarbonate are very common natural materials that are present in soils
- The amount of potassium or bicarbonate added to the soil following the application of Potassium hydrogen carbonate will be negligible compared with the amounts of potassium or bicarbonate already present
- Any potassium added to the soil will enter the mineral cycle driven by the equilibrium between soluble, extractable and bound potassium
- Potassium bicarbonate demonstrates a low level of activity against animals that have been tested
- As a consequence, adverse effects on earthworms from application of potassium bicarbonate are extremely unlikely

Therefore, a risk assessment considering the toxicity of Kumar to earthworms and other soil non-target macroorganisms is not considered necessary.

6.6.1.1 Toxicity

Please refer to 6.7.1.

6.6.1.2 Exposure

Please refer to 6.7.1.

6.6.1.3 Risk assessment –TER vaulues and overall conclusions

Please refer to 6.7.1.

6.6.2 Toxicity to Exposure Ratio

6.6.2.1 Acute risk

Please refer to 6.7.1.

6.6.2.2 Chronic risk

Please refer to 6.7.1.

6.6.3 Residue content of earthworms

Please refer to 6.7.1.

6.7 Effects on Soil Microbial Activity

6.7.1 Overview and summary

No studies with Potassium hydrogen carbonate on soil microbial activity have been conducted for the following reasons:

- Potassium and bicarbonate are very common natural materials that are present in soils
- The amount of potassium or bicarbonate added to the soil following the application of Potassium hydrogen carbonate will be negligible compared with the amounts of potassium or bicarbonate already present
- Any potassium added to the soil will enter the mineral cycle driven by the equilibrium between soluble, extractable and bound potassium
- Potassium is an essential nutrient for soil micro-organisms
- Potassium bicarbonate is effective against some foliar fungal pathogens through both pH and osmotic effects. Such modes of action will not be relevant in the soil due to the enormous buffering impact on pH and massive dilution factors.

As a consequence, adverse effects on soil microorganisms from the application of Kumar are extremely unlikely and thus, no further risk assessment is considered necessary.

6.7.1.1 Toxicity

Please refer to 6.8.1.

6.7.1.2 Exposure

Please refer to 6.8.1.

6.7.1.3 Risk assessment –overall conclusions

Please refer to 6.8.1.

6.8 Effects on Non-Target Plants

6.8.1 Overview and summary

No studies with Potassium hydrogen carbonate on terrestrial vascular plants were conducted for the following reasons:

- Potassium and bicarbonate are very common natural materials that are present in soils

- The amount of potassium or bicarbonate added to the soil following the application of Potassium hydrogen carbonate will be negligible compared with the amounts of potassium or bicarbonate already present
- Any potassium added to the soil will enter the mineral cycle driven by the equilibrium between soluble, extractable and bound potassium
- Potassium is an essential nutrient for plants and is often present in plant tissues at very high levels
- Potassium bicarbonate has been applied as a fungicide on a wide range of crops (vascular plants) for many years without any major incidents of selectivity

As a consequence, adverse effects on terrestrial vascular plants from the application of Kumar are extremely unlikely and thus, no further risk assessment is considered necessary.

6.8.1.1 Exposure

Please refer to 6.9.1.

6.8.1.2 Risk assessment –TER values and overall conclusions

Please refer to 6.8.1.

6.9 Other Non-Target Species (Flora and Fauna)

Tests on other non-target species are not required.

6.9.1 Overview and summary

6.9.1.1 Toxicity

6.9.1.2 Exposure

6.9.1.3 Risk assessment –overall conclusions

6.9.2 Toxicity to Exposure Ratio

6.10 Other/Special Studies

6.10.1 Laboratory studies

6.10.2 Field studies

6.11 Summary and Evaluation

6.11.1 Predicted distribution and fate in the environment and time courses involved

Please refer to Section 5 of this submission.

6.11.2 Non-target species at risk and extent of potential exposure

Potassium and bicarbonate are widely occurring natural inorganic ions present in soils, sediments, water bodies and alive orgnasims. Bicarbonate will either remain intact or transform into alkali earth metal carbonates, water and carbon dioxide, depending upon the soil type and acidity. Typical levels found in natural surface waters adjacent to agricultural land are between 100-500 mg/L. Potassium is an essential macronutrient for plants and micro-organisms and has a well known cycle via the food chain. It is very abundant in soil, although most is not bioavailable. <0.1% is considered to be in solution, 0.1-2.0% exchangeable, 1-10% fixed and 90-98% mineral. Plants and microorganisms can only readily access the soluble and exchangeable portions, although some of the fixed can be released if soil water concentrations become depleted.

Tests have shown potassium bicarbonate has very low toxicity to fish (LC_{50} 1400-1500 mg/L) and *Daphnia* (LC_{50} = 1200 mg/L). Armicarb 85 SP (syn. Kumar) has low toxicity to algae (ER_{50}>85.75 mg as/L), bees (LD_{50} >100 µg as/bee) and parasitoid wasp (LR_{50}> 7438 g as/ha). The LR_{50} on predatory mite is estimated at 5519 g as/ha, and on the predatory bug at 8702 g as/ha, using Kumar. An aged residue study has shown that the predatory mite would be able to recover 7 days after an application at the rate of 15 kg product/ha and that no unacceptable effects would occur for an exposure at a rate of 7.305 kg product/ha. Although no acute data are available for birds, there is ample evidence that potassium bicarbonate is non-toxic to birds. For example, sodium bicarbonate (and to a lesser extent potassium bicarbonate) is frequently used as feed and drink additive for poultry. It is added at concentrations up to 1% (10,000 ppm) without causing any adverse effects. As potassium and bicarbonate ions are naturally present in the environment and in most living organisms at concentrations much higher than they could be through the use of Kumar a waiver was accepted during EU review as regards conducting additional toxicity studies on birds, aquatic plants, earthworms, micro-organisms and beneficial organisms. No adverse effects on the non target organisms within the ecosystems exposed to Kumar at recommended use rates is considered likely and the environmental loading will not significantly alter natural balances.

Appendix 1 List of data submitted in support of the evaluation

Table A 1: List of data submitted in support of the evaluation

Annex point/reference No	**Author(s)**	**Year**	**Title Source (where different from company) Report-No. GLP or GEP status (where relevant), Published or not Authority registration No**	**Data protection claimed**	**Owner**	**How considered in dRR Study-Status/ Use***
OECD: KIIA <annex point>	<author>	<year>	<title> <report number> <Authority registration No>	Y/N		
OECD: KIIA	<author>	<year>	<title> <report number> <Authority registration No>			

*

1) accepted (study valid and considered for evaluation)

2) not accepted (study not valid and not considered for evaluation)

3) not considered (study not relevant for evaluation)

4) not submitted but necessary (study not submitted by applicant but necessary for evaluation)

5) supplemental (additional information, alone not sufficient to fulfill a data requirement, considered for evaluation)

Appendix 2 Detailed evaluation of studies relied upon

Report:	KIIIA1 10.2.2/01, E. Ythier, 2010
Title:	A laboratory limit test to study the side effects of ARMICARB (85% potassium bicarbonate) on the growth of the freshwater green alga *Pseudokirchneriella subcapitata* (Chlorophyceae).
Document No:	163SRFR10C2
Guidelines:	OECD 201 (March, 2006)
GLP	Yes

Study already submitted, evaluated, and accepted for the first authorisation of Armicarb 85 SP (syn. Kumar) on apple under Regulation 1107/2009

Report:	KIIIA1 10.5.2/02, D. Juan, 2010
Title:	Effects of the test item ARMICARB on the Predatory mite *Typhlodromus pyri*, Extended laboratory study.
Document No:	EPA-BHT-01-10
Guidelines:	Laboratory residual contact test with the predatory mite *Typhlodromus pyri* Scheuten (Acari: Phytoseidae) for regulatory testing of plant protection products. (Blümel et al., 2000) Modified and adapted for extended laboratory purposes.
GLP	Yes

Study already submitted, evaluated, and accepted for the first authorisation of Armicarb 85 SP (syn. Kumar) on apple under Regulation 1107/2009.

Report:	KIIIA1 10.5.2/03, Martinez, F.L. (2013)
Title:	An extended laboratory test to determine the LR_{50} of the formulated product "Armicarb 85 SP" (Potassium bicarbonate 85% w/w, SP) on the predatory bug *Orius laevigatus* (Fieber) (Heteroptera: Anthocoridae)
Document No:	TRC13-061BA
Guidelines:	Bakker *et al.* (2000) A laboratory test for evaluating the effects of plant protection products on the predatory bug, *Orius laevigatus* (Fieber) (Heteroptera: Anthocoridae). In: Candolfi *et al*. editors, 2000 ("Guidelines to evaluate side-effects of plant protection products to non-target arthropods").IOBC/wprs 2000: 57-70 pp. Kemmeter *et al*. (2000) Different extended laboratory methods to determine effects of plant protection products on beneficial arthropods. IOBC/wprs Bulletin Vol. 22 (9) 2000: pp.103-109. Integrated Control in Viticulture
GLP	Yes

Materials and methods:

The aim of the study was to determine the effects of fresh residues of the formulation "Armicarb 85 SP" (Potassium hydrogen carbonate 850 g/kg), applied to apple leaves, in two phases (mortality and fecundity), on the non-target arthropod *Orius laevigatus* (Fieber) (Heteroptera: Anthocoridae) under extended laboratory conditions.

A reference treatment (Dimethoate 400 g/L EC at 0.125 L FP/ha) was included to indicate the relative susceptibility of the test specimens and the test system and a water control was included in the test design to assess the natural mortality rates of the test specimens.

Armicarb 85 SP (batch B3220199) is a fungicide nominally containing 850 g potassium hydrogen carbonate/kg (analysed content: 87.22%).

The test comprised seven treatments: a water control, five rates of Armicarb 85 SP and a reference substance. Applications were made to freshly cut apple leaves (*Malus domestica*) placed in Petri dishes. Fifty leaf fragments per treatment were sprayed at an application volume of 200 L/ha with a laboratory track sprayer equipped with a Hardi ISO F-110 orange flat fan nozzle. The sprayer was calibrated prior to application and blank petri dishes were included with each treatment application to ensure the target application rate was achieved (<10% deviation measured).

Armicarb 85 SP was diluted in water and the test substance rates were 1.875, 3.75, 7.50, 15.00 and 20.00 kg /ha of formulated product (FP) (corresponding to 1.6354, 3.2708, 6.5415, 13.0830 and 17.4440 g potassium hydrogen carbonate/ha, respectively (based on actual purity)). A water control was used and dimethoate of nominal content of 400.0 g/L was applied 0.125L FP/ha (51.75 g dimethoate/ha).

Once leaves were dry (<2 hrs old), the test units were assembled and *O. laevigatus* nymphs (2nd nymph stage, 4 days old) were added to the treated leaves, with one nymph per exposure chamber. Nymphs originated from a synchronised batch of eggs from an in-house culture. Nymphs were continuously exposed until they reached the adult stage.

Mortality was assessed at days 1, 2, 5, 7, and 8. Repellency observations were made from test start. Afterwards, the surviving females were transferred to fecundity units to assess fecundity of females from all treatments in which corrected mortality was ≤ 50%.

For the fecundity assessment, groups of 3 females and 2 males were chosen at random from replicates of the same treatment, and were confined in breeding units. Instead of the apple leaf, a fragment of bean pod was used as the substrate for egg laying and was replaced every 2-3 days. *Orius* were fed *ad libitum* three times a week with deep frozen eggs of *Ephestia kuehniella*. The bean pods were placed in another plastic cup with a fine mesh as a lid until the egg-hatch was assessed. The fecundity period finished 10 days after the adult groups were confined and 4-6 days later, the nymphs which had hatched from the eggs were counted.

Table 10.5.2-1 Test conditions

Test	Duration	Temperature ºC (Min. – Max.)	Relative Humidity % (Min. – Max.)	Light intensity (Lux) Photoperiod 16:8 hours L:D
Mortality	8 days	23.7 – 26.8	56.7 – 91.2	1690 - 1900
Fecundity	10 days	23.6 – 26.8	55.9 – 94.2	
Fertility	4-6 days	23.7 – 26.7	55.9 – 93.0	

<u>Amendments to the study plan</u>

The mortality period was 8 days after the application instead of 10 days since all survivors had reached the adult stage by this time.

The larval hatching of the bean pods (evaluation of emerged nymphs) was assessed 4-6 days after the egg laying instead 4-5 days as the study plan indicates.

Validity criteria

The mortality and fecundity phases of this study are valid, because the following criteria were met.

The validity criteria for the water treated control were as follows:

- Maximum acceptable cumulative mortality (dead and stuck nymphs): ≤ 25% (16.0%).
- Fecundity (mean number of eggs per female per day): ≥2 (6.6)
- Fertility (mean hatching rate): ≥70% (96.0%).

Mortality in the reference substance treatment was higher than 50% (100%).

Findings

Results obtained following exposure to Armicarb 85 SP are summarised in the table below.

Table 10.5.2-2 Mortality results. Dead and stuck individuals.

Treatment	Treatment	Lost nymphs by technical loss or escape(1)	Number of dead nymphs	Number of stuck nymphs	Response (dead + stuck)	% Dead nymphs	% stuck nymps	Total % mortality(2)	% corrected mortality(3)
C	Water	0	2	6	8	4.0	12.0	16.0	/
T1	"ARMICARB 85 SP", 1.875 kg/ha	1	3	9	12	6.1	18.4	24.5	10.11
T2	"ARMICARB 85 SP", 3.75 kg/ha	1	2	16	18*	4.1	32.7	36.7	24.68
T3	"ARMICARB 85 SP", 7.5 kg/ha	1	3	21	24*	6.1	42.9	49.0	39.26
T4	"ARMICARB 85 SP", 15 kg/ha	0	5	34	39*	10.0	68.0	78.0	73.81
T5	"ARMICARB 85 SP", 20 kg/ha	0	8	37	45*	16.0	74.0	90.0	88.10
R	"Dimethoate 40% EC", 0.125 L PF/ha	0	50	0	50	100.0	0.0	100.0	100

(1) Initial nymphs per treatment = 50
(2) Total *O. laevigatus* mortality (%) up to the completion of adult emergence (pre-imaginal mortality).
(3) Corrected mortality (%) according Abbot's formula: Corrected M(%)=[(Mt-Mc]/(100-Mc)] x 100 ; t=treated, c=control
(*): Significantly different compared to control (Fisher's Exact Test, 1-sided)

Juvenile mortality in the control group was <25% and mortality in the reference treatment was 100%.

Effects on mortality of >50% were observed at ≥15 kg product/ha (13.0830 g a.s./ha).

Table 10.5.2-3 LR_{50}-value of the test product (FP= formulated product). Toxicity test.

	LR_{50} - Pre-imaginal
Test product	LR_{50} = 9.978 kg F.P./ha
Active substance	8702.81g Potassium hydrogen carbonate /ha

LR_{50} values in kg of formulated product /ha and the equivalent active substance.

Corrected mortality in the reference item was 100 % and statistically significantly different from the control.

The main observed effect was the immediate repellent effect on the nymphs, resulting in many sticking to the glue barrier in the first day of exposure.

Table 10.5.2-4 Reproduction results. Fecundity and fertility.

Treatment	Treatment	Fecundity[1]	% Reduction on fecundity	Fertility[2]	% Reduction on fertility
C	Water	6.6	-	96.0	-
T1	"ARMICARB 85 SP", 1.875 kg/ha	6.3	4.5	92.7	3.4
T2	"ARMICARB 85 SP", 3.75 kg/ha	5.5	16.7	85.5	10.9
T3	"ARMICARB 85 SP", 7.5 kg/ha	6.7	-1.5	93.4	2.6
T4	"ARMICARB 85 SP", 15 kg/ha	4.9	25.8	93.8	2.3
T5	"ARMICARB 85 SP", 20 kg/ha	4.8	27.3	89.5	6.8

(1) Mean of eggs per female per day.
(2) Mean of hatched eggs (nymphs from eggs)

There was no effect on fecundity during the study, with the mean number of eggs per female per day being above the guideline criterion of 2, and the reduction in fecundity in comparison to the control was always <50%.

Fertility was always above 70% with all assayed rates of Armicarb 85 SP and control treatments. Reduction in fertility compared to the control was always <50%.

Conclusion:

The maximum application rate at which <50% effects on mortality occurred was 7.5 kg Armicarb 85 SP/ha, equivalent to 6.5415 g potassium hydrogen carbonate/ha. The maximum application rate at which <50% effects on reproduction occurred was 20 kg Armicarb 85 SP/ha, equivalent to 17.4440 g potassium hydrogen carbonate/ha.

The LR_{50} for Armicarb 85 SP was 9.978 kg product/ha (8702.81 g a.s./ha). The ER_{50} was >20 kg product/ha (>17.4 kg a.s./ha).

Comments: IIIA 10.5.2/03	This study is valid (mortality in th control: 16%; mean number of eggs per female per day: 6.6 ; mean hatching rate: 96%).

	The results for tested rates of 15 and 20 kg PP/ha are not considered reliable and are not included for the determination of the sublethal endpoint as there were more than 50% of mortality at these rates.
Agreed endpoint/s: IIIA 10.5.2/03	LR50 = 9.978 kg product/ha (8702.81 g a.s./ha). ER50 > 7.5 kg product/ha (>6.54 kg a.s./ha ; 2.6% of effect are observed).

Report:	KIIIA1 10.5.2/04, F. Luna, 2013
Title:	Aged residue test with the formulation "Armicarb 85 SP (Potassium bicarbonate 85% w/w, SP)" on the predatory mite *Typhlodromus pyri* (Acari: Phytoseiidae)
Document No:	TRC13-060BA
Guidelines:	The study plan was based upon a modified version of the standard test methods described by Blümel *el al.* (2000) and SOP 9.1.2. The *T. pyri* extended laboratory test is not a standardized method; however it is widely used as a second tier regulatory test according to a method adapted from Oomen (1998) and described in Blümel *et al.* (2000). Some modifications, in order to perform the test in extended laboratory conditions, are described in Grim *et al.* (2001). The influence of leaf substrates has been studied by Pia Ternes *et al* (2001). The test method has been based in all the aforementioned publications and it is recorded in the SOP 9.1.2 of TrialCamp.
GLP	Yes

Materials and methods

The aim of the study is to evaluate the effects of the formulation "Armicarb 85 SP" (Potassium hydrogen carbonate 850 g/kg; batch number B3220199; analysed content: 87.22%) on the survival and reproduction of *Typhlodromus pyri* Scheuten (Acari: Phytoseiidae), exposing the test organisms to treated leaves after different periods of ageing of the residues under semi-field conditions (Valencia, Spain). The effects (mortality and fecundity) were evaluated under extended laboratory test conditions.

The natural substrate was obtained from an apple crop treated with the different rates of test substance. The target was one of the standard sensitive species: the predatory mite *Typhlodromus pyri* Scheuten (Acari: Phytoseiidae). The experimental phase started on July 1, 2013 and finished on August 12, 2013.

The endpoints were the following:

(1) To study the mortality at 7 days after exposure (lethal effect) to residues on leaves aged for the following periods: 0, 7, 21 and 28 days after application (DAA).

(2) To study the fecundity of the survivor females during 7 days following exposure to residues on leaves for the aforementioned ageing periods.

Predatory mites were obtained from Katz Biotech Ag. Individuals from one protonymph cohort were used, no later than 24 hours old from moulting. Mites were fed with tree pollen from the same commercial supplier.

The test substance was sprayed at 2 different rates according to the Guidance Document ESCORT II (Candolfi *et al.* 2000) and the summary of Good Agricultural Practice for this product. The application rates were 7.305 and 15.0 kg product /ha (equivalent to 6371.42 and 13083.0 g a.s./ha respectively).

Apple trees (*Malus domestica*) of the variety Golden Delicious were used for trial purposes in semi-field conditions (tunnel with a waterproof cover). Four plots with eight plants in espalier per plot were selected: One plot for negative control (water control), one plot for the positive control (toxic reference =

Deltamethrin 1.5% EW; batch number EQ06001361 0093) and one plot for each concentration. Plot size was 8 m^2 (4 m x 2 m). Buffer zones of 2 m were used, in addition to plastic fronts between plots at the moment of application to minimise cross contamination between plots. Plots were arranged in one crop row. In order to select leaves with the same age for the different exposures, the youngest leaves (1-2 cm size) were marked.

All doses of the test product were applied once in the field using a motorized Maruyama backpack sprayer at 15 bars of pressure equipped with a handheld with one hollow cone nozzle (Albuz ATR Hollow Cone Nozzle Red) simulating a commercial application in field (volume 1000 L/ha). The equipment was calibrated immediately before the application. The sprayer was cleaned with water between treatments. Treatments were applied in the following order: water control, test substance (low rate), test substance (high rate), toxic reference. Deviation in volume and test product application was less than 10%. Therefore, nominal application rates are referred to in the results.

After application, plants were maintained in semi-field conditions (detailed above) to allow “natural” weathering of the test substance residues. At each ageing residue period, at least 8 leaves per plot were sampled at random and transported to the laboratory to prepare the test arenas. Within each test arena (plastic Petri dish) was a leaf fragment (leaf cut to size: 1-1.5 x 4-5 cm), a water source and pollen as food (replaced every 2-3 days). Twenty protonymphs were placed in each arena, with five replicates per treatment. The test units were placed into an environmental chamber at 25 ± 2 ºC, 60-90% RH, with a 16:8h L:D photoperiod. All rates were studied at 0, 7, 21 and 28 days after application in order to study the effects on mortality and fecundity.

Mortality assessments were carried out after 1 and 7 days of each exposure. Data were obtained according to a quantal response. A quantal response is defined as y = k/n, where k is the number of responding organisms out of a total of n. Thus, per each replicate, the combined numbers of escaped and dead individuals was counted under a binocular microscope as number of responding individuals out of a total of 20 individuals. The glued individuals were assessed to observe the repellence effect. The cumulative number of responding individuals (juvenile mortality) within 7 days has been used. All mortality tests were considered valid as validity criteria were met; mortality in control treatments was below 20% and above 50% in reference treatments.

To assess any effect on the relative fecundity of the surviving mites, treatments with corrected mortality below 50% were continued until 14 days after the exposure. The number of male and female mites in each replicate was recorded 7 days after each exposure. The sex-ratio was above 5♀ and 1♂ (values less than 0.83) for several replicates at the exposure 7 DAA, so it was not necessary to adjust on day 7 by transferring males originating from another replicate from the same treatment to achieve an appropriate sex ratio. Reproduction per female was recorded 3 times from day 7 to day 14 with a maximum interval of 3 days. The number of eggs per female was determined by counting the number of females, eggs and larvae/nymphs on assessments days from day 7 on. Eggs laid up until day 7 inclusive were removed from the test arenas and were not counted. The number of eggs per female during the reproduction period until day 14 (inclusive) was summed up. The calculation was done per replicate. The result is the mean cumulative number of eggs per female. The tests were acceptable according to the validity criterion for fecundity; more than 4 eggs per female in the control treatments was achieved.

One replicate in the treatment “control” (C1) was not taken into account either in mortality or fertility in the exposure at 0DAA because a technical loss by scattered glue over the leaf surface. So, this treatment was studied with 4 replicates instead of 5.

For mortality data, the parametric Dunnett’s Test (α=0.05) was performed with results at the exposures 0, 21 and 28 DAA since normality and homogeneity of variance were obtained. The non-parametric Jonckheere-Terpstra test was performed for results at the exposure 7DAA, since normality was not achieved. For fecundity data, Dunnett's Test was performed for results at all exposures, since normality and homogeneity of variance were obtained. All the statistical analysis were performed using the software IBM© SPSS Statistics 19.0.

Results

The **mortalities** for the different assayed treatments after 7 days exposure are detailed in the table below:

Table 10.5.2-5 Mortality values (%)

Treatment	Rate (kg product/ha)	Rate (kg a.s./ha)	Bioassay(1)							
			0 DAA		7 DAA		21 DAA		28 DAA	
			%M	%Cm	%M	%Cm	%M	%Cm	%M	%Cm
Control (water)	-	-	5.0	-	3.0	-	5.0	-	5.0	-
Armicarb 85 SP	7.305	6.371	32.0(2)	28.4	9.0(3)	6.19	11.0(2)	6.32	5.0	0.0
	15.00	13.083	43.0(2)	40.0	15.0(3)	12.4	11.0(2)	6.32	9.0	4.21
Reference (Deltamethrin 1.5% EW)	0.830 (0.083%)	0.012	100	100	100	100	100	100	100	100

(1): DAA = days after application; %M = % mortality; %Cm = % corrected mortality

(2): Significant compared to the control (Dunnett t-test, > control, α = 0.05)

(3): Significant compared to the control (Jonckheere-Terpstra test, exact sig. (1 tailed))

None of the test item doses exceeded the mortality threshold of 50% from the day of application neither with the fresh and dry residue (0DAA), nor at 7, 21 and 28 DAA.

Significant acute lethal effects compared to control were observed with the assayed rates, 7.305 and 15.0 kg/ha of formulated product, for leaves aged up to 21 days after the application, although the mortality from leaves aged for 7 days after the application was still less than 20% (threshold for mortality for the control treatment as validity criterion).

No treatment related effects on repellency were observed in the study, based on the number of escaped individuals not being dose related. There was also no treatment related effect on the development of *T. pyri* in the test, with all individuals being at adult stage after 7 days of exposure.

The **fecundity** values (eggs per female and progeny reduction) are presented in the following table.

Table 10.5.2-6 Fecundity results – percentage of progeny reduction (%)

Treatment	Rate (kg product/ha)	Rate (kg a.s./ha)	Bioassay(1)							
			0 DAA		7 DAA		21 DAA		28 DAA	
			e/f	%R	e/f	%R	e/f	%R	e/f	%R
Control (water)	-	-	6.74	-	8.66	-	9.26	-	7.88	-
Armicarb 85 SP	7.305	6.371	4.23(2)	37.2	5.32(2)	38.6	7.90	14.7	6.90	12.4
	15.00	13.083	3.34(2)	50.4	4.42(2)	49.0	6.38(2)	31.1	6.60(2)	16.2

(1): DAA = days after application; e/f = eggs per female (mean); %R = % reduction

(2): Significant compared to the control (Dunnett t-test, > control, α = 0.05)

A significant reduction on reproduction compared to control above 50% was only observed with the In-field rate 15.0 kg of product/ha when the protonymphs were exposed with fresh and dry residues (0 DAA).

The percentage reduction on fecundity was below the ESCORT 2 trigger value of 50% from 7 DAA for the maximum rate of 15.0 kg product /ha, and from 0DAA (with fresh and dry residues) for the Off-field rate of 7.3050 kg product /ha. Effects on reproductive capacity following exposure of *T. pyri* to residues on leaves aged for 21 days or more were reduced.

Conclusions

None of the doses tested exceeded the mortality threshold of 50% (50% corrected mortality compared to the control) at the different exposure periods; 0, 7, 21 and 28 days after the application (DAA). Significant acute lethal effect compared to control was observed up to and including 21 DAA with both assayed rates, 15.00 and 7.305 kg/ha of formulated product, although the corrected mortality from the exposure at 7 DAA onwards was below 20% for both rates.

Reduction of reproduction compared to the control was below the ESCORT 2 trigger value of 50% for all assayed rates at the exposures 0, 7, 21 and 28 DAA, except for the highest tested rate 15.00 kg /ha of formulated product with the fresh and dry residue (0 DAA); with a percentage reduction of 50.44%.

Although significant sub-lethal effects on fecundity were found with the offspring up to and including 28 DAA at the In-field rate of 15.00 kg/ha of formulated product only 16.23% reduction in reproduction was seen at 28 DAA. Significant sub lethal effects on reproduction are only seen up to 7 DAA with the Off-field rate of 7.305 kg /ha of formulated product.

Comments: IIIA 10.5.2/04	This study is valid.
Agreed endpoint/s: IIIA 10.5.2/04	Mortality compared to the control was below the trigger value of 50% for all assayed rate at all the exposure. Reduction of reproduction compared to the control was below the trigger value of 50% for all assayed rates at all exposures. Except for the highest tested rate 15.00 kg /ha of formulated product with the fresh and dry residue (0 DAA); with a percentage reduction of 50.44%. Therefore, it is expected that *Typhlodromus pyri* would be able to recover 7 days after an application at the rate of 15.0 kg PP/ha and that no unacceptable effects would occur for an exposure at a rate of 7.305 kg PP/ha. .

A2-1 Active substance (generally only relevant in the case that new annex II data is provided after potassium hydrogen carbonate approval)

No new Annex II data has been provided by the applicant.

Appendix 3 Table of Intended Uses justification and GAP tables

PPP (product name/code)	**Kumar**	**Formulation type:**	**SP**
active substance	**Potassium bicarbonate**	**Conc. of as:**	**850 g/kg**
Applicant:	**Spiess Urania Chemicals GmbH**	**professional use**	☒
Zone(s):	**Central EU**	**non professional use**	☐

1	2	3	4	5	6	7	8	10	11	12	13	14
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**			**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	kg, L product / ha a) max. rate per appl. b) max. total rate per crop/season	g, kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
1	DE	Grape vine	F	*Botryotinia fuckeliana* BOTRYCI	spraying	BBCH 75 -89	a) 4 (8-30) b) 4 (8-30)	a) 5 kg/ha b) 20 kg/ha	a) 4.25 kg/ha b) 17 kg/ha	800 -1,600	1 day	1.25 kg product basis in 200-400 L water
2	DE	Grape vine	F	*Erysiphe necator* UNCINE	spraying	BBCH 57-85	a) 6 (7-10) b) 6 (7-10)	a) 5 kg/ha b) 30 kg/ha	a) 4.25 kg/ha b) 25.5 kg/ha	200-1,600	1 day	1.25 kg product basis in 200-400 L water BBCH 57: 1.25 kg/ha BBCH 61: 2.5 kg/ha BBCH 71: 3.75 kg/ha BBCH 75: 5 kg/ha

Remarks:
(a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds
(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(i) g/kg or g/l
(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) The minimum and maximum number of application possible under practical conditions of use must be provided
(l) PHI - minimum pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions

REGISTRATION REPORT
Part B

Section 6 Ecotoxicological Studies
Detailed summary of the risk assessment

Product name: **Kumar**

Active Substance: **potassium hydrogen carbonate 850 g/kg**

Central Zone
Zonal Rapporteur Member State: Germany

NATIONAL ADDENDUM – Germany

Applicant: Spiess-Urania Chemicals GmbH

Compiled by:

Company:	**DHD-Consulting GmbH**
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On behalf of:

Company:	**Spiess-Urania Chemicals GmbH**
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E-Mail:	braunwarth@spiess-urania.com

Date: **08.09.2017**

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Sec 6 ECOTOXICOLOGICAL STUDIES

No additional, National information available, see appendix 2 for justification. Refer to Core assessment document for further information.

6.1 Proposed use pattern and considered metabolites

Please refer to the core assessment.

6.1.1 Proposed use pattern

Please refer to the core assessment.

6.2 Effects on Birds

No additional, National information available, see appendix 2 for justification. Refer to Core assessment document for further information.

6.3 Effects on Terrestrial Vertebrates Other Than Birds

No additional, National information available, see appendix 2 for justification. Refer to Core assessment document for further information.

6.4 Effects on Aquatic Organisms

6.4.1 Overview and summary

No additional, National information available. Refer to Core assessment document for further information.

6.4.1.1 Toxicity

A summary of the toxicity exposure ratios for potassium hydrogen carbonate following the proposed use in grapes is shown below.

Table 6.4-1 Overview of Toxicity exposure ratios (TER) for aquatic species (most sensitive species of each group)

Test substance	Organism	Endpoint type	Toxicity endpoint (mg as /L)	PEC (mg/L)	TER	TER risk assessment trigger
$KHCO_3$	*Oncorhynchus mykiss*	acute	1400	0.6817	2054	100
$KHCO_3$	*Daphnia magna*	acute	1200	0.6817	1760	100
Armicarb 85 SP*	*Pseudokirchneriella subcapitata*	long-term	> 85.75 (yield and growth rate)	0.6817	>125.8	10

*syn. Kumar

6.4.1.2 Exposure

For authorization in Germany, exposure assessment of surface water generally considers the two routes of entry (i) spraydrift and volatilisation with subsequent deposition and (ii) run-off, drainage separately in order to allow risk mitigation measures separately for each entry route. However, since potassium hydrogen carbonate is not volatile and immediately dissociates to K^+ and HCO_3^- in the presence of water, only entry via spray drift is considered likely for Kumar and the intended use. Thus, the initial PEC_{sw} values calculated for entry via spray drift using drift values according to Rautmann, 2001[1] are considered sufficient also for risk assessment in Germany. The results of the calculations are summarized in the national addendum – section 5.

6.4.1.3 Overall conclusions

Overall it is concluded that no unacceptable risk to aquatic organisms is expected from the proposed use of Kumar SP.

6.4.2 Toxicity to Exposure ratio

6.4.2.1 TER values for the entry into surface water via spraydrift

The Kumar and potassium hydrogen carbonate risk assessments were carried out following according to the proposed use.

The initial risk assessments were carried out by comparing the PEC_{SW} values with the acute toxicity endpoints. Acute toxicity exposure ratios (TER_A) were calculated using the following equations:

$$TER_A = \frac{EC_{50} / LC_{50}}{PEC_{SW}}$$

Table 10.2-2: TER-values regarding the exposure via spraydrift scenario "grapevine (Model: EVA 3.0)

active substance	Potassimhydrogencarbonate							
use pattern/gap:	00-002 (worst-case)							
application rate/number of applications / interval	25500 g a.s./ha (= 6 × 4250 g as/ha) 7 d → 0 d (worst-case)							
$DissT_{50}$ (SFO) in water	No degradation between applications							
scenario/percentile:	vines / 90 %ile (assuming one single appliction of the total rate)							
distance (m)	PECsw via drift		PECsw via volatilisation		PECsw (via drift and volatilisation) (µg/L) depending on application technique (drift reduction)			
	(%)	(µg/L)	(%)	(µg/L)	common	50% red.	75% red.	90% red.
3	8.02	681.700	-/-	-/-	681.700	340.850	170.425	68.170
Relevant toxicity endpoint: EC50 > 85750 µg a.s./L (*Pseudokirchneriella subcapitata*) Relevant TER: 10								

[1] Rautmann, D; Streloke, M., Winkler, R. (2001): New basic drift values in the authorisation procedure for plant protection products. In Forster, R.; Streloke, M. Workshop on Risk Assessment and Risk Mitigation Measures in the Context of the Authorization of Plant Protection Products (WORMM). Mitt.Biol.Bundesanst.Land- Forstwirtsch. Berlin-Dahlem, Heft 381.

distance (m)	TER-value			
3	125.800	251.600	503.200	1257.900
Risk mitigation measures	**none**			

The TER value is above the trigger value of 10 for long term risks in algae, the most sensitive aquatic endpoint. However, a very conservative approach was used for the input values (PECsw based on a lumped application of 25500 g active substance/ha corresponding to the maximum number of recommended doses and the highest rate of application in a season). Overall it is concluded that no unacceptable risk to aquatic organisms is expected from the proposed use of Kumar.

6.5 Effects on Bees

In the honey bee risk assessment for the main application it was concluded that the risk to bees is acceptable when Kumar is used up to 7.5 kg/ha in bee attractive crops. Since the recommended application rate does not exceed this rate no further risk assessment is required.

6.5.1.1 Risk mitigation for non-target arthropods

Spray drift can be reduced by either the use of drift-reducing nozzles or by implementing a vegetated buffer strip between in-field crop and off-field areas. The following tables presents off-field PER and TER values for the use 00-002 (worst-case) with implemented drift reduction opportunities and 3 to 5 meters vegetated buffer strips.

Table 6.5-5: TER values for *T. pyri* exposed to KUMAR considering different risk mitigation measures

active substance	Potassimhydrogencarbonate							
use pattern/gap:	00-002 (worst-case)							
application rate/number of applications / interval	6 × 4250 g as/ha 8 d							
MAF:	3.2 (default value for six applications according to ESCORT II)							
Correction factor (2D/3D):	5 (exposure in the test system is based on a 2D exposure scenario)							
scenario/percentile:	vines / 90 %ile (assuming one single appliction of the total rate)							
distance (m)	PECact via drift		PECact via volatilisation		PECact (via drift and volatilisation) (g/ha) consid. of correction factor depending on application technique (drift reduction)			
	(%)	(g a.s./ha)	(%)	(g/ha)	common	50% red.	75% red.	90% red.
3	8.02	218.144	-/-	-/-	218.144	109.072	54.536	21.814
Relevant toxicity endpoint: ER50 ≈ 2688 g as/ha (approximation; lowest available toxicity endpoint) Relevant TER: 10								
distance (m)	TER-value							
3					12.300	24.600	49.300	123.200

Risk mitigation measures	**none**

For the intended uses 00-001 (17 kg a.s./ha max total rate per season) and 00-002 (25.5 kg a.s./ha max total rate per season), no risk mitigation measures are needed.

6.6 Effects on Earthworms, other Non-target Soil Organisms and Organic Matter Breakdown

6.6.1 Overview and summary

Please refer to the core assessment.

6.6.2 Exposure

Please refer to the core assessment.

6.6.3 Risk assessment –TER values and overall conclusions

As stated in the core assessment, any potassium added to the soil following application of the product will be negligible compared to background levels. Bicarbonate (HCO_3^-) is a natural product, present in soil pore waters as a result of CO_2 liberated from the respiration of soil organisms. Since earthworm will not be exposed to K^+ / HCO_3^- levels outside the natural range, no unacceptable effects to earthworms is expected when using KUMAR according to the proposed GAPs.

6.6.4 Toxicity to Exposure Ratio

Please refer to the core assessment.

6.6.5 Residue content of earthworms

Please refer to the core assessment.

6.7 Effects on Soil Microbial Activity

6.7.1 Overview and summary

Please refer to the core dossier for the central zone.

6.7.2 Toxicity

Please refer to the core dossier for the central zone.

6.7.3 Exposure

Please refer to the core assessment.

6.7.4 Risk assessment –overall conclusions

Please refer to the core assessment.

6.8 Effects on Non-Target Plants

Please refer to the core assessment.

Appendix 1: List of data submitted in support of the evaluation

No additional, National information available. Refer to Core assessment document for further information.

Appendix 2: Table of Intended Uses

GAP rev. 1, date: 2016-may-24

PPP (product name/code):	Kumar	Formulation type:	Water soluble powder (SP) [a, b]
Active substance 1:	Potassium hydrogen carbonate	Conc. of as 1:	850,00 g/kg [c]
Applicant:	Spiess-Urania Chemicals GmbH	Professional use:	☒
Zone(s):	central [d]	Non professional use:	☐
Verified by MS:	yes		

Field of use: herbicide, fungicide, insecticide etc

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f]
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		

Zonal uses (field or outdoor uses, certain types of protected crops)													
1	DE	Grape VITVI (utilisation as table and wine grape)	F	grey mould *Botrytis cinerea* BOTRCI	spraying or fine spraying (low volume spraying)	in case of danger of infection and/or after warning service appeal BBCH 75-89	a) 4 b) 6	8-30 days	a) 5.00 kg/ha b) 30.00 kg/ha	a) 4.25 kg as/ha b) 25.50 kg as/ha	800-1600	1	
2	DE	Grape VITVI (utilisation as table and wine grape)	F	powdery mildew of grape *Uncinula necator* UNCINE	spraying or fine spraying (low volume spraying)	in case of danger of infection and/or after warning service appeal BBCH 57-85	a) 6 b) 6	7-10 days	a) 5.00 kg/ha b) 30.00 kg/ha	a) 4.25 kg as/ha b) 25.50 kg as/ha [2]	200-1600	1	Dose rates staggered according to BBCH: basic application rate: 1.25 kg/ha in 200-400 L/ha Water BBCH 61: 2.50 kg/ha in 400-800 L/ha Water BBCH 71: 3.75 kg/ha in 600-1200 L/ha Water BBCH 75: 5.00 kg/ha in 800-1600 L/ha Water

Remarks table heading:

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008
(c) g/kg or g/l
(d) Select relevant
(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
(f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

Remarks columns:

1 Numeration necessary to allow references
2 Use official codes/nomenclatures of EU Member States
3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)
4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application
5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.
6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.
7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
8 The maximum number of application possible under practical conditions of use must be provided.
9 Minimum interval (in days) between applications of the same product
10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
13 PHI - minimum pre-harvest interval
14 Remarks may include: Extent of use/economic importance/restrictions

REGISTRATION REPORT
Part B
Section 7: Efficacy Data and Information
Detailed Summary

Product Code: Kumar (SPU 04930-F)

Reg. No.: ZV1 007547-00/10

Active Substance: Potassium bicarbonate 850 g/kg

Central Zone

Zonal Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant: Spiess-Urania Chemicals GmbH

Date: February 2017

Evaluator: Julius Kühn-Institut

Date: 2017-09-08

DATA PROTECTION CLAIM

The sponsor of this application is Spiess-Urania Chemicals GmbH.

The data, studies, reports and information (“Information”) listed in the attached document and submitted in support of this application is the property of the Sponsor Company and contains confidential business and trade secret information. Except as required or permitted by law, this Information should not be partially or fully (i) photocopied or released in any form to an outside party without the prior written consent of the Sponsor Company or its affiliates, or (ii) used by a registration authority to support the registration of any other product without the prior written consent of the Sponsor Company or its affiliates.

The following data and information were mainly provided by the applicant submitted as dRR and BAD.

Additional comments and the final evaluation by the zRMS in this Registration Report are marked by green boxes.

Person to contact

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IIIA1 6 Efficacy Data and Information (including Value Data) on the Plant Protection Product

Introduction

This document summarises the information related to the efficacy of the plant protection product Kumar (= ARMICARB) containing the active substance potassium bicarbonate (synonymous to potassium hydrogen carbonate) which was included into Annex I of Directive 91/414 (Commission Directive 2008/127/EC, without any specific provisions under Part B (in accordance with Commission Regulation (EC) No 2229/2004, as amended by Commission regulation (EC) No 1095/2007)) and is now listed in Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011.)

The corresponding documentation on the EC Review Report for potassium hydrogen carbonate (SANCO/2625/08, 28 October 2008), the EFSA Journal 2012, 10(1), p.2524 as well as the DAR for potassium hydrogen carbonate (Ireland, 2006) are considered to provide the relevant review information and serve as a reference to where such information can be found.

Potassium bicarbonate has long been used as a food supplement, including being used as a release agent, acidity regulator and baking agent. Despite the fact that potassium bicarbonate is registered for various commercial uses, the registration for fungicidal use is relatively new.

Please note, the test product was registered under the trade name “ARMICARB” and was later renamed as “Kumar”. In this document the current trade name “Kumar” (BVL Kenn-Nr. / authorisation number: 007547-00) is used while in the evaluated trials the former name “ARMICARB” is reported.

The current dRR, Part B, Section 7 and the corresponding BAD were compiled for label extension with regard to uses in grapes against *Botryotinia fuckeliana* and *Erysiphe necator*. Kumar is already authorized for the use against *Erysiphe necator* in grapevine acc. to Article 51 of Regulation 1107/2009 but efficacy and crop safety was not assessed by the applicant previously. Both uses can be considered as major use. However, with regard to the need of registered products for organic agriculture (Ökologischer Landbau) and the good efficacy of Kumar in the other uses already registered and herewith applied for, full approval is also sought with this submission for the use against *Botryotinia fuckeliana* and *Erysiphe necator*.

Appendix 1 of this document contains the reference to the Biological Assessment Dossier.

Appendix 2 of this document is the table of intended uses for Kumar.

Information on the detailed composition of Kumar can be found in the confidential dossier of this submission (Registration Report - Part C).

A detailed summary of efficacy data and information is presented in the following in accordance with the required EU dRR format (Part B, Section 7). The comprehensive BAD according to Uniform Principles is provided as separate document under reference KIIIA1 6.6/01. In the BAD is demonstrated in detail that sufficient biological data for the product Kumar is available.

IIIA1 6.1 Efficacy data

General information

Table 6- 1: Zonal rapporteur member state (zRMS) and concerned member states (cMS)

zRMS	Germany	DE
cMS	-	-

Recent registration situation

Table 6- 2: Existing registrations in Germany

Country	Product	Formulation		Authorisation No.	Registered rate(s) [kg/ha]	Uses
		Type	Conc.			
DE	Kumar	SP	850 g/kg Potassium bicarbonate	007547-00	Max. 3	Asparagus, garlic, pickling onion, shallot, bunching onion, Welsh onion – **leaf spot***
						Bottle gourd, cucumber, musky gourd, giant pumpkin, pumpkin, zucchini, pumpkin (bush), tea herbs, fresh herbs, aromatic herbs, tomato, strawberry, leguminous vegetables, cauliflower, wild cabbage, head of cabbage, turnip cabbage, root and tuber vegetables – **powdery mildew***
					Max. 5	Apple **– storage scab of apple**
						Apple – **fly speck***
						Apricot – **blossom blight***
						Hop, currant-like berries, raspberry-like berries, grape vine - **powdery mildew***

* Uses authorized acc. to article 51 of regulation 1107/2009

Information on crops and pests

Table 6- 3: Classification of crop and disease in the rapporteur member state (zRMS) and cMS[1]

Crop/Pathogen	EPPO-code	Classification of crop		Classification of disease	
		Major	Minor	Major	Minor
Grape vine / *Botryotinia fuckeliana*	VITVI / BOTRCI	DE	-	DE	-
Grape vine / *Erysiphe necator*	VITVI / UNCINE	DE	-	DE	-

[1] http://www.eumuda.eu

Information on the test product

<u>Identity of the active ingredient potassium bicarbonate:</u>

Empirical formula	$KHCO_3$
Molecular weight	100.12 g/mol
Physical state	solid (powder)

The mode of action of potassium bicarbonate is "not classified" since the target site is unknown. Despite the fact that the mechanism of the fungicidal activity of potassium bicarbonate is not yet completely investigated, potassium bicarbonate mainly acts as contact fungicides. The bicarbonate ion has been identified as the probable cause of growth inhibition in some bacteria and fungi. The mode of action of bicarbonate salts is linked to the perturbation of pH, osmotic pressure and the bicarbonate/carbonate ion balance of sensitive fungi. Bicarbonate acts by contact to fungi in aqueous solution and inhibits the development of fungal mycelium and spores. Several modes of action, including buffering, activity to raise the pH-level and osmotic pressure are relevant. The application of potassium bicarbonate provides detrimental conditions for fungal growth and prevents spore germination. The basic mechanism is an inhibitory effect, and thus potassium bicarbonate should to be applied as a preventive measure despite of a short curative efficacy.

<u>Identity of the test product Kumar (code: SPU-04930-F):</u>

Type of formulation	SP (water soluble powder)
Content of pure active ingredient	850 g/kg potassium bicarbonate

The product Kumar (SP, 850 g/kg potassium bicarbonate) presents a useful alternative for the application of copper-based products, which are known for their environmental side effects. According to the "Strategiepapier zu Kupfer als Pflanzenschutzmittel unter besonderer Berücksichtigung des Ökologischen Landbaus" copper-based products are subject to be reduced. This situation is especially pronounced for organic farming, as currently no other alternative products are available to be used as fungicides. The detailed composition of Kumar can be found in the confidential dossier of this submission (Registration Report - Part C).

Information on the biology of the different target organisms[2]

<u>BOTRCI: *Botryotinia fuckeliana*</u>

The target organism *Botryotinia fuckeliana* is a general parasitic fungus causing grey mould infection. *Botryotinia fuckeliana* is the teleomorph (sexual form), while the anamorph (asexual form) is referred to under the term *Botrytis cinerea*. Especially in grapevine grey mould infestation is of economic importance. The life cycle of *Botryotinia fuckeliana* is as follows: The fungus mainly overwinters as mycelium in intact plant tissues. After the germination in spring, conidiophores are produced. Conidia are mainly wind-dispersed, but by rain water as well. After the infection grey to brownish mycelium becomes visible on the plant tissues, mainly on leaves. Beside the vegetative reproduction cycle of *Botryotinia fuckeliana*, under special conditions a generative reproduction occurs as well. In this case sclerotia are produced which overwinter in soil even without the presence of intact plant tissues.

[2] Details on the biological characteristics and control of the target fungi and bacteria were retrieved from publications in the public domain e.g. websites of the German BVL (Federal Office of Consumer Protection and Food Safety), the German JKI (Federal Research Centre for Cultivated Plants), and official plant protection services.

UNCINE: *Erysiphe necator*

The target organism *Erysiphe necator,* formerly *Uncinula necator* (anamorph: *Oidium tuckeri*) is a host-specific fungus causing powdery mildew on grapevine. The ascomycete may cause severe damage by general yield reduction, but as well by reducing the wine quality. *Erysiphe necator* is a polycyclic disease, thus its life cycle is grouped into two successive stages: In the primary stage conidia are released from overwintering cleistothecia or mycelium in infested scales of winter buds which germinate under high humidity and are affecting the host plant. After primary infection so-called haustoria are developed. This becomes visible by whitish powdery patches on the surface of infected plant tissues. These structures are directly connected with plant cells under the epidermis. Even when under the secondary infection mainly the upper side of leaves becomes infected, symptoms may be on the stem, flowers, buds and berries as well. For further infection secondary inoculum is produced. Under special environmental conditions, again a cleistothecium is produced.

IIIA1 6.1.1 Preliminary range-finding tests

Preliminary trials are not considered to be required since potassium bicarbonate-based products are well known for their fungicidal use and have been on the market for a number of years.

IIIA1 6.1.2 Minimum effective dose tests

Label claim:

Crop	Target	Application timing	No. of appli-cations	Minimum application interval (days)	PHI (days)	Spray volume (L/ha)	Dose rate	
							kg/ha	g ai/ha
Grapevine	*Botryotinia fuckeliana*	BBCH 75 -89	4	8- 30	1 day	800 - 1,600	5.0	4250
	Erysiphe necator	BBCH 57-85	6	7-10	1 day	200 - 1,600*	5.0*	4250

* Dose rate and amount of water depend on the growth stage of the crop: BBCH 57: 1.25 kg/ha
BBCH 61: 2.5 kg/ha
BBCH 71: 3.75 kg/ha
BBCH 75: 5.0 kg/ha

Dose justification trials (refer to Table 6- 4 and Table 6- 5) with various application rates of the test product Kumar were performed in the course of the efficacy evaluation (refer to IIIA1 6.1.3). These trials cover a range of climatic and agricultural conditions, representing the diversity of situations in which the product can be applied. The dose justification was carried out with respect to the general terms of sustainable management: Plant protection measures should merely be used in amounts as high as necessary to achieve a good control of the disease, but at the same time as low as possible to avoid any undue exposure of potassium bicarbonate to the environment.

Table 6- 4: Overview of dose justification trials: Kumar in grapevine against **grey mould**

Country	2005	2008	2013	2014	2015
DE	1	2	3	2	3

Table 6- 5: Overview of dose justification trials: Kumar in grapevine against **powdery mildew**

Country	2005	2013	2014	2015
AT	2	-	-	-
CH	2	-	-	-
DE	-	2	2	3

As a fungicide with protective mode of action, Kumar has to be applied before an infection with BOTRCI or UNCINE occurs, when climatic conditions for a fungal infection are optimal.
In practical viticulture, it is necessary and usual to apply different fungicides within a spray sequence of a number of applications throughout the vegetation period to keep the plants healthy. In these spray sequences, it is generally usual to alternate products with different Modes of Action[3]. Reasons for this can be preventing the development of resistance, or compliance with national or international maximum amounts; e.g. in the case of copper, it is impermissible to exceed an amount of 3 kg/ha in organic viticulture[4].
In efficacy trials testing a protective product as “Kumar”, which is intended for 4 or 6 applications beginning at BBCH 57 (BOTRCI) and BBCH 75 (UNCINE), respectively, it is necessary to maintain disease free conditions until trial start, because an effective control would not be possible anymore if the plants were infected. The submitted trials simulate the application of Kumar within a usual spray sequence.
It would be possible to achieve disease free plants for such a long period until trial start by using a different fungicide with efficacy against the target diseases, but to exclude an impact on the efficacy in the submitted trials it was decided to use exclusively Kumar applications instead. This decision has no effect on the overall outcome of the trial, taking into account the fact that a very long lasting effect of the single applications is not to be expected.
A repeated application of Kumar does not increase the overall efficacy against the target diseases, but is necessary to prevent the crop from new infections as the active substance is washed away from the plant surfaces or is degraded between two applications.
Therefore, the submitted trials testing Kumar within a common spraying sequence, are considered to be valid to demonstrate the efficacy of the product at the intended dose rate.

(1) Grapevine (BOTRCI: *Botryotinia fuckeliana*)

Material and Methods

All trials were conducted according to GEP and followed the appropriate EPPO standards by officially recognised testing organisations. The study design used in all trials was a randomised complete block design with 4 to 5 replicates. The plot size ranges between 16.8 m^2 and 36.0 m^2. All trials were conducted in Germany between the years 2005 and 2015. The test product Kumar was applied at rates between 3.0 and 5.0 kg product/ha (in 1 trial 4.0 and 6.0 kg/ha was tested), representing between 60 % and 100 % of the maximum recommended rate. A comparative overview of the dose rates and corresponding concentrations of active substances for every application scenario is provided in Table 6- 6.

In general, in this dossier results in terms of pest severity (PESSEV) and pest incidence (PESINC) were calculated acc. to the Abbott formula. Class evaluations in terms of percentage of pest coverage were converted into [% of control] of the mean in the respective classes.

(2) Grapevine (UNCINE: *Erysiphe necator*)

All trials were conducted according to GEP and followed the appropriate EPPO standards by officially recognised testing organisations. The study design used in all trials was a randomised complete block design with 4 to 5 replicates. The plot size ranges between 9.0 m^2 and 48.0 m^2. All trials have been conducted in Switzerland, Austria and Germany between the years 2004 and 2015. The test product Kumar was applied at rates of 2.5 or 3.0 and 5.0 kg product/ha, representing 50 %, 60 % and 100 % of the maximum recommended rate. An overview of the dose rates of Kumar for the application scenarios of each trial is provided in Table 6- 7.
In general, in this dossier results in terms of pest severity (PESSEV) and pest incidence (PESINC) were calculated acc. to the Abbott formula. Class evaluations in terms of percentage of pest coverage were converted into [% of control] of the mean in the respective classes.

[3] http://www.dlr-rheinpfalz.rlp.de/Internet/global/themen.nsf/0/5E4958A40A79B6EFC1257E0D00529F7B/$FILE/rahmenempfehlung2015.pdf
[4] http://biosicherheit-bch.de/SharedDocs/Downloads/04_Pflanzenschutzmittel/psm_verz_3.pdf?__blob=publicationFile&v=9

Methods

Table 6- 6: Overview of dose rates of the product Kumar for the use against **grey mould**

<table>
<tr><th rowspan="2">Target use</th><th rowspan="2">Trial no.</th><th colspan="8">Rate per treatment / BBCH stage at application
[kg product/ha] and [g a.i./ha]</th></tr>
<tr><th>A</th><th>B</th><th>C</th><th>D</th><th>E</th><th>F</th><th>G</th><th>H</th></tr>
<tr><td rowspan="11">BOTRCI
in grapevine</td><td rowspan="2">01-22</td><td colspan="3">4.0 3400
6.0 5100
BBCH 61-87</td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td colspan="5">4.0 3400
6.0 5100
BBCH 61-88</td><td></td><td></td><td></td></tr>
<tr><td>01-23</td><td colspan="4">3.0 2550
5.0 4250
BBCH 68-87</td><td></td><td></td><td></td><td></td></tr>
<tr><td>01-24</td><td colspan="4">3.0 2550
5.0 4250
BBCH 65-89</td><td></td><td></td><td></td><td></td></tr>
<tr><td>01-28</td><td colspan="6">3.0 2550
5.0 4250
BBCH 75-83</td><td></td><td></td></tr>
<tr><td>01-29</td><td colspan="6">3.0 2550
5.0 4250
BBCH 65-83</td><td></td><td></td></tr>
<tr><td>01-30</td><td>1.5 1275
2.5 2125
BBCH 69</td><td>2.25 1913
3.75 3188
BBCH 71</td><td colspan="4">3.0 2550
5.0 4250
BBCH 75-79</td><td></td><td></td></tr>
<tr><td>01-31</td><td colspan="6">3.0 2550
5.0 4250
BBCH 79-85</td><td></td><td></td></tr>
<tr><td>01-32</td><td colspan="3">2.25 1913
3.75 3188
BBCH 71-73</td><td colspan="2">3.0 2550
5.0 4250
BBCH 75-79</td><td></td><td></td><td></td></tr>
<tr><td>01-33</td><td>1.5 1275
2.5 2125</td><td colspan="2">2.25 1913
3.75 3188</td><td colspan="5">3.0 2550
5.0 4250</td></tr>
</table>

<table>
<tr><th rowspan="2">Target use</th><th rowspan="2">Trial no.</th><th colspan="8">Rate per treatment / BBCH stage at application
[kg product/ha] and [g a.i./ha]</th></tr>
<tr><th>A</th><th>B</th><th>C</th><th>D</th><th>E</th><th>F</th><th>G</th><th>H</th></tr>
<tr><td rowspan="3"></td><td></td><td>BBCH 68</td><td colspan="2">BBCH 71-73</td><td colspan="5">BBCH 75-83</td></tr>
<tr><td>01-34</td><td>1.5 1275
2.5 2125
BBCH 65</td><td>2.25 1913
3.75 3188
BBCH 71</td><td colspan="5">3.0 2550
5.0 4250
BBCH 77-85</td><td></td></tr>
<tr><td>01-35</td><td>0.75 0.638
1.25 1063
BBCH 59</td><td colspan="3">1.5 1275
2.5 2125
BBCH 65-70</td><td colspan="2">2.25 1913
3.75 3188
BBCH 72</td><td colspan="2">3.0 2550
5.0 4250
BBCH 76</td></tr>
</table>

Table 6- 7: Overview of dose rates of the product Kumar for the use against **powdery mildew**

<table>
<tr><th rowspan="2">Target use</th><th rowspan="2">Trial no.</th><th colspan="11">Rate per treatment / BBCH stage at application
[kg product/ha] and [g a.i./ha]</th></tr>
<tr><th>A</th><th>B</th><th>C</th><th>D</th><th>E</th><th>F</th><th>G</th><th>H-I</th><th>J</th><th>K</th><th>L</th></tr>
<tr><td rowspan="6">UNCINE
in
grapevine</td><td>02-04</td><td colspan="9">2.5 2125
5.0 4250
BBCH 13-83</td><td></td><td></td></tr>
<tr><td>02-05</td><td colspan="9">2.5 2125
5.0 4250
BBCH 13-81</td><td></td><td></td></tr>
<tr><td>02-08</td><td colspan="6">2.5 2125
5.0 4250
BBCH 57-83</td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>02-09</td><td colspan="6">2.5 2125
5.0 4250
BBCH 57-84</td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>02-10</td><td colspan="2">0.75 0.638
12.5 1063
BBCH 19-57</td><td>1.5 1275
2.5 2125
BBCH 69</td><td>2.25 1913
3.75 3188
BBCH 71</td><td colspan="2">3.0 2550
5.0 4250
BBCH 75-79</td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>02-11</td><td colspan="2">0.75 0.638
1.25 1063
BBCH 53-55</td><td colspan="2">1.5 1275
2.5 2125
BBCH 63-69</td><td>2.25 1913
3.75 3188
BBCH 71</td><td>3.0 2550
5.0 4250
BBCH 75</td><td></td><td></td><td></td><td></td><td></td></tr>
</table>

<table>
<tr><th rowspan="2">Target use</th><th rowspan="2">Trial no.</th><th colspan="11">Rate per treatment / BBCH stage at application
[kg product/ha] and [g a.i./ha]</th></tr>
<tr><th>A</th><th>B</th><th>C</th><th>D</th><th>E</th><th>F</th><th>G</th><th>H-I</th><th>J</th><th>K</th><th>L</th></tr>
<tr><td rowspan="5"></td><td>02-12</td><td colspan="3">0.75 0.638
1.25 1063
BBCH 55-57</td><td>1.5 1275
2.5 2125
BBCH 65</td><td>2.25 1913
3.75 3188
BBCH 71</td><td colspan="5">3.0 2550
5.0 4250
BBCH 75-83</td><td></td></tr>
<tr><td>02-13</td><td colspan="4">0.75 0.638
1.25 1063
BBCH 15-60</td><td colspan="2">2.25 1913
3.75 3188
BBCH 71-74</td><td colspan="3">3.0 2550
5.0 4250
BBCH 76-79</td><td></td><td></td></tr>
<tr><td>02-14</td><td colspan="2">0.75 0.638
1.25 1063
BBCH 16-18</td><td>1.5 1275
2.5 2125
BBCH 61</td><td>2.25 1913
3.75 3188
BBCH 71</td><td colspan="4">3.0 2550
5.0 4250
BBCH 73-79</td><td></td><td></td><td></td></tr>
<tr><td>02-15</td><td colspan="3">0.75 0.638
1.25 1063
BBCH 53-55</td><td>1.5 1275
2.5 2125
BBCH 61</td><td colspan="2">2.25 1913
3.75 3188
BBCH 69-71</td><td colspan="5">3.0 2550
5.0 4250
BBCH 73-81</td></tr>
<tr><td>02-16</td><td colspan="2">0.75 0.638
1.25 1063
BBCH 17-55</td><td colspan="2">1.5 1275
2.5 2125
BBCH 61-65</td><td>2.25 1913
3.75 3188
BBCH 71</td><td>3.0 2550
5.0 4250
BBCH 75</td><td></td><td></td><td></td><td></td><td></td></tr>
</table>

Results

The following tables give an overview of the dose justification results for Kumar, ranging from a lower dose rate of testing 3.0 kg/ha for BOTRCI and 2.5 and 3.0 kg/ha for UNCINE, respectively, to the intended dose rate of 5.0 kg/ha. Results are presented site-by-site for each disease separately. For control of UNCINE the dose rate depends on the growth stage of the crop and assessments at earlier BBCH stage were carried out with a lower intended dose rate (3.75 kg/ha for BBCH 71-74). For dose justification, a lower dose than the intended was tested (2.25 kg/ha). It is differentiated between the mean effectiveness on grape bunches for grey mould (Table 6- 8 and Table 6- 9) and on bunches and leaves for powdery mildew (Table 6- 10 to Table 6- 21). All assessments with the same classification are evaluated in the same way (5, 6 or 7 classes).
In 1 trial, the application rate of 4.0 and 6.0 kg/ha for control of grey mould was tested. This trial was not shown in this document due to dose rates deviating from the intended dose rate.

On the basis of the presented results, the dose justification data show that there is a clear dose-response relationship for the use of the product Kumar considering **pest incidence** of **grey mould** on bunches (3.0 kg/ha: 49.9-78.9 %; 5.0 kg/ha: 63.9-83.8 %) and **severity** (3.0 kg/ha: 35.3-40.5 %; 5.0 kg/ha: 64.8 %) (refer to Table 6- 8). Additionally, for grey mould a scale was used to assess the percentage of infected bunch area (Table 6- 9). Considering BBCH 89, number of bunches at 5.0 kg/ha belonging to class 1 (low infestation) increased compared to 3.0 kg/ha and decreased at class 4 (high infestation).
Considering **pest incidence**, control of **powdery mildew** on **bunches** was tested at 2.5 and 5.0 kg/ha (2.5 kg/ha: 59.9-83.1 %, 5.0 kg/ha: 66.7-88.6 %), and at 3.0 and 5.0 kg/ha (3.0 kg/ha: 49.2-69.9 %, 5.0 kg/ha: 62.4-80.6 %). Dose response was more pronounced compared to **pest severity** comparing 2.5 and 5.0 kg/ha (2.5 kg/ha: 85.0-90.6 %, 5.0 kg/ha: 90.9-100.0 %) and 3.0 and 5.0 kg/ha (3.0 kg/ha: 3.6-10.5 %, 5.0 kg/ha: 13.9-39.9 %) (refer to Table 6- 10 and Table 6- 11). Application at BBCH 75 was carried out with a lower dose rate (acc. to the GAP). The assessment of bunches showed no clear dose response in this trial (incidence: 2.25 kg/ha: 52.3 %, 3.75 kg/ha: 57.0 %; severity: 2.25 kg/ha: 71.3 %, 3.75 kg/ha: 64.7 %, refer to Table 6- 12). On **leaves**, efficacy was similar or better at the intended dose testing 2.5 and 5.0 kg/ha (**incidence**: 2.5 kg/ha: 98.3 %, 5.0 kg/ha: 100.0 %; **severity**: 2.5 kg/ha: 99.1 %, 5.0 kg/ha: 100.0 %; refer to Table 6- 16) and 3.0 and 5.0 kg/ha (3.0 kg/ha **incidence**: 61.5-85.4 %; **severity**: 32.0 %; 5.0 kg/ha: **incidence**: 75.4-87-4 %; **severity**: 55.5 %; refer to Table 6- 17). Application at BBCH 74-75 was carried out with a lower dose rate (acc. to the GAP). The assessment of leaves at BBCH 74-75 showed no clear dose response at this growth stage in terms of incidence (2.25 kg/ha: 67.2 %; 3.75 kg/ha: 67.9 %; refer to Table 6- 18). Additional, for control of powdery mildew a scale was used to assess the percentage of infected bunch area and leaf surface (refer to Table 6- 13 to Table 6- 15 for bunches and Table 6- 20 to Table 6- 21 for leaves). Generally, number of bunches at 5.0 kg/ha belonging to class 1 (no or low infestation) increased compared to 2.5/3.0 kg/ha and decreased at higher classes (high infestation).

Dose rates below the recommended dose rate of 5.0 kg/ha are associated with reduced effectiveness levels for both target pests. This effect is more pronounced for the control of grey mould. Furthermore, for the interpretation of the results it must be noted that the infection of both target species is very much interrelated, as an early powdery mildew infection may promote a later infection with grey mould.

(1) Grapevine (BOTRCI: *Botryotinia fuckeliana*)

Table 6- 8: Dose justification for Kumar against **grey mould** on grapevine bunches in terms of **PESINC** and **PESSEV** (3.0 and 5.0 kg/ha)

Rating data type	Part rated	No. of appl.	Evaluation	UTC	Efficacy [%] acc. to Abbott	
					Test product [kg/ha]	
					3.0	5.0
BBCH 89						
PESINC	bunches	4-8	n	8	8	8
			Mean	**41.8**	**49.9**	**63.9**
			Min.	24.4	5.7	18.9
			Max.	94.0	73.5	100.0
PESSEV	bunches	4-6	n	4	4	4
			Mean	**19.2**	**40.5**	**64.8**
			Min.	7.7	21.9	46.3
			Max.	47.1	53.9	78.4
BBCH 75-87						
PESINC	bunches	3-7	n	4	4	4
			Mean	**40.1**	**78.9**	**83.8**
			Min.	6.8	58.3	59.4
			Max.	93.3	100.0	100.0
PESSEV	bunches	3	n	1	1	1
			Value	**7.5**	**35.3**	**64.8**

Table 6- 9: Dose justification for Kumar against **grey mould** on grapevine bunches in terms of **PESSEV** (4-class evaluation, 3.0 and 5.0 kg/ha)

Evaluation	**UTC**	**BBCH 89 (after 6-8 applications)**				**UTC**	**BBCH 85 (after 6-7 applications)**			
		Test product [kg/ha]					**Test product [kg/ha]**			
		3.0		**5.0**			**3.0**		**5.0**	
		[%]	**% of UTC**	**[%]**	**% of UTC**		**[%]**	**% of UTC**	**[%]**	**% of UTC**
Class 1 (1-5 % infestation)										
n	4	4	-	4	-	3	3	-	3	-
Mean	**4.0**	**3.4**	**86.1**	**3.8**	**95.6**	**1.7**	**0.1**	**4.0**	**0.3**	**20.0**
Min.	0.0	0.0	-	0.0	-	0.2	0.0	-	0.0	-
Max.	13.4	11.0	-	13.2	-	4.4	0.2	-	1.0	-
Class 2 (5-25 % infestation)										
n	4	4	-	4	-	3	3	-	3	-
Mean	**16.4**	**13.9**	**84.8**	**14.7**	**89.6**	**1.5**	**0.5**	**35.6**	**0.2**	**13.3**
Min.	7.6	4.0	-	4.4	-	0.6	0.0		0.0	-
Max.	34.4	34.2	-	40.2	-	2.4	1.2		0.6	-
Class 3 (25-50 % infestation)										
n	4	4	-	4	-	3	3	-	3	-
Mean	**14.4**	**8.5**	**59.2**	**7.2**	**50.3**	**0.2**	**0.0**	**-**	**0.1**	**33.3**
Min.	9.1	1.7	-	1.0	-	0.0	0.0	-	0.0	-
Max.	25.6	22.8	-	23.2	-	0.6	0.0	-	0.2	-
Class 4 (> 50 % infestation)										
n	4	4	-	4	-	3	3	-	3	-
Mean	**6.7**	**4.0**	**59.6**	**2.6**	**38.2**	**0.0**	**0.0**	**-**	**0.0**	**-**
Min.	0.0	0.0	-	0.0	-	0.0	0.0	-	0.0	-
Max.	11.2	12.0	-	6.8	-	0.0	0.0	-	0.0	-

(2) Grapevine (UNCINE: *Erysiphe necator*)

UNCINE - *Assessments on bunches*

Table 6- 10: Dose justification for Kumar against **powdery mildew** on grape bunches in terms of **PESINC** and **PESSEV** (2.5 and 5.0 kg/ha)

Rating data type	Part rated	No. of appl.	Evaluation	UTC	Efficacy [%] acc. to Abbott	
					Test product [kg/ha]	
					2.5	5.0
BBCH 79						
PESINC	bunches	5	n	1	1	1
			Value	**22.0**	**59.9**	**66.7**
PESSEV	bunches	5	n	1	1	1
			Value	**5.3**	**90.6**	**100.0**
BBCH 81-83						
PESINC	bunches	5-10	n	4	4	4
			Mean	**47.6**	**83.1**	**88.6**
			Min.	22.8	66.7	71.1
			Max.	90.0	100.0	100.0
PESSEV	bunches	5-10	n	4	4	4
			Mean	**22.2**	**85.0**	**90.9**
			Min.	5.2	66.7	75.0
			Max.	48.0	100.0	100.0

Table 6- 11: Dose justification for Kumar against **powdery mildew** on grape bunches in terms of **PESINC** and **PESSEV** (3.0 and 5.0 kg/ha)

Rating data type	Part rated	No. of appl.	Evaluation	UTC	Efficacy [%] acc. to Abbott	
					Test product [kg/ha]	
					3.0	5.0
BBCH 75-79						
PESINC	bunches	6-8	n	3	3	3
			Mean	**31.9**	**69.9**	**80.6**
			Min.	10.5	40.5	57.1
			Max.	65.0	100.0	100.0
BBCH 81-87						
PESINC	bunches	6-11	n	4	4	4
			Mean	**66.9**	**50.5**	**62.4**
			Min.	52.5	16.8	31.1
			Max.	83.5	66.7	76.1
PESSEV	bunches	6	n	1	1	1
			Value	**65.2**	**10.5**	**39.9**
BBCH 89						
PESINC	bunches	6-12	n	3	3	3
			Mean	**68.1**	**49.2**	**64.3**
			Min.	33.4	40.1	49.1
			Max.	90.0	66.7	77.8
PESSEV	bunches	6	n	1	1	1
			Value	**84.3**	**3.6**	**13.9**

Table 6- 12: Dose justification for Kumar against **powdery mildew** on grape bunches in terms of **PESINC** and **PESSEV** (2.25 and 3.75 kg/ha, considering the lower growth stage at application)

Rating data type	Part rated	No. of appl.	Evaluation	UTC	Efficacy [%] acc. to Abbott	
					Test product [kg/ha]	
					2.25	3.75
BBCH 75						
PESINC	bunches	5	n **Value**	1 **74.5**	1 **52.3**	1 **57.0**
PESSEV	bunches	5	n **Value**	1 **9.1**	1 **71.3**	1 **64.7**

Table 6- 13: Dose justification for Kumar against **powdery mildew** on grape bunches in terms of **PESSEV** (6-class evaluation, 2.5 and 5.0 kg/ha)

Evaluation	UTC	BBCH 79 (after 5 applications)				UTC	BBCH 83 (after 7-11 applications)			
		Test product [kg/ha]					Test product [kg/ha]			
		2.5		5.0			2.5		5.0	
		[%]	% of UTC	[%]	% of UTC		[%]	% of UTC	[%]	% of UTC
Class 1 (no disease)										
n	1	1	-	1	-	4	4	-	4	-
Mean	**40.0**	**48.7**	**121.8**	**50.0**	**125.0**	**23.6**	**59.0**	**250.0**	**62.3**	**263.8**
Min.	-	-	-	-	-	5.0	38.0	-	38.0	-
Max.	-	-	-	-	-	38.0	96.5	-	96.0	-
Class 2 (< 2.5 % infestation)										
n	1	1	-	1	-	2	2	-	2	-
Mean	**9.0**	**1.3**	**14.4**	**0.0**	**-**	**26.6**	**12.8**	**48.0**	**12.0**	**45.2**
Min.	-	-	-	-	-	17.3	4.7	-	3.7	-
Max.	-	-	-	-	-	35.8	20.8	-	20.3	-
Class 3 (2.6-10 % infestation)										
n	1	1	-	1	-	2	2	-	2	-
Mean	**2.3**	**0.0**	**-**	**0.0**	**-**	**15.5**	**3.5**	**22.6**	**4.8**	**31.0**
Min.	-	-	-	-	-	15.3	0.0	-	0.3	-
Max.	-	-	-	-	-	15.7	7.0	-	9.3	-
Class 4 (11-25 % infestation)										
n	1	1	-	1	-	2	2	-	2	-
Mean	**0.0**	**0.0**	**-**	**0.0**	**-**	**8.3**	**1.4**	**17.0**	**1.4**	**17.0**
Min.	-	-	-	-	-	5.7	0.0	-	0.0	-
Max.	-	-	-	-	-	10.8	2.8	-	2.8	-
Class 5 (26-50 % infestation)										
n	1	1	-	1	-	2	2	-	2	-
Mean	**0.0**	**0.0**	**-**	**0.0**	**-**	**6.4**	**1.0**	**15.6**	**0.2**	**2.3**
Min.	-	-	-	-	-	4.3	0.0	-	0.0	-
Max.	-	-	-	-	-	8.5	2.0	-	0.3	-
Class 6 (51-100 % infestation)										
n	1	1	-	1	-	2	2	-	2	-
Mean	**0.0**	**0.0**	**-**	**0.0**	**-**	**5.8**	**0.4**	**7.0**	**0.0**	**-**
Min.	-	-	-	-	-	3.0	0.0	-	0.0	-
Max.	-	-	-	-	-	8.5	0.8	-	0.0	-

Table 6- 14: Dose justification for Kumar against **powdery mildew** on grape bunches in terms of **PESSEV** (6-class evaluation, 3.0 and 5.0 kg/ha)

Evaluation	**UTC**	**BBCH 75-79 (after 6-8 applications)**				**UTC**	**BBCH 81-87 (after 7-12 applications)**				**UTC**	**BBCH 89 (after 12-13 applications)**			
		Test product [kg/ha]					**Test product [kg/ha]**					**Test product [kg/ha]**			
		3.0		**5.0**			**3.0**		**5.0**			**3.0**		**5.0**	
		[%]	% of UTC	[%]	% of UTC		[%]	% of UTC	[%]	% of UTC		[%]	% of UTC	[%]	% of UTC
Class 1 (< 5 % infestation)															
n	4	4	-	4	-	4	4	-	4	-	2	2	-	2	-
Mean	**8.8**	**15.2**	**173.0**	**13.9**	**158.2**	**6.4**	**8.5**	**131.8**	**9.3**	**145.0**	**2.8**	**2.2**	**78.2**	**2.4**	**87.3**
Min.	1.9	2.1	-	1.1	-	0.4	2.5	-	2.0	-	1.5	1.8	-	1.5	-
Max.	18.8	24.3	-	22.8	-	18.5	17.0	-	17.0	-	4.0	2.5	-	3.3	-
Class 2 (5-10 % infestation)															
n	4	4	-	4	-	5	5	-	5	-	2	2	-	2	-
Mean	**11.3**	**7.7**	**67.8**	**7.3**	**64.0**	**7.1**	**6.9**	**97.5**	**6.4**	**90.7**	**10.7**	**7.1**	**66.2**	**5.7**	**53.1**
Min.	9.3	1.3	-	1.0	-	0.2	0.7	-	3.3	-	9.0	5.3	-	4.3	-
Max.	12.8	17.0	-	17.0	-	13.0	12.3	-	12.8	-	12.3	8.8	-	7.0	-
Class 3 (11-25 % infestation)															
n	4	4	-	4	-	5	5	-	5	-	2	2	-	2	-
Mean	**7.6**	**2.1**	**27.4**	**2.0**	**25.7**	**6.7**	**6.1**	**91.0**	**4.9**	**73.4**	**7.4**	**5.3**	**71.9**	**2.8**	**38.0**
Min.	4.2	0.0	-	0.0	-	1.8	2.5	-	0.0	-	6.8	3.8	-	2.8	-
Max.	10.3	6.3	-	5.3	-	12.9	10.8	-	11.3	-	8.0	6.8	-	2.8	-
Class 4 (26-50 % infestation)															
n	4	4	-	4	-	5	5	-	5	-	2	2	-	2	-
Mean	**6.3**	**1.7**	**26.9**	**1.2**	**18.2**	**8.2**	**6.1**	**74.6**	**4.4**	**53.7**	**12.5**	**3.5**	**28.0**	**1.6**	**12.8**
Min.	2.3	0.0	-	0.0		2.0	0.0	-	0.0	-	11.8	0.5	-	0.9	-
Max.	12.8	6.5	-	4.5		18.3	16.8	-	13.8	-	13.3	6.5	-	2.3	-
Class 5 (50-75 % infestation)															
n	3	3	-	3	-	5	5	-	5	-	2	2	-	2	-
Mean	**2.4**	**0.6**	**24.9**	**0.2**	**6.9**	**6.7**	**2.5**	**36.7**	**2.7**	**40.3**	**4.9**	**0.8**	**16.4**	**0.0**	**-**
Min.	0.5	0.0	-	0.0		0.5	0.0	-	0.0	-	4.0	0.0	-	0.0	-
Max.	3.5	1.8	-	0.5		14.8	10.5	-	13.5	-	5.7	1.6	-	0.0	-
Class 6 (> 75 % infestation)															
n	2	2	-	2	-	3	3	-	3	-	2	2	-	2	-
Mean	**2.6**	**0.0**	**-**	**0.0**	**-**	**12.6**	**3.7**	**29.2**	**2.1**	**17.0**	**4.3**	**0.4**	**9.3**	**0.0**	**-**
Min.	1.1	0.0	-	0.0	-	2.0	0.0	-	0.0	-	2.0	0.0	-	0.0	-
Max.	4.0	0.0	-	0.0	-	24.0	11.0	-	6.4	-	6.6	0.8	-	0.0	-

Table 6- 15: Dose justification for Kumar against **powdery mildew** on grape bunches in terms of **PESSEV** (single trial, 5-class evaluation, 3.0 and 5.0 kg/ha)

Evaluation	**UTC**	**BBCH 75 (after 5 applications)**				**UTC**	**BBCH 81 (after 6 applications)**				**UTC**	**BBCH 89 (after 6 applications)**			
		Test product [kg/ha]					**Test product [kg/ha]**					**Test product [kg/ha]**			
		3.0		**5.0**			**3.0**		**5.0**			**3.0**		**5.0**	
		[%]	% of UTC	[%]	% of UTC		[%]	% of UTC	[%]	% of UTC		[%]	% of UTC	[%]	% of UTC
Class 1 (no disease)															
n	1	1	-	1	-	1	1	-	1	-	1	1	-	1	-
Value	**12.8**	**32.3**	**252.3**	**34.0**	**265.6**	**0.4**	**0.0**	**-**	**0.5**	**125.0**	**0.0**	**0.0**	**-**	**0.0**	**-**
Class 2 (1-5 % infestation)															
n	1	1	-	1	-	1	1	-	1	-	1	1	-	1	-
Value	**0.0**	**0.0**	**-**	**0.0**	**-**	**0.0**	**0.0**	**-**	**0.0**	**-**	**0.0**	**0.0**	**-**	**0.0**	**-**
Class 3 (6-25 % infestation)															
n	1	1	-	1	-	1	1	-	1	-	1	1	-	1	-
Value	**23.3**	**14.8**	**63.5**	**12.5**	**53.6**	**1.4**	**3.9**	**278.6**	**11.1**	**792.9**	**0.0**	**0.0**	**-**	**0.0**	**-**
Class 4 (26-50 % infestation)															
n	1	1	-	1	-	1	1	-	1	-	1	1	-	1	-
Value	**9.1**	**1.2**	**13.2**	**0.6**	**6.6**	**12.5**	**19.8**	**158.4**	**20.0**	**160.0**	**0.6**	**2.2**	**366.7**	**8.2**	**1366.7**
Class 5 (> 50 % infestation)															
n	1	1	-	1	-	1	1	-	1	-	1	1	-	1	-
Value	**2.6**	**0.5**	**19.2**	**1.3**	**50.0**	**33.7**	**25.5**	**75.7**	**11.1**	**32.9**	**49.3**	**47.5**	**96.3**	**41.8**	**84.8**

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Table 6- 16: Dose justification for Kumar against **powdery mildew** on grape leaves in terms of **PESINC** and **PESSEV** (2.5 and 5.0 kg/ha)

Rating data type	**Part rated**	**No. of appl.**	**Evaluation**	**UTC**	**Efficacy [%] acc. to Abbott**	
					Test product [kg/ha]	
					2.5	**5.0**
BBCH 83						
PESINC	leaves	10	n	2	2	2
			Mean	**66.0**	**98.3**	**100.0**
			Min.	45.0	96.6	100.0
			Max.	87.0	100.0	100.0
PESSEV	leaves	10	n	2	2	2
			Mean	**34.0**	**99.1**	**100.0**
			Min.	12.0	98.2	100.0
			Max.	56.0	100.0	100.0

Table 6- 17: Dose justification for Kumar against **powdery mildew** on grape leaves in terms of **PESINC** and **PESSEV** (3.0 and 5.0 kg/ha)

Rating data type	**Part rated**	**No. of appl.**	**Evaluation**	**UTC**	**Efficacy [%] acc. to Abbott**	
					Test product [kg/ha]	
					3.0	**5.0**
BBCH 81-89						
PESINC	leaves	6-11	n	6	6	6
			Mean	**39.3**	**61.5**	**75.4**
			Min.	11.2	7.1	48.6
			Max.	80.8	100.0	100.0
PESSEV	leaves	6	n	1	1	1
			Value	**23.5**	**32.0**	**55.5**
BBCH 75-79						
PESINC	leaves	6-8	n	2	2	2
			Mean	**9.8**	**85.4**	**87.4**
			Min.	8.8	70.7	74.8
			Max.	10.8	100.0	100.0

Table 6- 18: Dose justification for Kumar against **powdery mildew** on grape leaves in terms of **PESINC** and **PESSEV** (2.25 and 3.75 kg/ha, considering the lower growth stage at application)

Rating data type	**Part rated**	**No. of appl.**	**Evaluation**	**UTC**	**Efficacy [%] acc. to Abbott**	
					Test product [kg/ha]	
					2.25	**3.75**
BBCH 74-75						
PESINC	leaves	5-6	n	2	2	2
			Mean	**61.5**	**67.2**	**67.9**
			Min.	55.4	59.3	51.9
			Max.	67.5	75.1	83.9

Table 6- 19: Dose justification for Kumar against **powdery mildew** on grape leaves in terms of **PESSEV** (6-class evaluation, 2.5 and 5.0 kg/ha)

Evaluation	**UTC**	**BBCH 83 (after 10 applications)**			
		Test product [kg/ha]			
		2.5		**5.0**	
		[%]	**% of UTC**	**[%]**	**% of UTC**
Class 1 (no disease)					
n	2	2	-	2	-
Mean	**26.5**	**99.0**	**373.6**	**100.0**	**377.4**
Min.	13.0	98.0	-	100.0	-
Max.	40.0	100.0	-	100.0	-
Class 2 (< 2.5 % infestation)					
n	2	2	-	2	-
Mean	**24.5**	**1.5**	**6.1**	**0.0**	**-**
Min.	16.0	0.0	-	0.0	-
Max.	33.0	3.0	-	0.0	-

Evaluation	UTC	BBCH 83 (after 10 applications)			
		Test product [kg/ha]			
		2.5		5.0	
		[%]	% of UTC	[%]	% of UTC
Class 3 (2.6-10 % infestation)					
n	2	2	-	2	-
Mean	**26.5**	**0.0**	**-**	**0.0**	**-**
Min.	20.0	0.0	-	0.0	-
Max.	33.0	0.0	-	0.0	-
Class 4 (11-25 % infestation)					
n	2	2	-	2	-
Mean	**17.5**	**0.0**	**-**	**0.0**	**-**
Min.	8.0	0.0	-	0.0	-
Max.	27.0	0.0	-	0.0	-
Class 5 (26-50 % infestation)					
n	2	2	-	2	-
Mean	**5.5**	**0.0**	**-**	**0.0**	**-**
Min.	0.0	0.0	-	0.0	-
Max.	11.0	0.0	-	0.0	-
Class 6 (51-100 % infestation)					
n	2	2	-	2	-
Mean	**20.5**	**0.5**	**2.4**	**0.0**	**-**
Min.	0.0	0.0	-	0.0	-
Max.	41.0	1.0	-	0.0	-

Table 6- 20: Dose justification for Kumar against **powdery mildew** on grape leaves in terms of **PESSEV** (6-class evaluation, 3.0 and 5.0 kg/ha)

Evaluation	UTC	BBCH 81-89 (after 7-12 applications)				UTC	BBCH 76-79 (after 7-8 applications)			
		Test product [kg/ha]					Test product [kg/ha]			
		3.0		5.0			3.0		5.0	
		[%]	% of UTC	[%]	% of UTC		[%]	% of UTC	[%]	% of UTC
Class 1 (< 5 % infestation)										
n	5	5	5	5	5	4	4	4	4	4
Mean	**14.4**	**21.9**	**152.5**	**22.3**	**155.6**	**18.6**	**21.6**	**116.4**	**23.8**	**128.3**
Min.	5.4	3.8	-	2.4	-	4.0	0.0	-	0.0	-
Max.	33.3	52.5	-	57.5	-	36.0	49.0	-	49.5	-
Class 2 (5-10 % infestation)										
n	5	5	5	5	5	3	3	3	3	3
Mean	**20.9**	**16.9**	**80.6**	**11.5**	**55.1**	**19.5**	**13.5**	**69.3**	**9.2**	**47.0**
Min.	11.8	6.8	-	2.0	-	2.0	0.0	-	0.0	-
Max.	29.5	26.5	-	24.0	-	34.8	30.5	-	15.5	-
Class 3 (11-25 % infestation)										
n	5	5	-	5	-	2	2	-	2	-
Mean	**14.8**	**8.2**	**55.6**	**6.6**	**44.3**	**16.9**	**3.9**	**22.8**	**2.3**	**13.6**
Min.	5.4	0.0	-	0.0	-	15.3	2.2	-	1.8	-
Max.	25.0	23.5	-	24.0	-	18.5	5.5	-	2.8	-
Class 4 (26-50 % infestation)										
n	5	5	-	5	-	2	2	-	2	-
Mean	**26.1**	**19.7**	**75.5**	**20.1**	**76.8**	**16.4**	**0.4**	**2.1**	**0.0**	**-**
Min.	1.3	0.0	-	0.0	-	14.3	0.0	-	0.0	-
Max.	76.5	94.8	-	97.5	-	18.5	0.7	-	0.0	-
Class 5 (50-75 % infestation)										

Evaluation	UTC	BBCH 81-89 (after 7-12 applications)				UTC	BBCH 76-79 (after 7-8 applications)			
		Test product [kg/ha]					Test product [kg/ha]			
		3.0		5.0			3.0		5.0	
		[%]	% of UTC	[%]	% of UTC		[%]	% of UTC	[%]	% of UTC
n	5	5	-	5	-	2	2	-	2	-
Mean	**3.7**	**0.9**	**24.1**	**0.5**	**13.2**	**1.7**	**0.1**	**3.0**	**0.0**	**-**
Min.	0.0	0.0	-	0.0	-	0.5	0.0	-	0.0	-
Max.	14.8	4.3	-	2.3	-	2.8	0.1	-	0.0	-
Class 6 (> 75 % infestation)										
n	4	4	-	4	-	1	1	-	1	-
Mean	**4.0**	**0.1**	**1.9**	**0.0**	**0.6**	**0.3**	**0.0**	**-**	**0.0**	**-**
Min.	0.0	0.0	-	0.0	-	-	-	-	-	-
Max.	8.7	0.3	-	0.1	-	-	-	-	-	-

Table 6- 21: Dose justification for Kumar against **powdery mildew** on grape leaves in terms of **PESSEV** (single trial, 7-class evaluation, 3.0 and 5.0 kg/ha)

Evaluation	UTC	BBCH 75 (after 5 applications)				UTC	BBCH 81 (after 6 applications)			
		Test product [kg/ha]					Test product [kg/ha]			
		3.0		5.0			3.0		5.0	
		[%]	% of UTC	[%]	% of UTC		[%]	% of UTC	[%]	% of UTC
Class 1 (no disease)										
n	1	1	-	1	-	1	1	-	1	-
Value	**43.5**	**86.0**	**197.7**	**91.1**	**209.4**	**19.3**	**53.3**	**276.2**	**58.5**	**303.1**
Class 2 (< 5 % infestation)										
n	1	1	-	1	-	1	1	-	1	-
Value	**0.0**	**0.0**	**-**	**0.0**	**-**	**0.0**	**0.0**	**-**	**0.0**	**-**
Class 3 (5-10 % infestation)										
n	1	1	-	1	-	1	1	-	1	-
Value	**31.2**	**9.1**	**29.2**	**8.4**	**26.9**	**7.3**	**7.5**	**102.7**	**15.3**	**209.6**
Class 4 (11-25 % infestation)										
n	1	1	-	1	-	1	1	-	1	-
Value	**8.5**	**1.0**	**11.8**	**0.2**	**2.4**	**21.2**	**1.2**	**5.7**	**1.9**	**9.0**
Class 5 (26-50 % infestation)										
n	1	1	-	1	-	1	1	-	1	-
Value	**12.2**	**2.4**	**19.7**	**0.1**	**0.8**	**51.0**	**35.3**	**69.2**	**22.3**	**43.7**
Class 6 (50-75 % infestation)										
n	1	1	-	1	-	1	1	-	1	-
Value	**0.1**	**0.1**	**100.0**	**0.0**	**-**	**0.9**	**1.8**	**200.0**	**0.6**	**66.7**
Class 7 (> 75 % infestation)										
n	1	1	-	1	-	1	1	-	1	-
Value	**0.0**	**0.0**	**-**	**0.0**	**-**	**0.0**	**0.0**	**-**	**0.0**	**-**

Conclusion

The presented dose justification demonstrates that the dose rate applied for represents the minimum effective dose rate to achieve sufficient efficacy against the target pests, both on grape bunches as well as on leaves. The recommended treatment corresponding to the proposed GAP use of 1-4 applications of 5.0 kg/ha is considered to be suitable for the control of grey mould (BOTRCI: *Botryotinia fuckeliana*) in grapevine and the recommended treatment corresponding to the proposed GAP use of 1-6 applications of 5.0 kg/ha is considered to be suitable for the control of powdery mildew (UNCINE: *Erysiphe necator*) in grapevine.

Thus, the dose rate of 5.0 kg/ha constitutes the minimum effective dose rate for Kumar in accordance with the EPPO standard PP 1/225 '*Minimum effective dose'*. This rate reflects the proposed label rate.

As a fungicide with protective mode of action, Kumar has to be applied before an infection with BOTRCI or UNCINE occurs, when climatic conditions for a fungal infection are optimal.
In practical viticulture, it is necessary and usual to apply different fungicides within a spray sequence throughout the vegetation period to keep the plants healthy. In these spray sequence of a number of applications, it is generally usual to alternate products with different Modes of Action[5]. Reasons for this can be preventing the development of resistance, or compliance with national or international maximum amounts; e.g. in the case of copper, it is impermissible to exceed an amount of 3 kg/ha in organic viticulture[6].
In efficacy trials testing a protective product as "Kumar", which is intended for 4 or 6 applications beginning at BBCH 57 (BOTRCI) and BBCH 75 (UNCINE), respectively, it is necessary to maintain disease free conditions until trial start, because an effective control would not be possible anymore if the plants were infected. The submitted trials simulate the application of Kumar within a usual spray sequence.
It would be possible to achieve disease free plants for such a long period until trial start by using a different fungicide with efficacy against the target diseases, but in the submitted trials it was decided to use Kumar applications instead. This decision has no effect on the overall outcome of the trial, taking into account the fact that a very long lasting effect of the single applications is not to be expected.
A repeated application of Kumar does not increase the overall efficacy against the target diseases, but is necessary to prevent the crop from new infections as the active substance is washed away from the plant surfaces or is degraded between two applications.
Therefore, the submitted trials testing Kumar within a common spraying sequence, are considered to be valid to demonstrate the efficacy of the product at the intended dose rate.

In the efficacy trials summarized under point IIIA1 6.1.2 (Minimum effective dose tests), the test product Kumar was tested with various application rates in 11 trials for *Botrytis cinerea* (BOTRCI) and 11 trials for *Erysiphe necator* (UNCINE) with trial sites in Austria, Switzerland and Germany. Applications were made up to 8 times. In 9 of 11 trials for *Botrytis cinerea* (BOTRCI) and in 7 of 11 trials for *Erysiphe necator* (UNCINE) a higher number of applications was used as proposed in GAP.
On the basis of the presented results, the dose justification data show that there is a clear dose-response relationship for the use of the product Kumar. The dose rate applied for represent the minimum effective dose rate achieve sufficient efficacy against the target pests, both on grape

[5] http://www.dlr-rheinpfalz.rlp.de/Internet/global/themen.nsf/0/5E4958A40A79B6EFC1257E0D00529F7B/$FILE/rahmenempfehlung2015.pdf
[6] http://biosicherheit-bch.de/SharedDocs/Downloads/04_Pflanzenschutzmittel/psm_verz_3.pdf?__blob=publicationFile&v=9

bunches as well as on leaves. The use is intended for 4 or 6 applications beginning at BBCH 57 (BOTRCI) and BBCH 75 (UNCINE) with a max rate of 5.0 kg/ha. See Appendix 2.

Label claim:

Crop	Target	Application timing	No. of appli-cations	Minimum application interval (days)	PHI (days)	Spray volume (L/ha)	Dose rate	
							kg/ha	g ai/ha
Grapevine	*Botryotinia fuckeliana*	BBCH 75 - 89	4	8- 30	1 day	800 - 1,600	5.0	4250
	Erysiphe necator	BBCH 57-85	6	7-10	1 day	200 - 1,600*	5.0*	4250

* Dose rate and amount of water depend on the growth stage of the crop:
BBCH 57: 1.25 kg/ha in 200-400 L/ha Water
BBCH 61: 2.5 kg/ha in 400-800 L/ha Water
BBCH 71: 3.75 kg/ha in 600-1200 L/ha Water
BBCH 75: 5.0 kg/ha in 800-1600 L/ha Water

IIIA1 6.1.3 Efficacy tests

Introductory information on efficacy trials with Kumar in grapevine

A total of 44 trials were carried out to evaluate the efficacy of Kumar for the control of the fungal diseases **grey mould** (1) and **powdery mildew** (2) in grapevine. All trials followed the appropriate EPPO standards by officially recognized testing organisations and were conducted according to GEP or are classified as GEP-compliant. The trials were of a randomised complete block design or a 1-factor block design with four or five replicates and a minimum plot size of 9 m^2. Trials have been conducted between 2003 and 2015 in Switzerland, Austria, Germany and France, all representing the Maritime EPPO climatic zone.

In the following table an overview is provided on the efficacy trials per use submitted with this dossier.

Table 6- 22: Overview of effectiveness trials

Use no.	Crop	Pest	No. of efficacy trials	EPPO PP
(1)	Grapevine	BOTRCI: *Botryotinia fuckeliana*	28 trials	1/17(3)
(2)	Grapevine	UNCINE: *Erysiphe necator*	16 trials	1/4(3/4)

According to the GAP, the application should be conducted with a water amount of 800 - 1,600 L/ha (*Botryotinia fuckeliana*) or 200 - 1,600 L/ha (*Erysiphe necator*, amount of water depends on the BBCH stage of the crop). To avoid dripping losses, for practical use it is recommended to apply only a maximum of 800 L/ha (see Register of Plant Protection Products[7]). Therefore, water amount in field trials evaluated for this document may vary from the water amount stated in the GAP in Appendix 2.

For detailed information about the envisaged GAP use please refer to Appendix 2 of this document.

In the table below the number of trials per use, country and year are presented.

Table 6- 23: Number of efficacy trials included in the BAD, including **GEP** and **GEP-compliant** trials

No.	Pest	Year[1)] / Country	2003	2004	2005	2006	2007	2008	2009	2010	2011	2013	2014	2015	Total
(1)	BOTRCI	CH				4*)		3*)	1*)						**8**
		AT					3		1	3	1				**8**
		DE			1			2				**3**	**2**	**3**	**11**
		FR					1								**1**
(2)	UNCINE	CH	3*)	2*)				2*)							**7**
		AT		2*)											**2**
		DE										**2**	**2**	**3**	**7**
Total			**3**	**4**	**1**	**4**	**4**	**7**	**2**	**3**	**1**	**5**	**4**	**6**	**44**

[1)] The indicated year refers to the year of treatment
[*)] In Switzerland an official GEP certification system was not available prior to 2010. In Austria an official GEP certification was implemented in 2005. Nevertheless, all trials were conducted according to the respective EPPO guideline and are considered as GEP-compliant for the reasons outlined in detail on page 28.

[7] Available online: http://www.bvl.bund.de/EN/04_PlantProtectionProducts/02_AuthorizedPlantProtectionProducts/01_Register/PlantProtectionProducts_ppp_register_node.html (September 2015)

Table 6- 24: Guidelines and trial design, efficacy tests

GEP	GEP (27x), GEP compliant (17x)*
Standards	EPPO PP 1/4(3/4), 1/17(3), 1/31(2), 1/135(2/3), 1/152(2/3/4), 1/181(2/3/4), CEB No. 37
Number of replications	3 (2x), 4 (35x), 5 (7x)
Plot design	RB (43x), FB (1x)
Trials per crop	Grape vine (44x)
Trials per intended use	Grape vine – BOTRCI (28x) Grape vine – UNCINE (16x)
Number of varieties per crop	Bachus (1x) Chardonnay (1x) Chasselas (3x) Dornfelder (1x) Faberrebe (1x) Gamay (5x) Kerner (3x) Müller Thurgau/Riesling x Sylvaner (6x) Pinot blanc/Weissburgunder (4x) Pinot noir/Spätburgunder (7x) Riesling (1x) Sauvignon blanc (1x) Scheurebe (2x) Schwarzriesling/Pinot Meunier (3x) Sémillion (1x) Sylvaner (1x) Welschriesling (1x) Zweigelt (2x)
Sowing date	1972-2005, n.r. (4x)
Crop stage (BBCH) at 1st application	Grape vine – BOTRCI = BBCH 59-79 Grape vine – UNCINE = BBCH 13-57
Reference products	Please refer to Table 6- 26

* In Switzerland an official GEP certification system was not available prior to 2010. In Austria an official GEP certification was implemented in 2005. Nevertheless, all trials were conducted according to the respective EPPO guideline and are considered as GEP-compliant for the reasons outlined in detail on page 28.

Justification for GEP compliance of trials for which a GEP certificate was not available at the time of conduct

From Switzerland 18 efficacy trial reports, of which three trials merely cover selectivity results, and one processing trial report with two varieties are available from the test facility Stähler Suisse SA (formerly: Siegfried Agro AG) from the years 2003 until 2009. In Switzerland, as a Non-EU country, currently there is no obligatory GEP certification in place. Since 2010 a GEP accreditation system has been implemented in Switzerland on a voluntary basis. The test facility Stähler Suisse SA achieved a GEP accreditation from Swiss authorities in 2010 (29.10.2010).

From Austria 2 reports are available from the year 2004. In the context of the EU harmonisation, in Austria a GEP accreditation system has already been implemented in 1997. Nevertheless, GEP certificates were first issued since 2005 in Austria. Prior to this time only an official registration of test facilities was required.

However, also the herewith submitted trials from the years before the GEP accreditation in Switzerland and before the issuing of GEP certificates in Austria miss an official GEP certificate, these trials can be considered as equivalent to GEP, since the trials were conducted **according to EPPO guidelines** and the reports generally **reflect the fulfilment of GEP requirements** with regard to the following aspects:

- nomination of study director and investigator (for each name, position, address)
- signature of study director (in 10 out of 21 trials)
- use of study protocol (in 10 out of 21 trials)
- reporting of results as mean values and single plot data
- detailed description of trial location (latitude/longitude, postal code, landowner, address)
- definition of general AND of indication/use specific EPPO guidelines
- detailed definition of test product (s) (trade name, a.i. content, formulation type, provider)
- details on crop (name, EPPO code, age of plantation, variety)
- details on pest (name, scientific name)
- trial design (plot size, length/width, tillage type, site type, replication number)
- agricultural conditions (e.g. maintenance, soil description, weather during study)
- details of application(s) (date, time, type, weather conditions, crop stage, disease stage, spray equipment)
- treatment details (rate in g/ha of a.i. and product, spray concentration)
- details on reference products (product name, a.i. content, formulation type)

In addition, the evaluation and reporting was obviously conducted by the system ARM and thus guarantees a standardised and clear arranged reporting format and standard report contents.

Therefore, the above mentioned trials are specified in this BAD as GEP-compliant.

Material and methods

Assessment of efficacy data

The majority of trials were conducted in accordance with GEP principles and following the EPPO guideline PP 1/152 ‘*Design and Analysis of Efficacy Evaluation Trials’* and PP 1/181 ‘*Conduct and reporting of Efficacy Evaluation Trials’* by officially recognised testing organisations. The assessments of the fungal diseases, both of grey mould and powdery mildew, were carried according to the appropriate EPPO standard: PP 1/17(3) ‘*Botryotinia fuckeliana on grapevine*’ and PP 1/4(4) ‘*Uncinula necator*’.

In all efficacy trials one to four assessments were carried out to evaluate the effectiveness of the test and several reference products against the fungal diseases. If more than one assessment was performed according to the proposed EPPO interval, the one with the highest efficacy is shown. Initial pest populations on the control site were not reported. This is due to the fact that Kumar is used as a preventive measure. The assessment of the infection level of grey mould was usually carried out one to eight weeks after the third or eighth application. The assessment of powdery mildew was carried out one to six weeks after the fifth to twelfth application. The development stage of the grapevine during assessments was usually for grey mould at the crop growth stage of BBCH 75-87 and BBCH 89 and for powdery mildew at BBCH 74-79 and BBCH 81-89 for leaves and BBCH 74-79, BBCH 81-87 and BBCH 89 for bunches representing the development of fruits and the stage of berry ripening.

In general, in this dossier results in terms of pest severity (PESSEV) and pest incidence (PESINC) were calculated acc. to the Abbott formula. Class evaluations in terms of percentage of pest coverage were converted into [% of control] of the mean in the respective classes. Evaluation was separated in trials testing systemic and/or contact and/or mixed reference products where a tank mix of both systemic and contact fungicides was tested. Please note that presented means do not necessarily include the results of all trials included in each application scenario. This is due to the fact that not all reference products are evaluated in each trial. Furthermore, results with an infestation degree of the untreated control below 5 % were excluded from analysis with the exception of the evaluation of the infestation classes where all data are shown. Also, trials where neither the test nor the reference product achieved an acceptable efficacy were not considered as valid trials and were excluded from mean efficacy calculation. These trials are marked with an asterisk in the detailed tables.

Table 6- 25 gives an overview of the different rating types which were conducted to determine the efficacy of the product Kumar in grapevine. Basically, it was differentiated between efficacy on bunches and leaves in terms of PESSEV (pest severity) and PESINC (pest incidence).

Table 6- 25: Description of efficacy assessments

Pest	Type of assessments	Untreated plot	Treated plot
BOTRCI	PESSEV	**Pest severity on bunches (%):** Visual assessments of the percentage of pest coverage on bunches on each plot. **Pest severity (no.):** Visual assessment of the percentage of surface pest coverage of bunches in 4-6 classes (for scaling see tables of mean calculation). Equivalent to the intensity of damage by calculating the intensity in %.	Assessment of infection level: Refer to untreated plots. **Efficacy calculation acc. to Abbott:** Pest severity: $100^* [1-(SEV_{treatment}/SEV_{control})]$ Pest incidence: $100^* [1-(INC_{treatment}/INC_{control})]$ **% of control**: Pest severity: $(SEV_{treatment}/SEV_{control})^*100$
	PESINC	**Pest incidence on bunches (%):** Visual assessments of the percentage of infected bunches on each plot	
UNCINE	PESSEV	**Pest severity on bunches (%):** Visual assessments of the percentage of pest coverage on bunches on each plot. **Pest severity on leaves (%):** Visual assessments of the percentage of pest coverage on leaves on each plot. **Pest severity (no.):** Visual assessment of the percentage of surface pest coverage of bunches and leaves in 5-7 classes (for scaling see tables of mean calculation). Equivalent to the intensity of damage by calculating the intensity in %.	Assessment of infection level: Refer to untreated plots. **Efficacy calculation acc. to Abbott:** Pest severity: $100^* [1-(SEV_{treatment}/SEV_{control})]$ Pest incidence: $100^* [1-(INC_{treatment}/INC_{control})]$ **% of control**: Pest severity: $(SEV_{treatment}/SEV_{control})^*100$
	PESINC	**Pest incidence on bunches (%):** Visual assessments of the percentage of infected bunches on each plot **Pest incidence on leaves (%):** Visual assessments of the percentage of infected leaves on each plot	

The following Table 6- 26 gives an overview of all reference products and reference product mixtures, which are referred to in this dossier to determine the comparative efficacy of the product Kumar against the two target species grey mould (BOTRCI: *Botryotinia fuckeliana*) and powdery mildew (UNCINE: *Erysiphe necator)* in grapevine. Evaluation was separated in trials testing systemic and/or contact and/or mixed reference products where a tank mix of both systemic and contact fungicides was tested.

Table 6- 26: Overview of reference products used in efficacy trials

Reference product	Formulation	Active substance	Concentration [g/L, kg]
BOTRCI			
Topsin	SC	thiophanate-methyl	500
Frupica	WG	mepanipyrim	500
Frupica SC	SC	mepanipyrim	449.4
Cercobin	SC	thiophanate-methyl	550
Teldor	WG	fenhexamid	500
Euparen M WG M	WG	tolylfluanid	505
Switch	WG	cyprodinil+fludioxonil	375+250
Vitisan	WP	potassium bicarbonate	995
Frupica SC+ Teldor	SC WG	mepanipyrim fenhexamid	449.4 500
Switch+ Sumisclex	WG WG	cyprodinil+fludioxonil procymidone	375+250 500
UNCINE			
Prosper+ Amarel Folpet DF	EC WG	spiroxamine cymoxanil+folpet	499.5 80+535
Prosper+ Vincare	EC WG	spiroxamine benthiavalicarb-isopropyl +folpet	499.5 17.5+500
Topas Ortho-Phaltan Flüssig	EC SC	penconazol folpet	100 500
Oxykupfer+ Soufralo	WP WG	copper oxychloride sulphur	500 800
Systhane 20 EW	EW	myclobutanil	200
Kumulus WG	WG	sulphur	800
Netzschwefel Stulln	WG	sulphur	798.4
Olymp Duplo DF	WG	flusilazole+cymoxanil+folpet	20+80+500
Multivino	WG	folpet+copper+fenpropidine	300+150+60

Interpretation of efficacy data

Potassium bicarbonate is a pure protective contact fungicide without any systemic action. Therefore, several factors need to be considered to account for these specificities. One of the first requirements to be met in order to get full protection is the need to achieve a dense layer of the product on the target area, including both leaves and bunches. But in a canopy with different plant heights, leaves are shading each other. So it is not always guaranteed that each single leaf is reached by the fungicide, due to insufficient application machinery and/or technique, and thus may remain unprotected. Furthermore, the grapevine can already be infected with the target pests for several months (e.g. in dormant buds, bark, bunch stems, rotten berries), before first symptoms become visible.

These factors implement three consequences:

(i) Due to the shading effects, it is likely that the pathogen even after being treated with potassium bicarbonate can establish itself. Thus, the main objective of the treatment is not to eliminate the target pest completely, but to achieve a lower extent of the infestation. This effect is especially pronounced in crops with dense canopies. In this case the parameter of pest severity is considered to be more relevant.

(ii) The level of performance (expressed as efficacy) should be evaluated not only on an absolute scale, but always in the context of a comparable plant protection product. Therefore, the performance of another protective fungicide based on an inorganic active ingredient needs to be taken into account.

(iii) Potassium bicarbonate will never be applied successively as a sole component like it is done in the present trials, but it will always be implemented in a spray sequence, probably also containing systemic compounds.

(1) Grapevine (BOTRCI: *Botryotinia fuckeliana*)

Label claim:

Crop	Target	Application timing	No. of appl. and interval (days)	PHI (days)	Spray volume (L/ha)	Dose rate		Total rate/ season
						kg, L product/ ha	kg ai/ha	
Grape	*Botryotinia fuckeliana*	BBCH 75 -89	4 (8-30)	1 day	800 - 1,600	5.0	4.25	max. 17 kg/ha

Material and method

The test product Kumar was applied at a dose rate of 5.0 kg/ha (equivalent to 4250 g ai/ha). The number of applications ranged from 3 to 8 treatments with an interval of 7-55 days.

According to the proposed GAP use up to four treatments of Kumar at BBCH 75-89 is applied for control of BOTRCI. In efficacy trials BBCH stages range from 59-89. This trial design was chosen due to the fact that Kumar is a pure contact fungicide and needs to be applied as a preventive measure. Thus, to eliminate potential side effects arising from the application of additional fungicides, Kumar was applied throughout the cropping period.

Both, the percentage of bunch area infected (pest severity) as well as the percentage of infected bunches (pest incidence) on grape bunches should be assessed. Beside the overall assessment of pest severity per plot, furthermore, in the majority of trials the pest severity on bunches was classified according to different classes, ranging from no infection to the complete infestation of bunches.

In the majority of trials, one census was carried out, usually at BBCH 89, which refers to the development stage of *"berries ripe for harvest"*. Furthermore, in some trials earlier assessments were conducted at BBCH 75-87, referring to the development stage *"softening of berries"*.

In general, in this dossier results in terms of pest severity (PESSEV) and pest incidence (PESINC) were calculated acc. to the Abbott formula. Class evaluations in terms of percentage of pest coverage were converted into [% of control] of the mean in the respective classes. Evaluation was separated in trials testing systemic and/or contact and/or mixed reference products where a tank mix of both systemic and contact fungicides was tested. Please note that presented means do not necessarily include the results of all trials included in each application scenario. This is due to the fact that not all reference products are evaluated in each trial. Furthermore, results with an infestation degree of the untreated control below 5 % were excluded from analysis with the exception of the evaluation of the infestation classes where all data are shown. Also, trials where neither the test nor the reference product achieved an acceptable efficacy were not considered as valid trials and were excluded from mean efficacy calculation. These trials are marked with an asterisk in the detailed tables.

Results of GEP and GEP-compliant efficacy trials (BOTRCI)

In the following an overview is presented of relevant assessment dates with the mean Pest severity and Pest incidence in percent. Additionally, the effectiveness of Kumar after application in terms of the percentage of pest coverage was evaluated in terms of four to six different classes by converting into [% of control] of the mean in the respective classes.

On an aggregated level, the results of 28 trials were further processed, including trials over the years 2006-2015 in Switzerland, Austria, Germany and France. The mean infection level of the untreated control comprises fluctuating results from high to low infection levels, ranging across trials between 6.8-94.0 % in terms of pest incidence and 7.5-80.0 % in terms of pest severity on bunches. Evaluating trials conducted with systemic reference products the mean effectiveness of Kumar against grey mould ranges between 62.3 % (BBCH 89) and 76.4 % (BBCH 75-87) in terms of **pest incidence** and 60.9 % (BBCH 89) and 65.9 % (BBCH 75-87) in terms of **pest severity** on bunches. The mean effectiveness of the different **systemic reference products** ranges between 73.4 % (BBCH 89) and 88.3 % (BBCH 75-87) in terms of **pest incidence** and 68.8 % (BBCH 89) and 60.8 % (BBCH 75-87) in terms of **pest severity** on bunches (refer to Table 6- 27). Evaluating trials where a **contact fungicide** was used as reference product, mean effectiveness of Kumar at BBCH 89 was 70.9 % in terms of **pest incidence** and 77.9 % in terms of **pest severity** on bunches and therefore better compared to other contact fungicides. The mean effectiveness of the different contact reference products was 46.2 % in terms of **pest incidence** and 56.9 % in terms of **pest severity** on bunches (refer to Table 6- 27).

Additionally, in 20 trials, the effectiveness of Kumar regarding the infestation degree on grape bunches was evaluated in terms of four (4 trials) or six (16 trials) different classes. In general, it was shown that the percentage of plants belonging to class 1 (*no disease/low infestation level*) increased from the untreated control to the test and the reference product. Vice versa, the percentage of plants belonging to the highest class (*high infestation level*) decreased comparing the untreated control and the test and/or reference product. All assessment dates and classes are shown in the table below (refer to Table 6- 28 and Table 6- 29).

In conclusion, the results indicate that when the product Kumar is applied according to the envisaged GAP use, both the pest severity as well as the pest incidence can be controlled. Compared to systemic fungicides the efficacy of Kumar was slightly lower but was even better than other contact fungicides in the trials. In the following tables, an overview is presented of the mean effectiveness results. The efficacy data submitted for the use against grey mould in grapevine comply with the uniform principles as envisaged by EPPO (PP 1/181).

BOTRCI – *Assessments on bunches*

Table 6- 27: Mean effectiveness [%] of 5.0 kg/ha Kumar on bunches compared to reference products against grey mould in grapevine

Rating data type	Part rated	No. of appl.	Evaluation	UTC (trials testing systemic RP)	UTC (trials testing contact RP)	Efficacy [%] acc. to Abbott			
						Test product (trials testing systemic RP)	Test product (trials testing contact RP)	RP 1 (systemic)	RP 2 (contact)
						5.0 kg/ha	5.0 kg/ha		
BBCH 89									
PESINC	bunches	3-8	n	20	3	20	3	20	3
			Mean	**44.9**	**42.8**	**62.3**	**70.9**	**73.4**	**46.2**
			Min.	9.5	19.0	18.9	58.9	21.6	39.7
			Max.	94.0	60.7	100.0	81.7	100.0	57.9
PESSEV	bunches	3-6	n	17	3	17	3	17	3
			Mean	**29.3**	**30.6**	**60.9**	**77.9**	**68.8**	**56.9**
			Min.	7.7	8.5	23.8	65.9	25.0	47.8
			Max.	80.0	47.3	81.8	85.8	93.3	71.8
BBCH 75-87									
PESINC	bunches	2-8	n	5	-	5	-	5	-
			Mean	**42.8**		**76.4**		**88.3**	
			Min.	6.8		47.0		68.9	
			Max.	93.3		100.0		100.0	
PESSEV	bunches	2-6	n	2	-	2	-	2	-
			Mean	**8.1**		**65.9**		**60.8**	
			Min.	7.5		64.8		28.6	
			Max.	8.6		67.0		93.0	

Table 6- 28: Mean effectiveness [%] of 5.0 kg/ha Kumar on bunches compared to reference products against grey mould in grapevine in terms of **PESSEV** (4-class evaluation)

Evaluation	UTC	BBCH 89 (after 6-8 applications)				UTC	BBCH 85 (after 6-8 applications)			
		Test product 5.0 kg/ha		RP (systemic)			Test product 5.0 kg/ha		RP (systemic)	
		[%]	% of UTC	[%]	% of UTC		[%]	% of UTC	[%]	% of UTC
Class 1 (1-5 % infestation)										
n	4	4	-	4	-	3	3	-	3	-
Mean	**11.0**	**15.4**	**140.2**	**18.0**	**163.9**	**8.5**	**3.9**	**45.7**	**4.5**	**52.8**
Min.	0.0	0.0	-	0.0	-	0.4	0.0	-	0.0	-
Max.	29.2	46.8	-	52.2	-	20.6	10.6	-	12.6	-
Class 2 (5-25 % infestation)										
n	4	4	-	4	-	3	3	-	3	-
Mean	**20.8**	**16.6**	**80.0**	**13.2**	**63.6**	**0.9**	**0.0**	**-**	**0.0**	**-**
Min.	7.6	4.4	-	3.6	-	0.6	0.0	-	0.0	-
Max.	34.4	40.2	-	30.0	-	1.5	0.0	-	0.0	-
Class 3 (26-50 % infestation)										
n	4	4	-	4	-	3	3	-	3	-
Mean	**16.2**	**7.0**	**43.5**	**4.2**	**25.9**	**0.0**	**0.0**	**-**	**0.0**	**-**
Min.	11.1	1.0	-	1.1	-	0.0	0.0	-	0.0	-
Max.	25.6	23.2	-	12.4	-	0.0	0.0	-	0.0	-
Class 4 (> 50 % infestation)										
n	4	4	-	4	-	3	3	-	3	-
Mean	**5.6**	**2.6**	**45.5**	**0.9**	**16.1**	**0.0**	**0.0**	**-**	**0.0**	**-**
Min.	0.0	0.0	-	0.0	-	0.0	0.0	-	0.0	-
Max.	11.2	6.8	-	2.4	-	0.0	0.0	-	0.0	-

Table 6- 29: Mean effectiveness [%] of 5.0 kg/ha Kumar on bunches compared to reference products against grey mould in grapevine in terms of **PESSEV** (6-class evaluation)

Evaluation	UTC (trials testing systemic RP)	UTC (trials testing contact RP)	BBCH 89 (after 3-4 applications)							
			Test product (trials testing systemic RP)		Test product (trials testing contact RP)		RP 1 (systemic)		RP 2 (contact)	
			5.0 kg/ha		5.0 kg/ha					
			[%]	% of UTC	[%]	% of UTC	[%]	% of UTC	[%]	% of UTC
Class 1 (no disease)										
n	13	3	13	-	3	-	13	-	3	-
Mean	**33.4**	**57.5**	**50.6**	**151.7**	**89.2**	**155.2**	**56.9**	**170.5**	**75.4**	**131.3**
Min.	2.0	39.7	16.0	-	87.0	-	29.0	-	64.0	
Max.	90.5	81.0	98.5	-	92.3	-	100.0	-	92.0	
Class 2 (0-2.5 % infestation)										
n	13	3	13	-	3	-	13	-	3	-
Mean	**4.1**	**3.5**	**2.7**	**66.2**	**1.4**	**41.0**	**2.5**	**60.6**	**2.1**	**59.0**
Min.	0.0	1.7	0.0	-	0.0	-	0.0	-	0.0	
Max.	13.0	5.5	8.0	-	3.0	-	8.0	-	5.5	
Class 3 (2.5-10 % infestation)										
n	13	3	13	-	3	-	13	-	3	-
Mean	**8.3**	**5.9**	**6.2**	**74.1**	**4.2**	**71.8**	**4.7**	**56.8**	**5.5**	**93.2**
Min.	2.0	5.0	0.0	-	3.0	-	0.0	-	1.5	
Max.	29.0	7.0	21.0	-	6.7	-	15.0	-	8.0	
Class 4 (11-25 % infestation)										
n	13	3	13	-	3	-	13	-	3	-
Mean	**10.4**	**9.6**	**5.7**	**55.2**	**3.9**	**41.1**	**3.6**	**34.7**	**8.9**	**93.4**
Min.	2.0	3.0	0.0	-	1.8	-	0.0	-	0.8	
Max.	20.0	15.7	20.0	-	5.3	-	13.0	-	17.3	
Class 5 (26-50 % infestation)										
n	13	3	13	-	3	-	13	-	3	-
Mean	**6.5**	**10.5**	**3.0**	**46.5**	**1.0**	**9.5**	**1.8**	**27.1**	**5.3**	**50.8**
Min.	0.0	3.5	0.0	-	0.0	-	0.0	-	0.3	
Max.	18.8	14.7	15.0	-	2.0	-	7.0	-	8.7	
Class 6 (51-100 % infestation)										
n	13	3	13	-	3	-	13	-	3	-
Mean	**9.4**	**13.7**	**3.7**	**39.0**	**0.2**	**1.7**	**2.0**	**20.9**	**2.5**	**18.5**
Min.	0.0	0.0	0.0	-	0.0	-	0.0		0.0	
Max.	57.0	24.3	31.0	-	0.7	-	18.0		4.3	

Conclusion

The results demonstrate that good efficacy of Kumar against grey mould (BOTRCI: *Botryotinia fuckeliana*) is achieved when the product is applied according to the envisaged GAP use, comprising up to four applications of Kumar at rate of 5.0 kg/ha (equivalent to 4250 g ai/ha).

In general, the mean effectiveness results across the different application scenarios are very variable: low as well as high effectiveness levels were found for both the test product Kumar as well as for several reference products. This holds true for the direct comparison of the means of the test and the reference products as well. In this dossier, a number of different reference products and reference product-mixtures were used to evaluate the efficacy data. To account for this variation, it has to be differentiated between conventional products with chemically derived organic compounds and a systemic fungicidal action and alternative contact products, which are mainly based on inorganic active ingredients. Efficacy levels of reference products with organic active ingredients, like Teldor or Switch, usually show higher efficacy results than alternative products with inorganic compounds, like Vitisan (refer to Table 6- 42). The use of alternative products is especially relevant in organic farming as only a limited number of products are currently available.

Although, in the majority of trials the grey mould infection is equally controlled by the test product and the different reference products and reference product mixtures already on the market. In some trials the effectiveness of Kumar is slightly reduced when compared to the respective reference products. For example, the reference product Switch shows a constantly better performance than the test product Kumar (refer to Table 6- 28). Compared to other contact fungicides with inorganic compounds, Kumar shows better control of grey mould.

From the perspective of this dossier, it is suggested that the fluctuations regarding efficacy might be related to the high variation of the infection level of the untreated control. A high infection level often reduced the mean effectiveness of the test product Kumar. Thus, initial high infestation degrees are strongly associated with generally lower efficacy levels.

Kumar is considered to be an appropriate measure for the control of grey mould according to the proposed GAP use applied for (refer to Appendix 2), since good effectiveness of the application of the product Kumar is demonstrated. Despite the fact of highly variable results, the application of Kumar still demonstrates good efficacy, both in terms of pest severity and pest incidence on bunches. Thus, the envisaged GAP use of the test product Kumar in grape to treat grey mould infections is from the point of this dossier considered as valid.

(2) Grapevine (UNCINE: *Erysiphe necator*)

Label claim:

Crop	Target	Application timing	No. of appl. and interval (days)	PHI (days)	Spray volume (L/ha)	Dose rate		Total rate/ season
						kg, L product/ ha	kg ai/ha	
Grape	*Erysiphe necator*	BBCH 57-85	6 (7-10)	1 day	200 - 1,600*	5.0*	4.25	max. 25.5 kg/ha

* Dose rate and amount of water depend on the growth stage of the crop: BBCH 57: 1.25 kg/ha
BBCH 61: 2.5 kg/ha
BBCH 71: 3.75 kg/ha
BBCH 75: 5.0 kg/ha

Material and method

The test product Kumar was applied at a dose rate of 5.0 kg/ha (equivalent to 4250 g ai/ha). The dose rate depends on the growth stage of the crop and assessments at earlier BBCH stage were carried out with a lower dose rate (3.75 kg/ha for BBCH 71-74). The number of applications ranged between 5 to 12 with an interval of 7-16 days (twice: 2 days; application has to be renewed because of heavy rain). In the following an overview is given about the different application scenarios to evaluate the efficacy.

The assessment of the efficacy level was carried out in the majority of trials according to the respective EPPO guideline PP 1/4(4) "*Uncinula necator*". The percentage of pest coverage (pest severity) on leaves as well as on bunches should be assessed. Beside the overall assessment of pest severity and pest incidence on leaves and bunches per plot, furthermore, in most trials the pest severity was classified according to four to seven different classes, ranging from no infection to infestation levels up to 100 %.

The following assessments were carried out at BBCH 81-89 and an intermediate assessment at BBCH 74-79 on leaves and at BBCH 74-79, BBCH 81-87 and BBCH 89 on bunches according to the EPPO guideline PP 1/4(4). This covers early and late stages of berry development from "*berries pea-sized, bunches hang*" to "*berries ripe for harvest*".

In general, in this dossier results in terms of pest severity (PESSEV) and pest incidence (PESINC) were calculated acc. to the Abbott formula. In some Swiss and in Austrian trials a deviating calculation method, was used, accounting for each replicate respectively. In this case results were recalculated in this dossier to achieve a better comparability of results. Class evaluations in terms of percentage of pest coverage were converted into [% of control] of the mean in the respective classes. Evaluation was separated in trials testing systemic and/or contact and/or mixed reference products where a tank mix of both systemic and contact fungicides was tested. Please note, that presented means do not necessarily include the results of all trials included in each application scenario. This is due to the fact that not all reference products were evaluated in each trial. Furthermore, results with an infestation degree of the untreated control below 5 % were excluded from analysis with the exception of the evaluation of the infestation classes where all data are shown. Also, trials where neither the test nor the reference product achieved an acceptable efficacy were not considered as valid trials and were excluded from mean efficacy calculation.

Results of GEP and GEP-compliant efficacy trials (UNCINE)

In the following an overview is presented of relevant assessment dates with the mean Pest severity and Pest incidence in percent. Additionally, the effectiveness of Kumar after application in terms of the percentage of pest coverage was evaluated in terms of five to seven different classes by converting into [% of control] of the mean in the respective classes.

Firstly, the assessment of **vine leaves** is considered: the infection level of the untreated control includes high to low infection levels, ranging between 8.8-87.0 % in terms of pest incidence and 12.0-78.8 % in terms of pest severity on leaves. When evaluating the trials conducted with **systemic reference products** on leaves the mean effectiveness of Kumar at 5.0. kg/ha against powdery mildew ranges between 79.9 % (BBCH 81-89) and 87.4 % (BBCH 75-79) in terms of **pest incidence** and 55.5 % efficacy in terms of **pest severity**. The mean effectiveness of the different systemic reference products ranges between 27.8-43.3 % in terms of **pest incidence** and 38.3 % in terms of **pest severity**. In 2 trials a lower dose rate (3.75 kg/ha) adapted to a lower growth stage of the crop was tested and a slightly reduced efficacy was reported (**pest incidence**: test product: 67.9 %; reference product: 55.2 %; refer to Table 6- 30 and Table 6- 31). Overall, efficacy was better compared to the systemic reference products tested in trials.
When evaluating the trials conducted with **contact reference products** the mean effectiveness of Kumar at 5.0 kg/ha ranges between 77.6 % (BBCH 81-89) to 87.4 % (BBCH 75-79) in terms of pest incidence and 80.5 % efficacy in terms of pest severity on leaves. The mean effectiveness of the different contact reference products ranges between 78.6-89.7 % in terms of **pest incidence** and 82.0 % in terms of **pest severity** on leaves. In 2 trials a lower dose rate (3.75 kg/ha) adapted to a lower growth stage of the crop was tested and a slightly reduced efficacy was reported (**pest incidence**: test product: 67.9 %; reference product: 74.4 %; refer to Table 6- 31). Overall, efficacy was comparable to the contact reference products tested in trials.
In 3 trials a mixed reference product was used; the mean effectiveness of Kumar at BBCH 81-89 was 85.9 % in terms of **pest severity** on leaves. The mean effectiveness of the different mixed reference products was 89.9 % in terms of pest severity on leaves (refer to Table 6- 31).

Secondly, the assessment of **grape bunches** is considered: the infection level of the untreated control includes high to low infection levels, ranging between 10.5-90.0 % in terms of pest incidence and 5.2-84.3 % in terms of pest severity on bunches for all assessment dates (BBCH 75-79, BBCH 81-87, BBCH 89). When evaluating the trials conducted with **systemic reference products** the mean effectiveness of Kumar at 5.0 kg/ha against powdery mildew on bunches ranges between 62.4 % (BBCH 81-87), 71.9 % (BBCH 89) and 80.6 % (BBCH 75-79) in terms of pest incidence and 13.9 % (BBCH 89) and 39.9 % (BBCH 81-87) in terms of pest severity. The mean effectiveness of the different systemic reference products ranges between 5.6-46.2 % in terms of **pest incidence** and 7.7-46.2 % in terms of **pest severity** on bunches. In one trial a lower dose rate (3.75 kg/ha) adapted to a lower growth stage of the crop was tested and a better or comparable efficacy compared to the reference product was reported (**pest incidence**: test product: 57.0 %; reference product: 42.3 %; **pest severity**: test product: 64.7 %; reference product: 63.2 %; refer to Table 6- 32 and Table 6- 33). Overall, efficacy was better compared to the systemic reference products tested in trials.
When evaluating the trials conducted with **contact reference products** the mean effectiveness of Kumar ranges between 71.0 % (BBCH 81-87), 71.9 % (BBCH 89) and 80.6 % (BBCH 75-79) in terms of **pest incidence** and 13.9 % (BBCH 89) and 75.2 % (BBCH 81-87) in terms of **pest severity** on bunches. The mean effectiveness of the different contact reference products ranges between 61.2-69.3 % in terms of **pest incidence** and 57.2-67.4 % in terms of **pest severity** on bunches. In one trial a lower dose rate (3.75 kg/ha) adapted to a lower growth stage of the crop was tested and a better or comparable efficacy compared to the reference product was reported (**pest incidence**: test product: 57.0 %; reference product: 76.5 %; **pest severity**: test product: 64.7 %; reference product: 91.7 %; refer to Table 6- 32 and Table 6- 33). Overall, efficacy was better compared to the contact reference products tested in trials.
In 4 trials a mixed reference product was used; the mean effectiveness of Kumar ranges between 66.7 (BBCH 75-79) and 98.9 % (BBCH 81-87) in terms of **pest incidence** and 98.6 % (BBCH 81-87) and 100.0 % (BBCH 75-79) in terms of pest severity. The mean effectiveness of the mixed reference products

ranges between 66.7-99.7 % in terms of **pest incidence** and between 99.7-100.0 % in terms of **pest severity** (refer to Table 6- 33). Overall, the test product acted comparable to the mixed reference products.

Additionally, the effectiveness of Kumar regarding the infestation degree on grape bunches was evaluated in terms of five to seven different classes. In general, it was shown that the percentage of plants belonging to class 1 (*no disease/low infestation level*) increased from the untreated control to the test and the reference product. Vice versa, the percentage of plants belonging to the highest class (*high infestation level*) decreased comparing the untreated control and the test and/or reference product. All assessment dates and classes are shown in the tables below (refer to Table 6- 34 to Table 6- 41).

In conclusion, on an aggregated level, the results indicate that when the product Kumar is applied according to the envisaged GAP use the level of infection, both on bunches and leaves, is sufficiently controlled. In the following tables, an overview is presented with the mean effectiveness results. The efficacy data submitted for the use against powdery mildew in grapevine comply with the uniform principles as envisaged by EPPO (PP 1/181).

UNCINE – *Assessments on leaves*

Table 6- 30: Mean effectiveness [%] of 3.75 kg/ha (considering the lower growth stage at application) Kumar compared to reference products against powdery mildew on leaves in grapevine in terms of **PESINC**

Rating data type	Part rated	No. of appl.	Evaluation	UTC	Efficacy [%] acc. to Abbott		
					Test product	RP 1 (systemic)	RP 2 (contact)
					3.75 kg/ha		
BBCH 74-75							
PESINC	leaves	5-6	n	2	2	2	2
			Mean	**61.5**	**67.9**	**55.2**	**74.4**
			Min.	55.4	51.9	54.9	63.0
			Max.	67.5	83.9	55.6	85.7

Table 6- 31: Mean effectiveness [%] of 5.0 kg/ha Kumar compared to reference products against powdery mildew on leaves in grapevine

Rating data type	Part rated	No. of appl.	Evaluation	UTC (trials testing systemic RP)	UTC trials testing contact RP)	UTC trials testing mixed RP)	Efficacy [%] acc. to Abbott					
							Test product (trials testing systemic RP)	Test product (trials testing contact RP)	Test product (trials testing mixed RP)	RP 1 (systemic)	RP 2 (contact)	RP 3 (mixed)
							5.0 kg/ha	5.0 kg/ha	5.0 kg/ha			
BBCH 81-89												
PESINC	leaves	6-11	n	5	10	-	5	10	-	5	10	-
			Mean	**42.3**	**50.5**		**79.9**	**77.6**		**43.3**	**78.6**	
			Min.	11.2	11.2		48.6	46.0		19.5	52.0	
			Max.	80.8	87.0		100.0	100.0		71.6	100.0	
PESSEV	leaves	5-10	n	1	5	3	1	5	3	1	5	3
			Mean	**23.5**	**32.1**	**59.4**	**55.5**	**80.5**	**85.9**	**38.3**	**82.0**	**89.9**
			Min.	-	12.0	33.4	-	55.5	79.6	-	65.0	77.9
			Max.	-	56.0	78.8	-	100.0	91.8	-	100.0	97.9
BBCH 75-79												
PESINC	leaves	6-8	n	2	2	-	2	2	-	2	2	-
			Mean	**9.8**	**9.8**		**87.4**	**87.4**		**27.8**	**89.7**	
			Min.	8.8	8.8		74.8	74.8		14.4	79.4	
			Max.	10.8	10.8		100.0	100.0		41.1	100.0	

UNCINE – *Assessments on bunches*

Table 6- 32: Mean effectiveness [%] of 3.75 kg/ha (considering the lower growth stage at application) Kumar compared to reference products against powdery mildew on bunches in grapevine

Rating data type	Part rated	No. of appl.	Evaluation	UTC	Efficacy [%] acc. to Abbott		
					Test product	RP 1 (systemic)	RP 2 (contact)
					3.75 kg/ha		
BBCH 75							
PESINC	bunches	5-8	n	1	1	1	1
			Value	**74.5**	**57.0**	**42.3**	**76.5**
PESSEV	bunches	5	n	1	1	1	1
			Value	**9.1**	**64.7**	**63.2**	**91.7**

Table 6- 33: Mean effectiveness [%] of 5.0 kg/ha Kumar compared to reference products against powdery mildew on bunches in grapevine

Rating data type	Part rated	No. of appl.	Evaluation	UTC (trials testing systemic RP)	UTC trials testing contact RP)	UTC trials testing mixed RP)	Efficacy [%] acc. to Abbott					
							Test product (trials testing systemic RP)	Test product (trials testing contact RP)	Test product (trials testing mixed RP)	RP 1 (systemic)	RP 2 (contact)	RP 3 (mixed)
							5.0 kg/ha	5.0 kg/ha	5.0 kg/ha			
BBCH 75-79												
PESINC	bunches	5-8	n	3	3	1	3	3	1	3	3	1
			Mean	**31.9**	**31.9**	**22.0**	**80.6**	**80.6**	**66.7**	**46.2**	**69.3**	**66.7**
			Min.	10.5	10.5	-	57.1	57.1	-	7.7	40.5	-
			Max.	65.0	65.0	-	100.0	100.0	-	100.0	100.0	-
PESSEV	bunches	5	n	-	-	1	-	-	1	-	-	1
			Value	**-**	**-**	**5.3**	**-**	**-**	**100.0**	**-**	**-**	**100.0**
BBCH 81-87												
PESINC	bunches	5-11	n	4	7	4	4	7	4	4	7	4
			Mean	**66.9**	**59.8**	**32.9**	**62.4**	**71.0**	**98.9**	**19.9**	**61.2**	**99.7**
			Min.	52.5	24.0	20.5	31.1	31.1	95.7	0.0	17.8	98.9
			Max.	83.5	90.0	53.6	76.1	89.2	100.0	59.3	83.8	100.0
PESSEV	bunches	5-10	n	1	4	2	1	4	2	1	4	2
			Mean	**65.2**	**35.6**	**14.4**	**39.9**	**75.2**	**98.6**	**28.8**	**67.4**	**99.7**
			Min.	-	12.0	5.2	-	39.9	97.1	-	16.7	99.3
			Max.	-	65.2	23.5	-	94.1	100.0	-	88.2	100.0
BBCH 89												
PESINC	bunches	6-12	n	2	2	-	2	2	-	2	2	-
			Mean	**85.5**	**85.5**	**-**	**71.9**	**71.9**	**-**	**5.6**	**64.9**	**-**
			Min.	81.0	81.0	-	66.0	66.0	-	0.0	63.0	-
			Max.	90.0	90.0	-	77.8	77.8	-	11.1	66.7	-
PESSEV	bunches	6	n	1	1	-	1	1	-	1	1	-
			Value	**84.3**	**84.3**	**-**	**13.9**	**13.9**	**-**	**7.7**	**57.2**	**-**

UNCINE – *Assessments on leaves- class evaluation*

Table 6- 34: Mean effectiveness [%] of 5.0 kg/ha Kumar compared to a reference product against powdery mildew on leaves in grapevine m in terms of **PESSEV** (6-class evaluation)

Evaluation	UTC	BBCH 81-89 (after 7-12 applications)				UTC	BBCH 76-79 (after 7-8 applications)			
		Test product		RP (contact)			Test product		RP (contact)	
		5.0 kg/ha					5.0 kg/ha			
		[%]	% of UTC	[%]	% of UTC		[%]	% of UTC	[%]	% of UTC
Class 1 (< 5 % infestation)										
n	5	5	-	5	-	4	4	-	4	-
Mean	**14.4**	**22.3**	**155.6**	**21.7**	**151.0**	**18.6**	**23.8**	**128.3**	**21.6**	**116.2**
Min.	5.4	2.4	-	2.6	-	4.0	0.0	-	0.0	-
Max.	33.3	57.5	-	48.3	-	36.0	49.5	-	48.8	-
Class 2 (5-10 % infestation)										
n	5	5	-	5	-	3	3	-	3	-
Mean	**20.9**	**11.5**	**55.1**	**10.2**	**48.9**	**19.5**	**9.2**	**47.0**	**11.3**	**58.1**
Min.	11.8	2.0	-	3.0	-	2.0	0.0	-	0.0	-
Max.	29.5	24.0	-	18.3	-	34.8	15.5	-	24.5	-
Class 3 (11-25 % infestation)										
n	5	5	-	5	-	2	2	-	2	-
Mean	**14.8**	**6.6**	**44.3**	**4.4**	**30.0**	**16.9**	**2.3**	**13.6**	**2.0**	**11.5**
Min.	5.4	0.0	-	0.0	-	15.3	1.8	-	1.6	-
Max.	25.0	24.0	-	18.3	-	18.5	2.8	-	2.3	-
Class 4 (26-50 % infestation)										
n	5	5	-	5	-	2	2	-	2	-
Mean	**26.1**	**20.1**	**76.8**	**19.8**	**76.0**	**16.4**	**0.0**	**-**	**0.0**	**-**
Min.	1.3	0.0	-	0.0	-	14.3	0.0	-	0.0	-
Max.	76.5	97.5	-	99.0	-	18.5	0.0	-	0.0	-
Class 5 (50-75 % infestation)										
n	5	5	-	5	-	2	2	-	2	-
Mean	**3.7**	**0.5**	**13.2**	**0.2**	**5.5**	**1.7**	**0.0**	**-**	**0.0**	**-**
Min.	0.0	0.0	-	0.0	-	0.5	0.0	-	0.0	-
Max.	14.8	2.3	-	1.0	-	2.8	0.0	-	0.0	-
Class 6 (> 75 % infestation)										
n	4	4	-	4	-	1	1	-	1	-
Mean	**4.0**	**0.0**	**0.6**	**0.0**	**-**	**0.3**	**0.0**	**-**	**0.0**	**-**
Min.	0.0	0.0	-	0.0	-	-	-	-	-	-
Max.	8.7	0.1	-	0.0	-	-	-	-	-	-

Table 6- 35: Mean effectiveness [%] of 5.0 kg/ha Kumar compared to a reference product against powdery mildew on leaves in grapevine in terms of **PESSEV** (6-class evaluation)

Evaluation	UTC	BBCH 83-85 (after 9-10 applications)			
		Test product		RP (contact)	
		5.0 kg/ha			
		[%]	% of UTC	[%]	% of UTC
Class 1 (no disease)					
n	4	4	-	4	-
Mean	**29.5**	**86.0**	**291.5**	**77.8**	**263.6**
Min.	13.0	58.0	-	69.0	-
Max.	40.0	100.0	-	90.0	-
Class 2 (< 2.5 % infestation)					
n	4	4	-	4	-
Mean	**18.5**	**5.0**	**27.0**	**13.3**	**71.6**
Min.	12.0	0.0	-	7.0	-
Max.	33.0	12.0	-	20.0	-
Class 3 (2.6-10 % infestation)					
n	4	4	-	4	-
Mean	**23.3**	**5.8**	**24.7**	**7.8**	**33.3**
Min.	18.0	0.0	-	0.0	-
Max.	33.0	17.0	-	14.0	-
Class 4 (11-25 % infestation)					
n	4	4	-	4	-
Mean	**20.5**	**2.5**	**12.2**	**0.8**	**3.7**
Min.	8.0	0.0	-	0.0	-
Max.	27.0	10.0	-	3.0	-
Class 5 (26-50 % infestation)					
n	4	4	-	4	-
Mean	**9.0**	**0.0**	**-**	**0.0**	**-**
Min.	0.0	0.0	-	0.0	-
Max.	13.0	0.0	-	0.0	-
Class 6 (51-100 % infestation)					
n	4	4	-	4	-
Mean	**10.3**	**0.0**	**-**	**4.0**	**39.0**
Min.	0.0	0.0	-	0.0	-
Max.	41.0	0.0	-	8.0	-

Table 6- 36: Mean effectiveness [%] of 5.0 kg/ha Kumar compared to a reference product against powdery mildew on leaves in grapevine in terms of **PESSEV** (6-class evaluation)

Evaluation	**UTC**	**BBCH 85 (after 5 applications)**			
		Test product		**RP (mixed)**	
		5.0 kg/ha			
		[%]	**% of UTC**	**[%]**	**% of UTC**
Class 1 (no disease)					
n	3	3	-	3	-
Mean	**11.0**	**76.6**	**694.3**	**83.9**	**760.1**
Min.	0.0	71.8	-	66.8	-
Max.	32.8	80.5	-	93.8	-
Class 2 (< 2.5 % infestation)					
n	3	3	-	3	-
Mean	**6.9**	**9.9**	**143.7**	**6.3**	**91.3**
Min.	4.3	8.5	-	5.0	-
Max.	11.0	11.8	-	8.0	-
Class 3 (2.6-10 % infestation)					
n	3	3	-	3	-
Mean	**22.0**	**10.9**	**49.4**	**6.7**	**30.5**
Min.	13.5	7.8	-	0.5	-
Max.	28.5	14.8	-	15.8	-
Class 4 (11-25 % infestation)					
n	3	3	-	3	-
Mean	**20.1**	**1.9**	**9.6**	**2.6**	**12.9**
Min.	15.5	0.0	-	0.0	-
Max.	29.0	4.3	-	7.8	-
Class 5 (26-50 % infestation)					
n	3	3	-	3	-
Mean	**14.0**	**0.3**	**2.4**	**0.9**	**6.2**
Min.	7.8	0.0	-	0.0	-
Max.	21.5	1.0	-	1.8	-
Class 6 (51-100 % infestation)					
n	3	3	-	3	-
Mean	**25.9**	**0.0**	**-**	**0.0**	**-**
Min.	4.3	0.0	-	0.0	-
Max.	52.5	0.0	-	0.0	-

Table 6- 37: Mean effectiveness [%] of 5.0 kg/ha Kumar compared to a reference product against powdery mildew on leaves in grapevine in terms of **PESSEV** (single trial; 7-class evaluation)

Evaluation	UTC	BBCH 75 (after 5 applications)				UTC	BBCH 81 (after 6 applications)			
		Test product 5.0 kg/ha		RP (contact)			Test product 5.0 kg/ha		RP (contact)	
		[%]	% of UTC	[%]	% of UTC		[%]	% of UTC	[%]	% of UTC
Class 1 (no disease)										
n	1	1	-	1	-	1	1	-	1	-
Value	**43.5**	**91.1**	**209.4**	**92.7**	**213.1**	**19.3**	**58.5**	**303.1**	**75.5**	**391.2**
Class 2 (< 5 % infestation)										
n	1	1	-	1	-	1	1	-	1	-
Value	**0.0**	**0.0**	**-**	**0.0**	**-**	**0.0**	**0.0**	**-**	**0.0**	**-**
Class 3 (5-10 % infestation)										
n	1	1	-	1	-	1	1	-	1	-
Value	**31.2**	**8.4**	**26.9**	**5.5**	**17.6**	**7.3**	**15.3**	**209.6**	**13.5**	**184.9**
Class 4 (11-25 % infestation)										
n	1	1	-	1	-	1	1	-	1	-
Value	**8.5**	**0.2**	**2.4**	**0.7**	**8.2**	**21.2**	**1.9**	**9.0**	**4.3**	**20.3**
Class 5 (26-50 % infestation)										
n	1	1	-	1	-	1	1	-	1	-
Value	**12.2**	**0.1**	**0.8**	**0.6**	**4.9**	**51.0**	**22.3**	**43.7**	**6.5**	**12.7**
Class 6 (50-75 % infestation)										
n	1	1	-	1	-	1	1	-	1	-
Value	**0.1**	**0.0**	**-**	**0.1**	**100.0**	**0.9**	**0.6**	**66.7**	**0.0**	**-**
Class 7 (> 75 % infestation)										
n	1	1	-	1	-	1	1	-	1	-
Value	**0.0**	**0.0**	**-**	**0.0**	**-**	**0.0**	**0.0**	**-**	**0.0**	**-**

UNCINE – *Assessments on bunches- class evaluation*

Table 6- 38: Mean effectiveness [%] of 5.0 kg/ha Kumar compared to a reference product against powdery mildew on bunches in grapevine in terms of **PESSEV** (6-class evaluation)

Evaluation	UTC	BBCH 79 (after 5 applications)				UTC	BBCH 83 (after 7 applications)			
		Test product		RP (mixed)			Test product		RP (mixed)	
		5.0 kg/ha					5.0 kg/ha			
		[%]	% of UTC	[%]	% of UTC		[%]	% of UTC	[%]	% of UTC
Class 1 (no disease)										
n	1	1	-	1	-	2	2	-	2	-
Mean	**40.0**	**50.0**	**125.0**	**50.0**	**125.0**	**28.2**	**81.5**	**289.0**	**83.5**	**296.1**
Min.	-	-	-	-	-	18.3	67.0	-	68.0	-
Max.	-	-	-	-	-	38.0	96.0	-	99.0	-
Class 2 (< 2.5 % infestation)										
n	1	1	-	1	-	2	2	-	2	-
Mean	**9.0**	**0.0**	**-**	**0.0**	**-**	**26.6**	**12.0**	**45.2**	**10.3**	**38.6**
Min.	-	-	-	-	-	17.3	3.7	-	1.0	-
Max.	-	-	-	-	-	35.8	20.3	-	19.5	-
Class 3 (2.6-10 % infestation)										
n	1	1	-	1	-	2	2	-	2	-
Mean	**2.3**	**0.0**	**-**	**0.0**	**-**	**15.5**	**4.8**	**31.0**	**2.2**	**13.9**
Min.	-	-	-	-	-	15.3	0.3	-	0.0	-
Max.	-	-	-	-	-	15.7	9.3	-	4.3	-
Class 4 (11-25 % infestation)										
n	1	1	-	1	-	2	2	-	2	-
Mean	**0.0**	**0.0**	**-**	**0.0**	**-**	**8.3**	**1.4**	**17.0**	**0.2**	**1.8**
Min.	-	-	-	-	-	5.7	0.0	-	0.0	-
Max.	-	-	-	-	-	10.8	2.8	-	0.3	-
Class 5 (26-50 % infestation)										
n	1	1	-	1	-	2	2	-	2	-
Mean	**0.0**	**0.0**	**-**	**0.0**	**-**	**6.4**	**0.2**	**2.3**	**0.2**	**2.3**
Min.	-	-	-	-	-	4.3	0.0	-	0.0	-
Max.	-	-	-	-	-	8.5	0.3	-	0.3	-
Class 6 (51-100 % infestation)										
n	1	1	-	1	-	2	2	-	2	-
Mean	**0.0**	**0.0**	**-**	**0.0**	**-**	**5.8**	**0.0**	**0.0-**	**0.0**	**0.0-**
Min.	-	-	-	-	-	3.0	0.0	-	0.0	-
Max.	-	-	-	-	-	8.5	0.0	-	0.0	-

Table 6- 39: Mean effectiveness [%] of 5.0 kg/ha Kumar compared to a reference product against powdery mildew on bunches in grapevine in terms of **PESSEV** (6-class evaluation)

Evaluation	UTC	BBCH 83-85 (after 10-11 applications)			
		Test product		RP (contact)	
		5.0 kg/ha			
		[%]	% of UTC	[%]	% of UTC
Class 1 (no disease)					
n	3	3	-	3	-
Mean	**32.7**	**60.7**	**185.7**	**49.7**	**152.0**
Min.	5.0	38.0	-	13.0	-
Max.	60.0	96.0	-	94.0	-
Class 2 (< 2.5 % infestation)					
n	1	1	-	1	-
Value	**9.0**	**3.0**	**33.3**	**5.0**	**55.6**
Class 3 (2.6-10 % infestation)					
n	1	1	-	1	-
Value	**13.0**	**1.0**	**7.7**	**2.0**	**15.4**
Class 4 (11-25 % infestation)					
n	1	1	-	1	-
Value	**8.0**	**0.0**	**0.0**	**0.0**	**0.0**
Class 5 (26-50 % infestation)					
n	1	1	-	1	-
Value	**5.0**	**0.0**	**0.0**	**0.0**	**0.0**
Class 6 (51-100 % infestation)					
n	1	1	-	1	-
Value	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**

Table 6- 40: Mean effectiveness [%] of 5.0 kg/ha Kumar compared to a reference product against powdery mildew on bunches in grapevine in terms of **PESSEV** (6-class evaluation)

Evaluation	**UTC**	**BBCH 75-79 (after 6-8 applications)**				**UTC**	**BBCH 81-87 (after 7-12 applications)**				**UTC**	**BBCH 89 (after 12-13 applications)**			
		Test product		**RP (contact)**			**Test product**		**RP (contact)**			**Test product**		**RP (contact)**	
		5.0 kg/ha					**5.0 kg/ha**					**5.0 kg/ha**			
		[%]	% of UTC	[%]	% of UTC		[%]	% of UTC	[%]	% of UTC		[%]	% of UTC	[%]	% of UTC
Class 1 (< 5 % infestation)															
n	4	4	-	4	-	4	4	-	4	-	2	2	-	2	-
Mean	**8.8**	**13.9**	**158.2**	**12.0**	**136.6**	**6.4**	**9.3**	**145.0**	**8.6**	**134.5**	**2.8**	**2.4**	**87.3**	**2.3**	**83.6**
Min.	1.9	1.1	-	3.4	-	0.4	2.0	-	2.3	-	1.5	1.5	-	1.8	-
Max.	18.8	22.8	-	24.8	-	18.5	17.0	-	16.8	-	4.0	3.3	-	2.8	-
Class 2 (5-10 % infestation)															
n	4	4	-	4	-	5	5	-	5	-	2	2	-	2	-
Mean	**11.3**	**7.3**	**64.0**	**7.3**	**64.5**	**7.1**	**6.4**	**90.7**	**5.6**	**78.3**	**10.7**	**5.7**	**53.1**	**4.7**	**43.7**
Min.	9.3	1.0	-	2.5	-	0.2	3.3	-	0.9	-	9.0	4.3	-	4.3	-
Max.	12.8	17.0	-	17.5	-	13.0	12.8	-	11.3	-	12.3	7.0	-	5.0	-
Class 3 (11-25 % infestation)															
n	4	4	-	4	-	5	5	-	5	-	2	2	-	2	-
Mean	**7.6**	**2.0**	**25.7**	**2.9**	**38.6**	**6.7**	**4.9**	**73.4**	**4.9**	**73.4**	**7.4**	**2.8**	**38.0**	**4.4**	**59.7**
Min.	4.2	0.0	-	0.0	-	1.8	0.0	-	0.3	-	6.8	2.8	-	4.3	-
Max.	10.3	5.3	-	6.5	-	12.9	11.3	-	11.0	-	8.0	2.8	-	4.5	-
Class 4 (26-50 % infestation)															
n	4	4	-	4	-	5	5	-	5	-	2	2	-	2	-
Mean	**6.3**	**1.2**	**18.2**	**2.0**	**31.3**	**8.2**	**4.4**	**53.7**	**5.1**	**62.8**	**12.5**	**1.6**	**12.8**	**2.5**	**20.0**
Min.	2.3	0.0	-	0.0	-	2.0	0.0	-	0.0	-	11.8	0.9	-	2.0	-
Max.	12.8	4.5	-	7.3	-	18.3	13.8	-	16.8	-	13.3	2.3	-	3.0	-
Class 5 (50-75 % infestation)															
n	3	3	-	3	-	5	5	-	5	-	2	2	-	2	-
Mean	**2.4**	**0.2**	**6.9**	**0.0**	**-**	**6.7**	**2.7**	**40.3**	**2.9**	**43.2**	**4.9**	**0.0**	**-**	**0.1**	**2.1**
Min.	0.5	0.0	-	0.0	-	0.5	0.0	-	0.0	-	4.0	0.0	-	0.1	-
Max.	3.5	0.5	-	0.0	-	14.8	13.5	-	14.5	-	5.7	0.0	-	0.1	-
Class 6 (> 75 % infestation)															
n	2	2	-	2	-	3	3	-	3	-	2	2	-	2	-
Mean	**2.6**	**0.0**	**-**	**0.0**	**-**	**12.6**	**2.1**	**17.0**	**2.3**	**18.3**	**4.3**	**0.0**	**-**	**0.1**	**2.3**
Min.	1.1	0.0	-	0.0	-	2.0	0.0	-	0.0	-	2.0	0.0	-	0.0	-
Max.	4.0	0.0	-	0.0	-	24.0	6.4	-	6.9	-	6.6	0.0	-	0.2	-

Table 6- 41: Mean effectiveness [%] of 5.0 kg/ha Kumar compared to a reference product against powdery mildew on bunches in grapevine in terms of **PESSEV** (single trial; 5-class evaluation)

Evaluation	UTC	BBCH 75 (after 5 applications)				UTC	BBCH 81 (after 6 applications)				UTC	BBCH 89 (after 6 applications)			
		Test product 5.0 kg/ha		RP (contact)			Test product 5.0 kg/ha		RP (contact)			Test product 5.0 kg/ha		RP (contact)	
		[%]	% of UTC	[%]	% of UTC		[%]	% of UTC	[%]	% of UTC		[%]	% of UTC	[%]	% of UTC
Class 1 (no disease)															
n	1	1	-	1	-	1	1	-	1	-	1	1	-	1	-
Value	**12.8**	**34.0**	**265.6**	**41.3**	**322.7**	**0.4**	**0.5**	**125.0**	**12.2**	**3050.0**	**0.0**	**0.0**	**0.0**	**7.0**	**0.0**
Class 2 (< 5 % infestation)															
n	1	1	-	1	-	1	1	-	1	-	1	1	-	1	-
Value	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
Class 3 (6-25 % infestation)															
n	1	1	-	1	-	1	1	-	1	-	1	1	-	1	-
Value	**23.3**	**12.5**	**53.6**	**8.0**	**34.3**	**1.4**	**11.1**	**792.9**	**21.3**	**1521.4**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
Class 4 (26-50 % infestation)															
n	1	1	-	1	-	1	1	-	1	-	1	1	-	1	-
Value	**9.1**	**0.6**	**6.6**	**0.2**	**2.2**	**12.5**	**20.0**	**160.0**	**8.0**	**64.0**	**0.6**	**8.2**	**1366.7**	**23.9**	**3983.3**
Class 5 (> 50 % infestation)															
n	1	1	-	1	-	1	1	-	1	-	1	1	-	1	-
Value	**2.6**	**1.3**	**50.0**	**0.0**	**0.0**	**33.7**	**11.1**	**32.9**	**0.3**	**0.9**	**49.3**	**41.8**	**84.8**	**9.8**	**19.9**

Conclusion

The results demonstrate that good efficacy of Kumar against powdery mildew (UNCINE: *Erysiphe necator*) is achieved when the product is applied according to the envisaged GAP use, comprising up to six applications of Kumar at a rate of 5.0 kg/ha (equivalent to 4250 g ai/ha).

Furthermore, even under high infection levels still an overall good performance of the test product Kumar is achieved. The effectiveness level of the test product Kumar is comparable compared to the different reference products. In this dossier, a number of different reference products and reference product-mixtures were used to evaluate the efficacy data. This includes both: conventional products with systemic activity like Topas in mix with Ortho-Phaltan Flüssig or Systhane 20 EW, and alternative products like the tank mixture of Oxykupfer and Vincare or Kumulus WG and Netzschwefel Stulln with inorganic compounds (refer to Table 6- 43 and Table 6- 44). The use of alternative products is especially relevant in organic farming as only a limited number of products are currently available.

Kumar is considered to be an appropriate measure for the control of powdery mildew according to the proposed GAP use applied for (refer to Appendix 2), since acceptable effectiveness of the product Kumar is demonstrated. The application of Kumar demonstrates acceptable efficacy, both in terms of pest severity and pest incidence on leaves as well as on bunches. Thus, the envisaged GAP use of Kumar to treat grey mould infections in grapevine is from the point of this dossier considered as valid. Compared to other contact fungicides with inorganic compounds, Kumar shows better control of powdery mildew.

Overall conclusion on the effectiveness of Kumar against BOTRCI and UNCINE

Kumar and the active substance potassium bicarbonate is in contrast to conventional products with systemic activity, an inorganic compound which can be found in all natural compartments. So, a low environmental risk is associated with the use of Kumar. No further protective measures need to be considered by the applicant.

In general, the good effectiveness makes Kumar to a good tool for fungicidal control and can increase the limited availability of alternative products. This situation is especially pronounced in organic farming, as only a limited number of alternative products are available. Especially, with respect to the ongoing discussion to reduce the application of copper-based products, the product Kumar provides a useful alternative to treat fungal diseases. Furthermore, it has to be explicitly stated that inorganic fungicides are often the only alternative left in cases where the target fungi already developed resistances against various fungicides based on organic active ingredients.

In conclusion, the results of the efficacy trials presented in this dossier show that the mean effectiveness of the test product Kumar is – despite the high variability of results (BOTRCI: incidence 62.3-76.4 %; severity: 60.9-77.9 % and UNCINE: incidence on leaves: 67.9-87.4 % and on bunches: 57.0-98.9 %; severity on leaves: 55.5-85.9 % and on bunches: 13.9-100.0 %) – competitive with those of registered reference products for the use in grapevine, for both the treatment of grey mould (BOTRCI: *Botryotinia fuckeliana*) and powdery mildew (UNCINE*: Erysiphe necator*). It is additionally demonstrated in Table 6- 42 to Table 6- 44 below that the application of Kumar results in comparable or superior efficacy compared to other contact fungicides and a reduced effectiveness compared to systemic fungicides is expected due to a preventative nature of the active (data presented having the highest efficacy across all assessments in individual trials). Overall, Kumar is considered to be appropriate for the control of fungal diseases in grapevine according to the proposed GAP uses applied for and could be integrated in a spray sequence with other fungicides even in organic farming (refer to Appendix 2).
The application rate for the control of powdery mildew has to be adapted to the growth stage of the crop and in 2 trials the mean effectiveness considering the reduced dose rate of 3.75 kg/ha (BBCH 74-74) ranges between 67.9 % in terms of incidence and was similar or better than the reference products (systemic: 55.2 %; contact: 74.4 %) on leaves. On bunches the mean effectiveness ranges between 57.0 % in terms of incidence and 64.7 % in terms of severity and was similar or lower than the reference products (systemic: incidence: 42.3 %, severity: 63.2 %; contact: incidence: 76.5 %, severity: 91.7 %). Therefore, at earlier growth stages a reduction of the dose rate is considered sufficient for control of powdery mildew.

For the interpretation of the efficacy results several general aspects for the use of alternative products based on inorganic compounds, like potassium bicarbonate, needs to be considered. Potassium bicarbonate is a pure protective contact fungicide without any systemic action. Therefore, two prerequisites are necessary in order to achieve sufficient control: early application timing (most advisable already prior to the infection with phytopathogenic fungi) and a thoroughly coverage of the product. In this context, possible shading effects need to be considered, as especially in dense canopies a reduced coverage of the product on leaves and bunches may result in lower efficacy levels.

This can be underlined from the data presented in this dossier, as generally a sufficient efficacy, especially for the control of grey mould, was found in trials with varying infestation levels in the untreated control and acted better than other contact fungicides. Nevertheless, in trials with initially low infection rates in the untreated control, generally an overall good efficacy of the test product was achieved.

To conclude, Kumar is considered to be a good measure for the control of grey mould and powdery mildew according to the proposed GAP uses applied for since sufficient effectiveness of the application of the product Kumar is demonstrated even at high infestation level. Thus, the envisaged GAP uses of the test product Kumar in grape to treat grey mould (BOTRCI: *Botryotinia fuckeliana*) and powdery mildew (UNCINE*: Erysiphe necator*) infections is from the point of this dossier considered as valid.

The efficacy data submitted for the use in grapevine comply with the uniform principles.

The efficacy of Kumar against grey mould (BOTRCI) in grapevine was tested in 28 efficacy trials conducted in the years between 2005 and 2015 in Switzerland, Austria, Germany and France and against powdery mildew (UNCINE) in 16 efficacy trials conducted in the years between 2003 and 2015 in Switzerland, Austria and Germany. All representing the Maritime EPPO climatic zone.

The results of the presented efficacy trials show that the mean effectiveness of the test product Kumar at 5.0 kg/ha in grapevine are – despite the high variability of results – competitive with those of registered reference products, for grey mould (BOTRCI: *Botrytis cinerea*) and powdery mildew (UNCINE: *Erysiphe necator*).

BOTRCI: *Botrytis cinerea*: It is demonstrated that efficacy results by the use of Kumar are comparable to the effectiveness of other contact fungicides (only three trials) and that slightly lower effectiveness compared to systemic fungicides was observed.

UNCINE: *Erysiphe necator*: The results demonstrate that efficacy of Kumar was better compared to the contact reference products tested in trials and efficacy was better compared to the systemic reference products tested in trials. The results indicate that when the product Kumar is applied according to the envisaged GAP use the level of infection, both on bunches and leaves, is sufficiently controlled.

Table 6- 42: Overall efficacy of Kumar against **grey mould** (*Botryotinia fuckeliana*) in **Germany, Austria, France** and **Switzerland** 2006-2015 (total 27 trials)

Trial no.	Country	Assessment		**Effectiveness regarding pest incidence on bunches**			**PESINC (%) in UTC**	**Effectiveness regarding pest severity on bunches**			**PESSEV (%) in UTC**
		Date	DALA[1)]	Kumar (5.0 kg/ha)	RP (Contact fungicides)	RP (Systemic fungicides)		Kumar (5.0 kg/ha)	RP (Contact fungicides)	RP (Systemic fungicides)	
01-01	CH	09/10/06	34 DAD	(15)	-	(43)	99	24	-	54	80
01-02		09/10/06	34 DAD	39	-	56	90	42	-	63	59
01-03		22/09/06	44 DAC	58		63	38	59	-	59	29
01-04		22/09/06	44 DAC	89		85	27	82	-	82	11
01-07[*)]		22/09/08	14 DAD	31	-	52	48	42	-	54	26
01-08[*)]		06/10/08	28 DAD	76	-	94	46	80	-	93	15
01-09[*)]		15/10/08	37 DAD	69	-	82	54	77	-	90	30
01-12		22/09/09	49 DAC	(24)	-	(48)	67	35	-	59	32
Effectiveness ("GEP-compliant")				60	-	72		55	-	69	
01-05	FR	03/09/07	10 DAD	56		85	62	75	-	92	14
01-14	AT	19/09/07	48 DAC	84	-	100	9.5	(90)	-	(100)	(3.7)
01-15		11/09/07	17 DAD	64	-	82	31	71	-	88	19
01-16		11/09/07	17 DAD	67	-	79	71	79	-	88	54
01-17		23/09/09	36 DAD	35	-	60	53	36	-	68	31
01-18		22/09/10	30 DAC	59	58	-	19	66	72	-	8.5
01-19		18/09/10	38 DAC	72	40	-	49	82	48	85	36
01-20		23/09/10	43 DAC	82	41	-	61	86	51	-	47
01-21		24/09/11	46 DAC	67	-	74	33	75	-	79	22
01-23	DE	10/10/08	17 DAD	(45)	-	(20)	68	60	-	32	12
01-24		22/10/08	9 DAD	54	-	22	59	75	-	25	10
01-28		11/10/13	38 DAF	44	-	69	32	-	-	-	-
01-29		27/10/13	53 DAF	59	-	61	94	78	-	78	7.7
01-30		10/10/13	41 DAF	(7.5)	-	(23)	100	46	-	66	47
01-31		22/09/14	41 DAF	72	-	77	31	-	-	-	-

Trial no.	Country	Assessment		Effectiveness regarding pest incidence on bunches			PESINC (%) in UTC	Effectiveness regarding pest severity on bunches			PESSEV (%) in UTC
		Date	DALA[1)]	Kumar (5.0 kg/ha)	RP (Contact fungicides)	RP (Systemic fungicides)		Kumar (5.0 kg/ha)	RP (Contact fungicides)	RP (Systemic fungicides)	
01-32		05/09/14	20 DAE	100	-	100	42	-	-	-	-
01-33		28/09/15	45 DAH	19	-	53	24	-	-	-	-
01-34		15/09/15	33 DAG	77	-	78	25	-	-	-	-
01-35		17/09/15	50 DAF	87	-	96	27	(97)	-	(99)	(2.2)
Effectiveness (GEP)				65	46	74		69	57	70	
Effectiveness (overall)				**63**	**46**	**73**		**64**	**57**	**70**	

[1)] DALA: Days after last application, e.g. DAC = days after 3rd application

[*)] belong to a compiled reports of four reports. One report was excluded due to not sufficient efficacy of both, the test and the reference product.

Table 6- 43: Overall efficacy of Kumar against **powdery mildew** (*Erysiphe necator*) in **leaves** in **Austria, Switzerland** and **Germany** 2003-2015 (total 16 trials)

Trial no.	Country	Assessment		**Effectiveness regarding pest incidence on leaves**			**PESINC (%) in UTC**	**Effectiveness regarding pest severity on leaves**			**PESSEV (%) in UTC**
		Date	DALA (e.g. DAC = days after 3rd appl.)	Kumar (5.0 kg/ha)	RP (Contact fungicides)	RP (Systemic fungicides)		Kumar (5.0 kg/ha)	RP (Contact fungicides)	RP (Systemic fungicides)	
02-01	CH	20/08/03	54 DAE	-	-	-	-	92	-	98	66
02-02		20/08/03	67 DAE	-	-	-	-	86	-	78	79
02-03		22/08/03	56 DAE	-	-	-	-	80	-	94	33
02-04		12/08/04	2 DAJ	100	68	-	87	100	65	-	56
02-05		13/08/04	3 DAJ	100	100	-	45	100	100	-	12
02-06		25/09/08	43 DAI	78	83	-	63	88	91	-	32
02-07		26/09/08	44 DAI	46	61	-	74	60	73	-	37
02-08	AT	09/08/04	13 DAE	-	-	-	-	-	-	-	-
02-09		25/08/04	6 DAG	-	-	-	-	-	-	-	-
Effectiveness (“GEP-compliant”)				81	78	-		67	87	90	
02-10	DE	23/08/13	22 DAG	74	70	56	77	-	-	-	-
02-11		16/10/13	78 DAF	53	52	-	25	(55)	(61)	-	(0.4)
02-12		22/07/14	7 DAH	100	100	41	8.8	-	-	-	-
02-13*		26/06/14	1 DAF	52	63	56	68	-	-	-	-
02-14		28/07/15	7 DAH	77	84	38	23	-	-	-	-
02-15		04/08/15	4 DAK	100	99	72	11	-	-	-	-
02-16		13/07/15	30 DAF	49	70	31	81	56	82	38	24
Effectiveness (GEP)				72	77	49		56	82	38	
Effectiveness (overall)				**75**	**77**	**49**		**83**	**82**	**77**	

Table 6- 44: Overall efficacy of Kumar against **powdery mildew** (*Erysiphe necator*) in **bunches** in **Austria, Switzerland** and **Germany** 2003-2015 (total 16 trials)

Trial no.	Country	Assessment		Effectiveness regarding pest incidence on bunches			PESINC (%) in UTC	Effectiveness regarding pest severity on bunches			PESSEV (%) in UTC
		Date	DALA (e.g. DAC = days after 3rd appl.)	Kumar (5.0 kg/ha)	RP (Contact fungicides)	RP (Systemic fungicides)		Kumar (5.0 kg/ha)	RP (Contact fungicides)	RP (Systemic fungicides)	
02-01	CH	19/08/03	53 DAE	100	-	100	21	-	-	-	-
02-02		20/08/03	67 DAE	100	-	100	35	-	-	-	-
02-03		22/08/03	56 DAE	(100)	-	(100)	(3.8)	-	-	-	-
02-04		12/08/04	2 DAJ	71	18	-	90	75	17	-	48
02-05		13/08/04	3 DAJ	88	84	-	24	92	83	-	12
02-06		25/09/08	43 DAI	89	83	-	37	94	88	-	17
02-07		26/09/08	44 DAI	-	-	-	-	-	-	-	-
02-08	AT	09/08/04	13 DAE	100	-	100	23	100	-	100	5.2
02-09		25/08/04	6 DAG	96	-	99	54	97	-	99	24
Effectiveness (“GEP-compliant”)				92	62	100		92	63	100	
02-10	DE	23/08/13	22 DAG	31	48	59	84	-	-	-	-
02-11		16/10/13	78 DAF	(49)	(46)	-	33	(59)	(63)	-	(1.1)
02-12		08/08/14	8 DAJ	76	66	3.5	57	-	-	-	-
02-13*		26/06/14	1 DAF	(26)	(23)	(32)	78	-	-	-	-
02-14		28/07/15	7 DAH	69	67	17	53	-	-	-	-
02-15		16/07/15	7 DAH	85	67	7.7	65	-	-	-	-
02-16		12/08/15	30 DAF	(0.5)	(34)	(3)	(99)	40	82	30	65
Effectiveness (GEP)				65	62	22		40	82	30	
Effectiveness (overall)				**82**	**62**	**61**		**83**	**68**	**76**	

1) DALA: Days after last application, e.g. DAC = days after 3rd application
*3.75 kg/ha was applied acc. to growth stage of the crop

IIIA1 6.1.4 Effects on yield and quality

IIIA1 6.1.4.1 Impact on the quality of plants and plant products

Please refer to the combined presentation on yield data under point IIIA 6.1.4.3 below, where for ease of overview and less redundancy also the results on the quality of plants and plant products are summarised and evaluated.

IIIA1 6.1.4.2 Effects on the processing procedure

Please refer to the combined presentation on yield data under point IIIA 6.1.4.3 below, where for ease of overview and less redundancy also the results on the effects on processing procedure are summarised and evaluated.

IIIA1 6.1.4.3 Effects on the yield of treated plants and plant products

A total of 17 trials were carried out to evaluate the yield or quality of wine treated with Kumar. Seven trials out of the total amount were carried out as processing studies in Switzerland, France Austria and Germany. All trials were conducted according to GEP or under GEP-compliant conditions and followed the appropriate EPPO standards by officially recognised testing organisations. The study design used in all efficacy trials was a randomised complete block design with 3, 4 or 5 replicates and a plot size of usually 10.0-36.0 m^2. Trials were conducted between 2006 and 2015 in Switzerland, France, Austria and Germany.

In the following table an overview is provided on the harvested trials submitted with this dossier and covering the GAP uses of Kumar.

Table 6- 45: Overview of trials with yield determination

Crop	Target	**Efficacy trials**			**Processing trials**		
		No.	Country	Status[1)]	No.	Country	Status[1)]
Grapevine	BOTRCI	10	CH, AT, DE	GEP[2)]	7	CH, FR, AT, DE	GEP[2)]
Total		10			7		

[1)] For an overview of the testing facilities and the corresponding certificates please refer to IIIA1 6.7.
[2)] In Switzerland an official GEP certification system was not available prior to 2010. In Austria an official GEP certification was implemented in 2005. Nevertheless, all trials were conducted according to the respective EPPO guideline and are considered as GEP-compliant for the reasons outlined in detail on page 28.

Methods

Assessed characteristics

Assessed characteristics:	**Type:**	**Efficacy trials:**	**Processing trials:**
Yield	(t/ha)	5 trials	-
Yield	(kg/100 bunches)	1 trials	-
Sugar content	(° Oechsle)	2 trials	2 trials
Sugar content	(g/L)	2 trials	2 trials
Alcoholic content in must	(%)	-	2 trials
Alcoholic content in wine	(%)	-	2 trials
Total acidity	(g/L)	-	2 trials
Acidity	(g/L)	-	1 trial
Volatile Acidity	(g/L)	-	2 trials
Turbidity	NTU	-	1 trial
pH	-	-	2 trials
Total SO_2	(mg/L)	-	2 trials
Potassium	(mg/L)	-	2 trials
Assimilating N	(mg/L)	-	2 trials
Taste	(sensorial evaluation)	-	7 trials
Damaged berries	(%)	-	2 trials

Results of efficacy trials – yield

In a total of 6 efficacy trials conducted in Germany in the years 2013 to 2015 the yield of treated and untreated vine was determined. The yield of harvested berries as relevant criteria for grapevine cultivation was assessed in t/ha in 5 trials, in the other trial yield was determined in kg/100 bunches.

In 6 German trials, all applications of the test and reference products were conducted between BBCH 65 and 79. The test product Kumar was applied six to eight times at 5.0 kg/ha (equivalent to 4250 g potassium bicarbonate/ha).

At 5.0 kg/ha Kumar there was an increase of the yield of the test (192.4 %) or reference treatment (261.9 %) compared to the untreated control (10.3 t/ha and 30.0 kg/100 bunches). For an overview of the yield results please refer to Table 6- 46.

Table 6- 46: Summary of data concerning **impact on yield** (IIIA1-6.1.4), data from efficacy trials in **grapevine** carried out in **Germany**, 2013-2015 (total 6 trials)

Treatment		**Yield**								
Product	**Dose rate**	**Mean**			Min			Max		
		t/ha	kg/100 bunches	% of UTC	t/ha	kg/100 bunches	% of UTC	t/ha	kg/100 bunches	% of UTC
Untreated control	-	*10.3*	*30.0*	*100.0*	*0.7*	-	-	*18.2*	-	-
Test product	5.0 kg/ha	**12.5**	**31.5**	**192.4**	3.9	-	105.0	21.1	-	585.7
Switch	0.08 - 0.96 kg/ha	12.9	33.0	261.9	6.7	-	110.0	21.0	-	1007.1
No. of trials		5	1	6						

Results of efficacy trials – sugar content

In a total of 4 efficacy trials conducted in Switzerland and Austria in the years 2006 and 2010 the fruit quality of treated and untreated vine was determined. The sugar content in harvested berries as relevant criteria for grapevine cultivation was assessed in ° Oechsle in 2 trials, in the other 2 trials sugar content was stated in g/L.

Results of efficacy trials

In both trials from Switzerland (2006) all applications of the test and reference products were conducted between BBCH 61 and 85. The test product Kumar was applied four times at 5.0 kg/ha (equivalent to 4250 g potassium bicarbonate/ha).

There was no significant effect on the sugar content in °Oechsle of the test or reference treatment compared to control (100.0-103.0 % and 102.0 %, respectively). For an overview of the quality results please refer to Table 6- 47.

Table 6- 47: Summary of data concerning impact on **yield** (IIIA-6.1.4), data from efficacy trials in **grapevine** carried out in **Switzerland**, 2006 (total 2 trials)

Treatment		**Quality**			
Product	**Dose rate**	**Sugar content**			
		Trial 01-01		Trial 01-02	
		°Oechsle	% of UTC	°Oechsle	% of UTC
Untreated control	-	*61.0*	*100.0*	*73.0*	*100.0*
Test product	3 x 5.0	**61.0**	100.0	75.0	103.0
Topsin	4 x 2.0	63.0	102.0	74.0	102.0
No. of trials	2				

In both efficacy trials from Austria (2010) 3 applications of the test product and 2 applications of the reference products were conducted between BBCH 59 and 85. The test product Kumar was applied at 5.0 kg/ha (equivalent to 4250 g potassium bicarbonate/ha).

There was no significant effect on the sugar content in g/L of the test treatment compared to control (99.0 %). Compared to the reference treatment with two times Switch at 1.0 L/ha (sugar content: 155.48 g/L) the test treatment resulted in a similar level (sugar content: 156.76 g/L). For an overview of the quality results please refer to Table 6- 48.

Table 6- 48: Summary of data concerning impact on **yield** (IIIA-6.1.4), data from efficacy trials in **grapevine** carried out in **Austria**, 2010 (total 2 trials)

Treatment		**Quality** (% compared to control)			
Product	**Dose rate**	**Sugar content**			
		Trial 01-18		Trial 01-19	
		g/L	%/C	g/L	%/C
Untreated control	-	*180.1*	*100.0*	-	-
Test product	3 x 5.0	**178.8**	99.0	156.8	-
Switch	2 x 1.0	-	-	155.5	-
No. of trials	2				

Results of processing trials

In the years 2007-2009, a total of 5 processing tests were conducted in Austria (KIIIA1 6.4.1-01), Switzerland (KIIIA1 6.1.4-02) and France (KIIIA1 6.1.4-03) to determine the quality of treated vine grapes. Additionally, 2 triangle taint tests on the varieties Riesling (white wine) and Blauer Spätburgunder (red wine) were conducted in Germany 2013 testing 3.0 kg/ha Kumar (KIIIA1 6.1.4-10).

Statement for the requirement for a reduced number of processing trials and taint tests for the test product Kumar

The EPPO standard PP 1/268(1) describes the requirement of six processing trials for the registration of plant protection products in wine. In this dossier, only 2 trials follow this EPPO standard completely. However, for the registration of Kumar containing Potassium bicarbonate a reduced number of processing trials should be sufficient because of the following reasons:

a) Potassium bicarbonate is listed in EU Directive VO 606/2009 and EU Directive 479/2008 as legal fining agent for musts and vine. The substance is added regularly to the young wine during the fermentation process for deacidification in higher amounts/kg grapes than in the vineyard. Therefore, a negative impact on fermentation processes is not expected.
b) Potassium bicarbonate is a well-known additive in winemaking to regulate the content of Tartaric acid. For this purpose, Potassium bicarbonate is added under well-established conditions and empirical determined amounts to the grape juice. Afterwards Potassium bicarbonate reacts completely with the available Tartaric acid. Hence, Potassium bitartrate and Carbon dioxide (respectively Carbonic acid) are formed. Potassium bitartrate crystallizes and can be removed by simple filtration. Carbon dioxide escapes as a gas. The potential occurrence of negligible amounts of Potassium bicarbonate in grape juice from the application as a Plant protection product will not lead to any significant changes with regard to the process of regulating the content of Tartaric acid.
c) Potassium bicarbonate is well established as plant strengthener in the German viticulture since years applied in higher amounts as intended for Kumar and up to now no negative impact on the fermentation processes and the quality of the wine is evident (Registration Report VitiSan[8]).
d) In a diploma thesis at the Geisenheim University of Applied Science (Christian Rück, 2005) no influence on the fermentation and quality of wine was described.
e) Potassium bicarbonate is listed also as co-formulant in plant protection products[9].
   A co-formulant gives the product the necessary properties for application and has no impact on fermentation and quality of wine. Composition and function is well known by the authorities and no additional information is required during the registration process for a co-formulant listed[10]: This list contains Potassium chloride, Sodium chloride and Sodium bicarbonate but not Potassium bicarbonate. However, in aqueous solution all substances are fully dissociated and cannot be distinguished from each other.
f) In wine as an aqueous solution, Potassium bicarbonate is dissociated in naturally occurring Potassium and hydrogencarbonate and the active substance consequently is classified as no residue relevant.
g) Potassium is an important mineral cation and has sensoric characteristics in wine-making.

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[8] http://www.bvl.bund.de/SharedDocs/Downloads/04_Pflanzenschutzmittel/01_zulassungsberichte/007593-00-00.pdf?__blob=publicationFile&v=2) (January 2017)

[9] http://www.bvl.bund.de/DE/04_Pflanzenschutzmittel/03_Antragsteller/04_Zulassungsverfahren/04_Produktchemie/02_Wirkstoffe/Wirkstoffe_node.html) (January 2017)

[10] http://www.bvl.bund.de/SharedDocs/Downloads/04_Pflanzenschutzmittel/zul_info_liste_beistoffe.pdf?__blob=publicationFile&v=7) (January 2017)

An overview of the results regarding the **processing** is presented in the following.

Austria

In one trial, carried out in 2007 in Austria, the influence on fermentation and taste of treatments with Kumar compared to an untreated control was assessed in the variety Weissburgunder. Within the test treatment and the untreated control, it was additionally differentiated between spontaneous fermentation and fermentation with added yeast (AF). During alcoholic fermentation, visual evaluation of the variants was carried out daily. None of the samplings showed any abnormality. As expected, the variants with spontaneous fermentation showed a slower progress as the variants with added yeast (refer to Table 6- 49 and Figure 1).

Table 6- 49: Fermentation stages

Product variant	Fermentation	Repl.	Begin	Fermentation		
				Time to start	End time	Duration
Untreated	AF	1	11/09/2007	17/09	25/09	12
Untreated	AF	2	11/09/2007	14/09	23/09	12
Untreated	spontaneous	1	11/09/2007	18/09	28/09	17
Untreated	spontaneous	2	11/09/2007	20/09	01/10	20
Kumar (Agricure)	AF	1	11/09/2007	15/09	25/09	14
Kumar (Agricure)	AF	2	11/09/2007	16/09	25/09	14
Kumar (Agricure)	spontaneous	1	11/09/2007	21/09	01/10	20
Kumar (Agricure)	spontaneous	2	11/09/2007	20/09	03/10	22

AF: alcoholic fermentation with added yeast (Lalvin EC1118)
Spontaneous: without yeast

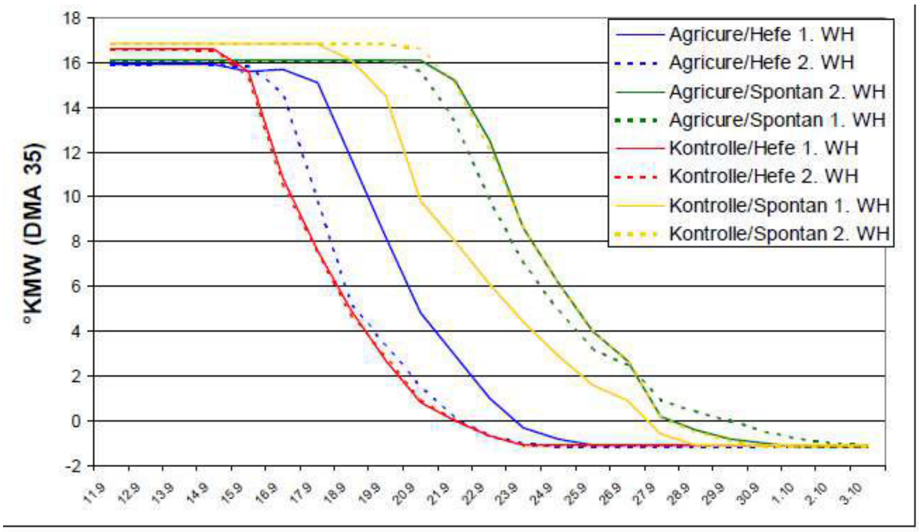

Figure 1: Fermentation kinetics in white wine variety Weissburgunder

The sensorial test was conducted at two organoleptic assessment dates after end of fermentation and clarification (8 jurors) and after 10 months (10 jurors)/more than one year (6 jurors) after end of fermentation (commissioned tasting). Despite the fact that at the initial organoleptic tasting on young wine (immediately after end of fermentation and 6 weeks later) no abnormality was found but still a slight fermentation flavour was described at both assessment dates (Table 6- 50).

Table 6- 50: Summary of data concerning **quality** of young **wine** (IIIA1-6.1.4), data from one **processing trial** in **wine** carried out in Austria 2007 (total 1 trial)

Fermentation	Repl.	First assessment (05/10/07)		Second assessment (19/11/07)	
		Control	**Kumar**	**Control**	**Kumar**
AF	1	+, clear note	Ø, slightly unclear	+, clear, pure	+, pure
	2	+, clear note	+, clear	+, clear, pure	+, clear, pure
Spontaneous	1	Ø, loud, yeasty	Ø, loud	Ø, loud (yeasty)	Ø, loud (yeasty)
	2	+, clear	Ø, loud	+, clear, pure	Ø, loud (yeasty)

At the second organoleptic tasting of bottled wine two assessments were conducted in a 4-step assessment (03/07/2008; 10 jurors) and 12/01/2009 (6 jurors)). Parameter Smell and Taste were evaluated separately. In general, the variants with spontaneous fermentation showed worse validation results as the ones with added yeast. This is in line with general findings and is considered as "well-known" problems of spontaneous fermentation. The available results do not show any influence of Kumar towards the fermentation and the sensorial characteristics (Table 6- 51 and Table 6- 52).
The results from the second assessment date (12/01/2009) clearly indicate that no sensorial disruptive taste could be found. Thus, possible deviations need to be considered as transient. There was no significant difference between reference and test product (Table 6- 53 and Table 6- 54).

Table 6- 51: Summary of data concerning **wine quality** (smell) (IIIA1-6.1.4), data from one **processing trial** in **wine** at 03/07/2008 carried out in Austria 2007 (total 1 trial)

Juror	Control				Kumar			
	AF		Spontaneous		AF		Spontaneous	
	1. Repl.	2. Repl.	1. Repl.	2. Repl.	1. Repl.	2. Repl.	1. Repl.	2. Repl.
1	1	1	2	2	1	1	2	2
2	1	1	1-2	1-2	1	1	1-2	2
3	1	1	2	1-2	1-2	1	1	2
4	1-2	1	2	1-2	1	1-2	1-2	2
5	3	1	2	2	1	1	1	1-3
6	1	2	2	1	1	1	2	2
7	1	1	1-2	1	1	1	1	1-2
8	1	1	1-3	1	1	1	1	1
9	2	2-3	1-3	3	2-3	2	2	2
10	1	1	2-3	2	1	1	2	2

1: without flaw/imperfection; 2: mild flaw/imperfection; 3: moderate flaw/imperfection

Table 6- 52: Summary of data concerning **wine quality** (taste) (IIIA1-6.1.4), data from one **processing trial** in **wine** at 03/07/2008 carried out in Austria 2007 (total 1 trial)

Juror	**Control**				**Kumar**			
	AF		**Spontaneous**		**AF**		**Spontaneous**	
	1. Repl.	2. Repl.	1. Repl.	2. Repl.	1. Repl.	2. Repl.	1. Repl.	2. Repl.
1	1	2	1	1	1	2	2	1
2	1	1-2	1	1	1	1	1	1
3	1	2	1-2	1	1	1-2	1-2	2
4	1	2	1-2	2	1	2	1-2	1
5	1	3	1	3	1	1	2-3	1
6	2	1-2	1-2	2	1	1	1	2
7	1	1	1	1	1	1	1	1-2
8	1	1	1	1	1	1	1	1
9	1	2-3	1-2	2	1-2	2	1	2-3
10	1	2	1	1	1	2	2	1

1: without flaw/imperfection; 2: mild flaw/imperfection; 3: moderate flaw/imperfection

Table 6- 53: Summary of data concerning **wine quality** (smell) (IIIA1-6.1.4), data from one **processing trial** in **wine** at 12/01/2009 carried out in Austria 2007 (total 1 trial)

Juror	**Control**				**Kumar**			
	AF		**Spontaneous**		**AF**		**Spontaneous**	
	1. Repl.	2. Repl.	1. Repl.	2. Repl.	1. Repl.	2. Repl.	1. Repl.	2. Repl.
1	1	1	1	1	1	1	1	1
2	1	1	1	1	1	1	1	1
3	1	1	1	1	1	1	1	1
4	1	1	1	1	1-2	1	1	1
5	1	1	1	1	1	1	1	2
6	1	1-2	1	1	1	1	1	1-2

1: without flaw/imperfection; 2: mild flaw/imperfection

Table 6- 54: Summary of data concerning **wine quality** (taste) (IIIA1-6.1.4), data from one **processing trial** in **wine** at 12/01/2009 carried out in Austria 2007 (total 1 trial)

Juror	**Control**				**Kumar**			
	AF		**Spontaneous**		**AF**		**Spontaneous**	
	1. Repl.	2. Repl.	1. Repl.	2. Repl.	1. Repl.	2. Repl.	1. Repl.	2. Repl.
1	1	1	1	1	1	1	1	1
2	1	1	1	1	1	1	1	1
3	1	1	1	1	1	1	1	1
4	1	1-2	1	1	1	1	1	1-2
5	1	1	1	1	1	1	1	1
6	1	1	1	1-2	1	1	1	1-2

1: without flaw/imperfection; 2: mild flaw/imperfection

Switzerland

The characteristics of fermentation, taste and vinification of harvested grapes of plants treated with 5.0 kg/ha Kumar according to a treatment plan in combination with other typical phytosanitary products (anti-mildew fungicides) were determined in two tests in 2007. One test was conducted with a white wine variety (Chasselas) and the other test with 4 red wine varieties (Pinot noir, Gamay, Gamaret, Garanoir). During vinification no problems with Chasselas were observed; and despite the (typical) discolouration of the red grape bunches the fermentation proceeded in a typical manner. No disturbance of yeasts during fermentation was reported and Kumar did not impart any unpleasant tastes on the wine. For details of the change in sugar content during fermentation please refer to Table 6- 55 and Figure 2 and Table 6- 56 and Figure 3.

Table 6- 55: Summary of data concerning impact on **quality** (IIIA1-6.1.4), data from **processing trials** in **grapevine (red wine varieties)** carried out in Switzerland 2007 (1 trial)**.**

Change in sugar content during fermentation		
Date	**°Oe**	**°C**
25/09/07	71	19.0
26/09/07	45	24.6
27/09/07	10	23.7
28/09/07	1	21.0
30/09/07	-3	19.6

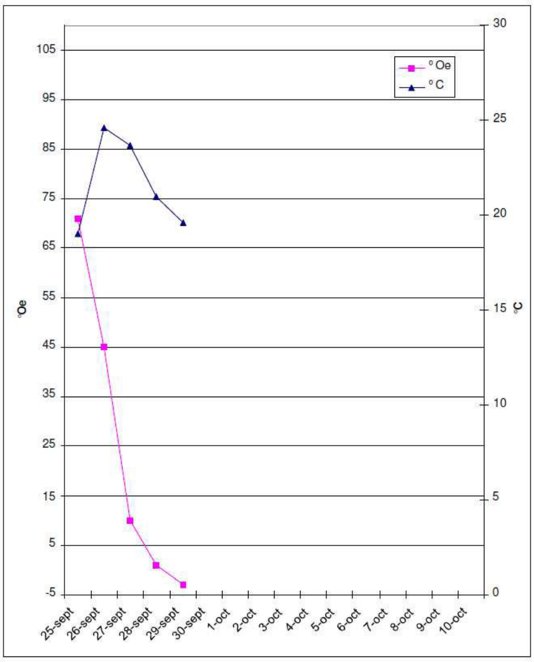

Figure 2: Fermentation kinetics of red grape varieties

Table 6- 56: Summary of data concerning impact on **quality** (IIIA1-6.1.4), data from **processing trials** in **grapevine (white wine: Chasselas)** carried out in Switzerland 2007 (1 trial)

Change in sugar content during fermentation		
Date	**°Oe**	**°C**
01/10/07	58	17.5
02/09/07	35	17.0
03/09/07	20	17.8
04/09/07	10	20.0
05/09/07	2	18.5
06/09/07	-1	18.2
07/09/07	-3	18.0

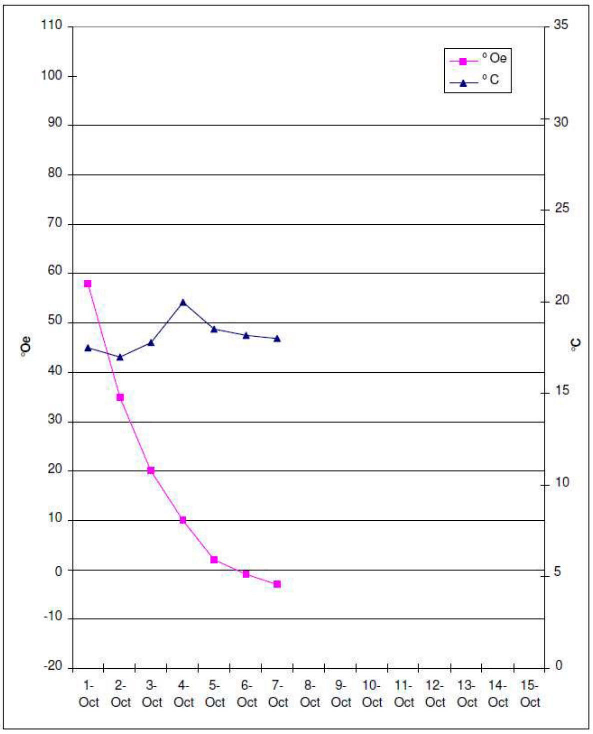

Figure 3: Fermentation kinetics of white wine (Chasselas)

France

In France two processing tests have been set up - each for one vine variety: Chardonnay (white wine) and Merlot (red wine). The quality of grapes in terms of sugar content, alcoholic content and total acidity during vinification and the characteristics of processed wine (in terms of taste) were assessed for comparison of Kumar and the conventional product Scala. Additionally, the potential influence on the length of vinification was examined. The test product was applied five times at 5.0 kg/ha, the reference product Scala four times at 2.5 L/h in both trials.

Most parameters did not significantly differ between the test and reference treatment (refer to Table 6- 57 to Table 6- 62). Merely the sugar content in Chardonnay must was a little bit lower after application of Kumar compared to Scala (216.2 g/L and 223.8 g/L). Influences on the length of vinification could not be observed despite of the significantly superior length of malolactic fermentation with lactic bacteria added to the Kumar treated sampling (refer to Table 6- 63 to Table 6- 65 and Figure 4 and Figure 5). The results of wine tasting did not show any differences between the two treatments neither for the white wine variety nor with the red wine variety. All in all, Kumar does not perturb the grape maturity, the fermentation kinetics and the gustatory qualities of the produced wines.

Table 6- 57: Determination of important **parameters and ingredients while processing** in must (IIIA1-6.1.4), data from processing tests in **wine** carried out in France, 2008/09

Treatment		Must					
Product	**Dose rate**	Sugar content (g/L)		Alcoholic content (%)		Total acidity (g/L H_2SO_2)	
		Chardonnay	Merlot	Chardonnay	Merlot	Chardonnay	Merlot
Kumar	5 x 5.0	**216.2**	**228.3**	**13.0**	**14.0**	**4.5**	**3.9**
Scala	4 x 2.5	223.8	230.4	13.6	14.0	4.5	3.4
Statistics		n.s.	n.s.	n.s.	n.s.	n.s.	n.s.

s. = significant
n.s. = not significant

Table 6- 58: Determination of important **parameters and ingredients while processing** in must (IIIA1-6.1.4), data from processing tests in **wine** carried out in France, 2008/09

Treatment		Must					
Product	**Dose rate**	Turbidity NTU final		pH		Total SO_2 (mg/L)	
		Chardonnay	Merlot	Chardonnay	Merlot	Chardonnay	Merlot
Kumar	5 x 5.0	**112.0**	**-**	**3.52**	**3.57**	**30.0**	**20.0**
Scala	4 x 2.5	121.0	-	3.51	3.52	30.0	20.0
Statistics		n.s.		n.s.	n.s.	n.s.	n.s.

s. = significant
n.s. = not significant

Table 6- 59: Determination of important **parameters and ingredients while processing** in must (IIIA1-6.1.4), data from processing tests in **wine** carried out in France, 2008/09

Treatment		Must					
Product	**Dose rate**	Potassium (mg/L)		Assimilating N (mg/L)		Volatile acidity (g/L H_2SO_2)	
		Chardonnay	Merlot	Chardonnay	Merlot	Chardonnay	Merlot
Kumar	5 x 5.0	**99.0**	**71.0**	**325**	**265.0**	**< 0.1**	**< 0.1**
Scala	4 x 2.5	91.0	65.0	349	264.0	< 0.1	< 0.1
Statistics		n.s.	n.s.	n.s.	n.s.	n.s.	n.s.

s. = significant
n.s. = not significant

Table 6- 60: Determination of important **parameters and ingredients before and after processing** in wine (IIIA1-6.1.4), data from processing tests in **wine** carried out in France, 2008/09

Treatment		Wine					
Product	**Dose rate**	Alcoholic content (%)		Total acidity (g/L H_2SO_2)		Volatile acidity (g/L H_2SO_2)	
		Chardonnay	Merlot	Chardonnay	Merlot	Chardonnay	Merlot
Kumar	5 x 5.0	**13.30**	**14.76**	**4.21**	**4.10**	**0.25**	**0.44**
Scala	4 x 2.5	13.78	14.53	4.12	4.19	0.24	0.38
Statistics		s.	n.s.	n.s.	n.s.	n.s.	n.s.

s. = significant
n.s. = not significant

Table 6- 61: Determination of important **parameters and ingredients before and after processing** in wine (IIIA1-6.1.4), data from processing tests in **wine** carried out in France, 2008/09

Treatment		Wine					
Product	**Dose rate**	Total SO_2 (mg/L)		Free SO_2 (mg/L)		pH	
		Chardonnay	Merlot	Chardonnay	Merlot	Chardonnay	Merlot
Kumar	5 x 5.0	**128.0**	**42.0**	**23.0**	**22.0**	**3.47**	**3.57**
Scala	4 x 2.5	134.0	45.0	32.0	27.0	3.45	3.50
Statistics		n.s.	n.s.	n.s.	n.s.	n.s.	n.s.

s. = significant
n.s. = not significant

Table 6- 62: Determination of important **parameters and ingredients before and after processing** in wine and grapes (IIIA1-6.1.4), data from processing tests in **wine** carried out in France, 2008/09

Treatment		Wine				Grapes	
Product	**Dose rate**	Sugar content (g/L)		OD_{420}		Maturity	
		Chardonnay	Merlot	Chardonnay	Merlot	Chardonnay	Merlot
Kumar	5 x 5.0	**1.1**	**1.7**	**0.05**	**3.50**	Inferior maturity	Similar maturity
Scala	4 x 2.5	1.3	1.9	0.04	3.42		
Statistics		n.s.	n.s.	n.s.	n.s.		

s. = significant
n.s. = not significant

Table 6- 63: Determination of important **parameters during fermentation** (IIIA1-6.1.4), data from processing tests in **wine** carried out in France, 2008/09

Treatment		Fermentation process					
Product	**Dose rate**	Latent period (days)		Alcoholic fermentation length (days)		Malolactic fermentation length (days)	
		Chardonnay	Merlot	Chardonnay	Merlot	Merlot with lactic bacteria	Merlot without lactic bacteria
Kumar	5 x 5.0	**2**	**2**	**7**	**11**	47	61
Scala	4 x 2.5	2	2	7	11	40	61
Statistics		n.s.	n.s.	n.s.	n.s.	s.	n.s.

s. = significant
n.s. = not significant

Table 6- 64: Fermentation stages (Chardonnay)

Date	**Density**		**Temperature (°C)**	
	Control (R)	**Kumar (P1)**	**Control (R)**	**Kumar (P1)**
02/09/2008	1095	1095	17.5	18.0
03/09/2008	1094	1090	19.0	20.0
04/09/2008	1071	1068	21.0	21.0
05/09/2008	1046	1045	19.0	19.0
06/09/2008	1020	1020	22.5	22.5
07/09/2008	1011	1010	21.0	21.0
08/09/2008	1006	1004	18.0	18.0
09/09/2008	997	996	20.0	19.5
10/09/2008	993	993	21.5	21.0
11/09/2008	991	991	21.5	21.0

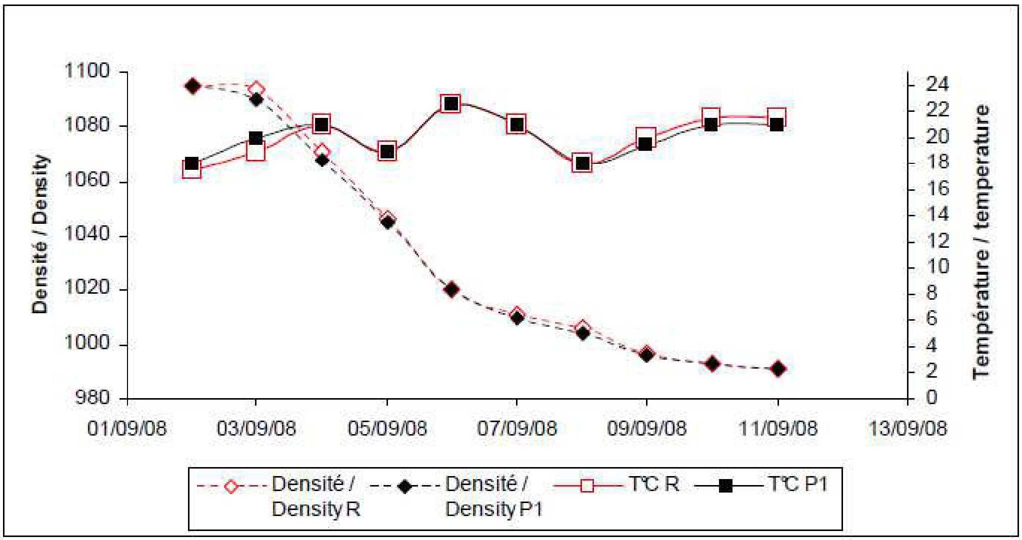

Figure 4: Fermentation kinetics of white wine (Chardonnay)

Table 6- 65: Fermentation stages (Merlot)

Date	Density		Temperature (°C)	
	Control (R)	Kumar (P1)	Control (R)	Kumar (P1)
04/09/2008	1105	1102	19.5	19.5
05/09/2008	1101	1101	19.5	19.5
06/09/2008	1080	1078	24.0	24.0
07/09/2008	1065	1063	22.5	22.0
08/09/2008	1057	1055	19.0	18.0
09/09/2008	1042	1038	21.0	21.0
10/09/2008	1030	1027	22.5	23.0
11/09/2008	1016	1013	23.0	23.0
12/09/2008	1006	1004	21.0	21.0
13/09/2008	1002	1000	19.0	19.0
14/09/2008	999	996	19.0	19.0
15/09/2008	997	995	18.0	18.0
16/09/2008	994	994	17.0	17.0
17/09/2008	994	994	17.0	18.0

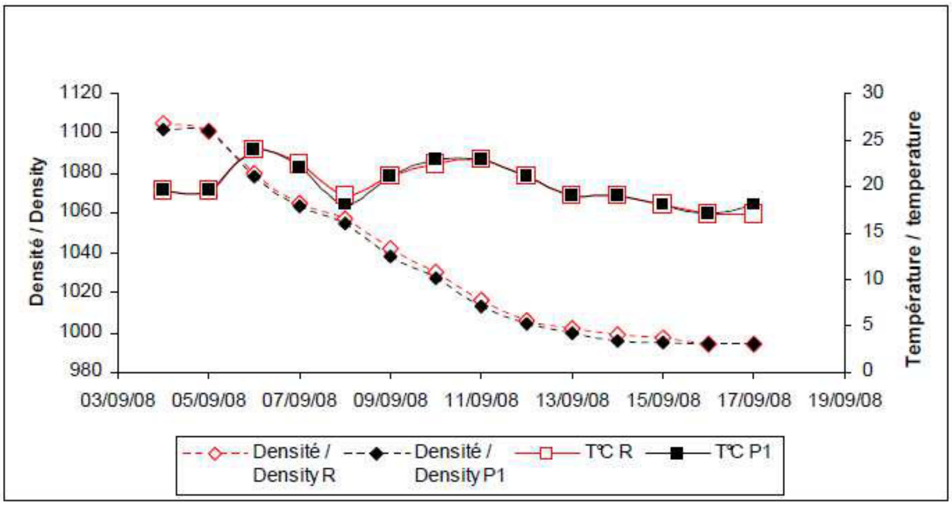

Figure 5: Fermentation kinetics of white wine (Merlot)

<u>Germany</u>

In one trial, carried out in 2013 in Germany, the influence on the taste of treatments with Kumar at 3.0 kg/ha compared to an untreated control in a red wine (Blauer Spätburgunder) and a white wine (Riesling) variety was assessed. 10 weeks after start of processing a triangle taint test was carried out with 18 jurors. If 10 or more persons found the difference correct, significant differences were observed.
No difference in taste was observed between untreated control and treatment with 3 kg/ha Kumar in both wine varieties (Table 6- 66).

Table 6- 66: Sampling details of triangle tests (IIIA1-6.1.4) in the vine varieties Riesling and Blauer Spätburgunder

Triangle Test No.	Plot	Number of test persons	Number of correct determined differences	Percent of correct determined differences	Significance (α = 0.05)
Triangle 1	Untreated	18	6	33.3	no
	3.0 kg/ha Kumar				
Triangle 2	Untreated	18	8	44.4	no
	3.0 kg/ha Kumar				

Conclusion on yield and quality data from efficacy and processing trials

In 10 efficacy trials conducted in Switzerland, Austria and Germany between the years 2006 and 2015, the yield and fruit quality of treated and untreated vine plants was determined. As to be expected, the yield was increased and wine quality of plots treated with Kumar was not negatively influenced compared to the untreated control and the reference standards. Furthermore, 7 tests with processing results were carried out in Switzerland, Austria, France and Germany, with no negative effects regarding the quality of harvested vine grapes, the wine making process and the wine as the processed product.

In conclusion, no negative effect of Kumar applied at the target rate was observed in any of the trials. Even with worst case applications (Kumar in combination with anti-mildew products) no negative effects are to be expected. Additionally, potassium bicarbonate is used since many years for de-acidification itself in wine; therefore, any negative effects of applied potassium bicarbonate on the grapes can be excluded. Thus, Kumar is considered as safe when applied according to the envisaged GAP use.

The yield data submitted for the use in grapevine comply with the uniform principles.

Effects on the yield and quality of treated plants and plant products

In a total of 6 efficacy trials conducted in Germany in the years 2013 to 2015 the yield of treated and untreated vine was determined. No negative effect after application of Kumar occurred.

In a total of 4 efficacy trials conducted in Switzerland and Austria there was no significant effect on the sugar content in °Oechsle of the test or reference treatment compared to control.

Effects on the processing procedure

Only two of seven required processing tests in Switzerland, Austria, France and Germany follow the EPPO standard (EPPO standard PP 1/268(1)). But potassium bicarbonate is well-known and is used as a plant strengthener in the German viticulture since years without negative impact on the fermentation processes and the quality of the wine.

The sensorial test was conducted at two assessment dates after end of fermentation and clarification and after 10 months and more than one year after end of fermentation. No negative effects occurred.

IIIA1 6.2 Adverse effects

IIIA1 6.2.1 Phytotoxicity to host crop

Introductory information on trials with phytotoxicity assessments in grapevine

Phytotoxicity on grapes was evaluated in a total of 47 efficacy trials (18 different varieties) and one processing trial (5 varieties), whereas a total number of 20 varieties (Varieties Chasselas, Pinot Noir and Gamay were assessed in both efficacy and processing trials) was tested in the whole BAD. All trials were conducted according to GEP and followed the appropriate EPPO standards by official or officially recognised testing organisations. The test design was a randomised complete block design with either 3, 4 or 5 replicates. The plot size ranged between 9.0 and 48.0 m^2. The trials were conducted between 2003 and 2015 in Germany, Switzerland, Austria and France representing the Maritime EPPO climatic zone (refer to Table 6- 67).

Table 6- 67: Overview of efficacy and processing trials with phytotoxicity assessment

No.	Pest	Efficacy trials			Processing trials			No. of Varieties 3)
		No.	Country	Status 1)	No.	Country	Status 1)	
(1)	*Botryotinia fuckeliana*	31	CH, AT, DE, FR	GEP 2)	1	CH	2)	11 (5)
(2)	*Erysiphe necator*	16	CH, AT, DE	GEP 2)	-	-	-	10
	Total	**47**			**1**			**20** 4)

1) Trials with "GEP" were carried out according to Good Experimental Practice and include a GEP certificate or an official recognition certificate. For an overview of the testing facilities and the corresponding certificates please refer to IIIA1 6.7.
2) In Switzerland an official GEP certification system was not available prior to 2010. In Austria an official GEP certification was implemented in 2005. Nevertheless, all trials were conducted according to the respective EPPO guideline and are considered as GEP-compliant for the reasons outlined in detail on page 28.
3) Numbers in brackets ( ): number of varieties in processing trials
4) Total number of varieties in all uses and all trials

(1) Grapevine (BOTRCI: *Botryotinia fuckeliana*)

Results and conclusion

In 9 out of the 31 trials slight phytotoxic effects in terms of chlorosis, necrosis or bronzing of leaves or bunches occurred.

Two trials from Switzerland showed necrotic and chlorotic effects on bunch 44 days after 3 applications of Kumar at a dose rate of 5.0 kg/ha. The effects ranged from 2 (necrosis) to 4 (chlorosis) on EWRS scale 1-9. Nevertheless, discolouration of grapes and burns may occur after application of potassium bicarbonate.

In four trials from Switzerland slight necrotic symptoms occurred after three or four applications of Kumar at 5.0 kg/ha. Whereas in two out of the four trials glossy bunches were reported after 4 applications, in the other two trials necrotic effects with a degree of 3 (EWRS scale 1-9) occurred after three as well as after four applications on bunches. In one of these trials bronzing on bunches occurred with degree of three as well.

In one trial, carried out in Austria in 2007, very slight necrotic symptoms on leaves occurred after application of Kumar at 5.0 kg/ha. The symptoms were typical after application of the test product and always of an acceptable level.

In two trials, carried out in Germany between 2013 and 2015, symptoms of general phytotoxicity were observed after application of 3.0 and 5.0 kg Kumar/ha. Symptoms were only visible at the latest one to two evaluations at assessment timing 8, 23, 38 and 41 DAF. With up to 8 % after 6 applications, the symptoms are of an acceptable level.

All in all, 22 out of the 31 efficacy trials in vine remained without any symptoms. Even if phytotoxicity occurred the symptoms were merely slight and acceptable and seem to appear more frequent after application on bunches with lower spray volumes (e.g. 250-300 L/ha water volume). Since the bunch application was merely carried out in the supportive trials and is not matching the proposed GAP use, Kumar is considered completely safe when applied in vine. Furthermore, any negative effect on the harvested grapes can be excluded based on the data on yield. Please refer to chapter IIIA1 6.1.4 for the corresponding yield data. Any variety dependent sensitivity is not indicated either.

The results demonstrated that Kumar can be regarded as safe for the crop grapevine when applied according to the envisaged GAP use (refer to Appendix 2). The phytotoxicity data submitted for the use against grey mould (BOTRCI: *Botryotinia fuckeliana)* in grapevine comply with the uniform principles.

(2) Grapevine (UNCINE: *Erysiphe necator*)

Results and conclusion

In 5 out of the 16 trials very slight phytotoxic effects in terms of necrosis or stunting of leaves or bunches occurred.

Two trials from Switzerland (2004) showed necrotic effects; one of them on bunches and leaves after application of 10 x 5 kg/ha, whereas the application of 10 x 2.5 kg/ha remained without any symptoms. In the other trial leaves and bunches showed necrotic symptoms after application of 10 x 5.0 kg/ha, after application of 10 x 2.5 kg/ha only bunches were affected. The effects were reported 2-15 days after application and ranged from 2-3 according to EWRS scale 1-9. Nevertheless, discolouration of bunches may occur after application of potassium bicarbonate and does usually not cause any negative long-time effects.

In two trials from Switzerland (2008) slight stunting symptoms occurred after application of Kumar 10 times at 5.0 kg/ha, whereas in one of these trials slight necrotic effects with a degree of 3 (EWRS scale 1-9) on bunches were reported as well.

In one trial, carried out in Germany in 2015, symptoms of general phytotoxicity were observed after application of 3.0 and 5.0 kg Kumar/ha. Symptoms were only visible at the latest two evaluations at assessment timings 4 DAK and 40 DAL. 12 applications have been conducted, resulting in symptoms of phytotoxicity with up to 13.8 %. However, these trials show no damage at assessment timing conducted after the intended 6 applications.

All in all, 11 out of the 16 efficacy trials in vine remained without any symptoms. Even if phytotoxicity occurred the symptoms was merely slight and acceptable. Furthermore, any negative effect on the harvested grapes can be excluded based on the data on yield. Please refer to chapter IIIA1 6.1.4 for the corresponding yield data. Any variety dependent sensitivity is not indicated either.

The results demonstrated that Kumar can be regarded as safe for the crop grapevine when applied according to the envisaged GAP use (refer to Appendix 2). The phytotoxicity data submitted for the use against powdery mildew in grapevine comply with the uniform principles.

Overall conclusion on the crop safety of Kumar - BOTRCI and UNCINE

Phytotoxic effects were evaluated in one processing trial and each of the 47 efficacy trials with Kumar in grapevine carried out against *Botrytis fuckeliana* and *Uncinula necator* in the years 2003 - 2015 in Germany, Switzerland, Austria and France. The trials included 20 different grapevine varieties. In some of the trials very slight phytotoxic effects in terms of necrosis or stunting of leaves or bunches occurred. All in all, most of the efficacy trials in vine remained without any symptoms. Even if phytotoxicity occurred the symptoms was merely slight and acceptable. No negative impact on the yield level or the yield quality could be expected.

Therefore, Kumar can be regarded as completely safe for the crop grapevine according to the envisaged GAP use. A presentation of the phytotoxicity results of all other trials in tabular format was omitted.

Thus, the acceptability of some slight phytotoxicity symptoms after treatment with Kumar does also take into account the limited availability of alternative products. Since conventional active substances often cause negative impact on beneficial and soil, the request for alternatives grows more and more by agriculturists and consumers. Inorganic compounds as potassium bicarbonate can offer useful alternatives. The alternation of conventional products with biological compounds (Kumar) could offer as well an alternative in situation where specific botryticides are showing resistance.

The phytotoxicity data submitted for the use in grapevine comply with the uniform principles.

Symptoms of phytotoxicity could not be excluded and occurred in 9 of 31 trials of BOTRCI and 5 of 16 trials of UNCINE. The trials included 20 different grapevine varieties. Even if phytotoxicity occurred the symptoms were merely slight and acceptable. No negative impact on the yield level or the yield quality could be expected. Therefore, Kumar can be regarded as safe for the crop grapevine according to the envisaged GAP use.

IIIA1 6.2.2 Adverse effects on health of host animals

This is not an EC data requirement.

IIIA1 6.2.3 Adverse effects on site of application

This is not an EC data requirement.

IIIA1 6.2.4 Adverse effects on beneficial organisms (other than bees)

During the course of the effectiveness trials (IIIA 6.1.3) observations indicating any effects whatsoever on beneficial or other non-target organisms were not reported. However, the lack of observations of negative impacts on non-target organisms is in accordance with the results of toxicity tests in ecotoxicologically relevant indicator species.

The evaluation of the risk for non-target arthropods was performed in accordance with the recommendations of the guidance document ESCORT 2 (Candolfi, 2001).

Key data on the toxicity to non-target arthropods are available from studies conducted with the product. In this context, extended laboratory tests with the sensitive indicator species *Aphidius rhopalosiphi* and *Typhlodromus pyri* using natural substrate were considered as key studies.

In brief, risk calculations for the in-field and the off-field indicate that Kumar poses a theoretical risk to non-target arthropods following application according to the proposed use patterns.

Since the last national assessment in Germany for the use in apple, new data (an extended laboratory study on predatory bug, and an aged residue study on the predatory mite) have been made available by the applicant. Therefore the national assessment on apple has been updated with this new data.

Effects on relevant beneficial organisms

The critical endpoints employed in the risk assessment for non-target arthropods are indicated in the table below.

Table 6- 68: Toxicity of ARMICARB (syn. Kumar) to non-target arthropods with reference to agreed endpoints

Test substance	Species	Exposed life stage	Study type	LR_{50} (g product/ha)	Sub-lethal effects	Reference (author/date/report
Armicarb 85 SP	*Aphidius rhopalosiphi*	Adult	Extended laboratory study on barley seedlings, 3D exposure (limit test)	LR_{50} > 8750 (>7438 g as/ha)	No repellent effect Reduction of reproduction: 11.57%	Juan,D. 03 Feb 2011 EPA-BHT-02-10
	Typhlodromus pyri	Protonymph	Extended laboratory study on bean leaf discs, 2D exposure (multi dose test)	LR_{50} = 6493 (5519 g as/ha) ER_{50} « 3162 * (2688 g as/ha) *approximation	Reduction of reproduction: 42% (1000 g/ha) 30% (1778 g/ha) 48% (3162 g/ha) Not significant reduction at 1778 g/ha	Juan, D. 04 Jan 2011 EPA-BHT-01-10
	Orius laevigatus	**2nd instar nymph**	**Extended laboratory study on detached apple leaves (multi dose test)**	**LR_{50} = 9.978 (equivalent to 8703 g as/ha)**	**ER_{50} > 7.5 (equivalent to > 6540 g as/ha) (2.6% reduction observed at 7.5 kg PP/ha)**	***Martinez, F.L. (2013)***
	Typhlodromus pyri	**Protonymph**	**Aged residue study (up to 28 days aging following application of either 6.37 or 13.1 kg**	**<50% mortality at ≥0 days after application (DAA) of both 6.37 and 13.1 kg a.s./ha**	**<50% effects on reproduction at 0 DAA of 6.37 kg a.s./ha <50% effects on reproduction at 7 DAA of 13.1 kg**	***Luna, F (2013)***

According to German requirements, TER values were calculated.

In-field Exposure and Risk assessment:

Non-target arthropods living in the crop can be exposed to residues from Kumar by direct contact either as a result of overspray or through contact with residues on plants and soil or in food items. Kumar is applied at a maximum rate of 6 x 4.25 kg as/ha. The maximum in-field exposure (Predicted Environmental Rate, PER) to foliar-dwelling or soil-dwelling organisms is therefore 13.600 kg as/ha, assuming the worst-case (contradiction) of 100% crop interception and 0% crop interception, respectively as well as a MAF of 3.2

The in-field exposure (predicted environmental residue, PER) is calculated according to ESCORT 2 using the following equation:

$$PER_{in-field} = \text{Application rate (g ai/ha)} \times MAF$$

The MAF is a generic multiple application factor, which is used to take into account the potential build-up of applied substances between applications based on the application interval, DT_{50} value and number of applications. Default foliar and soil MAF values following six applications are given in the ESCORT 2 Guidance Document. Kumar is applied six times per season and the foliar multiple application factor MAF is therefore 3.2 and for soil is 4.6. The soil route is considered not relevant, since only foliar dwelling species are concerned (see also the note under the MAF table in ESCORT 2). Therefore, the soil exposure route has been removed.

The maximum predicted environmental residues (PER) occurring within the field after application of Kumar at the maximum application rate are presented in Table 6- 69.

Table 6- 69: In-field PER values for application of Kumar

Substance	Application rate	PER (foliar)
Potassium hydrogen carbonate	Single application: 4250 g/ha	4250 g/ha
	6 x 4250 g/ha	13600 g/ha

The potential risk of Kumar to in-field non-target arthropods was assessed by calculation of the TER (Toxicity Exposure Ratio) with the predicted environmental rate (PER) and the lowest lethal rate (LR_{50}) values according to the following formula:

$$\text{In field TER} = \frac{ER_{50}}{\text{in - field PER}}$$

Since the in-field PER after 6 applications is higher than the L/ER_{50} of three tested non-target arthropod species, a potential risk to non-target arthropods cannot be excluded.

However given the multiplication of very conservative factors, no refinement is considered necessary and the risk is considered acceptable. In particular it should be noted that:

Realistic exposure will be less than estimated as availability of the potassium and bicarbonate ions will be reduced by buffering and binding in the foliar and soil environments.

- in practice, less than 6 applications will be applied in the field programme as farmers will alternate the product
- in practice, Kumar may be applied with a reduced dose (less applications)
- Worst case residues for foliar organisms assumed
- toxicity endpoints represent a very worst case under laboratory conditions: in the field, Kumar will be washed off between applications by wind and rain because of the nature of the product and the active substance

Table 6- 70: In-field TER value for non-target arthropods after 1 application of Kumar

Species	Application rate (kg as./ha)	L/ER50 (kg as/ha)	PERin-field (kg as/ha)	TERin--field
T. pyri	4.25	5.519 2.688	4.25	> 1 < 1
A.rhopalosiphi	4.25	> 7438	4.25	> 1
O. laevigatus	4.25	8.700	4.25	> 1

When considering a single application, the $PER_{in-field}$ is lower than the available endpoint in most cases. Only one of the available endpoints of *Typhlodromus pyri* is below the $PER_{in-field}$.indicating a possible risk.

However, since no effects on mortality are expected and the off-field risk is acceptable (see below), it is considered that the in-field population will be able to recover within a relevant period by recolonisation from out of the off-field area.

This conclusion is further supported by new data provided since the last core assessment in the central zone as explained hereafter for the use of Kumar in grapes (6 x 4250 kg /ha, PER = 13.6 kg a.s./ha (in-field)):

An aged residue study has been performed using the most sensitive species tested, *T. pyri*. The results of the aged residue study indicate that there is potential for recolonisation from off-field populations into affected treated areas in-field. Apple trees were treated with Kumar at one of two rates (6.37 or 13.1 kg a.s./ha) and residues allowed to age for up to 28 days under realistic outdoor conditions. Protonymphs of *T. pyri* were then exposed to these aged residues in the laboratory. Less than 50 % effects on mortality were observed following exposure to freshly dried residues i.e. 0 DAA. Less than 50 % effects on reproduction were observed at 0 DAA for 6.37 kg a.s./ha, and at 7 DAA for 13.1 kg a.s./ha. The predicted exposure rates (PERs) for the proposed use of Kumar on grapes are 13.6 kg a.s./ha (in-field) and 0.218 kg a.s./ha (off-field). The PERs are within the rates tested in the aged residue study. The effects (lethal and sublethal) on *T. pyri* were less than 50 % after residues had been aged for 0-7 days. Therefore, it is expected that *T. pyri* would successfully recolonize a treated area in much less than a year, which is the criteria under ESCORT II. As such, the risks from in-field exposure of *T. pyri* are considered to be acceptable.

Therefore it is concluded that populations of arthropods would be able to recover within the one year time-frame stated in ESCORT 2.

Off-field Exposure and Risk assessment:

Exposure of non-target arthropods living in non-target off-field areas to Kumar will mainly be due to spray drift from field applications. Off-field predicted environmental rates (PER-values) were calculated from in-field PERs in conjunction with drift values published by Rautmann et al. (2001[11]) as shown in the following equation:

$$\text{Off-field PER} = \frac{\text{Maximum in-field PER} \times \frac{\text{drift percentile}}{100}}{\text{vegetation distribution factor (vdf)}}$$

where:

vdf = vegetation distribution factor used in combination with test results derived from 2-dimensional exposure set-ups

Vegetation distribution factor: To account for interception and dilution by three-dimensional vegetation in off-crop areas, a vegetation distribution or dilution factor (vdf, see above) is incorporated into the equation when calculating off-field exposure in conjunction with toxicity endpoints derived from two-dimensional studies (e.g. glass plate or leaf discs). A dilution factor of 10 is recommended by the Guidance Document, but has been questioned. The risk assessment procedure here according to German requirements considers a dilution factor of 5 more appropriated. For endpoints resulting from 3-dimensional studies, i.e. where spray treatment is applied onto whole plants, the dilution factor is not used. For the results of the study with *T. pyri* exposed to Kumar, a vegetation distribution factor of **5** has to be considered (study conducted in 2D environment).

A MAF of 3.2 is used, according to ESCORT II and the EC Guidance Document on Terrestrial Ecotoxicology. The maximum in-field exposure (Predicted Environmental Rate, PER) to foliar-dwelling or soil-dwelling organisms is 13.600 kg as/ha (= 4250 g as/ha x 3.2).

The drift value at 3 m distance is 8.02% of the application rate (90th percentile drift, grapevine, late application). The drift factor (% drift/100) is therefore 8.02/100 = 0.0802.

Off-field PER values are presented in the following table:

Table 6- 71: Off-field PER values for the use groups following the use of Kumar

Use No.	Application rate (kg as/ha)	Drift scenario	Drift rate (% appl. rate)	MAF	Off-field PER (kg as/ha)
Grape	max. 4.25	Grapevine, late	8.02	3.2	0.218

[11] Rautmann, D.; Streloke, M.; Winkler, R.: "New basic drift values in the authorization procedure for plant protection products" Mitteilungen aus der Biologischen Bundesanstalt für Land- und Forstwirtschaft 383, 133-141 (2001).

The assessment of the risk to non-target arthropods following exposure to Kumar was performed on basis of the calculation of toxicity-exposure ratios (TER values) according the following formula:

$$TER = \frac{L(E)R50\,(L\ product/ha)}{Off\text{-}field\,PER\,(L\ product/ha)}$$

The risk is considered acceptable if the values obtained are $TER_{off\text{-}field}$ > 10 based on Tier 1 tests on glass plates (laboratory tests) or $TER_{off\text{-}field}$ > 5 based on Tier 2/higher-Tier tests (extended lab or field tests) with additional test species.

The resulting $TER_{off\text{-}field}$ value for the most sensitive species after the use of Kumar in grape is given in the following table:

Table 6- 72: Off-field TER value for non-target arthropods after the use of Kumar in grape

Species	use group no.	Application rate (kg as./ha)	ER_{50} (kg as/ha)	$PER_{off\text{-}field}$ (kg as/ha)	$TER_{off\text{-}field}$
T. pyri	-	4.25	2.688	0.218	12.33

The off-field TERvalues for indicator species are above the trigger values, indicating that Kumar does not pose an unacceptable risk to non-target arthropods in off-field areas. Thus, no risk mitigation measures need to be implemented. For further information, please refer to the core assessment, part B, section 6 of the plant protection product Kumar.

Effects on earthworms

The EU risk assessment considered higher application rates (8 x 5100 g a.s./ha) than this current dossier (6 x 4250 g a.s./ha).

The same waiver is presented here:

- Potassium and bicarbonate are very common natural materials that are present in soils.
- The amount of potassium or bicarbonate added to the soil following the application of Kumar will be negligible compared with the amounts of potassium or bicarbonate already present.
- Any potassium added to the soil will enter the mineral cycle driven by the equilibrium between soluble, extractable and bound potassium (see section 5, IIIA 9.1 and 9.3).
- Potassium bicarbonate demonstrates a low level of activity against all animals that have been tested.

In the EFSA conclusion, a data gap was identified for data to support the high background concentrations of K^+, and said 'If the background levels are confirmed to be higher than the exposure from the representative uses then the risk could be considered as low'. The applicant has now presented further support for the assumed background levels.

The worst case PECs in soil resulting from the application of Kumar in grape was calculated with the tool Escape version 2 according to German requirements. PECs are estimated as follows:

At soil depth of 2.5 cm
PEC_{soil} = Potassium = 10.608 mg/kg

PEC_{soil} = Bicarbonate = 16.592 mg/kg

At soil depth of 1 cm
PEC_{soil} = Potassium = 26.520 mg/kg
PEC_{soil} = Bicarbonate = 41.480 mg/kg

Given that agricultural soils normally have extractable potassium concentrations above 150 mg/kg, any adverse effects on earthworms from the application of Kumar are extremely unlikely.

For further information please refer to the core assessment, part B, section 6 for the label extension of the plant protection product Kumar in grape.

Effects on other non-target macro-organisms

In view of the high naturally occurring background levels of potassium and bicarbonate in the environment waivers from conducting specific studies on other non-target organisms (flora and fauna) are requested. When background levels of potassium and bicarbonate are compared to the worst-case levels estimated to arise from the GAP use of Kumar it is considered that there is no need for screening data for other organisms (flora and fauna).

Effects on organic matter breakdown

In view of the high naturally occurring background levels of potassium and bicarbonate in the environment no effect on organic matter breakdown is expected.

Effects on soil micro-organisms

The EU risk assessment considered higher application rates (8 x 5100 g a.s./ha) than this current dossier (6 x 4250 g a.s./ha).

The same waiver is presented here:

- Potassium and bicarbonate are very common natural materials that are present in soils.
- The amount of potassium or bicarbonate added to the soil following the application of Kumar will be negligible compared with the amounts of potassium or bicarbonate already present.
- Any potassium added to the soil will enter the mineral cycle driven by the equilibrium between soluble, extractable and bound potassium (see Section, IIIA 9).
- Potassium is an essential nutrient for soil micro-organisms.
- Potassium bicarbonate is effective against some foliar fungal pathogens through both pH and osmotic effects. Such modes of action will not be relevant in the soil due to the enormous buffering impact on pH and massive dilution factors.

As a consequence, adverse effects on soil microorganisms from the application of potassium bicarbonate are extremely unlikely.

The worst case PECs in soil resulting from the application of Kumar in grape was calculated with the tool Escape version 2 according to German requirements. PECs are estimated as follows:

At soil depth of 2.5 cm
PEC_{soil} = Potassium = 10.608 mg/kg
PEC_{soil} = Bicarbonate = 16.592 mg/kg

At soil depth of 1 cm
PEC_{soil} = Potassium = 26.520 mg/kg
PEC_{soil} = Bicarbonate = 41.480 mg/kg

Given that agricultural soils normally have extractable potassium concentrations above 150 mg/kg (please see IIIA 10.6), any adverse effects on soil microorganisms from the application of Kumar are extremely unlikely.

For further information please refer to the core assessment, part B, section 6 for the label extension of the plant protection product Kumar in grape.

IIIA1 6.2.5 Adverse effects on parts of plant used for propagating purposes

Submission of data is not considered to be required due to the fungicidal nature of the product (EPPO guideline PP 1/135(3)).

IIIA1 6.2.6 Impact on succeeding crops

Submission of data or information for the impact on succeeding crops is not required for the use in grapevine, since it is a perennial crop and not followed in rotation by succeeding crops.

Anyway, no negative impact of Kumar on succeeding crops is expected since the additional concentration of potassium bicarbonate residues in soil following the use of potassium bicarbonate sprays for disease control is rather small and insignificant compared to the existing background levels of potassium in soil. Residues of potassium bicarbonate in succeeding crops grown in rotation after crops treated with plant protection products containing potassium bicarbonate are not expected to be present at levels higher than these background levels. In addition, potassium bicarbonate is immediately immobilised in the soil due to adsorption to organic matter and clay minerals. Thus, the availability of potassium bicarbonate for plants is very low in the succeeding crop. Consequently, metabolism and distribution studies or field trials on representative crops are not considered necessary.

Furthermore, Kumar is a fungicide without any herbicidal action and therefore not expected to be harmful for any succeeding crop. Additionally, the applicant has not become aware of any negative impact on succeeding crops from the long-term practical experience in Europe with potassium bicarbonate-products.

For more details please refer to the risk assessment for non-target plants in dRR Section 6.

The fungicide Kumar (850 g/kg potassium hydrogen carbonate) has been proposed for application in grape at a total maximum application rate of 5 kg/ha and year (6 applications). Taking into account the potential disappearance of the active ingredient between the applications, the worst case exposition can be calculated to be approximately 16 kg/ha and year (using the maximum default value MAF of 3.2). This corresponds to 13.6 kg active substance/ha and year.
Throughout the field trials on effectiveness and selectivity there have been no reports or observations to suggest a detrimental impact of Kumar on beneficial or non-target organisms.
Appropriate studies on the potential adverse effects on beneficial arthropods were available from Registration Report Part B, Section 6, Annex Point IIIA 10.5 (Effects on Arthropods Other Than Bees), Core Assessment for the product ARMICARB (Potassiumbicarbonat 85 SP) which is similar to Kumar.

The toxicity of Kumar has been investigated by carrying out

- laboratory tests on *Typhlodromus pyri.*
- extended laboratory tests on *Aphidius rhopalosiphi, Orius laevigatus* and *Typhlodromus pyri.*

When laboratory tests and higher tier tests were available for the same species, only the results from the higher tier test are being used for the assessment. These results are presented in Table 6.2.4-1.

Table 6.2.4-1: Effects of ARMICARB (Potassiumbicarbonat 85 SP) on beneficial arthropods in extended laboratory tests on natural substrates.

Species (Exposed Stage)	Substrate	substance	Rate [g a.s./ha]	Corrected mortality [%]	Sublethal effect [%]	Reference
A. rhopalosiphi (A)	*H. vulgare*	Potassium-bicarbonat	7503.13	10.71	11.57	EPA-BHT-02-10 Juan, 2011
T. pyri (PN)	Glas	Potassium-bicarbonat	8575.0	11.46	41.95	EPA-BHT-01-10 Juan, 2011
			1524.88	16.67	29.70	
			2711.66	22.92	47.98	
			4993.57	55.21	-	
			85750.0	80.42	-	
T. pyri (PN)	Apple leaves	Potassium-bicarbonat	**0 DAA** 6371.42	28.42	37.17	TRC13-060BA Luna Martínez, 2013
			7 DAA 6371.42	6.19	38.57	
			21 DAA 6371.42	6.32	14.7	
			28 DAA 6371.42	0.00	12.41	
			0 DAA 13083.00	40.00	50.44	
			7 DAA 13083.00	12.37	48.95	
			21 DAA 13083.00	6.32	31.09	
			28 DAA 13083.00	4.21	16.23	
0. laevigatus (A)	Apple leaves	Potassium-bicarbonat	1635.40	10.11	3.4	TRC13-061BA Luna Martínez, 2013
			3270.80	24.68	10.9	

			6541.50	39.26	2.6	
			13083.00	73.81	2.3	
			17444.00	88.10	6.8	

A = adults, PN = protonymphs

On the basis of the presented results effects > 50% are expected for populations of *Orius laevigatus* when Kumar is applied according to the recommended use pattern. The total maximum application rate of 13.6 kg/ha and year has not been tested in the submitted studies for *Aphidius rhopalosiphi* and *Typhlodromus pyri*. For *Typhlodromus pyri,* application rates slightly lower than the total maximum application rate per year already resulted in sublethal effects > 50%. No assessment is possible for *Aphidius rhopalosiphi.* However, *Aphidius rhopalosiphi* is not a relevant antagonist in the proposed crops but similarly, no assessment is possible for relevant beneficial insect species.

Classification scheme of the effects:

Laboratory tests on artificial substrates (glass, quartz sand)

- < 30% = not harmful
- 30 – 80% = slightly harmful
- > 80% = harmful

Extended laboratory tests on natural substrates, semi-field and field tests

- < 25% = not harmful
- 25 – 50% = slightly harmful
- > 50% = harmful

<u>Proposal for classification</u>:

IIIA1 6.2.7 Impact on other plants including adjacent crops

In general, the risks to non-target plants following the use of potassium bicarbonate are considered to be very low. Potassium bicarbonate is naturally present in humans, animals, plants and virtually all living organisms. Under environmental conditions, potassium bicarbonate dissociates completely to potassium and bicarbonate ions and it is impossible to differentiate between ions naturally present and those of external origin. Bicarbonate is present in soil pore waters as a result of carbon dioxide liberated from the respiration of soil organism. Potassium is an essential plant and microbial nutrient that has a natural cycle in soil of uptake and utilisation by plants and microbes, followed by release resulting from the decomposition of rotting organisms. Additionally, it is used as an additive in winemaking, as a base in foods and to regulate pH. Therefore, potassium input resulting from use as a fungicide is considerably smaller than the crops' potassium needs.

Since Kumar is a fungicide and was tested on a range of crops, selectivity data can be taken from the efficacy trials presented in this document and former applications according to EPPO guideline PP 1/256(1). Any negative side effects on target or adjacent crops have not been reported in the efficacy trials. For more details please refer to the risk assessment for non-target plants in dRR Section 6.

IIIA1 6.2.8 Possible development of resistance or cross-resistance

A resistance risk analysis was conducted according to the EPPO guideline PP 1/213 (3). The currently available data on the resistance development in fungal diseases against potassium bicarbonate was retrieved from literature. In addition, data available on resistance occurring in the target pathogens *Botryotinia fuckeliana* and *Erysiphe necator* were retrieved from the FRAC database (fungicide resistance action committee). Potassium bicarbonate is a fungicide with a "not classified" mode of action (FRAC code NC) since the target site is unknown. Despite the fact that the mechanism of the fungicidal activity of potassium bicarbonate is not yet completely investigated, potassium bicarbonate mainly acts as contact fungicides. Therefore, resistance mechanisms as modification or metabolisation are not assumed to occur in the case of potassium bicarbonate and thus potassium bicarbonate is classified as low risk substance by FRAC. Potassium bicarbonate has extremely low potential for development of resistance due to its inorganic nature. Until now no resistance has been detected in the different fungicidal uses of potassium bicarbonate. Consequently, there is no cross-resistance with other fungicides either.

The combined risk of potassium bicarbonate is weak ('1' or '1.5') for both fungal pathogens, i.e. *Erysiphe necator* and *Botryotinia fuckeliana*. The overall risk for potassium bicarbonate combining the fungicide risk, the pathogen risk and the agronomic risk is considered to be weak for the envisaged GAP use assumed that the general measures of good agricultural practice and integrated pest management are considered. Thus, the risk is acceptable. This is based on the facts that the active substance poses a low resistance risk and that potassium bicarbonate is envisaged for a limited number of applications per year i.e. alternation with other fungicides with different modes of action takes place automatically.

Based on the data summarised in the Biological Assessment Dossier (BAD) it is shown that Kumar is an effective plant protection product for the GAP use applied for. Any undue risk from the application according to the GAP use specified in the BAD can be excluded. Therefore, application is sought for the proposed product registration corresponding to the envisaged GAP use listed in Appendix 2.

The data on the resistance risk submitted comply with the uniform principles.

The risk of development of resistance or cross-resistance is considered low. No risk phrases are required.

IIIA1 6.3 Economics

This is not an EU data requirement.

IIIA1 6.4 Benefits

IIIA1 6.4.1 Survey of alternative pest control measures

This is not an EU data requirement.

IIIA1 6.4.2 Compatibility with current management practices including IPM

This is not an EU data requirement.

IIIA1 6.4.3 Contribution to risk reduction

This is not an EU data requirement.

IIIA1 6.5 Other/special studies

Not relevant.

IIIA1 6.6 Summary and assessment of data according to points 6.1 to 6.5

This document was compiled for the submission to BVL in the context of a label extension of Kumar in Germany. The fungicide is a SP-formulation based on the active ingredient potassium bicarbonate at a concentration of 850 g potassium bicarbonate/kg. Potassium bicarbonate (synonymous to potassium hydrogen carbonate) has long been used as a food supplement, including being used as a release agent, acidity regulator and baking agent. Despite the fact that potassium bicarbonate is registered for various commercial uses, the registration for fungicidal use is relatively new.

In Germany, the product Kumar is registered for the following use:

Product name	**Registration no.**[*)]	**Crop**	**Pest**
Kumar	007547-00	pomiculture	*Venturia spp.*

[*)] Registration number according to German registration at BVL

Currently, potassium bicarbonate is listed for fungicidal use in organic production (EC No.404/2008). Within the context of the EU harmonisation in September 2009 the active ingredient potassium bicarbonate has been included into Annex I of Directive 91/414/EEC (Commission Directive 2008/127/EC, without any specific provisions under Part B (in accordance with Commission Regulation (EC) No 2229/2004, as amended by Commission regulation (EC) No 1095/2007)) and is now listed in Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011.

The corresponding documentation on the EC Review Report for potassium hydrogen carbonate (SANCO/2625/08, 28 October 2008), the EFSA Journal 2012, 10(1), p.2524 as well as the DAR for potassium hydrogen carbonate (Ireland, 2006) are considered to provide the relevant review information and serve as a reference.

The test product Kumar shows sufficient efficacy in the use applied for:

Use no.	Crop	Pest
(1)	Grapevine	Grey mould (BOTRCI: *Botryotinia fuckeliana*)
(2)	Grapevine	Powdery mildew (UNCINE: *Erysiphe necator*)

Please refer to Appendix 2 for detailed information about the proposed GAP uses. In this Biological Dossier trials are submitted which support the label claim.

Preliminary trials

Preliminary trials are not considered to be required since potassium bicarbonate-based products are well known for their fungicidal use and have been on the market for a number of years. For the use of Kumar in pomiculture official approval has already been sought.

Minimum effective dose tests

In the efficacy trials summarised under point IIIA1 6.1.3 below, the test product Kumar was tested with various application rates in 11 trials for BOTRCI (*Botryotinia fuckeliana)* and 11 trials for UNCINE (*Erysiphe necator*). In conclusion, the presented dose justification demonstrates that the dose rate applied for represent the minimum effective dose rate to achieve sufficient efficacy against the target pests, both on grape bunches as well as on leaves. The recommended treatment corresponding to the proposed GAP use of 1-4 applications of 5.0 kg/ha is considered to be suitable for the control of grey mould (BOTRCI) in grapevine and the recommended treatment corresponding to the proposed GAP use of 1-6 applications of 5.0 kg/ha is considered to be suitable for the control of powdery mildew (UNCINE) in grapevine. Thus, the dose rate of 5.0 kg/ha constitutes the minimum effective dose rate for Kumar.

Effectiveness of the test product

The efficacy of Kumar (850 g potassium bicarbonate /kg) against grey mould in grapevine was tested in 28 efficacy trials conducted in the years between 2005 and 2015 in Switzerland, Austria, Germany and France and against powdery mildew in 16 efficacy trials conducted in the years between 2003 and 2015 in Switzerland, Austria and Germany. The results of the efficacy trials presented in this dossier show that the mean effectiveness of the test product Kumar at 5.0 kg/ha are – despite the high variability of results – competitive with those of registered reference products for the use in grapevine, for both the treatment of grey mould (BOTRCI: *Botryotinia fuckeliana*) and powdery mildew (UNCINE: *Erysiphe necator*). It is additionally demonstrated in that Kumar result in comparable or even superior effectiveness compared to other contact fungicides and sufficient effectiveness compared to systemic fungicides. Thus, Kumar is considered to be appropriate for the control of fungal diseases in grapevine according to the envisaged GAP use.

Effects on the quality of treated plants or plant products

In 4 efficacy trials conducted in Switzerland and Austria in the years 2006 and 2010, the sugar content of treated and untreated vine plants was determined. As to be expected, the sugar content of plots treated with Kumar was not negatively influenced compared to the untreated control and the reference standards.

Effects on the processing procedure

Four trials (including seven tests) were carried out as processing studies in Switzerland, France, Austria and Germany to determine the quality of treated vine grapes. Regarding the quality of harvested vine grapes, the wine making process and the wine as the processed product no negative effects after application of Kumar occurred.

Effects on the yield of treated plants and plant products

Submission of data is not considered to be required since any negative impact is not to be expected due to the very slight-occurrence of phytotoxicity in the effectiveness trials. However, in 6 trials from Germany yield was determined and no negative effect after application of Kumar occurred.

Phytotoxicity to host crop

Phytotoxic effects were evaluated in one processing trial and each of the 47 efficacy trials with Kumar in grapevine carried out against *Botrytis fuckeliana* and *Uncinula necator* in the years 2003 - 2015 in Germany, Switzerland, Austria and France. The trials included 20 different grapevine varieties. In some of the trials very slight phytotoxic effects in terms of necrosis or stunting of leaves or bunches occurred. All in all, most of the efficacy trials in vine remained without any symptoms. Even if phytotoxicity occurred the symptoms was merely slight and acceptable. No negative impact on the yield level or the yield quality could be expected.

Adverse effects on beneficial organisms (other than bees)

During the course of the effectiveness trials (IIIA1 6.1.3) observations indicating any effects whatsoever on beneficial or other non-target organisms were not reported. However, the lack of observations of negative impacts on non-target organisms is in accordance with the results of toxicity tests in ecotoxicologically relevant indicator species.

The evaluation of the risk for non-target arthropods was performed in accordance with the recommendations of the guidance document ESCORT 2 (Candolfi, 2001).

Key data on the toxicity to non-target arthropods are available from studies conducted with the product. In this context, extended laboratory tests with the sensitive indicator species *Aphidius rhopalosiphi* and *Typhlodromus pyri* using natural substrate were considered as key studies.

In brief, risk calculations for the in-field and the off-field indicate that Kumar poses a theoretical risk to non-target arthropods following application according to the proposed use patterns.

Since the last national assessment in Germany for the use in apple, new data (an extended laboratory study on predatory bug, and an aged residue study on the predatory mite) have been made available by the applicant. Therefore the national assessment on apple has been updated with this new data.

Effects on relevant beneficial organisms

In-field Exposure and Risk assessment:

When considering a single application, the $PER_{in-field}$ is lower than the available endpoint in most cases. Only one of the available endpoints of *Typhlodromus pyri* is below the $PER_{in-field}$ indicating a possible risk.

However, since no effects on mortality are expected and the off-field risk is acceptable (see below), it is considered that the in-field population will be able to recover within a relevant period by recolonisation from out of the off-field area.

This conclusion is further supported by new data provided since the last core assessment in the central zone as explained hereafter for the use of Kumar in grapes (6 x 4250 kg /ha, PER = 13.6 kg a.s./ha (in-field)):

An aged residue study has been performed using the most sensitive species tested, *T. pyri*. The results of the aged residue study indicate that there is potential for recolonisation from off-field populations into affected treated areas in-field. Apple trees were treated with Kumar at one of two rates (6.37 or 13.1 kg a.s./ha) and residues allowed to age for up to 28 days under realistic outdoor conditions. Protonymphs of *T. pyri* were then exposed to these aged residues in the laboratory. Less than 50 % effects on mortality were observed following exposure to freshly dried residues i.e. 0 DAA. Less than 50 % effects on reproduction were observed at 0 DAA for 6.37 kg a.s./ha, and at 7 DAA for 13.1 kg a.s./ha. The predicted exposure rates (PERs) for the proposed use of Kumar on grapes are 13.6 kg a.s./ha (in-field) and 0.218 kg a.s./ha (off-field). The PERs are within the rates tested in the aged residue study. The effects (lethal and sublethal) on *T. pyri* were less than 50 % after residues had been aged for 0-7 days. Therefore, it is expected that *T. pyri* would successfully recolonize a treated area in much less than a year, which is the criteria under ESCORT II. As such, the risks from in-field exposure of *T. pyri* are considered to be acceptable.

Therefore it is concluded that populations of arthropods would be able to recover within the one year time-frame stated in ESCORT 2.

Off-field Exposure and Risk assessment:

The off-field TERvalues for indicator species are above the trigger values, indicating that Kumar does not pose an unacceptable risk to non-target arthropods in off-field areas. Thus, no risk mitigation measures need to be implemented. For further information, please refer to the core assessment, part B, section 6 of the plant protection product Kumar.

Effects on earthworms

Given that agricultural soils normally have extractable potassium concentrations above 150 mg/kg, any adverse effects on earthworms from the application of Kumar are extremely unlikely.

For further information please refer to the core assessment, part B, section 6 for the label extension of the plant protection product Kumar in grape.

Effects on other non-target macro-organisms

In view of the high naturally occurring background levels of potassium and bicarbonate in the environment waivers from conducting specific studies on other non-target organisms (flora and fauna) are requested. When background levels of potassium and bicarbonate are compared to the worst-case levels estimated to arise from the GAP use of Kumar it is considered that there is no need for screening data for other organisms (flora and fauna).

Effects on organic matter breakdown

In view of the high naturally occurring background levels of potassium and bicarbonate in the environment no effect on organic matter breakdown is expected.

Effects on soil micro-organisms

Given that agricultural soils normally have extractable potassium concentrations above 150 mg/kg (please see IIIA1 10.6), any adverse effects on soil microorganisms from the application of Kumar are extremely unlikely.

For further information please refer to the core assessment, part B, section 6 for the label extension of the plant protection product Kumar in grape.

Adverse effects on parts of plant used for propagating purposes

Submission of data is not considered to be required due to the fungicidal nature of the product (EPPO guideline PP 1/135(3)).

Impact on succeeding crops

Submission of data or information for the impact on succeeding crops is not required for the use in grapevine, since it is a perennial crop and not followed in rotation by succeeding crops.

Impact on other plants including adjacent crops

Since Kumar is a fungicide and was tested on a range of sensitive crops, phytotoxic data can be taken from the efficacy trials presented in former applications according to EPPO guideline PP 1/256(1). Any negative side effects on target or adjacent crops have not been reported in the efficacy trials. For more details please refer to the risk assessment for non-target plants in dRR Section 6.

Resistance risk

A resistance risk analysis was conducted according to the EPPO guideline PP 1/213 (3). The currently available data on the resistance development in fungal diseases against potassium bicarbonate was retrieved from literature. In addition, data available on resistance occurring in the target fungal diseases of Kumar (BOTRCI: *Botryotinia fuckeliana*, UNCINE: *Erysiphe necator*) was retrieved from the FRAC database. potassium bicarbonate-based products are, due to their inorganic nature, different when compared to other plant protection products which usually represent organic compounds. Therefore, resistance mechanisms as modification or metabolisation are not assumed to occur in the case of potassium bicarbonate by FRAC. Furthermore, the resistance risk of contact fungicides as sulfur, narrow-range petroleum oil and potassium bicarbonate is low. Thus, resistance to potassium bicarbonate is highly unlikely.

The combined risk of potassium bicarbonate is weak (‘1’ or ‘1.5’) for both fungal pathogens, i.e. *Erysiphe necator* and *Botryotinia fuckeliana*. The overall risk for potassium bicarbonate combining the fungicide risk, the pathogen risk and the agronomic risk is considered to be weak for the envisaged GAP use assumed that the general measures of good agricultural practice and integrated pest management are considered. Thus, the risk is acceptable. This is based on the facts that the active substance poses a low resistance risk and that potassium bicarbonate is envisaged for a limited number of applications per year i.e. alternation with other fungicides with different modes of action takes place automatically.

Based on the data summarised in this BAD it is shown that Kumar is an effective plant protection product for the GAP use applied for. Any undue risk from the application according to the GAP use specified in this BAD can be excluded. Therefore, application is sought for the proposed product registration corresponding to the envisaged GAP use listed in Appendix 2.

IIIA1 6.7 List of test facilities including the corresponding certificates

The list of test facilities including the corresponding certificates is located in the following report: IIIA 6.6/01 "Biological Assessment Dossier - Kumar- Central Zone".

Appendix 1: List of data submitted in support of the evaluation

Annex point/ reference number (OECD-Format)	Author(s)	Year	Title Testing Facility Report No GLP or GEP status (where relevant) Published or not	Data Protection Claimed yes/no	Owner
IIIA1 6/02	[redacted]	2014 (amended 2017)	Biological Assessment Dossier – SPU-04930-F (Kumar)-Central Zone Report no. SPU-140811-01 Not GLP / GEP Unpublished	yes	SPU

Appendix 1: Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data Point	Author(s)	Year	Title Report-No. Source GLP/GEP Published Authority registration No./JKI-No.	Vertebrate study (J=Yes O=Open N=No)	Data protection claimed (J=Yes O=Open N=No)	Justification if data protection is claimed	Owner
KIIIA1 3.9	[redacted]	2015	Vorläufige Gebrauchsanleitung Kumar - k.A. N/N N 2940696/436988	N	N		Spiess-Urania
KIIIA1 6	[redacted]	2015	Biological Assessment Dossier (BAD) Kumar 2015 (pdf) SPU-140811-01 k.A. N/N N 2940698/436989	N	J		Spiess-Urania
KIIIA1 6	[redacted]	2015	Biological Assessment Dossier (BAD) Kumar 2015 (word) SPU-140811-01 k.A. N/N N 2940699/436992	N	J		Spiess-Urania
KIIIA1 6.1.3	[redacted]	2006	Fungicides against Botrytis on vines 06WF232C-58 k.A. J/J N 2940700/436994	N	J		Stähler Austria GmbH & Co. KG
KIIIA1 6.1.3	[redacted]	2006	Fungicides against Botrytis on vines 06WF232C-59 k.A. J/J N 2940701/436995	N	J		Stähler Austria GmbH & Co. KG

KIIIA1 6.1.3	[redacted]	2006	Botryticides on vines 06WF232C-513 k.A. J/J N 2940702/436997	N	J		Stähler Austria GmbH & Co. KG
KIIIA1 6.1.3	[redacted]	2006	Botryticides on vines 06WF232C-514 k.A. J/J N 2940703/436999	N	J		Stähler Austria GmbH & Co. KG
KIIIA1 6.1.3	[redacted]	2013	Evaluation of the efficiency and selectivity of different specialities against Botrytis in grapes 07 DES 03 p k.A. J/J N 2940704/437001	N	J		DE SANGOSSE
KIIIA1 6.1.3	[redacted]	2008	Efficacy against Botrytis cinerea - grape vine 08WF07a k.A. J/J N 2940705/437002	N	J		Stähler Austria GmbH & Co. KG
KIIIA1 6.1.3	[redacted]	2009	Efficacy against Botrytis cinerea - grape vine 09WF221 k.A. J/J N 2940706/437003	N	J		Stähler Austria GmbH & Co. KG
KIIIA1 6.1.3	[redacted]	2007	Efficacy - Grape vine - Botryotinia fuckeliana - Kalch 07WF314-A4 k.A. J/J N 2940707/437004	N	J		Stähler Austria GmbH & Co. KG
KIIIA1 6.1.3	[redacted]	2007	Efficacy - Grape vine - Botryotinia fuckeliana - Poellau 07WF314-A5 k.A. J/J N 2940708/437005	N	J		Stähler Austria GmbH & Co. KG

KIIIA1 6.1.3	[redacted]	2007	Efficacy - Grape vine - Botryotinia fuckeliana - Auersbach 07WF314-A6 k.A. J/J N 2940709/437006	N	J		Stähler Austria GmbH & Co. KG
KIIIA1 6.1.3	[redacted]	2009	Efficacy - Grape vine - Botryotinia fuckeliana - Auersbach 09WF310-A2 k.A. J/J N 2940710/437007	N	J		Stähler Austria GmbH & Co. KG
KIIIA1 6.1.3	[redacted]	2010	ARMICARB for control of grey mold (Botryotinia fuckeliana) in grapevines 10WF303 k.A. J/J N 2940711/437008	N	J		Stähler Austria GmbH & Co. KG
KIIIA1 6.1.3	[redacted]	2011	Efficacy - Grape vine - Botryotinia fuckeliana - Sinabelkirchen 11WF08-A1 k.A. J/J N 2940712/437009	N	J		Stähler Austria GmbH & Co. KG
KIIIA1 6.1.3	[redacted]	2008	Field study to evaluate the selectivity and efficacy of ARMICARB for the control of grey moult in grapevine in Germany 2005 0-99-49-06-1 k.A. N/J N 2940713/437010	N	J		ATG
KIIIA1 6.1.3	[redacted]	2008	Efficacy - Grape vine - Botryotinia fuckeliana - Dienheim R-92-41-06-2 k.A. J/J N 2940714/437011	N	J		ATG

KIIIA1 6.1.3	[redacted]	2003	Efficacy against Uncinula necator (powdery mildew) 03WF213-C506 k.A. J/J N 2940715/437017	N	J		Spiess-Urania
KIIIA1 6.1.3	[redacted]	2003	Efficacy against Uncinula necator (powdery mildew) 03WF213-C507 k.A. J/J N 2940716/437018	N	J		Spiess-Urania
KIIIA1 6.1.3	[redacted]	2003	Efficacy against Uncinula necator (powdery mildew) 03WF213-C508 k.A. J/J N 2940717/437019	N	J		Spiess-Urania
KIIIA1 6.1.3	[redacted]	2004	Efficacy against Uncinula necator (powdery mildew) 04WF217-C537 k.A. N/J N 2940718/437020	N	J		Stähler Austria GmbH & Co. KG
KIIIA1 6.1.3	[redacted]	2004	Efficacy against Uncinula necator (powdery mildew) 04WF217-C538 k.A. N/J N 2940719/437021	N	J		Stähler Austria GmbH & Co. KG
KIIIA1 6.1.3	[redacted]	2008	Efficacy against Uncinula necator - Grape vine 08WF225 k.A. J/J N 2940720/437022	N	J		Stähler Austria GmbH & Co. KG
KIIIA1 6.1.3	[redacted]	2004	Efficacy - Grape vine - Uncinula necator - Eisenstadt 04WF12-A2 k.A. J/J N 2940721/437023	N	J		Stähler Austria GmbH & Co. KG

KIIIA1 6.1.4	[redacted]	2009	Versuchsbericht über die Gär- und Geschmacksprüfung im Rahmen der Mittelprüfung 2007 k.A. J/J N 2940722/437024	N	J		LIT
KIIIA1 6.1.4	[redacted]	2009	ARMICARB - Influence on the vinification of white wine and red wine 07WF23l k.A. J/J N 2940723/437025	N	J		Stähler Austria GmbH & Co. KG
KIIIA1 6.1.4	[redacted]	2009	Study of unintentional effects of experimental compound ARMICARB on production and quality of musts and wines CEB-08-4300 k.A. O/J N 2940724/437026	N	J		DE SANGOSSE
KIIIA1 6.1.4	[redacted]	2006	Fungicides against Botrytis on vines 06WF232C-58 k.A. N/J N 2940725/437027	N	J		Stähler Austria GmbH & Co. KG
KIIIA1 6.1.4	[redacted]	2006	Fungicides against Botrytis on vines 06WF232C-59 k.A. N/J N 2940726/437028	N	J		Stähler Austria GmbH & Co. KG
KIIIA1 6.1.4	[redacted]	2010	ARMICARB for control of grey mold (Botryotinia fuckeliana) in grapevines 10WF303 k.A. N/J N 2940727/437029	N	J		Stähler Austria GmbH & Co. KG

KIIIA1 6.2.1	[redacted]	2006	Fungicides against Botrytis on vines 06WF232C-58 k.A. N/J N 2940728/437030	N	J		Stähler Austria GmbH & Co. KG
KIIIA1 6.2.1	[redacted]	2006	Fungicides against Botrytis on vines 06WF232C-59 k.A. N/J N 2940729/437031	N	J		Stähler Austria GmbH & Co. KG
KIIIA1 6.2.1	[redacted]	2006	Botryticides on vines 06WF232C-513 k.A. N/J N 2940730/437032	N	J		Stähler Austria GmbH & Co. KG
KIIIA1 6.2.1	[redacted]	2006	Botryticides on vines 06WF232C-514 k.A. N/J N 2940731/437033	N	J		Stähler Austria GmbH & Co. KG
KIIIA1 6.2.1	[redacted]	2013	Efficiency Test Botrytis in Grapes: Evaluation of the efficiency and selectivity of different specialities against Botrytis in grapes 07 DES 03 p k.A. N/J N 2940732/437034	N	J		DE SANGOSSE
KIIIA1 6.2.1	[redacted]	2008	Efficacy against Botrytis cinerea - grape vine 08WF07a k.A. N/J N 2940733/437035	N	J		Stähler Austria GmbH & Co. KG
KIIIA1 6.2.1	[redacted]	2009	Efficacy against Botrytis cinerea - grape vine 09WF221 k.A. N/J N 2940734/437036	N	J		Stähler Austria GmbH & Co. KG

KIIIA1 6.2.1	[redacted]	2007	Efficacy - Grape vine - Botryotinia fuckeliana - Kalch 07WF314-A4 k.A. N/J N 2940735/437037	N	J		Stähler Austria GmbH & Co. KG
KIIIA1 6.2.1	[redacted]	2007	Efficacy - Grape vine - Botryotinia fuckeliana - Poellau 07WF314-A5 k.A. N/J N 2940736/437038	N	J		Stähler Austria GmbH & Co. KG
KIIIA1 6.2.1	[redacted]	2007	Efficacy - Grape vine - Botryotinia fuckeliana - Auersbach 07WF314-A6 k.A. N/J N 2940737/437039	N	J		Stähler Austria GmbH & Co. KG
KIIIA1 6.2.1	[redacted]	2009	Efficacy - Grape vine - Botryotinia fuckeliana - Auersbach 09WF310-A2 k.A. N/J N 2940738/437040	N	J		**ZBLHMAT [Hist.]
KIIIA1 6.2.1	[redacted]	2010	ARMICARB for control of grey mold (Botryotinia fuckeliana) in grapevines 10WF303 k.A. N/J N 2940739/437041	N	J		Stähler Austria GmbH & Co. KG
KIIIA1 6.2.1	[redacted]	2011	Efficacy - Grape vine - Botryotinia fuckeliana - Sinabelkirchen 11WF08-A1 k.A. N/J N 2940740/437042	N	J		**ZBLHMAT [Hist.]

KIIIA1 6.2.1	[redacted]	2005	Field study to evaluate the selectivity and efficacy of ARMICARB for the control of grey moult in grapevine in Germany 2005 O-99-49-06-1 k.A. N/N N 2940741/437043	N	J		**AGROH [Hist.]
KIIIA1 6.2.1	[redacted]	2008	Efficacy - Grape vine - Botryotinia fuckeliana - Heuchelheim R-92-41-06-1 k.A. J/J N 2940742/437044	N	J		ATG
KIIIA1 6.2.1	[redacted]	2008	Efficacy - Grape vine - Botryotinia fuckeliana - Dienheim R-92-41-06-2 k.A. N/J N 2940743/437045	N	J		**AGROH [Hist.]
KIIIA1 6.2.1	[redacted]	2003	Efficacy against Uncinula necator (powdery mildew) 03WF213-C506 k.A. N/J N 2940744/437046	N	J		Church & Dwight Inc.
KIIIA1 6.2.1	[redacted]	2003	Efficacy against Uncinula necator (powdery mildew) 03WF213-C507 k.A. N/J N 2940745/437047	N	J		Church & Dwight Inc.
KIIIA1 6.2.1	[redacted]	2003	Efficacy against Uncinula necator (powdery mildew) 03WF213-C508 k.A. N/J N 2940746/437048	N	J		Church & Dwight Inc.

KIIIA1 6.2.1	[redacted]	2004	Efficacy against Uncinula necator (powdery mildew) 04WF217-C537 k.A. N/J N 2940747/437049	N	J		Stähler Austria GmbH & Co. KG
KIIIA1 6.2.1	[redacted]	2004	Efficacy against Uncinula necator (powdery mildew) 04WF217-C538 k.A. N/J N 2940748/437050	N	J		Stähler Austria GmbH & Co. KG
KIIIA1 6.2.1	[redacted]	2008	Efficacy against Uncinula necator - Grape vine 08WF225 k.A. N/J N 2940749/437051	N	J		Stähler Austria GmbH & Co. KG
KIIIA1 6.2.1	[redacted]	2004	Efficacy - Grape vine - Uncinula necator - Gumpoldskirchen 04WF12-A1 k.A. J/J N 2940750/437052	N	J		Stähler Austria GmbH & Co. KG
KIIIA1 6.2.1	[redacted]	2004	Efficacy - Grape vine - Uncinula necator - Eisenstadt 04WF12-A2 k.A. N/J N 2940751/437053	N	J		Stähler Austria GmbH & Co. KG
KIIIA1 6.2.1	[redacted]	2009	ARMICARB - Influence on the vinification of white wine and red wine 07WF231 k.A. N/J N 2940752/437054	N	J		Stähler Austria GmbH & Co. KG

KIIIA1 10.5.2	[redacted]	2013	An extended laboratory test to determine the LR50 of the formulated product -Armicarb 85 SP - (potassium bicarbonate 85% w/w, SP) on the predatory bug Orius laeviagtus (Fieber) (Heteroptera: Anthocoridae) TRC13-061BA k.A. J/J N 2940761/437057	N	J		Spiess-Urania
KIIIA1 10.5.2	[redacted]	2013	Aged residue test with the formulation - Armicarb 85 SP (Potassium bicarbonate 85% w/w, SP) - on the predatory mite Typhlodromus pyri (Acari: Phytoseiidae) TRC13-060BA k.A. J/J N 2940762/437058	N	J		Spiess-Urania
MIIIA1 Sec 6	[redacted]	2015	dRR - B6 - core assess. - DE - 007547-00/10 - Kumar 2015 (PDF) k.A. k.A. O/O N 2940767/437063	N	O		Spiess-Urania
MIIIA1 Sec 6	[redacted]	2015	dRR - B6 - core assess. - DE - 007547-00/10 - Kumar 2015 (word) k.A. k.A. O/O N 2940768/437064	N	O		Spiess-Urania
MIIIA1 Sec 6	[redacted]	2015	dRR - B6 - nat. add. - DE - 007547-00/10 - Kumar 2015 (pdf) k.A. k.A. O/O N 2940769/437065	N	O		Spiess-Urania

MIIIA1 Sec 6	[redacted]	2015	dRR - B6 - nat. add. - DE - 007547-00/10 - Kumar 2015 (word) k.A. k.A. O/O N 2940770/437066	N	O		Spiess-Urania
MIIIA1 Sec 7	[redacted]	2015	dRR - B7 - core assess. - DE - 007547-00/10 - Kumar 2015 (pdf) k.A. k.A. O/O N 2940771/437067	N	O		Spiess-Urania
MIIIA1 Sec 7	[redacted]	2015	dRR - B7 - core assess. - DE - 007547-00/10 - Kumar 2015 (word) k.A. k.A. O/O N 2940772/437068	N	O		Spiess-Urania
Document N	[redacted]	2015	dRR - A - DE - 007547-00/10 - Kumar - k.A. O/O N 2940773/437069	N	O		Spiess-Urania
Document N	[redacted]	2015	dRR - A - DE - 007547-00/10 - Kumar O/O N 2953812/437072	N	O		Spiess-Urania
KIIIA1 6.1.3	[redacted]	2008	Efficacy - Grape vine - Botryotinia fuckeliana - Heuchelheim R-92-41-06-1 k.A. J/J N 3013576/437075	N	J		ATG
KIIIA1 6.1.3	[redacted]	2004	Efficacy - Grape vine - Uncinula necator - Gumpoldskirchen 04WF12-A1 k.A. J/J N 3013578/437076	N	J		Stähler Austria GmbH & Co. KG

KIIIA1 10.5.2	[redacted]	2011	Effects of Armicarb on the parasitoid Aphidius rhopalosiphi, extended laboratory study EPA-BHT-02-10 J/J N 3013888/437080	N	J		Agchem
KIIIA1 10.5.2	[redacted]	2011	Effects of the test item Armicarb on the predatory mite Typhlodromus pyri, extended laboratory study EPA-BHT-01-10 J/J N 3013889/437081	N	J		Agchem
KIIIA1 6	[redacted]	2017	Biological Assessment Dossier BAD Kumar Section 6 SPU-140811-01 k.A. N/N N 3346932/498765	N	J		Spiess-Urania Chemicals GmbH
KIIIA1 6	[redacted]	2017	Biological Assessment Dossier BAD Kumar Section 6 (Word) SPU-140811-01 k.A. N/N N 3346933/498768	N	J		Spiess-Urania Chemicals GmbH
KIIIA1 6.1.2	[redacted]	2008	Field study to evaluate the selectivity and efficacy of ARMICARB for the control of grey moult in grapevine in Germany 2005 O-99-49-06-1 k.A. N/J N 3346934/498770	N	J		Spiess-Urania Chemicals GmbH
KIIIA1 6.1.2	[redacted]	2008	Efficacy - Grape vine - Botryotinia fuckeliana - Heuchelheim R-92-41-06-1 k.A. N/J N 3346935/498772	N	J		Spiess-Urania Chemicals GmbH

KIIIA1 6.1.2	[redacted]	2008	Efficacy - Grape vine - Botryotinia fuckeliana - Dienheim R-92-41-06-2 k.A. N/J N 3346936/498774	N	J		Spiess-Urania Chemicals GmbH
KIIIA1 6.1.2	[redacted]	2016	Determination of Efficacy of Armicarb 85 SP against Grey Mould in Grapevine, 1 Site in Germany 2013 S13-02990-01 k.A. N/J N 3346937/498776	N	J		Spiess-Urania Chemicals GmbH
KIIIA1 6.1.2	[redacted]	2014	Evaluation of the efficacy of SPU-04930-F against Botryotinia fuckeliana in grapes in Germany 2013 1310471927 k.A. N/J N 3346938/498777	N	J		Spiess-Urania Chemicals GmbH
KIIIA1 6.1.2	[redacted]	2014	An evaluation of the efficacy of SPU-04930-F against Grey mould (Botrytis cinerea [Botryotinia fuckeliana]) on grapevine in Germany 2013 VP13-4-89D1 k.A. N/J N 3346939/498779	N	J		Spiess-Urania Chemicals GmbH
KIIIA1 6.1.2	[redacted]	2015	Determination of Efficacy of SPU-04930-F against Grey Mould in Grapevine, 1 Site in Germany 2014 S14-02809-01 k.A. N/J N 3346940/498780	N	J		Spiess-Urania Chemicals GmbH

KIIIA1 6.1.2	[redacted]	2016	Efficacy evaluation of SPU-04930-F against Botryotinia fuckeliana in grapevine SPU-04930-MTW-2014-BIO k.A. N/J N 3346941/498781	N	J		Spiess-Urania Chemicals GmbH
KIIIA1 6.1.2	[redacted]	2016	Determination of Efficacy of SPU-04930-F against Grey Mould in Grapevine, 1 Site in Germany 2015 S15-01705-01 k.A. N/J N 3346942/498782	N	J		Spiess-Urania Chemicals GmbH
KIIIA1 6.1.2	[redacted]	2016	Determination of Efficacy of SPU-04930-F against Grey Mould in Grapevine, 1 Site in Germany 2015 S15-01707-01 k.A. N/J N 3346943/498783	N	J		Spiess-Urania Chemicals GmbH
KIIIA1 6.1.2	[redacted]	2016	Field study to evaluate the efficacy of SPU-04930-F for the control of Botryotinia fuckeliana (BOTRCI) on grapevine 1510161716 k.A. N/J N 3346944/498785	N	J		Spiess-Urania Chemicals GmbH
KIIIA1 6.1.2	[redacted]	2004	Efficacy against Uncinula necator (powdery mildew) 04WF217C537 k.A. N/J N 3346945/498786	N	J		Spiess-Urania Chemicals GmbH
KIIIA1 6.1.2	[redacted]	2004	Efficacy against Uncinula necator (powdery mildew) 04WF217-C538 k.A. N/J N 3346946/498788	N	J		Spiess-Urania Chemicals GmbH

KIIIA1 6.1.2	[redacted]	2004	Efficacy - Grape vine - Uncinula necator - Gumpoldskirchen 04WF12-A1 k.A. N/J N 3346947/498789	N	J		Spiess-Urania Chemicals GmbH
KIIIA1 6.1.2	[redacted]	2004	Efficacy - Grape vine - Uncinula necator - Eisenstadt 04WF12-A2 k.A. N/J N 3346948/498791	N	J		Spiess-Urania Chemicals GmbH
KIIIA1 6.1.2	[redacted]	2016	Determination of Efficacy of Armicarb 85 SP against Powdery Mildew in Grapevine, 1 Site in Germany 2013 S13-02989-01 k.A. N/J N 3346949/498792	N	J		Spiess-Urania Chemicals GmbH
KIIIA1 6.1.2	[redacted]	2014	An evaluation of the efficacy of SPU-04930-F against Powdery mildew (Uncinula necator) on grapevine in Germany 2013 VP13-4-89D1 k.A. N/J N 3346950/498793	N	J		Spiess-Urania Chemicals GmbH
KIIIA1 6.1.2	[redacted]	2015	Determination of Efficacy of SPU-04930-F against Powdery Mildew in Grapevine, 1 Site in Germany 2014 S14-02812-01 k.A. N/J N 3346951/498795	N	J		Spiess-Urania Chemicals GmbH
KIIIA1 6.1.2	[redacted]	2015	Determination of Efficacy of SPU-04930-F against Powdery Mildew in Grapevine, 1 Site in Germany 2014 S14-02813-01 k.A. N/J N 3346952/498796	N	J		Spiess-Urania Chemicals GmbH

KIIIA1 6.1.2	[redacted]	2016	Determination of Efficacy of SPU-04930-F against Powdery Mildew in Grapevine, 1 Site in Germany 2015 S15-01714-01 k.A. N/J N 3346953/498798	N	J		Spiess-Urania Chemicals GmbH
KIIIA1 6.1.2	[redacted]	2016	Determination of Efficacy of SPU-04930-F against Powdery Mildew in Grapevine, 1 Site in Germany 2015 S15-01715-01 k.A. N/J N 3346954/498799	N	J		Spiess-Urania Chemicals GmbH
KIIIA1 6.1.2	[redacted]	2015	Field study to evaluate the efficacy of SPU-04930-F for the control of Uncinula necator (UNCINE) on grapevine 1510695050 k.A. N/J N 3346955/498801	N	J		Spiess-Urania Chemicals GmbH
KIIIA1 6.1.3	[redacted]	2008	Field study to evaluate the selectivity and efficacy of ARMICARB for the control of grey moult in grapevine in Germany 2005 O-99-49-06-1 k.A. N/J N 3346956/498803	N	J		Spiess-Urania Chemicals GmbH
KIIIA1 6.1.3	[redacted]	2008	Efficacy - Grape vine - Botryotinia fuckeliana - Heuchelheim R-92-41-06-1 k.A. N/J N 3346957/498805	N	J		Spiess-Urania Chemicals GmbH
KIIIA1 6.1.3	[redacted]	2008	Efficacy - Grape vine - Botryotinia fuckeliana - Dienheim R-92-41-06-2 k.A. N/J N 3346958/498807	N	J		Spiess-Urania Chemicals GmbH

KIIIA1 6.1.3	[redacted]	2004	Efficacy against Uncinula necator (powdery mildew) 04WF217C537 k.A. N/J N 3346959/498808	N	J		Spiess-Urania Chemicals GmbH
KIIIA1 6.1.3	[redacted]	2004	Efficacy against Uncinula necator (powdery mildew) 04WF217-C538 k.A. N/J N 3346960/498809	N	J		Spiess-Urania Chemicals GmbH
KIIIA1 6.1.3	[redacted]	2004	Efficacy - Grape vine - Uncinula necator - Gumpoldskirchen 04WF12-A1 k.A. N/J N 3346961/498810	N	J		Spiess-Urania Chemicals GmbH
KIIIA1 6.1.3	[redacted]	2004	Efficacy - Grape vine - Uncinula necator - Eisenstadt 04WF12-A2 k.A. N/J N 3346962/498812	N	J		Spiess-Urania Chemicals GmbH
KIIIA1 6.1.3	[redacted]	2016	Determination of Efficacy of Armicarb 85 SP against Grey Mould in Grapevine, 1 Site in Germany 2013 S13-02990-01 k.A. N/J N 3346963/498813	N	J		Spiess-Urania Chemicals GmbH
KIIIA1 6.1.3	[redacted]	2014	Evaluation of the efficacy of SPU-04930-F against Botryotinia fuckeliana in grapes in Germany 2013 1310471927 k.A. N/J N 3346964/498814	N	J		Spiess-Urania Chemicals GmbH

KIIIA1 6.1.3	[redacted]	2014	An evaluation of the efficacy of SPU-04930-F against Grey mould (Botrytis cinerea [Botryotinia fuckeliana]) on grapevine in Germany 2013 VP13-4-89D1 k.A. N/J N 3346965/498816	N	J		Spiess-Urania Chemicals GmbH
KIIIA1 6.1.3	[redacted]	2015	Determination of Efficacy of SPU-04930-F against Grey Mould in Grapevine, 1 Site in Germany 2014 S14-02809-01 k.A. N/J N 3346966/498817	N	J		Spiess-Urania Chemicals GmbH
KIIIA1 6.1.3	[redacted]	2016	Efficacy evaluation of SPU-04930-F against Botryotinia fuckeliana in grapevine SPU-04930-F-BOT-2014-BIO k.A. N/J N 3346967/498819	N	J		Spiess-Urania Chemicals GmbH
KIIIA1 6.1.3	[redacted]	2016	Determination of Efficacy of SPU-04930-F against Grey Mould in Grapevine, 1 Site in Germany 2015 S15-01705-01 k.A. N/J N 3346968/498821	N	J		Spiess-Urania Chemicals GmbH
KIIIA1 6.1.3	[redacted]	2016	Determination of Efficacy of SPU-04930-F against Grey Mould in Grapevine, 1 Site in Germany 2015 S15-01707-01 k.A. N/J N 3346969/498822	N	J		Spiess-Urania Chemicals GmbH

KIIIA1 6.1.3	[redacted]	2015	Field study to evaluate the efficacy of SPU-04930-F for the control of Botryotinia fuckeliana (BOTRCI) on grapevine 1510161716 k.A. N/J N 3346970/498823	N	J		Spiess-Urania Chemicals GmbH
KIIIA1 6.1.3	[redacted]	2016	Determination of Efficacy of Armicarb 85 SP against Powdery Mildew in Grapevine, 1 Site in Germany 2013 S13-02989-01 k.A. N/J N 3346971/498825	N	J		Spiess-Urania Chemicals GmbH
KIIIA1 6.1.3	[redacted]	2014	An evaluation of the efficacy of SPU-04930-F against Powdery mildew (Uncinula necator) on grapevine in Germany 2013 VP13-4-89D1 k.A. N/J N 3346972/498827	N	J		Spiess-Urania Chemicals GmbH
KIIIA1 6.1.3	[redacted]	2015	Determination of Efficacy of SPU-04930-F against Powdery Mildew in Grapevine, 1 Site in Germany 2014 S14-02812-01 k.A. N/J N 3346973/498828	N	J		Spiess-Urania Chemicals GmbH
KIIIA1 6.1.3	[redacted]	2015	Determination of Efficacy of SPU-04930-F against Powdery Mildew in Grapevine, 1 Site in Germany 2014 S14-02813-01 k.A. N/J N 3346974/498830	N	J		Spiess-Urania Chemicals GmbH

KIIIA1 6.1.3	[redacted]	2016	Determination of Efficacy of SPU-04930-F against Powdery Mildew in Grapevine, 1 Site in Germany 2015 S15-01714-01 k.A. N/J N 3346975/498831	N	J		Spiess-Urania Chemicals GmbH
KIIIA1 6.1.3	[redacted]	2016	Determination of Efficacy of SPU-04930-F against Powdery Mildew in Grapevine, 1 Site in Germany 2015 S15-01715-01 k.A. N/J N 3346976/498833	N	J		Spiess-Urania Chemicals GmbH
KIIIA1 6.1.3	[redacted]	2015	Field study to evaluate the efficacy of SPU-04930-F for the control of Uncinula necator (UNCINE) on grapevine 1510695050 k.A. N/J N 3346977/498835	N	J		Spiess-Urania Chemicals GmbH
KIIIA1 6.1.4	[redacted]	2008	Study the unintended side-effects of Armicarb on vine production and vine quality S08DSF.VIGMG25 k.A. N/J N 3346978/498837	N	J		Spiess-Urania Chemicals GmbH
KIIIA1 6.1.4	[redacted]	2008	Study the unintended side-effects of Armicarb on vine production and vine quality S08DSF.VIGDL33 k.A. N/J N 3346979/498838	N	J		Spiess-Urania Chemicals GmbH

KIIIA1 6.1.4	[redacted]	2017	Letter of Access to De Sangosse reports for the registration of the product Kumar in Germany by the Company Spiess-Urania Chemicals GmbH - k.A. N/N N 3346980/498840	N	N		Spiess-Urania Chemicals GmbH
KIIIA1 6.1.4	[redacted]	2014	Processing to and triangle taint test of white and red wine after six applications of SPU-04930-F in the field 1310471929 k.A. N/J N 3346981/498841	N	J		Spiess-Urania Chemicals GmbH
KIIIA1 6.1.4	[redacted]	2016	Determination of Efficacy of Armicarb 85 SP against Grey Mould in Grapevine, 1 Site in Germany 2013 S13-02990-01 k.A. N/J N 3346982/498843	N	J		Spiess-Urania Chemicals GmbH
KIIIA1 6.1.4	[redacted]	2014	Evaluation of the efficacy of SPU-04930-F against Botryotinia fuckeliana in grapes in Germany 2013 1310471927 k.A. N/J N 3346983/498844	N	J		Spiess-Urania Chemicals GmbH
KIIIA1 6.1.4	[redacted]	2014	An evaluation of the efficacy of SPU-04930-F against Grey mould (Botrytis cinerea [Botryotinia fuckeliana]) on grapevine in Germany 2013 VP13-4-89D1 k.A. N/J N 3346984/498846	N	J		Spiess-Urania Chemicals GmbH

KIIIA1 6.1.4	[redacted]	2015	Determination of Efficacy of SPU-04930-F against Grey Mould in Grapevine, 1 Site in Germany 2014 S14-02809-01 k.A. N/J N 3346985/498847	N	J		Spiess-Urania Chemicals GmbH
KIIIA1 6.1.4	[redacted]	2016	Determination of Efficacy of SPU-04930-F against Grey Mould in Grapevine, 1 Site in Germany 2015 S15-01705-01 k.A. N/J N 3346986/498848	N	J		Spiess-Urania Chemicals GmbH
KIIIA1 6.1.4	[redacted]	2016	Determination of Efficacy of SPU-04930-F against Grey Mould in Grapevine, 1 Site in Germany 2015 S15-01707-01 k.A. N/J N 3346987/498849	N	J		Spiess-Urania Chemicals GmbH
KIIIA1 6.2.1	[redacted]	2008	Field study to evaluate the selectivity and efficacy of ARMICARB for the control of grey moult in grapevine in Germany 2005 O-99-49-06-1 k.A. N/J N 3346988/498850	N	J		Spiess-Urania Chemicals GmbH
KIIIA1 6.2.1	[redacted]	2008	Efficacy - Grape vine - Botryotinia fuckeliana - Heuchelheim R-92-41-06-1 k.A. N/J N 3346989/498851	N	J		Spiess-Urania Chemicals GmbH
KIIIA1 6.2.1	[redacted]	2008	Efficacy - Grape vine - Botryotinia fuckeliana - Dienheim R-92-41-06-2 k.A. N/J N 3346990/498853	N	J		Spiess-Urania Chemicals GmbH

KIIIA1 6.2.1	[redacted]	2004	Efficacy against Uncinula necator (powdery mildew) 04WF217C537 k.A. N/J N 3346991/498854	N	J		Spiess-Urania Chemicals GmbH
KIIIA1 6.2.1	[redacted]	2004	Efficacy against Uncinula necator (powdery mildew) 04WF217-C538 k.A. N/J N 3346992/498855	N	J		Spiess-Urania Chemicals GmbH
KIIIA1 6.2.1	[redacted]	2004	Efficacy - Grape vine - Uncinula necator - Gumpoldskirchen 04WF12-A1 k.A. N/J N 3346993/498856	N	J		Spiess-Urania Chemicals GmbH
KIIIA1 6.2.1	[redacted]	2004	Efficacy - Grape vine - Uncinula necator - Eisenstadt 04WF12-A2 k.A. N/J N 3346994/498857	N	J		Spiess-Urania Chemicals GmbH
KIIIA1 6.2.1	[redacted]	2016	Determination of Efficacy of Armicarb 85 SP against Grey Mould in Grapevine, 1 Site in Germany 2013 S13-02990-01 k.A. N/J N 3346995/498858	N	J		Spiess-Urania Chemicals GmbH
KIIIA1 6.2.1	[redacted]	2014	Evaluation of the efficacy of SPU-04930-F against Botryotinia fuckeliana in grapes in Germany 2013 1310471927 k.A. N/J N 3346996/498859	N	J		Spiess-Urania Chemicals GmbH

KIIIA1 6.2.1	[redacted]	2014	An evaluation of the efficacy of SPU-04930-F against Grey mould (Botrytis cinerea [Botryotinia fuckeliana]) on grapevine in Germany 2013 VP13-4-89D1 k.A. N/J N 3346997/498861	N	J		Spiess-Urania Chemicals GmbH
KIIIA1 6.2.1	[redacted]	2015	Determination of Efficacy of SPU-04930-F against Grey Mould in Grapevine, 1 Site in Germany 2014 S14-02809-01 k.A. N/J N 3346998/498862	N	J		Spiess-Urania Chemicals GmbH
KIIIA1 6.2.1	[redacted]	2016	Efficacy evaluation of SPU-04930-F against Botryotinia fuckeliana in grapevine SPU-04930-F-BOT-2014-BIO k.A. N/J N 3346999/498864	N	J		Spiess-Urania Chemicals GmbH
KIIIA1 6.2.1	[redacted]	2016	Determination of Efficacy of SPU-04930-F against Grey Mould in Grapevine, 1 Site in Germany 2015 S15-01705-01 k.A. N/J N 3347000/498865	N	J		Spiess-Urania Chemicals GmbH
KIIIA1 6.2.1	[redacted]	2016	Determination of Efficacy of SPU-04930-F against Grey Mould in Grapevine, 1 Site in Germany 2015 S15-01707-01 k.A. N/J N 3347001/498866	N	J		Spiess-Urania Chemicals GmbH

KIIIA1 6.2.1	[redacted]	2015	Field study to evaluate the efficacy of SPU-04930-F for the control of Botryotinia fuckeliana (BOTRCI) on grapevine 1510161716 k.A. N/J N 3347002/498867	N	J		Spiess-Urania Chemicals GmbH
KIIIA1 6.2.1	[redacted]	2016	Determination of Efficacy of Armicarb 85 SP against Powdery Mildew in Grapevine, 1 Site in Germany 2013 S13-02989-01 k.A. N/J N 3347003/498869	N	J		Spiess-Urania Chemicals GmbH
KIIIA1 6.2.1	[redacted]	2014	An evaluation of the efficacy of SPU-04930-F against Powdery mildew (Uncinula necator) on grapevine in Germany 2013 VP13-4-90D1 k.A. N/J N 3347004/498871	N	J		Spiess-Urania Chemicals GmbH
KIIIA1 6.2.1	[redacted]	2015	Determination of Efficacy of SPU-04930-F against Powdery Mildew in Grapevine, 1 Site in Germany 2014 S14-02812-01 k.A. N/J N 3347005/498873	N	J		Spiess-Urania Chemicals GmbH
KIIIA1 6.2.1	[redacted]	2015	Determination of Efficacy of SPU-04930-F against Powdery Mildew in Grapevine, 1 Site in Germany 2014 S14-02813-01 k.A. N/J N 3347006/498874	N	J		Spiess-Urania Chemicals GmbH

KIIIA1 6.2.1	[redacted]	2016	Determination of Efficacy of SPU-04930-F against Powdery Mildew in Grapevine, 1 Site in Germany 2015 S15-01714-01 k.A. N/J N 3347007/498875	N	J		Spiess-Urania Chemicals GmbH
KIIIA1 6.2.1	[redacted]	2016	Determination of Efficacy of SPU-04930-F against Powdery Mildew in Grapevine, 1 Site in Germany 2015 S15-01715-01 k.A. N/J N 3347008/498878	N	J		Spiess-Urania Chemicals GmbH
KIIIA1 6.2.1	[redacted]	2015	Field study to evaluate the efficacy of SPU-04930-F for the control of Uncinula necator (UNCINE) on grapevine 1510695050 k.A. N/J N 3347009/498879	N	J		Spiess-Urania Chemicals GmbH
MIIIA1 Sec 7	[redacted]	2017	dRR - B7 - core - DE - 007547-00/10 - Kumar SPU-140811-02 k.A. N/N N 3347011/498881	N	J		Spiess-Urania Chemicals GmbH
MIIIA1 Sec 7	[redacted]	2017	dRR - B7 - core - MS - DE - 007547-00/10 - Kumar SPU-140811-02 k.A. N/N N 3347012/498883	N	J		Spiess-Urania Chemicals GmbH

Appendix 2: GAP table

PPP (product name/code) **Kumar**
active substance **potassium bicarbonate**

Formulation type: **SP**
Conc. of as: **850 g/kg**

Applicant: **Spiess-Urania Chemicals GmbH**
Zone(s): **Central EU**

professional use ☒
non professional use ☐

1	2	3	4	5	6	7	8	10	11	12	13	14
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**			**Application rate**			**PHI** (days)	**Remarks:** e.g. safener/synergist per ha
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	kg, L product / ha a) max. rate per appl. b) max. total rate per crop/season	g, kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
1	DE	Grape vine	F	*Botryotinia fuckeliana* BOTRYCI	spraying	BBCH 75 -89	a) 4 (8-30) b) 4 (8-30)	a) 5 kg/ha b) 20 kg/ha	a) 4.25 kg/ha b) 17 kg/ha	800 -1,600	1 day	1.25 kg product basis in 200-400 L water
2	DE	Grape vine	F	*Erysiphe necator* UNCINE	spraying	BBCH 57-85	a) 6 (7-10) b) 6 (7-10)	a) 5 kg/ha b) 30 kg/ha	a) 4.25 kg/ha b) 25.5 kg/ha	200-1,600	1 day	1.25 kg product basis in 200-400 L water BBCH 57: 1.25 kg/ha BBCH 61: 2.5 kg/ha BBCH 71: 3.75 kg/ha BBCH 75: 5 kg/ha

Appendix 1 ALL intended uses

Appendix 1.1 All intended uses (EU or ZONAL GAP)

GAP rev. 1, date: 2016-may-24

PPP (product name/code):	Kumar	Formulation type:	Water soluble powder (SP) [a, b]
Active substance 1:	Potassium hydrogen carbonate	Conc. of as 1:	850,00 g/kg [c]
Applicant:	Spiess-Urania Chemicals GmbH	Professional use:	☒
Zone(s):	central [d]	Non professional use:	☐
Verified by MS:	yes		

Field of use: herbicide, fungicide, insecticide etc

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f]
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	DE	Grape VITVI (utilisation as table and wine grape)	F	grey mould *Botrytis cinerea* BOTRCI	spraying or fine spraying (low volume spraying)	in case of danger of infection and/or after warning service appeal BBCH 75-89	a) 4 b) 6	8-30 days	a) 5.00 kg/ha b) 30.00 kg/ha	a) 4.25 kg as/ha b) 25.50 kg as/ha	800-1600	1	
2	DE	Grape VITVI (utilisation as table	F	powdery mildew of grape *Uncinula necator* UNCINE	spraying or fine spraying (low volume	in case of danger of infection and/or after warning service appeal	a) 6 b) 6	7-10 days	a) 5.00 kg/ha b) 30.00 kg/ha	a) 4.25 kg as/ha b) 25.50 kg as/ha [2]	200-1600	1	Dose rates staggered according to BBCH: basic application rate: 1.25 kg/ha in 200-400

		and wine grape)			spraying)	BBCH 57-85							L/ha Water BBCH 61: 2.50 kg/ha in 400-800 L/ha Water BBCH 71: 3.75 kg/ha in 600-1200 L/ha Water BBCH 75: 5.00 kg/ha in 800-1600 L/ha Water

Remarks table heading:

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008
(c) g/kg or g/l
(d) Select relevant
(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
(f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

Remarks columns:

1 Numeration necessary to allow references
2 Use official codes/nomenclatures of EU Member States
3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)
4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application
5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.
6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.
7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
8 The maximum number of application possible under practical conditions of use must be provided.
9 Minimum interval (in days) between applications of the same product
10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
13 PHI - minimum pre-harvest interval
14 Remarks may include: Extent of use/economic importance/restrictions

Appendix 1.2 Matching table for DE uses (07547-00/10)

GAP rev. 1, date: 2016-may-24

PPP (product name/code):	Kumar	Formulation type:	Water soluble powder (SP) [(a, b)]
Active substance 1:	Potassium hydrogen carbonate	Conc. of as 1:	850,00 g/kg [(c)]
Applicant:	Spiess-Urania Chemicals GmbH	Professional use:	☒
Zone(s):	central/ [(d)]	Non professional use:	☐
Verified by MS:	yes		
Field of use:	herbicide, fungicide, insecticide etc		

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [(e)]	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks/matching remarks:**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
001	DE	Grape VITVI (utilisation as table and wine grape)	F	grey mould *Botrytis cinerea* BOTRCI	spraying or fine spraying (low volume spraying)	in case of danger of infection and/or after warning service appeal BBCH 75-89	a) 4 b) 6	8-30 days	a) 5.00 kg/ha b) 30.00 kg/ha	a) 4.25 kg as/ha b) 25.50 kg as/ha	800-1600	1	This DE-use corresponds to or is part of EU/ZONAL-use no. 1
002	DE	Grape VITVI (utilisation as table and wine grape)	F	powdery mildew of grape *Uncinula necator* UNCINE	spraying or fine spraying (low volume spraying)	in case of danger of infection and/or after warning service appeal BBCH 57-85	a) 6 b) 6	7-10 days	a) 5.00 kg/ha b) 30.00 kg/ha	a) 4.25 kg as/ha b) 25.50 kg/ha ²	200-1600	1	This DE-use corresponds to or is part of EU/ZONAL-use no. 2 Dose rates staggered according to BBCH: basic application rate: 1.25 kg/ha in 200-400 L/ha Water BBCH 61: 2.50 kg/ha in 400-800 L/ha Water

													BBCH 71: 3.75 kg/ha in 600-1200 L/ha Water BBCH 75: 5.00 kg/ha in 800-1600 L/ha Water

Remarks table heading:

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008
(c) g/kg or g/l
(d) Select relevant
(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
(f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

Remarks columns:

1 Numeration necessary to allow references
2 Use official codes/nomenclatures of EU Member States
3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)
4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application
5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.
6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.
7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
8 The maximum number of application possible under practical conditions of use must be provided.
9 Minimum interval (in days) between applications of the same product
10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".
13 PHI - minimum pre-harvest interval
14 Remarks may include: Extent of use/economic importance/restrictions. Matching remarks includes information about the relation between DE-uses and the EU/Zonal-uses, if requirements for national crop (-groups) or pest (-groups) description results in refinements