REGISTRATION REPORT
Part A

EXTENSION OF USES
Risk Management

Product code:	**ABG-3206**
Product name :	**Berelex 40 SG**
Active Substance:	**Gibberellic Acid GA3 400 g/kg**

COUNTRY: Germany
Central Zone
Zonal Rapporteur Member State: Germany

NATIONAL ASSESSMENT

Applicant:	**Sumitomo Chemical Agro Europe (representing Valent BioSciences Corporation)**
Submission Date:	**10/02/2014**
Date:	**21/06/2017**

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PART A – Risk Management

This document describes the acceptable use conditions required for the extension of uses of BERELEX 40 SG containing gibberellic acid in Germany. This evaluation is required subsequent to the approval of gibberellic acid.

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part A, Part B Sections 1-7 (except for Section 3), Part C and where appropriate the addendum for Germany. There were no significant differences regarding the toxicological aspects to the the original product authorization from 2012. For this reason, no specific Part B, Section 3 was drafted. Instead, it is referred to the original German assessment report of BfR. The information, data and assessments provided in Registration Report, Parts B includes assessment of further data or information as required at national re-registration/registration by the EU review. It also includes assessment of data and information relating to BERELEX 40 SG where that data has not been considered in the EU review. Otherwise assessments for the safe use of BERELEX 40 SG have been made using endpoints agreed in the EU review of gibberellic acid.

This document describes the specific conditions of use and labelling required for Germany for the extension of uses of BERELEX 40 SG.

Appendix 1 of this document provides a copy of the final product authorisation in Germany.

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 16 of Directive 91/414/EEC.

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

1 Details of the application

1.1 Application background

This application was submitted by DHD Consulting on behalf of Sumitomo Chemical Agro Europe on 10 February 2014.

The application was for approval of Berelex 40 SG, a SG formulation containing 400 g/kg gibberellic acid for use as a growth regulator for easing the structure of grape-stalks, reduce cluster compactness, improve cluster aeration and thus enhance control of wine rots.

1.2 Annex I inclusion

Gibberellic acid was included on Annex I of Directive 91/414/EEC on 1 September 2009 under Inclusion Directive 2008/127/EC and implemented under Regulation (EU) No 540/2011.

Only uses as plant growth regulator may be authorised.

The Annex I Inclusion Directive for Gibberellic acid (2008/127/EC) 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 of Annex VI, the conclusions of the review report on gibberellic acid (SANCO/2613/2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 October 2008 shall be taken into account.

On 1 June 2012, the Standing Committee on Food Chain and Animal Health has taken note of the revision of the review report taking into account the EFSA conclusions referred to in points1, 2, 3, 4 and 5 of this report and after the entry into force of Regulation (EC) No 1107/2009. As already stated in Chapter 1 of this review report, documents providing clarifications on the assessment finalised after a decision has been taken shall be considered as background document C and as such they are part of this review report.

Conditions of use shall include, where appropriate, risk mitigation measures.

1.3 Regulatory approach

To obtain extension of uses the product BERELEX 40 SG must meet the conditions of Annex I inclusion and be supported by dossiers satisfying the requirements of Annex II and Annex III, with an assessment to Uniform Principles, using Annex I agreed end-points.

This application was submitted in order to allow the extension of uses of an already approved product in Germany in accordance with the above.

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of Berelex 40 SG, it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B, sections 1 - 7 and Part C.

1.5 Letters of Access

Data access has been proven.
Sumitomo Chemical Agro Europe also is the holder of the main authorisation. This point is not relevant.

2 Details of the authorisation

2.1 Product identity

Product Name	Berelex 40 SG (code: ABG-3206)
Authorization Number	006977-00/02
Function	Plant growth regulator

Applicant	Sumitomo Chemical Agro Europe (representing Valent BioSciences Corporation)
Composition	400 g/kg gibberellic acid GA_3
Formulation type	Water soluble granule [Code: SG]
Packaging	2.5 g and 20 g laminated foil sachets, 250 g HDPE bottles

2.2 Classification and labelling

2.2.1 Classification and labelling under Directive 99/45/EC

The following labelling is proposed in accordance with Directive 1999/45/EC:

Symbol(s)/Indication(s) of danger:	
Risk phrases:	
Safety phrases:	
S35	This material and its container must be disposed of in a safe way.
S57	Use appropriate container to avoid environmental contamination.
-	
Specific labelling requirement:	
SP001	To avoid risks to man and the environment, comply with the instructions for use.

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:	
-	
Hazard pictograms:	
Signal word:	
Hazard statements:	
Precautionary statements:	
P501	Dispose of contents/container to ...
Special rule for labelling of PPP:	
EUH401	To avoid risks to man and the environment, comply with the instructions for use.

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

None

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

2.2.4.1 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.
Ecosystem protection	
NW265	The product is toxic for higher aquatic plants.
NW468	Fluids left over from application and their remains, products and their remains, empty containers and packaging, and cleansing and rinsing fluids must not be dumped in water. This also applies to indirect entry via the urban or agrarian drainage system and to rain-water and sewage canals
Integrated Pest Management	
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)
	Mode of Action: none (growth regulator)
WH963	The use of plant growth modifiers can cause undesired side effects depending on the

	species and variety of the crops and also external conditions. It is recommended to apply the product according to the advice of the plant protection service and taking into consideration the instructions given.

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

Integrated Pest Management	
NN170	The product is classified as harmless for populations of the species Chrysoperla carnea (lacewing).
NN161	The product is classified as harmless for populations of the species Coccinella septempunctata (lacewing).

2.2.4.2 Specific restrictions linked to the intended uses

Some of the authorized uses are linked to the following conditions (mandatory labelling):

Ecosystem protection	
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.

2.3 Product uses

PPP (product name/code) Berelex 40 SG
active substance 1 gibberellic acid

Formulation type: SG
Conc. of as 1: 400 g/kg

Applicant: Sumitomo Chemical Agro Europe GmbH
Zone(s): central zone

professional use ☒
non professional use ☐

Verified by MS: yes

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 e.g. recommended or mandatory tank mixtures
					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		
001	DE	grape vine (VITVI)	F	easing structure of grape-stalk (YTRLO)	spraying or fine spraying (low volume spraying)	BBCH 62 to 68 preventive	a) 1 b) 1	a) 50 g/ha b) 50 g/ha	a) 20 g as/ha b) 20 g ashaL	1000 L	F *)	NW642-1 *) The PHI is covered by the conditions of use and/or the vegetation period remaining between the application of the plant protection product and the use of the product (e. g. harvest) or the setting of a PHI in days is not required resp.

Remarks:

(1) Numeration of uses in accordance with the application/as verified by MS
(2) Member State(s) or zone for which use is applied for
(3) 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)
(4) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(5) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds, developmental stages
(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 of treatment(s) (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 applications possible under practical conditions of use for each single application and per year (permanent crops) or crop (annual crops) must be provided
(8) Min. interval between applications (days) were relevant
(10) The application rate of the product a) max. rate per appl. and b) max. total rate per crop/season must be given in metric units (e.g. kg or L product / ha)
(11) The application rate of the active substance a) max. rate per appl. and b) max. total rate per crop/season must be given in metric units (e.g. g or kg / ha)
(12) The range (min/max) of water volume under practical conditions of use must be given (L/ha)
(13) PHI - minimum pre-harvest interval
(14) Remarks may include: Extent of use/economic importance/restrictions/minor use etc.

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 is a white granular solid with no distinct odour. It is not explosive, has no oxidising properties. In aqueous solution, the pH value is 2.9. The stability data indicate a shelf life of at least 2 years at ambient temperature. The technical characteristics are acceptable for a soluble granules formulation.

Implications for labelling: none

Compliance with FAO specifications:
There are no FAO specifications for gibberellic acid.

Compliance with FAO guidelines:
The product Berelex 40 SG complies with the general requirements for SG formulations according to the FAO/WHO Manual (2010).

Compatibility of mixtures:
No tank mixtures are recommended for Berelex 40 SG.

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 Berelex 40 SG 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)

Analytical methods for the determination of gibberellic acid in Berelex 40 SG are available.

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

No monitoring methods are required for food of plant and animal origin as no MRL exist. Enforcement methods for soil, water and air are also not needed as Gibberellic acid (GA3) is a naturally occurring non-toxic substance.

3.1.3 Mammalian Toxicology

The application under evaluation is based on an authorisation of Berelex 40 SG granted in 2012. Since then no significant differences regarding the toxicological aspects appeared. For this reason, no specific Part B, Section 3 was drafted. Instead, it is referred to the assessment report of BfR, the German assessment body.
If used properly and according to the intended conditions of use, adverse health effects for operators, workers, bystanders and residents will not be expected.

3.1.3.1 Acute Toxicity

Berelex 40 SG, containing 400 g/kg Gibberelic Acid (GA3) has a low toxicity in respect to oral, dermal and inhalation toxicity. It has no sensitizing properties and is not irritating to skin or the eyes.

3.1.3.2 Operator Exposure

Operator exposure was assessed against the AOEL agreed in the EU review. Dermal absorption of Berelex 40 SG was set to 100% (default).
The risk assessment has shown that the estimated exposure towards Gibberelic Acid (GA3) in Berelex 40 SG does not exceed the systemic AOEL for operators. No specific PPE is necessary.

3.1.3.3 Bystander and Resident Exposure

The risk assessment has shown that the estimated exposure towards Gibberelic Acid (GA3) in Berelex 40 SG does not exceed the systemic AOEL for bystanders and residents. Thus, it is concluded that there is no undue risk to bystanders or residents after accidental short-term exposure to Berelex 40 SG.

3.1.3.4 Worker Exposure

The risk assessment has shown that the estimated exposure towards Gibberelic Acid (GA3) in Berelex 40 SG does not exceed the systemic AOEL for workers. No specific PPE is necessary for workers in re-entry scenarios.

Implications for labelling resulting from operator, worker, bystander assessments:
Please refer to chapter 2.2.

3.1.4 Residues and Consumer Exposure (Part B, Section 4, Point 8)

Gibberellic Acid occurs naturally in a wide range of plants at levels of up to 0.1 mg/kg. Based on COMMISSION REGULATION (EU) No 588/2014 Gibberelic Acid was temporarily included in Annex IV to Regulation (EC) No 396/2005.

3.1.4.1 Residues (Part B, Section 4, Points 8.3 and 8.7)

Fundamental residue data on Gibberelic Acid (GA3) has been evaluated previously at EU level and is described in detail in the DAR of Gibberelic Acid (GA3) (Hungary, 2008) and the corresponding EFSA-Conclusion (EFSA, 2012).
No supervised residue trials from N-EU were available and none are considered necessary. Residues are not expected to exceed natural background concentrations. Additional information concerning the application of Gibberelic Acid (GA3) on grapes was submitted for Southern Europe. Residues were found to be below the LOQ of 0.05 mg/kg.

3.1.4.2 Consumer exposure (Part B, Section 4, Point 8.10)

The long-term and the short-term intake of Gibberelic Acid (GA3) residues is unlikely to present a public health concern. An estimation of dietary intake using EFSA PRIMo results in a maximum consumption of the respective ADI below 100 %.

Substance	ADI	Model / Diet	ADI Consumption
Gibberelic Acid (GA3)	0.68 mg/kg bw	TMDI, EFSA PRIMo, UK toddlers NTMDI, EFSA PRIMo, German children, aged 2-4 years	32 % 29%

As no ARfD was allocated there is no acute risk for consumers to be expected.

3.1.5 Environmental fate and behaviour (Part B, Section 5, Point 9)

A full exposure assessment for the plant protection product ABG-3206 in its intended uses in grape vine is documented in detail in the national assessment of the plant protection product ABG-3206 dated from September 2014 performed by Germany.
The following chapters summarize specific exposure assessment for soil and surface water and the specific risk assessment for groundwater for the authorization of ABG-3206 in Germany according to its intended use in grape vine (Use No. 00-001).

3.1.5.1 Predicted Environmental Concentration in Soil (PEC_{soil}) (Part B, Section 5, Points 9.4 and 9.5)

For the intended use of the plant protection product ABG-3206 in grape vine according to use No 00-001 PECsoil was calculated for the active substance gibberellic acid considering a soil depth of 2.5 cm. Due to the fast degradation of the active substance gibberellic acid in soil the accumulation potential of gibberellic acid was not considered.
Details are given in Part B National Addendum-Germany, Section5, chapter 5.5.
The results for PEC soil for the active substance and its metabolites were used for the eco-toxicological risk assessment.

3.1.5.2 Predicted Environmental Concentration in Ground Water (PEC_{GW}) (Part B, Section 5, Point 9.6)

1. Direct leaching into groundwater
Results of modelling with FOCUSPELMO_5.5.3 show that the active substance gibberellic acid is not expected to penetrate into groundwater at concentrations of ≥ 0.1µg/L in the intended use of ABG-3206 in grape vine according to use No.00-001.

2. Ground water contamination by bank filtration due to surface water exposure via run-off and drainage
According modelling with EXPOSIT 3.01, groundwater contamination at concentrations ≥ 0.1 µg/L by the active substance gibberellic acid due to surface run-off and drainage into the adjacent ditch with subsequent bank filtration can be excluded.

3.1.5.3 Predicted Environmental Concentration in Surface Water (PEC_{SW}) (Part B, Section 5, Points 9.7 and 9.8)

For the intended use of the plant protection product ABG-3206 in grape vine according to use No 00-001 PECsw was calculated for the active substance gibberellic acid considering the two routes of entry (i) spraydrift and volatilization with subsequent deposition and (ii) run-off, drainage separately.
The calculation of concentrations in surface water was based on spray drift data by Rautmann and Ganzelmeier. Since the vapour pressure at 20 °C of the active substance gibberellic acid is $< 10^{-5}$ Pa, exposure of surface water due to deposition following volatilization was not considered.
The concentration of the active substance gibberellic acid in adjacent ditch due to surface run-off and drainage was calculated using the model EXPOSIT 3.01.
Details are given in Part B, National Addendum-Germany, Section5, chapter 5.6.
The results for PEC surface water for the active substance were used for the eco-toxicological risk assessment.

3.1.5.4 Predicted Environmental Concentration in Air (PEC_{Air}) (Part B, Section 5, Point 9.9)

The vapour pressure at 20 °C of the active substance gibberellic acid is $< 10^{-5}$ Pa. Hence the active substance gibberellic acid is regarded as non-volatile. Atmospheric half-life calculated according to Atkinson was estimated to less than 2 days. Therefore, long-range transport is considered as negligible.

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

A full risk assessment according to Uniform Principles for the plant protection product ABG-3206 in its intended uses in vine is documented in detail in the national addendum of the plant protection product ABG-3206 dated from September 2014 performed by Germany.

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

The risk assessment for effects on birds and other terrestrial vertebrates was carried out according to the European Food Safety Authority Guidance Document on Risk Assessment for Birds and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438).
Based on the presumptions of the screening step, the calculated TER values for the acute and long-term risk resulting from an exposure of birds and mammals to the active substance gibberellic acid according to the intended use of the formulation ABG-3206 in vine achieve the acceptability criteria TER ≥ 10 and TER ≥ 5, respectively, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. The results of the assessment indicate an acceptable risk for birds and mammals.

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

Results of aquatic risk assessment for the intended for uses of ABG-3206 in vine based on FOCUS Surface Water PEC values is presented in the core assessment, Part B, Section 6, chapter 6.4.
For authorization in Germany, exposure assessment of surface water considers the two routes of entry (i) spraydrift and volatilization with subsequent deposition and (ii) run-off, drainage separately in order to allow risk mitigation measures separately for each entry route.

1. Exposure by spraydrift and deposition following volatilization
Based on the relevant toxicity of gibberellic acid, the calculated TER values for the risk to aquatic organism resulting from an exposure of surface water by spraydrift to ABG-3206 according to the use No 00-001 achieve the acceptability criteria of TER ≥ 10, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. Risk mitigation measures do not need to be applied.
For details see Part B, National Addendum-Germany, Section 6, chapters 6.4.3.

2. Exposure by surface run-off and drainage
The concentration of the active substance gibberellic acid in adjacent ditch due to surface runoff and drainage was calculated using the model EXPOSIT 3.0.1.
The calculated TER values for the risk to aquatic organisms resulting from an exposure of surface water by the active substances gibberellic acid due to run-off and drainage according to the use No 00-001 achieve the acceptability criteria of TER ≥ 100 or 10 respectively, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. Risk mitigation measures do not need to be applied.
For details see Part B, National Addendum-Germany, Section 6, chapters 6.4.4.

However, the application of PPP in the immediate vicinity of surface or coastal waters is not permitted in Germany, minimum buffer zones stipulated by state law must be observed and no additional entries as those according to the evaluated use pattern and good agricultural practice are acceptable.

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

10.5)

Bees

In the honey bee risk assessment for the main application it was concluded that the risk to bees is acceptable when Berelex 40 SG is used up to 0.0375 kg/ha in greenhouse. All hazard quotients are clearly below the trigger of 50 (HQ < 0.2), indicating that the intended use poses also a low risk to bees in the field. The recommended field application rate (0.05 kg/ha) slightly exceeds this rate. However, since the hazard quotients is still clearly below the trigger of 50 and gibberellic acids is known to be ubiquitous in higher plants no further risk assessment is required.
The product is classified as non-hazardous to bees, even when the maximum application rate as stated for authorisation is applied.

Other non-target arthropods

Based on the calculated rates of ABG-3206 in off-field, the calculated TER values describing the risk resulting from an exposure of non-target arthropods to gibberellic acid according to the GAP of the formulation achieve the acceptability criteria TER ≥ 10 (Tier 1) resp. 5 (Higher tier), according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. The results of the assessment indicate an acceptable risk for non-target arthropods due to the intended use of ABG-3206 in vine according to the label.
For details please refer to the core assessment Part B, section 6, chapter 6.6.

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

Based on the predicted concentrations of gibberellic acid in soils, the TER values describing the acute risk for earthworms and other non-target soil organisms following exposure to ABG-3206 according to the GAP of the formulation ABG-3206 achieve the acceptability criteria TER ≥ 10 according to commission implementing regulation (EU) No 546/2011, Annex, Part I C, 2. Specific principles, point 2.5.2. The results of the assessment indicate an acceptable risk for soil organisms due to the intended use of ABG-3206 in vine according to the label.
For details please refer to the core assessment Part B, section 6, chapter 6.7.

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

The risk for organic matter breakdown resulting from an exposure to gibberellic acid was not assessed, since since $DT_{90field}$ values are less than 365 days and no risk was identified for soil fauna, soil micro-organisms and non-target arthropods from the use of ABG-3206.
For details please refer to the core assessment Part B, section 6, chapter 6.7.

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

Based on the predicted concentrations of gibberellic acid in soils, the risk to soil microbial processes following exposure to gibberellic acid according to the GAP of the formulation ABG-3206 is considered to be acceptable according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2.
For details please refer to the core assessment Part B, section 6, chapter 6.8.

3.1.6.7 Assessment of Potential for Effects on Other Non-target Organisms (Flora and

Fauna) (Part B, Section 6, Point 10.8)

Terrestrial plants
It is shown that GA3 will not persist in the soil and that long-term GA3 levels from the proposed use of GA3 on grapes will be insignificant compared to naturally occurring GAs. It is therefore considered that there will be no acute or long-term risk to non-target plants from the proposed use of GA3.
For details please refer to the core assessment Part B, section 6, chapter 6.9.

Implications for labelling resulting from ecotoxicological assessment:

<u>Standard Phrases for special risks and safety precautions under Regulation (EU) 547/2011 Annex II and III / conditions of use</u>
All uses:

NW 468	Fluids left over from application and their remains, products and their remains, empty containers and packaging, and cleansing and rinsing fluids must not be dumped in water. This also applies to indirect entry via the urban or agrarian drainage system and to rain-water and sewage canals.

<u>Other labels</u>

NW 265	Gibberellic acid: NOEC = 0.0116 mg a.s./L (Myriophyllum spicatum)

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

Considering data presented are sufficient to prove efficacy in easing structure of grape-stalk reduce cluster compactness, improve cluster aeration and thus enhance control of wine rots. The minimum effective dose was demonstrated to be the desired target dose.
No adverse effects have been observed to the quality of plants or plant products or phytotoxicity to target plants. Given the timing of applications in early spring and the absence of residues at harvest, it is not anticipated that this formulation would have any negative effects on the processing grapes. has not been observed. No waiting period or other precautions between the last application and sowing or planting of a succeeding crop is necessary.
Berelex 40 SG is classified as harmless for populations of *Chrysoperla carnea* and *Coccinella septempunctata.* No adverse effects on other beneficial organisms or soil quality indicators were observed.
Resistance or cross-resistance is not applicable because GA_3 operates along with and in the same way as the active substance already present in the plant.

3.2 Conclusions

With respect to physical, chemical and technical properties of the formulation an authorisation can be granted.
Concerning analytical methods (formulation, residues) an authorisation can be granted.
With respect to efficacy, toxicology, residues and consumer protection 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.

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 below.

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 16 of Directive 91/414/EEC.

Appendix 3 – Letter of Access

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

Bundesamt für
Verbraucherschutz und
Lebensmittelsicherheit

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AKTENZEICHEN (bitte bei Antwort angeben) 200.22100.006977-00/02.99526

DATUM 29. Juni 2017

ZV1 006977-00/02

Berelex 40 SG

Zulassungsverfahren für Pflanzenschutzmittel

Ergänzungsbescheid

Die Zulassung des oben genannten Pflanzenschutzmittels

mit dem Wirkstoff:	400 g/kg	Gibberellinsäure
Zulassungsnummer:	006977-00	
Versuchsbezeichnungen:	SCF-00040-W-0-SG	
Antrag vom:	10. Februar 2014	

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
006977-00/02-001	Lockerung des Trau-benstielgerüstes	Weinrebe	

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. Karsten Hohgardt
stellvertretender Abteilungsleiter

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

Anlage

Anlage 1 zugelassene Anwendung: 006977-00/02-001

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Lockerung des Traubenstielgerüstes

Pflanzen/-erzeugnisse/Objekte: Weinrebe

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Weinbau
Anwendungsbereich:	Freiland
Anwendung im Haus- und Kleingartenbereich:	Nein
Stadium der Kultur:	62 bis 68
Anwendungszeitpunkt:	Vorbeugend
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	1
- für die Kultur bzw. je Jahr:	1
Anwendungstechnik:	spritzen oder sprühen
Aufwand:	
-	50 g/ha in 1000 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

(F)	Freiland: Weinrebe Die Wartezeit ist durch die Anwendungsbedingungen und/oder die Vegetationszeit abgedeckt, die zwischen Anwendung und Nutzung (z. B. Ernte) verbleibt bzw. die Festsetzung einer Wartezeit in Tagen ist nicht erforderlich.

3 Anwendungsbezogene Anwendungsbestimmungen

- keine -

REGISTRATION REPORT
Part B

Section 1: Identity, physical and chemical properties, other information

Detailed summary of the risk assessment

Product code:	**Berelex 40 SG**
	(ABG-3206)
Active Substance:	**Gibberellic Acid GA_3 400 g/kg**

Central Zone
Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant:	**Sumitomo Chemical Agro Europe (representing Valent BioSciences Corporation)**
Submission Date:	**10/02/2014**
Date:	**21/06/2017**

Table of Contents

Introduction

This document summarises the information related to the identity, the physical and chemical properties, the data on application, further information and the classification for the product Berelex 40 SG (ABG-3206) containing the active substance gibberellic acid GA_3 which was approved according to Regulation (EC) No 1107/2009.

This product was not the representative formulation. The product has not been previously evaluated according to Uniform Principles. Berelex 40 SG (ABG-3206) was not listed as a representative product for Annex I, but it is used on grapes in the same manner as that supported for the Annex I review.

The following table provides the EU endpoints to be used in the evaluation.

Agreed EU End-points

End-Point	**Gibberellic acid** (Reg. (EU) No 540/2011)
Purity of active substance	min 850 g/kg

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

Information on the detailed composition of Berelex 40 SG (ABG-3206) can be found in the confidential dossier of this submission (Registration Report - Part C).

IIIA 1 IDENTITY OF THE PLANT PROTECTION PRODUCT

IIIA 1.1 Applicant

Sumitomo Chemical Agro Europe SAS, representing Valent BioSciences Corporation

Parc d'Affaires de Crécy

2, rue Claude Chappe

FR – 69370 Saint-Didier-au-Mont-d'Or

France

Contact person: Denise Munday

Tel.No.: +33 478643260

Fax No: none

e-mail: Denise.MUNDAY@sumitomo-chem.fr

IIIA 1.2 Manufacturer of the Preparation, Manufacturer and Purity of the Active Substance(s)

IIIA 1.2.1 Manufacturer(s) of the preparation

Confidential information - data provided separately (Part C).

IIIA 1.2.2 Manufacturer(s) of the active substance(s)

Confidential information - data provided separately (Part C).

IIIA 1.2.3 Statement of purity (and detailed information on impurities) of the active substance(s)

Gibberellic acid: minimum 850 g/kg

Further information/justification is provided in Part C.

IIIA 1.3 Trade Names and Manufacturer's Code Numbers for the Preparation

Trade name:	Berelex 40 SG or
	ProGibb 40 SG, SmartGrass, GA3 40%, GA3 40 SG, RyzUp SmartGrass
Company code number:	ABG-3206
	INT 310

IIIA 1.4 Detailed Quantitative and Qualitative Information on the Composition of the Preparation

IIIA 1.4.1 Content of active substance and formulants

The formulation was not the representative formulation.

Pure active substance:

content of pure gibberellic acid GA_3:	400 g/kg
limits gibberellic acid GA_3:	388 - 412 g/kg

Technical active substance:

content of technical gibberellic acid GA_3 at minimum purity (85.0 %):	470.6 g/kg	(47.06 % w/w)
content of technical gibberellic acid GA_3 at typical purity (90.0 %):	444.5 g/kg	(44.45 % w/w)

None of the active substances in the formulation are present in the form of a salt, ester, anion or cation.

Further information on the active substances and on the certified limits of formulants is considered confidential and is provided separately (Part C).

IIIA 1.4.2 Certified limits of each component

This is not an EC data requirement/ not required by regulation (EU) 2011/545.

IIIA 1.4.3 Common names and code numbers for the active substance(s)

Data Point	Type	Name/Code Number
1.4.3.1	ISO common name	Gibberellic acid
1.4.3.2	CAS No.	77-06-5
1.4.3.2	EINECS No.	201-001-0
1.4.3.2	CIPAC No.	307
1.4.3.2	ELINCS	–
1.4.3.3	Salt, ester anion or cation present	–

IIIA 1.4.4 Co-formulant details: identity, structure, codes, trade name, specification and function.

CONFIDENTIAL information - data provided separately (Part C).

IIIA 1.4.5 Formulation process

IIIA 1.4.5.1 Description of formulation process

This is not an EC data requirement/ not required regulation (EU) 2011/545.

IIIA 1.4.5.2 Discussion of the formation of impurities of toxicological concern

Gibberellic acid GA_3 does not contain any impurities of toxicological or ecotoxicological concern.

IIIA 1.5 Type of Preparation and Code

Type : Water soluble granule Code : SG

IIIA 1.6 Function

The product will be used as plant growth regulator.

IIIA 1.7 Other/Special Studies

None.

IIIA 2 PHYSICAL, CHEMICAL AND TECHNICAL PROPERTIES OF THE PLANT PROTECTION PRODUCT

In the following table only newly submitted studies are evaluated.

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
Colour, odour and Physical state (IIIA 2.1)	Visual inspection and assessment of odour	GA_3 40 SG Lot No: 202-377-S4	White granular solid with no discernible odour.	Y	Comb, A.L. 2011	**Acceptable**
Auto-flammability (IIIA 2.3.3)	EEC Method A16	GA_3 40 SG Lot no.: 202-377-S4	Under the conditions of the test, GA_3 40 SG does not self-ignite below 400 °C.	Y	Comb, A.L. 2011	**Acceptable**
Acidity or alkalinity and pH (IIIA 2.4.1)	CIPAC MT 31.1.1	GA_3 40 SG Lot No: 202-377-S4	Initial: 6.2 % w/w as sulphuric acid after 14 days at 54°C: 6.2 % w/w as sulphuric acid	Y	Comb, A.L. 2011	**Acceptable**
pH of a 1% aqueous dilution, emulsion or dispersion (IIIA 2.4.2)	CIPAC MT 75.3	GA_3 40 SG Lot No: 202-377-S4	Initial: pH 2.9 after 14 days at 54°C: pH 2.9	Y	Comb, A.L. 2011	**Acceptable**
Bulk or tap density (IIIA 2.6.2)	CIPAC MT 186	GA_3 40 SG Lot No: 208-834-S4	Pour density: 0.53 g/mL Tap density: 0.55 g/mL	Y	Comb, A.L. 2012	**Acceptable**
Storage Stability after 14 days at 54° C (IIIA 2.7.1)	OPPTS 830.1700 (please refer to KIIIA1 5.2.1-01)	GA_3 40 SG Lot No: 202-377-S4	Storage material: HDPE bottles Initial: mean: 39.7 % w/w after 14 days at 54°C: mean: 39.2 % w/w	Y	Comb, A.L. 2011	**Acceptable**
Wettability (IIIA 2.8.1)	CIPAC MT 53.3.1	GA_3 40 SG Lot No: 202-377-S4	Initial: 1 s after 14 d at 54°C: 1 s	Y	Comb, A.L. 2011	**Acceptable**

Test or study & Annex point	Method used / deviations	Test material purity and specification	Findings	GLP Y/N	Reference	Acceptability / comments
Persistence of foaming (IIIA 2.8.2)	CIPAC MT 47.2	GA_3 40 SG Lot No: 202-377-S4	Initial: after 1 minute: 11 mL foam after 14 days at 54°C: after 1 minute: 12 mL foam	Y	Comb, A.L. 2011	**Acceptable**
Dilution stability (IIIA 2.8.4)	CIPAC MT 179	GA_3 40 SG Lot No: 202-377-S4	Initial: Residues after 5 min: 4.0 % Residues after 18 hours: 0.02 % after 14 days at 54°C: Residues after 5 min: 5.7 % Residues after 18 hours: 0.06 %	Y	Comb, A.L. 2011	**Acceptable**
Particle size distribution (IIIA 2.8.6.1)	CIPAC MT 58.2	GA_3 40 SG Lot No: 202-377-S4	Initial: > 250 µm: 99.0 % 250 – 150 µm: 0.02 % < 150 µm: 0.9 % after 14 days at 54°C: > 250 µm: 98.7 % 250 – 150 µm: 0.03 % < 150 µm: 1.2 %	Y	Comb, A.L. 2011	**Acceptable**
Dust content (IIIA 2.8.6.3)	CIPAC MT 171	GA_3 40 SG Lot No: 202-377-S4	Initial: 0.87 mg after 14 d at 54°C: 0.93 mg Nearly dust free before and after storage.	Y	Comb, A.L. 2011	**Acceptable**

Summary

The product is a white granular solid with no distinct odour. It is not explosive, has no oxidising properties. In aqueous solution, the pH value is 2.9. The stability data indicate a shelf life of at least 2 years at ambient temperature. The technical characteristics are acceptable for a soluble granules formulation.

IIIA 3 DATA ON APPLICATION OF THE PLANT PROTECTION PRODUCT

IIIA 3.1 Field of Use

The application is for growth regulation in wine grapes.

IIIA 3.2 Nature of the Effects on Harmful Organisms

The product is a growth regulator for easing the structure of grape-stalks, reduce cluster compactness, improve cluster aeration and thus enhance control of wine rots.

IIIA 3.3 Details of Intended Use

IIIA 3.3.1 Details of existing and intended uses

Please refer to Appendix 2 - Critical Uses - and Part B Section 7.

IIIA 3.3.2 Details of harmful organisms against which protection is afforded

Please refer to Appendix 2 - Critical Uses - and Part B Section 7.

IIIA 3.3.3 Effects achieved

Please refer to Part B Section 7.

IIIA 3.4 Proposed Application Rates (Active Substance and Preparation)

Please refer to Appendix 2 - Critical Uses - and Part B Section 7.

IIIA 3.5 Concentration of the Active Substance in the Material Used

Please refer to Appendix 2 - Critical Uses - and Part B Section 7.

IIIA 3.6 Method of Application, Type of Equipment Used and Volume of Diluent

Please refer to Appendix 2 - Critical Uses - and Part B Section 7.

IIIA 3.7 Number and Timings of Applications, Timing, Growth Stages (of Crop and Harmful Organism) and Duration of Protection

IIIA 3.7.1 Maximum number of applications and their timings

Please refer to Appendix 2 - Critical Uses - and Part B Section 7.

IIIA 3.7.2 Growth stages of crops or plants to be protected

Please refer to Appendix 2 - Critical Uses - and Part B Section 7.

IIIA 3.7.3 Development stages of the harmful organism concerned

Please refer to Appendix 2 - Critical Uses - and Part B Section 7.

IIIA 3.7.4 Duration of protection afforded by each application

Please refer to Part B Section 7.

IIIA 3.7.5 Duration of protection afforded by the maximum number of applications

Please refer to Part B Section 7.

IIIA 3.8 Necessary Waiting Periods or Other Precautions to Avoid Phytotoxic Effects on Succeeding Crops

IIIA 3.8.1 Minimum waiting periods or other precautions between last application and sowing or planting succeeding crops

Please refer to Part B Section 7.

IIIA 3.8.2 Limitations on choice of succeeding crops

Please refer to Part B Section 7.

IIIA 3.8.3 Description of damage to rotational crops

Please refer to Part B Section 7.

IIIA 3.9 Proposed Instructions for Use as Printed on Labels

Please refer to Registration Report – Part A, Appendix 2 for the relevant country.

IIIA 3.10 Other/Special Studies

This is not an EC data requirement/ not required by Directive 91/414/EEC.

IIIA 4 FURTHER INFORMATION ON THE PLANT PROTECTION PRODUCT

There is no change regarding the Section 1 of the Part B of the Registration Report compared to the main application. Therefore no evaluation is necessary.

IIIA 4.3 Re-entry Periods to Protect Man, Livestock and the Environment

IIIA 4.3.1 Pre-harvest interval (in days) for each relevant crop

See section 4.

IIIA 4.3.2 Re-entry period (in days) for livestock, to areas to be grazed

See section 4.

IIIA 4.3.3 Re-entry period (in hours or days) for man to crops, buildings or spaces treated

See section 4.

IIIA 4.3.4 Withholding period (in days) for animal feeding stuffs

See section 4.

IIIA 4.3.5 Waiting period (in days) between application and handling of treated products

See section 4.

IIIA 4.3.6 Waiting period (in days) between last application and sowing or planting succeeding crops

See section 4.

IIIA 4.3.7 Information on specific conditions under which the preparation may or may not be used

See section 4.

IIIA 4.4 Statement of the Risks Arising and the Recommended Methods and Precautions and Handling Procedures to Minimise Those Risks

There is no change regarding the Section 1 of the Part B of the Registration Report compared to the main application. Therefore no evaluation is necessary.

Report:	Anonymous, 2006
Title:	Safety data sheet Gibberellic acid A3 40 SG

The safety data sheet complies with actual EEC regulations and is based on the present state of knowledge.

IIIA 11 FURTHER INFORMATION

IIIA 11.1 Information of Authorisations in Other Countries

see EU pesticide data base (http://ec.europa.eu/sanco_pesticides/public/)

IIIA 11.2 Information on Established Maximum Residue Limits (MRL) in Other Countries

No MRLs are set at European level, see Annex VI of Regulation (EC) No. 396/2005.

IIIA 11.3 Justified Proposals for Classification and Labelling

There is no change regarding the Section 1 of the Part B of the Registration Report compared to the main application. Therefore no evaluation is necessary.

Toxicology

see section 3.

Ecotoxicology/Environment

see section 6.

IIIA 11.4 Proposals for Risk and Safety Phrases

Please refer to Registration Report – Part A.

IIIA 11.5 Proposed Label

Please refer to Registration Report – Part A.

IIIA 11.6 Specimens of Proposed Packaging

Specimens of the packaging were not provided as there was no request.

Appendix 1: List of data used 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)**	**Data protection claimed**	**Owner**	**How considered in dRR Study-Status / Usage***
KIIIA1 2.1/03 2.4.1./3 2.4.2/2 2.7.1/01 2.8.1/02 2.8.2/02 2.8.5.2/02 2.8.6.1/01 2.8.6.3/02 2.8.4/02 4.1.2/03 4.1.3/03	Comb, A.L.	2011	GA_3 40 SG Accelerated Storage Stability Huntingdon Life Sciences Ltd. Report no. ZAB0153 GLP, Unpublished.	Y	VBC	1
KIIIA1 2.3.3/01	Comb, A.L.	2011	GA3 40 SG Relative Self-Ignition Temperature for Solids Huntingdon Life Sciences Ltd, England Project No: ZAB0154 GLP, Unpublished	Y	VBC	1
KIIIA1 2.6.2/02	Comb, A.L.	2012	GA_3 40 SG Bulk and Tap Density ZAB0159 GLP, Unpublished	Y	VBC	1

* 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: Critical Uses – Justification and GAP tables

PPP (product name/code) Berelex 40 SG
active substance 1 Gibberellinsäure

Formulation type: SG
Conc. of as 1: 400 g/kg

Applicant: Sumitomo Chemical Agro Europe GmbH
Zone(s): central zone

professional use ☒
non professional use ☐

Verified by MS: yes

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 e.g. recommended or mandatory tank mixtures
					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		
001	DE	grape vine (VITVI)	F	easing structure of grape-stalk (YTRLO)	spraying or fine spraying (low volume spraying)	BBCH 62 to 68 preventive	a) 1 b) 1	a) 50 g/ha b) 50 g/ha	a) 20 g as/ha b) 20 g ashaL	1000 L		NW642-1

Remarks:

(1) Numeration of uses in accordance with the application/as verified by MS

(2) Member State(s) or zone for which use is applied for

(3) 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)
(4) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(5) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds, developmental stages
(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 of treatment(s) (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 applications possible under practical conditions of use for each single application and per year (permanent crops) or crop (annual crops) must be provided
(8) Min. interval between applications (days) were relevant
(10) The application rate of the product a) max. rate per appl. and b) max. total rate per crop/season must be given in metric units (e.g. kg or L product / ha)
(11) The application rate of the active substance a) max. rate per appl. and b) max. total rate per crop/season must be given in metric units (e.g. g or kg / ha)
(12) The range (min/max) of water volume under practical conditions of use must be given (L/ha)
(13) PHI - minimum pre-harvest interval
(14) Remarks may include: Extent of use/economic importance/restrictions/minor use etc.

REGISTRATION REPORT
Part B

Section 2: Analytical Methods
Detailed summary of the risk assessment

Product code:	**Berelex 40 SG**
	(ABG-3206)
Active Substance:	**Gibberellic Acid GA_3 400 g/kg**

Central Zone
Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant:	**Sumitomo Chemical Agro Europe (representing Valent BioSciences Corporation)**
Submission Date:	**10/02/2014**
Date:	**21/06/2017**

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IIIA 5 METHODS OF ANALYSIS

This document summarises the information related to the analytical methods for the product Berelex 40 SG (ABG-3206) containing the active substance gibberellic acid GA_3 which was approved according to Regulation (EC) No 1107/2009.

This product was not the representative formulation. The product has not been previously evaluated according to Uniform Principles.

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

Information on the detailed composition of Berelex 40 SG (ABG-3206) can be found in the confidential dossier of this submission (Registration Report - Part C).

IIIA 5.1 Analytical Standards and Samples

IIIA 5.1.1 Samples of the preparation

A sample of the preparation was provided by the applicant but no analysis of the contents of the active substance gibberellic acid GA_3 was performed.

IIIA 5.1.2 Analytical standards for the pure active substance

Analytical standards of gibberellic acid GA_3 was not provided because there was no request.

IIIA 5.1.3 Samples of the active substance as manufactured

No samples were provided because there was no request.

IIIA 5.1.4 Analytical standards for relevant metabolites and all other components included in the residue definition

No samples were provided because there was no request.

IIIA 5.1.5 Samples of reference substances for relevant impurities

Gibberellic acid GA_3 does not contain any impurity of toxicological or ecotoxicological concern.

IIIA 5.2 Methods for the Analysis of the Plant Protection Product

Analytical methods for the determination of gibberellic acid GA_3 and their impurities and relevance of CIPAC methods were evaluated as part in the EU review. The respective data are considered adequate and are not included in this submission.

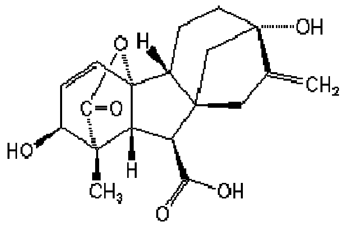
There is no change regarding the Section 2 of the Part B of the Registration Report compared to the main application. Therefore, no evaluation is necessary.

IIIA 5.3 Description of Analytical Methods for the Determination of Residues

IIIA 5.3.1 Evaluation of Gibberellic acid

The conclusions regarding the peer review of the analytical methods for residues of gibberellic acid (GA3) are summarized in EFSA's conclusion (EFSA Journal 2012; 10(1):2507; ASB2012-3194).

Table 3-1: Information on the active substance gibberellic acid

Name of component of residue definition substance code IUPAC name formula	Structural formula
Gibberellic acid (GA3) (3*S*,3a*S*,4*S*,4a*S*,7*S*,9a*R*,9b*R*,12*S*)-7,12-dihydroxy-3-methyl-6-methylene-2-oxoperhydro-4a,7-methano-9b,3-propenoazuleno[1,2-*b*]furan-4-carboxylic acid or (3*S*,3a*R*,4*S*,4a*S*,6*S*,8a*R*,8b*R*,11*S*)-6,11-dihydroxy-3-methyl-12-methylene-2-oxo-4a,6-ethano-3,8b-prop-1-enoperhydroindeno[1,2-*b*]furan-4-carboxylic acid $C_{19}H_{22}O_6$, molecular mass: 346.37 g/mol	

IIIA 5.3.1.1 Overview of residue definitions and levels for which compliance is required

The current legal residue definition for food of plant and animal origin is no longer proposed by EFSA in their conclusion on the peer review (EFSA Journal 2012; 10(1):2507; ASB2012-3194), in which no plant residue definition for monitoring is considered necessary and inclusion in Annex IV to Reg (EC) No 396/2005 is proposed. The reason for this is the low toxicity of the substance and the fact that it is not possible to distinguish between exogenous and natural residues of gibberellic acid.

Table 3-2: Relevant residue definitions

Matrix	Relevant residue	Reference Remarks
Plant material	Gibberellic acid[1]	Regulation (EC) No 149/2008, annex III part A
	Not relevant	EFSA conclusion, EFSA Journal 2012; 10(1):2507; ASB2012-3194;
Foodstuff of animal origin	Gibberellic acid[1]	Regulation (EC) No 149/2008, annex III part A
	Not relevant	EFSA conclusion, EFSA Journal 2012; 10(1):2507; ASB2012-3194;
Soil	Gibberellic acid (pending on data gaps in section 4)	EFSA conclusion, EFSA Journal 2012; 10(1):2507; ASB2012-3194;
Surface water	Gibberellic acid (pending on data gaps in section 4)	EFSA conclusion, EFSA Journal 2012; 10(1):2507; ASB2012-3194;
Drinking/ground water	Gibberellic acid (pending on data gaps in section 4)	EFSA conclusion, EFSA Journal 2012; 10(1):2507; ASB2012-3194;
Air	Gibberellic acid	EFSA conclusion, EFSA Journal 2012; 10(1):2507; ASB2012-3194;

Matrix	Relevant residue	Reference Remarks
Body fluids/tissue	Not defined	Not classified as T / T+

[1] MRLs are currently under reconsideration (Art. 12 (1)). Evaluating Member State is the Czech Republic. It is expected, that GA3 will also be nominated as a candidate for Annex IV.

Table 3-3: Levels for which compliance is required

Matrix	MRL	Reference for MRL/level Remarks
Plant, high water content	5 mg/kg [1]	Regulation (EC) No 149/2008, annex III part A
Plant, acidic commodities	5 mg/kg [1]	Regulation (EC) No 149/2008, annex III part A
Plant, dry commodities	0.1 mg/kg [1]	Regulation (EC) No 149/2008, annex III part A
Plant, high oil content	5 mg/kg [1]	Regulation (EC) No 149/2008, annex III part A
Plant, difficult matrices (hops, spices, tea)	0.1 mg/kg [1]	Regulation (EC) No 149/2008, annex III part A
Meat	0.1 mg/kg [1]	Regulation (EC) No 149/2008, annex III part A
Milk	0.1 mg/kg [1]	Regulation (EC) No 149/2008, annex III part A
Eggs	0.1 mg/kg [1]	Regulation (EC) No 149/2008, annex III part A
Fat	0.1 mg/kg [1]	Regulation (EC) No 149/2008, annex III part A
Liver, kidney	5 mg/kg [1]	Regulation (EC) No 149/2008, annex III part A
Soil	0.05 mg/kg	common limit
Drinking/ground water	0.1 µg/L	general limit for drinking water
Surface water	0.05 mg/kg	common limit
Air	0.1 µg/L	general limit for drinking water
Tissue (meat or liver)	17 000 µg/L	E_bC_{50} *Pseudokirchnerielle subcapitata*, EFSA conclusion, EFSA Journal 2012; 10(1):2507; ASB2012-3194
Body fluids	not required	not classified as T / T+ / Xi / Xn

[1] MRLs are currently under reconsideration (Art. 12 (1)). Evaluating Member State is the Czech Republic. It is expected that GA3 will be nominated as a candidate for Annex IV.

IIIA 5.3.1.2 Description of Analytical Methods for the Determination of Residues of Gibberellic acid in Plant Matrices (OECD KIII A 5.3.1)

No methods are required for plant matrices since the intended use of gibberellic acid is as a plant growth regulator for grapes only. Moreover, MRLs are currently under reconsideration (Art. 12 (1)). Evaluating Member State is the Czech Republic. It is expected that gibberellic acid will be included in Annex IV of regulation (EC) No 396/2005.

IIIA 5.3.1.3 Description of Analytical Methods for the Determination of Residues of Gibberellic acid in Animal Matrices (OECD KIII A 5.3.1)

The intended use as plant growth regulator for grapes only is not relevant for production of feeding stuffs. Moreover, MRLs are currently under reconsideration (Art. 12 (1)). Evaluating Member State is the Czech Republic. It is expected that gibberellic acid will be included in Annex IV of regulation (EC) No 396/2005. Therefore, analytical methods for gibberellic acid in food of animal origin are not required.

IIIA 5.3.1.4 Description of Methods for the Analysis of Gibberellic acid in Soil (OECD KIII A 5.4)

Based on SANCO/825/00 rev. 8.1 enforcement methods for naturally occurring non-toxic substances in soil are not needed.

IIIA 5.3.1.5 Description of Methods for the Analysis of Gibberellic acid in Water (OECD KIII A 5.6)

Based on SANCO/825/00 rev. 8.1 guidance document enforcement methods for naturally occurring non-toxic substances in water are not needed.

IIIA 5.3.1.6 Description of Methods for the Analysis of Gibberellic acid in Air (OECD KIII A 5.7)

Based on SANCO/825/00 rev. 8.1 guidance document enforcement methods for naturally occurring non-toxic substances in air are not needed.

IIIA 5.3.1.7 Description of Methods for the Analysis of Gibberellic acid in Body Fluids and Tissues (OECD KIII A 5.8)

Methods for the determination of residues in body fluids and tissues are not required since the active substance is not classified as toxic or highly toxic.

IIIA 5.3.1.8 Other Studies/ Information

Other studies were not provided.

IIIA 5.4 Conclusion on the availability of analytical methods for the determination of residues

Analytical methods for residues are not required. Consequently, data gaps do not exist.

Appendix 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	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)

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Data protection claimed	Owner	How considered in dRR *
	EFSA	2011	European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance gibberellic acid EFSA Journal 2012;10(1):2507, 1-45 ASB2012-3194			Add

* Y Yes , relied on
N No, not relied on
Add: Relied on, study not submitted by applicant but necessary for evaluation

REGISTRATION REPORT
Part B

Section 4: Metabolism and Residues

Detailed summary of the risk assessment

Product code: Berelex 40 SG

Active Substance: 400 g/kg Gibberellic acid

Central Zone
Zonal Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant: SUMITOMO CHEMICAL

Date: 21/06/2017

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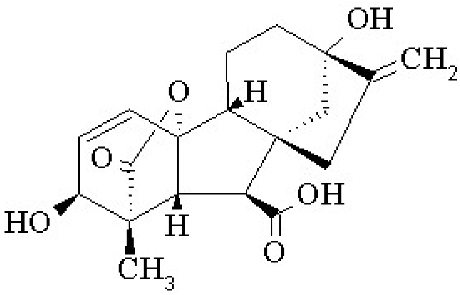
4 METABOLISM AND RESIDUES DATA

4.1 Evaluation of the active substances

Table 4.1-1: Identity of the active substance

Structural formula	
Common Name	Gibberellic acid (GA3)
CAS number	77-06-5

4.1.1.1 Storage stability

A brief summary of the storage stability data on gibberellic acid (GA 3) is given in the following table. Data that has been previously evaluated at EU level is described in detail in the DAR of gibberellic acid (Hungary, 2008, ASB2010-10315) and the corresponding EFSA-Conclusion (EFSA, 2012 ASB2012-3194).

Table 4.1-2: Stability of residues (Annex IIA, point 6.1)

Stability of GA3	Residues of GA3 in grapes were shown to be stable for up to 24 months following storage at -18°C.

4.1.1.2 Metabolism in plants and plant residue definition(s)

Table 4.1-3: Metabolism in plants (Annex IIA, point 6.2.1; 6.5.1, 6.5.2, 6.6.2 and 6.7.1)

Plant groups covered	Not relevant. Gibberellic acid occurs naturally in a wide range of plants at levels of up to 0.1 mg/kg. Metabolism data are not relevant.
Rotational crops	Not applicable
Metabolism in rotational crops similar to metabolism in primary crops? (yes/no)	Not relevant
Distribution of the residue in peel/ pulp	Not applicable
Processed commodities (nature of residue)	Not relevant
Residue pattern in raw and processed commodities similar? (yes/no)	Not relevant

Plant residue definition for monitoring	Not relevant Note: According to Reg. (EC) No 396/2005, MRLs have been established at a level of 5 mg/kg in plant matrices (DoR: GA3). These MRLs are, however, currently under re-consideration (Art. 12 (1)). Evaluating Member State is the Czech Republic. It is expected, that GA3 will also be nominated as a candidate for Annex IV.
Plant residue definition for risk assessment	GA3
Conversion factor(s) (monitoring to risk assessment)	None

4.1.1.3 Metabolism in livestock and animal residue definition(s)

Table 4.1-4: Metabolism in livestock (Annex IIA, point 6.2.2 to 6.2.5 and 6.7.1)

Animals covered	Not required
Time needed to reach a plateau concentration in milk and eggs	Not applicable.
Animal residue definition for monitoring	Not relevant Note: According to Reg. (EC) No 396/2005, MRLs have been established at a level of 0.1 mg/kg in animal matrices (DoR: GA3). These MRLs are, however, currently under re-consideration (Art. 12 (1)). Evaluating Member State is the Czech Republic. It is expected, that GA3 will also be nominated as a candidate for Annex IV.
Animal residue definition for risk assessment	Not relevant
Conversion factor(s) (monitoring to risk assessment)	Not applicable
Metabolism in rat and ruminant similar (yes/no)	Not applicable
Fat soluble residue: (yes/no)	No (log $P_{O/W}$ = 0.72)

4.1.1.4 Residues in rotational crops

Table 4.1-5: Residues in rotational crops (Annex IIA, point 6.6.3)

Field studies	Not relevant.

4.1.1.5 Residues in livestock

Calculation of the dietary burden

Not required

Table 4.1-6: Conditions of requirement of livestock feeding studies on GA3

	Ruminant:	**Poultry:**	**Pig:**
Expected intakes by livestock ≥0.1 mg/kg diet (dry weight basis) (yes/no – If yes, specify the level)	Not applicable	Not applicable	Not applicable
Potential for accumulation (yes/no):	no	no	no
Metabolism studies indicate potential level of residues ≥0.01 mg/kg in edible tissues (yes/no)	Not applicable	Not applicable	Not applicable

Livestock feeding studies were neither available nor required.

4.2 Evaluation of the intended use(s)

4.2.1 Selection of critical use and justification

The critical GAP used for consumer intake and risk assessment is presented in Table 4.2-1.

Table 4.2-1: Critical Use (worst case) used for consumer intake and risk assessment

1	2	3	4	5	6	7	8	9	10	11	12	13
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)** **(a)**	**F G or I** **(b)**	**Pests or Group of pests controlled** **(additionally: developmental stages of the pest or pest group)** **(c)**	**Application**			**Application rate**			**PHI (days) (i)**	**Remarks:** **e.g. safener/synergist per ha** **e.g. recommended or mandatory tank mixtures** **(j)**
					Method / Kind **(d-f)**	**Timing / Growth stage of crop & season** **(g)**	**Max. number (min. interval between applications) a) per use b) per crop/ season (h)**	**kg product / ha a) max. rate per appl. b) max. total rate per crop/season**	**kg as/ha** **a) max. rate per appl. b) max. total rate per crop/season**	**Water L/ha** **min / max**		
1	DE	Wine grapes	F	plant growth regulator, easing structure of grape-stalk. for preventive treatment	spraying or fine spraying	BBCH 62-68	a) 1 b) 1	a) 0.05 b) 0.05	a) 0.02 b) 0.02	1000	F	

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) All abbreviations used must be explained
(e) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(f) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(g) 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
(h) The minimum and maximum number of application possible under practical conditions of use must be provided
(i) PHI - minimum pre-harvest interval
(j) Remarks may include: Extent of use/economic importance/restrictions

4.2.2 Grapes

4.2.2.1 Residues in primary crops

No supervised residue trials from N-EU were available and none are considered necessary. Residues are not expected to exceed natural background concentrations. Additional information concerning the application of gibberellic acid on grapes was submitted for Southern Europe (ASB2011-5153, ASB2011-5154). Residues were found to be below the LOQ of 0.05 mg/kg.

4.2.2.2 Distribution of the residue in peel/pulp

Not relevant.

4.2.2.3 Residues in processed commodities

Not relevant.

4.2.2.4 Proposed pre-harvest intervals, withholding periods

Not necessary.

4.3 Consumer intake and risk assessment

The key data for consumer intake assessment are summarized in Table 4.3-1.

Table 4.3-1: Key data for consumer intake assessment derived for the intended uses

Commodity	Long-term intake		Short-term intake	
	Input value (mg/kg)	**Comment**	**Input value (mg/kg)**	**Comment**
Wine grapes	0.05	STMR	not applicable, no ARfD allocated	

The toxicological reference values and all input values used for consumer risk assessment are stated in Table 4.3-2. To illustrate the results of the chronic risk assessment, a screenshot of the TMDI results obtained with EFSA PRIMO is displayed in Appendix 3.

Table 4.3-2: Consumer risk assessment (Annex IIA, point 6.9, Annex IIIA, point 8.8)

Chronic risk assessment	
ADI	0.68 mg/kg bw
TMDI (% ADI) according to EFSA PRIMo	32 % (based on UK toddlers, body weight: 14.15 kg)
NTMDI (% ADI) according to German NVS II	29 % (based on DE children, individual consumption/body weight ratio)
IEDI (% ADI) according to EFSA PRIMo rev.2	Not calculated
NEDI (% ADI) according to German NVS II	Not calculated
Factors included in IEDI and NEDI	None
Acute risk assessment	
ARfD	n.n.
IESTI (% ARfD) according to EFSA PRIMo rev.2	Not applicable
NESTI (% ARfD) according to German NVS II	Not applicable
Factors included in IESTI and NESTI	None

4.4 Proposed maximum residue levels (MRLs)

No new MRLs are required.

4.5 Conclusion

The data available are considered sufficient for risk assessment. An exceedance of the current MRL of 5 mg/kg for gibberellic acid as laid down in Reg. (EU) 396/2005 is not expected. In addition, gibberellic acid has been proposed as a candidate for inclusion into Annex IV of Reg. (EU) 396/2005.

The long-term and the short-term intake of gibberellic acid residues are unlikely to present a public health concern.

As far as consumer health protection is concerned, BfR/Germany agrees with the authorization of the intended use.

Appendix 1 Reference list

Table A 1: Reference list

Annex point/ reference No	Author(s)	Year	Title Report-No. Authority registration No	Data protection claimed	Owner	How considered in dRR *
All	Hungary	2008	Gibberellic acid: Draft Assessment Report Vol. 1-3 GLP: Open Published: Yes ASB2010-10315	Open		Add
All	EFSA	2012	European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance gibberellic acid EFSA Journal 2012;10(1):2507, 1-45 ASB2012-3194	Open		Add
OECD: K IIA 6.3	Greig, I.	2005	To determine the magnitude of Gibberellic Acid (GA3) residues at harvest and intervals in the raw agricultural commodity seedless table grapes resulting from six sequential overall applications of ProGibb 40% in Greece and Spain (2003) AF/6993/VB GLP: Yes Published: No BVL-2038216, BVL-2206897, BVL-2285803, ASB2011-5154	Yes	SCF SUM	Y
OECD: KIIA 6.3	Harrison, C.; Partington, K.	2008	To determine the stability of GA3 in grape specimens following storage at -18°C for 1,3,6,12,18 and 24 months. (2004-2008) AD/6995/VB GLP: Yes Published: No BVL-2038214, BVL-2206895, BVL-2206937, BVL-2285801, ASB2011-5153	Yes	SCF SUM	Y

* Y yes , relied on
N No, not relied on
Add: Relied on, study not submitted by applicant but necessary for evaluation

Appendix 2 Detailed evaluation of the additional studies relied upon

No further studies submitted/needed.

Appendix 3 Pesticide Residue Intake Model (PRIMo rev.2)

Gibberellic acid

Status of the active substance:		Code no.	
LOQ (mg/kg bw):		proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**0,68**	ARfD (mg/kg bw):	**n.n.**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2012**	Year of evaluation:	**2012**

Explain choice of toxicological reference values.
The risk assessment has been performed on the basis of the MRLs collected from Member States in April 2006. For each pesticide/commodity the highest national MRL was identified (proposed temporary MRL = pTMRL).
The pTMRLs have been submitted to EFSA in September 2006.

Chronic risk assessment

TMDI (range) in % of ADI
minimum - maximum
6 - 32

No of diets exceeding ADI: ---

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	pTMRLs at LOQ (in % of ADI)
32,3	UK Toddler	16,8	Sugar beet (root)	4,7	FRUIT (FRESH OR FROZEN)	4,4	VEGETABLES	
28,8	WHO Cluster diet B	10,6	VEGETABLES	8,7	CEREALS	5,3	FRUIT (FRESH OR FROZEN)	
27,9	FR infant	15,4	VEGETABLES	11,2	FRUIT (FRESH OR FROZEN)	0,7	CEREALS	
27,1	DE child	16,9	FRUIT (FRESH OR FROZEN)	5,4	VEGETABLES	4,1	CEREALS	
24,6	FR toddler	12,7	VEGETABLES	8,6	FRUIT (FRESH OR FROZEN)	2,2	CEREALS	
24,5	NL child	11,0	FRUIT (FRESH OR FROZEN)	8,4	VEGETABLES	4,1	CEREALS	
21,6	UK Infant	7,4	Sugar beet (root)	4,8	VEGETABLES	4,0	FRUIT (FRESH OR FROZEN)	
20,3	IE adult	7,9	FRUIT (FRESH OR FROZEN)	6,6	VEGETABLES	4,9	CEREALS	
17,3	WHO cluster diet E	6,7	VEGETABLES	4,5	CEREALS	4,2	FRUIT (FRESH OR FROZEN)	
17,1	DK child	7,7	CEREALS	5,4	VEGETABLES	3,8	FRUIT (FRESH OR FROZEN)	
16,0	WHO cluster diet D	6,7	VEGETABLES	6,2	CEREALS	2,1	FRUIT (FRESH OR FROZEN)	
15,6	SE general population 90th percentile	7,4	VEGETABLES	4,3	FRUIT (FRESH OR FROZEN)	3,7	CEREALS	
13,5	WHO Cluster diet F	5,2	VEGETABLES	4,0	CEREALS	2,8	FRUIT (FRESH OR FROZEN)	
13,5	PT General population	4,7	FRUIT (FRESH OR FROZEN)	4,0	VEGETABLES	4,0	CEREALS	
13,2	ES child	4,1	FRUIT (FRESH OR FROZEN)	3,8	CEREALS	3,6	VEGETABLES	
12,9	WHO regional European diet	6,8	VEGETABLES	2,7	CEREALS	2,6	FRUIT (FRESH OR FROZEN)	
12,0	IT kids/toddler	6,2	CEREALS	3,1	VEGETABLES	2,6	FRUIT (FRESH OR FROZEN)	
11,6	UK vegetarian	2,8	Sugar beet (root)	2,8	VEGETABLES	2,5	FRUIT (FRESH OR FROZEN)	
10,3	FR all population	4,5	FRUIT (FRESH OR FROZEN)	2,7	VEGETABLES	2,5	CEREALS	
10,2	NL general	4,3	VEGETABLES	3,6	FRUIT (FRESH OR FROZEN)	2,0	CEREALS	
10,0	UK Adult	2,9	Sugar beet (root)	2,2	VEGETABLES	2,1	FRUIT (FRESH OR FROZEN)	
8,9	ES adult	3,0	FRUIT (FRESH OR FROZEN)	2,8	VEGETABLES	2,3	CEREALS	
8,9	IT adult	3,7	CEREALS	3,0	VEGETABLES	2,1	FRUIT (FRESH OR FROZEN)	
7,6	LT adult	3,8	VEGETABLES	2,0	CEREALS	1,7	FRUIT (FRESH OR FROZEN)	
7,3	DK adult	2,6	VEGETABLES	2,4	FRUIT (FRESH OR FROZEN)	2,1	CEREALS	
7,0	PL general population	4,5	VEGETABLES	2,5	FRUIT (FRESH OR FROZEN)	0,0	PULSES, DRY	
5,5	FI adult	2,0	VEGETABLES	1,8	FRUIT (FRESH OR FROZEN)	1,4	CEREALS	

Conclusion:
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of Gibberellic acid is unlikely to present a public health concern.

REGISTRATION REPORT
Part B

Section 5 Environmental Fate
Detailed summary of the risk assessment

Product name: Berelex 40 SG
Product code: ABG-3206
Active Substance: Gibberellic Acid GA_3 (400 g/kg)

Central Zone
Zonal Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant: Sumitomo Chemical Agro Europe
(representing Valent BioSciences Corporation)
Date: 21/06/2017

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

This document comprises the risk assessment for groundwater and the exposure assessment of surface water and soil for the plant protection product AGB-3206 containing the active substance Gibberellic acid $_{GA3}$ in its intended uses in wine grapes according to Appendix 3.

National Addenda are included containing country specific assessments for some annex points.

5.1 General Information on the formulation

Table 5.1-1: General information on the formulation ABG-3206

Code	ABG-3206
plant protection product	Berelex 40 SG
applicant	Sumitomo Chemical Agro Europe (representing Valent BioSciences Corporation)
date of application	Vine grapes; BBCH 62-68; 20. July - 03. August
Formulation type	SG
active substance	Gibberellic Acid
Concentration of as	400g/Kg (techn. 444.5g/Kg)

5.2 Proposed use pattern

The critical GAPs used for exposure assessment is presented in Table 5.2-1.

Table 5.2-1: Critical use pattern of ABG-3206

Group	Crop/growth stage	Application method / Drift scenario	Number of applications, Minimum application interval, interception, application time (season)	Application rate, cumulative (g as/ha)	Soil effective application rate (g as/ha)
00-001	Grape vine/ 62-68	spraying or fine spraying (low volume spraying)	1 - 70% 20. July - 03. August (AppDate 2)	20	6

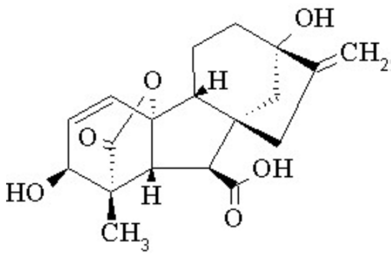
5.3 Information on the active substances

5.3.1 Gibberellic Acid

5.3.1.1 Identity, further information of Gibberellic acid

Table 5.3-1: Identity, further information of Gibberellic acid

Active substance (ISO common name)	Gibberellic acid – GA_3
IUPAC	(3S,3aS,4S,4aS,7S,9aR,9bR,12S)-7,12-dihydroxy-3-methyl-6-methylene-2-oxoperhydro-4a,7-methano-9b,3-propenoazuleno[1,2-b]furan-4-carboxylic acid

Function	Plant growth regulator
Status under Reg. (EC) No 1107/2009	Approved / included into Annex I of Directive 91/414 according to the amending Directive 2008/127/EC
Date of approval	20.12.2008
Conditions of approval	
Confirmatory data	PART A Only uses as plant growth regulator may be authorised. PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on gibberellic acid (SANCO/2613/ 2008) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health shall be taken into account. Conditions of use shall include, where appropriate, risk mitigation measures.
RMS	Hungary
Minimum purity of the active substance as manufactured (g/kg)	purity of the technical active substance of 90 % w/w
Molecular formula	C19H22O6
Molecular mass	346.4 g/mol
Structural formula	

5.3.1.2 *Physical and chemical properties of Gibberellic acid*

Physical and chemical properties of Gibberellic Acid as agreed at EU level (see SANCO/2613/08 – rev. 1) and considered relevant for the exposure assessment are listed inTable 5.3-2.

Table 5.3-2: EU agreed physical chemical properties of Gibberellinsäure relevant for exposure assessment

	Value	**Reference**
Vapour pressure (at 25 °C) (Pa)	1 x 10^{-5} Pa at 25°C (98 %) (extrapolated)	Comb, A.L2005b Huntingdon Life Sciences Report No. NFJ003/043761
Henry's law constant (Pa × m³ × mol⁻¹)	7.5 x 10^{-7} Pa m^3 mol^{-1} at 25 °C (calculated)	DAR
Solubility in water (at 25 °C in mg/L)	at 20°C (98 %): in pure water 4.28 g/L pH 4 buffer11.7 g/L pH 7 buffer>250 g/L pH 10 buffer >250 g/L at 20°C (91.1 %): 4.28 g/L	Comb. A.L (2005c) NFJ004/043758

	at 25°C (88 % GA_3) 4.6 g/L (at both later studies the effect of pH was not investigated)	
Partition co-efficient (at 25 °), log P_{OW}	in pH 2.2 buffer at 22°C (98%): P_{ow} = 5.19 log P_{ow} = 0.72 (in a non OECD other study pH dependency was observed)	Da Conceicao L. (2003c) 09/C/3967 Nufarm
Dissociation constant, pKa	pKa: 4.1 (Ka = $8x10^{-5}$) The pKa value was calculated from the points on the titration curve.	Comb, A.L. (2005d)
Hydrolytic degradation	pH 1.2 37 ºC: 14.6 hours half-life pH 4 DT50 (30°C) 217 h pH 7 DT50 (30°C) 164 h pH 9 DT50 (30°C) 46 h Decomposition of GA_3 and its loss of biological activity in buffered aqueous solutions. Half lives for GA_3 loss at 30°C were 77.8 and 57.8 hrs at pH 5 and pH 7 respectively.	Da Conceicao L. (2003d) 09/C/3996 Nufarm Perez,F., Vecchiola, A., Pinto, M. And Agosin, E. (1996)
Photolytic degradation	irradiated/ non-irradiated water DT50:376/ 271 pH5 DT50:473/249 Photodegradation was not primary mechanism of degradation.	Button, S. (2005) Nufarm (Japan) K.K. Report No NJF002/052203
Quantum yield of direct phototransformation in water > 290 nm	Φ = no data	
Photochemical oxidative degradation in air (calculation according to Atkinson)	Photochemical reaction with OH radicals and ozone: half life 0.98 hrs and 12.1 hrs respectively (12 hr day; 1.5 x 10^6 OH/cm^3 and 7 x 10^{11} mol/cm^3 ozone	Calculation using AOPWIN v 1.91 (US EPA, 2000)

5.3.1.3 Metabolites of Gibberellic acid

According to the results of the assessment of Gibberellic acid for the EU approval, no relevant environmental metabolites of Gibberellic acid are mentioned. Gibberellic acid occurs naturally in a wide range of plants. Therefore it will not be possible to distinguish naturally occurring levels from those resulting from the use of plant growth regulators. Hence metabolism data are not relevant.

No new studies on the fate and behaviour of Gibberellic acid have been performed. .

5.4 Summary on input parameter for environmental exposure assessment

5.4.1 Rate of degradation in soil

5.4.1.1 Laboratory studies

Gibberellic acid

No new studies have been submitted regarding the route and rate of degradation of Gibberellic acid in soil. The environmental exposure assessment is based on the EU agreed DT_{50} values from the laboratory studies, are summarized in Table 5.4-1.

Table 5.4-1: Summary of aerobic degradation rates for Gibberellic acid - laboratory studies

Soil type	OC %	pH (H_2O)	T°C/ %MWHC	DT50/DT90 /d	DT_{50} (d) 20 °C pF2/10 kPa	Method of calculation	St (r^2)	Reference
Clay	1.4	5.9	25°C/60%	2.96/9.77	4.4	SFO	0.923	Addendum 08/2011
Loam	479	7.01	25°C/60%	1.46/4.82	2.3	SFO	0.859	Addendum 08/2011

5.4.1.2 Field studies

Gibberellic acid

no data available

5.4.2 Adsorption/desorption

Gibberellic acid

No new studies have been submitted regarding adsorption/desorption in soil of Gibberellic acid. The exposure modeling is based on the EU K_{foc} values as summarized in Table 5.4-2

Table 5.4-2: K_f, K_{foc} and 1/n (Freundlich exponent) values for Gibberellic acid

Soil Type	OC (%)	soil pH	K_f (mL g^{-1})	K_{foc} (mL $g^{-1)}$	1/n	Reference
Bromsgrove; Sandy loam	1.0	4.5	0.039	3.92	0.98	Addendum 08/2011
Elmton; Sandy clay loam	5.9	7.4	0.052	0.875	0.96	
Malham;Silt loam	6.6	7.0	0.74	1.13	0.51	
Saitama; Volcanic ash	3.2	5.4	0.94	29.7	0.91	
Speyer 2.2; Sand	2.1	6.2	0	0	-	

Arithmetic mean	**0.221**	**7.125**	**0.84***	
pH dependence	No			

*Arithmetic mean of 4 studies

5.4.3 Rate of degradation in water and sediment

Gibberellic acid

Neither a water/sediment study is available nor a new water/sediment study has been submitted. However as mentioned in the addendum 08/2011, Gibberellic acid degrades rapidly by chemical hydrolysis and has a very low soil sorption constant, so that it can be considered that it will degrade rapidly in natural waters and will not partition to sediment.

5.5 Estimation of concentrations in soil (PEC_{soil}) (KIIIA1 9.4)

PEC_{soil} calculations are based on the recommendations of the FOCUS workgroup on degradation kinetics. A soil bulk density of 1.5 g/cm^3, a soil depth of 5 cm and a tillage depth of 20 cm (arable crop)/5 cm (permanent crops) were assumed. The PEC_{soil} calculations were performed with ESCAPE 2.0 based on the input parameters as presented in tables below.

Table 5.5-1: Input parameters related to application for PEC_{Soil} calculations

Plant protection product	ABG-3206
Use No.:	00-001
Crop:	grape vine
Application rate:	20g/ha ; (6g/ha soil relevant)
Number of application/interval:	1 /-
Crop interception:	70%

Table 5.5-2: Input parameter for active substance for PEC_{soil} calculation

Active substance	**DT_{50}**	**value in accordance to EU endpoint**
Gibberellic acid	4.4 d (SFO Maximum laboratory study, see Table 5.4-1)	Yes

Due to the fast degradation of Gibberellic acid in soil (DT_{90} << 365 d, SFO, laboratory data) the accumulation potential of Gibberellic acid does not need to be considered.

Table 5.5-3: Results of PEC_{soil} calculation for application of ABG-3206 in grape vine (soil bulk density 1.5 g/cm^{-3}, soil depth 5 cm) according to use No. 00-001

active substance/ preparation	**soil relevant application rate (g/ha)**	**PEC_{act} (mg/kg)**	**PEC_{twa} 21 d (mg/kg)**	**tillage depth (cm)**	**PEC_{bkgd} (mg/kg)**	**PEC_{accu} = PEC_{act} + PEC_{bkgd} (mg/kg)**
Gibberellic acid	6	0.008	0.0003	5	<0.0001	0.008

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

PEC_{sw} and PEC_{sed} calculations are provided according to the recommendations of the FOCUS working group on surface water scenarios in a stepwise approach considering the pathways drainage and runoff.

The relevant input parameters used for PEC calculation are summarized in the tables below.

Table 5.6-1: Input parameters for Gibberellic acid for $PEC_{sw/sed}$ calculations

Parameter	Endpoint used for $PEC_{sw/sed}$ calculation	Values in accordance to EU endpoint in LoEP	Remarks
Active substance	Gibberellic acid		
Molecular weight (g/mol)	346.4	yes	see Table 5.3-1
Saturated vapour pressure (Pa)	1 x 10^{-5} Pa at 25°C (98 %) (extrapolated)	yes	see Table 5.3-2
Water solubility (mg/L)	4280	-	see Table 5.3-2
Diffusion coefficient in water (m²/d)	4.3 x 10^{-5}	--	default
Diffusion coefficient in air (m²/d)	0.43	--	default
Koc (mL g-1)	7.1	yes	Arithmetic mean (see Table 5.4-2)
Freundlich Exponent 1/n	0.84	yes	Arithmetic mean (see Table 5.4-2)
Plant Uptake	0	-	default for non-systemic substances
Wash-Off factor from Crop (1/mm)	0.05 (MACRO) 0.50 (PRZM)	-	default
DT_{50},soil (d)	4.4	yes	Maximum (1st order, pF2,20°C) Laboratory data (see Table 5.4-1)
DT_{50},water (d)	no data (1000d)		default
DT_{50},sed (d)	no data (1000d)		default
DT_{50},whole system (d)	no data (1000d)		default

Table 5.6-2: Input parameters related to application for $PEC_{sw/sed}$ calculations

Plant protection product	ABG-3206
Use No.	00-001
Crop:	grape vine (late application; June - Sep.
Application rate:	20g ai /ha
Number of application/interval:	1 / -
Application method:	spraying
Crop interception:	70% (full canopy)

Table 5.6-3: FOCUS Step 3 Scenario related input parameters for $PEC_{SW/sed}$ calculations for the application of ABG-3206

Crop	Scenario	Possible window of application
vines	D6	18.Jan - 17.Feb
	R1	01.Apr-01.May
	R2	01.Mar-31.Mar
	R3	18.Mar-17.Apr
	R4	24.Feb-26.Mar

Results of FOCUS SW calculations for the worst-case application scenario of ABG-3206 are summarized in the tables below.

Table 5.6-4: Maximum FOCUS Step 1 and Step 2 PEC_{sw} and PEC_{sed} of Gibberellic acid for the application of ABG-3206 in vines according to use No00-001

Gibbe-rellic acid	FOCUS Step 1	PECsw (µg/L)	PECsed (µg/L)
		7.14	0.51
	FOCUS Step 2	**PECsw (µg/L)**	**PECsed (µg/L)**
	North Europe	0.74 on day 4	0.05 on day 5
	South Europe	0.85 on day 4	0.06 on day 5

Table 5.6-5: Global maximum FOCUS Step 3 PEC_{sw} and PEC_{sed} values for Gibberellic acid for the application of ABG-3206 in vines according to use No.00-001

	FOCUS STEP 3 Scenario	Water Body	PEC_{sw} global max (µg/L)	PEC_{sw} (µg/L) twa, 21 d	PEC_{SED} global max (µg/kg)
	D6	ditch	0.343	0.148	0.0887
	R1	pond	0.0122	0.0122	0.00875
	R1	stream	0.249	0.00198	0.00990
	R2	stream	0.331	0.00180	0.00862
	R3	stream	0.351	0.00444	0.0170
	R4	stream	0.249	0.00301	0.00954

5.7 Risk assessment ground water (KIIIA1 9.6)

5.7.1 Predicted environmental concentration in groundwater (PEC_{GW}) calculation for active substance

Groundwater contamination by direct leaching of the active substance and its metabolites, degradation or reaction products through soil is generally assessed by groundwater model calculations.

The PEC of Gibberellic acid in ground water have been assessed with standard FOCUS scenarios to obtain outputs from the FOCUS PELMO 5.5.3. The FOCUS calculation was performed by RMS

Table 5.7-1: Input parameters related to application for PEC_{GW} modelling

plant protection product	ABG-3206
use No.	00-001
application rate (kg as/ha)	0.020
crop (crop rotation)	grape vine
relative application date	20th July / relative application date (day 201)
interception (%)	70
soil moisture	100 % FC
Q10-factor	2.58
moisture exponent	0.7
simulation period (years)	26

Table 5.7-2: Input parameters related to active substance for PEC_{GW} modelling

Parent	**Gibberellic acid**	**Remarks/Reference**
molecular weight (g/mol)	346.4	see Table 5.3-1
DT_{50} in soil (d)	4.4	max. Lab. pF2 (see Table 5.4-1)
K_{foc}	7.1	arithm mean; (see Table 5.4-2)
1/n	0.84	arithm mean; (see Table 5.4-2)
plant uptake factor	0	-

Table 5.7-3: PEC_{GW} at 1 m soil depth for Gibberellic acid for the application of ABG-3206 in grape vine (based on max. lab. for DT_{50} (pF2) value and arithm. mean for K_{foc})

Crop use No.	**Szenario**	**80th Percentile PEC_{GW} at 1 m Soil Depth (µg L^{-1}) groundwater model: FOCUSPELMO_5.5.3**
		Gibberellic acid
vines 00-001	**Châteaudun**	<0.001
	Hamburg	<0.001
	Kremsmünster	<0.001
	Piacenza	0.002
	Porto	0.001
	Sevilla	<0.001
	Thiva	<0.001

According to the PEC_{GW} modelling using FOCUSPELMO_5.5.3. a groundwater contamination of the active substance Gibberellic acid at a concentration of ≥ 0.1 µg/L is not expected for all relevant FOCUS groundwater scenarios.

5.7.2 Higher tier leaching assessment (Tier 3)

Not available, not required.

5.7.3 Summary of risk assessment for ground water

Results of modelling using FOCUSPELMO_5.5.3. show that the active substance Gibberellic acid is not expected to penetrate into groundwater at concentrations of ≥ 0.1 µg/L in the intended uses in vines.

5.8 Potential of active substance for aerial transport

The vapour pressure at 20 °C of the active substance Gibberellic acid is < 10^{-5} Pa. Hence the active substance Gibberellic acid is regarded as non-volatile.

Appendix 1 List of data submitted in support of the evaluation

No new studies were submitted.

Appendix 2 Detailed evaluation of studies relied upon

No new studies have been submitted.

Appendix 3 Table of Intended Uses justification and GAP tables

GAP-Table of intended uses for Germany

GAP rev. (No), date: 2014-03-11

PPP (product name/code)	**Berelex 40 SG**	**Formulation type:**	**SG**
active substance 1	**Gibberellinsäure**	**Conc. of as 1:**	**400 g/kg**
Applicant:	**Sumitomo Chemical Agro Europe GmbH**	**professional use**	**x**
Zone(s):	**central zone**	**non professional use**	☐

Verified by MS: yes

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 e.g. recommended or mandatory tank mixtures
					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		
001	DE	grape vine (VITVI)	F	easing structure of grape-stalk (YTRLO)	spraying or fine spraying (low volume spraying)	BBCH 62 to 68 preventive	a) 1 b) 1	a) 50 g/ha b) 50 g/ha	a) 20 g as/ha b) 20 g ashaL	1000 L		

Remarks:

(1) Numeration of uses in accordance with the application/as verified by MS
(2) Member State(s) or zone for which use is applied for
(3) 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)
(4) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(5) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds, developmental stages
(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 of treatment(s) (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 applications possible under practical conditions of use for each single application and per year (permanent crops) or crop (annual crops) must be provided
(8) Min. interval between applications (days) were relevant
(10) The application rate of the product a) max. rate per appl. and b) max. total rate per crop/season must be given in metric units (e.g. kg or L product / ha)
(11) The application rate of the active substance a) max. rate per appl. and b) max. total rate per crop/season must be given in metric units (e.g. g or kg / ha)
(12) The range (min/max) of water volume under practical conditions of use must be given (L/ha)
(13) PHI - minimum pre-harvest interval
(14) Remarks may include: Extent of use/economic importance/restrictions/minor use etc.

REGISTRATION REPORT
Part B

Section 6: Ecotoxicological studies
Detailed summary of the risk assessment

Product namee: Berelex 40 SG
Product code: ABG-3206
Active Substance: Gibberellic Acid GA_3 (400 g/kg)

Central Zone
Zonal Rapporteur Member State: Germany

CORE ASSESSMENT / NATIONAL ADDENDUM

Applicant: Sumitomo Chemical Agro Europe (representing Valent BioSciences Corporation)
Date: 21/06/2017

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Sec 6 ECOTOXICOLOGICAL STUDIES (MIIIA 10)

Note: This application contains only uses for Germany Therefore this document represents the assessment of the intended use in Germany and thus may not be representative for other member states.

A full risk assessment according to Uniform Principles for the plant protection product ABG-3206 in its intended uses in grape vine is documented in detail in the national risk assessment of the plant protection product ABG-3206dated from December 2011 performed by Germany.

This document comprises specific risk assessment for some annex points for authorization of the plant protection product ABG-3206 in Germany according to the uses listed in Appendix 2.

General information on the formulation ABG-3206 can be found in Table 5.1-1of Section 5 of the National addendum Germany (April 2013).

6.1 Proposed use pattern and considered metabolites

6.1.1 Grouping of intended uses for risk assessment

Full details of the proposed use pattern of the formulation ABG-3206 that will be assessed are presented in **Fehler! Verweisquelle konnte nicht gefunden werden.** and summarized in the table below.

The following table lists the grouping of the intended uses in order to perform a risk envelope approach.

Table 6.1-1: Critical use pattern of ABG-3206

Group	Crop/growth stage	Application method / Drift scenario	Number of applications, Minimum application interval, interception, application time (season)	Application rate, cumulative (g as/ha)	Soil effective application rate (g as/ha)
00-001	Grape vine/ 62-68	spraying or fine spraying (low volume spraying)	1 - 70% 20. July - 03. August (AppDate 2)	20	6

6.1.2 Consideration of metabolites

According to the results of the assessment of Gibberellic acid for the EU approval, no relevant environmental metabolites of Gibberellic acid are mentioned. Gibberellic acid occurs naturally in a wide range of plants. Therefore it will not be possible to distinguish naturally occurring levels from those resulting from the use of plant growth regulators. Hence metabolism data are not relevant.

6.2 Effects on birds (MIIIA 10.1, KPC 10.1, KPC 10.1.1)

6.2.1 Overview and summary

Avian acute oral and long-term reproduction studies have been carried out with Gibberellic acid. Full details of avian toxicity studies are provided in the respective EU DAR. The studies with the relevant acute and long-term endpoints were agreed during EU review process and are used for the risk assessment.

The risk assessment for effects on birds and other terrestrial vertebrates is carried out according to the European Food Safety Authority Guidance Document on Risk Assessment for Birds and Mammals (EFSA Journal 2009; 7(12): 1438).

6.2.1.1 Toxicity

The studies with the relevant acute and long-term endpoints which are used in the risk assessment procedure are listed in the following table.

Table 6.2-1: Toxicity of Gibberellic acid to birds with reference to agreed endpoints

Species	**Substance**	**Exposition** **Duration** **System**	**Results** **Toxicity**	**Reference** Author **Date** **Report No.**	**ICS-No.**
Anas platyrhynchos	Gibberellic acid (GA3); Purity: 91.2%	1 d acute	LD_{50} : > 2000 mg/kg bw[1] Mortality	[redacted] 1991 ISN 263/91970	77265

1) EFSA conclusion List of Endpoints (2011), EFSA Journal 2012;10(1)

As indicated above, an acute oral study with the formulated product has not been conducted. Consequently, the toxicity of ABG-3206 has been assessed considering data generated on the active substance..

Three acute oral studies have been submitted by the applicant. The study listed above was chosen because it provides the lowest endpoint. In the DAR of 2008 this study is considered as relevant for the risk assessment.

6.2.1.2 Exposure

ABG-3206 is a plant growth regulator containing Gibberellic acid as active substances. The product is formulated as a soluble granule. It will be used to ease the stem structure of wine grapes in order to improve aeration and thus to enhance the control of grey mold and bunch rots. .

Exposure to standard generic focal species was estimated according to the Guidance Document on Risk Assessment for Birds and Mammals (EFSA Journal 2009; 7(12): 1438)

$$DDD = \sum_i \frac{PD_i \times FIR_{total}}{bw} \times RUD \times AR \times PT$$

$$= \sum_i \frac{FIR_i}{bw} \times RUD \times AR \times PT$$

where:

DDD	= Daily dietary dose (mg/kg bw/day)
PDi	= composition of diet obtained from treated area
FIRi	= Food intake rate of indicator species i (g fresh weight/d)
bw	= Body weight (g)
RUD	= Residue per unit dose, bases on an application rate of 1 kg a.s./ha and assuming broadcast seedling
AR	= Application rate (kg/ha)
PT	= Proportion of diet obtained in the treated area (0…1)

In a first approach, it is assumed that birds do not avoid contaminated food items, that they feed exclusively in the treated area and on a single food type. Factors PT and PD are therefore equal to 1.

The risk assessment procedure follows a stepwise approach. A first screening step involves standard scenarios and default values for the exposure estimate, representing a "reasonable worst case". If a potential risk is indicated in the screening step, then one or several refinement steps (Tier 1, Tier2) may follow. According to the Guidance Document, no further assessment is required if all uses are safe in the screening step.

Mixture toxicty

Since ABG-3206 contains only one active substance, assessment of mixture toxicity is not needed.

6.2.1.3 Risk Assessment –overall conclusions

For risk assessment purposes, a risk envelope approach was used to cover highest risk for birds from intended use 00-001 (see also **Fehler! Verweisquelle konnte nicht gefunden werden.**, page6).

The results of the acute and reproductive risk assessments are summarized in the following table.

Table 6.2-2: TER for birds

Compound	**Risk assessment level**	**Indicator species**	**Time scale**	**TER**	**TER Annex VI trigger**
Gibberellic acid	Screening	Small omnivorous bird	Acute	>1049,3	10
TER shown in bold are below the relevant trigger					

Based on the presumptions of the screening step, the calculated TER values for the acute risk resulting from an exposure of birds to the active substance Gibberellic acid according to the GAP of the formulation ABG-3206 achieve the acceptability criteria TER ≥ 10, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. The results of the assessment indicate an acceptable risk for birds.

Drinking water risk assessment

Drinking water assessment is not required as the ratio of effective treatment rate to toxicological endpoint does not exceed the trigger. Please refer to chapter 6.2.3.

Food chain behaviour

An assessment of the risk from secondary poisoning is not required due to log P_{OW} values of Gibberellic acid being below the trigger. Please refer to chapter 6.2.9.

6.2.2 Toxicity to exposure ratio for birds (K III A 10.2.1)

6.2.2.1 Acute toxicity to exposure ratio (TERA)

Screening step

In the screening step, the risk to indicator bird species from an exposure to ABG-3206 is assessed. These indicators are considered to have highest exposure in a specific crop at a particular time due to their size and feeding habits and represent a worst case scenario.

The indicator bird species for the intended uses of ABG-3206 are listed in the following table.

Table 6.2-3: Avian indicator species for the use of ABG-3206 and shortcut values. Shortcut values from section 4.1 of EFSA/2009/1438

Crop	Indicator species	Shortcut value (90th percentile RUD)
Vineyard	Small omnivorous bird	95.3

To estimate the daily dietary doses , following equations were used:

Daily dietary dose (DDD):

$$DDD_{single\ application} = \text{application rate [kg a.s./ha]} \times \text{shortcut value}^1$$

[1] see section 4.1 of EFSA/2009/1438

In case of multiple applications, the daily dietary dose for a single application is multiplied with an appropriate multiple application factor for 90th percentile residue data (MAF_{90}; see Table 7 of EFSA/2009/1438).A specific MAF_{90} may be calculated according to Appendix H of EFSA/2009/1438 for non-standard application intervals.

$$DDD_{multiple\ application} = DDD_{single\ application} \times MAF_{90}{}^1$$

Toxicity exposure ratio (acute):

$$TER_A = \frac{LD_{50}\ \text{(mg/kg bw/day)}}{\text{Acute DDD (mg/kg bw/day)}}$$

The resulting TER_A values are summarised in the following table.

Table 6.2-4: Acute screening risk assessment (TER_A) for birds. See text for details

Substance	Indicator species	Application rate (kg/ha)	Shortcut value, acute	MAF	DDD (mg/kg bw)	LD_{50} (mg/kg bw)	TER_A
Gibberellic acid	Small omnivorous bird	0.02	95.3	1	1.906	> 2000	>1049,3
TERs shown in bold fall below the relevant trigger.							

Based on the highly conservative presumptions of the screening step, the calculated TER values for the acute risk resulting from an exposure of birds to the active substanceGibberellic acid according to the GAP of the formulation ABG-3206 achieve the acceptability criteria TER ≥ 10, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. for acute effects. The results of the assessment indicate an acceptable risk for birds.

6.2.2.2 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.

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

Screening step

For the reproductive risk assessment, the calculation of the long-term toxicity exposure ratio (TER_{LT}) in principle follows the same procedure as for the acute risk assessment. However, the defined daily dose is obtained by multiplying the application rate with the mean short-cut values (based on mean RUD according to the new Guidance Document (EFSA, 2009)) as summarized in the following table.

Table 6.2-5: Avian generic focal species for the intended uses of ABG-3206 and relevant shortcut values for long-term exposure

Crop	Indicator species	Shortcut value (mean RUD)
Vineyard	Small omnivorous bird	38.9

As stated in the guidance document, it is justified to apply a time-weighted average (TWA) factor of 0.53 based on a default observation interval of 21 days and a default DT_{50} of 10 days for the calculation of the DDD (daily dietary dose):

$$DDD_{single\ application} = \text{application rate [kg/ha]} \times \text{shortcut value} \times TWA^*$$

* see section 4.3 of EFSA/2009/1438

Toxicity exposure ratio (Long-term):

$$TER_{LT} = \frac{NOEL\,(mg/kg\,bw/day)}{Long\text{-}term\,DDD\,(mg/kg\,bw/day)}$$

No avian long-term toxicity studies with Gibberellic acid have been performed. Given that Gibberellic acid is naturally occurring in the diet of herbivorous birds and birds that feed on herbivorous animals, a permanent exposure is taking place. As can be seen from acute oral and short-term dietary data (see DAR 2008), Gibberellic acid shows no toxicity to birds. Taking into account the plant-specific hormonal mode of action and accordingly the low application rate, no long-term toxic effects on birds are expected.

The following table provides the theoretical NOEL value that would be necessary to calculate an acceptable TER_{LT} above the trigger.

Table 6.2-6: Calculated NOEL value for birds exposed to ABG-3206

Substance	Indicator bird	Application rate (kg/ha)	Shortcut value (long-term)	f_{TWA}	DDD /mg/kg bw/d)	MAF	TER_{LT}	Calculated NOEL (mg/kg bw/d)	Annex VI acceptable TER_{LT} value
Gibberellic acid	Small omnivorous bird	0.02	38.9	0.53	0.412	1	5.5	2.27	≥ 5
	TERs shown in bold fall below the relevant trigger.								

The calculated TER_{LT} will be above the trigger for a chronic toxicity higher than 2.27 mg a.s./kg bw/d. Since Gibberellic acid naturally occurs in the diet of birds and has a plant-specific, non-toxic mode of action, it is expected that the long-term toxicity value for birds will be higher than 2.27 mg/kg bw/d.

No refinement is needed.

6.2.3 Drinking water exposure

Birds might be exposed via drinking water from puddles. According to the new Guidance Document (EFSA, 2009), no specific calculations of drinking water exposure and TER are necessary when the ratio of effective application rate (in g/ha) to the relevant endpoint (in mg/kg bw/d) does not exceed 50 in the case of less sorptive substances (Koc < 500 L/kg) or 3000 in the case of more sorptive substances (Koc ≥ 500 L/kg). This is due to the characteristics of the exposure scenario in connection with the standard assumptions for water uptake by birds (for further details please refer to chapter 5.5. of the Guidance Document). The puddle scenario has been taken into account to calculate the exposure concentration of Gibberellic acid formed on a field after rainfall. The ratios do not exceed the value of 50 for Gibberellic acid (Koc = 7.125 L/kg) and , thus it is not necessary to conduct a drinking water risk assessment for birds.

6.2.4 Details on formulation type in proportion per item

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

ABG-3206 is not formulated as bait. The formulation is intended for use as a foliar spray, and therefore this information is not required.

6.2.4.2 Pellets, granules, prills or treated seed

ABG-3206 is not formulated as pellets, granules, prills or treated seeds. <Product name> 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 LD50 per 100 items and per gram of items

Not applicable.

Size and shape of pellet, granule or prill

Not applicable.

6.2.5 Acute toxicity of the formulation

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

6.2.6 Metabolites

Avian toxicity tests with metabolites of Gibberellic acid were not performed and are not considered necessary.

Please refer to section 6.2.1 for an overview of the risk assessment for birds.

6.2.7 Supervised cage or field trials

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

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

ABG-3206 is intended for use as a foliar spray, and therefore this information is not required.

6.2.9 Effects of secondary poisoning

The EFSA birds and mammals guidance document (EFSA Journal 2009; 7(12): 1438) states that a log $K_{ow} \geq 3$ is used to indicate that there might be a potential for bioaccumulation (see chapter 5.6 "Bioaccumulation and food chain behaviour"). Since the log K_{ow} values of Gibberellic acid is 0.72 (pH=2.2), the active substance is deemed to have a negligible potential to bioaccumulate in animal tissues. No formal risk assessment from secondary poisoning is therefore required.

Consequences for authorization:

none

6.3 Effects on Terrestrial Vertebrates Other Than Birds (MIIIA 10.3, KPC 10.1, KPC 10.1.2)

6.3.1 Overview and summary

The risk assessment for effects on mammals is carried out according to the European Food Safety Authority Guidance Document on Risk Assessment for Birds and Mammals (EFSA Journal 2009; 7(12): 1438).

6.3.1.1 Toxicity

Table 6.3-1: Toxicity of Gibberellic acid /ABG-3206 to mammals with reference to agreed end-points

Species	Substance	Exposition Duration System	Results Toxicity	Reference Author Date Report No.	ICS-No.
Rat	FALGRO technical (91% Gibberellinsäure GA3)	Akut oral	LD50 : >5000 mg/kg bw[1,2]	[redacted] 1995 FNA 14/940705/AC	72202
Rat	GA3 40 SG = ABG-3206	Akut oral	LD50 : >5000 mg/kg bw[3]	[redacted] 2005 18149	77332

1) EFSA conclusion List of Endpoints (2011), EFSA Journal 2012;10(1)e.g.!

2) DAR 02/2008

3) New study submitted by the applicant

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). Please see chapter 6.2.1.2, page 7 for detailed information on the estimation of daily intake rates and the assessment of mixture toxicity.

6.3.1.3 Risk assessment –overall conclusions

The overall conclusion on the risk assessment for mammals and the calculated TER-values are shown in the following table.

Table 6.3-2: Minimum TER values for mammals after uses of ABG-3206 in the intended uses

Substance	Risk assessment level	Indicator mammal	Time scale	TER	TER trigger
ABG-3206	Screening	Small herbivorous mammal	Acute	>1832.8	10
TERs shown in bold fall below the relevant trigger.					

Based on the presumptions of the screening step, the calculated TER values for the acute risk resulting from an exposure of mammals to the formulation ABG-3206 according to the GAP achieves the acceptability criteria TER ≥ 10, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. The results of the assessment indicate an acceptable risk for mammals.

6.3.2 Toxicity exposure ratio

6.3.2.1 Acute toxicity exposure ratio (TER_A)

Screening step

In the screening step, indicator species are used. These indicators are considered to have highest exposure in a specific crop at a particular time due to their size and feeding habits and represent a worst case scenario.

The indicator mammal species for the intended uses are listed in the following table.

Table 6.3-3: Indicator species for mammals according to intended use of ABG-3206 and shortcut values. Shortcut values from section 4.1 of EFSA/2009/1438

Crop	Indicator species	Shortcut value (90th percentile RUD)
Vineyard	Small herbivorous mammal	136.4

For the estimation of Daily dietary doses (DDD) and the calculation of TER-values please refer to 6.2.2.1

Table 6.3-4: Acute screening risk assessment (TERA) for mammals. See text for details

Substance	Indicator species	Application rate (kg/ha)	Shortcut value, acute	MAF	DDD (mg/kg bw)	LD_{50} (mg/kg bw)	TER_A
ABG-3206	Small herbivorous mammal	0.05	136.4	1	6.82	>5000	> 733.1
TERs shown in bold fall below the relevant trigger.							

Based on the highly conservative presumptions of the screening step, the calculated TER value for the acute risk resulting from an exposure of mammals to the formulation ABG-3206 according to the GAP achieves the acceptability criteria TER ≥ 10, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. for acute effects. The results of the assessment indicate an acceptable risk for mammals due to the intended use of ABG-3206 in wine grapes..

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 peformed.

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

Screening step

For the reproductive risk assessment, the calculation of the long-term toxicity exposure ratio (TER_{LT}) follows in principle the same procedure as for the acute risk assessment.

The defined daily dietary dose is obtained by multiplying the application rate with the mean short-cut value (based on the mean RUD according to the new Guidance Document (EFSA, 2009)) as summarized in the following table.

Table 6.3-5: Mammal generic focal species for the intended uses of ABG-3206 and relevant shortcut values for long-term exposure

Crop	Indicator species	Shortcut value (mean RUD)
Vineyard	Small herbivorous mammal	72.3

Please refer to section 6.2.2.3 for the equation employed in the estimation of the daily dietary doses and the calculation of TER-values.

No mammalian long-term toxicity studies with Gibberellic acid have been performed. Given that Gibberellic acid is naturally occurring in the diet of herbivorous mammals and mammals that feed on herbivorous animals, a permanent exposure is taking place. As can be seen from acute oral and short-term dietary data (see DAR 2008), Gibberellic acid shows no toxicity to mammals. Taking into account the plant-specific hormonal mode of action and accordingly the low application rate, no long-term toxic effects on mammals are expected.

The following table provides the theoretical NOEL value that would be necessary to calculate an acceptable TER_{LT} above the trigger.

Table 6.3-6: **Calculated NOEL value for birds exposed to ABG-3206**

Substance	Indicator bird	Application rate (kg/ha)	Shortcut value (long-term)	f_{TWA}	DDD /mg/kg bw/d)	MAF	TER_{LT}	Calculated NOEL (mg/kg bw/d)	Annex VI acceptable TER_{LT} value
Gibberellic acid	Small omnivorous mammal	0.05	72.3	0.53	1.916	1	5.5	10.5	≥ 5
TERs shown in bold fall below the relevant trigger.									

The calculated TER_{LT} will be above the trigger for a chronic toxicity higher than 10.5 mg a.s./kg bw/d. Since Gibberellic acid naturally occurs in the diet of mammals and has a plant-specific, non-toxic mode of action, it is expected that the long-term toxicity value for mammals will be higher than 10.5 mg/kg bw/d.

No refinement is needed.

6.3.3 Drinking water exposure

Mammals might be exposed via drinking water from puddles. According to the new Guidance Document (EFSA, 2009), no specific calculations of drinking water exposure and TER are necessary when the ratio of effective application rate (in g/ha) to the relevant endpoint (in mg/kg bw/d) does not exceed 50 in the case of less sorptive substances (Koc < 500 L/kg) or 3000 in the case of more sorptive substances (Koc ≥ 500 L/kg). This is due to the characteristics of the exposure scenario in connection with the standard assumptions for water uptake by mammals (for further details please refer to chapter 5.5. of the Guidance Document).). The puddle scenario has been taken into account to calculate the exposure concentration of Gibberellic acid formed on a field after rainfall. The ratios do not exceed the value of 50 for Gibberellic acid (Koc = 7.125 L/kg), thus it is not necessary to conduct a drinking water risk assessment for mammals.

6.3.4 Details on formulation type in proportion per item

Please refer to section 6.2.4 for details on the formulation type of ABG-3206.

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

Please refer to section 6.2.4.

6.3.4.2 Pellets, granules, prills or treated seed

Please refer to section 6.2.4.

Amount of active substance in or on each item

Please refer to section 6.2.4.

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

Please refer to section 6.2.4.

Size and shape of pellet, granule or prill

Please refer to section 6.2.4.

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

Mammal toxicity tests with metabolites of Gibberellic acid were not performed, since it is possible to extrapolate from data obtained with the active substances.

6.3.7 Supervised cage or field trials

The risk assessment above has demonstrated that the proposed uses of ABG-3206 pose no unacceptable acute or long-term risks to mamamls, and therefore further studies are not considered necessary.

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

ABG-3206 is intended for use as a foliar spray, and therefore this information is not required.

6.3.9 Effects of secondary poisoning

The EFSA birds and mammals guidance document (EFSA Journal 2009; 7(12): 1438) states that a log $K_{ow} \geq 3$ is used to indicate that there might be a potential for bioaccumulation (see chapter 5.6 "Bioaccumulation and food chain behaviour"). Since the log K_{ow} values of Gibberellic acid is 0.72 (pH=2.2), the active substance is deemed to have a negligible potential to bioaccumulate in animal tissues. No formal risk assessment from secondary poisoning is therefore required.

Consequences for authorization:

none

6.4 Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) (KPC 10.1.3)

Not yet considered.

Consequences for authorization:

none

6.5 Effects on aquatic organisms (MIIIA 10.2, KPC 10.2, KPC 10.2.1)

6.5.1 Overview

For authorization in Germany, exposure assessment of surface water 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. Hence, aquatic risk assessment differs from those in the core assessment.

The risk assessment for aquatic organism for authorization of ABG-3206 is outlined in the following chapters.

6.5.2 Toxicity

Table 6.5-1: Ecotoxicological endpoints for aquatic species exposed to Gibberellic acid and ABG-3206 with indication to agreed endpoints

Species	Substance	Exposition Duration System	Results Toxicity	Reference Date author Report No.	ICS-No.
Acute toxicity to fish					
Cyprinus carpio	Gibberellinsäure (GA3); Purity: 95.3% w/w	4 d static	LC_{50} : >100 mg/L Mortality[1,2]	[redacted] 2003 SPL 821/015	77271
Acute toxicity to aquatic invertebrates					
Daphnia magna	Gibberellinsäure (GA3); Purity: 95.3% w/w	2 d static	EC_{50} : 76 mg/L[1,2] Immobilisation	Wetton, P.M., McKenzie, J. 2003 SPL 821/016	77275
Toxicity to algae					
Pseudokirchneriella subcapitata	Gibberellinsäure (GA3); Purity: 95.3% w/w	3 d static	EbC_{50} : 17 mg/L[1,2] Biomass real NOEC : 5.21 mg/L real	Mead, C., McKenzie, J. 2003 SPL 821/017	77276
Pseudokirchneriella subcapitata	Gibberellinsäure (GA3); Purity: 95.3% w/w	3 d static	ErC_{50} : 25 mg/L[1,2] Growth rate NOEC : 11.2 mg/L real	Mead, C., McKenzie, J. 2003 SPL 821/017	77276
Pseudokirchneriella subcapitata	ProGibb 40% water soluble granules (SG) = ABG-3206	3 d static	EbC_{50} : >100 mg/L Biomass nom NOEC : ≥ 100 mg/L nom	Desjardins, D., Kendall, T.Z., Krueger, H.O. 2006 529A-102	77297
Pseudokirchneriella subcapitata	ProGibb 40% water soluble granules (SG) = ABG-3206	3 d static	ErC_{50} : >100 mg/L Growth rate NOEC : ≥ 100 mg/L nom	Desjardins, D., Kendall, T.Z., Krueger, H.O. 2006 529A-102	77297
Toxicity to water plants					
Myriophyllum spicatum	ProGibb 40% (Gibberellic acid, GA3)	14 d semistatic	EyC50 : << 130 mg a.s./L [3] NOEC : << 130 mg a.s./L [3] (based on promoted growth)	Kirkwood, A. 2013 13828.6109	84989
Myriophyllum spicatum	GA3 10% ST	14 d semistatic	NOEC: 0.0116 mg a.s./L EC50: 0.048 mg a.s./L [4] (based on promoted growth)	Juckeland, D. 2013 13 10 48 016 W	84995
Lemna gibba	ProGibb 40% SG	7 d semistatic	EbC50: 96.76 mg a.s./L[3] NOEC: 59 mg a.s./L[3]	Arnie, J.R. Kendall, T.Z. Porch, J.R.	84994

			(based on promoted growth; biomass dry weight)	2012 529P-101	

1) EFSA conclusion List of Endpoints (2011), EFSA Journal 2012;10(1)e.g.!

2) DAR 02/2008

3) New study submitted by the applicant

4) Study submitted by another applicant for another authorization procedure

For *Myriophyllum spicatum* the study Kirkwood (2013) was submitted by the applicant. This study was designed as a limit test with a test concentration of 130 mg a.s./L. At this concentration, strong facilitation effects of over 200% on shoot length occurred. Although this was not an inhibitory effect, it is still considered relevant. Strong growth of aquatic plants can have significant effects on the communities of ecosystems. Additionally, all plants of the treatment group showed 10 to 20% necrosis at test termination. This indicates that the strong shoot elongation can have negative effects on the individuals as well. Since at the test concentration far more than 50% effect occurred, no EC50 value can be derived. Another study with *M. spicatum* is available which provides a far lower endpoint, Juckeland (2013).

6.5.3 Toxicity to exposure ratios for aquatic species (MIIIA 10.2.1)

The evaluation of the risk for aquatic and sediment-dwelling organisms was performed in accordance with the recommendations of the "Guidance Document on Aquatic Ecotoxicology", as provided by the Commission Services (SANCO/3268/2001 rev.4 (final), 17 October 2002).

6.5.3.1 TER values for the entry into surface water via spraydrift and deposition following volatilization

The calculation of concentrations in surface water is based on spray drift data by Rautmann and Ganzelmeier. Gibberellic acid has a vapour pressure of 5.1 x 10^{-6} Pa and is therefore classified as non-volatile. Hence, deposition following volatilization has not been considered. The input parameters for Gibberellic acid are given in Section 5.6.1.

Several ecotoxicological endpoints are available to assess the risk of the active substances Gibberellic acid, Gibberellic acid and the formulation ABG-3206 (see chapter 6.5.2). The choice of the relevant scenario is based on the ratio of endpoint to the highest PEC for each active substance and the formulation, related to the relevant trigger TER value.

Based on the table above, *Myriophyllum spicatum* provides for Gibberellic acid the lowest ratio of endpoint and relevant TER trigger and is therefore the relevant scenario for risk assessment.

Table 6.5-2: Risk assessment for Gibberellic acid for aquatic organisms for the entry route via spraydrift and deposition following volatilization under the implementation of different risk mitigation measures

Compound:			Gibberellic acid					
Crop/Application rate:			Vine, 1 x 20 g/ha					
Growth stage and season			BBCH 62-68					
Intended use:			00-001					
DT_{50} water (SFO):								
PEC-selection:			actual					
Drift-Percentile:			90th					
Buffer zone	**Entry via spraydrift**		**Entry via deposition following volatilization**		**PECsw; conventional and drift reducing technique**			
					0% conv.	**50% red.**	**75% red.**	**90% red.**
[m]	**[%]**	**[g/ha]**	**[%]**	**[µg/L]**	**[µg /L]**			
1					0.535	0.267	0.134	0.053
5					0.241	0.121	0.060	0.024
10					0.082	0.041	0.021	0.008
15					0.043	0.022	0.011	0.004
20					0.028	0.014	0.007	0.003
Relevant toxicity endpoint: LC_{50} =48 µg a.i./L (*Myriophyllum spicatum)* Relevant TER: 10								
Buffer zone [m]					**TER**			
1					**89.8**	**179.6**	**359.1**	**897.8**
5					**198.9**	**397.8**	**795.6**	**1989.0**
10					**585.4**	**1170.7**	**2341.5**	**5853.7**
15					**1107.7**	**2215.4**	**4430.8**	**11076.9**
20					**1714.3**	**3428.6**	**6857.1**	**17142.9**
Risk mitigation measures			none					

PEC: predicted environmenral concentration; TER: Toxicity exposure ratio. TER values in bold fall below the relevant trigger.

6.5.3.2 TER values for the entry into surface water via run-off and drainage

The concentration of the active substance Gibberellic acid in adjacent ditch due to surface runoff and drainage is calculated using the model EXPOSIT 3.01. The input parameters for Gibberellic acid for exposure modelling with EXPOSIT 3.01 are given in the German National Addendum Section 5, chapter 5.6.2.

Table 6.5-3: Risk assessment for Gibberellic acid for aquatic organisms for the entry route via run-off and drainage under the implementation of different risk mitigation measures

Compound:	Gibberellic acid
Application rate:	20 g a.s./ha
Intended use	00-001
Relevant toxicity endpoint:	LC_{50} =48 µg a.i./L (*Myriophyllum spicatum)*

Relevant TER:	10	
Run-off		
Buffer zone	**PEC**	**TER**
[m]	**[µg/L]**	>1000
0	0.02	>1000
5	0.01	>1000
10	0.01	>1000
20	0.01	>1000
Drainage		
Time of application	**PEC**	**TER**
	[µg/L]	
Autumn/winter/early spring	0.04	>1000
Spring/summer	0.01	>1000
Risk mitigation measures	none	

PEC: predicted environmenral concentration; TER: Toxicity exposure ratio. TER values in bold fall below the relevant trigger.

6.5.3.3 Consideration of Metabolites

Please refer to the core assessment.

6.5.4 Overall conclusions

Based on the calculated concentrations of Gibberellic acid in surface water (EVA 2.1, EXPOSIT 3.0.1), the calculated TER values for the acute and long-term risk resulting from an exposure of aquatic organisms to Gibberellic acid according to the GAP of the formulation ABG-3206 achieve the acceptability criteria TER ≥ 10, according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. for long-term effects. The results of the assessment indicate an acceptable risk for aquatic organisms due to the intended use of ABG-3206 in vine according to the label.

Consequences for authorization:

For the authorization of the plant protection product ABG-3206 following labeling and conditions of use are mandatory:

Required Labelling

NW 265	Gibberellic acid: NOEC = 0.0116 mg a.s./L (*Myriophyllum spicatum)*

Conditions for use

ABG-3206	NW 468

6.6 Effects on bees (MIIIA 10.4, KPC 10.3.1)

In the honey bee risk assessment for the main application it was concluded that the risk to bees is acceptable when Berelex 40 SG is used up to 0.0375 kg/ha in greenhouse. All hazard quotients are clearly below the trigger of 50 (HQ < 0.2), indicating that the intended use poses also a low risk to bees in the field. The recommended field application rate (0.05 kg/ha) slightly exceeds this rate. However, since the hazard quotients is still clearly below the trigger of 50 and gibberellic acids is known to be ubiquitous in higher plants no further risk assessment is required.

Consequences for authorization:

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)

6.7 Effects on arthropods other than bees (MIIIA 10.5, KPC 10.3.2)

6.7.1 Overview and summary

6.7.1.1 Toxicity

Table 6.7-1: Toxicity of Gibberellic acid/ABG-3206 to non-target arthropods with reference to agreed endpoints

Species	Substance	Exposition Duration System	Results Toxicity	Reference Author Date Report No.	ICS-No.
Tier 1					
Aphidius colemani	GibGro Technical, 95.3% Gibberellin GA3	2 d Glass plate	LR50 : >10 g a.i./ha[1,2] Mortality	Nagaoka, H., Takagi, Y. 2003	79251
Chrysoperla carnea	GibGro Technical, 95.3% Gibberellin GA3	2 d Glass plate	LR50 : >10 g a.i./ha[1,2] Mortality	Kanmoto, T., Takagi, Y. 2003	79253
Orius strigicollis	GibGro Technical, 95.3% Gibberellin	2 d Glass plate	LR50 : > 10 g/ha[1,2] Mortality	Takagi, Y., Kanmoto, T. 2003	79269
Higher tier					
Chrysoperla carnea	ProGibb 40%	12 d	LR50 : >280 g/ha	Röhlig, U. 2008[3]	77298
Coccinella septempunctata	ProGibb 40%	28 d	LR50 : >280 g/ha	Röhlig, U. 2008[3]	77299

1) EFSA conclusion List of Endpoints (2011), EFSA Journal 2012;10(1)

2) DAR 02/2008

3) New study submitted by the applicant

6.7.1.2 Exposure

The risk assessment for 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 ABG-3206 will mainly be due to spray drift from field applications. Off-field PER values were calculated from in-field PERs in conjunction with drift values published by the *BBA (2000)*[1] as shown in the following equation:

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

Vegetation distribution factor: 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-dimensional (glass plate or leaf disc) studies. A dilution factor of 10 is recommended by ESCORT 2. In line with German national requirements, a vegetation distribution factor of 5 has to be applied, based on experimental data. However, for 3-dimensional studies, i.e. where spray treatment is applied onto whole plants, the dilution factor is not used, as any dilution over the 3-dimensional vegetation surface is accounted for in the study design.

3-dimensional structures were used for application in the extended laboratory studies on *Aphidius* and *Typhlodromus*. Therefore, no vegetation distribution factor was used for the off-field assessment for these species, whereas the factor of 5 was applied for the assessment for *Aleochara* accounting for the 2-dimensional structure treated in the test on this species.

The drift value at 1 m distance is 2.77% of the application rate (90th percentile drift). The drift factor (% drift/100) is therefore 2.77/100 = 0.0277. As for a herbicide ground-directed application is assumed, the field crop drift values are used for all crops.

The resulting PERoff-field value is shown in the following Table:

Table 6.7-2: Off-field foliar Predicted environmental rates (PER) resulting from the intended uses of ABG-3206

Study type	Max. rate (g Prod./ha)	MAF	Maximum in-field PER (g Prod./ha)	Drift rate (% appl. rate)	Vegetation distribution factor	Off-field PER (g Prod./ha)
3-dimensional	20	1	20	8.02%	1	1.604
2-dimensional	20	1	20	8.02%	5	0.3208

[1] 90^{th} percentile drift according to BBA (2000): Bundesanzeiger Jg. 52 (Official Gazette), Nr 100, S. 9879-9880 (25.05.2000) Bekanntmachung über die Abtrifteckwerte, die bei der Prüfung und Zulassung von Pflanzenschutzmitteln herangezogen werden

6.7.1.3 Risk assessment –overall conclusions

Based on the calculated rates of ABG-3206 in off-field, the calculated TER values describing the risk resulting from an exposure of non-target arthropods to Gibberellic acid according to the GAP of the formulation achieve the acceptability criteria TER ≥ 10 (Tier 1) resp. 5 (Higher tier), according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2. The results of the assessment indicate an acceptable risk for non-target arthropods due to the intended use of ABG-3206 in vine according to the label.

Table 6.7-3: Tier 1 off-field TER values for non-target arthropods

Species	**ER_{50}** [g product/ha]	Test type/ treatment scheme	**Off-field PER [g product/ha]**	**Off-field** TER	**Trigger value**
Aphidius colemani	> 10	2-dimensional	0.3208	> 31.2	10

6.7.2 Risk assessment for Arthropods other than Bees

The risk assessment for non-target arthropods is done on basis of the calculation of toxicity-exposure ratio (TER) values as in line with German national requirements according the following formula:

$$\frac{LR_{50} / ER_{50} \text{ [L product/ha]}}{\text{max. exposure level x MAF x (\% drift / 100 x correction factor “5”) [L product/ha]}}$$

The risk is considered acceptable if the off-field TER obtained is > 10 (tier 1) or > 5 (higher tier assessment).

The resulting $TER_{off\text{-}field}$ values are given in the following Table:

Table 6.7-6: Tier 1 off-field TER values for non-target arthropods

Species	**ER_{50} [g product/ha]**	**Test type/ treatment scheme**	**Off-field PER** [g product/ha]	**Off-field TER**	**Trigger value**
Aphidius colemani	> 10	2-dimensional	0.3208	> 31.2	10

Consequences for authorization:

None

6.8 Effects on non-target soil meso- and macrofauna (MIIIA 10.6, KPC 10.4, KPC 10.4.1, KPC 10.4.2)

6.8.1 Toxicity

Table 6.8-1: Ecotoxicological endpoints for terrestrial non-target soil fauna and organic matter breakdown following exposure to Gibberellic acid with indication to agreed endpoints

Species	Substance	Exposition Duration System	Results Toxicity	Reference Author Date Report No.	ICS-No.
Eisenia foetida	Gibberellic acid (GA3); Purity: 92.6% w/w	14 d acute	LC_{50} : >1111 mg/kg soil[3] Mortality	Rodgers, M. H. 2007 ZAB 0082/073894	77301

1) EFSA conclusion List of Endpoints (2011), EFSA Journal 2012;10(1)

2) DAR 02/2008

3) New study submitted by the applicant

6.8.2 Toxicity exposure ratios for earthworms and other soil macro- and mesofauna, TER_A and TER_{LT} (MIIIA 10.6.1)

The evaluation of the risk for earthworms and other soil macro-organisms was performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002).

For the calculations of predicted environmental concentrations in soils (PEC soil), reference is made to the environmental fate section (Part B, Section 5) of this submission. The resulting maximum PECsoil values for the active substances Gibberellic acid and the major soil degradation products are presented in the table below.

For German exposure assessment the applied soil depth is based on experimental data (Fent, Löffler, Kubiak: Ermittlung der Eindringtiefe und Konzentrationsverteilung gesprühter Pflanzenschutzmittelwirkstoffe in den Boden zur Berechnung des PEC-Boden. Abschlussbericht zum Forschungsvorhaben FKZ 360 03 018, UBA, Berlin 1999). Generally for active substances with a $K_{f,oc} < 500$ a soil depth of 2.5 cm is applied whereas for active substances with a $K_{f,oc} > 500$ a soil depth of 1 cm is applied. As soil bulk density 1.5 g cm^{-3} is assumed.

The acute risk for earthworms and other non-target soil macro- and mesofauna resulting from an exposure to Gibberellic acid was assessed by comparing the maximum PEC_{SOIL} with the 14-day LC_{50} value to generate acute TER values. The TER_A was calculated as follows:

$$TER_A = \frac{LC_{50}\ (mg/kg)}{PEC_{soil}\ (mg/kg)}$$

The chronic risk for earthworms, other non-target soil macro- and mesofauna and organic matter breackdown resulting from an exposure to Gibberellic acid was not assessed, since since $DT_{90field}$ values are less than 365 days and no risk was identified for soil fauna, soil micro-organisms and non-target arthropods from the use of ABG-3206.

The results of the risk assessment are summarized in the following table.

Table 6.8-2: TER values for earthworms and other soil macro- and mesofauna (Tier-1) for the use in vine

Test substance	Intended use (g a.s./ha)	Timescale	Endpoint (mg/kg dw soil)	PEC (mg/kg soil dw)	TER	TER trigger
Earthworms (*Eisenia fetida*)						
Gibberellic acid	20	Acute	>1111	0.016	69438	10
		Long-term	n.a.		-	5
TER values in bold are below the trigger						

6.8.3 Higher tier risk assessment

Not relevant.

6.8.4 Overall conclusions

Based on the predicted concentrations of Gibberellic acid in soils, the TER values describing the acute risk for earthworms and other non-target soil organisms following exposure to ABG-3206 according to the GAP of the formulation ABG-3206 achieve the acceptability criteria TER ≥ 10 according to commission implementing regulation (EU) No 546/2011, Annex, Part I C, 2. Specific principles, point 2.5.2. The results of the assessment indicate an acceptable risk for soil organisms due to the intended use of ABG-3206 in vine according to the label.

Consequences for authorization:

none

6.9 Effects on soil microbial activity (MIIIA 10.7, KPC 10.5)

6.9.1 Overview and summary

Soil microorganisms will be exposed to plant protection products containing Gibberellic acid whenever contamination of soil may occur as a result of the intended uses of ABG-3206.

The following EU agreed endpoints for effects on soil microbial activity exposed to the active substance Gibberellic acid are reported in the DAR 2008 (see table below).

6.9.1.1 Toxicity

Table 6.9-1: Ecotoxicological endpoints for soil microbial activity following exposure to Gibberellic acid with indication to agreed endpoints

Process	Substance	Exposition Duration System	Results Toxicity	Reference Author Date Report No.	ICS-No.
N-tranformation	Gibberellic acid (GA3); Purity: 93.7%	28 d	16% Facilitation[2] 0.11 mg/kg soil dw Application rate	Cardinali, V.C.B 2007 0035.218.195.06	77303
N-tranformation	Gibberellic acid (GA3); Purity: 93.7%	28 d	13.6% Facilitation[2] 0.53 mg/kg soil dw Application rate	Cardinali, V.C.B 2007 0035.218.195.06	77303
C-transformation	Gibberellic acid (GA3); Purity: 93.7%	28 d	9.6% Facilitation 0.11 mg/kg soil dw Application rate	Cardinali, V.C.B 2007 0035.201.232.06	77302
C-transformation	Gibberellic acid (GA3); Purity: 93.7%	28 d	1.9% Facilitation 0.53 mg/kg soil dw Application rate	Cardinali, V.C.B 2007 0035.201.232.06	77302

1) EFSA conclusion List of Endpoints (2011), EFSA Journal 2012;10(1)

2) DAR 02/2008

3) New study submitted by the applicant

6.9.1.2 Exposure

Please refer to section 6.7.1.2 above for the predicted environmental concentrations in soil (PECsoil) of Gibberellic acid.

6.9.1.3 Risk assessment –overall conclusions

The Predicted Environmental Concentrations of the the active substance Gibberellic acid of the formulation ABG-3206 is below the concentrations at which no unacceptable effects (< 25%) regarding the soil microbial activity were observed after 28 days of exposure.

The results of the comparison expressed as Margin of Safety (MoS) are presented in the following table.

Table 6.9-2: Summary of risk assessment for soil micro-organisms exposed to Gibberellic acid following the use of ABG-3206

Substance	Test type	Maximum initial PEC (mg/kg soil dw)	Effects <25% (mg/kg soil dw)	MoS
Gibberellic acid	N transformation	0.016	0.11	6.9
	C transformation		0.11	6.9

	N transformation	0.016	0.53	33.1
	C transformation		0.53	33.1

For the active ingredient in ABG-3206, Gibberellic acid, the soil concentrations which caused no deviations greater than ±25% in the activity of the soil microorganisms are at least 7-times higher than the corresponding maximum PEC in soil.

Based on the predicted concentrations of Gibberellic acid in soils, the risk to soil microbial processes following exposure to Gibberellic acid according to the GAP of the formulation ABG-3206 is considered to be acceptable according to commission implementing regulation (EU) No 546/2011, Annex, Part I C , 2. Specific principles, point 2.5.2.

Consequences for authorization:

none

6.10 Effects on non-target plants (MIIIA 10.8, KPC 10.6)

6.10.1 Effects on non-target terrestrial plants (MIIIA 10.8.1)

Concerning the risk for non-target plants, reference is made to the DAR:

GA3 is a naturally occurring plant hormone. Because it is a naturally occurring compound with a non-toxic mode of action in target plants, Gibberellic acid has been classified as a biochemical pesticide by the US EPA (EPA RED).

The PECsoil for GA3 at day 0 following single application of GA3 to grapes has been estimated to be 0.016 mg/kg. As GA3 is a naturally occurring gibberellin which is found both in plant material (up to 10 mg/kg), in soil (bacterial production seen at 1 mg/L) and from fungi it is considered that non-target plants will not be exposed to concentrations higher than naturally occurring levels from the proposed use of GA3. The degradation rate of GA3 in the soil is very rapid with a maximum field DT50 value of ca. 4.5 days. These data show that GA3 will not persist in the soil and that long-term GA3 levels from the proposed use of GA3 on grapes will be insignificant compared to naturally occurring GAs. It is therefore considered that there will be no acute or long-term risk to non-target plants from the proposed use of GA3.

Consequences for authorization:

None

Appendix 1 Table of Intended Uses in Germany

PPP (product name/code) **Berelex 40 SG** **Formulation type:** **SG**
active substance 1 **Gibberellinsäure** **Conc. of as 1:** **400 g/kg**

Applicant: **Sumitomo Chemical Agro Europe GmbH** **professional use** **x**
Zone(s): **central zone** **non professional use** ☐

Verified by MS: yes

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 e.g. recommended or mandatory tank mixtures
					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		
001	DE	grape vine (VITVI)	F	easing structure of grape-stalk (YTRLO)	spraying or fine spraying (low volume spraying)	BBCH 62 to 68 preventive	a) 1 b) 1	a) 50 g/ha b) 50 g/ha	a) 20 g as/ha b) 20 g ashaL	1000 L		

Remarks:

(1) Numeration of uses in accordance with the application/as verified by MS
(2) Member State(s) or zone for which use is applied for
(3) 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)
(4) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(5) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds, developmental stages
(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 of treatment(s) (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 applications possible under practical conditions of use for each single application and per year (permanent crops) or crop (annual crops) must be provided
(8) Min. interval between applications (days) were relevant
(10) The application rate of the product a) max. rate per appl. and b) max. total rate per crop/season must be given in metric units (e.g. kg or L product / ha)
(11) The application rate of the active substance a) max. rate per appl. and b) max. total rate per crop/season must be given in metric units (e.g. g or kg / ha)
(12) The range (min/max) of water volume under practical conditions of use must be given (L/ha)
(13) PHI - minimum pre-harvest interval
(14) Remarks may include: Extent of use/economic importance/restrictions/minor use etc.

REGISTRATION REPORT

Part B

Section 7: Efficacy Data and Information

Detailed Summary

Product Code: Berelex 40 SG

Reg. No.: 006977-00/02

Active Substance: Gibberellic Acid GA3 (400 g/kg)

Central Zone

Zonal Rapporteur Member State: Germany

CORE ASSESSMENT

Applicant: Sumitomo Chemical Agro Europe

(representing Valent BioSciences Corporation)

Date: 2014-05-28

Evaluator: Julius Kühn-Institut

Date: 2017-06-21

Table of contents

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

Introduction

GA_3 40% SG (BERELEX 40 SG) is currently registered for a number of different uses in various EU countries. During its commercialisation, GA_3 40% SG (BERELEX 40 SG) has performed well and provided growers with excellent efficacy on a range of crops: artichoke (harvest anticipation and yield increase), cherry (fruit quality), citrus (fruitset and peel quality), grapes (reduced cluster compactness by stretching and thinning, berry sizing both seeded and seedless cultivars), pear (fruitset) and other miscellaneous uses to enhance either quality or yield (celery, lettuce, ornamentals, potato, rhubarb, strawberries and tomato). GA_3 as Ryzup® and Release® is also used to improve seed germination and promote growth in monocots (rice, wheat, sorghum and grass pasture).

This Biological Assessment Dossier (BAD) presents efficacy and crop safety results for GA_3 40% SG (BERELEX 40 SG) for reduction of cluster compactness on wine grapes in EU Central. The introduction that follows immediately below will present the active ingredient GA_3 in general and briefly discuss its mode of action and provide information on its use. A literature review to support the intended label claims on wine grapes in EU Central is given under IIIA1 6.1.1. Efficacy results are presented under datapoint IIIA1 6.1.3 (please refer to KIIIA 6.6/01) and adverse effects under IIIA1 6.2.

Gibberellic acid (GA_3)

Gibberellic acid (GA_3) is a naturally occurring fungal metabolite and part of a large group of naturally occurring plant growth hormones collectively known as 'gibberellins'. Gibberellins were first discovered in the early 1900s when Japanese researchers observed that symptoms of the rice disease 'Bakanae' or 'foolish seedling disease' (rice plants with abnormally long extended stems) could be mimicked in healthy rice plants by filtrates from the fungus *Gibberella fujikuroi* (Mander, 2003). This discovery, along with the chemical characterization of gibberellins in the 1950s and 60s resulted in the commercialisation of gibberellins by the I.C.I. company (Petracek et al., 2003).

The gibberellins presently form a group of approximately 130 highly functionalized diterpenoids, which are widely distributed in both higher plants (including angiosperms, gymnosperms and ferns), and fungi (Mander, 2003). The structures of the various gibberellins are known and they can be found on the internet at (http://www.plant-hormones.info/index.htm). For classification purposes, each GA variant has been assigned a number instead of an arbitrary name as an identifier according to its order of discovery (i.e. GA1, GA2, GA3, etc.). Many gibberellins have no known activity and are presumed to be either precursors or metabolites of the active hormones. GAs' are synthesized from glyceraldehyde-3-phosphate, via isopentenyl diphosphate, in young shoots and developing seeds (Sponsel and Hedden 2004). Gibberellins are involved in many aspects of plant growth and development such as cell growth, seed germination, dormancy, flowering, stem elongation, fruit development and fruit senescence.

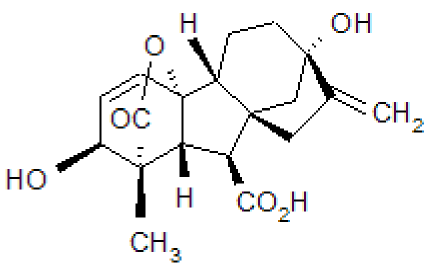

Figure 6- 1: Gibberellic acid GA_3 structural formula (active substance)

Table 6- 1: GA_3 relevant information (active substance)

Common name:	Gibberellic acid (BSI, ISO)	
Synonyms:	Gibberellin A3, GA3	
Chemical name as in Annex I to Directive 67/548/EEC:		Gibberellic acid
IUPAC:	(3S, 3aS, 4S, 4aS, 7S, 9aR, 9bR, 12S)-7,12-dihydroxy-3-methyl-6-methylene-2-oxoperhydro-4a,7-methano-9b,3-propeno[1,2-b]furan-4-carboxylic acid Alt: (3S, 3aR, 4S, 4aS, 6S, 8aR, 8bR, 11S)-6,11-dihydroxy-3-methyl-12-methylene-2-oxo-4a,6-ethano-3,8b-prop-1-enoperhydroindeno[1,2-b]furan-4-carboxylic acid.	
CA	(1α, 2β, 4aα, 4bβ, 10β)-2,4a,7-trihydroxy-1-methyl-8-methylenegibb-3-ene-1, 10-dicarboxylic acid 1,4a-lactone	
Molecular formula:	C19 H22 O6	
Molecular mass:	346.37	
CAS No:	77-06-5	
Trade names	ProGibb®, Berelex®, Accel®, Activol®, Grocel®, Ryzup®, and Release®	

GA_3 40% SG (BERELEX 40 SG) is a water soluble granule formulation containing the plant growth regulator gibberellic acid (GA_3) at a concentration of 400 g a.s./kg. GA_3 40% SG (BERELEX 40 SG) has been developed by Valent BioSciences Corporation in the U.S.A. under the code number BERELEX 40 SG. The identities of the formulants as well as the specifications of purity of the active substance and the identity of impurities are commercial trade secrets for which confidentiality is requested.

GA_3 40% SG (BERELEX 40 SG) was first registered in the US in 1999 as ProGibb® 40% SG and is currently also registered for use as a plant growth regulator in Australia, Canada, Chile, Ecuador, Egypt, Greece, Honduras, Israel, Italy, Mexico, New Zealand, South Africa, Spain, Vietnam and others.

GA_3 40% SG (BERELEX 40 SG) has demonstrated no loss of activity when stored under four-week accelerated storage conditions at 54°C. The product is also stable when stored under ambient conditions (20 and 30°C) for 3 years. The physical & technical properties of GA_3 40% SG (BERELEX 40 SG) are given in Annex III Section 1 of the Core Dosseier.

Mode of action of GA_3 applied against grape berry rots

Gibberellins are known to be involved in many aspects of plant growth and development such as cell growth, seed germination, dormancy, flowering, fruit development, stem elongation and others. The intracellular site of biosynthesis is known in many cases, but we have little understanding of the differences in hormonal content between or within plant cells. The role of GAs in plant development is broad and encompasses every stage of plant growth from germination to flower and fruit maturation. One of the most notable effects of GAs is their ability to elongate plant cells.

Since the initial work in the 1950s, researchers and growers worldwide have gained considerably more experience with GA_3 applications on grape vines. GA_3 treatments provide a number of different effects when sprayed on grapes over the time of flowering and cluster development. These effects involve cluster stretching, thinning and increases in berry size. Both, cluster stretching and thinning are important effects to reduce cluster compactness.

The different plant responses to GA_3 in terms of stretching, thinning and sizing are best explained by the timing of the GA_3 application in relation to the stage of plant development and the growth processes active in the grape cluster at the time of application (Halsey and Little, 1966).

When GA_3 is applied before bloom on wine grapes, it will elongate clusters. When gibberellic acid (GA_3) is applied over bloom (BBCH 63-65) it will elongate clusters but mainly thin berries within the cluster. Both effects of elongation and thinning of grape clusters provide more space for larger berries to make the cluster less compact and more open for plant protection sprays (Turner, 1972). Exogenous GA_3 is only active in the plant for a short time thus the correct timing of GA_3 applications in relation to plant development is important to obtain the desired effects.

In wine grapes the infection with the fungal disease grey mould caused by *Botrytis cinerea* brings about great economical losses every year. Available fungicides alone are not sufficient to control grey mould on susceptible grape wine cultivars when disease pressure is high and conditions favour the disease. Therefore, there is a special interest to prevent *Botrytis cinerea* infection and other diseases (e.g. sour rots) by reducing grape cluster compactness and in addition to help lower the risk of pesticide resistance.

Details of intended use

The gibberellin GA_3 is a plant growth regulator that occurs naturally in higher plants. Gibberellins are involved in many (perhaps all) aspects of plant growth and development such as: cell growth; seed germination; dormancy; flowering; fruit development; and stem elongation. The cellular processes affected by GAs are very complex and not fully understood, but GAs induce the transcription of genes coding for enzymes involved in both generative and vegetative growth processes, these processes loosen cell wall structures and allow cell expansion and plant growth to take place (Sun, 2004; Cho and Kende, 1997; Uozu et al., 2000; Xu et al., 1996).

As reviewed and discussed above, GA_3 has been successfully used commercially for over 50 years in field trials conducted in many countries around the world and this is very strong evidence to suggest that the current GA_3 40% SG (BERELEX 40 SG) formulation can be used successfully on wine grapes and other crops and uses in EU Central.

It is our intention to present data to support the registration of GA_3 40% SG (BERELEX 40 SG) on wine grapes in EU Central to reduce cluster compactness, improve cluster aeration and to enhance disease control and consequently wine quality. We will show efficacy and crop safety data summaries for the GA_3 40% SG (BERELEX 40 SG) formulation on a range of wine grape cultivars as presented in chapters IIIA1 6.1.3 and IIIA1 6.2 below.

Table 6- 2: Summary of intended uses for GA_3 40% SG (BERELEX 40 SG) in EU Central

Crop	Wine grape
Varieties	Need to be defined for each country
Use area	Field
Uses	Reduction of cluster compactness to enhance wine rot control
Method of application	Spraying, directed to the bunch zone.
Dose Rate	2.5 to 5.0 g product/hL (corresponding to 10 to 20 ppm GA_3) Dose rates to be defined for each cultivar
Water volume	400-1000 L/ha
Product concentration	10 to 50.0 g product/ha (4 to 20 g a.s./ha)
Application timing	1 application at 20-80 % of flowerhoods fallen (corresponding to BBCH 62-68)
Waiting period	0

Abbreviations used in this sub-section

Abbreviation	*Meaning*
abs.	Absolute
a.i.	Active ingredient
ANOVA	Analysis of variance
applic.	Application
approx.	Aproximately
a.s.	Active substance
AT	Austria
BAD	Biological Assessment Dossier
BBCH	Biological plant stage
Conc.	Concentration
DAA	Days after first application
DE	Germany
e. g.	Example given
EPPO	European Plant Protection Organization
EU	European Union
F	Field use
f.p.	Formulated product
FR	France
G	Glasshouse use
GA	Gibberellic acid
GAP	Good agricultural practice
GEP	Good experimental practice
ID	Identification
IPM	Integrated Pest Management
IT	Italy
K-doc	Documents listed by datapoint
Max	Maximum
Min	Minimum
N.A.	Not applicable
no.	Number
n.r.	Not reported
OECD	Organization for Economic Co-operation and Development
p	Probability
PGR	Plant growth regulator
PHI	Pre harvest interval
ppm	Parts per million
prod.	Product
Rep. / Repl.	Replicate(s)
RCB	Randomized Complete Block
spp	Species
Stats	Statistical evaluation
TBD	To be determined
US/USA	United States of America
UTC	Untreated control
VBC	Valent BioSciences Corporation
VOC	Volatile organic compounds
Vol.	Volume
%UTC	Percentage of the untreated control parameter value
23 DAA	Read as '23 days after first application'
#	Read as 'number of'
2005MSCHR032	An example of a VBC test report number, the first 4 numbers show the year followed by 5 letters and 3 numbers to uniquely identify each test report.

Product code, abbreviations and synonyms

BERELEX 40 SG, GA_3 40% SG, ProGibb 40 SG or Berelex 40 SG

IIIA1 6.1 Efficacy data

IIIA1 6.1.1 Preliminary range-finding tests

Published data

In most cases, there are no published studies on wine grapes available that use the current GA_3 40% SG (BERELEX 40 SG) formulation but the studies found in our literature search and presented below are still considered relevant background information because they show the efficacy of GA_3 to reduce wine grape cluster compactness as we are requesting. Furthermore, we believe there is very strong evidence from the considerable years of commercial user experience on a wide range of crops and applications to show that GA_3 efficacy can be maintained even when the applied formulations are markedly different (e.g. tablets and liquid formulations versus a water soluble granule).

The literature review that follows is not intended to be comprehensive. It presents a limited number of published peer reviewed studies to demonstrate the efficacy of GA_3 on a variety of wine grape cultivars to reduce cluster compactness and improve disease control.

Prevention of rots in susceptible grape cultivars

Vail and Marois (1991) found that grape cultivars with the most compact clusters were more severely affected by bunch rots in the field than those with loose clusters. In compact grape clusters with grey mould, wine quality and yield were markedly reduced (Loinger et al., 1977).

Water favours the development of *Botrytis cinerea* and in compact clusters water tends to persist longer than in loose ones. Open clusters have better aeration and a microclimate that is less favourable to the development of *Botrytis* and other rots. In loose clusters, fungicidal sprays applied to control *Botrytis* are able to reach the inside of the clusters to provide better spray coverage and disease control. This is also true for insecticides as applied for Totrix moth control in wine grapes.

Quality management to ensure a healthy (disease free) grape vintage now plays an increasingly important role in European wine production. Over the last few decades, more favourable spring growing conditions have led to an increase in berry set that can develop into very compact clusters of large sized berries by the time of harvest. During fruit ripening, these clusters can become very pressured with split berries, to create huge problems with increased harvest rots like *Botrytis* (grey mould), *Penicillium* (blue mould) or sour bunch rots, especially when the weather conditions also favour disease development (Böll, 2009).

Rots not only result in a direct yield loss at harvest, as affected grape bunches need to be removed but rots can cause further losses in the must fermentation process (Ipach, 2009). In seasons with a high disease incidence, individual vineyards or even whole regions can suffer severe yield and quality losses.

In situations that favour *Botrytis* and other rots there are a number of different factors that are responsible for an increase in wine rots, these factors are complex and can interact with each other. After climatic influences (temperature, humidity, rainfall, hail), genetic factors specific to an individual cultivar (bunch compactness, berry skin thickness and strength) and cultural management factors (leaf management, fertilization, plant protection spray programmes) all play important roles.

For many years, wine grape growers have made huge efforts to find suitable cultural management measures to reduce harvest rots in susceptible wine grape cultivars. Management methods have included cluster separation, hand thinning of clusters, early leaf removal and moderate or adapted fertilizer programmes. These measures need to be supported with an effective *Botrytis* fungicide spray programme.

In seasons with high rainfall shortly before harvest existing management measures often do not provide effective disease control. A good or sub-optimal water supply during the last fruit ripening phase increases the turgor pressure within the berries and encourages berry splitting. When there are open wounds and no pre-existing fungicide cover, fungal rots can easily infect berries. In these situations, even the application of an effective *Botrytis* fungicide will not provide adequate control. For this reason it is essential before any *Botrytis* fungicide is applied that the pressure and splitting within the compacted grape clusters is reduced by other appropriate management methods (Ipach, 2009).

It is practically impossible, under unfavourable climatic conditions with rainfall and high humidity to influence the associated splitting of berries so that the only practicable measure to reduce harvest rots in compact wine grape cultivars is the application of plant growth regulators such as GA_3 or Prohexadione Calcium (Regalis).

GA_3 is the preferred compound in cultivars of the 'Burgundy' family ('Chardonay', 'Grauburgunder', 'Schwarzriesling', 'Spätburgunder', 'Weißburgunder'), 'Muskateller' or 'Portugieser'. Regalis can cause unacceptable high thinning and yield reduction in these cultivars. On the other hand, GA_3 cannot be used on cultivars like 'White Riesling' as it shows negative effects on return bloom in the year following the application (Bleyer and Kast, 2010; Renner 2010).

Summary on cluster stretching effects of GA3

Weaver and McCune (1960) treated 'Carignane' grape clusters before flowering with GA_3 at dose rates of 0, 1, 5, 10, 25 or 100 ppm and linearly increased cluster length with increasing GA_3 concentration. Significant increases were obtained with rates between 10 to 100 ppm.

When Weaver et al. (1962) treated the compact seeded wine grapes cultivars 'Zinfandel', 'Carignane' and 'Tinta Madeira' some 2 to 3 weeks before bloom with 1 to 5 ppm gibberellic acid, clusters were elongated and loosened. Over two successive years the elongated and more open clusters were correlated with a significant decrease in rots without any decrease in yield or other adverse effects.

Romisondo et al. (1970) found that one pre-bloom application of 15 ppm GA_3 on 'Dolcetto' grapes significantly increased cluster and pedicel length and increased bunch weight while grey mould disease was notably reduced.

Rivera and Mavrich (1978) applied GA_3 at 10, 20 or 30 ppm to 'Pinot Gris' grape vines before full bloom when the cluster rachis was 2-5 cm, to increase the cluster length by some 10%, 12% or 15%, respectively. Significantly less *Botrytis* damage was observed in the GA_3 treatments due to cluster stretching and better aeration of the berries. *Botrytis* infection significantly decreased from 28% in the untreated control to 8% (10 ppm) and 4% (20 and 30 ppm). Cluster weight and fruit set was not affected.

Pre-blossom treatment of 'Zinfandel' grape vines with 5, 10, 25 or 50 ppm GA_3 significantly decreased cluster compactness as the dose rate increased. The cluster length increased numerically in all treatments and was significant for the 25 and 50 ppm dose rates (Miele et al., 1978).

In 'Semillon' wine grapes some cluster stretching was obtained when 10 ppm GA_3 was applied twenty days before full bloom, but cluster compactness was reduced more at 20 ppm because of the additional effect of fruit thinning (Gil and Escobar, 1979).

GA_3 acts as a thinning agent when applied at higher rates and timed closer to full bloom. Berry thinning appeared to be more efficient than cluster stretching to control *Botrytis* and sour rots on cultivars with very compact clusters. Accordingly, Spies and Hill (2008) reported that berry thinning is necessary on grape cultivars of the 'Burgundy' group since applications for cluster stretching did not provide a sufficient reduction in cluster compactness in these cultivars. Also, Fox (2006) showed that berry thinning effectively controlled *Botrytis* and sour rots on cultivars with compact clusters.

Summary on cluster thinning effects of GA3

Thinning of wine grapes decreases cluster compactness and reduces diseases caused by *Botrytis cinerea* and other bunch rots and at the same time increases the vintage and wine quality and reduces the work load for the grower (Teszlák, et al., 2005). Hand thinning and trimming of bunches is practiced wherever high quality wine is produced and GA_3 treatments can make these operations much easier and cheaper (Petgen, 2005). Therefore, growers in Europe are showing an increasing interest in the use of GA_3 for thinning purposes especially when grape cultivars have particularly compact clusters (Haas et al., 2009; Müller, 2003). Cultivars with compact clusters are more severely affected by bunch rots than those with loose clusters and require an intensive berry thinning within a cluster which is impossible to be carried out by hand (Ferree et al., 2003; Ipach, 2009).

The application of GA_3 at bloom has successfully thinned various grape cultivars (Ferree *et al.*, 2003). The thinning effect of GA_3 bloom sprays is most likely due to its action as a pollenicide as identified by Weaver and McCune (1960). This may explain the increase in efficacy with progressing cap fall during bloom, indicating that the caps serve as barriers to keep the spray material from contacting pollen and ovaries. Accordingly, Weaver and Pool (1971) reported that applications of GA_3 at or after 50% capfall resulted in significantly fewer berries per cluster than did earlier treatments. Applications after bloom appeared to be ineffective and an application timing from early bloom to full bloom is therefore recommended (Petgen, 2005 & 2009).

Weaver and Pool (1971) demonstrated that the number of berries per cluster gradually decreased with increasing concentrations of GA_3 showing best thinning results at a concentration of 20 ppm. Since the early 1970s, this concentration rate has been widely used on grapes in Europe, in scientific studies as well as commercially in Germany (emergency case approval) and in Italy, Greece and Spain. Spray water volumes ranging from 600 to 800 L/ha are widely recommended to provide effective berry thinning and to effectively reduce cluster compactness (Petgen, 2005; Siegfried and Jüstrich, 2008).

In all cases, use permits are specific for particular cultivars with clear recommendations in terms of timing and dose rates. The label recommendations are cultivar specific because the responsiveness in efficacy and effects on return bloom vary markedly between different wine grape cultivars.

For seeded wine grapes registrations exist in Italy for GA_3 40% SG (BERELEX 40 SG) on the cultivars: ‘Chardonnay’; ‘Picolit’ and ‘Tocai’ and in Spain for the cultivar ‘Macabeo’. Further registrations exist for Berelex® tablets (9.4% GA_3) for the same use in Italy on the cultivars: ‘Barbera’; ‘Dolcetto’; ‘Muller’; ‘Nebbiolo’ and ‘Tocai’.

In this document we will show efficacy and crop safety data for the GA_3 40% SG (BERELEX 40 SG) formulation. The cultivars tested were: ‘Blauburger’, ‘Chardonnay’, ‘Grauburgunder’, ‘Grüner Veltliner’, ‘Muskateller’, ‘Portugieser’, ‘Sauvignon’, ‘Schwarzriesling’, ‘Spätburgunder’, ‘Traminer’, ‘Weiß-burgunder’, ‘Welschriesling’ and ‘Zweigelt’. These cultivars are known to have compact clusters and are susceptible to *Botrytis* and other harvest rots e.g. sour rot (Essigfäule). These are important diseases for wine production in EU Central and of high relevance for the future use of GA_3 40% SG (BERELEX 40 SG).

The following table summarises published results and experiences on important wine grape cultivars in EU Central.

Table 6.1.1- 1: Summary of published study results in EU Central on cluster compactness, control of berry rots, yield and quality

Reference	Cultivar/s	Dose rate, water volume	GA_3 Formulation	Application timing	Effects achieved
Hill, G., Hill, M. & Butterfass, J. 2003	13 different cultivars, e.g. Dornfelder, Grauburgunder,Portugieser, Regent, Riesling, Spätburgunder, Weißburgunder, etc.	10–100 ppm 800 L/ha	GA_3 (formulation not defined)	BBCH 61, 65, 67	GA_3 applications during bloom reduced the number of berries per cluster while treatments applied after flowering did not thin. Weißburgunder showed 30% less berries while Riesling showed an increase of 20% with half of the berries being seedless. Even at the highest dose rates the yield reduction was never below 50%. Results on rot control for Spätburgunder, Weißburgunder and Schwarzriesling (6 trial sites) were outstandingly good, ranging between 40% to 75% control with good control at relatively low dose rates of 10 or 20 ppm. GA_3 at 40 ppm applied to

Reference	Cultivar/s	Dose rate, water volume	GA_3 Formulation	Application timing	Effects achieved
					Ruläner showed very good efficacy on sour rots (previously not controllable) with 11.2% sour rot incidence compared with 73.5% incidence in the UTC. In the year following the application of GA_3 at 40 ppm no negative effects on return bloom were observed on cultivars of the "Burgundy" family and Schwarzriesling. Also Portugieser seemed to be unaffected by GA_3 sprays. Only Riesling showed a significant reduction in flowering. Sensory wine tasting results showed a clear preference for GA_3 treatments.
Fader, B., Hill, G. & Spies, S. 2004	Spätburgunder, Schwarzriesling, Weißburgunder	20 ppm, 2 x 400 from both sides of the row	Gibb 3 TB (10% GA_3)	BBCH 67	GA_3 applications clearly reduced *Botrytis* incidence and in relation to the reduction in cluster compactness. *Botrytis* control for Schwarzriesling, Weißburgunder and Spätburgunder was ~75%, ~60% and ~65%, respectively. Yield of Schwarzriesling was not reduced, Weißburgunder yield was reduced by 23% when compared to the UTC. No real differences in internal quality (values were high in all treatments – very favourable year).
Kast, W.K., Fox, R. & Schiefer, H.C. 2005	Grauburgunder,Spätburgunder, Schwarzriesling, Weißburgunder	150 g f.p./ha 800 L/ha (= 18.75 ppm)	Gibb 3 TB (10% GA_3)	BBCH 65	Significant reduction in cluster compactness and in rot incidence. Yield was not strongly reduced. Positive changes in wine quality. No negative effects on return bloom.
Petgen, M. 2006	Grauburgunder Spätburgunder	80 – 160 g f.p./ha 800 L/ha (= 10 – 20 ppm, respectively)	Gibb 3 TB (10% GA_3)	BBCH 63-68	Reduced berry number per cluster in Spätburgunder and Grauburgunder by 60.4% and 30.1%, respectively compared to the UTC. For Grauburgunder the rot incidence was 42.5% in the UTC and 4.5% in the GA_3 BBCH 65 treatment, for Spätburgunder ~19% incidence in the UTC compared to ~5%, 6% or 2% incidence for the BBCH 63, 65 or 68 timings, respectively.
Bleyer, K. & Kast, W.K. 2010	Spätburgunder, Schwarzriesling, Weißburgunder	150 g f.p./ha 200, 400 or 800 L/ha (= 75.0, 37.50 or 18.75 ppm, respectively)	Gibb 3 TB (10% GA_3)	BBCH 63, 65, 68	Excellent results on cluster compactness, *Botrytis* and sour rot control with little difference between application timing. Best results were recorded at the highest spray water volume of 800 L/ha or a dose rate of 18.75 ppm. Yields were sometimes reduced by up to 25% but on average a 10 to 15% yield reduction should be expected. Sensory wine tasting results showed a

Reference	Cultivar/s	Dose rate, water volume	GA_3 Formulation	Application timing	Effects achieved
					clear preference for GA_3 treatments which showed the highest anthocyanin and phenolic compound contents in the red wines when compared to the UTC.
Renner, W. 2010	Muskateller Weißburgunder, Zweigelt	25 – 37.5 g f.p./ha, water volume not given	GA_3 40% SG (40 % GA_3)	BBCH 65	GA_3 40% SG reduced rots significantly. Return bloom effects were variable ranging from 0% to 25% yield reduction in the year following the application.

The published data presented above fully support our intended use of GA_3 40% SG (BERELEX 40 SG) on wine grapes in EU Central to reduce cluster compactness when applied once at BBCH 62-65 or BBCH 62-68, with a spray water volume of 400 – 1000 L/ha and a dose rate range of 10 to 20 ppm (2.5 to 5 g f.p./hL).

Non-published data - Information from related formulations

There are no available studies on wine grapes that use any of the related GA_3 formulations currently registered in Europe (ProGibb®, Berelex®, Accel®). This is because the current registrations are old and the original studies undertaken by ICI (the previous license holder) were not transferred to Valent BioSciences Corporation. For this reason we would like to present an American study undertaken in California.

Experimental details

Study 1995RFRIT490 (two trial locations) used a 4% GA_3 liquid formulation (ProGibb) and a dose range of 3.8, 7.5, 11.3 or 15.0 ppm applied at BBCH 55-57, BBCH 60 or BBCH 62. Rots were present at harvest only at trial site 1 and disease results for this study are presented below.

Table 6.1.1- 2: Dose rate trial with related formulation

Test report no. Year GEP Region, Country	Trial ID and location	Wine cultivar	Single application rate (a.s.) spray water volume	Application timing	Testing method and design
1995RFRIT490 1995 Non GEP California, US	Trial 1:Sacramento-Lodi-Woodbridge	'Petite Sirah'	3.8 ppm 7.5 ppm 11.3 ppm 15.0 ppm ~1000 L/ha water	BBCH 55-57, BBCH 60 BBCH 62	Randomized complete blocks 4 replications, 2 vines Evaluation at BBCH 87

Efficacy on disease control

The ProGibb (4%) treatments substantially reduced both the incidence and severity of *Botrytis* and other rots when compared to the UTC.
For *Botrytis* the best control for disease incidence and severity was shown by the highest GA_3 dose rate of 15 ppm. Pre-bloom sprays were less effective than sprays over bloom (BBCH 60 to BBCH 62). For sour rots the dose rate response was less clear, however efficacy increased as flowering progressed with the best efficacy at BBCH 62.
These results demonstrate the advantage of bloom sprays over pre-bloom sprays with best results for *Botrytis* at a spray concentration of 15 ppm.

The efficacy on Botrytis control is given in Table 6.1.1- 3 and for sour rots in Table 6.1.1- 4 immediately below.

Table 6.1.1- 3: *Botrytis* control for the related formulation (ProGibb 4 %) at three application timings

Parameter assessed Growth stage at application	**Control (abs. value)**	**% infected clusters or area (%UTC)**			
		3.8 ppm	**7.5 ppm**	**11.3 ppm**	**15.0 ppm**
***Botrytis* incidence (% infected clusters)**					
BBCH 55-57	47 (100%)	42 (89%)	35 (74%)	34 (72%)	36 (77%)
BBCH 60	47 (100%)	48 (102%)	47 (100%)	47 (100%)	24 (51%)
BBCH 62	47 (100%)	41 (87%)	45 (96%)	33 (70%)	25 (53%)
***Botrytis* severity (% infected area)**					
BBCH 55-57	11.0 (100%)	9.9 (90%)	6.5 (59%)	4.9 (45%)	6.1 (55%)
BBCH 60	11.0 (100%)	8.0 (73%)	9.5 (86%)	11.4 (104%)	1.9 (17%)
BBCH 62	11.0 (100%)	9.9 (90%)	7.5 (68%)	6.1 (55%)	3.1 (28%)

Table 6.1.1- 4: Sour rot control for the related formulation (ProGibb 4 %) at three application timings

Parameter assessed Growth stage at application	**Control (abs. value)**	**% infected clusters or area (%UTC)**			
		3.8 ppm	**7.5 ppm**	**11.3 ppm**	**15.0 ppm**
Sour rot incidence (% infected clusters)					
BBCH 55-57	34 (100%)	29 (85%)	22 (65%)	20 (59%)	28 (82%)
BBCH 60	34 (100%)	28 (82%)	17 (50%)	30 (88%)	19 (56%)
BBCH 62	34 (100%)	30 (88%)	26 (76%)	14 (41%)	14 (41%)
Sour rot severity (% infected area)					
BBCH 55-57	11.8 (100%)	8.7 (74%)	3.1 (26%)	6.5 (55%)	8.0 (68%)
BBCH 60	11.8 (100%)	7.3 (62%)	5.5 (47%)	12.1 (103%)	5.8 (49%)
BBCH 62	11.8 (100%)	8.2 (69%)	3.4 (28%)	1.8 (15%)	1.0 (8%)

Non-published data - Information from relevant formulations

There are no non-published studies on wine grapes available that use the current GA_3 40% SG (BERELEX 40 SG) formulation.

IIIA1 6.1.2 Minimum effective dose tests

In thirty-seven studies GA_3 40% SG (BERELEX 40 SG) was tested at a concentration range of 5, 10, 20, 40 or 80 ppm in a GAP spray water volume of 400-1000 L/ha (the majority of 30 studies applied 500-600 L/ha). The 5, 10 or 20 ppm concentrations were tested to determine the minimum effective as well as the intended maximum effective rate as presented in chapter IIIA1 6.1.3. The 40 and 80 ppm dose rates were tested as 2x and 4x dose rates, respectively to demonstrate crop safety. Data for the 40 ppm and 80 ppm dose rates are given under crop safety in chapter IIIA1 6.2. The majority of thirty-six studies tested more than one concentration. Study 2004MSCHR016 tested the 80 ppm (4x) dose rate only and the data are presented under crop safety only in IIIA1 6.2 and not under IIIA1 6.1.3.

IIIA1 6.1.3 Efficacy tests

Experimental details

Thirty-six GEP trials were carried out in Austria (25x) and Germany (11x) during 2004 (5x), 2005 (11x), 2006 (2x), 2007 (2x), 2010 (6x) and 2011 (10x) to evaluate the efficacy of GA_3 40% SG (BERELEX 40 SG) to reduce cluster compactness and the intensity and severity of grey mold caused by *Botrytis cinerea* in wine grapes. The cultivars tested were: 'Blauburger', 'Chardonnay', 'Grauburgunder', 'Grüner Veltliner', 'Muskateller', 'Portugieser', 'Sauvignon', 'Schwarzriesling', 'Spätburgunder', 'Traminer', 'Weiβburgunder', 'Welschriesling' and 'Zweigelt'. These cultivars are known to have compact clusters and are susceptible to *Botrytis* and other harvest rots e.g. sour rot (Essigfäule). These are important diseases for wine production in EU Central and of high relevance for the future use of GA_3 40% SG (BERELEX 40 SG). An overview of the studies by number of cultivar and years is given in Table 6.1.3- 1 immediately below.

Table 6.1.3- 1: Summary of GEP studies by cultivar undertaken in EU Central

Cultivar	Number of Studies	Number of Years	Dose Justification (studies with ≥ 2 dose rates)	Number of studies with highest recommended rate
Chardonnay	3	2	0	3
Grauburgunder	6	2	6	6
Spätburgunder	2	3	3	2
Schwarzriesling	3	2	3	3
Weiβburgunder	4	4	1	4
Portugieser	3	2	3	3
Blauburger	2	1	1	2
Grüner Veltliner	4	3	2	4
Muskateller	1	1	1	1
Sauvignon	2	2	0	2
Traminer	1	1	0	1
Welschriesling	1	1	0	1
Zweigelt	3	1	0	3

Please note, that Stähler Austria provided a letter of access for their efficacy data generated from studies in Austria conducted between 2004 and 2007.

Nine GEP efficacy studies were undertaken by Stähler Austria in 2005 to show the most effective application timing of GA_3 40% SG (ABG.3206). Unfortunately the trial protocol used different rates for the different timings and results are impossible to compare for the different timings and do no allow for valid conclusions. Therefore, only results for the timing at BBCH 62-65 are presented in the tables below.
In all other studies presented under chapter IIIA1 6.1.3, one application was conducted at BBCH 61-68 (10-80% of flowerhoods fallen). The majority of thirty-three studies conducted treatments between BBCH 62-65, 20-50% of flowerhoods fallen. An overview of the relevant BBCH growth stages for wine grapes is given on the following page.

Guidelines

All studies were conducted in accordance with the following EPPO Guidelines.

General guidelines followed:
- EPPO Standard PP 1/135 (2) or (3): Phytotoxicity assessment.
- EPPO Standard PP 1/152 (2) or (3): Design and analysis of efficacy evaluation trials.
- EPPO Standard PP 1/181 (2) or (3): Conduct and reporting of efficacy evaluation trials including good experimental practice.

Crop specific guidelines followed:
- EPPO Standard PP 1/171 (2): Regulation of growth in grapevine (except sucker control).
- EPPO Standard PP 1/17 (3): *Botryotinia fuckeliana* in grapevine (followed in 5 studies only).

GEP

All studies were conducted by officially recognized organizations in accordance with the principles of Good Experimental Practice (GEP). Detailed information on the test facilities and copies of their GEP certificates are given in IIIA1 6.7 (KIIIA 6.6/01).

Reference substances

Regalis (10% Prohexadione Calcium) is registered in Austria and Germany on wine grapes to reduce cluster compactness on 'Riesling', 'St Laurent' and 'Sauvignon blanc'. The target cultivars for Regalis and GA_3 are different, thus, Regalis was not used as reference product in the majority of the studies (31x). Five studies conducted in Austria in 2010 or 2011 used the reference product Regalis. The reference product Regalis showed good efficacy in these studies as shown below in IIIA1 6.1.3.

Trial locations and plot sizes

Trial locations were selected to follow EPPO guideline PP 1/241 (1) in areas representative of those typically used for commercial wine grape production. Thus, all studies can be considered relevant for EU Central.

Each trial was arranged in a randomized complete block design with four replicates. Trial plot sizes ranged from 13 to 30 m^2 with 7-10 plants.

Statistical analysis

Untransformed or transformed data were analysed using a two-way analysis of variance (ANOVA) and the statistical tools as indicated in **Fehler! Verweisquelle konnte nicht gefunden werden.** below. Please note, the efficacy summary tables do not show statistics but statistics for all test reports have been provided by the applicant in the BAD.

Efficacy evaluation

Efficacy was evaluated by comparing the treatment effect with an untreated control (%UTC =100%). Efficacies on *Botrytis* incidence and severity and for other rots (e. g. sour rot) were calculated using the Abbott efficacy formula.
It is important to note that the summary tables present mean efficacy values separately for each wine grape cultivar. The tables also show an overall mean value, median, standard deviation, maximum and minimum values. The median value describes the central tendency of a data distribution but reduces the influence of outliers. The mean efficacy values are shown without decimal places in the summary tables.

Assessment methods

All plots were harvested by hand. The parameters cluster compactness, cluster length and grey mould incidence and severity data as well as quality and yield parameters were assessed as shown in the overview.

Cluster compactness was determined visually by grouping the bunches into compactness classes. Cluster compactness was assessed in all studies at or shortly before harvest (BBCH83-89) and a mean cluster compactness value per treatment was calculated. The test reports used two assessment scales with either 1 to 5 classes or 1 to 9 classes. The two different scales can be related as follows:

- Class 1$^{(1 \& 2)}$: Grapes are not compact, stalks of the berries are very good visible
- Class 2$^{(1)}$ or 3$^{(2)}$: Grapes are not compact, just a few stalks are visible
- Class 3$^{(1)}$ or 5$^{(2)}$: Berries are very regular distributed on the grapes, stalks are not visible
- Class 4$^{(1)}$ or 7$^{(2)}$: Grapes are compact, berries cannot be moved
- Class 5$^{(1)}$ or 9$^{(2)}$: Grapes are very compact, berries press each other

$^{(1)}$: Related to a 1 to 5 scale
$^{(2)}$: Related to a 1 to 9 scale

Please note, when the cluster compactness values are expressed as efficacy values (as a %UTC with the UTC=100%) in the summary tables, then the % efficacy values that are greater than 100% will represent a decrease in the absolute cluster compactness and values less than 100% will represent an increase in absolute cluster compactness.

Cluster (bunch) length was also measured in four test reports for the treatments applied at BBCH 63-68. Measurements were made at harvest at 79 to 107 DAA, from the bottom of the rachis (the main axis of a grape inflorescence) to the point of first berry insertion at the top of the cluster.

The incidence of *Botrytis* (grey mold) and other rots (e.g. sour rots) was determined as the % of infected clusters and the severity as the % of infected area.

The grape quality parameters soluble solids (sugar) content, acid content and pH of grape juice were measured in some studies.

Yield was assessed as kg per plot, kg per vine or kg of marketable fruit per vine.

In the year following the applications, return bloom (as the number of fully developed clusters per vine) was assessed in the majority of twenty-four studies (1 study at 80 ppm only).

Efficacy on cluster compactness

Efficacy on cluster compactness is summarized in
Table 6.1.3- 2 immediately below. Cluster compactness was assessed visually at or just before harvest and a mean cluster compactness per treatment was calculated. The cluster compactness classes are described above under assessment methods.

When compared to the % UTC (100%) efficacy values greater than 100% show a reduction in cluster compactness, efficacy values less than 100% represent an increase in cluster compactness.

GA_3 40% SG (BERELEX 40 SG) at the 5, 10 or 20 ppm dose rates reduced mean cluster compactness over all studies and cultivars by:

- 111%, 118% or 122%, respectively when compared to the UTC (100%) with the reference at 122%.

The 5 ppm dose rate clearly showed the lowest mean efficacy and cluster compactness decreased with increasing dose rate to show the best efficacy at 20 ppm.

All tested cultivars showed excellent responses to GA_3 40% SG (BERELEX 40 SG) and can be broadly divided into three response groups. The cultivars ‘Blauburger’, ‘Grauburgunder’, ‘Grüner Veltliner‘ and ‘Portugieser‘ showed the strongest response to the GA_3 40% SG (BERELEX 40 SG) treatments at 20 ppm with efficacies of 126% to 147%. While the cultivars ‘Chardonnay’, ‘Muskateller’ and ‘Traminer’ appeared to be less responsive with efficacies of 106% to 113%. The cultivars ‘Sauvignon’, ‘Schwarziesling’, Spätburgunder’, Welschriesling’, ‘Weißburgunder’ and ‘Zweigelt’ all showed a more intermediate response with efficacies of 114% to 121%.

As discussed in the literature, relatively small decreases in cluster compactness can result in considerably less disease incidence when conditions favour disease development as shown below in Table 6.1.3- 4 and Table 6.1.3- 6.

Table 6.1.3- 2: Cluster compactness at or just before harvest

Test report no.		Control (raw data)	Efficacy (% UTC) *			
			Reference Regalis - 113 ppm	BERELEX 40 SG		
				5 ppm	10 ppm	20 ppm
Blauburger 2005MSCHR032; 2005MSCHR035		6.9	-	112	121	147
Chardonnay 2004MSCHR015; 2005MSCHR028; 2005MSCHR036	Mean value	7.6	-	-	-	113

Test report no.		Control (raw data)	Efficacy (% UTC) *			
			Reference Regalis - 113 ppm	BERELEX 40 SG		
				5 ppm	10 ppm	20 ppm
Grauburgunder 2010MSCHR441; 2010MSCHR442; 2010MSCHR524; 2011MSCHR433; 2011MSCHR434; 2011MSCHR494	Mean value	4.2	122	112	121	126
Grüner Veltliner 2005MSCHR029; 2006MSCHR010; 2006MSCHR011; 2007MSCHR014	Mean value	6.1	-	-	118	132
Muskateller 2005MSCHR034		7.2	-	107	113	108
Portugieser 2010MSCHR491; 2011MSCHR505; 2011MSCHR506	Mean value	4.0	-	115	125	127
Sauvignon 2004MSCHR017; 2005MSCHR033	Mean value	6.2	-	-	-	118
Schwarzriesling 2010MSCHR492; 2011MSCHR495; 2011MSCHR507	Mean value	3.9	-	104	108	114
Spätburgunder 2010MSCHR490; 2011MSCHR493; 2011MSCHR504	Mean value	3.9	-	111	115	115
Traminer 2004MSCHR014		8.0	-	-	-	106
Weiβburgunder 2004MSCHR018; 2005MSCHR027; 2007MSCHR015; 2011MSCHR435	Mean value	6.0	121	114	125	119
Welschriesling 2004MSCHR019		7.0	-	-	-	121
Zweigelt 2005MSCHR030; 2005MSCHR031; 2005MSCHR037	Mean value	6.5	-	-	-	116
Evaluation of all trials						
	Mean value	**n.c.**	**122**	**111**	**118**	**122**

Test report no.		Control (raw data)	Efficacy (% UTC) *			
			Reference Regalis - 113 ppm	BERELEX 40 SG		
				5 ppm	10 ppm	20 ppm
Standard deviation		n.c.	2.97	6.86	11.85	14.11
Min value		n.c.	119	102	104	106
Max value		n.c.	126	121	147	170
Number of trials		36	5	18	20	36
Median		n.c.	121	112	117	120

* %UTC = 100%. Values >100% show a reduction in cluster compactness. Values < 100% show a more compact cluster.
** The cluster compactness scale 1-9 is not defined in the report. However, according to the text in the report we can assume that 1 is less compact and 9 is very compact.

Efficacy on cluster length

The reduction in cluster compactness results from both, cluster stretching and berry thinning effects within the cluster from the spray treatments applied during early flowering (BBCH 62-65).

Cluster length was measured at harvest in four studies as shown in Table 6.1.3- 3 below. Efficacy is shown as the % of the UTC (100%).

GA_3 40% SG (BERELEX 40 SG) at the 20 ppm dose rate showed a mean increase in cluster length of 105% when compared to the UTC (100%).
With the exception of 'Blauburger', cluster length was not clearly increased by the 20 ppm dose rate treatments applied at BBCH 63-68. As already mentioned above, both stretching effects and berry thinning effects within the grape cluster will result in changes in cluster compactness. However, as these data show, gibberellin spray applications made to wine grape clusters during early to mid flowering (BBCH 62-65) are likely to have a minimal effects on cluster lengthening and the reduction in cluster compactness (as shown above) will more likely be the result of berry thinning effects. These findings are confirmed by the published literature as presented above.

Table 6.1.3- 3: Cluster length [cm] at harvest

Test report no.		Control (raw data)	Efficacy (% UTC) *			
			Reference Regalis - 113 ppm	BERELEX 40 SG		
				5 ppm	10 ppm	20 ppm
Blauburger 2005MSCHR032		12.5	-	0	56	117
Chardonnay 2005MSCHR036		11.0	-	-	-	100
Grüner Veltiner 2005MSCHR029		13.3	-	-	-	102
Zweigelt 2005MSCHR031		12.3	-	-	-	102
Evaluation of all trials						
Mean value		**12.3**	**-**	**-**	**-**	**105**
Standard deviation		0.95	-	-	-	7.93
Min value		11.0	-	-	-	100
Max value		13.3	-	-	-	117
Number of trials		4	-	-	-	4
Median		12.4	-	-	-	102

Efficacy on *Botrytis* incidence and severity

The efficacy of GA_3 40% SG (BERELEX 40 SG) on disease control is summarized for *Botrytis* incidence in Table 6.1.3- 4 and Table 6.1.3- 5 for *Botrytis* severity in Table 6.1.3- 6.
The summary tables show efficacy as % Abbott.

Over all studies GA_3 40% SG (BERELEX 40 SG) at the 5, 10 or 20 ppm dose rates showed % Abbott efficacies:

- On *Botrytis* incidence of 45%, 57% or 48%, respectively with the reference at 60%.
- On *Botrytis* severity of 46%, 58% or 51%, respectively with the reference at 66%.

Using the same number of datapoints (studies using the same dose rate range), GA_3 40% SG (BERELEX 40 SG) at the 10 or 20 ppm dose rates showed % Abbott efficacies:

- On *Botrytis* incidence of 57% or 67%, respectively with the reference at 60%.
- On *Botrytis* severity of 58% or 65%, respectively with the reference at 66%.

Over all studies the GA_3 40% SG (BERELEX 40 SG) treatments clearly and importantly reduced both, *Botrytis* incidence and severity by improving aeration and fungicide coverage through looser and more open clusters. The 5 ppm dose rate clearly showed the lowest mean control of *Botrytis* and either the 10 or 20 ppm dose rate provided the best control. 20 ppm provided approximately 8 to 10% better *Botrytis* control compared to the 10 ppm. These differences can be significant for producing premium wine quality, especially when disease pressure is high, but also a 10% yield difference is important for the wine grower.

The higher dose rate of 20 ppm would be recommended when the expected disease pressure is high and cultivars have very compact clusters. The 10 ppm dose rate can be considered as the minimum necessary dose rate to provide effective cluster compactness reduction and related disease control.

Table 6.1.3- 4: *Botrytis* incidence (% of infected clusters)

Test report no.		Control (raw data)	Efficacy (% UTC) *			
			Reference	BERELEX 40 SG		
			Regalis - 113 ppm	5 ppm	10 ppm	20 ppm
Blauburger 2005MSCHR032; 2005MSCHR035	Mean value	37.4	-	0	56	39
Chardonnay 2004MSCHR015; 2005MSCHR028; 2005MSCHR036	Mean value	51.2	-	-	-	19
Grauburgunder 2010MSCHR441; 2010MSCHR442; 2010MSCHR524; 2011MSCHR433; 2011MSCHR434; 2011MSCHR494	Mean value	15.0	56	37	56	69
Grüner Veltliner 2005MSCHR029	Mean value	62.8	-	-	-	33
Muskateller 2005MSCHR034		41.6	-	36	32	35

Test report no.		Control (raw data)	Efficacy (% UTC) *			
			Reference Regalis - 113 ppm	BERELEX 40 SG		
				5 ppm	10 ppm	20 ppm
Portugieser 2011MSCHR505; 2011MSCHR506	Mean value	14.1	-	60	68	76
Sauvignon 2004MSCHR017; 2005MSCHR033	Mean value	37.8	-	-	-	21
Schwarzriesling 2011MSCHR495		7.0	-	100	57	86
Spätburgunder 2011MSCHR504		25.0	-	50	75	83
Traminer 2004MSCHR014		25	-	-	-	70
Weißburgunder 2004MSCHR018; 2005MSCHR027; 2007MSCHR015; 2011MSCHR435	Mean value	34.1	77	57	49	47
Welschriesling 2004MSCHR019		9.6	-	-	-	25
Zweigelt 2005MSCHR030; 2005MSCHR031; 2005MSCHR037	Mean value	63	-	-	-	24
Evaluation of all trials						
	Mean value	**32.5**	**60**	**45**	**57**	**48**
	Standard deviation	24.78	16.10	27.21	15.65	27.27
	Min value	5.0	42	0	30	0
	Max value	93.3	77	100	77	86
	Number of trials	28	5	13	13	28
	Median	24.6	63	45	60	53

Table 6.1.3- 5: *Botrytis* incidence (% of infected clusters) comparison between 10 and 20 ppm

Test report no.		Control (raw data)	Efficacy (% UTC) *		
			Reference Regalis - 113 ppm	BERELEX 40 SG	
				10 ppm	20 ppm
Blauburger 2005MSCHR035		38.1	-	56	44
Grauburgunder 2010MSCHR441; 2010MSCHR442; 2010MSCHR524; 2011MSCHR433;	Mean value	15.0	56	56	69

Test report no.		Control (raw data)	Efficacy (% UTC) *		
			Reference Regalis - 113 ppm	BERELEX 40 SG	
				10 ppm	20 ppm
2011MSCHR434; 2011MSCHR494					
Muskateller 2005MSCHR034		41.6		32	35
Portugieser 2011MSCHR505; 2011MSCHR506	Mean value	14.1		68	76
Schwarzriesling 2011MSCHR495		7.0		57	86
Spätburgunder 2011MSCHR504		25.0		75	83
Weißburgunder 2011MSCHR435		17.3	77	49	61
Evaluation of all trials					
	Mean value	**19.0**	**60**	**57**	**67**
	Number of trials	13	5	13	13

Table 6.1.3- 6: *Botrytis* severity (% infected area)

Test report no.		Control (raw data)	Efficacy (% UTC) *			
			Reference Regalis - 113 ppm	BERELEX 40 SG		
				5 ppm	10 ppm	20 ppm
Blauburger 2005MSCHR032; 2005MSCHR035	Mean value	18.9	-	0	63	48
Chardonnay 2004MSCHR015; 2005MSCHR028; 2005MSCHR036	Mean value	30.8	-	-	-	30
Grauburgunder 2010MSCHR441; 2010MSCHR442; 2010MSCHR524; 2011MSCHR433; 2011MSCHR434; 2011MSCHR494	Mean value	10.0	62	43	60	63
Grüner Veltliner 2005MSCHR029		27.9	-	-	-	42
Muskateller 2005MSCHR034		14.6	-	39	43	31

Test report no.		Control (raw data)	Efficacy (% UTC) * Reference Regalis - 113 ppm	BERELEX 40 SG 5 ppm	10 ppm	20 ppm
Portugieser 2011MSCHR505; 2011MSCHR506	Mean value	5.5	-	40	61	74
Sauvignon 2004MSCHR017; 2005MSCHR033	Mean value	14.7	-	-	-	35
Schwarzriesling 2011MSCHR495		4.3	-	100	30	77
Spätburgunder 2011MSCHR504		11.3	-	60	73	73
Traminer 2004MSCHR014		8.1	-	-	-	73
Weiβburgunder 2004MSCHR018; 2005MSCHR027; 2007MSCHR015; 2011MSCHR435	Mean value	13.8	85	64	65	60
Welschriesling 2004MSCHR019		3.5	-	-	-	31
Zweigelt 2005MSCHR030; 2005MSCHR031; 2005MSCHR037	Mean value	35.0	-	-	-	28
Evaluation of all trials						
	Mean value	**16.4**	**66**	**46**	**58**	**51**
	Standard deviation	13.15	17.66	27.83	23.43	26.25
	Min value	3.5	44	0	0	0
	Max value	45.5	85	100	86	82
	Number of trials	28	5	13	13	28
	Median	10.8	75	52	65	58

Table 6.1.3- 7: *Botrytis* severity (% infected area) comparison between 10 and 20 ppm

Test report no.		Control (raw data)	Efficacy (% UTC) * Reference Regalis - 113 ppm	BERELEX 40 SG 10 ppm	20 ppm
Blauburger 2005MSCHR035		14.9	-	63	51
Grauburgunder 2010MSCHR441; 2010MSCHR442; 2010MSCHR524; 2011MSCHR433;	Mean value	10.0	62	60	63

Test report no.		Control (raw data)	Efficacy (% UTC) *		
			Reference Regalis - 113 ppm	BERELEX 40 SG	
				10 ppm	20 ppm
2011MSCHR434; 2011MSCHR494					
Muskateller 2005MSCHR034		14.6	-	43	31
Portugieser 2011MSCHR505; 2011MSCHR506	Mean value	5.5	-	61	74
Schwarzriesling 2011MSCHR495		4.3	-	30	77
Spätburgunder 2011MSCHR504		11.3	-	73	73
Weißburgunder 2011MSCHR435		7.8	85	65	82
Evaluation of all trials					
	Mean value	**9.5**	**66**	**58**	**65**
	Number of trials	13	5	13	13

Efficacy on wine rots other than Botrytis (e.g. sour rot)

Although we do not have any extensive database on the control of wine rots other than Botrytis control, the efficacy to reduce cluster compactness in relation to wine rot control is very well documented in the literature. Therefore we consider a reduction in cluster compactness as a general tool to control all rots in wine grapes.

In most cases, there are no published studies on wine grapes available that use the current GA_3 40% SG (BERELEX 40 SG) formulation but the studies found in our literature search and presented below are still considered relevant background information because they show the efficacy of GA_3 to reduce wine grape cluster compactness as we are requesting. Furthermore, we believe there is very strong evidence from the considerable years of commercial user experience on a wide range of crops and applications to show that GA_3 efficacy can be maintained even when the applied formulations are markedly different (e.g. tablets and liquid formulations versus a water soluble granule).

The literature review that follows is not intended to be comprehensive. It presents a limited number of published peer reviewed studies to demonstrate the efficacy of GA_3 on a variety of wine grape cultivars to reduce cluster compactness and to improve disease control.

Prevention of rots in susceptible grape cultivars

Vail and Marois (1991) found that grape cultivars with the most compact clusters were more severely affected by bunch rots in the field than those with loose clusters (Loinger et al., 1977). Rots not only result in a direct yield loss at harvest, as affected grape bunches need to be removed but rots can cause further losses in the must fermentation process (Ipach, 2009). In seasons with a high disease incidence, individual vineyards or even whole regions can suffer severe yield and quality losses.

In seasons with high rainfall shortly before harvest existing management measures often do not provide effective disease control. A good or sub-optimal water supply during the last fruit ripening phase increases the turgor pressure within the berries and encourages berry splitting. When there are open wounds and no pre-existing fungicide cover, fungal rots can easily infect berries (Ipach, 2009).

It is practically impossible, under unfavourable climatic conditions with rainfall and high humidity to influence the associated splitting of berries so that the only practicable measure to reduce harvest rots (sour rots) in compact wine grape cultivars is the application of plant growth regulators such as GA_3 or Prohexadione Calcium (Regalis).

For seeded wine grapes registrations exist in Italy for GA_3 40% SG (BERELEX 40 SG) on the cultivars: 'Chardonnay'; 'Picolit' and 'Tocai' and in Spain for the cultivar 'Macabeo'. Further registrations exist for Berelex® tablets (9.4% GA_3) for the same use in Italy on the cultivars: 'Barbera'; 'Dolcetto'; 'Muller'; 'Nebbiolo' and 'Tocai'. Also in Germany several years of emergency case approvals showed that GA_3 can effectively control wine rots such as sour rot (Essigfäule) and grey mould and other rots.

The following table summarises published results and experiences on important wine grape cultivars in relation to wine rot control in EU Central.

Table 6.1.3- 8: Summary of published study results in EU Central on **sour rots**

Reference	Cultivar/s	Dose rate, water volume	GA_3 Formulation	Application timing	Effects achieved
Hill, G., Hill, M. & Butterfass, J. 2003	13 different cultivars, e.g. Dornfelder, Grauburgunder,Portugieser, Regent, Riesling, Spätburgunder, Weißburgunder, etc.	10–100 ppm 800 L/ha	GA_3 (formulation not defined)	BBCH 61, 65, 67	GA_3 applications during bloom reduced the number of berries per cluster while treatments applied after flowering did not thin. Weißburgunder showed 30% less berries while Riesling showed an increase of 20% with half of the berries being seedless. Even at the highest dose rates the yield reduction was never below 50%. Results on rot control for Spätburgunder, Weißburgunder and Schwarzriesling (6 trial sites) were outstandingly good, ranging between 40% to 75% control with good control at relatively low dose rates of 10 or 20 ppm. GA_3 at 40 ppm applied to Ruläner showed very good efficacy on **sour rots** (previously not controllable) with 11.2% sour rot incidence compared with 73.5% incidence in the UTC. In the year following the application of GA_3 at 40 ppm no negative effects on return bloom were observed on cultivars of the "Burgundy" family and Schwarzriesling. Also Portugieser seemed to be unaffected by GA_3 sprays. Only Riesling showed a significant reduction in flowering. Sensory wine tasting results showed a clear preference for GA_3 treatments.
Kast, W.K., Fox, R. & Schiefer, H.C. 2005	Grauburgunder,Spätburgunder, Schwarzriesling, Weißburgunder	150 g f.p./ha 800 L/ha (= 18.75 ppm)	Gibb 3 TB (10% GA_3)	BBCH 65	Significant reduction in cluster compactness and in rot incidence (including **sour rot** incidence). Yield was not strongly reduced. Positive changes in wine quality. No negative effects on return bloom.
Bleyer, K. & Kast,	Spätburgunder,	150 g f.p./ha	Gibb 3 TB (10% GA_3)	BBCH 63, 65, 68	Excellent results on cluster compactness, *Botrytis* and **sour rot**

Reference	Cultivar/s	Dose rate, water volume	GA_3 Formulation	Application timing	Effects achieved
W.K. 2010	Schwarzriesling, Weißburgunder	200, 400 or 800 L/ha (= 75.0, 37.50 or 18.75 ppm, respectively)			control with little difference between application timing. Best results were recorded at the highest spray water volume of 800 L/ha or a dose rate of 18.75 ppm. Yields were sometimes reduced by up to 25% but on average a 10 to 15% yield reduction should be expected. Sensory wine tasting results showed a clear preference for GA_3 treatments which showed the highest anthocyanin and phenolic compound contents in the red wines when compared to the UTC.
Renner, W. 2010	Muskateller Weißburgunder, Zweigelt	25 – 37.5 g f.p./ha, water volume not given	GA_3 40% SG (40 % GA_3)	BBCH 65	GA_3 40% SG reduced **rots** significantly. Return bloom effects were variable ranging from 0% to 25% yield reduction in the year following the application.

The published data presented above is only a partial overview of the scientific literature and commercial experience but it clearly shows that GA_3 can control wine rots other than Botrytis by reducing cluster compactness.

Non-published data - Information from related formulations

There are no available studies on wine grapes that use any of the related GA_3 formulations currently registered in Europe (ProGibb®, Berelex®, Accel®). This is because the current registrations are old and the original studies undertaken by ICI (the previous license holder) were not transferred to Valent BioSciences Corporation. For this reason we would like to present an American study undertaken in California.

Experimental details

Duncan 1995 (Study 1995RFRIT490, two trial locations) used a 4% GA_3 liquid formulation (ProGibb) and a dose range of 3.8, 7.5, 11.3 or 15.0 ppm applied at BBCH 55-57, BBCH 60 or BBCH 62. Rots were present at harvest only at trial site 1 and disease results for this study are presented below. Only data from rots other than Botrytis are presented here.

Table 6.1.3- 9: Dose rate trial with related formulation

Test report no. Year GEP Region, Country	Trial ID and location	Wine cultivar	Single application rate (a.s.) spray water volume	Application timing	Testing method and design
1995RFRIT490 1995 Non GEP California, US	Trial 1:Sacramento-Lodi-Woodbridge	'Petite Sirah'	3.8 ppm 7.5 ppm 11.3 ppm 15.0 ppm ~1000 L/ha water	BBCH 55-57, BBCH 60 BBCH 62	Randomized complete blocks 4 replications, 2 vines Evaluation at BBCH 87

Efficacy on disease control

The ProGibb (4%) treatments reduced both the incidence and severity rots other than Botrytis when compared to the UTC. For sour rots the dose rate response was less clear than for Botrytis, however efficacy increased as flowering progressed with the best efficacy at BBCH 62. These results demonstrate the advantage of bloom sprays over pre-bloom sprays with best results for *Botrytis* at a spray concentration of 15 ppm.

The efficacy on **sour rots** control is given in Table 6.1.1- 3the table below.

Table 6.1.3- 10: Sour rot control for the related formulation (ProGibb 4 %) at three application timings

Parameter assessed Growth stage at application	**Control (abs. value)**	**% infected clusters or area (%UTC)**			
		3.8 ppm	**7.5 ppm**	**11.3 ppm**	**15.0 ppm**
Sour rot incidence (% infected clusters)					
BBCH 55-57	34 (100%)	29 (85%)	22 (65%)	20 (59%)	28 (82%)
BBCH 60	34 (100%)	28 (82%)	17 (50%)	30 (88%)	19 (56%)
BBCH 62	34 (100%)	30 (88%)	26 (76%)	14 (41%)	14 (41%)
Sour rot severity (% infected area)					
BBCH 55-57	11.8 (100%)	8.7 (74%)	3.1 (26%)	6.5 (55%)	8.0 (68%)
BBCH 60	11.8 (100%)	7.3 (62%)	5.5 (47%)	12.1 (103%)	5.8 (49%)
BBCH 62	11.8 (100%)	8.2 (69%)	3.4 (28%)	1.8 (15%)	1.0 (8%)

All data presented fully support our intended use of GA_3 40% SG (BERELEX 40 SG) to effectively control rots – besides the botrytis rot – on wine grapes in EU Central. And they are supporting our intended use recommendation to reduce cluster compactness and to control wine rots when applied once at BBCH 62-65 or BBCH 62-68, with a spray water volume of 400 – 1000 L/ha and a dose rate range of 10 to 20 ppm (2.5 to 5 g f.p./hL).

The effectivity of GA3 preparations for control of sour rot is also confirmed by German official vine institutes. Any measurement reducing the cluster compactness will lead to a reduced infestation of rot diseases and besides other formulations the use of GA3 is still recommended to prevent sour rot disease[1,2].

Summary and conclusions of preliminary chapter and GEP efficacy studies

The review of published data and non published data with related formulations presented in chapter IIIA1 6.1.1 fully support our intended use with GA_3 40% SG (BERELEX 40 SG) on wine grapes in EU Central.

Thirty-six GEP trials were carried out in Austria (25x) and Germany (11x) during 2004 (5x), 2005 (11x), 2006 (2x), 2007 (2x), 2010 (6x) and 2011 (10x) to evaluate the efficacy of GA_3 40% SG (BERELEX 40 SG) to reduce cluster compactness and the intensity and severity of grey mold caused by *Botrytis cinerea* in wine grapes. The cultivars tested were: ‘Blauburger’, ‘Chardonnay’, ‘Grauburgunder’, ‘Grüner Veltliner’, ‘Muskateller’, ‘Portugieser’, ‘Sauvignon’, ‘Schwarzriesling’, ‘Spätburgunder’, ‘Traminer’, ‘Weiβburgunder’, ‘Welschriesling’ and ‘Zweigelt’. These cultivars are known to have compact clusters and are susceptible to *Botrytis* and other harvest rots (e.g. sour rot). They are important for wine production in EU Central and of high relevance for the future use of GA_3 40% SG (BERELEX 40 SG).

Studies tested GA_3 40% SG (BERELEX 40 SG) a concentration range of 5, 10, 20, 40 or 80 ppm applied in a GAP spray water volume of 400-1000 L/ha (the majority of twenty-nine studies applied 500-600 L/ha). The 5, 10 or 20 ppm concentrations were tested to determine the minimum effective as well as the intended maximum effective rate. The 40 and 80 ppm dose rates were tested as the 2x and 4x dose rates, respectively to demonstrate crop safety.

[1] http://p7115.typo3server.info/fileadmin/fdw/FDWJahresbericht_2007.pdf
[2] http://www.zg-raiffeisen.de/fileadmin/Bereiche/Agrar/PflanzlicheProduktion/PP_Downloads_Dokumente/Petgen_Essigfaeule_im_Fokus.pdf

In all studies presented under chapter IIIA1 6.1.3, one application was conducted at BBCH 61-68 (10-80% of flowerhoods fallen). The majority of thirty-three studies conducted treatments between BBCH 62-65, 20-50% of flowerhoods fallen.

All tested cultivars showed excellent responses to GA_3 40% SG (BERELEX 40 SG) and can be broadly divided into three response groups based on cluster compactness. The cultivars ‘Blauburger’, ‘Grauburgunder’, ‘Grüner Veltliner‘ and ‘Portugieser‘ showed the strongest response to the GA_3 40% SG (BERELEX 40 SG) treatments with efficacies of 126% to 147%. While the cultivars ‘Chardonnay’, ‘Muskateller’ and ‘Traminer’ appeared to be less responsive with efficacies of 106% to 113%. The cultivars ‘Sauvignon’, ‘Schwarziesling’, Spätburgunder’, Welschriesling’, ‘Weißburgunder’ and ‘Zweigelt’ all showed a more intermediate response with efficacies of 114% to 121%.

Overall studies, GA_3 40% SG (BERELEX 40 SG) at the 5, 10 or 20 ppm dose rates showed reduced mean cluster compactness of 111%, 118% or 122%, respectively when compared to the UTC (100%) with the reference at 122%. The 5 ppm dose rate clearly showed the lowest mean efficacy and cluster compactness decreased with increasing dose rate to show the best efficacy at 20 ppm.

Cluster length was not clearly increased by the 20 ppm dose rate treatments applied at BBCH 63-68. Gibberellin spray applications made to wine grape clusters during early to mid flowering (BBCH 62-65) are likely to have a minimal effect on cluster lengthening and the reduction in cluster compactness (as shown above) will more likely be the result of berry thinning effects.

Over all studies the GA_3 40% SG (BERELEX 40 SG) treatments clearly and importantly reduced both, *Botrytis* incidence and severity by improving aeration and fungicide coverage through looser and more open clusters. The 5 ppm dose rate clearly showed the lowest mean control of *Botrytis* and either the 10 or 20 ppm dose rate provided the best control. 20 ppm provided approximately 8 to 10% better *Botrytis* control compared to the 10 ppm. These differences can be significant for producing premium wine quality, especially when disease pressure is high, but also a 10% yield difference is important for the wine grower.

The published and non published data presented under chapter IIIA1 6.1.1 and the results of the 36 GEP studies undertaken in EU Central (Austria and Germany) fully support our intended use of GA_3 40% SG (BERELEX 40 SG) on wine grapes in EU Central when applied once at BBCH 62-65 or BBCH 62-68, with a spray water volume of 400 – 1000 L/ha and a dose rate range of 10 to 20 ppm (2.5 to 5 g f.p./hL).

IIIA1 6.1.4 Effects on yield and quality

The quality parameters soluble solids (sugar) content, acidity and pH of grape juice were determined in ten studies and results are presented below in Table 6.1.4.1- 1, Table 6.1.4.1- 2 and Table 6.1.4.1-3 starting below. Yield (kg/vine) was determined in sixteen studies and results are presented in Table 6.1.4.3- 1. Effects on return bloom (# of fully developed clusters in the year following the application) were determined in twenty-three studies and results are given in Table 6.1.4.3- 2..

IIIA1 6.1.4.1 Impact of the quality of plants or plant products

The active substance GA_3 is known to reduce cluster compactness and to reduce rots (grey mould and sour rots) in wine grapes by improving aeration and fungicide coverage through looser and more open clusters. Besides marketable yields, wine quality is also improved with GA_3 applications as a result of improved rot control. Reductions in cluster compactness are one of the few potential control measures the wine grower has against sour rots (Essigfäule) which unlike *Botrytis* is not controlled by pesticide applications.
The mean soluble solids (sugar) content was slightly increased by the GA_3 40% SG (BERELEX 40 SG) treatments, especially at the 20 ppm dose rate with 106% compared to the UTC (100%). Please refer to Table 6.1.4.1- 1 below.
The acidity and pH were largely unaffected by the application of GA_3 40% SG (BERELEX 40 SG) at the 5, 10 or 20 ppm dose rates. Please refer to Table 6.1.4.1- 2 and Table 6.1.4.1- 3.

Table 6.1.4.1- 1: Sugar content (g/L) of grape juice in wine grape studies in EU Central

Test report no.		Control (raw data)	Efficacy (% UTC) *			
			Reference Regalis - 113 ppm	BERELEX 40 SG		
				5 ppm	10 ppm	20 ppm
Blauburger 2005MSCHR032; 2005MSCHR035	Mean value	160.4	-	95	105	107
Chardonnay 2005MSCHR028; 2005MSCHR036	Mean value	159.3	-	-	-	109
Muskateller 2005MSCHR034		173.2	-	102	98	101
Sauvignon 2005MSCHR033		160.4	-	-	-	118
Weißburgunder 2005MSCHR027; 2007MSCHR015	Mean value	164.7	-	-	-	103
Zweigelt 2005MSCHR031; 2005MSCHR037	Mean value	167.9	-	-	-	102
Evaluation of all trials						
	Mean value	**163.8**	**-**	**99**	**102**	**106**
	Standard deviation	12.77	-	4.95	4.95	7.00
	Min value	136.6	-	95	98	98
	Max value	184.1	-	102	105	118
	Number of trials	10	-	2	2	10
	Median	163.7	-	99	102	104

Table 6.1.4.1- 2: Acid content (g/L) of grape juice in wine grape studies in EU Central

Test report no.		Control (raw data)	Efficacy (% UTC) *			
			Reference Regalis - 113 ppm	BERELEX 40 SG		
				5 ppm	10 ppm	20 ppm
Blauburger 2005MSCHR032; 2005MSCHR035	Mean value	7.9	-	105	93	94
Chardonnay 2005MSCHR028; 2005MSCHR036	Mean value	7.6	-	-	-	99
Muskateller 2005MSCHR034		7.5	-	119	107	99
Sauvignon 2005MSCHR033		11.0	-	-	-	94
Weißburgunder 2005MSCHR027; 2007MSCHR015	Mean value	9.1	-	-	-	100
Zweigelt 2005MSCHR031;	Mean value	7.5	-	-	-	100

Test report no.		Control (raw data)	Efficacy (% UTC) *			
			Reference Regalis - 113 ppm	BERELEX 40 SG		
				5 ppm	10 ppm	20 ppm
2005MSCHR037						
Evaluation of all trials						
	Mean value	**8.3**	**-**	**112**	**100**	**98**
	Standard deviation	1.22	-	9.90	9.90	6.20
	Min value	7.1	-	105	93	89
	Max value	11.0	-	119	107	108
	Number of trials	10	-	2	2	10
	Median	8.0	-	112	100	96

Table 6.1.4.1- 3: pH of grape juice in wine grape studies in EU Central

Test report no.		Control (raw data)	Efficacy (% UTC) *			
			Reference Regalis - 113 ppm	BERELEX 40 SG		
				5 ppm	10 ppm	20 ppm
Blauburger 2005MSCHR032; 2005MSCHR035	Mean value	3.3	-	94	97	99
Chardonnay 2005MSCHR028; 2005MSCHR036	Mean value	3.1	-	-	-	100
Muskateller 2005MSCHR034		3.2	-	97	97	100
Sauvignon 2005MSCHR033		3.0	-	-	-	100
Weißburgunder 2005MSCHR027; 2007MSCHR015	Mean value	2.9	-	-	-	100
Zweigelt 2005MSCHR031; 2005MSCHR037	Mean value	3.2	-	-	-	100
Evaluation of all trials						
	Mean value	**3.1**	**-**	**96**	**97**	**100**
	Standard deviation	0.22	-	2.12	0.00	2.22
	Min value	2.5	-	94	97	94
	Max value	3.4	-	97	97	103
	Number of trials	10	-	2	2	10
	Median	3.1	-	96	97	100

IIIA1 6.1.4.2 Effects on the processing procedure

Results from residue studies conducted with GA_3 40% SG (BERELEX 40 SG) show no residual active substance at or above the limit of determination at harvest. Given the timing of applications in early spring and the absence of residues at harvest, it is not anticipated that this formulation would have any negative effects on the processing grapes.

The improved control of rots provided by GA_3 40% SG (BERELEX 40 SG) has substantial positive effects on wine making processes and wine quality. Furthermore, as shown under IIIA1 6.1.4.1 above

GA_3 40% SG (BERELEX 40 SG) did not negatively affect the grape juice and therefore negative effects on wine making processes cannot be expected.

IIIA1 6.1.4.3 Effects on the yield of treated plants and plant products

Sixteen GEP studies are available to show the effects of GA_3 40% SG (BERELEX 40 SG) on yield (kg/vine) in Table 6.1.4.3- 1. Twenty-three studies are available to show return bloom (potential yield in the year following the application) in Table 6.1.4.3- 2. Results for the 40 ppm and 80 ppm dose rates are presented under crop safety in IIIA1 6.2.

GA_3 40% SG (BERELEX 40 SG) at the 5, 10 or 20 ppm dose rates showed overall studies and cultivars:

- A mean yield (kg/vine) of 95%, 94% or 93%, respectively compared to the UTC (100%) with the reference at 92%.
- A mean return bloom of 103%, 98% or 97%, respectively compared to the UTC (100%) with the reference at 93%.

There was no negative effect on mean total yield (marketable and unmarketable kg/vine overall cultivars and studies) at any of the tested dose rates ranging from 5 to 20 ppm in the year of application. If the cluster compactness was reduced more by berry thinning than by cluster stretching, a reduction in yield was observed by ~20% when compared to the UTC (e.g. test reports 2006MSCHR010 & 2010MSCHR442). However, it has to be pointed out that even if total yields are reduced the wine yield would be increased if clusters would be affected by berry rots. Furthermore, most wine grape cultivars require some degree of cluster thinning and yield reduction to produce the required grape quality and this thinning has become a standard grower practice. Therefore, some cultivar specific yield reduction is acceptable and commercially has no negative impact for the wine grower.
In some cases a reduction in return bloom was observed even though the overall mean of all studies and cultivars was no different to the UTC. However, some cultivars showed a trend of less return bloom at the 20 ppm dose rate, with values of ~80% of the UTC, e. g. 'Blauburger' or 'Grüner Veltliner'. Negative effects on return bloom following GA_3 applications are very well known and reported but as indicated above would have no commercial relevance on yield at this level. Furthermore, the positive effects of GA_3 applications on wine yield and especially wine quality by improved disease control would clearly compensate for any yield losses resulting from berry thinning or reduced return bloom.

Table 6.1.4.3- 1: Yield (kg/vine)

Test report no.		Control (raw data)	Efficacy (% UTC) *			
			Reference Regalis - 113 ppm	BERELEX 40 SG		
				5 ppm	10 ppm	20 ppm
Grauburgunder 2010MSCHR441; 2010MSCHR442; 2010MSCHR524; 2011MSCHR433; 2011MSCHR434; 2011MSCHR494	Mean value	1.5	94	97	94	98
Grüner Veltliner 2006MSCHR010		4.2	-	-	96	81
Portugieser 2010MSCHR491; 2011MSCHR505; 2011MSCHR506	Mean value	5.6	-	91	93	90
Schwarzriesling 2010MSCHR492; 2011MSCHR495	Mean value	2.3	-	101	100	99

Test report no.		Control (raw data)	Efficacy (% UTC) *			
			Reference Regalis - 113 ppm	BERELEX 40 SG		
				5 ppm	10 ppm	20 ppm
Spätburgunder 2011MSCHR493; 2010MSCHR490; 2011MSCHR504	Mean value	3.5	-	96	94	90
Weißburgunder 2007MSCHR015; 2011MSCHR435	Mean value	2.8	83	87	83	90
Evaluation of all trials						
	Mean value	**3.1**	**92**	**95**	**94**	**93**
	Standard deviation	1.89	11.79	10.22	10.19	14.91
	Min value	1.1	83	82	80	76
	Max value	8.0	108	112	110	136
	Number of trials	16	4	14	15	16
	Median	2.7	88	95	92	91

Table 6.1.4.3- 2: Return bloom (# of fully developed clusters/vine in the following year)

Test report no.		Control (raw data)	Efficacy (% UTC) *			
			Reference Regalis - 113 ppm	BERELEX 40 SG		
				5 ppm	10 ppm	20 ppm
Blauburger 2005MSCHR032; 2005MSCHR035	Mean value	20.0	-	109	109	85
Chardonnay 2004MSCHR015; 2005MSCHR028; 2005MSCHR036	Mean value	20.8	-	-	-	109
Grauburgunder 2010MSCHR441; 2010MSCHR442; 2010MSCHR524	Mean value	18.8	93	97	102	101
Grüner Veltliner 2005MSCHR029; 2006MSCHR010; 2006MSCHR011	Mean value	12.6	-	-	90	88
Muskateller 2005MSCHR034		21.5	-	102	103	90
Portugieser 2010MSCHR491		21.5	-	105	95	90
Sauvignon 2004MSCHR017; 2005MSCHR033	Mean value	16.8	-	-	-	91

Test report no.		Control (raw data)	Efficacy (% UTC) *			
			Reference Regalis - 113 ppm	BERELEX 40 SG		
				5 ppm	10 ppm	20 ppm
Schwarzriesling 2010MSCHR492		6.5	-	105	97	92
Spätburgunder 2010MSCHR490		23.0	-	112	95	88
Traminer 2004MSCHR014		11.0	-	-	-	116
Weißburgunder 2004MSCHR018; 2005MSCHR027	Mean value	18.5	-	-	-	103
Welschriesling 2004MSCHR019		18.0	-	-	-	97
Zweigelt 2005MSCHR030; 2005MSCHR037	Mean value	14.9	-	-	-	99
Evaluation of all trials						
	Mean value	**17.3**	**93**	**103**	**98**	**97**
	Standard deviation	5.26	1.41	6.45	7.31	11.38
	Min value	6.5	92	94	85	77
	Max value	25.3	94	112	109	128
	Number of trials	23	2	8	10	23
	Median	18.3	93	104	96	94

Overall summary and conclusions for quality and yield of the studies in EU Central

The active substance GA_3 is known to reduce cluster compactness and to reduce rots (e.g. grey mould and sour rots) in wine grapes by improving aeration and fungicide coverage through looser and more open clusters. Besides marketable yields, wine quality is also improved with GA_3 applications as a result of improved rot control.
Reductions in cluster compactness are one of the few potential control measures the wine grower has against sour rots which unlike *Botrytis* are not controlled by pesticide applications.

The mean soluble solids (sugar) content of the grape juice was slightly increased by the GA_3 40% SG (BERELEX 40 SG) treatments, especially at the 20 ppm dose rate with 106% compared to the UTC (100%).
Acidity and pH of the grape juice were largely unaffected by the application of GA_3 40% SG (BERELEX 40 SG) at the 5, 10 or 20 ppm dose rates.

There was no negative effect on mean total yield (marketable and unmarketable kg/vine overall cultivars and studies) at any of the tested dose rates ranging from 5 to 20 ppm in the year of application. If the cluster compactness was reduced more by berry thinning than by cluster stretching, a reduction in yield was observed by ~20% when compared to the UTC (e.g. test reports 2006MSCHR010 & 2010MSCHR442). However, it has to be pointed out that even if total yields are reduced the wine yield would be increased if clusters would be affected by berry rots. Furthermore, most wine grape cultivars require some degree of cluster thinning and yield reduction to produce the required grape quality and this thinning has become a standard grower practice. Therefore, some cultivar specific yield reduction is acceptable and commercially has no negative impact for the wine grower.

In some cases a reduction in return bloom was observed even though the overall mean of all studies and cultivars was no different to the UTC. However, some cultivars showed a trend of less return bloom at the 20 ppm dose rate, with values of ~80% of the UTC, e. g. 'Blauburger' or 'Grüner Veltliner'. Negative effects on return bloom following GA_3 applications are very well known and reported but as indicated above would have no commercial relevance on yield at this level of return bloom reduction. Furthermore, the positive effects of GA_3 applications on wine yield and wine quality by improved disease control would clearly compensate for any yield losses resulting from berry thinning or reduced return bloom.

These data fully support our intended use on wine grapes in EU Central with GA_3 40% SG (BERELEX 40 SG) when applied once at BBCH 62-65 or BBCH 62-68, with a spray water volume of 400 – 1000 L/ha and a dose rate range of 10 to 20 ppm (2.5 to 5 g f.p./hL).

IIIA1 6.2 Adverse effects

IIIA1 6.2.1 Phytotoxicity to host crop

In thirty-seven GEP studies crop safety assessments were conducted at different dates after application by visually comparing treated and untreated plots according to EPPO Standard PP 1/135 (2) or (3).

No phytotoxicity or other negative effects in terms of necrosis or modifications in colour and quantity or quality of yield were observed after GA_3 40% SG BERELEX 40 SG applications at any of the tested rates.

When applied at the recommended intended use rates and timings, GA_3 40% SG (BERELEX 40 SG) can be considered completely safe to the target crop. GA_3 40% SG (BERELEX 40 SG) was tested at dose rates of up to 40 ppm and/or 80 ppm which corresponds to two to four times the maximum intended use rate. GA_3 40% SG (BERELEX 40 SG) showed good efficacy on cluster compactness and disease control at all tested rates. No phytotoxicity or any other negative effects on yield or return bloom were observed overall studies and cultivars. However, in one instance (test report 2004MSCHR015) the return bloom was markedly lower at the 80 ppm dose rate. Since the highest intented use rate is 20 ppm we would not consider this effect on return bloom to be a risk for the wine grower. Overall, we conclude that GA_3 40% SG (BERELEX 40 SG) is completely safe to wine grapes when applied at the recommended timing and rates. Please refer to Table 6.2.1- 1 and Table 6.2.1- 2.

Table 6.2.1- 1: Crop safety and efficacy of GA_3 40% (BERELEX 40 SG) at the 40 ppm dose rate.

Test report no.	Country	BERELEX 40 SG 2X dose rate	Phytotoxicity recorded	Efficacy (% UTC)								
				Compactness *	Cluster length	*Botrytis* Incidence **	*Botrytis* Severity **	Yield	Sugar content	Acid content	pH	Return bloom
Blauburger												
2005MSCHR032	AT	40 ppm	none	173	118	38	58	-	105	89	103	80
2005MSCHR035	AT	40 ppm	none	138	-	71	74	-	102	101	94	100
			Mean value	**156**	**118**	**54**	**66**	**-**	**104**	**95**	**99**	**90**
Chardonnay												
2004MSCHR015	AT	40 ppm	none	133	-	8	44	-	-	-	-	82
2005MSCHR028	AT	40 ppm	none	111	-	34	50	-	103	88	100	100
2005MSCHR036	AT	40 ppm	none	120	106	14	15	-	117	111	100	105
			Mean value	**121**	**106**	**19**	**36**	**-**	**110**	**100**	**100**	**96**
Grauburgunder												
2010MSCHR441	AT	40 ppm	none	149	-	82	81	95	-	-	-	96
2010MSCHR442	AT	40 ppm	none	136	-	60	61	97	-	-	-	97
2010MSCHR524	DE	40 ppm	none	125	-	84	25	112	-	-	-	96
2011MSCHR433	AT	40 ppm	none	133	-	45	57	-	-	-	-	-
2011MSCHR434	AT	40 ppm	none	131	-	74	82	82	-	-	-	-
2011MSCHR494	DE	40 ppm	none	106	-	82	62	78	-	-	-	-
			Mean value	**130**	**-**	**71**	**61**	**93**	**-**	**-**	**-**	**96**
Grüner Veltliner												
2005MSCHR029	AT	40 ppm	none	132	104	13	29	-	102	98	103	82
2006MSCHR010	AT	40 ppm	none	135	-	-	-	75	-	-	-	90
2006MSCHR011	AT	40 ppm	none	139	-	-	-	-	-	-	-	98
2007MSCHR014	AT	40 ppm	none	139	-	-	-	-	-	-	-	-
			Mean value	**136**	**104**	**13**	**29**	**75**	**102**	**98**	**103**	**90**
Muskateller												
2005MSCHR034	AT	40 ppm	none	**111**	**-**	**34**	**40**	**-**	**101**	**99**	**97**	**99**
Portugieser												
2010MSCHR491	DE	40 ppm	none	133	-	-	-	100	-	-	-	93
2011MSCHR505	DE	40 ppm	none	156	-	67	67	75	-	-	-	-
2011MSCHR506	DE	40 ppm	none	121	-	89	65	78	-	-	-	-
			Mean value	**137**	**-**	**78**	**66**	**84**	**-**	**-**	**-**	**93**
Sauvignon												

Test report no.	Country	BERELEX 40 SG 2X dose rate	Phytotoxicity recorded	Efficacy (% UTC)								
				Compactness *	Cluster length	*Botrytis* Incidence **	*Botrytis* Severity **	Yield	Sugar content	Acid content	pH	Return bloom
2004MSCHR017	AT	40 ppm	none	150	-	88	95	-	-	-	-	90
2005MSCHR033	AT	40 ppm	none	119	-	23	38	-	122	94	100	76
			Mean value	**135**	**-**	**55**	**66**	**-**	**122**	**94**	**100**	**83**
Schwarzriesling												
2010MSCHR492	DE	40 ppm	none	124	-	-	-	111	-	-	-	105
2011MSCHR495	DE	40 ppm	none	114	-	79	58	105	-	-	-	-
2011MSCHR507	DE	40 ppm	none	116	-	-	-	-	-	-	-	-
			Mean value	**118**	**-**	**79**	**58**	**108**	**-**	**-**	**-**	**105**
Spätburgunder												
2010MSCHR490	DE	40 ppm	none	121	-	-	-	93	-	-	-	99
2011MSCHR493	DE	40 ppm	none	138	-	-	-	82	-	-	-	-
2011MSCHR504	DE	40 ppm	none	117	-	90	73	98	-	-	-	-
			Mean value	**125**	**-**	**90**	**73**	**91**	**-**	**-**	**-**	**99**
Traminer												
2004MSCHR014	AT	40 ppm	none	**138**	**-**	**50**	**58**	**-**	**-**	**-**	**-**	**108**
Weißburgunder												
2004MSCHR018	AT	40 ppm	none	127	-	74	79	-	-	-	-	143
2005MSCHR027	AT	40 ppm	none	117	-	10	28	-	101	100	100	102
2007MSCHR015	AT	40 ppm	none	122	-	92	97	69	109	100	101	-
2011MSCHR435	AT	40 ppm	none	142	-	84	93	82	**-**	**-**	**-**	-
			Mean value	**127**	**-**	**65**	**74**	**76**	**105**	**100**	**101**	**123**
Welschriesling												
2004MSCHR019	AT	40 ppm	none	**129**	**-**	**75**	**75**	**-**	**-**	**-**	**-**	**113**
Zweigelt												
2005MSCHR030	AT	40 ppm	none	113	-	21	28	-	-	-	-	107
2005MSCHR031	AT	40 ppm	none	147	109	46	58	-	97	101	100	-
2005MSCHR037	AT	40 ppm	none	112	-	5	14	-	95	105	97	104
			Mean value	**124**	**109**	**24**	**34**	**-**	**96**	**103**	**99**	**106**
Evaluation of all trials												
			Mean value	**130**	**109**	**55**	**57**	**89**	**105**	**99**	**100**	**99**
			Standard deviation	14.52	6.30	29.79	23.59	13.70	8.17	6.60	2.66	13.63
			Min value	106	104	5	14	69	95	88	94	76

Test report no.	Country	BERELEX 40 SG 2X dose rate	Phytotoxicity recorded	Efficacy (% UTC)								
				Compactness *	Cluster length	*Botrytis* Incidence **	*Botrytis* Severity **	Yield	Sugar content	Acid content	pH	Return bloom
			Max value	173	118	92	97	112	122	111	103	143
			Number of trials	36	4	28	28	16	11	11	11	23
			Median	130	108	63	58	87	102	100	100	99

* Efficacies are calculated compared to the UTC = 100%. Values >100% show a reduction in cluster compactness. Values < 100% show a more compact cluster when compared to the UTC.
** Efficacy is % Abbott

Table 6.2.1- 2: Crop safety and efficacy of GA_3 40% (BERELEX 40 SG) at the 80 ppm dose rate.

Test report no.	Country	BERELEX 40 SG 4X dose rate	Phytotoxicity recorded	Efficacy (% UTC)			
				Compactness *	*Botrytis* Incidence **	*Botrytis* Severity **	Return bloom
Chardonnay							
2004MSCHR015	AT	80 ppm	none	140	42	72	58
Sauvignon							
2004MSCHR017	AT	80 ppm	none	150	79	88	84
Traminer							
2004MSCHR014	AT	80 ppm	none	144	86	85	100
Weißburgunder							
2004MSCHR018	AT	80 ppm	none	140	87	93	116
Welschriesling							
2004MSCHR019	AT	80 ppm	none	143	75	75	125
Zweigelt							
2004MSCHR016	AT	80 ppm	none	124	18	37	138
Evaluation of all trials							
			Mean value	**140**	**64**	**75**	**103**
			Standard deviation	8.73	28.01	20.36	29.38
			Min value	124	18	37	58
			Max value	150	87	93	138
			Number of trials	6	6	6	6
			Median	142	77	80	108

* Efficacies are calculated compared to the UTC = 100%. Values >100% show a reduction in cluster compactness. Values < 100% show a more compact cluster when compared to the UTC.
** Efficacy is % Abbott

IIIA1 6.2.2 Adverse effects on health of host animals

Not applicable since GA_3 40% SG (BERELEX 40 SG) is a plant growth regulator. No target animals have been associated with this product. GA_3 40% SG (BERELEX 40 SG) has been used under practical conditions since 2009 in various European countries (Greece, Italy, Spain, Switzerland) and many other countries worldwide. During this time negative effects on animals have never been reported from researchers or growers in the countries mentioned above.

IIIA1 6.2.3 Adverse effects on site of application

Field efficacy studies with GA_3 40% SG (BERELEX 40 SG) and user experience from other countries have never shown any adverse effects on the site of application. GA_3 40% SG (BERELEX 40 SG) has been used under practical conditions since 2009 in various European countries (Greece, Italy, Spain, Switzerland) and many other countries worldwide. During this time negative effects on the site of application have never been reported from researchers or growers in the countries mentioned above.

IIIA1 6.2.4 Adverse effects on beneficial organisms (other than bees)

The toxicity of ProGipp 40% on beneficial organisms has been investigated by carrying out tests under extended laboratory conditions on *Chrysoperla carnea* and *Coccinella septempunctata.*
The results of these tests are presented in Table 6.2.4-1 and Table 6.2.4-2.
On the basis of these results no effects ≥ 25% are expected for populations of the beneficial insect species *Chrysoperla carnea* and *Coccinella septempunctata,* when Berelex 40 SG is applied according to the recommended use pattern, i.e. one application of 50 g/ha to vineyards.

Table 6.2.4-1: Effects of ProGipp 40% on *Chrysoperla carnea* (exposed stage: larva) in an extended laboratory test (substrate: bean leaves)

Application rate [g/ha]	Corrected mortality [%]	Effect on fertility [%]	Reference
700	0	-1.4	Document MIIIA1 Sec. 6 April 2012

Table 6.2.4-2: Effects of ProGipp 40% on *Coccinella septempunctata* (exposed stage: larva) in an extended laboratory test (substrate: bean leaves)

Application rate [g/ha]	Corrected mortality [%]	Effect on fertility [%]	Reference
700	0	6.3	Document MIIIA1 Sec. 6 April 2012

Conclusions
Berelex 40 SG is classified as not harmful for populations of *Chrysoperla carnea and Coccinella septempunctata*.

Adverse effects on soil quality indicators (e. g. microorganisms, earthworms) are considered in Section 6 Ecotoxicological Studies in the Registration Report.

IIIA1 6.2.5 Adverse effects on parts of plants used for propagating purposes

Not required according to EPPO guideline PP 1/131 (2).

IIIA1 6.2.6 Impact on succeeding crops

Wine grapes are cultivated as a perennial crop. There is no yearly minimum waiting period or other precautions between the last application and sowing or planting of a succeeding crop.

Gibberellins are naturally occurring plant growth regulators which have been found to be present in numerous crops and plants. Even in the case that a vineyard would be removed following harvest and replanted with another crop, there would be no risk of a significant effect from GA_3 40% SG

(BERELEX 40 SG) residues in succeeding crops and no risk of phytotoxicity given the rapid degradation of GA_3 40% SG (BERELEX 40 SG) and its metabolites in soil. Based on the application timing it is unlikely that the gibberellins levels would be higher than the background level.

IIIA1 6.2.7 Impact on another plants including adjacent crops

The product GA_3 40% SG (BERELEX 40 SG) is a water soluble granule product containing a naturally occurring plant growth regulator. On the basis of long experience of practical use of the active substance and extensive field testing on wine grapes, there is no reason to believe there would be a negative impact on other plants including adjacent crops. Furthermore, field testing has shown no evidence of phytotoxicity in other plants or adjacent crops when the product is used according to the GAP.

There has been no evidence of phytotoxicity to adjacent crops during field trials that have been conducted with GA_3 40% SG (BERELEX 40 SG) and presented in this Biological Assessment Dossier. This is further confirmed by the long term use of GA_3 products in many countries worldwide where GA_3 has been registered for use or used under experimental approval schemes. Moreover, there is a wealth of published data on the natural occurrence of GA_3 and its effects on plants. Furthermore, the 'Draft Assessment Report (DAR) for the EU evaluation for Annex I listing of the existing active substance Gibberellins: July 2006', gibberellic acid (GA_3) is naturally occurring plant hormone with a non-toxic mode of action on plants. It also concludes the following with respect to non-target flora and fauna:

Gibberellic acid (GA_3) is a naturally occurring plant hormone. Because it is a naturally occurring compound with a non-toxic mode of action in target plants, GA_3 has been classified as a biochemical pesticide by the US EPA (EPA RED).
The PECsoil for GA_3 at day 0 following single applications of GA_3 to grapes has been estimated to be 0.04 mg/kg (after multiple applications: 0.064 mg/kg). As GA_3 is a naturally occurring gibberellin which is found in plant material (up to 10 mg/kg), in soil (bacterial production seen at 1 mg/L) and from fungi it is considered that non-target plants will not be exposed to concentrations higher than naturally occurring levels from the proposed use of GA_3. The degradation rate of GA_3 in the soil is very rapid with a maximum field DT_{50} value of *ca.* 4.5 days. These data show that GA_3 will not persist in the soil and that long-term GA_3 levels from the proposed use of GA_3 on grapes will be insignificant compared to naturally occurring GAs. It is therefore considered that there will be no acute or long-term risk to non-target plants from the proposed use of GA_3.
Applications of GA_3 to influence fruit development of grapes are not expected to affect the development and growth of non-target terrestrial plants exposed to lateral spray-drift into the off-crop margins or vertical deposition onto ground-cover vegetation on the orchard floor. Laboratory and greenhouse studies to determine effects on seed germination, seedling emergence or vegetative vigour are therefore unnecessary, as are terrestrial field tests.
No data gap has been identified and no risk management/labelling is considered necessary. Consequently applications of GA_3 for the reduction of cluster compactness on wine grapes are not expected to affect the development and growth of non-target terrestrial plants exposed to lateral spray-drift into the off-crop margins or vertical deposition onto ground-cover vegetation on the vineyard floor.

IIIA1 6.2.8 Possible development of resistance or cross resistance

The product GA_3 40% SG (BERELEX 40 SG) is a plant growth regulator containing the gibberellin A3 which naturally occurs in plants. GA_3 is applied to enhance natural processes and operates in the natural biochemical pathways of the plant. Resistance or cross-resistance is not applicable because GA_3 operates along with and in the same way as the active substance is already present in the plant.

IIIA1 6.3 Economics

No EU data requirement. However, GA_3 40% SG (BERELEX 40 SG) shows positive effects on rot control and consequently improved wine yield and quality. Both wine yield and quality are decisive for the economic success of a winery.

IIIA1 6.4 Benefits

IIIA1 6.4.1 Survey of alternative pest control measures

For the production of high quality wines it is essential to control *Botrytis cinerea* infections (except for some dessert wines) and other rots (e.g. sour rot). Grape growers have made huge efforts to find suitable cultural management measures to reduce harvest rots in susceptible wine grape cultivars. Management methods have included cluster separation, hand thinning of clusters, early leaf removal and moderate or adapted fertilizer programmes. Non chemical measures to obtain more open and aerated bunches do not exist. Hand thinning is labour intensive and expensive and also causes damage to the bunches that can increase the risk of disease.

In seasons with high rainfall shortly before harvest existing management measures often do not provide effective disease control. An excess water supply during the last fruit ripening phase increases the turgor pressure within the berries and encourages berry splitting. When there are open wounds and no pre-existing fungicide cover, fungal rots can easily infect berries. This is also true when wounds are caused by Tortrix moth feeding damage. Even the application of an effective *Botrytis* fungicide and/or insecticide will not provide adequate control when clusters are too compact. In addition, no effective pesticide exists for sour rot control thus control measures must be based on maintaining an open cluster to avoid this disease.
For these reasons it is essential that the pressure and splitting within the compacted grape clusters is reduced. This can be achieved chemically by GA_3 or Prohexadione Calcium (Regalis) applications. Prohexadione Calcium (Regalis) is not as effective as GA_3 on some wine grape cultivars (please refer to the introduction chapter IIIA1 6.1.1.).
Therefore, GA_3 40% SG (BERELEX 40 SG) remains the only existing management method to help control rot diseases in specific wine grape cultivars.

IIIA1 6.4.2 Compatibility with current management practices including IPM

GA_3 40% SG (BERELEX 40 SG) improves the performance of other pesticides and fits as a perfect tool into IPM programmes. This is confirmed by the commercial use of GA_3 40% SG (BERELEX 40 SG) in many other countries worldwide.

IIIA1 6.4.3 Contribution to risk reduction

The GA_3 40% SG (BERELEX 40 SG) formulation as a high concentration, fast dissolving, water-soluble, granular formulation, makes a significant contribution to reduce environmental risks when compared to other commercially available GA_3 formulations.

The new GA_3 40% SG (BERELEX 40 SG) formulation reduces shipping costs, storage space, and container disposal costs. Granules are user friendly and are considered safer due to ease of clean up after accidental spills and absence of respirable dust size particles. Unlike liquids, granules can be easily swept up for disposal and do not require absorbents or special equipment. Granules can be brushed from clothing if spilled and do not wet the skin, thus reducing the potential of dermal worker exposure. The high quality granular formulations, GA_3 40% SG BERELEX 40 SG are dust free and reduce the potential for worker exposure through inhalation. These soluble granular formulations do not contain volatile organic compounds and thus do not have a negative impact on air quality.

IIIA1 6.5 Other/special studies

No EU data requirement.

IIIA1 6.6 Summary and assessment of data corresponding to points 6.1 to 6.5

6.0: Public available data and own experimental data of the applicant were presented in a BAD and in Caddy K-documents. GEP requirements were fulfilled and EPPO-Guidelines considered. The assessment is valid for the Central zone. The application modalities were outlined appropriately and the biology of the host has been considered appropriately.
6.1.1 Preliminary range finding tests were apprpriately documented
6.1.2 The minimum effective dose was demonstrated to be the desired target dose.
6.1.3 Suffcient efficacy has been approved.

6.1.4.1 With respect to the quality of plants or plant products no adverse effects have been observed.
6.1.4.2 Given the timing of applications in early spring and the absence of residues at harvest, it is not anticipated that this formulation would have any negative effects on the processing grapes.
6.2.1 Phytotoxicity to target plants has not been observed.
6.2.4 Berelex 40 SG is classified as not harmful for populations of *Chrysoperla carnea and Coccinella septempunctata*.
Adverse effects on soil quality indicators (e. g. microorganisms, earthworms) are considered in Section 6 Ecotoxicological Studies in the Registration Report
6.2.6 Wine grapes are cultivated as a perennial crop. There is no yearly minimum waiting period or other precautions between the last application and sowing or planting of a succeeding crop.
6.2.7 No data gap has been identified and no risk management/labelling is considered necessary. Consequently applications of GA_3 for the reduction of cluster compactness on wine grapes are not expected to affect the development and growth of non-target terrestrial plants exposed to lateral spray-drift into the off-crop margins or vertical deposition onto ground-cover vegetation on the vineyard floor.
6.2.8 The resistance risk is negligible due to an appropriate management plan.
. GA_3 is applied to enhance natural processes and operates in the natural biochemical pathways of the plant. Resistance or cross-resistance is not applicable because GA_3 operates along with and in the same way as the active substance already present in the plant.

IIIA1 6.7 List of test facilities including the corresponding certificates

GEP-Trials

The GEP studies undertaken on wine grapes between 2004 and 2011 were conducted in Austria by "Stähler Austria GmbH. & Co KG" or the "Technisches Büro für Landwirtschaft" and in Germany by "Versuchswesen Pflanzenschutz". These organisations are officially recognized for efficacy testing by their respective Ministries of Agriculture. An overview of the test facilities, country, test report numbers and GEP certificate status is given inTable 6.7- 1 immediately below. Copies of the GEP certificates are given in KIIIA 6.6/01.

Table 6.7- 1: Test facilities, test report numbers & GEP certificate for wine grape studies in EU Central

Test facility	Country	Test report no.	GEP certificate
Stähler Austria GmbH. & Co KG	AT	2004MSCHR014; 2004MSCHR015; 2004MSCHR016; 2004MSCHR017; 2004MSCHR018; 2004MSCHR019; 2005MSCHR027; 2005MSCHR028; 2005MSCHR029; 2005MSCHR030; 2005MSCHR033; 2005MSCHR034; 2005MSCHR035; 2005MSCHR037; 2006MSCHR010; 2006MSCHR011; 2007MSCHR014	Yes
Technisches Büro für Landwirtschaft	AT	2005MSCHR031; 2005MSCHR032; 2005MSCHR036; 2007MSCHR015; 2010MSCHR441; 2010MSCHR442; 2011MSCHR433; 2011MSCHR434; 2011MSCHR435	Yes
Versuchswesen Pflanzenschutz	DE	2010MSCHR490; 2010MSCHR491; 2010MSCHR492; 2010MSCHR524; 2011MSCHR493; 2011MSCHR494; 2011MSCHR495; 2011MSCHR504; 2011MSCHR505; 2011MSCHR506; 2011MSCHR507	Yes

Non-GEP-Trials

Table 6.7- 2: Non-GEP test facility

Institute, Authority	Country	Test report no.	Address

University of California	US	1995RFRIT490	Stanislaus County, 733 County Center II Court, Modesto, CA 95355, USA

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

Annex Point	Author	Year	Title Source Report-No. GLP/GEP Published Authority registration No./JKI-No.	Data protection claimed (J=Yes O=Open N=No)	Owner	How considered in dRR Study-Status / Usage
KIIIA1 3.9	Anonymous	2012	Gebrauchsanleitung . N/N J 2579240/347151	J	Sumitomo Chemical	Y
KIIIA1 6	Mander, L.	2003	Twenty years of gibberellin research The Royal Society of Chemistry N/N J 2579247/347158	N	LIT	Y
KIIIA1 6	Petracek, P.D., Silverman, F.P. & Greene, D.W.	2003	A history of commercial plant growth regulators in apple production HortScience N/N J 2579248/347160	N	LIT	Y
KIIIA1 6	Sponsel, V.M. & Hedden, P.	2004	Gibberellin biosynthesis and inactivation In Plant Hormones: Biosynthesis, Signal Transduction, Action 3rd Edition 2004 Davies P.J. (ed) pp N/N J 2579249/347163	N	LIT	Y
KIIIA1 6	Halsey, D.D. & Little, T.M.	1966	GIBBERELLIN TIMING important for table grapes California Agriculture (1966), March, k.A. N/N J 2579250/347165	N	Sumitomo Chemical	Y
KIIIA1 6	Turner, J.N.	1972	Practical uses of gibberellins in agriculture and horticulture Outlook on Agriculture N/N J 2579251/347167	N	Sumitomo Chemical	Y

Annex Point	Author	Year	Title Source Report-No. GLP/GEP Published Authority registration No./JKI-No.	Data protection claimed (J=Yes O=Open N=No)	Owner	How considered in dRR Study-Status / Usage
KIIIA1 6	Sun, T.	2004	Gibberellin Signal Transduction in Stem Elongation & Leaf Growth In Plant Hormones: Biosynthesis, Signal Transduction, Action 3rd Edition 2004 Davies P.J. (ed) pp N/N J 2579252/347169	N	Sumitomo Chemical	Y
KIIIA1 6	Cho, H-T & Kende, H.	1997	Expression of expansion genes is correlated with growth in deepwater rice Plant Cell (1997) k.A. N/N J 2579253/347170	N	Sumitomo Chemical	Y
KIIIA1 6	Uozu, S., Tanaka-Ueguchi, M., Kitano, H., Hattori, K. & Matsuoka, M.	2000	Characterization of XET-related genes of rice Plant Physiol. (2000) 122: 853-859. N/N J 2579254/347171	N	Sumitomo Chemical	Y
KIIIA1 6	Xu, W., Campell, P., Vargheese, A.K. & Braam, J.	1996	The Arabidopsis XET related gene family: environmental and hormonal regulation of expression Plant Journal (1996) N/N J 2579255/347172	N	Sumitomo Chemical	Y
KIIIA1 6.1.1	Vail M.E. & Marois J.J.	1991	Grape cluster architecture and susceptibility of berries to Botrytis cinerea The American Phytopathological Society N/N J 2579256/347173	N	LIT	Y

Annex Point	Author	Year	Title Source Report-No. GLP/GEP Published Authority registration No./JKI-No.	Data protection claimed (J=Yes O=Open N=No)	Owner	How considered in dRR Study-Status / Usage
KIIIA1 6.1.1	Loinger C., Cohen, S. Dror N. & Berlinger M.J.	1977	Effect of grape cluster rot on wine quality Am. J. Enol Viticult. N/N J 2579257/347174	N	LIT	Y
KIIIA1 6.1.1	Böll S., Schwappach P. & Wahl K.	2009	Vergleichende morphologisch-anatomische Untersuchungen zur Wirkung der Wachstumsregulatoren Gibberellin GA3 und Prohexadione-Ca auf den Befruchtungsvorgang, die Samenentwicklung und die Differenzierung der Infloreszenzen bei unterschiedlich sensiblen Reb Sachgebiet Rebschutz und Rebphysiologie ; Bayerische Landesanstalt für Weinbau und Gartenbau; Veitshöchheim, Deutschland 8503.187 N/N J 2579258/347175	N	LIT	Y
KIIIA1 6.1.1	Ipach, R.	2009	Fäulnisvermeidung ¿ Welche Maßnahmen bringen Erfolg? Vortrag 62. Pfälzische Weinbautage N/N J 2579259/347176	N	LIT	Y
KIIIA1 6.1.1	Bleyer, K. & Kast, W.K.	2010	Einsatz von Bioregulatoren in Weinsberg. Immer locker bleiben. Das Deutsche Weinmagazin N/N J 2579260/347177	N	LIT	Y
KIIIA1 6.1.1	Renner, W.	2010	Herbst 2010 Bioregulatoren haben sich bewährt. Haidegger Perspektiven N/N J 2579261/347178	N	LIT	Y

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KIIIA1 6.1.1	Weaver, R.J. & McCune, S.B.	1960	Further studies with gibberellin on Vitis vinifera grapes Botanical Gazette N/N J 2579262/347179	N	LIT	Y
KIIIA1 6.1.1	Weaver R.J., Kasimatis A.N. & McCune S.B.	1962	Studies with gibberellin on wine grapes to decrease bunch rot Am. J. Enol. Vitic. N/N J 2579263/347180	N	LIT	Y
KIIIA1 6.1.1	Romisondo, P., Borzini, G. & Me, G.	1970	The effect of gibberellic acid on the fruit clusters of wine grapes.; (ital. Effetti dell¿acido gibberellico sul grappolo di vitigni da vino) Annali dell Accademia di Agricoltura di Torino, Italy 112 N/N J 2579264/347181	N	LIT	Y
KIIIA1 6.1.1	Rivera, J.C. & Mavrich E.	1978	Lutte contre le Botrytis cinerea: utilisation de la gibberelline pour allonger les grappes de Pinot gris a Mendoza (Argentine). (Engl. Controlling Botrytis cinerea: Utilisation of gibberellin for elongating grapes of Pinot gris in Mendoza (Argentina)). Progr. Agric. Vatic. (Montpellier) N/N J 2579265/347182	N	LIT	Y
KIIIA1 6.1.1	Miele A., Weaver RJ. & Johnson J.	1978	Effect of potassium gibberellate on fruit-set and development of Thompson Seedless and Zinfandel grapes) Am. J. Enol. Vitic. N/N J 2579266/347183	N	LIT	Y

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KIIIA1 6.1.1	Gil, G. & Escobar R.	1979	Empleo del acido giberelico para regular la compactacion de racimos en parronales vigorosos; (Engl. Usefulness of gibberellic acid for regulating grape cluster compactness in vigorous overhead arbors.) Ciencia E Investigation Agraria N/N J 2579267/347184	N	LIT	Y
KIIIA1 6.1.1	Spies, S. & Hill, G.K.	2008	Lockere Trauben durch Gibberelline im Frühjahr? Der Deutsche Weinbau N/N J 2579268/347185	N	LIT	Y
KIIIA1 6.1.1	Fox, R.	2006	Essigfäule Ursachen und Gegenmaßnahmen Das Deutsche Weinmagazin N/N J 2579269/347186	N	LIT	Y
KIIIA1 6.1.1	Teszlák, P., Gaal, K. & Pour-Nikfardajam, M.S.	2005	Influence of grapevine flower treatment with gibberellic acid (GA3) on polyphenol content of Vitis vinifera L. wine. Analytica Chimica Acta N/N J 2579270/347187	N	LIT	Y
KIIIA1 6.1.1	Petgen, M.	2005	Gibberellin-Einstaz zur Qualitätsregulierung Schweiz. Z. Obst-Weinbau N/N J 2579271/347188	N	LIT	Y
KIIIA1 6.1.1	Haas, E., Roschatt, C. & Schweigkofler, W.	2009	Chemische Ausdünnung im Weinbau Obstbau/Weinbau N/N J 2579272/347189	N	LIT	Y

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KIIIA1 6.1.1	Müller, E.	2003	Ertragsregulierung Möglichkeiten, Chancen und Risiken Kreuznacher Wintertagung N/N J 2579273/347190	N	LIT	Y
KIIIA1 6.1.1	Ferree, D.C., Ellis, M.A., McArtney, S.J., Brown, M.V. & Scurlock D.M.	2003	Comparison of Fungicide, Leaf Removal and Gibberellic Acid on Development of Grape Clusters and Botrytis Bunch Rot of Vignoles and Pinot Gris. Small Fruits Review N/N J 2579274/347191	N	LIT	Y
KIIIA1 6.1.1	Weaver, R.J. & Pool, R.M.	1971	Thinning Tokay¿ and Zinfandel¿ grapes by bloom sprays of gibberellin J. Amer. Soc. Hort. Sci. N/N J 2579275/347192	N	LIT	Y
KIIIA1 6.1.1	Petgen, M.	2009	Einsatz von Bioregulatoren Meilensteine in der Fäulnisbekämpfung Das Deutsche Weinmagazin N/N J 2579276/347193	N	LIT	Y
KIIIA1 6.1.1	Siegfried, W. & Jüstrich, H.	2009	Gibberellin-Versuche 2007 im Rebbau Schweiz. Z. Obst-Weinbau (N/N J 2579277/347194	N	LIT	Y
KIIIA1 6.1.1	Hill, G.; Hill, M. & Butterfass, J.	2003	Kleiner, weniger, besser? Das Deutsche Weinmagazin N/N J 2579278/347195	N	LIT	Y

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KIIIA1 6.1.1	Fader, B; Hill, G. & Spies, S.	2004	Locker bleiben. Das Deutsche Weinmagazin N/N J 2579279/347196	N	LIT	Y
KIIIA1 6.1.1	Kast, W.K.; Fox, R. & Schiefer, H.C.	2005	Bio-Wachstumsregulatoren Chancen und Risiken beim Einsatz im Weinbau http://www.landwirtschaft-mlr.baden-wuerttemberg.de/servlet/PB/menu/1169238_l1/index.html N/N J 2579280/347197	N	LIT	Y
KIIIA1 6.1.1	Petgen, M.	2006	Möglichkeiten und Grenzen der Ertragsbildung ¿ Was bringen alternative Ausdünnungsmöglichkeiten wirklich WEINbau N/N J 2579281/347198	N	LIT	Y
KIIIA1 6.1.1	Duncan, R.A.	1996	Timing and concentration of ProGibb for reducing bunch rot in Zinfandel wine grapes in the Sacramento Valley 1995RFRIT490 N/N N 2579282/347199	J	Sumitomo Chemical	Y
KIIIA1 6.1.2	Karrer, R. & Hilweg, M.	2005	To evaluate the potential for thinning in grapevines 04WD312-A3, 2004MSCH N/J N 2579283/347200	J	Sumitomo Chemical	Y
KIIIA1 6.1.3	Karrer, R. & Hilweg, M.	2005	To evaluate the potential for thinning in grapevines. 04WD312-A3, 2004MSCH N/J N 2579284/347201	J	Sumitomo Chemical	Y

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KIIIA1 6.1.3	Karrer, R. & Hilweg, M.	2005	To evaluate the potential for thinning in grapevines 04WD312-A1, 2004MSCH J/J N 2579285/347202	J	Sumitomo Chemical	Y
KIIIA1 6.1.3	Karrer, R. & Hilweg, M.	2005	To evaluate the potential for thinning in grapevines. 04WD312-A2, 2004MSCH N/J N 2579286/347203	J	Sumitomo Chemical	Y
KIIIA1 6.1.3	Karrer, R. & Hilweg, M.	2005	To evaluate the potential for thinning in grapevines 04WD312-A4, 2004MSCH N/J N 2579287/347204	J	Sumitomo Chemical	Y
KIIIA1 6.1.3	Karrer, R. & Hilweg, M.	2005	To evaluate the potential for thinning in grapevines 04WD312-A5, 2004MSCH N/J N 2579288/347205	J	Sumitomo Chemical	Y
KIIIA1 6.1.3	Karrer, R. & Hilweg, M.	2005	To evaluate the potential for thinning in grapevines 04WD312-A6, 2004MSCH N/J N 2579289/347206	J	Sumitomo Chemical	Y
KIIIA1 6.1.3	Karrer, R. & Hilweg, M.	2006	To evaluate the potential for thinning in grapevines 05WD314-A2, 2005MSCH N/J N 2579290/347207	J	Sumitomo Chemical	Y

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KIIIA1 6.1.3	Karrer, R. & Hilweg, M.	2006	To evaluate the potential for thinning in grapevines 05WD314-A3, 2005MSCH N/J N 2579291/347208	J	Sumitomo Chemical	Y
KIIIA1 6.1.3	Fünfkirchen, M. & Hilweg, M.	2006	To evaluate the potential for thinning in grapevines 05WD314-A4, 2005MSCH N/J N 2579292/347209	J	Sumitomo Chemical	Y
KIIIA1 6.1.3	Fünfkirchen, M. & Hilweg, M.	2006	To evaluate the potential for thinning in grapevines 05WD314-A5, 2005MSCH N/J N 2579293/347210	J	Sumitomo Chemical	Y
KIIIA1 6.1.3	Hiebler, A. & Hilweg, M.	2006	Field Test to Evaluate the Efficacy ProGibb for Thinning in Grapevines. 05WD314-A6, 2005MSCH N/J N 2579294/347211	J	Sumitomo Chemical	Y
KIIIA1 6.1.3	Hiebler, A. & Hilweg, M.	2006	Field Test to Evaluate the Efficacy ProGibb for Thinning in Grapevines. 05WD314-A7, 2005MSCH N/J N 2579295/347212	J	Sumitomo Chemical	Y
KIIIA1 6.1.3	Karrer, R. & Hilweg, M.	2006	To evaluate the potential for thinning in grapevines 05WD314-A8, 2005MSCH N/J N 2579296/347213	J	Sumitomo Chemical	Y

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KIIIA1 6.1.3	Karrer, R. & Hilweg, M.	2006	To evaluate the potential for thinning in grapevines 05WD314-A9, 2005MSCH N/J N 2579297/347214	J	Sumitomo Chemical	Y
KIIIA1 6.1.3	Karrer, R. & Hilweg, M.	2006	To evaluate the potential for thinning in grapevines 05WD314-A10, 2005MSC N/J N 2579298/347215	J	Sumitomo Chemical	Y
KIIIA1 6.1.3	Hiebler, A. & Hilweg, M.	2006	Field Test to Evaluate the Efficacy ProGibb for Thinning in Grapevines. 05WD314-A11, 2005MSC N/J N 2579299/347216	J	Sumitomo Chemical	Y
KIIIA1 6.1.3	Karrer, R. & Hilweg, M.	2006	To evaluate the potential for thinning in grapevines 05WD314-A1, 2005MSCH N/J N 2579300/347217	J	Sumitomo Chemical	Y
KIIIA1 6.1.3	Fünfkirchen, M.	2007	To evaluate the potential for thinning in grapevines 06WD317-A2, 2006MSCH N/J N 2579301/347218	J	Sumitomo Chemical	Y
KIIIA1 6.1.3	Fünfkirchen, M.	2007	To evaluate the potential for thinning in grapevines 06WD317-A3, 2006MSCH N/J N 2579302/347219	J	Sumitomo Chemical	Y

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KIIIA1 6.1.3	Fünfkirchen, M.	2007	To generate bridging data (Pro Gibb vs. Berelex) for thinning in grapevines 07WD322-A1, 2007MSCH N/J N 2579303/347220	J	Sumitomo Chemical	Y
KIIIA1 6.1.3	Hiebler, A. & Fünfkirchen, M.	2007	Field Test to Generate Bridging Data (ProGibb vs. Berelex) for Thinning in Grapevines. 07WD322-A2, 2007MSCH N/J N 2579304/347221	J	Sumitomo Chemical	Y
KIIIA1 6.1.3	Hiebler, A.	2011	Field test to evaluate the efficacy and selectivity of different rates of GA3 40% (BERELEX 40 SG) for reducing bunch density and the intensity of grey mould caused by Botrytis cinerea on wine grapes. 2010MSCHR441 N/J N 2579305/347222	J	Sumitomo Chemical	Y
KIIIA1 6.1.3	Hiebler, A.	2011	Field test to evaluate the efficacy and selectivity of different rates of GA3 40% (BERELEX 40 SG) for reducing bunch density and the intensity of grey mould caused by Botrytis cinerea on wine grapes. 2010MSCHR442 N/J N 2579306/347223	J	Sumitomo Chemical	Y
KIIIA1 6.1.3	Reh, P., Braun, K. & Sonneborn, S.	2011	An evaluation of the efficacy of GA3 40% (BERELEX 40 SG) for reducing bunch density and the intensity of grey mould caused by Botrytis cinerea and other vine rot diseases on grapevine. 2010MSCHR490 N/J N 2579307/347224	J	Sumitomo Chemical	Y

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KIIIA1 6.1.3	Reh, P., Braun, K. & Sonneborn, S.	2011	An evaluation of the efficacy of GA3 40% (BERELEX 40 SG) for reducing bunch density and the intensity of grey mould caused by Botrytis cinerea and other vine rot diseases on grapevine. 2010MSCHR491 N/J N 2579308/347225	J	Sumitomo Chemical	Y
KIIIA1 6.1.3	Reh, P., Braun, K. & Sonneborn, S.	2011	An evaluation of the efficacy of GA3 40% (BERELEX 40 SG) for reducing bunch density and the intensity of grey mould caused by Botrytis cinerea and other vine rot diseases on grapevine. 2010MSCHR492 N/J N 2579309/347226	J	Sumitomo Chemical	Y
KIIIA1 6.1.3	Reh, P., Braun, K. & Sonneborn, S.	2011	An evaluation of the efficacy of GA3 40% (BERELEX 40 SG) for reducing bunch density and the intensity of grey mould caused by Botrytis cinerea and other vine rot diseases on grapevine. 2010MSCHR524 N/J N 2579310/347227	J	Sumitomo Chemical	Y
KIIIA1 6.1.3	Hiebler, A.	2011	Field test to evaluate the efficacy and selectivity of different rates of GA3 40% (BERELEX 40 SG) for reducing bunch density and the intensity of grey mould caused by Botrytis cinerea on wine grapes 2011MSCHR433 N/J N 2579311/347228	J	Sumitomo Chemical	Y

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KIIIA1 6.1.3	Hiebler, A.	2011	Field test to evaluate the efficacy and selectivity of different rates of GA3 40% (BERELEX 40 SG) for reducing bunch density and the intensity of grey mould caused by Botrytis cinerea on wine grapes. 2011MSCHR434 N/J N 2579312/347229	J	Sumitomo Chemical	Y
KIIIA1 6.1.3	Hiebler, A.	2011	Field test to evaluate the efficacy and selectivity of different rates of GA3 40% (BERELEX 40 SG) for reducing bunch density and the intensity of grey mould caused by Botrytis cinerea on wine grapes. 2011MSCHR435 N/J N 2579313/347230	J	Sumitomo Chemical	Y
KIIIA1 6.1.3	Reh, P., Heitsch, K., Braun, K. & Sonneborn, S.	2011	An evaluation of the efficacy of GA3 40% (BERELEX 40 SG) for reducing bunch density and the intensity of grey mould caused by Botrytis cinerea and other wine rot diseases on grapevine. 2011MSCHR493 N/J N 2579314/347231	J	Sumitomo Chemical	Y
KIIIA1 6.1.3	Reh, P., Heitsch, K., Braun, K. & Sonneborn, S.	2011	An evaluation of the efficacy of GA3 40% (BERELEX 40 SG) for reducing bunch density and the intensity of grey mould caused by Botrytis cinerea and other wine rot diseases on grapevine. 2011MSCHR494 N/J N 2579315/347232	J	Sumitomo Chemical	Y

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KIIIA1 6.1.3	Reh, P., Heitsch, K., Braun, K. & Sonneborn, S.	2011	An evaluation of the efficacy of GA3 40% (BERELEX 40 SG) for reducing bunch density and the intensity of grey mould caused by Botrytis cinerea and other wine rot diseases on grapevine. 2011MSCHR495 N/J N 2579316/347233	J	Sumitomo Chemical	Y
KIIIA1 6.1.3	Reh, P., Heitsch, K., Braun, K. & Sonneborn, S.	2011	An evaluation of the efficacy of GA3 40% (BERELEX 40 SG) for reducing bunch density and the intensity of grey mould caused by Botrytis cinerea and other wine rot diseases on grapevine. 2011MSCHR504 N/J N 2579317/347234	J	Sumitomo Chemical	Y
KIIIA1 6.1.3	Reh, P., Heitsch, K., Braun, K. & Sonneborn, S.	2011	An evaluation of the efficacy of GA3 40% (BERELEX 40 SG) for reducing bunch density and the intensity of grey mould caused by Botrytis cinerea and other wine rot diseases on grapevine. 2011MSCHR505 N/J N 2579318/347235	J	Sumitomo Chemical	Y
KIIIA1 6.1.3	Reh, P., Heitsch, K., Braun, K. & Sonneborn, S.	2011	An evaluation of the efficacy of GA3 40% (BERELEX 40 SG) for reducing bunch density and the intensity of grey mould caused by Botrytis cinerea and other wine rot diseases on grapevine. 2011MSCHR506 N/J N 2579319/347236	J	Sumitomo Chemical	Y

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KIIIA1 6.1.3	Reh, P., Heitsch, K., Braun, K. & Sonneborn, S.	2011	An evaluation of the efficacy of GA3 40% (BERELEX 40 SG) for reducing bunch density and the intensity of grey mould caused by Botrytis cinerea and other wine rot diseases on grapevine. 2011MSCHR507 N/J N 2579320/347237	J	Sumitomo Chemical	Y
KIIIA1 6.1.3	Vail M.E. & Marois J.J.	1991	Grape cluster architecture and susceptibility of berries to Botrytis cinerea Phytopathol. N/N J 2579321/347239	N	LIT	Y
KIIIA1 6.1.3	Loinger C., Cohen, S. Dror N. & Berlinger M.J.	1977	Effect of grape cluster rot on wine quality Am. J. Enol Viticult. N/N J 2579322/347241	N	LIT	Y
KIIIA1 6.1.3	Ipach, R.	2009	Fäulnisvermeidung Welche Maßnahmen bringen Erfolg? Vortrag 62. Pfälzische Weinbautage . N/N J 2579323/347244	N	LIT	Y
KIIIA1 6.1.3	Bleyer, K. & Kast, W.K.	2010	Einsatz von Bioregulatoren in Weinsberg. Immer locker bleiben. Das Deutsche Weinmagazin N/N J 2579324/347245	N	LIT	Y
KIIIA1 6.1.3	Renner, W.	2010	Herbst 2010 Bioregulatoren haben sich bewährt. Haidegger Perspektiven k.A. N/N J 2579325/347247	N	LIT	Y

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KIIIA1 6.1.3	Hill, G.; Hill, M. & Butterfass, J.	2003	Kleiner, weniger, besser? Das Deutsche Weinmagazin (N/N J 2579326/347249	N	Sumitomo Chemical	Y
KIIIA1 6.1.3	Kast, W.K.; Fox, R. & Schiefer, H.C.	2005	Bio-Wachstumsregulatoren Chancen und Risiken beim Einsatz im Weinbau http://www.landwirtschaft-mlr.baden-wuerttemberg.de/servlet/PB/menu/1169238_l1/index.html, 4 pages N/N J 2579327/347251	N	Sumitomo Chemical	Y
KIIIA1 6.1.3	Duncan, R.A.	1996	Timing and concentration of ProGibb for reducing bunch rot in Zinfandel wine grapes in the Sacramento Valley 1995RFRIT490 N/N N 2579328/347253	J	Sumitomo Chemical	Y
KIIIA1 6.1.4	Karrer, R. & Hilweg, M.	2005	To evaluate the potential for thinning in grapevines 04WD312-A1, 2004MSCH N/J N 2579329/347255	J	Sumitomo Chemical	Y
KIIIA1 6.1.4	Karrer, R. & Hilweg, M.	2005	To evaluate the potential for thinning in grapevines 04WD312-A2, 2004MSCH N/J N 2579330/347257	J	Sumitomo Chemical	Y
KIIIA1 6.1.4	Karrer, R. & Hilweg, M.	2005	To evaluate the potential for thinning in grapevines 04WD312-A4, 2004MSCH N/J N 2579331/347259	J	Sumitomo Chemical	Y

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KIIIA1 6.1.4	Karrer, R. & Hilweg, M.	2005	To evaluate the potential for thinning in grapevines 04WD312-A5, 2004MSCH N/J N 2579332/347261	J	Sumitomo Chemical	Y
KIIIA1 6.1.4	Karrer, R. & Hilweg, M.	2005	To evaluate the potential for thinning in grapevines 04WD312-A6, 2004MSCH N/J N 2579333/347263	J	Sumitomo Chemical	Y
KIIIA1 6.1.4	Karrer, R. & Hilweg, M.	2006	To evaluate the potential for thinning in grapevines 05WD314-A2, 2005MSCH N/J N 2579334/347266	J	Sumitomo Chemical	Y
KIIIA1 6.1.4	Karrer, R. & Hilweg, M.	2006	To evaluate the potential for thinning in grapevines. 05WD314-A3, 2005MSCH N/J N 2579335/347268	J	Sumitomo Chemical	Y
KIIIA1 6.1.4	Fünfkirchen, M. & Hilweg, M.	2006	To evaluate the potential for thinning in grapevines 05WD314-A4, 2005MSCH N/J N 2579336/347269	J	Sumitomo Chemical	Y
KIIIA1 6.1.4	Fünfkirchen, M. & Hilweg, M.	2006	To evaluate the potential for thinning in grapevines 05WD314-A5, 2005MSCH N/J N 2579337/347271	J	Sumitomo Chemical	Y

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KIIIA1 6.1.4	Hiebler, A. & Hilweg, M.	2006	Field Test to Evaluate the Efficacy ProGibb for Thinning in Grapevines. 05WD314-A6, 2005MSCH N/J N 2579338/347274	J	Sumitomo Chemical	Y
KIIIA1 6.1.4	Hiebler, A. & Hilweg, M.	2006	Field Test to Evaluate the Efficacy ProGibb for Thinning in Grapevines. 05WD314-A7, 2005MSCH N/J N 2579339/347276	J	Sumitomo Chemical	Y
KIIIA1 6.1.4	Karrer, R. & Hilweg, M.	2006	To evaluate the potential for thinning in grapevines. 05WD314-A8, 2005MSCH N/J N 2579340/347279	J	Sumitomo Chemical	Y
KIIIA1 6.1.4	Karrer, R. & Hilweg, M.	2006	To evaluate the potential for thinning in grapevines 05WD314-A9, 2005MSCH N/J N 2579341/347281	J	Sumitomo Chemical	Y
KIIIA1 6.1.4	Karrer, R. & Hilweg, M.	2006	To evaluate the potential for thinning in grapevines 05WD314-A10, 2005MSC N/J N 2579342/347284	J	Sumitomo Chemical	Y
KIIIA1 6.1.4	Hiebler, A. & Hilweg, M.	2006	Field Test to Evaluate the Efficacy ProGibb for Thinning in Grapevines. 05WD314-A11, 2005MSC N/J N 2579343/347286	J	Sumitomo Chemical	Y

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KIIIA1 6.1.4	Karrer, R. & Hilweg, M.	2006	To evaluate the potential for thinning in grapevines. 05WD314-A1, 2005MSCH N/J N 2579344/347288	J	Sumitomo Chemical	Y
KIIIA1 6.1.4	Fünfkirchen, M.	2007	To evaluate the potential for thinning in grapevines 06WD317-A2, 2006MSCH N/J N 2579345/347289	J	Sumitomo Chemical	Y
KIIIA1 6.1.4	Fünfkirchen, M.	2007	To evaluate the potential for thinning in grapevines 06WD317-A3, 2006MSCH N/J N 2579346/347292	J	Sumitomo Chemical	Y
KIIIA1 6.1.4	Fünfkirchen, M.	2007	To generate bridging data (Pro Gibb vs. Berelex) for thinning in grapevines 07WD322-A1, 2007MSCH N/J N 2579347/347294	J	Sumitomo Chemical	Y
KIIIA1 6.1.4	Hiebler, A. & Fünfkirchen, M.	2007	Field Test to Generate Bridging Data (ProGibb vs. Berelex) for Thinning in Grapevines. 07WD322-A2, 2007MSCH N/J N 2579348/347295	J	Sumitomo Chemical	Y
KIIIA1 6.1.4	Hiebler, A.	2011	Field test to evaluate the efficacy and selectivity of different rates of GA3 40% (BERELEX 40 SG) for reducing bunch density and the intensity of grey mould caused by Botrytis cinerea on wine grapes. 2010MSCHR441 N/J N 2579349/347298	J	Sumitomo Chemical	Y

Annex Point	**Author**	**Year**	**Title** **Source** **Report-No.** **GLP/GEP** **Published** **Authority registration No./JKI-No.**	**Data protection claimed (J=Yes O=Open N=No)**	**Owner**	**How considered in dRR** Study-Status / Usage
KIIIA1 6.1.4	Hiebler, A.	2011	Field test to evaluate the efficacy and selectivity of different rates of GA3 40% (BERELEX 40 SG) for reducing bunch density and the intensity of grey mould caused by Botrytis cinerea on wine grapes. 2010MSCHR442 N/J N 2579350/347300	J	Sumitomo Chemical	Y
KIIIA1 6.1.4	Reh, P., Braun, K. & Sonneborn, S.	2011	An evaluation of the efficacy of GA3 40% (BERELEX 40 SG) for reducing bunch density and the intensity of grey mould caused by Botrytis cinerea and other vine rot diseases on grapevine. 2010MSCHR490 N/J N 2579351/347302	J	Sumitomo Chemical	Y
KIIIA1 6.1.4	Reh, P., Braun, K. & Sonneborn, S.	2011	An evaluation of the efficacy of GA3 40% (BERELEX 40 SG) for reducing bunch density and the intensity of grey mould caused by Botrytis cinerea and other vine rot diseases on grapevine. 2010MSCHR491 N/J N 2579352/347304	J	Sumitomo Chemical	Y
KIIIA1 6.1.4	Reh, P., Braun, K. & Sonneborn, S.	2011	An evaluation of the efficacy of GA3 40% (BERELEX 40 SG) for reducing bunch density and the intensity of grey mould caused by Botrytis cinerea and other vine rot diseases on grapevine. 2010MSCHR492 N/J N 2579353/347306	J	Sumitomo Chemical	Y

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KIIIA1 6.1.4	Reh, P., Braun, K. & Sonneborn, S.	2011	An evaluation of the efficacy of GA3 40% (BERELEX 40 SG) for reducing bunch density and the intensity of grey mould caused by Botrytis cinerea and other vine rot diseases on grapevine. 2010MSCHR524 N/J N 2579354/347308	J	Sumitomo Chemical	Y
KIIIA1 6.1.4	Hiebler, A.	2011	Field test to evaluate the efficacy and selectivity of different rates of GA3 40% (BERELEX 40 SG) for reducing bunch density and the intensity of grey mould caused by Botrytis cinerea on wine grapes 2011MSCHR433 N/J N 2579355/347310	J	Sumitomo Chemical	Y
KIIIA1 6.1.4	Hiebler, A.	2011	Field test to evaluate the efficacy and selectivity of different rates of GA3 40% (BERELEX 40 SG) for reducing bunch density and the intensity of grey mould caused by Botrytis cinerea on wine grapes. 2011MSCHR434 N/J N 2579356/347313	J	Sumitomo Chemical	Y
KIIIA1 6.1.4	Hiebler, A.	2011	Field test to evaluate the efficacy and selectivity of different rates of GA3 40% (BERELEX 40 SG) for reducing bunch density and the intensity of grey mould caused by Botrytis cinerea on wine grapes. 2011MSCHR435 N/J N 2579357/347315	J	Sumitomo Chemical	Y

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KIIIA1 6.1.4	Reh, P., Heitsch, K., Braun, K. & Sonneborn, S.	2011	An evaluation of the efficacy of GA3 40% (BERELEX 40 SG) for reducing bunch density and the intensity of grey mould caused by Botrytis cinerea and other wine rot diseases on grapevine. 2011MSCHR493 N/J N 2579358/347317	J	Sumitomo Chemical	Y
KIIIA1 6.1.4	Reh, P., Heitsch, K., Braun, K. & Sonneborn, S.	2011	An evaluation of the efficacy of GA3 40% (BERELEX 40 SG) for reducing bunch density and the intensity of grey mould caused by Botrytis cinerea and other wine rot diseases on grapevine. 2011MSCHR494 N/J N 2579359/347319	J	Sumitomo Chemical	Y
KIIIA1 6.1.4	Reh, P., Heitsch, K., Braun, K. & Sonneborn, S.	2011	An evaluation of the efficacy of GA3 40% (BERELEX 40 SG) for reducing bunch density and the intensity of grey mould caused by Botrytis cinerea and other wine rot diseases on grapevine. 2011MSCHR495 N/J N 2579360/347321	J	Sumitomo Chemical	Y
KIIIA1 6.1.4	Reh, P., Heitsch, K., Braun, K. & Sonneborn, S.	2011	An evaluation of the efficacy of GA3 40% (BERELEX 40 SG) for reducing bunch density and the intensity of grey mould caused by Botrytis cinerea and other wine rot diseases on grapevine. 2011MSCHR504 N/J N 2579361/347323	J	Sumitomo Chemical	Y

Annex Point	Author	Year	Title Source Report-No. GLP/GEP Published Authority registration No./JKI-No.	Data protection claimed (J=Yes O=Open N=No)	Owner	How considered in dRR Study-Status / Usage
KIIIA1 6.1.4	Reh, P., Heitsch, K., Braun, K. & Sonneborn, S.	2011	An evaluation of the efficacy of GA3 40% (BERELEX 40 SG) for reducing bunch density and the intensity of grey mould caused by Botrytis cinerea and other wine rot diseases on grapevine. 2011MSCHR505 N/J N 2579362/347326	J	Sumitomo Chemical	Y
KIIIA1 6.1.4	Reh, P., Heitsch, K., Braun, K. & Sonneborn, S.	2011	An evaluation of the efficacy of GA3 40% (BERELEX 40 SG) for reducing bunch density and the intensity of grey mould caused by Botrytis cinerea and other wine rot diseases on grapevine. 2011MSCHR506 N/J N 2579363/347328	J	Sumitomo Chemical	Y
KIIIA1 6.2.1	Karrer, R. & Hilweg, M.	2005	To evaluate the potential for thinning in grapevines 04WD312-A3, 2004MSCH N/J N 2579364/347330	J	Sumitomo Chemical	Y
KIIIA1 6.2.1	Karrer, R. & Hilweg, M.	2005	To evaluate the potential for thinning in grapevines 04WD312-A1, 2004MSCH N/J N 2579365/347332	J	Sumitomo Chemical	Y
KIIIA1 6.2.1	Karrer, R. & Hilweg, M.	2005	To evaluate the potential for thinning in grapevines 04WD312-A2, 2004MSCH N/J N 2579366/347333	J	Sumitomo Chemical	Y

Annex Point	Author	Year	Title Source Report-No. GLP/GEP Published Authority registration No./JKI-No.	Data protection claimed (J=Yes O=Open N=No)	Owner	How considered in dRR Study-Status / Usage
KIIIA1 6.2.1	Karrer, R. & Hilweg, M.	2005	To evaluate the potential for thinning in grapevines 04WD312-A4, 2004MSCH N/J N 2579367/347335	J	Sumitomo Chemical	Y
KIIIA1 6.2.1	Karrer, R. & Hilweg, M.	2005	To evaluate the potential for thinning in grapevines 04WD312-A5, 2004MSCH N/J N 2579368/347337	J	Sumitomo Chemical	Y
KIIIA1 6.2.1	Karrer, R. & Hilweg, M.	2005	To evaluate the potential for thinning in grapevines 04WD312-A6, 2004MSCH N/J N 2579369/347339	J	Sumitomo Chemical	Y
KIIIA1 6.2.1	Karrer, R. & Hilweg, M.	2006	To evaluate the potential for thinning in grapevines. 05WD314-A2, 2005MSCH N/J N 2579370/347341	J	Sumitomo Chemical	Y
KIIIA1 6.2.1	Karrer, R. & Hilweg, M.	2006	To evaluate the potential for thinning in grapevines 05WD314-A3, 2005MSCH N/J N 2579371/347343	J	Sumitomo Chemical	Y
KIIIA1 6.2.1	Fünfkirchen, M. & Hilweg, M.	2006	To evaluate the potential for thinning in grapevines 05WD314-A4, 2005MSCH N/J N 2579372/347345	J	Sumitomo Chemical	Y

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KIIIA1 6.2.1	Fünfkirchen, M. & Hilweg, M.	2006	To evaluate the potential for thinning in grapevines 05WD314-A5, 2005MSCH N/J N 2579373/347347	J	Sumitomo Chemical	Y
KIIIA1 6.2.1	Hiebler, A. & Hilweg, M.	2006	Field Test to Evaluate the Efficacy ProGibb for Thinning in Grapevines. 05WD314-A6, 2005MSCH N/J N 2579374/347349	J	Sumitomo Chemical	Y
KIIIA1 6.2.1	Hiebler, A. & Hilweg, M.	2006	Field Test to Evaluate the Efficacy ProGibb for Thinning in Grapevines. 05WD314-A7, 2005MSCH N/J N 2579375/347351	J	Sumitomo Chemical	Y
KIIIA1 6.2.1	Karrer, R. & Hilweg, M.	2006	To evaluate the potential for thinning in grapevines 05WD314-A8, 2005MSCH N/J N 2579376/347353	J	Sumitomo Chemical	Y
KIIIA1 6.2.1	Karrer, R. & Hilweg, M.	2006	To evaluate the potential for thinning in grapevines 05WD314-A9, 2005MSCH N/J N 2579377/347355	J	Sumitomo Chemical	Y
KIIIA1 6.2.1	Karrer, R. & Hilweg, M.	2006	To evaluate the potential for thinning in grapevines. 05WD314-A10, 2005MSC N/J N 2579378/347357	J	Sumitomo Chemical	Y

Annex Point	Author	Year	Title Source Report-No. GLP/GEP Published Authority registration No./JKI-No.	Data protection claimed (J=Yes O=Open N=No)	Owner	How considered in dRR Study-Status / Usage
KIIIA1 6.2.1	Hiebler, A. & Hilweg, M.	2006	Field Test to Evaluate the Efficacy ProGibb for Thinning in Grapevines. 05WD314-A11, 2005MSC N/J N 2579379/347359	J	Sumitomo Chemical	Y
KIIIA1 6.2.1	Karrer, R. & Hilweg, M.	2006	To evaluate the potential for thinning in grapevines 05WD314-A1, 2005MSCH N/J N 2579380/347361	J	Sumitomo Chemical	Y
KIIIA1 6.2.1	Fünfkirchen, M.	2007	To evaluate the potential for thinning in grapevines 06WD317-A2, 2006MSCH N/J N 2579381/347363	J	Sumitomo Chemical	Y
KIIIA1 6.2.1	Fünfkirchen, M.	2007	To evaluate the potential for thinning in grapevines 06WD317-A3, 2006MSCH N/J N 2579382/347365	J	Sumitomo Chemical	Y
KIIIA1 6.2.1	Fünfkirchen, M.	2007	To generate bridging data (Pro Gibb vs. Berelex) for thinning in grapevines 07WD322-A1, 2007MSCH N/J N 2579383/347366	J	Sumitomo Chemical	Y
KIIIA1 6.2.1	Hiebler, A. & Fünfkirchen, M.	2007	Field Test to Generate Bridging Data (ProGibb vs. Berelex) for Thinning in Grapevines. 07WD322-A2, 2007MSCH N/J N 2579384/347368	J	Sumitomo Chemical	Y

Annex Point	Author	Year	Title Source Report-No. GLP/GEP Published Authority registration No./JKI-No.	Data protection claimed (J=Yes O=Open N=No)	Owner	How considered in dRR Study-Status / Usage
KIIIA1 6.2.1	Hiebler, A.	2011	Field test to evaluate the efficacy and selectivity of different rates of GA3 40% (BERELEX 40 SG) for reducing bunch density and the intensity of grey mould caused by Botrytis cinerea on wine grapes. 2010MSCHR441 N/J N 2579385/347371	J	Sumitomo Chemical	Y
KIIIA1 6.2.1	Hiebler, A.	2011	Field test to evaluate the efficacy and selectivity of different rates of GA3 40% (BERELEX 40 SG) for reducing bunch density and the intensity of grey mould caused by Botrytis cinerea on wine grapes. 2010MSCHR442 N/J N 2579386/347373	J	Sumitomo Chemical	Y
KIIIA1 6.2.1	Reh, P., Braun, K. & Sonneborn, S.	2011	An evaluation of the efficacy of GA3 40% (BERELEX 40 SG) for reducing bunch density and the intensity of grey mould caused by Botrytis cinerea and other vine rot diseases on grapevine. 2010MSCHR490 N/J N 2579387/347374	J	Sumitomo Chemical	Y
KIIIA1 6.2.1	Reh, P., Braun, K. & Sonneborn, S.	2011	An evaluation of the efficacy of GA3 40% (BERELEX 40 SG) for reducing bunch density and the intensity of grey mould caused by Botrytis cinerea and other vine rot diseases on grapevine. 2010MSCHR491 N/J N 2579388/347376	J	Sumitomo Chemical	Y

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KIIIA1 6.2.1	Reh, P., Braun, K. & Sonneborn, S.	2011	An evaluation of the efficacy of GA3 40% (BERELEX 40 SG) for reducing bunch density and the intensity of grey mould caused by Botrytis cinerea and other vine rot diseases on grapevine. 2010MSCHR492 N/J N 2579389/347378	J	Sumitomo Chemical	Y
KIIIA1 6.2.1	Reh, P., Braun, K. & Sonneborn, S.	2011	An evaluation of the efficacy of GA3 40% (BERELEX 40 SG) for reducing bunch density and the intensity of grey mould caused by Botrytis cinerea and other vine rot diseases on grapevine. 2010MSCHR524 N/J N 2579390/347380	J	Sumitomo Chemical	Y
KIIIA1 6.2.1	Hiebler, A.	2011	Field test to evaluate the efficacy and selectivity of different rates of GA3 40% (BERELEX 40 SG) for reducing bunch density and the intensity of grey mould caused by Botrytis cinerea on wine grapes 2011MSCHR433 N/J N 2579391/347383	J	Sumitomo Chemical	Y
KIIIA1 6.2.1	Hiebler, A.	2011	Field test to evaluate the efficacy and selectivity of different rates of GA3 40% (BERELEX 40 SG) for reducing bunch density and the intensity of grey mould caused by Botrytis cinerea on wine grapes. 2011MSCHR434 N/J N 2579392/347385	J	Sumitomo Chemical	Y

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KIIIA1 6.2.1	Hiebler, A.	2011	Field test to evaluate the efficacy and selectivity of different rates of GA3 40% (BERELEX 40 SG) for reducing bunch density and the intensity of grey mould caused by Botrytis cinerea on wine grapes. 2011MSCHR435 N/J N 2579393/347387	J	Sumitomo Chemical	Y
KIIIA1 6.2.1	Reh, P., Heitsch, K., Braun, K. & Sonneborn, S.	2011	An evaluation of the efficacy of GA3 40% (BERELEX 40 SG) for reducing bunch density and the intensity of grey mould caused by Botrytis cinerea and other wine rot diseases on grapevine. 2011MSCHR493 N/J N 2579394/347389	J	Sumitomo Chemical	Y
KIIIA1 6.2.1	Reh, P., Heitsch, K., Braun, K. & Sonneborn, S.	2011	An evaluation of the efficacy of GA3 40% (BERELEX 40 SG) for reducing bunch density and the intensity of grey mould caused by Botrytis cinerea and other wine rot diseases on grapevine. 2011MSCHR494 N/J N 2579395/347391	J	Sumitomo Chemical	Y
KIIIA1 6.2.1	Reh, P., Heitsch, K., Braun, K. & Sonneborn, S.	2011	An evaluation of the efficacy of GA3 40% (BERELEX 40 SG) for reducing bunch density and the intensity of grey mould caused by Botrytis cinerea and other wine rot diseases on grapevine. 2011MSCHR495 N/J N 2579396/347393	J	Sumitomo Chemical	Y

Annex Point	Author	Year	Title Source Report-No. GLP/GEP Published Authority registration No./JKI-No.	Data protection claimed (J=Yes O=Open N=No)	Owner	How considered in dRR Study-Status / Usage
KIIIA1 6.2.1	Reh, P., Heitsch, K., Braun, K. & Sonneborn, S.	2011	An evaluation of the efficacy of GA3 40% (BERELEX 40 SG) for reducing bunch density and the intensity of grey mould caused by Botrytis cinerea and other wine rot diseases on grapevine. 2011MSCHR504 N/J N 2579397/347395	J	Sumitomo Chemical	Y
KIIIA1 6.2.1	Reh, P., Heitsch, K., Braun, K. & Sonneborn, S.	2011	An evaluation of the efficacy of GA3 40% (BERELEX 40 SG) for reducing bunch density and the intensity of grey mould caused by Botrytis cinerea and other wine rot diseases on grapevine. 2011MSCHR505 N/J N 2579398/347397	J	Sumitomo Chemical	Y
KIIIA1 6.2.1	Reh, P., Heitsch, K., Braun, K. & Sonneborn, S.	2011	An evaluation of the efficacy of GA3 40% (BERELEX 40 SG) for reducing bunch density and the intensity of grey mould caused by Botrytis cinerea and other wine rot diseases on grapevine. 2011MSCHR506 N/J N 2579399/347399	J	Sumitomo Chemical	Y
KIIIA1 6.2.1	Reh, P., Heitsch, K., Braun, K. & Sonneborn, S.	2011	An evaluation of the efficacy of GA3 40% (BERELEX 40 SG) for reducing bunch density and the intensity of grey mould caused by Botrytis cinerea and other wine rot diseases on grapevine. 2011MSCHR507 N/J N 2579400/347401	J	Sumitomo Chemical	Y
KIIIA1 6	Schröder, M.	2012	Biological Assessment Report: VBC-BERELEX 40 SG-11-S6-B N/N N 2579401/347404	J	Sumitomo Chemical	Y

Annex Point	**Author**	**Year**	**Title** **Source** **Report-No.** **GLP/GEP** **Published** **Authority registration No./JKI-No.**	**Data protection claimed** **(J=Yes** **O=Open** **N=No)**	**Owner**	**How considered in dRR** Study-Status / Usage
MIIIA1 Sec 6	Sumitomo Chemical Agro Europe	2012	dRR - B6 - nat. add. - DE - 006977-00/02 - Berelex 40 SG k.A. N/N N 2579409/347417	J	Sumitomo Chemical	Y
MIIIA1 Sec 6	Sumitomo Chemical Agro Europe	2012	dRR - B6 - nat. add. - DE - 006977-00/02 - Berelex 40 SG k.A. N/N N 2579410/347419	J	Sumitomo Chemical	Y
MIIIA1 Sec 7	Sumitomo Chemical Agro Europe	2012	dRR - B7 - core assess. - DE - 006977-00/02 - Berelex 40 SG k.A. N/N N 2579411/347422	J	Sumitomo Chemical	Y
MIIIA1 Sec 7	Sumitomo Chemical Agro Europe	2012	dRR - B7 - core assess. - DE - 006977-00/02 - Berelex 40 SG k.A. N/N N 2579412/347424	J	Sumitomo Chemical	Y
KIIIA1 6.2.1	Karrer, R. & Hilweg, M.	2005	To evaluate the potential for thinning in grapevines. k.A. 04WD312-A3, 2004MSCH J/J N 2592717/347438	J	LIT	Y

Appendix 2: GAP table

GAP rev. (No), date: 2014-03-11

PPP (product name/code) Berelex 40 SG
active substance 1 Gibberellinsäure

Formulation type: SG
Conc. of as 1: 400 g/kg

Applicant: Sumitomo Chemical Agro Europe GmbH
Zone(s): central zone

professional use x
non professional use ☐

Verified by MS: yes

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 e.g. recommended or mandatory tank mixtures
					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		
001	DE	grape vine (VITVI)	F	easing structure of grape-stalk (YTRLO)	spraying or fine spraying (low volume spraying)	BBCH 62 to 68 preventive	a) 1 b) 1	a) 50 g/ha b) 50 g/ha	a) 20 g as/ha b) 20 g ashaL	1000 L		

Remarks:

(1) Numeration of uses in accordance with the application/as verified by MS
(2) Member State(s) or zone for which use is applied for
(3) 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)
(4) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(5) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds, developmental stages
(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 of treatment(s) (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 applications possible under practical conditions of use for each single application and per year (permanent crops) or crop (annual crops) must be provided
(8) Min. interval between applications (days) were relevant

(10) The application rate of the product a) max. rate per appl. and b) max. total rate per crop/season must be given in metric units (e.g. kg or L product / ha)

(11) The application rate of the active substance a) max. rate per appl. and b) max. total rate per crop/season must be given in metric units (e.g. g or kg / ha)

(12) The range (min/max) of water volume under practical conditions of use must be given (L/ha)

(13) PHI - minimum pre-harvest interval
(14) Remarks may include: Extent of use/economic importance/restrictions/minor use etc.