REGISTRATION REPORT
Part A

Risk Management

Product name: Banarg
Product code: -
Active Substance: Ethylene 40 g/kg

COUNTRY: Germany
Central Zone
Zonal Rapporteur Member State: Germany

NATIONAL ASSESSMENT

Applicant: Linde AG
Submission date: 03/07/2015
Finalisation date: 10/10/2017

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PART A – Risk Management

This document describes the acceptable use conditions required for the registration of Banarg containing Ethylene in Germany. This evaluation is required subsequent to the inclusion of Ethylene on Annex 1.

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

This document describes the specific conditions of use and labelling required for Germany for the registration of Ethylene.

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

Appendix 2: The submitted draft product label has been checked by the competent authority. The applicant is requested to amend the product label in accordance with the decisions made by the competent authority. The final version of the label has to fulfil the requirements according to Article 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.

Appendix 4 of this document provides a copy of the final product authorisation Germany.

1 Details of the application

1.1 Application background

This application was submitted by Linge Agroconsultancy B.V. on behalf of Linde AG, Linde Gas Division on 03.07.2015.

The application was for approval of Banarg, a compressed gas containing 40 g/kg ethylene for use as a growth regulator for post-harvest use for ripening and degreening of bananas and degreening of citrus fruit.

1.2 Annex I inclusion

Ethylene was included in Annex I of Directive 91/414/EEC by Commission Directive 2008/127/EC of 18 December 2008. The directive entered into force on 1st September 2009. The active substance was also approved under Regulation (EC) 1107/2009 by Regulation (EC) 540/2011, which was updated by Regulation (EC) 187/2013.

The approval Regulation for ethylene (EC) 187/2013 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 the ethylene, and in particular Appendices I and III thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 01/02/2013. On the basis of the proposed and supported uses (see Point 2.3 Product uses), the following issues have been identified as requiring particular attention from all Member States, in the framework of any authorisations to be granted:

(1) the active substance ethylene should have a purity of 99.9% with < 1 mg/kg ethylene oxide
(2) the protection of operators, workers and bystanders. Conditions of authorisation shall include, where appropriate, risk mitigation measures.

These issues were evaluated in the dossier of Barnag and were concluded to result in a safe uses.

1.3 Regulatory approach

To obtain approval the product Barnag 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 first approval of this 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 Banarg, it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B, sections 1 - 8 and Part C.

1.5 Letters of Access

Regarding the data for the active substance, the applicant presented a LoA from the Ethylen-Task Force.

2 Details of the authorisation

2.1 Product identity

Product Name Code	Banarg Ethylene 4 %
Authorization Number (for re-registration)	X008487-00/00
Function	Plant Growth Regulator
Applicant	Linde AG, Linde Gas Division
Composition	40 g/kg Ethylene
Formulation type	Gas [Code: DA]
Packaging	Cylinder of 20 L to 50 L at 200 bar

2.2 Classification and labelling

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

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

Hazard classes and categories:	
None	
Hazard pictograms:	
GHS04	Compressed gas
Signal word:	
Warning	
Hazard statements:	
H280	Contains gas under pressure; may explode if heated
Precautionary statemtents:	
P403	Store in a well ventilated place.
P410	Protect from sunlight.
Special rule for labelling of PPP:	
EUH401	To avoid risks to man and the environment, comply with the instructions for use.
Further labelling statements under Regulation (EC) No 1272/2008:	
None	

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

None

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

2.3.1 Restrictions linked to the PPP

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

Human health protection	
SB001	Avoid any unnecessary contact with the product. Misuse can lead to health damage.
SB005	If medical advice is needed, have product container or label at hand.
SB010	Keep out of the reach of children.
SB110	The directive concerning requirements for personal protective gear in plant protection, "Personal protective gear for handling plant protection products" of the Federal Office of Consumer Protection and Food Safety must be observed.
SB166	Do not eat, drink or smoke when using this product.
SE1201	Wear tight fitting eye protection when applying/handling the product.

SF1471	During the period of control, rooms may only be entered with respiratory equipment. After the period of control/before the rooms are re-entered, they must be aired thoroughly.
SF169	The rooms/stores must be marked with a warning sign during treatment.
SF250	Treated rooms may not be entered after airing without protective respiratory equipment until the concentration of ethylene in the room is below 1 ppm.
SS1201	Wear standard protective gloves (plant protection) when handling/applying the product.
SS2204	Wear a protective suit for plant protection products and sturdy shoes (e.g. rubber boots) when applying/handling the product.
ST2203	When applying/handling the product, a half mask with combination filter A2-P2 (identification colour: brown/white) must be worn according to the BVL Directive on requirements regarding personal protective equipment in plant protection, as amended.
Integrated pest management (IPM)/sustainable use	
	Mode of action (HRAC group): none (Growth regulator)
NB663	Due to the manner in which authorisation governs application of the product, bees are not endangered.(B3)
Ecosystem protection	
NW467	The product and its remains, empty containers and packaging 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.

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

Integrated pest management (IPM)/sustainable use	
NN000	Due to the manner in which authorisation governs application of the product, populations of relevant beneficial organisms are not endangered.

2.3.2 Specific restrictions linked to the intended uses

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

Integrated pest management (IPM)/sustainable use	
WH963-1	The use of plant growth regulators can cause undesired side effects depending on the species and variety of the crops and also external conditions. Observe the advice of the plant protection service and the sensitivity of the cultivar.
Ecosystem protection	
none	

2.4 Product uses

GAP-Table of intended uses for Germany

GAP rev. (No), date: 2017-05-23

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PPP (product name/code) **Banarg**
active substance 1 **Ethylene**

Formulation type: **GA**
Conc. of as 1: **40.00 g/kg (c)**

safener -
synergist -

Conc. of safener: -
Conc. of synergist: -

Applicant: **Linde AG**
Zone(s): **central/interzonal**

professional use ☒
non professional use ☐

Verified by MS: Yeso

-

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	banana (MUBSS)	K M	Increase of fruit-ripening (YREIF), fruit degreening (YFENTG)	fumigate from gas cylinder	After harvest, immediately before placing on the market	a) 1 b) 1 (24 hours per stored batch of bananas)	a) 25 L/m³ b) 25.00 L/m³	a) 1.00 L/m³ b) 1.00 L/m³	001	1	Dose range 11,25 -25 L/m³ WH963-1
002	DE	sweet orange (CIDSI)	K M	fruit degreening (YFENTG)	fumigate from gas cylinder	Immediately after harvest, before storage ~~during gathering the harvest in the storage room~~	a) 1 b) 1 (72 hours per stored batch of citrus fruits)	a) 0.25 L/m³ b) 0.25 L/m³	a) 0.01 L/m³ b) 0.01 L/m³	002	F*	Dose range 0,025-0,25 L/m³ WH963-1 * 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.
003	DE	mandarin (CIDRE)	K M	fruit degreening (YFENTG)	fumigate from gas cylinder	Immediately after harvest before storage, ~~during gathering the harvest in the storage room~~	a) 1 b) 1 (72 hours per stored batch of citrus fruits)	a) 0.25 L/m³ b) 0.25 L/m³	a) 0.01 L/m³ b) 0.01 L/m³	003	F	Dose range 0,025-0,25 L/m³ WH963-1
004	DE	lemon (CIDLI)	K M	fruit degreening (YFENTG)	fumigate from gas cylinder	Immediately after harvest, before storage ~~during gathering the harvest in the storage room~~	a) 1 b) 1 (72 hours per stored batch of citrus fruits)	a) 0.25 L/m³ b) 0.25 L/m³	a) 0.01 L/m³ b) 0.01 L/m³	004	F	Dose range 0,025-0,25 L/m³ WH963-1
005	DE	lime (CIDAF)	K M	fruit degreening (YFENTG)	fumigate from gas cylinder	Immediately after harvest, before storage ~~during gathering the harvest in the storage room~~	a) 1 b) 1 (72 hours per stored batch of citrus fruits)	a) 0.25 L/m³ b) 0.25 L/m³	a) 0.01 L/m³ b) 0.01 L/m³	005	F	Dose range 0,025-0,25 L/m³ WH963-1
006	DE	grapefruit (CIDPA)	K M	fruit degreening (YFENTG)	fumigate from gas cylinder	Immediately after harvest, before storage ~~during gathering the harvest in the storage room~~	a) 1 b) 1 (72 hours per stored batch of citrus fruits)	a) 0.25 L/m³ b) 0.25 L/m³	a) 0.01 L/m³ b) 0.01 L/m³	006	F	Dose range 0,025-0,25 L/m³ WH963-1

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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 Banarg is a gas formulation (GA) composed of 4% w/w of ethylene in nitrogen gas. It has no apparent undesirable physico-chemical properties. Its properties indicate that no particular problems are to be expected when the preparation is handled, stored or applied as recommended.

Implications for labelling:

Warning.

Hazard statement:
H280: Contains gas under pressure; may explode if heated

Compliance with FAO specifications: not applicable since there are no FAO specifications for plant protection products formulated as gas.

Compatibility of mixtures: No mixtures with other chemicals are recommended on the product label.

Nature and characteristics of the packaging: Information with regard to type, dimensions, capacity, quality of the packaging, have been submitted in the EU dossier, evaluated and is considered to be acceptable. An expert statement on the compatibility with the formulation was submitted sufficiently proofing that the content can be stored safe in the proposed steel cylinders.

Nature and characteristics of the protective clothing and equipment:
Not applicable

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)

Ethylene active substance is a product of high purity (approximately 99.9%) produced at high industrial volumes. The main impurities are methane and ethane and there are no impurities or additives know to represent any risk of toxicity.

A method to determine residues in and/or on plants, plant products, foodstuffs (of plant and animal origin), feeding stuffs is not required as Ethylene is a product naturally emitted by fruits, flowers, and other vegetation and no MRL is proposed.

An analytical method for the determination of the active substance in the plant protection products and in air were assessed in the EU review (Draft Assessment Report, 2007). A GC-FID method with a LOQ of 0.6 µg/kg in air is available.

Ethylene oxide is not a significant impurity in the technical ethylene (<1 mg/kg) but might be formed in air outside the gassing facility upon photo-oxidation. A method for determination of ethylene oxide was evaluated in the Draft Assessment Report (2007).

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

Analytical methods for the determination of residues of ethylene in food of plant and animal origin, soil and water are not required as no MRLs are set and environmental contamination is not expected. For the determination of ethylene in air, a method was assessed in the EU peer review. However, this method was not validated according to the Guidance Document SANCO/825/00 rev. 8.1. This data gap should be addressed in the context of the next renewal of the approval of ethylene according to Reg. (EC) No 1107/2009. Methods for body fluids and tissues are not required since ethylene is not classified as toxic or highly toxic.

3.1.3 Mammalian Toxicology

If used properly and according to the intended conditions of use, adverse health effects for operators, workers, bystanders and residents will not be expected.
As a result of the German assessment no additional evaluation is regarded necessary to cover the national situation. For further details please refer to the registration report of the zonal RMS NL.

3.1.3.1 Acute Toxicity

Please refer to the registration report of the zonal RMS NL.

3.1.3.2 Operator Exposure

Please refer to the registration report of the zonal RMS NL.

3.1.3.3 Bystander Exposure

Please refer to the registration report of the zonal RMS NL.

3.1.3.4 Worker Exposure

Please refer to the registration report of the zonal RMS NL.

Implications for labelling resulting from operator, worker, bystander assessments:
See 2.2

3.1.4 Residues and Consumer Exposure

Not relevant. No MRL is proposed for fruits. Ethylene has been included in Annex IV to Reg. (EC) No 396/2005. A risk for consumers through the consumption of food possibly containing residues of the active substances is not expected.
For further details please refer to the registration report of the zonal RMS NL.

3.1.4.1 Residues

Please refer to the registration report of the zonal RMS NL.

3.1.4.2 Consumer exposure

Please refer to the registration report of the zonal RMS NL.

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

As the intended product use is only indoor, the contamination of soil, surface water, groundwater or air is unlikely. For details please refer to the core assessment.

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

see above

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

see above

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

see above

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

see above

Implications for labelling resulting from environmental fate assessment: (Phrase **Rxx** should be added to the label)
none

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

No relevant exposure of non-target organisms is to be expected from the intended use of Ethylene 100%.

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

Exposure of birds and other terrestrial vertebrates from the use of Banarg as storage treatment is expected to be negligible.
Thus TER values were not calculated. The results of the assessment indicate an acceptable risk for birds due to the intended use of Banarg in fruit storage according to the label.

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

TER values for aquatic organisms were not calculated, taking into account the expected negligible exposure of surface water to the product Banarg.
The results of the assessment indicate an acceptable risk for aquatic organisms due to the intended use of Banarg in storage fruit treatment according to the label.

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

Bees

No data have been submitted. Due to the representative uses of ethylene, exposure is considered to be minimal and hence data are not required. The voluntary labelling NB663 (Due to the manner in which authorisation governs application of the product, bees are not endangered.(B3)) is assigned.

Other non-target arthropods

TER values for non-target arthropods in off-field habitats were not calculated. The results of the assessment indicate an acceptable risk for non-target arthropods in off-field habitats due to the intended use of Banarg in storage fruits according to the label.

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

TER values for earthworms and other soil non-target macro- and micro-organisms were not calculated. The results of the assessment indicate an acceptable risk for earthworms and other soil non-target macro- and micro-organisms due to the intended use of Banarg in fruit storage according to the label.

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

not relevant

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

TER values for earthworms and other soil non-target macro- and micro-organisms were not calculated. The results of the assessment indicate an acceptable risk for earthworms and other soil non-target macro- and micro-organisms due to the intended use of Banarg in fruit storage according to the label.

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

TER values for non-target terrestrial plants were not calculated. The results of the assessment indicate an acceptable risk for non-target terrestrial plants due to the intended use of Banarg in fruit storage according to the label.

Implications for labelling resulting from ecotoxicological assessment:

see Chapter 2.2 of this document

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

The applicant did not provide any preliminary trials. Instead an extensive literature review was given. The zRMS agreed that the provided information is sufficient and no additional preliminary trials are required.
The number of trials to suppport the minimum effective dose is limited. However, according to the zRMS a dose related effect was demonstrated, both in banana and citrus fruit. Since the effectiveness is influenced by a number of variables as temperature, humidity, matureness of the fruit, and desired effect (depending on the market demand), the application rate may be adapted as long as the maximum application rates stated in the German GAP are observed. The time of application was changed in accordance with the authorization of the zRMS.
Based on the presented efficacy trial data, literature and expert judgement, the zRMS concluded that Banarg is effective for the ripening and degreening of banana fruit at the proposed dose range of 11,25 -25 L/m³ and application duration of 24 hours as well as for the degreening of citrus fruit at the proposed dose rate range of 0,025-0,25 L/m³ and application duration of 72 hours..
Based on the presented data and data obtained from literature, it is concluded that the product is crop safe in the tested citrus varieties and in banana. No negative effects to the fruits were observed in any of the trials. However, it is known that application of ethylene can cause undesired side effects depending on the sensitivity of crop species and varieties and also external conditions. The advice of plant protection services should be observed (WH963-1).
Populations of relevant beneficial organisms are not endangered due to the application of the product in fumigation chambers.
Resistance development does not need to be considered, because ethylene is a plant hormone that is naturally present in higher plants.

3.2 Conclusions

With regard to efficacy evaluation, all uses applied for can be authorised.

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

With regard to fate and ecotoxicology evaluation, all uses applied for can be authorised.

With respect to toxicology, residues and consumer protection an authorisation can be granted.

Authorisation can be granted for all uses.

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

No further information is required.

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

Appendix 2 – Copy of the product label

The submitted draft product label has been checked by the competent authority. The applicant is requested to amend the product label in accordance with the decisions made by the competent authority. The final version of the label has to fulfil the requirements according to Article 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.

Appendix 4 – Copy of the product authorisation

Bundesamt für
Verbraucherschutz und
Lebensmittelsicherheit

Bundesamt für Verbraucherschutz und Lebensmittelsicherheit
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IHR ZEICHEN
IHRE NACHRICHT VOM

AKTENZEICHEN 200.22100.008487-00/00.129921
(bitte bei Antwort angeben)

DATUM 16. November 2017

ZV3 008487-00/00

Banarg

Zulassungsverfahren für Pflanzenschutzmittel

Bescheid

Das oben genannte Pflanzenschutzmittel

mit dem Wirkstoff:	40 g/kg	Ethylen
Zulassungsnummer:	008487-00	
Versuchsbezeichnungen:	LID-00100-W-0-GA	
Antrag vom:	3. Juli 2015	

wird auf der Grundlage von Art. 29 der Verordnung (EG) Nr. 1107/2009 des Europäischen Parlaments und des Rates vom 21. Oktober 2009 über das Inverkehrbringen von Pflanzenschutzmitteln und zur Aufhebung der Richtlinien 79/117/EWG und 91/414/EWG des Rates (ABl. L 309 vom 24.11.2009, S. 1), wie folgt zugelassen:

Zulassungsende

Die Zulassung endet am 31. August 2023.

Festgesetzte Anwendungsgebiete bzw. Anwendungen

Es werden folgende Anwendungsgebiete bzw. Anwendungen festgesetzt (siehe Anlage 1):

Anwendungs-nummer	Schadorganismus/ Zweckbestimmung	Pflanzen/-erzeugnisse/ Objekte	Verwendungszweck
008487-00/00-006	Fruchtentgrünung	Grapefruit	
008487-00/00-005	Fruchtentgrünung	Limone	
008487-00/00-003	Fruchtentgrünung	Mandarine	
008487-00/00-002	Fruchtentgrünung	Orange	
008487-00/00-004	Fruchtentgrünung	Zitrone	
008487-00/00-001	Fruchtentgrünung, Reifebeschleunigung	Banane	

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:

(NW467)
Mittel und dessen Reste, entleerte Behältnisse oder Packungen sowie Spülflüssigkeiten nicht in Gewässer gelangen lassen. Dies gilt auch für indirekte Einträge über die Kanalisation, Hof- und Straßenabläufe sowie Regen- und Abwasserkanäle.
Begründung:
Der im o.g. Pflanzenschutzmittel enthaltene Wirkstoff Ethylen weist aufgrund seiner Toxizität ein hohes Gefährdungspotenzial für aquatische Organismen auf. Jeder Eintrag von Rückständen in Oberflächengewässer, der den Eintrag als Folge der bestimmungsgemäßen und sachgerechten Anwendung des Mittels entsprechend der guten fachlichen Praxis übersteigt, würde daher zu einer Gefährdung des Naturhaushaltes aufgrund von nicht akzeptablen Auswirkungen auf Gewässerorganismen führen. Da ein erheblicher Anteil der in Oberflächengewässern nachzuweisenden Pflanzenschutzmittelfrachten auf Einträge aus kommunalen Kläranlagen zurückzuführen ist, muss dieser Gefährdung durch die bußgeldbewehrte Anwendungsbestimmung durchsetzbar begegnet werden.

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

Verpackungen

Gemäß § 36 Abs. 1 S. 2 Nr. 1 PflSchG sind für das Pflanzenschutzmittel die nachfolgend näher beschriebenen Verpackungen für den beruflichen Anwender zugelassen:

Verpackungs-art	Verpackungs-material	Anzahl		Inhalt		
		von	bis	von	bis	Einheit
Druckbehälter	Metall	1	16	20,00	50,00	l

Die Verpackungen für den beruflichen Anwender sind wie folgt zu kennzeichnen:
Anwendung nur durch berufliche Anwender zulässig.

Auflagen

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

Kennzeichnungsauflagen:

(SB001)
Jeden unnötigen Kontakt mit dem Mittel vermeiden. Missbrauch kann zu Gesundheitsschäden führen.

(SB005)
Ist ärztlicher Rat erforderlich, Verpackung oder Etikett des Produktes bereithalten.

(SB010)
Für Kinder unzugänglich aufbewahren.

(SB111)
Für die Anforderungen an die persönliche Schutzausrüstung beim Umgang mit dem Pflanzenschutzmittel sind die Angaben im Sicherheitsdatenblatt und in der Gebrauchsanweisung des Pflanzenschutzmittels sowie die BVL-Richtlinie "Persönliche Schutzausrüstung beim Umgang mit Pflanzenschutzmitteln" des Bundesamtes für Verbraucherschutz und Lebensmittelsicherheit (www.bvl.bund.de) zu beachten.

(SB166)
Beim Umgang mit dem Produkt nicht essen, trinken oder rauchen.

(SE1201)
Dicht abschließende Schutzbrille tragen bei der Ausbringung/Handhabung des Mittels.

(SF1471)
Räume während der Einwirkungszeit des Mittels nur mit Atemschutz betreten. Nach der Einwirkungszeit/vor dem Aufenthalt von Personen in den Räumen diese gründlich lüften.

(SF169)

Während der Behandlungsmaßnahmen sind die Räume/Lager mit einem Warnhinweis zu kennzeichnen.

(SF250)
Behandelte Räume dürfen nach der Belüftung ohne Atemschutzausrüstung erst unterhalb einer Ethylenkonzentration von 1 ppm in der Raumluft betreten werden.

(SS1201)
Universal-Schutzhandschuhe (Pflanzenschutz) tragen bei Ausbringung/Handhabung des Mittels.

(SS2204)
Schutzanzug gegen Pflanzenschutzmittel und festes Schuhwerk (z. B. Gummistiefel) tragen bei der Ausbringung/Handhabung des Mittels.

(ST2203)
Halbmaske mit Kombinationsfilter A2-P2 (Kennfarbe: braun/weiß) gemäß BVL-Richtlinie für die Anforderungen an die persönliche Schutzausrüstung im Pflanzenschutz, in der jeweils geltenden Fassung, tragen bei der Ausbringung/Handhabung des Mittels.

Siehe anwendungsbezogene Kennzeichnungsauflagen in Anlage 1, jeweils unter Nr. 2.

Vorbehalt

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

Angaben zur Einstufung und Kennzeichnung gemäß Verordnung (EG) Nr. 1272/2008

Signalwort:

(S1) Achtung

Gefahrenpiktogramme:

(GHS04) Gasflasche

Gefahrenhinweise (H-Sätze):
(H280)
Enthält Gas unter Druck; kann bei Erwärmung explodieren.

(EUH 401)
Zur Vermeidung von Risiken für Mensch und Umwelt die Gebrauchsanleitung einhalten.

Sicherheitshinweise (P-Sätze):
(P403)
An einem gut belüfteten Ort aufbewahren.

(P410)
Vor Sonnenbestrahlung schützen.

Abgelehnte Anwendungsgebiete bzw. Anwendungen

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

Hinweise

Auf dem Etikett und in der Gebrauchsanleitung kann angegeben werden:
(NB663)
Aufgrund der durch die Zulassung festgelegten Anwendungen des Mittels werden Bienen nicht gefährdet (B3).

(NN000)
Aufgrund der durch die Zulassung festgelegten Anwendungen des Mittels werden Populationen relevanter Nutzorganismen nicht gefährdet.

Weitere Hinweise und Bemerkungen
Vorsorglich weise ich darauf hin, dass bisher mitgeteilte Forderungen bestehen bleiben, soweit sie noch nicht erfüllt sind.

Unterbleibt eine Beanstandung der vorgelegten Gebrauchsanleitung, so ist daraus nicht zu schließen, dass sie als ordnungsgemäß angesehen wird. Die Verantwortung des Zulassungsinhabers für die Übereinstimmung mit dem Zulassungsbescheid bleibt bestehen.

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: 008487-00/00-001

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Fruchtentgrünung, Reifebeschleunigung

Pflanzen/-erzeugnisse/Objekte: Banane

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Obstbau
Anwendungsbereich:	Begasungskammer mit Kreislaufbegasung
Anwendung im Haus- und Kleingartenbereich:	Nein
Anwendungszeitpunkt:	Nach der Ernte, unmittelbar vor der Vermarktung
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	1
- für die Kultur bzw. je Jahr:	1
Anwendungstechnik:	begasen
- Erläuterungen:	aus Gasflasche
Aufwand:	
-	25 l/m³
- Erläuterungen:	Einwirkungszeit: 24 Stunden / Anwendungskonzentration 11,25 - 25 L/m³

2.2 Sonstige Kennzeichnungsauflagen

(WH963-1)
Die Anwendung von Wachstumsregulatoren kann in Abhängigkeit von Art und Sorte der Kulturpflanzen sowie von äußeren Rahmenbedingungen unerwünschte Nebenwirkungen mit sich bringen. Regionale Empfehlungen der Fachberatung und Sortenempfindlichkeiten beachten.

2.3 Wartezeiten

1 Tag	Begasungskammer mit Kreislaufbegasung: Banane

3 Anwendungsbezogene Anwendungsbestimmungen

- keine -

Anlage 1 zugelassene Anwendung: 008487-00/00-002

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Fruchtentgrünung

Pflanzen/-erzeugnisse/Objekte: Orange

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Obstbau
Anwendungsbereich:	Begasungskammer mit Kreislaufbegasung
Anwendung im Haus- und Kleingartenbereich:	Nein
Anwendungszeitpunkt:	Unmittelbar nach der Ernte, vor der Einlagerung
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	1
- für die Kultur bzw. je Jahr:	1
Anwendungstechnik:	begasen
- Erläuterungen:	aus Gasflasche
Aufwand:	
-	0,25 l/m³
- Erläuterungen:	Einwirkzeit: 72 Stunden / Anwendungskonzentration 0,025 - 0,25 L/m³

2.2 Sonstige Kennzeichnungsauflagen

(WH963-1)
Die Anwendung von Wachstumsregulatoren kann in Abhängigkeit von Art und Sorte der Kulturpflanzen sowie von äußeren Rahmenbedingungen unerwünschte Nebenwirkungen mit sich bringen. Regionale Empfehlungen der Fachberatung und Sortenempfindlichkeiten beachten.

2.3 Wartezeiten

(F)	Begasungskammer mit Kreislaufbegasung: Orange 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 -

Anlage 1 zugelassene Anwendung: 008487-00/00-003

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Fruchtentgrünung

Pflanzen/-erzeugnisse/Objekte: Mandarine

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Obstbau
Anwendungsbereich:	Begasungskammer mit Kreislaufbegasung
Anwendung im Haus- und Kleingartenbereich:	Nein
Anwendungszeitpunkt:	Unmittelbar nach der Ernte, vor der Einlagerung
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	1
- für die Kultur bzw. je Jahr:	1
Anwendungstechnik:	begasen
- Erläuterungen:	aus Gasflasche
Aufwand:	
-	0,25 l/m³
- Erläuterungen:	Einwirkzeit: 72 Stunden / Anwendungskonzentration 0,025 - 0,25 L/m³

2.2 Sonstige Kennzeichnungsauflagen

(WH963-1)
Die Anwendung von Wachstumsregulatoren kann in Abhängigkeit von Art und Sorte der Kulturpflanzen sowie von äußeren Rahmenbedingungen unerwünschte Nebenwirkungen mit sich bringen. Regionale Empfehlungen der Fachberatung und Sortenempfindlichkeiten beachten.

2.3 Wartezeiten

(F)	Begasungskammer mit Kreislaufbegasung: Mandarine 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 -

Anlage 1 zugelassene Anwendung: 008487-00/00-004

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Fruchtentgrünung

Pflanzen/-erzeugnisse/Objekte: Zitrone

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Obstbau
Anwendungsbereich:	Begasungskammer mit Kreislaufbegasung
Anwendung im Haus- und Kleingartenbereich:	Nein
Anwendungszeitpunkt:	Unmittelbar nach der Ernte, vor der Einlagerung
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	1
- für die Kultur bzw. je Jahr:	1
Anwendungstechnik:	begasen
- Erläuterungen:	aus Gasflasche
Aufwand:	
-	0,25 l/m³
- Erläuterungen:	Einwirkzeit: 72 Stunden / Anwendungskonzentration 0,025 - 0,25 L/m³

2.2 Sonstige Kennzeichnungsauflagen

(WH963-1)
Die Anwendung von Wachstumsregulatoren kann in Abhängigkeit von Art und Sorte der Kulturpflanzen sowie von äußeren Rahmenbedingungen unerwünschte Nebenwirkungen mit sich bringen. Regionale Empfehlungen der Fachberatung und Sortenempfindlichkeiten beachten.

2.3 Wartezeiten

(F)	Begasungskammer mit Kreislaufbegasung: Zitrone 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 -

Anlage 1 zugelassene Anwendung: 008487-00/00-005

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Fruchtentgrünung

Pflanzen/-erzeugnisse/Objekte: Limone

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Obstbau
Anwendungsbereich:	Begasungskammer mit Kreislaufbegasung
Anwendung im Haus- und Kleingartenbereich:	Nein
Anwendungszeitpunkt:	Unmittelbar nach der Ernte, vor der Einlagerung
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	1
- für die Kultur bzw. je Jahr:	1
Anwendungstechnik:	begasen
- Erläuterungen:	aus Gasflasche
Aufwand:	
-	0,25 l/m³
- Erläuterungen:	Einwirkzeit: 72 Stunden / Anwendungskonzentration 0,025 - 0,25 L/m³

2.2 Sonstige Kennzeichnungsauflagen

(WH963-1)
Die Anwendung von Wachstumsregulatoren kann in Abhängigkeit von Art und Sorte der Kulturpflanzen sowie von äußeren Rahmenbedingungen unerwünschte Nebenwirkungen mit sich bringen. Regionale Empfehlungen der Fachberatung und Sortenempfindlichkeiten beachten.

2.3 Wartezeiten

(F)	Begasungskammer mit Kreislaufbegasung: Limone 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 -

Anlage 1 zugelassene Anwendung: 008487-00/00-006

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Fruchtentgrünung

Pflanzen/-erzeugnisse/Objekte: Grapefruit

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet:	Obstbau
Anwendungsbereich:	Begasungskammer mit Kreislaufbegasung
Anwendung im Haus- und Kleingartenbereich:	Nein
Anwendungszeitpunkt:	Unmittelbar nach der Ernte, vor der Einlagerung
Maximale Zahl der Behandlungen	
- in dieser Anwendung:	1
- für die Kultur bzw. je Jahr:	1
Anwendungstechnik:	begasen
- Erläuterungen:	aus Gasflasche
Aufwand:	
-	0,25 l/m³
- Erläuterungen:	Einwirkzeit: 72 Stunden / Anwendungskonzentration 0,025 - 0,25 L/m³

2.2 Sonstige Kennzeichnungsauflagen

(WH963-1)
Die Anwendung von Wachstumsregulatoren kann in Abhängigkeit von Art und Sorte der Kulturpflanzen sowie von äußeren Rahmenbedingungen unerwünschte Nebenwirkungen mit sich bringen. Regionale Empfehlungen der Fachberatung und Sortenempfindlichkeiten beachten.

2.3 Wartezeiten

(F)	Begasungskammer mit Kreislaufbegasung: Grapefruit 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 5

Environmental Fate

Detailed summary of the risk assessment

Product name(s): Banarg

Chemical active substance:

Ethylene 40 g/kg

Central Zone

Zonal Rapporteur Member State: The Netherlands

NATIONAL ADDENDUM – GERMANY

(authorisation)

Applicant: Linde Gas Benelux B.V.

Submission date: 03.07.2015

MS Finalisation date: November 2016

Version history

When	What
September 2017	final assessment by UBA
29. September 2017	Title Page changed to comply with the template used by the zRMS. Numbering inside the document remained according to the new template.

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8 Fate and behaviour in the environment (KCP 9)

The exposure assessment of the plant protection product Banarg in its intended uses as a ripening agent in bananas and citrus fruits is documented in detail in the core assessment of the plant protection product Banarg dated from November 2016 performed by The Netherlands.
This national addendum has been produced to support a national decision on the authorisation of the product Banarg in Germany for the uses listed below. It reflects the impact of specific German environmental or agricultural circumstances on the exposure and risk assessment for Banarg including risk mitigation measures.

The plant protection product Banarg has not yet been authorized in Germany for storage treatment.

8.1 Critical GAP and overall conclusions

8.1.1 Table of critical GAPs

Table 8.1-1: Critical use pattern of the formulated product

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use-No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			PHI (days)	Remarks: e.g. g safener/ synergist per ha	**Conclusion**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Groundwater
Intended for uses in Germany														
00-001	DE	Banana Plant growth regulator (ripening agent)	I	-	Gassing in a hermetic gassing room within a building	After harvest, storage treatment	a) 1 b) 1	-	1 L/m^3	a) 25 L/m^3 b) 25 L/m^3	-	-		
00-002	DE	Orange Plant growth regulator (ripening agent)	I						0.01 L/m^3	a) 0.25 L/m^3 b) 0.25 L/m^3				
00-003	DE	Mandarin orange Plant growth regulator (ripening agent)	I											
00-004	DE	Lemon Plant growth regulator (ripening agent)	I											
00-005	DE	Lime Plant growth regulator (ripening agent)	I											
00-	DE	Grapefruit	I											

006		Plant growth regulator (ripening agent)												

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

Explanation for column 15 “Conclusion”

A	Safe use
R	Further refinement and/or risk mitigation measures required
N	No safe use

8.1.2 Overall conclusion

The assessment of the intended uses of Banarg was based on the evaluation during Annex I inclusion.

As the product is used only indoor, the contamination of soil, surface water, groundwater or air is unlikely.

Consequences for authorization:

None.

Table 8.1-2: Critical use pattern of Banarg grouped according to use rate

Group	Intended uses	Application rate (L/m^3)
A	Banana Plant growth regulator (ripening agent)	25 L/m^3
B	Orange, mandarin, lemon, lime, grapefruit Plant growth regulator (ripening agent)	0.25 L/m^3

8.2 Metabolites considered in the assessment

Please refer to the core assessment.

8.3 Predicted Environmental Concentrations in soil (PEC_{soil}) (KCP 9.1.3)

Negligible. No contamination of soil expected.
Please refer to the core assessment.

Consequences for authorization:

None.

8.4 Predicted Environmental Concentrations in groundwater (PEC_{gw}) (KCP 9.2.4)

No PEC are considered necessary as for all practical purposes, ethylene is distributed to the air and therefore exposure of the water is considered to be minimal.
Please refer to the core assessment.

Consequences for authorization:

None.

8.5 Predicted Environmental Concentrations in surface water (PEC_{sw}) (KCP 9.2.5)

No PEC are considered necessary as for all practical purposes, ethylene is distributed to the air and therefore exposure of the water is considered to be minimal.
For details please refer to the core assessment.

8.6 Fate and behaviour in air (KCP 9.3, KCP 9.3.1)

The fate and behaviour in air of ethylene was evaluated during the Annex I Inclusion. No additional studies have been performed. In conclusion, as ethylene and ethylene oxide are naturally present in the atmosphere and the manner of use of Banarg indicates that any loading of ethylene and ethylene oxide to air is relatively negligible, there is no additional risk for men and environment due to the use of Linde Gas 100% Ethyleen. For further details please refer to the core assessment.

8.7 Classification and labelling

8.7.1 GHS Classification and labelling

Please refer to the core assessment Part B Section 9.

8.7.2 National labelling

No specific labelling required.

8.7.3 Standard phrases under Regulation (EU) No 547/2011

None.

Appendix 1 Lists of data considered in support of the evaluation

Please refer to the core assessment.

Appendix 2 Detailed evaluation of the new Annex II studies

Not relevant.

REGISTRATION REPORT

Part B

Section 6

Ecotoxicology

Detailed summary of the risk assessment

Product name: Banarg

Chemical active substance:

Ethylene, 40 g/kg

Interzonal

Zonal Rapporteur Member State: The Netherlands

National Addendum

Germany

(authorisation)

Applicant: Linde Gas Benelux B.V.

Submission date: 03/07/2015

MS Finalisation date: November 2016

Version history

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9 Ecotoxicology (KCP 10)

9.1 Critical GAP and overall conclusions

Table 9.1-1: Table of critical GAPs

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
Use-No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			PHI (days)	Remarks: e.g. g safener/ synergist per ha	**Conclusion**						
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Birds	Mammals	Aquatic organisms	Bees	Non-target arthropods	Soil organisms	Non-target plants
National uses (field or outdoor uses, certain types of protected crops)																				
00-001	DE	Banana Plant growth regulator (ripening agent)	I	-	Gassing in a hermetic gassing room within a building	After harvest, storage treatment	a) 1 b) 1	-	25 L/m³	a) 25 L/m³ 25 L/m³	-	-	-							
00-002	DE	Orange Plant growth regulator (ripening agent)	I						0.25 L/m³	a) 0.25 L/m³ b) 0.25 L/m³										
00-003	DE	Mandarin orange Plant growth regulator (ripening agent)	I																	
00-004	DE	Lemon Plant growth regulator (ripening agent)	I																	
00-005	DE	Lime Plant growth regulator (ripening agent)	I																	
00-	DE	Grapefruit	I																	

Banarg
Part B – Section 9 - National Addendum
Germany

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
006		Plant growth regulator (ripening agent)																		

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

Explanation for column 15 – 21 "Conclusion"

A	Acceptable, Safe use
R	Further refinement and/or risk mitigation measures required
C	To be confirmed by cMS
N	No safe use

Remarks table:

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

9.1.1 Overall conclusions

The active substance ethylene was approved under Regulation (EC) 1107/2009 by Regulation (EC) 540/2011. The peer review was finished at 1 February 2013 and the conclusions were laid down in document SANCO/2608/08 rev. 3. (01/02/2013). An amended approval Regulation was published accordingly (Regulation (EC) 187/2013).
The product Banarg was not evaluated as the "representative formulation" during the Annex I inclusion of active substance ethylene. No new data on the active substance or product was provided by the applicant. The existing data was considered adequate by zRMS.

No relevant exposure of non-target organisms is to be expected from the intended use of Banarg .

Consequences for authorisation

None.

9.2 Effects on birds (KCP 10.1.1)

No exposure expected.
Please refer to the core assessment.

9.2.1 Overall conclusions

Exposure of birds from the use of Banarg as storage treatment is expected to be negligible.
Thus TER values for birds were not calculated. The results of the assessment indicate an acceptable risk for birds due to the intended use of Banarg in fruit storage according to the label.

Consequences for authorisation

None.

9.3 Effects on terrestrial vertebrates other than birds (KCP 10.1.2)

No exposure expected.
Please refer to the core assessment.

9.3.1 Overall conclusions

Exposure of mammals from the use of Banarg as storage treatment is expected to be negligible.

Thus TER values were not calculated. The results of the assessment indicate an acceptable risk for mammals due to the intended use of Banarg in fruit storage according to the label.

Consequences for authorisation

None.

9.4 Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) (KCP 10.1.3)

Not yet considered. Exposure is expected to be negligible.

9.5 Effects on aquatic organisms (KCP 10.2)

9.5.1 Toxicity data

Please refer to the core assessment.

9.5.2 Risk assessment

In paragraph III 9.7 of Section B5 of the core dossier, it was concluded that exposure of surface water by ethylene is very unlikely as ethylene is expected to exist almost entirely in the vapour phase and significant deposition to surface water via wet or dry deposition is not likely . PECsw value was not calculated (not considered necessary). No risk has to be expected for aquatic organisms and an aquatic risk assessment therefore is not necessary.

9.5.3 Overall conclusions

TER values for aquatic organisms were not calculated, taking into account the expected negligible exposure of surface water to the product Banarg.
The results of the assessment indicate an acceptable risk for aquatic organisms due to the intended use of Banarg in storage fruit treatment according to the label.

Consequences for authorisation

None.

9.6 Effects on bees (KCP 10.3.1)

Due to the manner in which authorisation governs application of the product, bees are not endangered.

9.7 Effects on arthropods other than bees (KCP 10.3.2)

No new data are generated for Banarg. No relevant co-formulants are present in the product. In the EFSA conclusion (2012;10(1):2508) it was stated that due to the negligible levels of exposure, the risk to arthropods other than bees is considered to be low.

Exposure of arthropods other than bees to ethylene oxide based on the uses supported in the dossier is expected to be minimal. It is considered that this point is not relevant for Ethylene oxide.

Table 9.7-1: Overall conclusions

TER values for non-target arthropods in off-field habitats were not calculated. The results of the assessment indicate an acceptable risk for non-target arthropods in off-field habitats due to the intended use of Banarg in storage fruits according to the label.

Consequences for authorisation

None.

9.8 Effects on non-target soil meso- and macrofauna (KCP 10.4),

Effects on soil microbial activity (KCP 10.5)

Exposure of earthworms and other soil non-target macro- and micro-organisms to ethylene and ethylene oxide based on the uses supported in the dossier is expected to be minimal since the manner of use of Banarg precludes soil contamination. It is considered that this point is not relevant for ethylene and ethylene oxide. For further details please refer to the core assessment.

9.8.1 Overall conclusions

TER values for earthworms and other soil non-target macro- and micro-organisms were not calculated. The results of the assessment indicate an acceptable risk for earthworms and other soil non-target macro- and micro-organisms due to the intended use of Banarg in fruit storage according to the label.

Consequences for authorisation

None.

9.9 Effects on non-target terrestrial plants (KCP 10.6)

No data toxicity have been submitted, however due to the representative uses of ethylene, exposure is considered to be minimal and hence data are not required.
No risk assessment required.

9.9.1 Overall conclusions

TER values for non-target terrestrial plants were not calculated. The results of the assessment indicate an acceptable risk for non-target terrestrial plants due to the intended use of Banarg in fruit storage according to the label.

Consequences for authorisation

None.

9.10 Effects on other terrestrial organisms (flora and fauna) (KCP 10.7)

Not relevant.

9.11 Monitoring data (KCP 10.8)

Not relevant.

9.12 Classification and Labelling

-/- (No data available.)

Appendix 1 Lists of data considered in support of the evaluation

Not relevant.