HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

1. VOORGENOMEN BESLUIT

Op 29 december 2017 is van

Agrauxine S.A.
Rue Henri Becquerel 4
F-49070 BEAUCOUZÉ
France

een aanvraag tot wederzijdse erkenning van een gewasbeschermingsmiddel ontvangen voor het middel

ROMEO

op basis van de werkzame stof Cerevisane.

HET COLLEGE IS VOORNEMENS TE BESLUITEN tot toelating van bovenstaand middel.

Alle bijlagen, waaronder registratierapport deel A en deel B, vormen een onlosmakelijk onderdeel van dit besluit.

1.1 Samenstelling, vorm en verpakking

De toelating geldt uitsluitend voor het middel in de samenstelling, vorm en de verpakking als waarvoor de toelating is verleend.

1.2 Gebruik

Het middel mag slechts worden gebruikt volgens het wettelijk gebruiksvoorschrift, letterlijk en zonder enige aanvulling, zoals opgenomen in deel A van het registratierapport, Appendix I.

1.3 Classificatie en etikettering

Mede gelet op de onder “wettelijke grondslag” vermelde wetsartikelen, dienen alle volgende aanduidingen en vermeldingen conform de geldende regelgeving op of bij de verpakking te worden vermeld:

- De aanduidingen, letterlijk en zonder enige aanvulling, zoals vermeld onder “verpakkingsinformatie” in bijlage I.
- Het wettelijk gebruiksvoorschrift, letterlijk en zonder enige aanvulling, zoals opgenomen in deel A van het registratierapport, Appendix I.
- Overige bij wettelijk voorschrift voorgeschreven aanduidingen en vermeldingen.
- De classificatie die overeenkomstig het toelatingsbesluit is vastgesteld, moet volgens de voorschriften op de verpakking worden vermeld, zoals beschreven in bijlage II en in hoofdstuk 2 van deel A van het registratierapport.

1.4 Aflever- en opgebruiktermijn (respijtperiode)

Niet van toepassing. Het betreft een nieuwe toelating.

2. WETTELIJKE GRONDSLAG

Besluit	artikel 40 van de Verordening (EG) 1107/2009
Classificatie en etikettering	artikel 31 en artikel 65 van de Verordening (EG) 1107/2009
Gebruikt toetsingskader	Bgb en Rgb d.d. 16 december 2011 en Evaluation Manual 2.1 en de Guidance on semiochemicals

3. BEOORDELINGEN

3.1 Fysische en chemische eigenschappen

De aard en de hoeveelheid van de werkzame stoffen en de in humaan-toxicologisch en ecotoxicologisch opzicht belangrijke onzuiverheden in de werkzame stof en de hulpstoffen zijn bepaald. De identiteit van het middel is vastgesteld. De fysische en chemische eigenschappen van het middel zijn vastgesteld en voor juist gebruik en adequate opslag van het middel aanvaardbaar geacht.

3.2 Analysemethoden

De geleverde analysemethoden voldoen aan de vereisten om de residuen te kunnen bepalen die vanuit humaan-toxicologisch en ecotoxicologisch oogpunt van belang zijn, volgend uit geoorloofd gebruik.

3.3 Risico voor de mens

Van het middel wordt voor de toegelaten toepassingen volgens de voorschriften geen onaanvaardbaar risico voor de mens verwacht.

3.4 Risico voor het milieu

Van het middel wordt voor de toegelaten toepassingen volgens de voorschriften geen onaanvaardbaar risico voor het milieu verwacht.

3.5 Werkzaamheid

Van het middel wordt voor de toegelaten toepassingen volgens de voorschriften verwacht dat het werkzaam is.

Voor nadere onderbouwing van de beoordelingen verwijzen wij u naar deel A en B van het Registration Report als toegevoegd aan de bijlagen van dit besluit overeenkomstig Besluit beleidsregel bekendmaken delen A en B van het Registration Report.

Zienswijzenprocedure

Ingevolge artikel 2:3 Besluit bestuursreglement regeling toelating gewasbeschermingsmiddelen en biociden Ctgb 2007 geldt dat dit ontwerpbesluit gedurende twee weken ter inzage wordt gelegd op het Ctgb; hiervan wordt mededeling gedaan in de Staatscourant. Het ontwerpbesluit wordt gedurende deze periode tevens op de website van het Ctgb geplaatst. Belanghebbenden kunnen gedurende de ter inzagelegging schriftelijk bij het Ctgb aangeven dat zij een zienswijze zullen indienen; de zienswijze dient schriftelijk binnen twee weken na de inzageperiode te worden ingediend.

Ede, 7 december 2018

Het College voor de toelating van
gewasbeschermingsmiddelen en biociden,
voor deze:
de voorzitter,

Ir. J.F. de Leeuw

BIJLAGE I DETAILS VAN DE AANVRAAG EN TOELATING

2.1 Aanvraaginformatie

Aanvraagnummer:	20180010 NLWERGZ
Type aanvraag:	aanvraag tot toelating van een gewasbeschermingsmiddel op basis van wederzijdse erkenning
Middelnaam:	ROMEO
Verzenddatum aanvraag:	20 december 2017
*Formele registratiedatum: **	30 januari 2018
Datum in behandeling name:	22 augustus 2018
Datum compliance check:	n.v.t.

* Datum waarop zowel de aanvraag is ontvangen als de aanvraagkosten zijn voldaan.

Aangezien ROMEO een voor Nederland nieuwe werkzame stof bevat (Cerevisane, zie hieronder), is de zienswijzeprocedure zoals bedoeld in artikel 2:3 Besluit bestuursreglement regeling toelating gewasbeschermingsmiddelen en biociden Ctgb 2007 van toepassing.

2.2 Stofinformatie

Werkzame stof	Gehalte
Cerevisane	941 g/kg

- De stof is per 23 april 2015 goedgekeurd volgens Verordening (EU) 1107/2009 (Uitvoeringsverordening (EU) 2015/553 d.d. 7 april 2015). De goedkeuring van deze werkzame stof expireert op 23 april 2030.

2.3 Toelatingsinformatie

Toelatingsnummer:	15726 N
Expiratiedatum:	23 april 2031
Afgeleide parallel of origineel:	Origineel
Biocide, gewasbeschermingsmiddel of toevoegingsstof:	Gewasbeschermingsmiddel
Gebruikers:	Professioneel

2.4 Verpakkingsinformatie

Aard van het preparaat:
Spuitpoeder

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

BIJLAGE II Etikettering van het middel ROMEO

Professioneel gebruik
de identiteit van alle stoffen in het mengsel die bijdragen tot de indeling van het mengsel:
Cerevisane

Pictogram	GHS08
Signaalwoord	Gevaar
Gevarenaanduidingen	H334 Kan bij inademing allergie- of astmasymptomen of ademhalingsmoeilijkheden veroorzaken.
Voorzorgsmaatregelen	P261 Inademing van stof/rook/gas/nevel/damp/spuitnevel vermijden. P304 + P340 NA INADEMING: de persoon in de frisse lucht brengen en ervoor zorgen dat deze gemakkelijk kan ademen. P342 + P311 Bij ademhalingssymptomen: een ANTIGIFCENTRUM of een arts raadplegen.
Aanvullende etiketelementen	EUH401 Volg de gebruiksaanwijzing om gevaar voor de menselijke gezondheid en het milieu te voorkomen. SP 1 Zorg ervoor dat u met het product of zijn verpakking geen water verontreinigt.
Kinderveilige sluiting verplicht	Nee
Voelbare gevaarsaanduiding verplicht	Nee

DRAFT REGISTRATION REPORT

Part A

Risk Management

Product code: ALD1901

Product name(s): ROMEO

Chemical active substance:

Cerevisane (cell walls of *Saccharomyces cerevisiae* strain LAS 117), 941 g/kg

Mutual recognition

Member State: NL

NATIONAL ASSESSMENT

The Netherlands

(authorization of use)

Applicant: Agrauxine S.A.

Date: November 2018

Evaluator: Ctgb, NL

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PART A
RISK MANAGEMENT

1 Details of the application

This document describes the acceptable conditions of use required for the authorisation via mutual recognition from France in the Netherlands of ROMEO, production code ALD1901, containing:

- 941 g/kg Cerevisane which has been approved as a low risk substance in accordance with Regulation (EC) No.1107/2009 (Commission Implementing Regulation (EU) 2015/553 of 7 April 2015.

This Part A NL is written to support the mutual recognition of the product ROMEO currently registered in France (the reference Member State) under the registration number 2170654 for use by professionals only in diverse greenhouse and field cultures. The risk assessment conclusions are based on the information, data and assessments provided in two **Registration Reports, Part B Sections 1-9 and Part C** supporting the interzonal dossier for use in greenhouse and the Southern zone dossier for the field uses for which France has acted as the zRMS.

The information, data and assessments provided in **Registration Report, Parts B** include 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 ALD1901/ROMEO where that data have not been considered in the EU review process. Otherwise assessments for the safe use have been made using endpoints agreed in the EU review of Cerevisane.

This document describes the specific conditions of use and labelling required for the Netherlands for the registration of ROMEO.

Appendix 1 of this document is a copy of the proposed product label.

Appendix 2 of this document is a statement of the purchase of all relevant data.

Appendix 3 of this document is a list of data in support of the evaluation.

1.1 Application background

This application is submitted by Agrauxine S.A. as part of a mutual recognition according to Article 40 of Regulation (EC) No 1107/2009 of the plant protection product ROMEO currently registered in France (AMM 2170654).

France has acted as the izRMS for interzonal use in Greenhouse, and the zRMS for Southern EU zone for field uses.

The application concerns the first approval of ROMEO in the Netherlands. ROMEO is a wettable powder product containing 941 g/kg Cerevisane applied for use as a fungicide.

1.2 Letters of Access

Please note, that although a letter of access to data held by third parties was required for the French application, since that application was made, all relevant data (notably efficacy reports) have been purchased by Agrauxine. A letter of access is therefore not included in this application.

All data are owned by Agrauxine S.A.

Appendix 2 of this document is a copy of the statement of the purchase of all relevant data formerly held by third parties.

1.3 Justification for submission of tests and studies

Studies on dermal irritation, eye irritation and skin sensitisation were available in the original dossier, however, due to the final evaluation of Cerevisane as a chemical active substance during the EU review, the studies were revisited again.

1.4 Data protection claims

Data protection is claimed in accordance with Article 59 of Regulation (EC) No. 1107/2009 as provided for in the list of references in Appendix 3.

2 Details of the authorization decision

2.1 Product identity

Product code	ALD1901
Product name in MS	ROMEO
Authorisation number	-
Function	fungicide
Applicant	Agrauxine S.A.
Active substance(s) (incl. content)	Cerevisane (cell walls of *Saccharomyces cerevisiae* strain LAS 117), 941 g/kg
Formulation type	WP
Packaging	2.5 kg and 5 kg Kraft (paper) bags 2.5 g; 5 g; 10g; 12.5 g; 20 g and 25 g small PET packages 125 g; 250 g; 500g and 1000g HDPE pot 2000 g and 4000 g LDPE bag in Polypropylene (PP) bucket
Coformulants of concern for national authorizations	Not applicable
Restrictions related to identiy	None
Mandatory tank mixtures	Not applicable
Recommended tank mixtures	Not applicable

2.2 Conclusion

The assessment conducted for ROMEO was in accordance with the Uniform Principles and demonstrates an acceptable risk to human health and the environment. An authorisation can therefore be granted.

2.3 Substances of concern for national monitoring

Not applicable

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

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

The identity of all substances in the mixture that contribute to the classification of the mixture *:			
Cerevisane			
Pictogram:	GHS08	Signal word:	Danger
H-statements:	H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.	
P-statements:	P261	Avoid breathing dust/fume/gas/mist/vapours/spray.	
	P304+P340	Remove person to fresh air and keep comfortable for breathing.	
	P342+P311	If experiencing respiratory symptoms: Call a POISON CENTER/doctor/...	
Supplemental Hazard information:	EUH401	To avoid risks to human health and the environment, comply with the instructions for use.	
	SP1	Do not contaminate water with the product or its container.	
Child-resistant fastening obligatory?			not applicable
Tactile warning of danger obligatory?			not applicable

Explanation:	
Pictogram:	According to Reg. (EC) 1272/2008
H-statements:	According to Reg. (EC) 1272/2008
P-statements:	P261, P304+P340 and P342+P311 are prescribed based on the risk assessment to reduce the minimal inhalation expected by mixing and loading powder. Furthermore, they are highly recommended according to CLP.
Other:	SP1 based on guideline 547/2011. EUH401 for all PPPs.

* according to Reg. (EC) 1272/2008, Title III, article 18, 3 (b)

2.5 Intended uses (only NATIONAL GAP)

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f]
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg 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		
Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)													
1	NL	Tomato LYPES	G	Systemic Resistance Inducer (Sclerotiniaceae BOTRCI, SCLESP, BOTRSP)	Foliar spray	BBCH12 to BBCH89 Jan-Dec	a) 8 b) 8	7	a) 0.5 kg/ha b) 4 kg/ha	a) 0.47 kg/ha b) 4.71 kg/ha	100 / 1000	1	Preventive treatment Crop covered by the use No 01146031 (Tomato) in France
Minor uses (field or outdoor uses, certain types of protected crops)													
2	NL	Cucumber CUMSA	F	Systemic Resistance Inducer (Mildew diseases ERYSCI, PODOXA, LEVESP)	Foliar spray	BBCH12 to BBCH89 (April – September)	a) 8 b) 8	7	a) 0.5 kg/ha b) 4 kg/ha	a) 0.47 kg/ha b) 3.76 kg/ha	100 / 1000	1	Preventive treatment Crop covered by the use No 00516001 (Cucumber) in France Minor crop
3	NL	Zucchini, marrow squash with edible peel CUUPG	F	Systemic Resistance Inducer (Mildew diseases ERYSCI, PODOXA, LEVESP)	Foliar spray	BBCH12 to BBCH89 (April – September)	a) 8 b) 8	7	a) 0.5 kg/ha b) 4 kg/ha	a) 0.47 kg/ha b) 3.76 kg/ha	100 / 1000	1	Preventive treatment Crop covered by the use No 00516001 (Cucumber) in France

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f]
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg 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		
													Minor crop
4	NL	Gherkin CUMSG Other edible peal cucurbits	F	Systemic Resistance Inducer (Mildew diseases ERYSCI, PODOXA, LEVESP)	Foliar spray	BBCH12 to BBCH89 (April – September)	a) 8 b) 8	7	a) 0.5 kg/ha b) 4 kg/ha	a) 0.47 kg/ha b) 3.76 kg/ha	100 / 1000	1	Preventive treatment Crop covered by the use No 00516001 (Cucumber) in France Minor crop
5	NL	Melon CUMME	F	Systemic Resistance Inducer (Mildew diseases ERYSCI, PODOXA, UNCISP, SPHRSP PODOSP, PHYLSP, OIDISP MCRSSP, LEVESP, 1GOLOG)	Foliar spray	BBCH12 to BBCH89 (April – October)	a) 8 b) 8	7	a) 0.5 kg/ha b) 4 kg/ha	a) 0.47 kg/ha b) 3.76 kg/ha	100 / 1000	1	Preventive treatment Crop covered by the use No 00516002 (Melon) in France Minor crop
6	NL	Watermelon CITLA	F	Systemic Resistance Inducer (Mildew diseases ERYSCI, PODOXA, UNCISP, SPHRSP PODOSP, PHYLSP, OIDISP MCRSSP, LEVESP, 1GOLOG)	Foliar spray	BBCH12 to BBCH89 (April – October)	a) 8 b) 8	7	a) 0.5 kg/ha b) 4 kg/ha	a) 0.47 kg/ha b) 3.76 kg/ha	100 / 1000	1	Preventive treatment Crop covered by the use No 00516002 (Melon) in France Minor crop
7	NL	Pumpkin CUUMA Other non-edible peel cucurbits	F	Systemic Resistance Inducer (Mildew diseases ERYSCI, PODOXA,	Foliar spray	BBCH12 to BBCH89 (April – October)	a) 8 b) 8	7	a) 0.5 kg/ha b) 4 kg/ha	a) 0.47 kg/ha b) 3.76 kg/ha	100 / 1000	1	Preventive treatment Crop covered by the use No

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f]
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg 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		
				UNCISP, SPHRSP PODOSP, PHYLSP, OIDISP MCRSSP, LEVESP, 1GOLOG)									00516002 (Melon) in France Minor crop
8	NL	Lettuce LACSA and other Salads	F	Systemic Resistance Inducer (Peronosporaceae BREMSP, PEROSP, Botrytis BOTRSP)	Foliar spray	BBCH12 to BBCH89 (February – November)	a) 8 b) 8	7	a) 0.75 kg/ha b) 6 kg/ha	a) 0.71 kg/ha b) 5.65 kg/ha	100 / 1000	1	Preventive treatment Crop covered by the use No 01128015 (Lettuce) in France Minor crop
9	NL	Strawberry FRASS	F	Systemic Resistance Inducer (*Botrytis cinerea* BOTRCI)	Foliar spray	BBCH12 to BBCH89 (March – October)	a) 8 b) 8	7	a) 0.75 kg/ha b) 6 kg/ha	a) 0.71 kg/ha b) 5.65 kg/ha	100 / 1000	1	Preventive treatment Crop covered by the use No 01125023 (Strawberry) in France Minor crop
10	NL	Eggplant SOLME	F	Systemic Resistance Inducer (Sclerotiniaceae BOTRCI, SCLESP, BOTRSP)	Foliar spray	BBCH12 to BBCH89 Jan-Dec	a) 8 b) 8	7	a) 0.5 kg/ha b) 4 kg/ha	a) 0.47 kg/ha b) 4.71 kg/ha	100 / 1000	1	Preventive treatment Crop covered by the use No 01146031 (Tomato) in France Major crop
11	NL	Cucumber	G	Systemic Resistance Inducer	Foliar spray	BBCH12 to BBCH89	a) 8	7	a) 0.5 kg/ha	a) 0.47 kg/ha	100 / 1000	1	Preventive treatment

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f]
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg 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		
		CUMSA		(Mildew diseases ERYSCI, PODOXA, LEVESP)		Jan-Dec	b) 8		b) 4 kg/ha	b) 3.76 kg/ha			Crop covered by the use No 00516001 (Cucumber) in France Minor crop
12	NL	Zucchini, marrow squash with edible peel CUUPG	G	Systemic Resistance Inducer (Mildew diseases ERYSCI, PODOXA, LEVESP)	Foliar spray	BBCH12 to BBCH89 Jan-Dec	a) 8 b) 8	7	a) 0.5 kg/ha b) 4 kg/ha	a) 0.47 kg/ha b) 3.76 kg/ha	100 / 1000	1	Preventive treatment Crop covered by the use No 00516001 (Cucumber) in France Minor crop
13	NL	Gherkin CUMSG Other edible peal cucurbits	G	Systemic Resistance Inducer (Mildew diseases ERYSCI, PODOXA, LEVESP)	Foliar spray	BBCH12 to BBCH89 Jan-Dec	a) 8 b) 8	7	a) 0.5 kg/ha b) 4 kg/ha	a) 0.47 kg/ha b) 3.76 kg/ha	100 / 1000	1	Preventive treatment Crop covered by the use No 00516001 (Cucumber) in France Minor crop
14	NL	Melon CUMME	G	Systemic Resistance Inducer (Mildew diseases ERYSCI, PODOXA, UNCISP, SPHRSP PODOSP, PHYLSP, OIDISP MCRSSP,	Foliar spray	BBCH12 to BBCH89 Jan-Dec	a) 8 b) 8	7	a) 0.5 kg/ha b) 4 kg/ha	a) 0.47 kg/ha b) 3.76 kg/ha	100 / 1000	1	Preventive treatment Crop covered by the use No 00516002 (Melon) in France

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f]
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg 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		
				LEVESP, 1GOLOG)									Minor crop
15	NL	Watermelon CITLA	G	Systemic Resistance Inducer (Mildew diseases ERYSCI, PODOXA, UNCISP, SPHRSP PODOSP, PHYLSP, OIDISP MCRSSP, LEVESP, 1GOLOG)	Foliar spray	BBCH12 to BBCH89 Jan-Dec	a) 8 b) 8	7	a) 0.5 kg/ha b) 4 kg/ha	a) 0.47 kg/ha b) 3.76 kg/ha	100 / 1000	1	Preventive treatment Crop covered by the use No 00516002 (Melon) in France Minor crop
16	NL	Pumpkin CUUMA Other non-edible peel cucurbits	G	Systemic Resistance Inducer (Mildew diseases ERYSCI, PODOXA, UNCISP, SPHRSP PODOSP, PHYLSP, OIDISP MCRSSP, LEVESP, 1GOLOG)	Foliar spray	BBCH12 to BBCH89 Jan-Dec	a) 8 b) 8	7	a) 0.5 kg/ha b) 4 kg/ha	a) 0.47 kg/ha b) 3.76 kg/ha	100 / 1000	1	Preventive treatment Crop covered by the use No 00516002 (Melon) in France Minor crop
17	NL	Lettuce LACSS and other Salads	G	Systemic Resistance Inducer (Peronosporaceae BREMSP, PEROSP, *Botrytis* BOTRSP)	Foliar spray	BBCH12 to BBCH89 Jan-Dec	a) 8 b) 8	7	a) 0.75 kg/ha b) 6 kg/ha	a) 0.71 kg/ha b) 5.65 kg/ha	100 / 1000	1	Preventive treatment Crop covered by the use No 01128015 (Lettuce) in France Minor crop
19	NL	Strawberry FRASS	G	Systemic Resistance Inducer (*Botrytis cinerea* BOTRCI)	Foliar spray	BBCH12 to BBCH89 Jan-Dec	a) 8 b) 8	7	a) 0.75 kg/ha b) 6 kg/ha	a) 0.71 kg/ha b) 5.65 kg/ha	100 / 1000	1	Preventive treatment Crop covered by the use No 01125023

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f]
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg 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		
													(Strawberry) in France Minor crop
20	NL	Eggplant SOLME	G	Systemic Resistance Inducer (Sclerotiniaceae BOTRCI, SCLESP, BOTRSP)	Foliar spray	BBCH12 to BBCH89 Jan-Dec	a) 8 b) 8	7	a) 0.5 kg/ha b) 4 kg/ha	a) 0.47 kg/ha b) 4.71 kg/ha	100 / 1000	1	Preventive treatment Crop covered by the use No 01146031 (Tomato) in France Minor crop

3 Background of authorization decision and risk management

3.1 Physical and chemical properties (Part B, Section 2)

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of beige powder. It is not explosive, has no oxidising properties. The product is not considered as highly flammable and has no self-heating properties as the self-ignition temperature is 219°C. In 1% aqueous solution, it has a pH value around 3.2 at 21°C with an acidity of 1.87% w/w H_2SO_4 at 10% suspension. The tap density is 0.65 g/mL, however no pour density was determined.

There is no effect of high temperature on the stability of the formulation, since after 14 days at 54°C in LDPE packaging; neither the active ingredient content was changed significantly (this has been determined indirectly by the content crude fat/proteins, humidity, carbohydrates, mannans and glucans as the active substance can't be determined directly) nor any microbial contaminants were formed. However, the technical properties were not within the criteria, as the WP formulation did experience difficulties with the wettability and suspensibility tested (see below for comment under technical properties) Nevertheless, this was found acceptable as a restriction phrase for application was included on the product label. The storage stability was only partially shown for the 2 year shelf life study at ambient temperature in Kraft (paper) packaging, as only the appearance and technical properties were tested before and after storage (similar results to the accelerated study for 14 days at 54°C). The content of the active substance and the formation of microbial contaminants was not investigated, which is required to show storage stability. Therefore a data gap was identified and information on the content of the active substance and formation of the microbial contaminants should be provided before and after storage of the 2 year shelf-life at ambient temperature, however this can be set as a post data requirement for the authorisation and therefore this has been accepted. Additionally, based on the results of the accelerated storage and the technical properties of the 2 year shelf-life at ambient temperature a 2 years at ambient temperature when stored in LDPE and Kraft (paper) is granted. As these packaging materials are considered worst-case to HDPE and PET these results can also be extrapolated. Therefore, also a 2 year shelf-life at ambient temperature in HDPE and PET is granted, as these packaging types are also applied for.

Its technical characteristics are acceptable for a *wettable powder* (WP) formulation. The in-use concentrations are between 0.025% and 0.5% for field uses and between 0.05% and 0.75% for greenhouse uses. The formulation has been tested at 0.01% and 1%, which covers the whole in-use concentration range. However, the preparation is not considered as wettable, as the suspensibility of the preparation is far below acceptable limits (between 0%-31.2%). Nevertheless, as the formulation is applied under continuous agitation, no more data required. The wettability without swirling is between 179 – 265s and 70-135s with swirling, therefore "continuous agitation during application" should be included on the product label to improve suspensibility and prevent solid matter to be at the top of the surface of the spray fluid which could block the spray nozzle.

ALD1901 used in water at 1% (w/v) rate results in a mixture with a pH of 3.2. This can provide adverse effects on products which cannot be used in acid medium. Conversely, under provision of a normal use, meaning a limited time of mixing, no effect is expected on ALD1901 by mixing it with whatever other product, either chemical or biological.

Labeling: According to Regulation (EC) No 1272/2008 as amended, the physico-chemical properties for ROMEO do not require it to be classified. Based on the technical properties the label should contain the following phrase "agitate continuously during application", as the wettability and suspensibility were not within the criteria.

Compliance with FAO specifications: The product ROMEO complies with FAO specifications.

Compatibility of mixtures: No data have been provided and is required regarding the physical and chemical compatibility of tank mixes, as no tank mixtures are proposed on the label.

Nature and characteristics of the packaging: The core packaging proposed for ROMEO is 2.5 kg and 5 kg Kraft (paper) bags, 2.5 g; 5 g; 10g; 12.5 g; 20 g and 25 g small PET packages, 125 g; 250 g; 500g and 1000g HDPE pot and 2000 g and 4000 g LDPE bag in Polypropylen (PP) bucket canister. Information/data on this packaging type, dimensions, capacity, size of opening, type of closure, strength, leakproofness, resistance to normal transport and handling, resistance to and compatibility with the contents of the packaging, have been submitted, evaluated and are considered to be acceptable.

3.2 Efficacy (Part B, Section 3)

3.2.1 Efficacy data

The product is authorised in France for the uses in greenhouse grown lettuce, strawberry, cucurbits aubergine, grapevine and tomatoes. Climatological and environmental circumstances relevant for the aspect efficacy in the claimed uses in The Netherlands are not always comparable to those in France and the Mediterranean climate where the trials have been carried out. For this reason, the applicant has claimed the majority of these as minor uses under article 51 for which no efficacy needs to be evaluated and for the use in tomato the applicant has provided a formal justification document.

From this document and extra information provided from greenhouses in both zones it is clear that the product was tested in comparable conditions. The active compound is a systemic inducer that acts on the plant itself and therefore the growth stage of the plant (and not the season/month) determines the application timing and therefore the efficacy is likely to be similar across greenhouses with similar climatic setting throughout Europe. The cultivation method is comparable in both countries and there are no country-specific situations for the use of Romeo as a fungicide in the claimed uses.

Efficacy evaluation
For the evaluation of the aspect 'Efficacy' we refer to the evaluation of the member state of the original authorisation (France).

From the zRMS evaluation "The efficacy level of ROMEO is considered as partial and variable for all the claimed uses. However it is considered as acceptable considering the kind of product with an induction of systemic resistance mode of action. The interest of the preparation ROMEO has been especially demonstrated for use in a treatment program (tank mix and sequence partners with other fungicides). Given the mode of action and the level of efficacy of ROMEO, only the uses of systemic resistance inducer plants were considered as acceptable in terms of efficacy in France. Each CMS has to decide about the registration of the different uses at their own level. The phytotoxicity level of ROMEO is considered as negligible for all the claimed uses. The risks of negative impact on yield, quality, transformation processes, propagation, succeeding crops, adjacent crops are considered as negligible. The risk of resistance development or appearance to Cerevisane is considered as very low for the claimed uses.

Considering this evaluation and the current French authorisation, a warning statement will be amended on the Dutch label:
"*In de bovengenoemde teelten kan de werking variabel zijn. Dit middel is gebaseerd op een micro-organisme en kan bijdragen aan de preventieve bestrijding van grauwe schimmel en sclerotiënrot".*

Harmful effects
For the evaluation of the aspect 'Harmful effects' we refer to the evaluation of the member state of the original authorisation (France).

3.2.2 Information on the occurrence or possible occurrence of the development of resistance

Cerevisane is a new active substance. Thus practical resistances against Cerevisane are not known yet. Furthermore, due to its mode of action as an inducer of systemic resistance of the plants to fungal attacks, development of resistance is not expected.

3.3 Methods of analysis (Part B, Section 5)

Sufficiently sensitive and selective analytical methods are available for the active substance Cerevisane. No relevant impurities are expected in the plant protection product.

3.3.1 Analytical method for the formulation

The plant protection product contains the technical active substance which is not a living microorganism, but an inert derivative of *Saccharomyces cerevisiae*. Technical active substance is composed of the usual components of living beings: proteins, carbohydrates, lipids, and mineral matters. Acceptable methods are provided.

3.3.2 Analytical methods for residues

As no residue definition was set, analytical methods for the determination of residues are not necessary.

3.4 Mammalian toxicology (Part B, Section 6)

The technical active substance in the plant protection product is an inert derivative of the yeast *Saccharomyces cerevisiae*.

Saccharomyces cerevisiae is a well-known yeast strain (Baker's Yeast or Brewer's Yeast), already used in various sectors of food industry. It is also ubiquitous in nature, being present on fruits and vegetables[1]. This yeast has not been associated with pathogenicity toward humans except for severely debilitated traumatized or immune-deficient patients representing a very small and specific population (please refer to Point IIM 5.2.3 of the OECD dossier for the approval of the microorganism *Saccharomyces cerevisiae* LAS02 as an active substance under regulation (EC) 1107/2009). *Saccharomyces cerevisiae* has not been shown to have adverse effects on the environment. It is considered a Class 1 Containment Agent under the National Institute of Health[2] (NIH) Guidelines for Recombinant DNA Molecules and considered as QSP (Qualified Presumption of Safety) by the EFSA[3] since 2010. Moreover "Yeast for baking" is registered in Directive No.95/2/EC[4] on food additives other than colours and sweeteners, with a maximum level "*quantum satis*". No maximum level is specified; humans can be in constant contact with this yeast without risk for health.

3.4.1 Acute toxicity

The acute dermal toxicity and eye irritancy potential of ALD.SA1 technical has been studied in rabbits (see KCP 7.1.4 and KCP 7.1.5). A skin sensitisation study in mice was also performed to demonstrate the absence of sensitising properties (see KCP 7.1.6). According to the detailed composition of the preparation (please refer to Part C), the results obtained with the technical active substance can be extrapolated to the representative product ROMEO (see Point IIM 5.3.1).

The results of toxicological studies conducted with the technical active substance are summarised in **Table 3.4.1-1**. These studies were performed with the batch No. 2011002 which is one of the six representative batches used for chemical and microbiological analysis (please refer to Part C).

Table 3.4.1-1: Summary of evaluation of the studies on acute toxicity including irritancy and skin sensitisation for ALD.SA1 technical

Type of test, species, model system (Guideline)	Result	Acceptability	Classification (acc. to the criteria in Reg. 1272/2008)	Reference
Acute oral toxicity	No study performed – no acute oral toxicity expected (Baker's Yeast derivative)			

[1] US EPA (1997), Saccharomyces cerevisiae Final Risk Assessment – Attachment I
[2] National Institute of Health (1988), Guidelines for the use and safety of genetic engineering techniques or recombinant DNA technology
[3] Scientific Opinion on the maintenance of the list of QPS biological agents intentionally added to food and feed (2010 update), EFSA on Biological Hazards (BIOHAZ)
[4] European Parliament and Council Directive No.95/2/EC of 20/02/1995 on food additives other than colours and sweeteners

Acute dermal toxicity	No study performed – no acute dermal toxicity expected (Baker's Yeast derivative)			
Acute inhalation toxicity	No study performed – no acute inhalation toxicity expected (Baker's Yeast derivative)			
Acute skin irritation, New Zealand Rabbit (OECD 404 & EEC B4)	Non-irritating	Yes	Not classified	2011a
Acute eye irritation, New Zealand Rabbit, (OECD 405 & EEC B5)	Slightly irritating	Yes	Not classified	2011b
LLNA, Mice CBA/CA (OECD 429 & EEC B42)	Non-skin sensi-tising	Yes	Not classified	2011c
Supplementary studies for combina-tions of plant protection products	N ot required			

As indicated previously the preparation is not expected to be a risk for human by oral, dermal, and inhalation routes. Considering study results, ROMEO is neither an eye nor a skin irritant nor a skin sensitizer. No information was submitted in order to exclude possible sensitisation by inhalation. In the literature, positive cases of allergenic effects were described in humans exposed by inhalation to *Saccharomyces cerevisiae.* Allergenic effects might be caused by sensitization to cereal flour and secondary to fungal enzymes used as food improvement agents. However, these allergenic effects might be also caused by sensitisation by inhalation to components that might be present in the cell wall of *Saccharomyces cerevisiae,* such as enolase. The relevance of these allergenic effects to Cerevisane was discussed at the Pesticides Peer Review Experts‟ Teleconference 96: given the uncertainties the majority of experts (the RMS disagreed) did not exclude this hazard for Cerevisane and proposed the Hazard statement H334 "May cause allergy or asthma symptoms or breathing difficulties if inhaled".

Classification and labelling

According to the criteria of Annex I to Regulation (EC) No.1272/2008, ROMEO needs toxicological classification with H334.

3.4.2 Operator exposure

The operator exposure risk assessment results presented below have already been evaluated and found acceptable by the French Authorities during the ROMEO authorisation. This operator risk assessment covers all of the proposed uses in the Netherlands.

ROMEO is a resistance inducer formulated as a wettable powder containing 941 g/kg Cerevisane. It is intended to be applied in tomatoes, salads, strawberry and cucurbits with application rates from 0.471 kg a.s./ha to 0.706 kg a.s./ha and an application water volume of 100 to 1000 L/ha. The applications are considered to be done on the field and in greenhouses by professional.

Operator exposure may occur during mixing, loading and application. However, Cerevisane will not penetrate intact skin, as this is an effective barrier for microorganisms. Thus, external skin exposure will not lead to systemic exposure and skin protection equipment is not necessary from a risk assessment point of view. ROMEO is a wettable powder and as such can be inhaled during mixing and loading. Although the expected inhalation exposure will be minimal by using the highly recommended P-statements P261, P304+P340 and P342+P311.

A part of the inhalation exposure will be cleared by mucocilliary clearance mechanisms. During this process oral ingestion is likely. The oral exposure is of no toxicological concern due to the absence of hazardous properties after oral exposure and the natural background exposure to *Saccharomyces cerevisiae* (Baker's yeast). No target organ exists and no dose-effect response (LOAEL) can be determined. Thus, calculations on the health risk for operators become meaningless.

3.4.3 Worker exposure

Workers are often dermally exposed indirectly by handling treated crop or by so-called re-entry exposure. However, ROMEO is not of toxicological concern for human health after dermal exposure. The qualitative risk assessment have shown that operators are not at risk when applying the product. Since dermal exposure is considered to be the most relevant route of exposure during crop maintenance and harvesting activities in the field and the intact skin is an effective barrier for microorganisms, worker exposure to Cerevisane is considered to be negligible.

Therefore it is concluded that workers are not at risk when re-entering crops treated with ROMEO. No re-entry period for handling treated product is necessary.

3.4.4 Bystander and resident exposure

Bystander and resident exposure is lower than operator exposure since exposure during application will normally be very short. No significant volatilization is to be expected and bystander exposure will result primarily from drift.

Thus, as concluded for operator exposure, ROMEO does not represent a risk to human health. Hence it is concluded that bystanders and residents are also not at risk when applying the plant protection product according to Good Agricultural Practice.

3.5 Residues and consumer exposure (Part B, Section 7)

For the aspect 'Residues' and risk for consumers we refer to the member state of the original authorisation (FR). The Guidelines for the generation of data concerning residue data Appendix C 7524/VI/95 rev.2 require that the residue situation in rotational crops must always be considered if, after the treated crop has been harvested (or in the event of early ploughing), it is possible to sow or plant a crop which can be used as a foodstuff and/or feed. Since the product was assessed according to the Uniform Principles by the member state of the original authorisation, residues in succeeding crops need no further consideration.

3.6 Environmental fate and behaviour (Part B, Section 8)

The technical active substance in the plant protection product is an inert derivative of the yeast *Saccharomyces cerevisiae*.

Yeast is a common micro-organism present in the environment. It has been recovered from a variety of sites under varying ecological conditions. *S.cerevisiae* is a normal inhabitant of soils and is widespread in nature *S. cerevisiae* was isolated from various environmental locations: 10 strains from soil in Pennsylvania, 14 strains from soil in North Carolina, 10 and 14 strains from vineyard in north Carolina and Australia respectively, 18 strains from 18 fruits and 16 strains from brewery.

The organism is used in a variety of industrial scenarios and several of human activities release *S. cerevisiae* in environment. It is also commonly recovered from a variety of fresh fruits and vegetables, generally those fruits with high levels of fermentable sugars. This yeast was isolated from leaf surfaces of 4 species of fruit trees grown in south-West Slovakia: 2 strains on apple, 10 strains on plum, 8 strains on apricot and 10 strains on peach. Moreover *Saccharomyces sp.* were isolated from forest tree leaves near Bratislava, Slovakia: 13 strains on spruce (*Picea abies),* 18 strains on pine (*Pinus silvestris),* 20 strains on oak (*Quercus robur),* 13 strains on maple (*Acer campestre),* 47 strains on hornbeam (*Carpinus betulus),* 18 strains on linden (*Tiia cordata),* 8 strains on acacia (*Robinia pseudoacacia)* and 25 strains on ash (*Fraxinus excelsior).*

Saccharomyces cerevisiae was also isolated on exudates material, bark and soil samples from oaks (*Quercus* spp.) sampled in a mature second-growth forest in Lima, PA, USA, dominated by stands of native tulip poplar (*Liriodendron tulipifera),* American beech (*Fagus grandifolia),* maples (*Acer* spp.) and oaks (*Quercus* spp.).There is an extensive history of use of and exposure to *S. cerevisiae* with a very limited record of adverse effects to the environment or human health. Overall, it can be concluded that *S. cerevisiae* is present naturally worldwide in soils and on different types of crops, leaves and fruits. The degradation of Cerevisane releases protein material, lipid material and organic matter. These natural degradation compounds are not considered relevant for risk assessment.

3.6.1 Predicted environmental concentrations in soil (PEC_{SOIL})

No predicted concentration in soil is calculated for Cerevisane. The active substance is the cell wall of Saccharomyces cerevisiae. Saccharomyces cerevisiae is a yeast and when a cell dies, autolysis occurs naturally, and the Cerevisane fraction of the cell is released. So where *S. cerevisiae* is present in the environment, Cerevisane is also present. It is currently estimated that over one million tons of naturally-occurring yeasts are produced annually during brewing and distilling practices. *Saccharomyces cerevisiae* (and hence, Cerevisane) is already present in significant quantities in the environment and the applications of ROMEO will not lead to any significant increase in environmental exposure to soil including soil organisms.

3.6.2 Predicted environmental concentrations in groundwater (PEC_{GW})

The yeast *Saccharomyces cerevisiae* is not very mobile in soil, therefore it may be considered also Cerevisane will have a low leaching potential. No risk for leaching to groundwater is expected.

3.6.3 Predicted environmental concentrations in surface water (PEC_{SW})

The exposure to surface water of Cerevisane from the use of ROMEO in field and greenhouse crops can be considered negligible compared to natural presence and industrial exposure.

The following was mentioned in the Core dossier:

The exposure to surface water of Cerevisane from the use of ALD1901/ROMEO in field crops can be considered negligible compared to natural presence and industrial exposure. According to EFSA journal (2014), an estimation of surface water exposure at EU level was compared with the amount of yeast released to water by a yeast production company. However, the relevance of these point source releases in relation to the agricultural use is not assessed. In particular, the comparison seems to ignore possible effects of the sewage plant treatments on the industrial residual yeast material. However a conservative PEC_{SW} calculations of 2 mg/L was proposed at EU level (See EFSA journal, 2014) following 8 cumulative applications of 0.75 kg a.s./ha (100% of the product reaching the water surface). Since all intended uses of this preparation is covered by EU risk assessment, no more calculations are deemed necessary. PEC_{SW} of 2 mg/L can be used for risk assessment of the aquatic organisms.

Monitoring data groundwater and surface water

No monitoring data for groundwater and surface water are available nor required. Methods of analysis for residues are not available and are not required due to the nature of this substance.

Drinking water criterion

Yeast and thus a.s. Cerevisane is commonly present in the environment. Therefore, no additional assessment regarding the drinking water criterion is performed, and the standards for surface water destined for the production of drinking water are met.

3.6.4 Predicted environmental concentrations in air (PEC_{AIR})

Not relevant.

3.7 Ecotoxicology (Part B, Section 9)

No new studies are presented; all data were reviewed in the EU review of Cerevisane. The EU review concluded that under the proposed and supported conditions of use there are no unacceptable effects on the environment. The results obtained with the technical active substance can be extrapolated to the representative product.

There was some discrepancy in the French registration report for field uses, where the following was mentioned (Page 11 under 9.2 (cerevisane Final RR B9 ROMEO(ALD1901) AgroLevures 2017-05 FR field uses):

ALD1901/ROMEO is a WP formulation containing 941 g/kg Cerevisane. It is intended to be applied as fungicide and systemic resistance inducer on various crops (melon, cucurbits grapevine and table grapes).
The maximum application rate is 8 applications at 0.47 kg pure a.s./ha with a minimum 7d-interval between applications (See table 9-1-1).

In NL GAP there is a use in lettuce with 8 applications 7 days interval of 0.71 kg a.s./ha. However, on the French label, the use in lettuce is authorised also at 0.75 kg a.s./ha. Due to these two contradictory statements in the French authorisation it is not clear to the Ctgb whether or not the field use in lettuce is covered by the French authorisation. The applicant was requested to provided relevant evidence as to whether the uses in NL are indeed covered by the French authorisation or not.

The applicant provided the following response:

"Indeed, there is some discrepancy between what is written in RR and the French decision. However, France authorised 8 applications at 0.75 kg Romeo/ha (corresponding to 0.71 kg pure as/ha, as it is presented on the NL GAP) on lettuce in field because they did the assessment based on such worst case exposure. Indeed, in the efate section of GH RR, it is indicated PECsw was estimated based on 8 apps*0.75 kg ppp/ha/app and considering as a very worst case 100% of the product reaches the surface water. Hence, this evaluation takes into account both field and GH exposures, and the risk is acceptable in both situations even if well overestimated.

This PECsw calculation was issued during EU evaluation of Cerevisane, and it covers the risk for lettuce in field with the same dose and number of applications (8*0.75 kg ppp/ha/app or 8*0.71kg pure ai/ha/app).

For soil, it was concluded as not relevant by EFSA, hence no risk assessment was performed."

This justification is accepted by the Ctgb.

3.7.1 Effects on terrestrial vertebrates

S. cerevisiae is present worldwide in soils and on different types of crops, on leaves and on fruits. When a *S. cerevisiae* cell dies, an autolysis occurs naturally, and the Cerevisane fraction of the cell is released and progressively degraded. So where *S. cerevisiae* is present in the environment, Cerevisane is also present.
Birds and mammals are thus naturally exposed to *Saccharomyces cerevisiae* since this microbial active substance occurs ubiquitously in the environment and also to Cerevisane.
Moreover, *Saccharomyces cerevisiae* is used in animal feeding since the last decades. The effects of this yeast in bird feed was investigated in two publications that were evaluated in the peer review of the a.s. Cerevisane.

3.7.2 Effects on aquatic species

Literature data show that *Saccharomyces cerevisiae* cell walls are used in fish feeding with no harmful effect. Studies on the toxicity to aquatic organisms have been carried out with Cerevisane on *Daphnia magna* and algae (*Pseudokirchneriella subcapitata*). Effects on aquatic organisms of ROMEO were not submitted. However, the provision of further data on the formulation is not considered essential, because according to the detailed composition of the preparation, the results obtained with the technical active substance can be extrapolated to the representative product.

For the intended uses calculated PEC/RAC ratios indicate an acceptable risk for the most sensitive groups of aquatic organisms. Therefore, the risk to aquatic organisms is acceptable.

3.7.3 Effects on bees

Information was submitted to show the use of *Saccharomyces cerevisiae* (Brewer's yeast) as food supplement for bees indicating that *Saccharomyces cerevisiae*, hence Cerevisane, is not toxic for bees. The use of such yeast is beneficial for bees. Indeed, brewer's yeast is highly palatable to bees and has the nutritive requirements for their growth and reproduction. These study results can be extrapolated to the preparation ROMEO. The use of ROMEO will not pose a potential risk to bees.

3.7.4 Effects on other arthropod species other than bees

Non-target arthropods are already naturally exposed to *S. cerevisiae* in significant quantities in the environment and this for a long time. Applications of ROMEO will not lead to any significant change in the environment. Therefore, the risk of ROMEO to non-target arthropods is negligible.

3.7.5 Effects on soil organisms

For greenhouse uses the risk to soil organisms is considered less relevant. Overall, it can be concluded that *S. cerevisiae* is present worldwide in soils. Where *S. cerevisiae* is present in the environment, Cerevisane is also present. Consequently, *Saccharomyces cerevisiae* (and hence, Cerevisane) is already present in significant quantities in the environment and applications of ALD1901/ROMEO will not lead to any significant change in levels present the soil environment including soil organisms.

3.7.6 Effects on non-target terrestrial plants

No data on the effect of Cerevisane on non-target plants are submitted. Such data are considered not required.

3.7.7 Effects on other terrestrial organisms (Flora and Fauna)

No data is submitted. No data are required.

3.8 Relevance of metabolites (Part B, Section 10)

Not relevant. No metabolites that are considered relevant for further risk assessment are formed.

4 Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)

Not relevant.

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

None.

Appendix 1 Copy of the proposed product label

Wettelijk Gebruiksvoorschrift
Het middel is uitsluitend toegelaten als schimmelbestrijdingsmiddel voor het professionele gebruik door middel van een gewasbehandeling in de volgende toepassingsgebieden (volgens Definitielijst toepassingsgebieden versie 2.1 Ctgb juni 2015) onder de hierna vermelde toepassingsvoorwaarden.

Toepassingsvoorwaarden:

Toepassingsgebied	Werkzaamheid getoetst op	Dosering* middel per toepassing	Maximaal aantal toepassingen per 12 maanden	Minimum interval tussen toepassingen in dagen	Veiligheidstermijn in dagen
Tomaat (bedekte teelt)	Grauwe schimmel[11, 14] Sclerotiënrot[15]	0,5 kg/ha	8	7	1

* Verlaging van de dosering is toegestaan, maar van het maximaal aantal toepassingen en de andere toepassingsvoorwaarden mag niet worden afgeweken. Werkzaamheid is vastgesteld voor de genoemde dosering per toepassing en niet voor verlaagde doseringen.
[11] Grauwe schimmel (*Botytris cinerea*)
[14] Grauwe schimmel (*Botrytis* spp.)
[15] Sclerotiënrot (*Sclerotinia* spp.)

Het gebruik in de teelt van aardbei, sla, vruchtgroenten van *Curcurbitaceae* eetbare schil, vruchtgroenten van *Curcurbitaceae* niet-eetbare schil en aubergine is beoordeeld conform artikel 51 EG 1107/2009. Er is voor deze toepassing/en geen werkzaamheids- en fytotoxiciteitonderzoek uitgevoerd. Er wordt daarom aangeraden een proefbespuiting uit te voeren voordat het middel gebruikt wordt. Het risico voor het gewas bij gebruik van dit middel in dit/deze toepassingsgebied/en valt onder verantwoordelijkheid van de gebruiker.

Toepassingsgebied	Werkzaamheid aannemelijk tegen	Dosering* middel per toepassing	Maximaal aantal toepassingen per 12 maanden	Minimum interval tussen toepassingen in dagen	Veiligheidstermijn in dagen

Toepassingsgebied	Werkzaamheid aannemelijk tegen	Dosering* middel per toepassing	Maximaal aantal toepassingen per 12 maanden	Minimum interval tussen toepassingen in dagen	Veiligheidstermijn in dagen
Aardbei	Grauwe schimmel[11]	0,75 kg/ha	8	7	1
Sla	Valse meeldauw[12, 13], Grauwe schimmel[14]	0,75 kg/ha	8	7	1
Vruchtgroenten van *Curcurbitaceae* eetbare schil	Echte meeldauw[1, 2, 3]	0,5 kg/ha	8	7	1
Vruchtgroenten van *Curcurbitaceae* niet-eetbare schil	Echte meeldauw [1, 2, 3, 4, 5, 6, 7, 8, 9, 10]	0,5 kg/ha	8	7	1
Aubergine	Grauwe schimmel[11, 14], Sclerotiënrot[15]	0,5 kg/ha	8	7	1

* Verlaging van de dosering is toegestaan, maar van het maximaal aantal toepassingen en de andere toepassingsvoorwaarden mag niet worden afgeweken.

[1] Echte meeldauw (*Golovinomyces cichoracearum*)
[2] Echte meeldauw (*Podosphaera xanthii*)
[3] Echte meeldauw (*Leveillula* spp.)
[4] Echte meeldauw (*Uncinula* spp.)
[5] Echte meeldauw (*Sphaerotheca* spp.)
[6] Echte meeldauw (*Podosphaera* spp.)
[7] Echte meeldauw (*Phyllactinia* spp.)
[8] Echte meeldauw (*Oidium* spp.)
[9] Echte meeldauw (*Microsphaera* spp.)
[10] Echte meeldauw (*Golovinomyces* spp.)
[11] Grauwe schimmel (*Botytris cinerea*)
[12] Valse meeldauw (*Bremia* spp.)
[13] Valse meeldauw (*Peronospora* spp.)
[14] Grauwe schimmel (*Botrytis* spp.)
[15] Sclerotiënrot (*Sclerotinia* spp.)

Overige toepassingsvoorwaarden
In de bovengenoemde teelten het middel toepassen in 100-1000 L water per ha.

Continu roeren tijdens toepassing.

In de bovengenoemde teelten kan de werking variabel zijn. Dit middel is gebaseerd op een micro-organisme en kan bijdragen aan de preventieve bestrijding van grauwe schimmel en sclerotiënrot.

Appendix 2 Statement of the purchase of all relevant data

Please note that although a letter of access to data held by third parties was required for the French application, since that application was made, all relevant data (notably efficacy reports) have been purchased by Agrauxine, a letter of access is therefore not included in this application (See administrative documents for documents of acquisition).

Appendix 3 Lists of data considered for national authorization

No new data have been submitted.