REGISTRATION REPORT

Part B

Section 0

Product Background, Regulatory Context and GAP information

Product code: A23109A

Product name: ORONDIS VIP

Chemical active substances:

Metalaxyl-M, 174.4 g/L
Oxathiapiprolin, 30 g/L

Interzonal

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(New authorisation)

Applicant: Syngenta
Submission date: June 2022
MS Finalisation date: December 2022 / July 2023 (initial Core Assessment)
November 2023 (final Core Assessment)

Version history

When	What
July 2022	Version 1 Applicant dRR submitted by applicant to the Polish Ministry of Agriculture and Rural Development
September 2022	Submission to the evaluation unit
December 2022	zRMS finalized dRR evaluation (in the scope of ecotoxicology, fate and behaviour)
July 2023	Initial izRMS assessment (other section) The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information are ~~struck through~~ and shaded for transparency.
December 2023	Final report (Core Assessment updated following the commenting period) Additional information/assessments included by the zRMS in the report in response to comments received from the cMS and the Applicant are highlighted in yellow. Not agreed or not relevant information are ~~struck through~~ and shaded for transparency.

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0 Product background, regulatory context and GAP information

0.1 Introduction

0.1.1 Reason for application

This application from Syngenta for the 1st registration of 'Orondis VIP' (A23109A) under Article 33 of Regulation (EC) No. 1107/2009.

No equivalence assessment is required.

This application follows the data requirements for the active substance laid down in in Regulation (EC) No. 544/2011 for Metalaxyl-M and in Regulation (EC) No. 283/2013 for oxathiapiprolin, and the data requirements for the plant protection product laid down in Regulation (EC) No. 284/2013.

All data relied on are provided with this application. The reference list at Appendix 1 of dRR B. 1-10 define the data owner and data access. Data protection is a national concern and is addressed in Part A, Appendix 4.

0.1.2 Details of zRMS(s) and concerned MS

Table 0.1-1: Overview of zRMS and cMS

	zRMS, product name and authorization no. (if relevant)	**(if relevant) Concerned MS, MS' product name and authorization number (if applicable)**
Northern zone	n/a	
Central zone	Poland – Orondis VIP (n/a)	Austria – Orondis VIP (n/a) Belgium – Orondis VIP (n/a) Czech Republic – Orondis VIP (n/a) Germany – Orondis VIP (n/a) Netherlands – Orondis VIP (n/a) Slovakia – Orondis VIP (n/a)
Southern zone	France– Orondis VIP (n/a)	n/a
Inter-zonal	Poland– Orondis VIP (n/a)	Austria – Orondis VIP (n/a) Belgium – Orondis VIP (n/a) Czech Republic – Orondis VIP (n/a) France – Orondis VIP (n/a) Germany – Orondis VIP (n/a) Netherlands – Orondis VIP (n/a) Slovakia – Orondis VIP (n/a)
National Submission	GB – Orondis VIP (n/a)	

0.1.3 Regulatory history of the active(s)

0.1.3.1 Metalaxyl-M

Table 0.1-2: Summary of regulatory history of CAS No: 70630-17-0

Status	
Approved in EU	Y
Commission Implementing Regulation	Commission Implementing Regulation (EU) 2020/617 of 5 May 2020
RMS	Belgium
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01/06/2020

Status	
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	01/09/2020
Date of final Commission (re-registration) deadline (Step 2)	Not applicable (renewal under 1107)
Current expiration of approval	31/05/2035
Low risk substance or Candidate for Substitution?	N

Issues that need to be considered as part of the EU approval are listed below.

When used for seed treatment, only the treatment of seeds intended to be sown in greenhouses may be authorised.

In this overall assessment Member States must pay particular attention to:

- the specification of the technical material as commercially manufactured;
- the protection of operators and workers, ensuring that the conditions of use prescribe the use of adequate personal protective equipment, where appropriate;
- the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions;
- the protection of non-target arthropods, birds and mammals.

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

The SANTE report for Metalaxyl-M (SANTE/11112/2019 Rev 5 of 24 March 2020) is considered to provide the relevant information on the evaluation or a reference to where such information can be found.

An EFSA Peer review of the pesticide risk assessment of the active substance Metalaxyl-M was made available in **EFSA Journal 2015;13(3):3999** (3rd of March 2015).

Table 0.1-3: Information on minimum purity of Metalaxyl-M

EU agreed minimum purity from Inclusion Directive or Implementing regulation	**(if different) Minimum purity of active substance used in the product / information on available equivalency report *, **
Minimum purity; 920 g/kg	n/a

* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification) and as a result the purity of the active substance has changed (see Part C).

** If the specification of the active substance is different to that used as reference specification for EU approval then please refer to the equivalency document from the RMS.

The following table provides the endpoints used in the evaluation in the case that they deviate from EU endpoints.

Endpoint	**Active Substance**	
	EU agreed endpoint from EFSA Journal 2015;13(3):3999	**Endpoint used***
Honeybee adult chronic oral toxicity	-	~~Chronic LDD_{50} = 20.3 µg a.s./bee/day~~
Honeybee oral larval development	-	~~Larva NOED = 40.0 µg a.s./larva~~
Metalaxyl-M SEU uses: DT_{50} in soil (d)	6.5 Median	7.74 Geometric mean[a]
NOA409045 DT_{50} in soil (d)	31.3 Geometric mean	30.5 Geometric mean[b]

Endpoint	Active Substance	
	EU agreed endpoint from EFSA Journal 2015;13(3):3999	**Endpoint used***
SYN546520 Formation fraction	0.47 from NAO409045	0.1 from NOA409045[c]
Metalaxyl-M SEU uses: K_{FOC} / K_{FOM} (ml/g)	40 / 23.2 Median	50.63 / 29.37 Geometric mean[a]
NOA409045 SEU uses: K_{FOC} / K_{FOM} (ml/g)	12.1 / 7.02 Arithmetic mean	13.44 / 7.80 Geometric mean[a]
CGA67868 SEU uses: K_{FOC} / K_{FOM} (ml/g)	19.0 / 11.0 Arithmetic mean	18.93 / 10.98 Geometric mean[a]
SYN546520 SEU uses K_{FOC} / K_{FOM} (ml/g)	15.2 / 8.82 Arithmetic mean	7.79 / 4.52 Geometric mean[a]

* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification, confirmatory data)

[a] Differs from the EFSA conclusion as the latest guideline (EFSA Journal 2014;12(5):3662) recommends the use of the geometric mean instead of the arithmetic mean or median. The individual values from which the geometric mean is calculated, are those established in metalaxyl-M, EFSA Journal 2015; 13(3):3999

[b] The overall DT_{50} value used in modelling has been re-calculated, as the geomean value of 31.3 days (EFSA, 2015) was incorrect

[c] For the metabolite SYN546520, as a tiered approach, the PEC_{GW} were calculated with two different formation fractions: 0.47 (Tier 1, EFSA 2015) and 0.1 (Tier 2, derived from inverse modelling, EFSA 2015)

0.1.3.2 Oxathiapiprolin

Table 0.1-4: Summary of regulatory history of CAS No: 1003318-67-9

Status	
Approved in EU	Y
Commission Implementing Regulation	Commission Implementing Regulation (EU) No 2017/239
RMS	Ireland
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	03.03.2017
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	Not applicable
Date of final Commission (re-registration) deadline (Step 2)	Not applicable (approval under 1107)
Current expiration of approval	03.03.2027
Low risk substance or Candidate for Substitution?	N/A

Commission Implementing Regulation (EU) No 2017/239 of 10th February 2017 provides no specific provisions for oxathiapiprolin which need to be considered by the applicant in the preparation of their submission and by the MS prior to granting an authorisation since none are needed.

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

These specific concerns are addressed within the current submission.

The notifier shall submit confirmatory information by 3 September 2017 on:

1. The technical specification of the active substance as manufactured (based on commercial scale production) including the relevance of impurities;

2. The compliance of the toxicity and ecotoxicity batches with the confirmed technical specification.

The EFSA Scientific Review for oxathiapiprolin (EFSA Journal 2016;14(7):4504) is considered to provide the relevant information on the evaluation or a reference to where such information can be found.

Syngenta is not the notifier for renewal of the active substance. The notifier is Corteva Agriscience International Sàrl (formally DuPont International Operations Sàrl; change effective January 4, 2021) (hereafter called "Corteva") and appropriate letters of access are included in this submission.

Table 0.1-5: Information on minimum purity of oxathiapiprolin

EU agreed minimum purity from Inclusion Directive or Implementing regulation	(if different) Minimum purity of active substance used in the product / information on available equivalency report *, **
950 g/kg	n/a

* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification) and as a result the purity of the active substance has changed (see Part C).

** If the specification of the active substance is different to that used as reference specification for EU approval then please refer to the equivalency document from the RMS.

The following table provides the endpoints used in the evaluation in the case that they deviate from EU endpoints.

Endpoint	Oxathiapiprolin	
	EU agreed endpoint from EFSA Journal 2016;14(7):4504	Endpoint used*
~~Honeybee adult chronic oral toxicity~~	-	~~Chronic LDD_{50} = 34.7 µg a.s./bee/day~~ [a]
~~Honeybee oral larval development~~	-	~~Larva NOED = 7.02 µg a.s./larva~~
Oxathiapiprolin SEU uses: K_{FOC} / K_{FOM} (ml/g)	6242.6 / 3621 Arithmetic mean	6128 / 3555 Geometric mean[b]
IN-RDT31 SEU uses: K_{FOC} / K_{FOM} (ml/g)	1168.4 / 677.7 Arithmetic mean	1012 / 587 Geometric mean[b]
IN-RAB06 SEU uses: K_{FOC} / K_{FOM} (ml/g)	495.6 / 287.5 Arithmetic mean	487 / 282 Geometric mean[b]
IN-QPS10 SEU uses: K_{FOC} / K_{FOM} (ml/g)	4880.2 / 2830.7 Arithmetic mean	3484 / 2021 Geometric mean[b]

* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification, confirmatory data)

[a] Tested as Oxathiapiprolin 100 g/L OD

[b] Differs from the EFSA conclusion as the latest guideline (EFSA Journal 2014;12(5):3662) recommends the use of the geometric mean instead of the arithmetic mean or median. The individual values from which the geometric mean is calculated, are those established in oxathiapiprolin, EFSA Journal 2016; 14(7):4504

0.1.4 Regulatory history of the product (if relevant)

Not relevant as the product has not yet been authorised.

0.2 zRMS conclusion

See column 15 of the GAP table presented in Appendix 1 of this document.

Section B8
The results of leaching simulation run with FOCUS PELMO, FOCUS PEARL and FOCUS MACRO demonstrate

that the PEC_{GW} values for metalaxyl-M metabolite NOA409045 are above 0.1 µg/L for all FOCUS scenarios. The assessment of metabolite NOA409045 is crucial for the authorisation process. Therefore further refinement and toxicological data are required. Please refer to Part B Section 10.
The exposure of adjacent surface waters and terrestrial ecosystems by metalaxyl-M and oxathiapiprolin due to volatilization with subsequent deposition is considered to be low.

Section B9
Based on the risk assessment in section of ecotoxicology it can be concluded that the proposed uses of A23109A poses acceptable risk to non-target organisms, if applied according to the recommended use pattern. Particular precautions to reduce the environmental concentrations resulting from A23109A applications are not required.

Uses to be considered safe on the basis of EU methodology:

See column 15 of the GAP table presented in Appendix 1 of this document.

Section B8 Environmental Fate: All uses, if the groundwater metabolite NOA409045 will be consider as not relevant in Section B10.
Section B9 Ecotoxicology: All uses.

Uses to be considered non-safe on the basis of EU methodology:

See column 15 of the GAP table presented in Appendix 1 of this document.

Section B8 Environmental Fate: None
Section B9 Ecotoxicology: None

Uses for which safety has been established only following additional risk mitigation at a national (non-core) level or for which the evaluation is to be confirmed by relevant cMS:

See column 15 of the GAP table presented in Appendix 1 of this document.

Section B8 Environmental Fate: None
Section B9 Ecotoxicology: None

All uses/ GAPs are covered by established MRLs except for use in watercress.

Appendix 1 ALL intended uses

GAP rev. 2, date: 2023-07

PPP (product name/code):	Orondis VIP / A23109A	Formulation type:	DC
Active substance 1:	Metalaxyl-M	Conc. of as 1:	174.4 g/L (c)
Active substance 2:	Oxathiapiprolin	Conc. of as 2:	30 g/L (c)
Applicant:	Syngenta	Professional use:	☒
Zone(s):	interzonal (d)	Non professional use:	☐
Verified by MS:	no		
Field of use:	Fungicide		

1	2	3	4	5	6	7	8	9	10	11	11	12	13	14	15*							
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)	**zRMS Conclusions**							
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g MFX/ha a) max. rate per appl. b) max. total rate per crop/season	g OXTP/ha a) max. rate per appl. b) max. total rate per crop /season	Water L/ha min / max			Phys-chem	Analytical methods	Toxicology	Residues	Groundwater	Ecotoxicology	Relevance of metabolites in groundwater	Efficacy
Zonal uses (field or outdoor uses, certain types of protected crops)																						
N/A																						
Minor uses according to Article 51 (zonal uses)																						
None																						
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)																						
AT-47	Austria	Baby leaves	G	~~*Bremia lactucae* [BREMLA]~~ Downy Mildews (1PEROF-Peronosporaceae)	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Max 2 app per year in same field	A	A	A	A	R	A	A	C
AT-48	Austria	Chicory [CICIN]	G	~~*Bremia lactucae* [BREMLA]~~ Downy Mildews (1PEROF-Peronosporaceae)	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Max 2 app per year in same field	A	A	A	A	R	A	A	C

AT-49	Austria	Cress [CRESS]	G	~~*Bremia lactucae* [BREMLA]~~ Downy Mildews (1PEROF-Peronosporaceae)	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Max 2 app per year in same field	A	A	A	A	R	A	A	C
AT-50	Austria	Endive [CICEN]	G	~~*Bremia lactucae* [BREMLA]~~ Downy Mildews (1PEROF-Peronosporaceae)	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Max 2 app per year in same field	A	A	A	A	R	A	A	C
AT-51	Austria	Escarole [CICEL]	G	~~*Bremia lactucae* [BREMLA]~~ Downy Mildews (1PEROF-Peronosporaceae)	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Max 2 app per year in same field	A	A	A	A	R	A	A	C
AT-52	Austria	Lamb's lettuce [VLLLO]	G	~~*Bremia lactucae* [BREMLA]~~ Downy Mildews (1PEROF-Peronosporaceae)	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Max 2 app per year in same field	A	A	A	A	R	A	A	C
AT-53	Austria	Lettuce [LACSA]	G	~~*Bremia lactucae* [BREMLA]~~ Downy Mildews (1PEROF-Peronosporaceae)	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Max 2 app per year in same field	A	A	A	A	R	A	A	A
AT-54	Austria	Purple-vein rocket [ERUVE]	G	~~*Bremia lactucae* [BREMLA]~~ Downy Mildews (1PEROF-Peronosporaceae)	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Max 2 app per year in same field	A	A	A	A	R	A	A	C
AT-55	Austria	Watercress [NAAOF]	G	~~*Bremia lactucae* [BREMLA]~~ Downy Mildews (1PEROF-Peronosporaceae)	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Max 2 app per year in same field	A	A	A	N	R	A	A	C
BE-36	Belgium	Baby leaves	G	*Bremia lactucae* [BREMLA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Max 2 app per year in same field	A	A	A	A	R	A	A	C

BE-38	Belgium	Cress [CRESS]	G	*Bremia lactucae* [BREMLA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Max 2 app per year in same field	A	A	A	A	R	A	A	C
BE-39	Belgium	Endive [CICEN]	G	*Bremia lactucae* [BREMLA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Max 2 app per year in same field	A	A	A	A	R	A	A	C
BE-40	Belgium	Escarole [CICEL]	G	*Bremia lactucae* [BREMLA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Max 2 app per year in same field	A	A	A	A	R	A	A	C
BE-41	Belgium	Lamb's lettuce [VLLLO]	G	*Bremia lactucae* [BREMLA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Max 2 app per year in same field	A	A	A	A	R	A	A	C
BE-42	Belgium	Lettuce [LACSA]	G	*Bremia lactucae* [BREMLA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Max 2 app per year in same field	A	A	A	A	R	A	A	A
BE-43	Belgium	Purple-vein rocket [ERUVE]	G	*Bremia lactucae* [BREMLA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Max 2 app per year in same field	A	A	A	A	R	A	A	C
BE-44	Belgium	Watercress [NAAOF]	G	*Bremia lactucae* [BREMLA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Max 2 app per year in same field	A	A	A	N	R	A	A	C
CZ-50	Czech Republic	Baby leaves	G	*Bremia lactucae* [BREMLA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Max 2 app per year in same field Minor use	A	A	A	A	R	A	A	C
CZ-51	Czech Republic	Chicory [CICIN]	G	*Bremia lactucae* [BREMLA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Max 2 app per year in same field Minor use	A	A	A	A	R	A	A	C
CZ-52	Czech Republic	Cress [CRESS]	G	*Bremia lactucae* [BREMLA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Max 2 app per year in same field Minor use	A	A	A	A	R	A	A	C
CZ-53	Czech Republic	Endive [CICEN]	G	*Bremia lactucae* [BREMLA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Max 2 app per year in same field Minor use	A	A	A	A	R	A	A	C
CZ-54	Czech Republic	Escarole [CICEL]	G	*Bremia lactucae* [BREMLA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Max 2 app per year in same field Minor use	A	A	A	A	R	A	A	C

CZ-55	Czech Republic	Iceberg lettuce	G	*Bremia lactucae* [BREMLA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Max 2 app per year in same field Minor use	A	A	A	A	R	A	A	C
CZ-56	Czech Republic	Lamb's lettuce [VLLLO]	G	*Bremia lactucae* [BREMLA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Max 2 app per year in same field Minor use	A	A	A	A	R	A	A	C
CZ-57	Czech Republic	Lettuce [LACSA]	G	*Bremia lactucae* [BREMLA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Max 2 app per year in same field Minor use	A	A	A	A	R	A	A	A
CZ-58	Czech Republic	Purple-vein rocket [ERUVE]	G	*Bremia lactucae* [BREMLA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Max 2 app per year in same field Minor use	A	A	A	A	R	A	A	C
CZ-59	Czech Republic	Watercress [NAAOF]	G	*Bremia lactucae* [BREMLA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Max 2 app per year in same field Minor use	A	A	A	N	R	A	A	C
DE-47	Germany	Baby leaves	G	*Bremia lactucae* [BREMLA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Max 2 app per year in same field Consideration of authorization on the grounds of art. 51 on the national level	A	A	A	A	R	A	A	n.r.
DE-48	Germany	Chicory [CICIN]	G	*Bremia lactucae* [BREMLA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Max 2 app per year in same field Consideration of authorization on the grounds of art. 51 on the national level	A	A	A	A	R	A	A	n.r.

DE-49	Germany	Cress [CRESS]	G	*Bremia lactucae* [BREMLA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Max 2 app per year in same field Consideration of authorization on the grounds of art. 51 on the national level	A	A	A	A	R	A	A	n.r.
DE-50	Germany	Endive [CICEN]	G	*Bremia lactucae* [BREMLA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Max 2 app per year in same field Consideration of authorization on the grounds of art. 51 on the national level	A	A	A	A	R	A	A	n.r.
DE-51	Germany	Escarole [CICEL]	G	*Bremia lactucae* [BREMLA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Max 2 app per year in same field Consideration of authorization on the grounds of art. 51 on the national level	A	A	A	A	R	A	A	n.r.
DE-52	Germany	Lamb's lettuce [VLLLO]	G	*Bremia lactucae* [BREMLA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Max 2 app per year in same field Consideration of authorization on the grounds of art. 51 on the national level	A	A	A	A	R	A	A	n.r.
DE-53	Germany	Lettuce [LACSA]	G	*Bremia lactucae* [BREMLA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Max 2 app per year in same field	A	A	A	A	R	A	A	A
DE-54	Germany	Purple-vein rocket [ERUVE]	G	*Bremia lactucae* [BREMLA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Max 2 app per year in same field Consideration of authorization on the grounds of art. 51 on the national level	A	A	A	A	R	A	A	n.r.

DE-55	Germany	Watercress [NAAOF]	G	*Bremia lactucae* [BREMLA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Max 2 app per year in same field Consideration of authorization on the grounds of art. 51 on the national level	A	A	A	N	R	A	A	n.r.
FR-30	France	Baby leaves	G	*Bremia lactucae* [BREMLA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Max 2 app per year in same field	A	A	A	A	R	A	A	C
FR-31	France	Chicory [CICIN]	G	*Bremia lactucae* [BREMLA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Max 2 app per year in same field	A	A	A	A	R	A	A	C
FR-32	France	Endive [CICEN]	G	*Bremia lactucae* [BREMLA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Max 2 app per year in same field	A	A	A	A	R	A	A	C
FR-33	France	Escarole [CICEL]	G	*Bremia lactucae* [BREMLA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Max 2 app per year in same field	A	A	A	A	R	A	A	C
FR-35	France	Lamb's lettuce [VLLLO]	G	*Bremia lactucae* [BREMLA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Max 2 app per year in same field	A	A	A	A	R	A	A	C
FR-36	France	Lettuce [LACSA]	G	*Bremia lactucae* [BREMLA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Max 2 app per year in same field	A	A	A	A	R	A	A	A
FR-37	France	Purple-vein rocket [ERUVE]	G	*Bremia lactucae* [BREMLA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Max 2 app per year in same field	A	A	A	A	R	A	A	C
NL-34	Netherlands	Baby leaves	G	*Bremia lactucae* [BREMLA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Max 2 app per year in same field	A	A	A	A	R	A	A	A
NL-36	Netherlands	Endive [CICEN]	G	*Bremia lactucae* [BREMLA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Max 2 app per year in same field	A	A	A	A	R	A	A	A
NL-37	Netherlands	Escarole [CICEL]	G	*Bremia lactucae* [BREMLA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Max 2 app per year in same field	A	A	A	A	R	A	A	A
NL-38	Netherlands	Lamb's lettuce [VLLLO]	G	*Bremia lactucae* [BREMLA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Max 2 app per year in same field	A	A	A	A	R	A	A	A

NL-39	Netherlands	Lettuce [LACSA]	G	*Bremia lactucae* [BREMLA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Max 2 app per year in same field	A	A	A	A	R	A	A	A
NL-40	Netherlands	Purple-vein rocket [ERUVE]	G	*Bremia lactucae* [BREMLA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Max 2 app per year in same field	A	A	A	A	R	A	A	A
PL-47	Poland	Baby leaves	G	*Bremia lactucae* [BREMLA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Minor Use – Art 51 Max 2 app per year in same field	A	A	A	A	R	A	A	n.r.
PL-48	Poland	Chicory [CICIN]	G	*Bremia lactucae* [BREMLA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Minor Use – Art 51 Max 2 app per year in same field	A	A	A	A	R	A	A	n.r.
PL-49	Poland	Cress [CRESS]	G	*Bremia lactucae* [BREMLA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Minor Use – Art 51 Max 2 app per year in same field	A	A	A	A	R	A	A	n.r.
PL-50	Poland	Endive [CICEN]	G	*Bremia lactucae* [BREMLA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Minor Use – Art 51 Max 2 app per year in same field	A	A	A	A	R	A	A	n.r.
PL-51	Poland	Escarole [CICEL]	G	*Bremia lactucae* [BREMLA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Minor Use – Art 51 Max 2 app per year in same field	A	A	A	A	R	A	A	n.r.
PL-52	Poland	Lamb's lettuce [VLLLO]	G	*Bremia lactucae* [BREMLA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Minor Use – Art 51 Max 2 app per year in same field	A	A	A	A	R	A	A	n.r.
PL-53	Poland	Lettuce [LACSA]	G	*Bremia lactucae* [BREMLA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Max 2 app per year in same field	A	A	A	A	R	A	A	A
PL-54	Poland	Purple-vein rocket [ERUVE]	G	*Bremia lactucae* [BREMLA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Minor Use – Art 51 Max 2 app per year in same field	A	A	A	A	R	A	A	n.r.

PL-55	Poland	Watercress [NAAOF]	G	*Bremia lactucae* [BREMLA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Minor Use – Art 51 Max 2 app per year in same field	A	A	A	N	R	A	A	n.r.
SK-42	Slovakia	Baby leaves	G	*Bremia lactucae* [BREMLA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Max 2 app per year in same field	A	A	A	A	R	A	A	N
SK-43	Slovakia	Cress [CRESS]	G	*Bremia lactucae* [BREMLA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Max 2 app per year in same field	A	A	A	A	R	A	A	N
SK-44	Slovakia	Lettuce [LACSA]	G	*Bremia lactucae* [BREMLA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Max 2 app per year in same field	A	A	A	A	R	A	A	N
SK-45	Slovakia	Watercress [NAAOF]	G	*Bremia lactucae* [BREMLA]	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	Max 2 app per year in same field	A	A	A	N	R	A	A	N
Minor uses according to Article 51 (interzonal uses)																				
None																				

Remarks table heading:

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

Remarks columns:

1 Numeration necessary to allow references
2 Use official codes/nomenclatures of EU Member States
3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)
4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application
5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.
6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.
7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
8 The maximum number of application possible under practical conditions of use must be provided.
9 Minimum interval (in days) between applications of the same product
10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".
13 PHI - minimum pre-harvest interval
14 Remarks may include: Extent of use/economic importance/restrictions
15 Overall conclusions - explanation for the column 15 is below *

* Explanation for column 15 "Overall conclusions"

A	Acceptable
R	Acceptable with further restriction
C	To be confirmed by cMS
N	Not acceptable / evaluation not possible
n.r.	Not relevant