REGISTRATION REPORT

Part B

Section 3

Efficacy Data and Information

Concise summary

Product code: A23109A

Product name: ORONDIS VIP

Chemical active substances:

Metalaxyl-M (R-enantiomer), 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: March 2023 (initial Core Asssessment)

November 2023 (final Core Assessment)

Version history

When	What
June 2022	Initial version of dRR for submission to zRMS
March 2023	Initial zRMS assessment 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.
November 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.

The summaries and evaluations contained in this registration report may be based on unpublished proprietary data submitted for the purpose of the assessment undertaken by the regulatory authority that prepared it. Other registration authorities should not grant, amend or renew a registration on the basis of the summaries and evaluation of unpublished proprietary data contained in this registration report unless they have received the data on which the summaries and evaluation are based.

Either from the owner of the data, or

- From a second party that has obtained permission from the owner of the data for this purpose or, alternatively, the applicant has received permission from the data owner that the summaries and evaluation contained in this registration report may be used in lieu of the data, or

- Following expiry of any period of exclusive use, by offering, in certain jurisdictions, mandatory compensation,

unless the period of protection of the proprietary data concerned has expired.

Applicants wishing to avail of information in this registration report should seek advice from the regulatory authority to which the application is made concerning the requirements in their country.

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

Transformation of the dRR (applicant version) into the RR (zRMS version)

Comments of zRMS:

Conclusions from the assessment were prepared using grey commenting boxes placed at the end of each chapter. Textual changes were done using grey highlights in the text. The parts of the text amended or added by the zRMS evaluator are highlighted in grey, whereas the parts struck off are ~~visibly marked with the grey font~~.

3.1 Summary and conclusions of zRMS on Section 3: Efficacy (KCP 6)

Abstract

Abstract of the evaluation, by the zRMS:

This application has been submitted for the authorization of new product A23109A (Orondis VIP) in Poland, Austria, Belgium, Czech Republic, Germany, France, Netherlands and Slovakia. Orondis VIP contains two active substances: metalaxyl-M (174,4 g/l) and oxathiapiprolin (30 g/l). This product is intended to use as fungicide in vegetables under protected conditions.

MED
Based on the submitted trial results, dose rate of 0,5 l/ha can be determined minimum effective dose to control of disease pathogens in vegetables intended in the GAP table.

Efficacy
A23109A at 0,5 l/ha is effective to control of *Bremia lactucae* on lettuce under protected conditions. No efficacy trials were available for other claimed leafy vegetables. The cMSs are kindly asked to consider these uses on national level*.

Selectivity
2 protected selectivity trials have been submitted in lettuce. The phytotoxicity assessment was provided also in efficacy trials. No negative symptoms were observed in all presented trials. A23109A at dose rate of 0,5 l/ha is safe for lettuce.

Resistance risk
The resistance management strategy for A23109A is based on limitation of number applications (two applications per crop/season) and use of alternation with products from different cross resistance groups. The general anti-resistance recommendations are presented in the chapter 3.3.

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*Please note, that where a particular use is marked blue in the GAP table, it means that taking individual decision on that use by the respective cMS is welcome. It should not be meant as an off-loading, of the decision-taking, by the zRMS to the cMS. Instead, it aims at allowing the cMSs to take decisions different from that taken by zRMS for their own country, in recognition of the cMSs` different national requirements or preferences. Bearing that in mind, zRMS has discussed, in the commenting boxes, any doubtful issues, highlighting positive efficacy results where relevant, while also sharing with cMSs the reasons for which taking different decisions may be justified in different zones.
In case of the draft Registration Report there is still time for any cMS to express their view and argue, in favour or against the authorization in their country. That is why the zRMS is kindly asking the cMSs to not only take their decisions, but also to share the underlying information with the zRMS PL, within the commenting period framework. Only then will the zRMS be able to complete the GAP table unambiguously, in the final Registration Report, for all the EPPO zones and for all the concerned Member States, for which the present dossier has been submitted.

Table 3.1-1: Acceptability of intended uses (and respective fall-back GAPs, if applicable)

1	2	3	4	5	6	7	8	9	10	11	11	12	13	14	15
Use-No. [e]	**Member state(s)**	**Crop**	**F, G, or I**	**Pests or Group of pests controlled**	**Application**				**Application rate**				**PHI** (days)	**Remarks:**	**zRMS Conclusion (efficacy)**
					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			
Interzonal uses (greenhouses (or other closed places of plant production))															
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	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	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	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	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	C

1	2	3	4	5	6	7	8	9	10	11	11	12	13	14	15
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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	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
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	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	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	C
BE-37	Belgium	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	C

1	2	3	4	5	6	7	8	9	10	11	11	12	13	14	15
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					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			
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	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	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	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	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
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	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	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	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	C

1	2	3	4	5	6	7	8	9	10	11	11	12	13	14	15
Use-No. [e]	**Member state(s)**	**Crop**	**F, G, or I**	**Pests or Group of pests controlled**	**Application**				**Application rate**				**PHI** (days)	**Remarks:**	**zRMS Conclusion (efficacy)**
					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			
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	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	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	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	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	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
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	C

1	2	3	4	5	6	7	8	9	10	11	11	12	13	14	15
Use-No. [e]	**Member state(s)**	**Crop**	**F, G, or I**	**Pests or Group of pests controlled**	**Application**				**Application rate**				**PHI** (days)	**Remarks:**	**zRMS Conclusion (efficacy)**
					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			
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	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	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	n.r.

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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	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	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	n.r.

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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	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
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	n.r.

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					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			
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	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	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	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	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	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	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

1	2	3	4	5	6	7	8	9	10	11	11	12	13	14	15
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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	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
NL-35	Netherlands	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
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
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
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
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
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
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	n.r.

1	2	3	4	5	6	7	8	9	10	11	11	12	13	14	15
Use-No. [e]	**Member state(s)**	**Crop**	**F, G, or I**	**Pests or Group of pests controlled**	**Application**				**Application rate**				**PHI** (days)	**Remarks:**	**zRMS Conclusion (efficacy)**
					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			
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	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	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	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	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	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

1	2	3	4	5	6	7	8	9	10	11	11	12	13	14	15
Use-No. [e]	**Member state(s)**	**Crop**	**F, G, or I**	**Pests or Group of pests controlled**	**Application**				**Application rate**				**PHI** (days)	**Remarks:**	**zRMS Conclusion (efficacy)**
					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			
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	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	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	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	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	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	N
Minor uses according to Article 51 (interzonal uses)															
None															

* 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, G: professional greenhouse use, I: indoor application

Column 15: zRMS conclusion.

A	Acceptable
R	Acceptable with further restriction
C	To be confirmed by cMS
N	Not acceptable / evaluation not possible
n.r.	Not relevant for section 3

3.2 Efficacy data (KCP 6)

Introduction

This document summarises the information related to the efficacy data of the plant protection product A23109A containing:

- oxathiapiprolin which was approved under Regulation (EC) No 1107/2009 by Commission Implementing Regulation (EU) No 540/2011 and amended by Commission Implementing Regulation (EU) Regulation 2017/239, in force
- and metalaxyl-M included in Annex I of Council Directive 91/414/EEC by Commission Directive 2002/64/EC and approved under Regulation (EC) No 1107/2009 by Commission Implementing Regulation (EU) No 540/2011 and amended by Commission Implementing Regulation (EU) 2020/617 of 5 May 2020 renewing the approval of the active substance metalaxyl-M up to 31 May 2035.

The SANCO/EFSA report for oxathiapiprolin (SANTE/11169/2016 rev 3 – 7 December 2016, amended on 25 March 2021) is considered to provide the relevant review information or a reference to where such information can be found. The EFSA Scientific Review for oxathiapiprolin (EFSA Journal 2016;14(7):4504) is considered to provide the relevant review information or a reference to where such information can be found.

The SANCO/EFSA report for metalaxyl-M (SANTE/11112/2019 Rev 5 – 24 March 2020) is considered to provide the relevant review information or a reference to where such information can be found.

The data presented in this dossier fully support the registration of A23109A for the control of downy mildew on lettuce and herbs. The intended member states for an authorisation of the product are:

- Austria, Belgium, Czech Republic, France, Germany, Netherlands, Poland, Slovakia

The detailed assessment of the individual trial and study data is located in the following report:

Report:	**KCP 6 / 01 Biological Assessment Dossier <A23109A>** Syngenta File No. VV-882408

Description of active substances

A23109A is a dispersible concentrate (DC) containing 30 g oxathiapiprolin and 174.4 g metalaxyl-M (R-enantiomer) per litre product.

<u>Oxathiapiprolin</u>

Oxathiapiprolin is a preventive fungicide with limited curative, and residual activity against oomycete fungi and used for the control of Phytophthora and downy mildews of numerous crops. Oxathiapiprolin belongs to the chemical group Piperidinyl thiazole isoxazolines, mode of action OSBPI oxysterol binding protein homologue inhibition, FRAC code 49. Oxathiapiprolin inhibits an oxysterol binding protein (OSBP) homologue. Oxysterol binding proteins are implicated in the movement of lipids between membranes, among other processes. Inhibiting OSBP may disrupt other processes in the fungal cell, such as signaling, maintaining cell membranes, and the formation of more complex lipids that are essential for the cell to survive.

Metalaxyl-M

Metalaxyl-M can be formulated as liquid and as solid products. In product mixtures, the formulation type must suit the characteristics of all active ingredients present in the mixture.
It is admitted that metalaxyl-M is taken up very rapidly following root, stem or leaf application. Translocation of the compound is primarily acropetal. This acropetal or upward movement is a gradual and continuous process, thus providing additional fungicide activity and disease control as new plant growth occurs over several weeks (or months after soil treatment). Several studies showed limited basipetal (phloem) transport of metalaxyl; this is also expected to apply to metalaxyl-M. The important systemic properties of the compound provide more uniform distribution than is normally achieved with protectant fungicides and make it less susceptible to removal by rainfall.
Metalaxyl-M inhibits mycelium growth and spore formation both *in vivo* and *in vitro*. Foliar pathogens are inhibited only after they have penetrated the leaves.
Metalaxyl-M inhibits the fungus by selectively interfering with the synthesis of ribosomal RNA; more specifically, it inhibits the activity of the RNA polymerase 1-template complex.

Mode of action

Table 3.2-1: Details of the active substances

Active substance	Oxathiapiprolin	Metalaxyl-M
Concentration (Unit: g/kg or g/L...)	30 g/L	174.4 g/L
Chemical group	Piperidinyl-thiazole isoxazolines	Phenylamide (acylalanine)
Mode of action	F9: lipid homeostasis and transfer/storage OSBPI oxysterol binding protein homologue inhibition Preventative with residual disease control. It acts via an oxysterol binding protein. FRAC code: 49	A1: RNA polymerase I Nucleic acid methabolism FRAC code: 4
Plant translocation	Locally systemic fungicide, translaminar mobility, translocated in the xylem	systemic
Biological action	Preventive fungicide with some curative, and residual activity	Foliar and root, preventive and curative fungicide

Description of the plant protection product

A23109A is a dispersible concentrate (DC) containing 30 g oxathiapiprolin and 174.4 g metalaxyl-M (R-enantiomer) per litre product. Please note that the rate of MFX in A23109A based on EU MFX definition is 87.2 g ai/ha although indicated 90 g ai/ha in the trial reports, based on global definition (R+S enantiomer).

In leafy vegetable crops, the proposed maximum rate of A23109A is 0.5 litre per hectare (l/ha) with a maximum of 2 applications per season, which will deliver 15 g oxathiapiprolin per hectare and 87.2 g metalaxyl-M per hectare. To support the proposed uses of A23109A, data is presented from trials conducted on lettuce over two seasons 2019 and 2020 in a wide range of European countries in the Maritime EPPO zone (Belgium, Germany, France), Mediterranean EPPO zone (Spain, Italy, Portugal) and in North-East EPPO zone (Poland) under field and protected conditions. The combination of oxathiapiprolin and metalaxyl-M in A23109A will provide broad spectrum control against downy mildews with good crop safety.

Table 3.2-2: Simplified table of currently requested uses for A23109A Interzonal

USES		Member state	Minor use	Requested registered uses		Comments/other relevant details on the GAPs
Crops	Targets			L product / ha a) max. rate per appl. b) max. total rate per crop/season	Max. appl. number a) per use b) per crop/ season	
baby leaves	~~*Bremia lactucae*~~/downy mildew	Austria	Yes	a) 0.5 b) 1	a) 2 b) 2	max 2 app per year in same field: 1 app in 2 crop cycles or 2 app in 1 crop cycle
chicory	~~*Bremia lactucae*~~/downy mildew	Austria	Yes	a) 0.5 b) 1	a) 2 b) 2	max 2 app per year in same field: 1 app in 2 crop cycles or 2 app in 1 crop cycle
cress	~~*Bremia lactucae*~~/downy mildew	Austria	Yes	a) 0.5 b) 1	a) 1 b) 2	max 2 app per year in same field; PR MFX 74-136 g /ha
endive	~~*Bremia lactucae*~~/downy mildew	Austria	Yes	a) 0.5 b) 1	a) 2 b) 2	max 2 app per year in same field: 1 app in 2 crop cycles or 2 app in 1 crop cycle
escarole	~~*Bremia lactucae*~~/downy mildew	Austria	Yes	a) 0.5 b) 1	a) 2 b) 2	max 2 app per year in same field: 1 app in 2 crop cycles or 2 app in 1 crop cycle
lamb's lettuce	~~*Bremia lactucae*~~/downy mildew	Austria	Yes	a) 0.5 b) 1	a) 2 b) 2	max 2 app per year in same field: 1 app in 2 crop cycles or 2 app in 1 crop cycle
lettuce	~~*Bremia lactucae*~~/downy mildew	Austria	Yes	a) 0.5 b) 1	a) 2 b) 2	max 2 app per year in same field: 1 app in 2 crop cycles or 2 app in 1 crop cycle
purple-vein rocket	~~*Bremia lactucae*~~/downy mildew	Austria	Yes	a) 0.5 b) 1	a) 2 b) 2	max 2 app per year in same field: 1 app in 2 crop cycles or 2 app in 1 crop cycle
watercress	~~*Bremia lactucae*~~/downy mildew	Austria	Yes	a) 0.5 b) 1	a) 2 b) 2	max 2 app per year in same field: 1 app in 2 crop cycles or 2 app in 1 crop cycle
baby leaves	*Bremia lactucae*	Belgium	Yes	a) 0.5 b) 1	a) 2 b) 2	max 2 app per year in same field: 1 app in 2 crop cycles or 2 app in 1 crop cycle
chicory	*Bremia lactucae*	Belgium	Yes	a) 0.5 b) 1	a) 2 b) 2	max 2 app per year in same field: 1 app in 2 crop cycles or 2 app in 1 crop cycle
cress	*Bremia lactucae*	Belgium	Yes	a) 0.5 b) 1	a) 1 b) 2	max 2 app per year in same field; PR MFX 74-136 g /ha
endive	*Bremia lactucae*	Belgium	Yes	a) 0.5 b) 1	a) 2 b) 2	max 2 app per year in same field: 1 app in 2 crop cycles or 2 app in 1 crop cycle
escarole	*Bremia lactucae*	Belgium	Yes	a) 0.5 b) 1	a) 2 b) 2	max 2 app per year in same field: 1 app in 2

USES		Member state	Minor use	Requested registered uses		Comments/other relevant details on the GAPs
Crops	Targets			L product / ha a) max. rate per appl. b) max. total rate per crop/season	Max. appl. number a) per use b) per crop/ season	
						crop cycles or 2 app in 1 crop cycle
lamb's lettuce	*Bremia lactucae*	Belgium	Yes	a) 0.5 b) 1	a) 2 b) 2	max 2 app per year in same field: 1 app in 2 crop cycles or 2 app in 1 crop cycle
lettuce	*Bremia lactucae*	Belgium	Yes	a) 0.5 b) 1	a) 2 b) 2	max 2 app per year in same field: 1 app in 2 crop cycles or 2 app in 1 crop cycle
purple-vein rocket	*Bremia lactucae*	Belgium	Yes	a) 0.5 b) 1	a) 2 b) 2	max 2 app per year in same field: 1 app in 2 crop cycles or 2 app in 1 crop cycle
watercress	*Bremia lactucae*	Belgium	Yes	a) 0.5 b) 1	a) 2 b) 2	max 2 app per year in same field: 1 app in 2 crop cycles or 2 app in 1 crop cycle
baby leaves	*Bremia lactucae*	Czech Republic	Yes	a) 0.5 b) 1	a) 2 b) 2	max 2 app per year in same field: 1 app in 2 crop cycles or 2 app in 1 crop cycle
chicory	*Bremia lactucae*	Czech Republic	Yes	a) 0.5 b) 1	a) 2 b) 2	max 2 app per year in same field: 1 app in 2 crop cycles or 2 app in 1 crop cycle
cress	*Bremia lactucae*	Czech Republic	Yes	a) 0.5 b) 1	a) 1 b) 2	max 2 app per year in same field; PR MFX 74-136 g /ha
endive	*Bremia lactucae*	Czech Republic	Yes	a) 0.5 b) 1	a) 2 b) 2	max 2 app per year in same field: 1 app in 2 crop cycles or 2 app in 1 crop cycle
escarole	*Bremia lactucae*	Czech Republic	Yes	a) 0.5 b) 1	a) 2 b) 2	max 2 app per year in same field: 1 app in 2 crop cycles or 2 app in 1 crop cycle
iceberg lettuce	*Bremia lactucae*	Czech Republic	Yes	a) 0.5 b) 1	a) 2 b) 2	max 2 app per year in same field: 1 app in 2 crop cycles or 2 app in 1 crop cycle
lamb's lettuce	*Bremia lactucae*	Czech Republic	Yes	a) 0.5 b) 1	a) 2 b) 2	max 2 app per year in same field: 1 app in 2 crop cycles or 2 app in 1 crop cycle
lettuce	*Bremia lactucae*	Czech Republic	Yes	a) 0.5 b) 1	a) 2 b) 2	max 2 app per year in same field: 1 app in 2 crop cycles or 2 app in 1 crop cycle
purple-vein rocket	*Bremia lactucae*	Czech Republic	Yes	a) 0.5 b) 1	a) 2 b) 2	max 2 app per year in same field: 1 app in 2 crop cycles or 2 app in 1 crop cycle
watercress	*Bremia lactucae*	Czech Republic	Yes	a) 0.5 b) 1	a) 2 b) 2	max 2 app per year in same field: 1 app in 2

USES		Member state	Minor use	Requested registered uses		Comments/other relevant details on the GAPs
Crops	Targets			L product / ha a) max. rate per appl. b) max. total rate per crop/season	Max. appl. number a) per use b) per crop/ season	
						crop cycles or 2 app in 1 crop cycle
baby leaves	*Bremia lactucae*	France - N	No	a) 0.5 b) 1	a) 2 b) 2	max 2 app per year in same field: 1 app in 2 crop cycles or 2 app in 1 crop cycle
chicory	*Bremia lactucae*	France - N	No	a) 0.5 b) 1	a) 2 b) 2	max 2 app per year in same field: 1 app in 2 crop cycles or 2 app in 1 crop cycle
endive	*Bremia lactucae*	France - N	No	a) 0.5 b) 1	a) 2 b) 2	max 2 app per year in same field: 1 app in 2 crop cycles or 2 app in 1 crop cycle
escarole	*Bremia lactucae*	France - N	No	a) 0.5 b) 1	a) 2 b) 2	max 2 app per year in same field: 1 app in 2 crop cycles or 2 app in 1 crop cycle
Herbs and edible flowers	*Peronospora sp.*	France - N	Yes	a) 0.5 b) 1	a) 2 b) 2	max 2 app per year in same field: 1 app in 2 crop cycles or 2 app in 1 crop cycle
lamb's lettuce	*Bremia lactucae*	France - N	No	a) 0.5 b) 1	a) 2 b) 2	max 2 app per year in same field: 1 app in 2 crop cycles or 2 app in 1 crop cycle
lettuce	*Bremia lactucae*	France - N	No	a) 0.5 b) 1	a) 2 b) 2	max 2 app per year in same field: 1 app in 2 crop cycles or 2 app in 1 crop cycle
purple-vein rocket	*Bremia lactucae*	France - N	No	a) 0.5 b) 1	a) 2 b) 2	max 2 app per year in same field: 1 app in 2 crop cycles or 2 app in 1 crop cycle
baby leaves	*Bremia lactucae*	Germany	Yes	a) 0.5 b) 1	a) 2 b) 2	max 2 app per year in same field: 1 app in 2 crop cycles or 2 app in 1 crop cycle
chicory	*Bremia lactucae*	Germany	Yes	a) 0.5 b) 1	a) 2 b) 2	max 2 app per year in same field: 1 app in 2 crop cycles or 2 app in 1 crop cycle
cress	*Bremia lactucae*	Germany	Yes	a) 0.5 b) 1	a) 1 b) 2	max 2 app per year in same field; PR MFX 74-136 g /ha
endive	*Bremia lactucae*	Germany	Yes	a) 0.5 b) 1	a) 2 b) 2	max 2 app per year in same field: 1 app in 2 crop cycles or 2 app in 1 crop cycle
escarole	*Bremia lactucae*	Germany	Yes	a) 0.5 b) 1	a) 2 b) 2	max 2 app per year in same field: 1 app in 2 crop cycles or 2 app in 1 crop cycle
lamb's lettuce	*Bremia lactucae*	Germany	Yes	a) 0.5 b) 1	a) 2 b) 2	max 2 app per year in same field: 1 app in 2

USES		Member state	Minor use	Requested registered uses		Comments/other relevant details on the GAPs
Crops	Targets			L product / ha a) max. rate per appl. b) max. total rate per crop/season	Max. appl. number a) per use b) per crop/ season	
						crop cycles or 2 app in 1 crop cycle
lettuce	*Bremia lactucae*	Germany	Yes	a) 0.5 b) 1	a) 2 b) 2	max 2 app per year in same field: 1 app in 2 crop cycles or 2 app in 1 crop cycle
purple-vein rocket	*Bremia lactucae*	Germany	Yes	a) 0.5 b) 1	a) 2 b) 2	max 2 app per year in same field: 1 app in 2 crop cycles or 2 app in 1 crop cycle
watercress	*Bremia lactucae*	Germany	Yes	a) 0.5 b) 1	a) 2 b) 2	max 2 app per year in same field: 1 app in 2 crop cycles or 2 app in 1 crop cycle
baby leaves	*Bremia lactucae*	Netherlands	Yes	a) 0.5 b) 1	a) 2 b) 2	max 2 app per year in same field: 1 app in 2 crop cycles or 2 app in 1 crop cycle
chicory	*Bremia lactucae*	Netherlands	Yes	a) 0.5 b) 1	a) 2 b) 2	max 2 app per year in same field: 1 app in 2 crop cycles or 2 app in 1 crop cycle
endive	*Bremia lactucae*	Netherlands	Yes	a) 0.5 b) 1	a) 2 b) 2	max 2 app per year in same field: 1 app in 2 crop cycles or 2 app in 1 crop cycle
escarole	*Bremia lactucae*	Netherlands	Yes	a) 0.5 b) 1	a) 2 b) 2	max 2 app per year in same field: 1 app in 2 crop cycles or 2 app in 1 crop cycle
lamb's lettuce	*Bremia lactucae*	Netherlands	Yes	a) 0.5 b) 1	a) 2 b) 2	max 2 app per year in same field: 1 app in 2 crop cycles or 2 app in 1 crop cycle
lettuce	*Bremia lactucae*	Netherlands	Yes	a) 0.5 b) 1	a) 2 b) 2	max 2 app per year in same field: 1 app in 2 crop cycles or 2 app in 1 crop cycle
purple-vein rocket	*Bremia lactucae*	Netherlands	Yes	a) 0.5 b) 1	a) 2 b) 2	max 2 app per year in same field: 1 app in 2 crop cycles or 2 app in 1 crop cycle
baby leaves	*Bremia lactucae*	Poland	Yes	a) 0.5 b) 1	a) 2 b) 2	Minor Use – Art. 51 max 2 app per year in same field: 1 app in 2 crop cycles or 2 app in 1 crop cycle
chicory	*Bremia lactucae*	Poland	Yes	a) 0.5 b) 1	a) 2 b) 2	Minor Use – Art. 51 max 2 app per year in same field: 1 app in 2 crop cycles or 2 app in 1 crop cycle
cress	*Bremia lactucae*	Poland	Yes	a) 0.5 b) 1	a) 1 b) 2	Minor Use – Art 51 max 2 app per year in same field; PR MFX 74-136 g /ha

USES		Member state	Minor use	Requested registered uses		Comments/other relevant details on the GAPs
Crops	Targets			L product / ha a) max. rate per appl. b) max. total rate per crop/season	Max. appl. number a) per use b) per crop/ season	
endive	*Bremia lactucae*	Poland	Yes	a) 0.5 b) 1	a) 2 b) 2	Minor Use – Art 51 max 2 app per year in same field: 1 app in 2 crop cycles or 2 app in 1 crop cycle
escarole	*Bremia lactucae*	Poland	Yes	a) 0.5 b) 1	a) 2 b) 2	Minor Use – Art 51 max 2 app per year in same field: 1 app in 2 crop cycles or 2 app in 1 crop cycle
lamb's lettuce	*Bremia lactucae*	Poland	Yes	a) 0.5 b) 1	a) 2 b) 2	Minor Use – Art 51 max 2 app per year in same field: 1 app in 2 crop cycles or 2 app in 1 crop cycle
lettuce	*Bremia lactucae*	Poland	Yes	a) 0.5 b) 1	a) 2 b) 2	max 2 app per year in same field: 1 app in 2 crop cycles or 2 app in 1 crop cycle
purple-vein rocket	*Bremia lactucae*	Poland	Yes	a) 0.5 b) 1	a) 2 b) 2	Minor Use – Art 51 max 2 app per year in same field: 1 app in 2 crop cycles or 2 app in 1 crop cycle
watercress	*Bremia lactucae*	Poland	Yes	a) 0.5 b) 1	a) 2 b) 2	Minor Use – Art 51 max 2 app per year in same field: 1 app in 2 crop cycles or 2 app in 1 crop cycle
baby leaves	*Bremia lactucae*	Slovakia	Yes	a) 0.5 b) 1	a) 2 b) 2	max 2 app per year in same field: 1 app in 2 crop cycles or 2 app in 1 crop cycle
cress	*Bremia lactucae*	Slovakia	Yes	a) 0.5 b) 1	a) 1 b) 2	max 2 app per year in same field; PR MFX 74-136 g /ha
lettuce	*Bremia lactucae*	Slovakia	Yes	a) 0.5 b) 1	a) 2 b) 2	max 2 app per year in same field: 1 app in 2 crop cycles or 2 app in 1 crop cycle
watercress	*Bremia lactucae*	Slovakia	Yes	a) 0.5 b) 1	a) 2 b) 2	max 2 app per year in same field: 1 app in 2 crop cycles or 2 app in 1 crop cycle

Further details are in the table “All intended uses” in Part B - Section 0.

Description of the target pests

Table 3.2-3: Glossary of pests mentioned in the dossier

EPPO code	Scientific name
1BREMG	Bremia

EPPO code	Scientific name
BREMLA	*Bremia lactucae*
PEROPA	*Hyaloperonospora parasitica*
HPERBR	*Peronospora brassicae*
PERODE	*Peronospora destructor*
PEROSP	*Peronospora* sp.
PHYTPO	*Phytophthora porri*

***Bremia lactucae* in lettuce** (PP 2/3(2): Lettuce under protected cultivation)

Bremia lactucae causes the most serious disease of lettuce under protected cultivation. It persists as oospores in soil and is air-dispersed as sporangia. Lettuce plants can be infected at the seedling stage and all the way through the growing period. Lesions on leaves are first discoloured, and finally rot after sporulation of the pathogen.

Basic strategy:
The treatments applied to seedling compost or soil against fungi are not very effective against *B. lactucae* oospores. If possible, soils in which significant downy mildew was seen on a previous lettuce crop should be avoided. Lettuce cultivars with resistance to *B. lactucae* are available. This is often through the combination of several vertical resistance genes, but numerous corresponding pathotypes of *B. lactucae* exist. It is not advised to use a resistant cultivar, without chemical treatment, relying on the absence of the matching pathotype, as the pathotypes which occur on the crop may not correspond to the resistance of the plant. However, under such circumstances, the number of treatments could be reduced, if no downy mildew is seen.

Table 3.2-4: Major / minor status of intended uses (for all cMS and zRMS)
Interzonal

Crop and/or situation	Crop status		Pests or group of pests controlled	Pest status	
	Major	minor		Major	minor
baby leaves	FR - N	AT, BE, CZ, DE, NL, PL, SK	*Bremia lactucae*/downy mildew	FR - N	AT, BE, CZ, DE, NL, PL, SK,
chicory	FR - N	AT, BE, CZ, DE, NL, PL	*Bremia lactucae*/downy mildew	FR - N	AT, BE, CZ, DE, NL, PL
cress	-	AT, BE, CZ, DE, PL, SK	*Bremia lactucae*/downy mildew	-	AT, BE, CZ, DE, PL, SK
endive	FR - N	AT, BE, CZ, DE, NL, PL	*Bremia lactucae*/downy mildew	FR - N	AT, BE, CZ, DE, NL, PL
escarole	FR - N	AT, BE, CZ, DE, NL, PL	*Bremia lactucae*/downy mildew	FR - N	AT, BE, CZ, DE, NL, PL
Herbs & edible flowers	-	FR - N	*Peronospora sp.*	-	FR - N
iceberg lettuce	-	CZ	*Bremia lactucae*	-	CZ
lamb's lettuce	FR - N	AT, BE, CZ, DE, NL, PL	*Bremia lactucae*/downy mildew	FR - N	AT, BE, CZ, DE, NL, PL
lettuce	FR - N	AT, BE, CZ, DE, NL, PL, SK	*Bremia lactucae*/downy mildew	FR - N	AT, BE, CZ, DE, NL, PL, SK
purple-vein rocket	FR - N	AT, BE, CZ, DE, NL, PL	*Bremia lactucae*/downy mildew	FR - N	AT, BE, CZ, DE, NL, PL
watercress	-	AT, BE, CZ, DE, PL, SK	*Bremia lactucae*/downy mildew	-	AT, BE, CZ, DE, PL, SK

Compliance with the Uniform Principles

The overall assessment presented in this dossier was performed according to the Uniform Principles. All trials were conducted by GEP recognized testing units and according to EPPO guidelines.

No major deviation was recorded and when slight deviations occurred (example some deviations to EPPO guidelines), they were always considered as acceptable. All trials summarized in this dossier were considered as reliable and valid.

For more details on trial methodology, please refer to Table 3.2-16 and site details in Appendix 2 of the Biological Assessment Dossier.

Information on trials submitted (3.1 Efficacy data)

Table 3.2-5: Presentation of trials (efficacy trials, preliminary trials...)

Crop(s)*	Target(s)*	Country	Years	Type of trial**	Number of trials					GEP, non-GEP, official***	Comments (any other relevant information)
					Maritime zone (field trials)	Mediterranean zone	North-East zone (field trials)	Protected conditions	South-East zone (field trials)		
Lettuce	*Bremia lactucae*/ downy mildew	Belgium	2019	P+MED+E	1	-	-	2	-	GEP	
				MED+E	2	-	-	-	-	GEP	
			2020	P+MED+E	2	-	-	2	-	GEP	
		France	2019	P+MED+E	-	-	-	1	-	GEP	
				~~MED+E~~	-	1	-	-	-	GEP	
			2020	P+MED+E	2	-	-	1	-	GEP	
				MED+E	-	-	-	1	-	GEP	
		Germany	2019	P+MED+E	1	-	-	-	-	GEP	
		Italy	2019	MED+E	-	1	-	1	-	GEP	
			~~2020~~	~~P+MED+E~~	-	1	-	-	-	GEP	
		Poland	2019	P+MED+E	-	-	2	-	-	GEP	
			2020	P+MED+E	-	-	3	-	-	GEP	
				MED+E	-	-	1	-	-	GEP	
		Portugal	2020	MED+E	-	-	-	1	-	GEP	
		~~Spain~~	~~2019~~	~~P+MED+E~~	-	1	-	-	-	GEP	
				~~MED+E~~	-	1	-	-	-	GEP	
			~~2020~~	~~P+MED+E~~	-	1	-	-	-	GEP	
		TOTAL	**2019-2020**	**-**	**8**	6	**6**	**9**	**-**	**-**	
Onion	*Peronospora destructor*	Belgium	2019	P	1	-	-	-	-	GEP	-
		Czech Republic	2020	P	1	-	-	-	-	GEP	-
		France	2019	P	1	-	-	-	-	GEP	-
			2020	P	1	-	-	-	-	GEP	-
			2021	P	1	-	-	-	-	GEP	-
		Germany	2021	P	1	-	-	-	-	GEP	-
		~~Greece~~	~~2021~~	~~P~~	-	2	-	-	-	~~GEP~~	-
		~~Italy~~	~~2020~~	~~P~~	-	1	-	-	-	~~GEP~~	-
			~~2021~~	~~P~~	-	2	-	-	-	~~GEP~~	-
		Poland	2019	P	-	-	1	-	-	GEP	-

Crop(s) *	Target(s)*	Country	Years	Type of trial**	Number of trials					GEP, non-GEP, official***	Comments (any other relevant information)
					Maritime zone (field trials)	Mediterranean zone	North-East zone (field trials)	Protected conditions	South-East zone (field trials)		
			2020	P	-	-	~~2~~	-	-	GEP	-
		Romania	2021	P	-	-	-	-	1	GEP	-
		Slovakia	2021	P	-	-	-	-	1	GEP	-
		~~Spain~~	~~2019~~	~~P~~	-	~~2~~	-	-	-	~~GEP~~	-
			~~2020~~	~~P~~	-	~~1~~	-	-	-	~~GEP~~	-
		The Netherlands	2019	P	1	-	-	-	-	GEP	-
			2020	P	3	-	-	-	-	GEP	-
		TOTAL	**2019-2021**	**-**	**10**	~~8~~	**3**	-	**2**	-	-
Brassica	***Peronospora* spp.**	Belgium	2020	P	1	-	-	-	-	GEP	-
		Germany	2019	P	1	-	-	-	-	GEP	-
			2020	P	1	-	-	-	-	GEP	-
			2021	P	1	-	-	-	-	GEP	-
		~~Greece~~	~~2021~~	~~P~~	-	~~2~~	-	-	-	~~GEP~~	-
		Poland	2019	P	-	-	1	-	-	GEP	-
			2020	P	-	-	1	-	-	GEP	-
			2021	P	-	-	1	-	-	GEP	-
		~~Portugal~~	~~2021~~	~~P~~	-	~~1~~	-	-	-	~~GEP~~	-
		~~Romania~~	~~2021~~	~~P~~	-	-	-	-	2	~~GEP~~	-
		The Netherlands	2019	P	1	-	-	-	-	GEP	-
			2020	P	1	-	-	-	-	GEP	-
			2021	P	1	-	-	-	-	GEP	-
		TOTAL	**2019-2021**	**-**	**7**	~~3~~	**3**	-	**2**	-	-
		TOTAL			**25**	~~17~~	**12**	**9**	**4**	-	-

* According to the GAP table. Timing of the application(s) can be added if relevant (e.g. Pre-mergence vs post-emergence, spring vs autumn).

** P = preliminary trial, MED = minimum effective dose, E = efficacy trial.

*** GEP: Good Experimental Practices. Official: carried out by a national official organisation.

Table 3.2-6: Presentation of reference standards used in efficacy trials

Crop(s)	EPPO ZONE	Reference standard	Country(ies) where the product is registered (1)	Authorization number	Active substance(s)	Formulation		Registered application rate (3)	Application rate in trials (per treatment)	Remark(4)
						Type (2)	Concentration of a.s.			
Lettuce	Protected conditions	Revus (A12946B)	Belgium	9604P/B	Mandipropamid	SC	250 g/L	0.6 L/ha	0.6 L/ha	
			France	2080098	Mandipropamid	SC	250 g/L	0.6 L/ha	0.6 L/ha	
			Italy	13382	Mandipropamid	SC	250 g/L	0.6 L/ha	0.6 L/ha	Registered under the tradename « Pergado SC »
			Portugal	0815	Mandipropamid	SC	250 g/L	0.6 L/ha	0.6 L/ha	
	Maritime (field trials)	Revus (A12946B)	Belgium	9604P/B	Mandipropamid	SC	250 g/L	0.6 L/ha	0.6 L/ha	-
			Germany	026221-00	Mandipropamid	SC	250 g/L	0.6 L/ha	0.6 L/ha	-
			France	2080098	Mandipropamid	SC	250 g/L	0.6 L/ha	0.6 L/ha	-
	~~Mediterranean~~	~~Revus (A12946B)~~	~~Spain~~	~~25186~~	~~Mandipropamid~~	~~SC~~	~~25%~~	~~0.4 0.6 L/ha~~	~~0.6 L/ha~~	-
			~~France~~	~~2080098~~	~~Mandipropamid~~	~~SC~~	~~250 g/L~~	~~0.6 L/ha~~	~~0.6 L/ha~~	-
			~~Italy~~	~~13382~~	~~Mandipropamid~~	~~SC~~	~~250 g/L~~	~~0.6 L/ha~~	~~0.6 L/ha~~	~~Registered under the tradename « Pergado SC »~~
	North-East (field trials)	Revus (A12946B)	Poland	R-12/2009	Mandipropamid	SC	250 g/L	0.6 L/ha	0.6 L/ha	-

(1) only on use(s) applied for (with the test product).
(2) e.g. WP (wettable powder), EC (emulsifiable concentrate), etc.
(3) dose(s) / dose range authorized on that use in the country.
(4) Other relevant information (e.g. uses, number of applications, spray volume, method of application, etc.).

3.2.1 Preliminary tests (KCP 6.1)

Component and ratio justifications of A23109A are primarily based on resistance management strategy and currently minimum recommended rates of both active ingredients for the main targeted pathogens by A23109A.
The loss of multisite active substances on the fungicide market leads to the need of new resistance management tools. The development of A23109A offers a good solution combining fully effective rates of oxathiapiprolin (OXTP) and metalaxyl-M (MFX), securing, with their different modes of action, an effective control without increasing the risk of resistance occurrence development[1].

Resistance management for metalaxyl-M and oxathiapiprolin depends on three different parameters: intrinsic fungicide risk, pathogen risk and agronomic risk. Additionally, to the risk to the individual fungicides also the combined risk towards the mixture needs to be evaluated.
These considerations were taken into account when designing the product mixture. Based on current knowledge, the intrinsic fungicide risk for oxathiapiprolin is moderate to high and the intrinsic resistance risk of phenylamide fungicides is considered as high (FRAC). The use of two fungicides in a mixture is considered as valuable anti-resistance strategy compared to the use of solo compounds. Each component of the mixture must provide good efficacy in its own right and also be resilient to the development of resistance. For all these reasons the ratio of the product A23109A was based on currently registered rates of solo products respectively with OXTP and with MFX.
For OXTP, we have considered 15 g OXTP/ha as the minimum effective dose against *Peronospora destructor* in onion and *Bremia lactucae* in lettuce, based on current registration rates in Europe of Zorvec Endavia (benthiavalicarbe mixture) on onion, and Zorvec Enicade, solo OXTP formulation on lettuce.
Regarding MFX, its minimum effective dose against Downy mildew in vegetables as *Peronospora destructor* in onion, *Bremia lactucae* in lettuce and *Hyaloperonospora parasitica* in brassica crops, is considered to be around 90 g MFX/ha (global MFX definition), based on minimum registered or old MFX rates in mixture formulations against ~~these~~ this pathogen~~s~~.
This efficacy rate is confirmed by recent studies done in 2021 against *Peronospora destructor* in onion and *Hyaloperonospora parasitica* in brassica where it is clearly seen that the rate of 0.2 L PR/ha, equivalent to 93 g MFX/ha is needed to reach a similar efficacy level as the Standard Infinito, compared to 0.135 L PR/ha (= 63 g MFX/ha) which is clearly less efficient. These results are illustrated in **Figure 3.2-1** and **Figure 3.2-2** below.

[1]FRAC, January 2010, FRAC recommendations for fungicide mixtures designed to delay resistance evolution., available online in March 2022: https://www.frac.info/docs/default-source/publications/frac-recommendations-for-fungicide-mixtures/frac-recommendations-for-fungicide-mixtures---january-2010.pdf
FRAC; March 2020, FRAC Recommendations on Resistance Management for Phenylamides, available online in March 2022, https://www.frac.info/frac-teams/expert-fora/phenylamides/recommendations-for-phenylamides
FRAC, April 2021, FRAC Recommendations for OSBPI fungicides, available online in March 2022, https://www.frac.info/frac-teams/working-groups/osbpi-fungicides/recommendations-for-osbpi

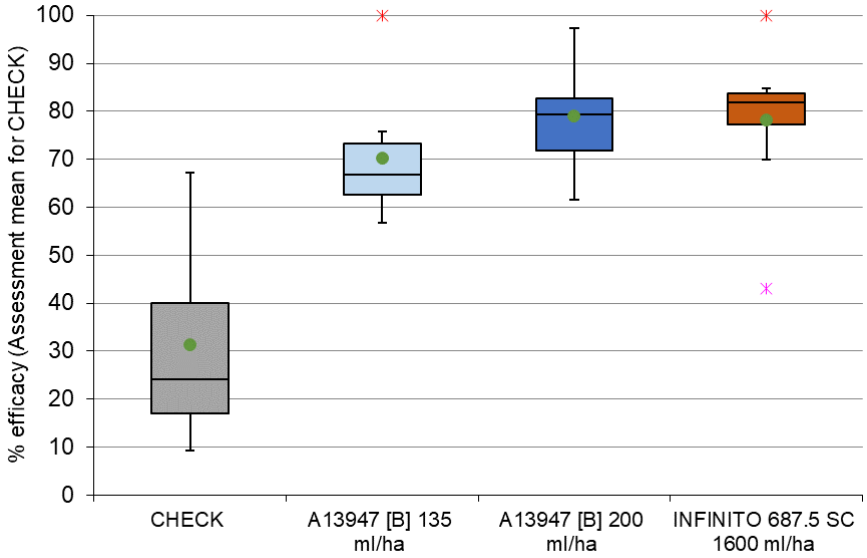

Figure 3.2-1:MFX (A13947B) efficacy against *Peronospora destructor* in onion – mean 8 EU trials done in 2021 – pest severity leaves

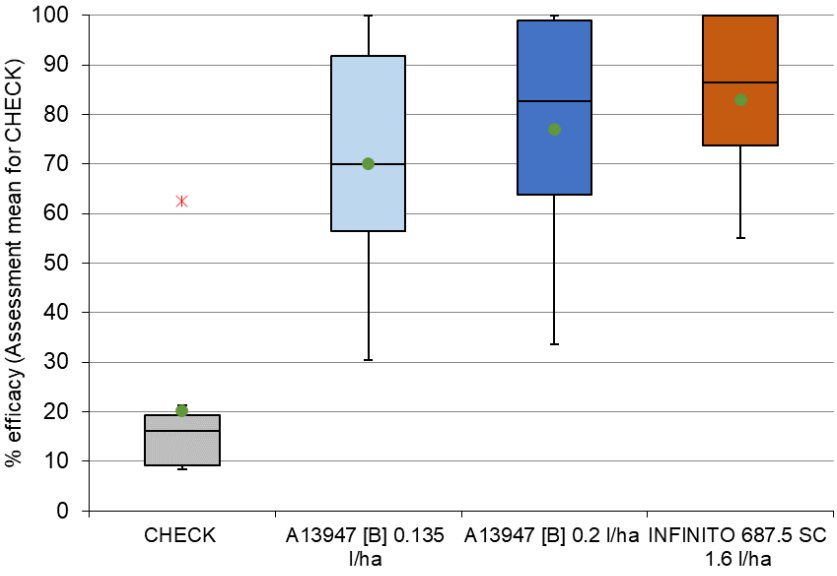

Figure 3.2-2:MFX (A13947B) efficacy against *Hyaloperonospora parasitica* in brassica crops – mean 8 EU trials done in 2021 – pest severity leaves

A23109A contents 30 g/L OXTP + 174.4 g/L MFX (EU definition only R enantiomer or 180 g/L MFX global definition R+S enantiomer) and brings at its targeted rate of 0.5 L PR/ha, 15 g/ha OXTP + 87.2 - 90 g/ha MFX (EU - global MFX definition) which meets the considered minimum effective dose of both active substances on the main pathogens, difficult to control, claimed on the label.

In this section, component justification trials are presented to show the efficacy benefit of the combination of OXTP and MFX, as done in the product A23109A. Efficacy trials testing the product A23109A and straight products A20941B (oxathiapiprolin – 100 g/L, OD) and A13947 (metalaxyl-M – 480 g/L, SL global MFX definition or 465.2 g/L based on EU MFX definition) at similar rates of the single active substances were selected to check the robustness of the product A23109A.

For material and method of the trials refer to Site and application details located in Appendix 2 of the

Biological Assessment Dossier. Please note that the rate of MFX in A23109A based on EU MFX definition is 87.2 g ai/ha although indicated 90 g ai/ha in the trial reports, based on global definition (R+S enantiomer)- same for A13947A which will bring 88.4 g MFX/ha based on EU definition.

3.2.1.1 Component justification on lettuce

A total of ~~20~~ 6 trials on lettuce ~~(6x~~ under protected conditions~~, 6x in Maritime, 3x in Mediterranean and 5x in North-East EPPO zone)~~ are summarized for component justification of A23109A. All the set of trials were carried out over seasons 2019 and 2020.

A23109A contents 30 g/L OXTP + 174.4 g/L MFX (EU definition only R enantiomer or 180 g/L MFX global definition R+S enantiomer) and brings at its targeted rate of 0.5 L PR/ha, 15 g/ha OXTP + 87.2 - 90 g/ha MFX (EU - global MFX definition).

All these efficacy trials testing the product A23109A and straight products A20941B (oxathiapiprolin – 100 g/L, OD) and A13947 (metalaxyl-M – 480 g/L, SL global MFX definition or 465.2 g/L based on EU MFX definition) at similar rates of the single active substances were selected to check the robustness of the product A23109A.

Table 3.2-7 shows a summary of relevant disease severity assessments on lettuce for the control of *Bremia lactucae*. Only trials where challenging disease severity was observed (above 5% for lettuce) were averaged.

According to the presented results of disease severity control on lettuce across all zones, the efficacy of the solo ais at the mixture rate is confirmed for both OXTP and MFX at their mixture rate. In addition mixture efficacy benefit is also observed, A23109A provided better control than both OXTP and MFX straight products against *Bremia lactucae* on lettuce.

In summary, the combination of OXTP and MFX in the product A23109A will provide effective and robust control in terms of severity against downy mildews on lettuce.

Table 3.2-7: Component justification of A23109A against *Bremia lactucae* on lettuce

Target	Assessment type	EPPO zone	Number of trials~~; Number of assessments~~	Infestation of the untreated control (% pest severity)		% control					
						Test product A23109A 15 g oxathiapiprolin/ha + 90 g metalaxyl-M/ha*		A20941B 15 g oxathiapiprolin/ha		A13947A 91.2 g metalaxyl-M/ha**	
				Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max
Mean of all trials ~~assessments (last assessment per trial)~~											
Bremia lactucae (BREMLA)	PESSEV 0-100 index	Protected conditions (after 1 application)	n=6~~; N=6~~	63.5	18.9 - 87.9	97	87.0-100	94.2	74.1-100	54.8	38.0 - 79.8
		~~MAR~~	~~n=6; N=6~~	~~62.3~~	~~25.8 - 98.6~~	~~76.1~~	~~48.6-100~~	~~79.9~~	~~55.9-100~~	~~63.9~~	~~18.1 - 94.0~~
		~~MED~~	~~n=3; N=3~~	~~48.9~~	~~9.6-100~~	~~89.1~~	~~73.1-98.6~~	~~89.7~~	~~81.3-94.2~~	~~21.7~~	~~0.1-47.8~~
		~~NE~~	~~n=5; N=5~~	~~70.4~~	~~31.9-100~~	~~90.6~~	~~77.7-100~~	~~79.1~~	~~62.8-97~~	~~55.1~~	~~30.9-97~~
		~~All zones~~	~~n=20; N=20~~	~~61.3~~	~~48.9 - 70.4~~	~~88.2~~	~~76.1-97~~	~~85.7~~	~~79.1-94.2~~	~~48.9~~	~~21.7 - 63.9~~

*A23109A will bring 87.2 g MFX/ha based on EU MFX definition
**A13947A will bring 88.4 g MFX/ha based on EU MFX definition

Comments of zRMS:
6 preliminary trials under protected conditions have been submitted for component justification. The mix of oxathiapiprolin and metalaxyl-M including in A23109A achieved similar efficacy compared to oxathiapiprolin after 1 application in all trials. The test product controlled disease pathogens superior than single active substance of metalaxyl-M with result of 97% vs 54,8%. In opinion of zRMS, mix of oxathiapiprolin and metalaxyl-M is justified to control of *Bremia lactucae* on lettuce.

3.2.1.2 Component justification on onion

A total of 15 trials on onion (8x in Maritime; 4x in Mediterranean, 3x in North-East EPPO zone) are summarized for component justification of A23109A. All the set of trials were carried out over seasons 2019 and 2020.

A23109A contents 30 g/L OXTP + 174.4 g/L MFX (EU definition only R enantiomer or 180 g/L MFX global definition R+S enantiomer) and brings at its targeted rate of 0.5 L PR/ha, 15 g/ha OXTP + 87.2 – 90 g/ha MFX (EU – global MFX definition).

All these efficacy trials testing the product A23109A and straight products A20941B (oxathiapiprolin – 100 g/L, OD) and A13947 (metalaxyl-M – 480 g/L, SL global MFX definition or 465.2 g/L based on EU MFX definition) at similar rates of the single active substances were selected to check the robustness of the product A23109A.

Table 3.2-8 show a summary of relevant disease severity assessments on onion for the control of *Peronospora destructor*. Only trials where challenging disease severity was observed (above 10% for onion) were averaged.

According to the presented results of disease severity control on onion across all zones, the efficacy of the solo ais at the mixture rate is confirmed for both OXTP and MFX at their mixture rate. In addition mixture efficacy benefit is also observed, A23109A provided better control than both OXTP and MFX straight products against *Peronospora destructor* on onion.

In summary, the combination of OXTP and MFX in the product A23109A will provide effective and robust control in terms of severity against downy mildews on onion.

Table 3.2-8: Component justification of A23109A against *Peronospora destructor* on onion

Target	Assessment type	EPPO zone	Number of trials; Number of assessments	Infestation of the untreated control (% pest severity)		% control					
						Test product A23109A 15 g oxathiapiprolin/ha + 90 g metalaxyl-M/ha*		A20941B 15 g oxathiapiprolin/ha		A13947A 91.2 g metalaxyl-M/ha**	
				Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max
Mean of all assessments (last assessment per trial)											
Peronospora destructor (PERODE)	PESSEV % disease on leaves per plot	MAR	n=5; N=5	72.3	38.8 -100	92.5	75.1-100	73.3	48.7-96.3	75.3	58.8 - 88.1
		MED	n=3; N=3	35.4	23.6 - 47.5	61.4	54.3-73.7	48.3	11.1-75.8	16.5	0 - 26.5
		All zones	n=8; N=8	53.8	35.4 - 72.3	77.0	61.4-92.5	60.8	48.3-73.3	45.9	16.5 - 75.3
	PESSEV % disease	MAR	n=4; N=4	61.2	32.1 - 80.0	78.7	66.8-98.9	46.7	31.7-57.9	36.1	6.7 - 76.6

Target	Assessment type	EPPO zone	Number of trials; Number of assessments	Infestation of the untreated control (% pest severity)		% control					
						Test product A23109A 15 g oxathiapiprolin/ha + 90 g metalaxyl-M/ha*		A20941B 15 g oxathiapiprolin/ha		A13947A 91.2 g metalaxyl-M/ha**	
				Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max
	area per leaf	MED	n=4; N=4	32.1	22.6 - 36.0	79.1	65.5-88.8	64.0	48.8-85.2	33.4	13.4 - 76.9
		NE	n=3; N=3	31.4	15.2 - 42.6	73	53.4-95.9	70.5	50.8-97.2	55.1	30.8 - 73.0
		All zones	n=11; N=11	41.6	31.4 - 61.2	76.9	73-79.1	60.4	46.7-70.5	41.5	33.4 - 55.1
Mean of all assessments after 2 applications from disease appearance											
Peronospora destructor (PERODE)	PESSEV % disease on leaves per plot	MAR	n=2; N=2	39.6	31.2 - 47.9	99.8	99.5-100	79.7	66.9-92.5	73.6	57.6 - 89.5
		MED	n=1; N=1	23.6	-	73.7	-	75.8	-	23.0	-
		All zones	n=3; N=3	31.6	23.6 - 39.6	86.8	73.7-99.8	77.8	75.8-79.7	48.3	23 - 73.6
	PESSEV % disease area per leaf	MAR	n=3; N=3	43	24.1 - 72.5	86.1	66.8-100	62.1	31.7-92.7	42.2	11.4 - 92.5
		MED	n=1; N=1	36	-	84.9	-	85.2	-	76.9	-
		NE	n=2; N=2	12.7	10.2 - 15.2	65.5	53.4-77.6	69.2	50.8-87.5	68.1	61.5 - 74.7
		All zones	n=3; N=3	30.6	12.7 -43	78.8	65.5-86.1	72.2	62.1-85.2	62.4	42.2 - 76.9

*A23109A will bring 87.2 g MFX/ha based on EU MFX definition
**A13947A will bring 88.4 g MFX/ha based on EU MFX definition

3.2.1.3 Component justification on Brassica crops

A total of 7 trials in brassica crops (5x in Maritime and 2x in North East zone) are summarized for component justification of A23109A. All the set of trials were carried out over seasons 2019 and 2020.

A23109A contents 30 g/L OXTP + 174.4 g/L MFX (EU definition only R enantiomer or 180 g/L MFX global definition R+S enantiomer) and brings at its targeted rate of 0.5 L PR/ha, 15 g/ha OXTP + 87.2 – 90 g/ha MFX (EU – global MFX definition).

All these efficacy trials testing the product A23109A and straight products A20941B (oxathiapiprolin – 100 g/L, OD) and A13947 (metalaxyl-M – 480 g/L, SL global MFX definition or 465.2 g/L based on EU MFX definition) at similar rates of the single active substances were selected to check the robustness of the product A23109A.

Table 3.2-9 show a summary of relevant disease severity assessments on brassica crops for the control of *Peronospora* spp. Only trials where challenging disease severity was observed (above 5% for brassica crops) were averaged.

According to the presented results of disease severity control on brassica crops across all zones, the efficacy of the solo ais at the mixture rate is confirmed for both OXTP and MFX at their mixture rate. In addition mixture efficacy benefit is also observed, A23109A provided better control than both OXTP

and MFX straight products against *Peronospora* spp. on brassica crops.

In summary, the combination of OXTP and MFX in the product A23109A will provide effective and robust control in terms of severity against downy mildews on brassica crops

Table 3.2.9: Component justification of A23109A against *Peronospora* spp. on brassica crops

Target	Assessment type	EPPO zone	Number of trials; Number of assessments	Infestation of the untreated control (% pest severity)		% control					
						Test product A23109A 15 g oxathiapiprolin/ha + 90 g metalaxyl-M/ha*		A20941B 15 g oxathiapiprolin/ha		A13947A 91.2 g metalaxyl-M/ha**	
				Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max
Mean of all assessments (last assessment per trial)											
Peronospora spp. (1PEROG)	% PESSEV on leaf	MAR	n=5; N=5	23.2	5.9 - 75.6	80.6	51.1-91.3	79.4	60.0-89.3	49.0	10.7 - 85.1
		NE	n=2; N=2	23.6	20.0 - 27.1	99.0	99.0	98.5	97.8-99.1	95.5	92.0 - 98.9
		All zones	n=7; N=7	23.4	23.2 - 23.6	89.8	80.6-99	89.0	79.4-98.5	72.3	49 - 95.5
Mean of all assessments after 2 applications from disease appearance											
Peronospora spp. (1PEROG)	% PESSEV on leaf	MAR	n=1; N=1	13.7	-	90.0	-	81.1	-	85.1	-
		NE	n=1; N=1	17.6	-	100	-	100	-	100	-
		All zones	n=2; N=2	15.7	13.7 - 17.6	95.0	90-100	90.6	81.1-100	92.6	85.1 -100

*A23109A will bring 87.2 g MFX/ha based on EU MFX definition
**A13947A will bring 88.4 g MFX/ha based on EU MFX definition

3.2.1.4 Summary and conclusions on the preliminary trials

Component justification of the product A23109A is primarily based on resistance management strategy. The loss of multisite active substances on the fungicide market leads to the need of new resistance management tools. The development of A23109A offers a good solution combining effective rates of oxathiapiprolin (OXTP) and metalaxyl-M (MFX), securing, with their different modes of action, an effective control without increasing the risk of resistance occurrence development.

Indeed, the product A23109A is composed of two effective active ingredients against downy mildews, OXTP and MFX. The mixture of these two effective active ingredients brought some efficacy gains. For foliar applications, the phenylamides as well as OSBPI should be used in a mixture containing an unrelated effective partner and used in a sound management program. The mixture of these two active substances from different modes of action should thus allow to give effective control of the target diseases while avoiding new development of resistance cases.

In addition to this resistance-based argumentation, component justification trials are presented to show the efficacy benefit of the combination of OXTP and MFX, as done in the product A23109A and the solo a.i. efficacy at the a.i. rates in the mixture to confirm their efficacy at the mixture rate on main representative pathogens targeted by A23109A.

A total of 20 6 trials on lettuce (6x under protected conditions, 6x in Maritime, 3x in Mediterranean and 5x in North-East EPPO zone), 15 trials on onion (8x in Maritime; 4x in Mediterranean, 3x in North-East EPPO zone), 7 trials in brassica crops (5x in Maritime and 2x in North-East zone) are summarized for component justification of A23109A. All the set of trials were carried out over seasons 2019 and 2020.

A23109A contents 30 g/L OXTP + 174.4 g/L MFX (EU definition only R enantiomer or 180 g/L MFX global definition R+S enantiomer) and brings at its targeted rate of 0.5 L PR/ha, 15 g/ha OXTP + 87.2 - 90 g/ha MFX (EU - global MFX definition).
Efficacy trials testing the product A23109A and straight products A20941B (oxathiapiprolin – 100 g/L, OD) and A13947 (metalaxyl-M – 480 g/L, SL global MFX definition or 465.2 g/L based on EU MFX definition) at similar rates of the single active substances were selected to check the robustness of the product A23109A.

Please note that the rate of MFX in A23109A based on EU MFX definition is 87.2 g ai/ha although indicated 90 g ai/ha in the trial reports and tables below, based on global definition (R+S enantiomer)- same for A13947A which will bring 88.4 g MFX/ha based on EU definition.

Table 3.2-10 to Table 3.2-14 show a summary of relevant disease severity assessments on lettuce, onion and brassica crops for the control of respectively *Bremia lactucae*, *Peronospora destructor* and *Peronospora* spp. Only trials where challenging disease severity was observed (above 5% for Brassica crops and lettuce and above 10% for onion) were averaged.

According to the presented results of disease severity control, the efficacy of the solo a.i. at the rates in the mixture is confirmed for both OXTP and MFX at their mixture rate. In addition, mixture efficacy benefit is also observed. A23109A provided better control than both OXTP and MFX straight products mainly against *Peronospora destructor* on onion and *Peronospora* spp. on brassica crops and in some extend against *Bremia lactucae* on lettuce.

In summary, the combination of OXTP and MFX in the product A23109A will provide effective and robust control in terms of severity against downy mildews on lettuce, onion and brassica crops.

~~**Table 3.2-10: MFX (A13947B) efficacy against *Peronospora destructor* in onion**~~

~~Target~~	~~Assessment type~~	~~EPPO zone~~	~~Number of trials; Number of assessments~~	~~Infestation of the untreated control (% pest severity)~~		~~% control~~					
						~~A13947 [B] 0.135 l/ha 91.2 g metalaxyl-M/ha~~		~~A13947 [B] 0.200 l/ha 91.2 g metalaxyl-M/ha~~		~~INFINITO 687.5 SC 1.6 l/ha 100 g propamocarb hydrochloride/ha + 100 g fluopicolide/ha~~	
				~~Mean~~	~~Min & Max~~	~~Mean~~	~~Min & Max~~	~~Mean~~	~~Min & Max~~	~~Mean~~	~~Min & Max~~
~~**Mean of all assessments**~~											
~~*Peronospora destructor* (PERODE)~~	~~PESSEV % area per 1 leaf~~	~~All zones~~	~~n=8; N=8~~	~~31.4~~	~~9.2-67.0~~	~~9.4~~	~~0.0-100.0~~	~~80.3~~	~~61.6-97.4~~	~~8.7~~	~~0.0-38.3~~

~~**Table 3.2-11: MFX (A13947B) efficacy against *Hyaloperonospora parasitica* in brassica crops**~~

~~Target~~	~~Assessment type~~	~~EPPO zone~~	~~Number of trials; Number of assessments~~	~~Infestation of the untreated control (% pest severity)~~		~~% control~~					
						~~A13947 [B] 0.135 l/ha 91.2 g metalaxyl-M/ha~~		~~A13947 [B] 0.200 l/ha 91.2 g metalaxyl-M/ha~~		~~INFINITO 687.5 SC 1.6 l/ha 100 g propamocarb hydrochloride/ha + 100 g fluopicolide/ha~~	
				~~Mean~~	~~Min & Max~~	~~Mean~~	~~Min & Max~~	~~Mean~~	~~Min & Max~~	~~Mean~~	~~Min & Max~~
~~**Mean of all assessments**~~											
~~*Peronospora destructor* (PERODE)~~	~~PESSEV %area per 1 or 20 plants~~	~~All zones~~	~~n=8; N=8~~	~~20.2~~	~~8.5-62.5~~	~~6.9~~	~~0.0-24.5~~	~~75.8~~	~~33.6-100~~	~~3.3~~	~~0.0-7.3~~

Table 3.2-12: Component justification of A23109A against *Bremia lactucae* on lettuce

Target	**Assessment type**	**EPPO zone**	**Number of trials**~~; Number of assessments~~	**Infestation of the untreated control (% pest severity)**		**% control**					
						Test product A23109A 15 g oxathiapiprolin/ha + 90 g metalaxyl-M/ha*		**A20941B 15 g oxathiapiprolin/ha**		**A13947A 91.2 g metalaxyl-M/ha****	
				Mean	**Min & Max**	**Mean**	**Min & Max**	**Mean**	**Min & Max**	**Mean**	**Min & Max**
Mean of all trials ~~assessments (last assessment per trial)~~											
Bremia lactucae (BREMLA)	PESSEV 0-100 index	Protected conditions (after 1 appl.)	n=6~~; N=6~~	63.5	18.9-87.9	97	87.0-100	94.2	74.1-100	54.8	38.0-79.8
		~~MAR~~	~~n=6; N=6~~	~~62.3~~	~~25.8-98.6~~	~~76.1~~	~~48.6-100~~	~~79.9~~	~~55.9-100~~	~~63.9~~	~~18.1-94.0~~

		MED	n=3; N=3	48.9	9.6-100	89.1	73.1-98.6	89.7	81.3-94.2	21.7	0.1-47.8
		NE	n=5; N=5	70.4	31.9-100	90.6	77.7-100	79.1	62.8-97	55.1	30.9-97
		All zones	n=20; N=20	61.3	48.9-70.4	88.2	76.1-97	85.7	79.1-94.2	48.9	21.7-63.9

*A23109A will bring 87.2 g MFX/ha based on EU MFX definition; **A13947A will bring 88.4 g MFX/ha based on EU MFX definition

Table 3.2-13: Component justification of A23109A against *Peronospora destructor* on onion

Target	Assessment type	EPPO zone	Number of trials; Number of assessments	Infestation of the untreated control (% pest severity)		% control					
						Test product A23109A 15 g oxathiapiprolin/ha + 90 g metalaxyl-M/ha*		A20941B 15 g oxathiapiprolin/ha		A13947A 91.2 g metalaxyl-M/ha**	
				Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max
Mean of all assessments (last assessment per trial)											
Peronospora destructor (PERODE)	PESSEV % disease on leaves per plot	MAR	n=5; N=5	72.3	38.8-100	92.5	75.1-100	73.3	48.7-96.3	75.3	58.8-88.1
		MED	n=3; N=3	35.4	23.6-47.5	61.4	54.3-73.7	48.3	11.1-75.8	16.5	0-26.5
		All zones	n=8; N=8	53.8	35.4-72.3	77.0	61.4-92.5	60.8	48.3-73.3	45.9	16.5-75.3
	PESSEV % disease area per leaf	MAR	n=4; N=4	61.2	32.1-80.0	78.7	66.8-98.9	46.7	31.7-57.9	36.1	6.7-76.6
		MED	n=4; N=4	32.1	22.6-36.0	79.1	65.5-88.8	64.0	48.8-85.2	33.4	13.4-76.9
		NE	n=3; N=3	31.4	15.2-42.6	73	53.4-95.9	70.5	50.8-97.2	55.1	30.8-73.0
		All zones	n=11; N=11	41.6	31.4-61.2	76.9	73-79.1	60.4	46.7-70.5	41.5	33.4-55.1
Mean of all assessments after 2 applications from disease appearance											
Peronospora destructor (PERODE)	PESSEV % disease on leaves per plot	MAR	n=2; N=2	39.6	31.2-47.9	99.8	99.5-100	79.7	66.9-92.5	73.6	57.6-89.5
		MED	n=1; N=1	23.6	-	73.7	-	75.8	-	23.0	-
		All zones	n=3; N=3	31.6	23.6-39.6	86.8	73.7-99.8	77.8	75.8-79.7	48.3	23-73.6
	PESSEV % disease area per leaf	MAR	n=3; N=3	43	24.1-72.5	86.1	66.8-100	62.1	31.7-92.7	42.2	11.4-92.5
		MED	n=1; N=1	36	-	84.9	-	85.2	-	76.9	-
		NE	n=2; N=2	12.7	10.2-15.2	65.5	53.4-77.6	69.2	50.8-87.5	68.1	61.5-74.7
		All zones	n=3; N=3	30.6	12.7-43	78.8	65.5-86.1	72.2	62.1-85.2	62.4	42.2-76.9

*A23109A will bring 87.2 g MFX/ha based on EU MFX definition
**A13947A will bring 88.4 g MFX/ha based on EU MFX definition

Table 3.2-14: Component justification of A23109A against *Peronospora* spp. on brassica crops

Target	Assessment type	EPPO zone	Number of trials; Number of assessments	Infestation of the untreated control (% pest severity)		% control					
						Test product A23109A 15 g oxathiapiprolin/ha + 90 g metalaxyl-M/ha*		A20941B 15 g oxathiapiprolin/ha		A13947A 91.2 g metalaxyl-M/ha**	
				Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max
Mean of all assessments (last assessment per trial)											
Peronospora spp. (1PEROG)	% PESSEV on leaf	MAR	n=5; N=5	23.2	5.9-75.6	80.6	51.1-91.3	79.4	60.0-89.3	49.0	10.7-85.1
		NE	n=2; N=2	23.6	20.0-27.1	99.0	99.0	98.5	97.8-99.1	95.5	92.0-98.9
		All zones	n=7; N=7	23.4	23.2-23.6	89.8	80.6-99	89.0	79.4-98.5	72.3	49-95.5
Mean of all assessments after 2 applications from disease appearance											
Peronospora spp. (1PEROG)	% PESSEV on leaf	MAR	n=1; N=1	13.7	-	90.0	-	81.1	-	85.1	-
		NE	n=1; N=1	17.6	-	100	-	100	-	100	-
		All zones	n=2; N=2	15.7	13.7-17.6	95.0	90-100	90.6	81.1-100	92.6	85.1-100

*A23109A will bring 87.2 g MFX/ha based on EU MFX definition
**A13947A will bring 88.4 g MFX/ha based on EU MFX definition

3.2.2 Minimum effective dose tests (KCP 6.2)

A23109A contains 30 g/L OXTP + 174.4 g/L MFX (EU definition only R enantiomer or 180 g/L MFX global definition R+S enantiomer) and brings at its targeted rate of 0.5 L PR/ha, 15 g/ha OXTP + 87.2 - 90 g/ha MFX (EU - global MFX definition).
It is to note that the rates of MFX in A23109A indicated in the trial reports and the tables of results is calculated on global definition (R+S enantiomer) although the rate of MFX in A23109A is well based on EU MFX definition.

A total of 9 protected trials ~~and 20 field supportive trials~~ were established in order to determine the minimum effective dose for the control of the *Bremia lactucae* on lettuce. A23109A was tested at 0.25 to 0.5 L PR/ha on lettuce for the control of *Bremia lactucae*. The rates reflect the proposed label rate and 80% and 50% of the full recommended rate of A23109A, in accordance with the EPPO standard PP 1/225 '*Minimum effective dose'*. This dose is selected on the basis of its efficacy performance, product safety parameters and environmental limitations. ~~Efficacy was tested under a range of environmental conditions to fully challenge the product. Data are presented across Europe to fully reflect the range of climatic and agronomic conditions.~~ Trials were conducted under protected conditions in ~~(~~Belgium, France, Italy and Portugal~~)~~ ~~and also under field conditions in Maritime EPPO zone (Belgium, Germany and France), Mediterranean EPPO zone (France, Italy and Spain), North-East EPPO zone (Poland) and~~ between 2019 and 2020.

For material and method of the trials refer to Annex Point IIIA 3.2.3 (KCP 6.2).
The methodology for means calculation and data presentation in this chapter 3.2.2 is similar to the one in chapter 3.2.3 except for the following points:

In the detailed tables of results of this chapter, a selection of one representative assessment per trial was made for means calculation and data presentation. In general, the last assessment of the trial with the highest level of infestation was kept. In some cases, more than one assessment per trial were selected depending on epidemic size and duration.

The infestation thresholds in the untreated check considered as sufficient to reliably assess the efficacy of the product were set up at 5% of pest incidence or pest severity for lettuce (10% in Point 3.2.3).

When possible, a special means calculation was made after 2 applications following disease appearance in order to reflect the GAP, as the number of applications of A23109A is limited to 2 per season.

3.2.2.1 Minimum effective dose against *Bremia lactucae* on lettuce

A total of 9 protected trials ~~and 20 field supportive trials~~ were established in order to determine the minimum effective dose for the control of the *Bremia lactucae* on lettuce. These trials have been conducted between 2019 and 2020 in Belgium (~~9~~ 4x), ~~Germany (1x),~~ France (~~6~~ 3x), Italy (~~3~~ 1x), ~~Poland (6x),~~ Portugal (1x) ~~and Spain (3x)~~. A23109A was tested at 0.25, 0.4 and 0.5 L PR/ha dose rates in lettuce for the control of *Bremia lactucae*. The rates reflect the proposed label rate and 80% and 50% of the full recommended rate of A23109A, in accordance with the EPPO standard PP 1/225 'Minimum effective dose'. A summary of the dose response results is provided in Table 3.2-15.

In these ~~2~~9 trials, the disease level of infection in untreated plots was adequate to validate the trials and reliably assess the efficacy of A23109A.

It is to note that the rates of MFX in A23109A indicated in the trial reports and the tables of results is calculated on global definition (R+S enantiomer) although the rate of MFX in A23109A is well based on EU MFX definition. A23109A brings at its targeted rate of 0.5 L PR/ha, 15 g/ha OXTP + 87.2 - 90 g/ha MFX (EU - global MFX definition).

The means presented in the **Table 3.2-15** were calculated from the assessment timings where the disease pressure was at least of 5% in the untreated check and where the standard performed as expected.

Table 3.2-15: Minimum effective dose. Efficacy of A23109A at proposed label rate, at 80% and 50% dose rates on lettuce against *Bremia lactucae*

Target	Assessment type	Grouping	EPPO zone	Number of trials; Number of assessments	Infestation of the untreated control (% pest incidence or % pest severity)		% control					
							A23109 [A] (EXF16956C) at 0.25 L PR/ha (50% of full rate)		A23109 [A] (EXF16956C) at 0.4 L PR/ha (80% of full rate)		A23109 [A] (EXF16956C) at 0.5 L PR/ha (Full rate)	
					Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max
Bremia lactucae (BREMLA)	% PESSEV on plant	All assessments	MAR	n=5; N=5	24.0	9.2-42.5	91.6	73.8-100.0	93.6	77.9-99.9	95.1	80.3-100.0
			MED	n=4; N=4	24.8	6.9-70.6	99.5	98.2-100.0	99.5	98.2-100.0	99.7	98.8-100.0
			NE	n=6; N=6	29.7	7.2-80.1	93.7	78.2-100.0	94.8	72.5-100.0	97.2	84.2-100.0
			Protected conditions	n=5; N=5	19.3	8.1-27.8	92.4	62.4-100.0	98.2	90.9-100	98.4	91.9-100.0
		After 1 appl.	Protected conditions	n=4	17.2	8.1-22.8	99.9	99.7-100	100.0	100-100	100.0	100-100
		After 2 appl.	NE	n=2; N=2	48.1	38.9-57.3	98.9	97.8-100.0	99.7	99.3-100.0	99.8	99.5-100.0
			Protected conditions	n=1; N=1	27.8	-	62.4	-	90.9	-	91.9	-
	0-100 index PESSEV on plant	All assessments	MAR	n=6; N=6	62.3	25.8-98.6	69.0	14.3-100.0	70.9	37.7-99.6	76.1	48.6-100.0
			MED	n=3; N=3	48.9	9.6-100.0	80.2	70.1-90.9	87.6	76.9-98.8	89.1	73.1-98.6
			NE	n=6; N=6	59.8	6.9-100.0	82.3	68.4-97.8	88.2	74.8-100.0	92.2	77.7-100.0
			Protected conditions	n=8; N=8	49.7	7.5-87.9	91.9	68.8-100.0	93	78.1-100.0	95.4	84.4-100.0
		After 1 appl.	Protected conditions	n=7	55.5	7.5-87.9	95.2	79.1-100	95.1	82.1-100	96.9	87.0-100
		After 2 appl.	NE	n=3; N=3	68.9	31.9-100.0	76.4	68.4-87.8	85.2	80.3-92.8	91.8	90.0-94.2
			Protected conditions	n=1; N=1	8.9	-	68.8	-	78.1	-	84.4	-
	nb PESINC on plant	All assessments	MAR	n=8; N=8	42.8	9.6-60.0	83.5	43.9-100.0	83.2	54.9-100.0	90.2	68.6-100.0
			MED	n=6; N=6	27.6	6.5-41.8	96.7	71.9-100.0	96.2	86.2-100.0	98.5	94.4-100.0
			NE	n=6; N=6	16.3	5.8-30.0	83.9	61.5-100.0	88.6	61.5-100.0	90.8	65.6-100.0
			Protected conditions	n=9; N=9	21.3	8.0-30.0	82.8	0.0-100.0	91.4	58.3-100.0	91.8	65.0-100.0
		After 1 appl.	Protected conditions	n=8	20.2	8.0-30.0	93.1	66.7-100	95.6	74.3-100	95.2	82.9-100
		After 2 appl.	NE	n=2; N=2	28.0	26.0-30.0	83.8	67.5-100.0	90.9	81.7-100.0	92.5	85.0-100.0
			Protected conditions	n=1; N=1	30.0	-	0	-	58.3	-	65.0	-

Protected conditions

According to the presented results of disease severity (%area) over all assessments, both dose rates of 0.4 and 0.5 L PR/ha of A23109A provided the optimum control and should be considered as effective against *Bremia lactucae* on lettuce.

According to the presented results of disease severity (0-100 index) over all assessments, the dose rate of 0.5 L PR/ha of A23109A performed slightly superior to the lower dose rates of 0.25 and 0.4 L PR/ha. The dose rate of 0.5 L PR/ha of A23109A provided the optimum overall control and should be considered as effective against *Bremia lactucae* on lettuce, for which activity of A23109A is claimed.

According to the presented results of disease incidence over all assessments, both dose rates of 0.4 and 0.5 L PR/ha of A23109A provided the optimum control and should be considered as effective against *Bremia lactucae* on lettuce.

~~**Overall conclusion under protected and field conditions**~~

~~According to the presented results of disease severity (%area; 0-100 index) and disease incidence accross all EPPO zones (under field and protected conditions), there is a dose response in favor of 0.5 L PR/ha. Overall, A23109A at 0.5 L PR/ha performed either equivalent or superior to the lower dose rate of 0.4 L PR/ha. The dose response in favor of 0.5 L/ha was also confirmed after two applications following the disease appearance.~~

~~As a result, the dose of 0.5 L PR/ha of A23109A provided the optimum overall control and should be considered the minimum effective dose to deliver robust control of *Bremia lactucae* on lettuce, for which activity of A23109A is claimed.~~

Comments of zRMS:

9 protected efficacy trials have been submitted to determine minimum effective dose in lettuce. A23109A has been used at three dose rates of 0,25 l/ha (0,5N), 0,4 l/ha (0,8N) and 0,5 l/ha (1N). Based on PESSEV on plant, no significant differences between effectiveness of dose rates are visible. The mean efficacy was >99% after 1 application following appearance of disease. Only 1 result has been presented after 2 applications and dose rate of 0,5 l/ha was comparable to lower dose of 0,4 l/ha. Similar effect between doses was noted in case of PESSEV index with the results >90% after 1 application in 7 out of 8 trials. The test product at 0,5 l/ha was superior compared lower doses after 2 applications. PESINC on plant confirms above trend and presents high effective of dose rate of 0,5 l/ha.

Taking into account above conclusions, dose rate of 0,5 l/ha can be considered minimum effective dose to control of *Bremia lactucae* on lettuce.

3.2.2.2 Summary and conclusions on the minimum effective dose

A23109A contains 30 g/L OXTP + 174.4 g/L MFX (EU definition only R enantiomer or 180 g/L MFX global definition R+S enantiomer) and brings at its targeted rate of 0.5 L PR/ha, 15 g/ha OXTP + 87.2 - 90 g/ha MFX (EU - global MFX definition).
It is to note that the rates of MFX in A23109A indicated in the trial reports and the tables of results is calculated on global definition (R+S enantiomer) although the rate of MFX in A23109A is well based on EU MFX definition.

A total of 9 protected trials ~~and 20 field supportive data~~ were established to determine the minimum effective dose for the control of the *Bremia lactucae* on lettuce. A23109A was tested at 0.25 to 0.5 L PR/ha on lettuce for the control of *Bremia lactucae*. The rates reflect the proposed label rate and 80% and 50% of the full recommended rate of A23109A. Trials were conducted under protected conditions as well as in field conditions in Maritime, Mediterranean and North-East EPPO zones.

In general, the dose response was demonstrated both in term of disease severity and incidence.

Considering the resistance risk to MFX, for which the highest rate is preferred and according to the presented results, the dose rate 0.5 L PR/ha of A23109A provided the optimum overall control and should be considered as effective against this major disease on lettuce grown in field or greenhouse, for which activity of A23109A is claimed.

As a result, the proposed rate delivering maximum 0.5 L PR/ha as specified in the GAP should be considered the minimum effective dose to deliver robust control of symptoms of *Bremia lactucae* on lettuce providing significant disease control under a wide range of environmental conditions.

3.2.3 Efficacy tests (KCP 6.2)

A total of 9 protected efficacy trials ~~and 20 field supportive trials~~ with A23109A were conducted in Belgium, Germany, France, Italy, Spain, ~~Poland~~ and Portugal between 2019 and 2020 to demonstrate the efficacy of A23109A for the control of *Bremia lactucae* on lettuce (under protected and field conditions).

A23109A contains 30 g/L OXTP + 174.4 g/L MFX (EU definition only R enantiomer or 180 g/L MFX global definition R+S enantiomer) and brings at its targeted rate of 0.5 L PR/ha, 15 g/ha OXTP + 87.2 - 90 g/ha MFX (EU - global MFX definition).
It is to note that the rate of MFX in A23109A based on EU MFX definition is 87.2 g ai/ha although indicated 90 g ai/ha in the trial reports and the tables of results, calculated based on global definition (R+S enantiomer).

Trials in this dossier were carried out by Syngenta organisations, contractor companies and Official Research institutes, all of which follow the EPPO guidelines and are officially recognized by the competent authorities to carry out field registration trials in accordance with the principles of Good Experimental Practice (GEP). The hyperlinks to relevant GEP certificates from the above-mentioned official country testing organisations are available under Annex Point IIIA 3.7.

Methodology for efficacy data summary and discussion

The efficacy data of A23109A discussed in this dossier correspond to the %control of untreated check based on pest severity or pest incidence results. Disease severity is considered to be the most relevant variable, however additional results on pest incidence are also presented in this dossier. The assessment types used in this dossier are described below for each crop. Other assessment types are available in the single trials reports.

Lettuce

Assessment Data Type, unit	Description
Pest severity, % plant area	% Disease on surface per plant, out of 30 or 60 plants
Pest severity, 0-100 index	% Infestation degree on plants (Townsend-Heuberger Index) per plot
Pest incidence, number/30 or 60 plants	Count of infected plants, out of 30 or 60 plants

Methodology for means calculation

All assessment timings where the disease pressure was sufficient and where the standard offered an adequate level of control were included in the mean calculation.
The infestation thresholds in the untreated check considered as sufficient to reliably assess the efficacy of the product were set up at 10% of pest incidence or pest severity for lettuce.

In addition, assessment timings where there was an important decrease of efficacy after the last application were not included in the means calculation.

As in practice, A23109A will be used in program with other fungicide products either preventively or curatively, the product was applied twice to seven times with intervals between applications of 7-14 days. However, to support the GAP with the number of applications of A23109A limited to 2 per season, special means calculation was made after 1 and after 2 applications from disease appearance.

Table 3.2-16: Details on trial methodology
***Bremia lactucae* on lettuce under protected conditions**

Guidelines	General guidelines	EPPO PP 1/135(4), EPPO PP 1/152(4), EPPO PP 1/181(4)
	Specific guidelines	EPPO PP 1/65(3)
Experimental design	Plot design	Randomized Complete Block (RCB) (9 trials)
	Plot size	3-11,029 m²
	Number of replications	4 (9 trials)
Crop	Trials per crop	Lettuce (LACSA) (7 trials) Garden lettuce (LACSA) (1 trial) Head lettuce (LACSC) (1 trial)
	Varieties per crop	Lettuce : Gennarì (1 trial), Etincel (1 trial), Goldorac (1 trial), Cosmopolia (1 trial), Panisse (1 trial), Soupiraï (1 trial), Gardia (1 trial) Garden lettuce : Séminis (6621) (1 trial) Head lettuce : Gardia (1 trial)
	Planting date	September 2019 (2 trials), October 2019 (1 trial), November 2019 (1 trial), April 2020 (1 trial), May 2020 (2 trials), September 2020 (1 trial), January 2021 (1 trial)
Application	Crop stage (BBCH) at application	Lettuce from BBCH 13 to BBCH 49 Garden lettuce : from BBCH 12 to BBCH 35 Head lettuce : from BBCH 16 to BBCH 45
	Timing at application	Preventive and curative applications
	Number of applications Intervals between applications	3 appl. (1 trial) with intervals of 7 days 4 appl. (5 trials) with intervals of 8-11 days 5 appl. (3 trials) with intervals of 7-10 days
	Spray volumes	300-600 L/ha
Assessment	Assessment types	Pest incidence (nb) on plant, pest incidence (%) on plant, pest severity (%) on plant, pest severity (index scale) on plant, yield (kg) marketable plants, count (%) marketable plants, phytotoxicity - general/injury (%) on plant
	Assessment dates	0-22 DALA*
Other relevant information	Soil type, pH (in case of soil active substance …)	Clay sandy loam (1 trial), loam (1 trial), loamy sand (1 trial), fine loamy sand (1 trial), sandy loam (2 trials), sand (1 trial), fine sand (2 trials)
	Natural / artificial innoculation…	Artificial (4 trials), natural (5 trials)
	Field / Greenhouse...	Protected conditions (9 trials)

* DALA = Days After Last Application

Bremia lactucae on lettuce in Maritime EPPO zone

Guidelines	General guidelines	EPPO PP 1/135(4), EPPO PP 1/152(4), EPPO PP 1/181(4)
	Specific guidelines	EPPO PP 1/65(3)
Experimental design	Plot design	Randomized Complete Block (RCB) (8 trials)
	Plot size	6,65-135 m²
	Number of replications	4 (8 trials)
Crop	Trials per crop	Lettuce (LACSA) (6 trials) Cos lettuce (LACSR) (1 trial) Garden lettuce (LACSA) (1 trial)
	Varieties per crop	Lettuce : Nadine (2 trials), Lollo bionda Aleppo (1 trial), Robinson (1 trial), Maximus (1 trial), Excursus (1 trial) Cos lettuce : Actina (1 trial) Garden lettuce : Sansula (1 trial)
	Planting date	July 2019 (1 trial), August 2019 (3 trials), May 2020 (1 trial), August 2020 (3 trials)
Application	Crop stage (BBCH) at application	Lettuce : from BBCH 35 to BBCH 49 Cos lettuce : from BBCH 17 to BBCH 41 Garden lettuce : from BBCH 15 to BBCH 46
	Timing at application	Preventive and curative applications
	Number of applications Intervals between applications	4 appl. (1 trial) with intervals of 9-10 days 5 appl. (5 trials) with intervals of 7-14 days 7 appl. (2 trials) with intervals of 7-14 days
	Spray volumes	300-500 L/ha
Assessment	Assessment types	Pest incidence (nb) on plant, pest incidence (%) on plant, pest severity (% area) on plant, pest severity (0-100 index scale) on plant, pest severity (0-3 scale) on plant, yield (kg) marketable plants, count (%) marketable plants, phytotoxicity - general/injury (%) on plant
	Assessment dates	0-35 DALA*
Other relevant information	Soil type, pH (in case of soil active substance …)	Loamy sand (4 trials), n.d. (1 trial), fine sand (1 trial), sand (1 trial), sandy loam (1 trial)
	Natural / artificial innoculation…	Artificial (1 trial), natural (7 trials)
	Field / Greenhouse...	Field (8 trials)

* DALA = Days After Last Application

Bremia lactucae on lettuce in Mediterranean EPPO zone

Guidelines	General guidelines	EPPO PP 1/135(4), EPPO PP 1/152(4), EPPO PP 1/181(4)
	Specific guidelines	EPPO PP 1/65(3)
Experimental design	Plot design	Randomized Complete Block (RCB) (8 trials)
	Plot size	7,5-16 m²
	Number of replications	4 (8 trials)
Crop	Trials per crop	Lettuce (LACSA) (7 trials) Garden lettuce (LACSA) (1 trial)
	Varieties per crop	Lettuce : Impulsion (1 trial), Baqueira (1 trial), Babieka (1 trial), Centore (1 trial), Tsarina (2 trials), Romana Avidius (1 trial) Garden lettuce : Penelope (1 trial)
	Planting date	September 2019 (2 trials), October 2019 (2 trials), March 2020 (1 trial), September 2020 (1 trial) September 2019 (3 trials), October 2019 (3 trials), March 2020 (1 trial), September 2020 (1 trial)
Application	Crop stage (BBCH) at application	Lettuce : from BBCH 14 to BBCH 48 Garden lettuce : from BBCH 12 to BBCH 43
	Timing at application	Preventive and curative applications
	Number of applications Intervals between applications	3 appl. (2 trials) with intervals of 7-9 days 4 appl. (3 trials) with intervals of 7-11 days 5 appl. (2 trials) with intervals of 8-10 days 6 appl. (1 trial) with intervals of 8-10 days
	Spray volumes	300-800 L/ha
Assessment	Assessment types	Pest incidence (nb) on plant, pest incidence (%) on plant, pest severity (% area) on plant, pest severity (0-100 index scale) on plant, pest severity (0-3 scale) on plant, count (%) marketable plants, yield (kg) marketable plants
	Assessment dates	0-29 DALA*
Other relevant information	Soil type, pH (in case of soil active substance …)	Clay sandy loam (1 trial), clay loam (3 trials), silty clay (1 trial), sandy clay loam (1 trial), calcareous clay (1 trial), n.d. (1 trial)
	Natural / artificial innoculation…	Artificial (2 trials), natural (6 trials)
	Field / Greenhouse...	Field (8 trials)

* DALA = Days After Last Application

Bremia lactucae on lettuce in North-East EPPO zone

Guidelines	General guidelines	EPPO PP 1/135(4), EPPO PP 1/152(4), EPPO PP 1/181(4)
	Specific guidelines	EPPO PP 1/65(3), EPPO PP 1/065(3)
Experimental design	Plot design	Randomized Complete Block (RCB) (6 trials)
	Plot size	10,5-36 m²
	Number of replications	4 (6 trials)
Crop	Trials per crop	Lettuce (LACSA) (6 trials)
	Varieties per crop	Maugli (1 trial), Juleczka (1 trial), Bakata (1 trial), Królowa Majowych (1 trial), Królowa Majowa (1 trial), Torpedo (1 trial)
	Planting date	August 2019 (2 trials), April 2020 (1 trial), July 2020 (1 trial), August 2020 (2 trials)
Application	Crop stage (BBCH) at application	from BBCH 17 to BBCH 48
	Timing at application	Preventive and curative applications
	Number of applications Intervals between applications	4 appl. (3 trials) with intervals of 9-10 days 5 appl. (3 trials) with intervals of 6-11 days
	Spray volumes	300-600 L/ha
Assessment	Assessment types	Pest incidence (nb) on plant, pest incidence (%) on plant, pest severity (% area) on plant, pest severity (0-100 index scale) on plant, pest severity (0-3 index scale) on plant, yield (kg) marketable plants, count (%) marketable plants
	Assessment dates	6-25 DALA*
Other relevant information	Soil type, pH (in case of soil active substance …)	Silty clay (1 trial), sandy clay loam (1 trial), sandy loam (1 trial), clay sandy loam (1 trial), loamy sand (1 trial), silt loam (1 trial)
	Natural / artificial innoculation…	Natural (6 trials)
	Field / Greenhouse...	Field (6 trials)

* DALA = Days After Last Application

3.2.3.1 Efficacy against *Bremia lactucae* on lettuce

A total of 9 protected efficacy trials and 20 field supportive trials were carried out to evaluate the efficacy of A23109A for the control of *Bremia lactucae* in lettuce.

Efficacy data for *Bremia lactucae* are presented from 29 efficacy trials assessed. 9 trials were carried out under protected conditions over the seasons 2019 and 2020 in Belgium (4x), France (3x), Italy (1x) and Portugal (1x). 20 trials have been conducted in field conditions as supportive data between 2019 and 2020 in Belgium (5x), Germany (1x), Spain (3x), France (3x), Italy (2x) and Poland (6x).

In these 29 trials, the disease level of infection in untreated plots was adequate to validate the trials and reliably assess the efficacy of A23109A.

Table 3.2-17 shows a summary of relevant disease severity and incidence assessments on lettuce for *Bremia lactucae.* The means presented in these tables were calculated from the assessment timings where the disease pressure was at least of 10% in the untreated check and where the standard performed as expected.

It is to note that the rate of MFX in A23109A based on EU MFX definition is 87.2 g ai/ha although it is indicated 90 g ai/ha in the trial reports and the tables of results, which is calculated based on global definition (R+S enantiomer).

Table 3.2-17: Efficacy of A23109A at the proposed label rate against *Bremia lactucae* on lettuce

Target	Assessment type	Grouping	EPPO zone	Number of trials; Number of assessments	Infestation of the untreated control (% pest incidence or % pest severity)		% control			
							A23109A at 0.5 L PR/ha		Standard Revus (=A12946B) at 0.6 L PR/ha	
					Mean	Min & Max	Mean	Min & Max	Mean	Min & Max
Bremia lactucae (BREMLA)	PESSEV on plant % Area	All assessments 1 appl.	MAR	n=4; N=6	27.6	14.4-42.5	**95.9**	80.3-100.0	91.4	76.6-99.9
			MED	n=2; N=5	43.7	13.3-71.4	**100.0**	99.9-100.0	95.8	94.2-97.7
			NE	n=4; N=8	33.5	10.2-80.1	**97.9**	84.2-100.0	91.3	75.2-100
		1 appl.	Protected conditions	n=4; N=9	18.6 18.5	9.7-27.8 13.3-22.8	**99.1** **100**	91.9-100.0 100-100	97.4 99.4	84.8-98.2-100
		2 appl.	Protected conditions	n=1	27.8	-	**91.9**	-	84.8	-
		After 1 appl.	MED	n=2; N=4	51.3	13.3-71.4	**100.0**	99.9-100.0	96.3	94.2-97.7
			NE	n=4; N=4	13.9	10.2-15.9	**96.0**	84.2-100.0	88.1	75.2-100
		After 2 appl.	NE	n=2; N=3	44.3	36.6-57.3	**99.8**	99.5-100.0	93.9	85.2-99.4
	PESSEV on plant 0-100 index	All assessments 1 appl.	MAR	n=6; N=6	62.3	25.8-98.6	**76.1**	48.6-100.0	67.1	42.7-99.8
			MED	n=3; N=3	48.9	9.6-100.0	**89.1**	73.1-98.6	79.1	69.6-86.3
			NE	n=5; N=6	67.3	31.9-100.0	**91.3**	77.7-99.7	72.6	43.5-91.4
		1 appl.	Protected conditions	n=6; N=7	56.7 63.5	15.8-87.9 18.9-87.9	**96.2** **97.0**	87.0-100.0	88.4 89.6	61.9-99.9
		After 1 appl.	NE	n=1; N=1	57.2	-	**77.7**	-	60.4	-
		After 2 appl.	NE	n=3; N=4	64.5	31.9-100	**92.5**	90.0-94.6	71.1	43.5-91.4
	PESINC on plant Number	All assessments 1 appl.	MAR	n=8; N=16	35.5	6.5-60.0	**94.8**	68.6-100.0	83.5	4.0-100
			MED	n=6; N=13	25.8	5.2-42.0	**98.6**	94.4-100.0	88.6	58.8-100
			NE	n=6; N=16	14.4	3.0-30.0	**93.9**	57.1-100.0	81.6	15.0-100
		1 appl.	Protected conditions	n=9; N=20	20.6 21.3	4.2-30.0 8.0-30.0	**96.3** **95.7**	65.0-100.0 82.9-100	91.2 91.0	37.5-100 63.0-100
		2 appl.	Protected conditions	n=1	30.0	-	**100**	-	97.5	-
		After 1 appl.	MED	n=3; N=7	31.2	7.2-42.0	**98.6**	94.4-100.0	83.2	58.8-100
			NE	n=6; N=6	13.7	5.8-30.0	**93.7**	65.5-100.0	85.5	53.3-100
		After 2 appl.	NE	n=2; N=3	28.7	26.0-30.0	**95.0**	85.0-100.0	57.5	15.0-91.8

Protected conditions

Data from protected conditions demonstrated that the efficacy of the A23109A at the proposed rate of 0.5 L PR/ha was superior to the efficacy of standard Revus (A12946B) at 0.6 L PR/ha against *Bremia lactucae* on lettuce.

~~**Overall conclusion under protected and field conditions**~~

~~Data from protected and field conditions demonstrated that the efficacy of the A23109A at the proposed rate of 0.5 L PR/ha was superior to the efficacy of standard Revus (A12946B) at 0.6 L PR/ha against *Bremia lactucae* on lettuce. This trend is well confirmed when considering only the efficacy achieved after the maximum number of two applications following disease appearance in the North-East EPPO zone.~~

~~The data also demonstrated that there was no difference in the performance of A23109A when trial data was grouped as presented in Table 3.2-17.~~

Efficacy against downy mildew on Leafy vegetables

According to EPPO extrapolation Table 14/19578: "Extrapolation table for effectiveness of fungicides► - Diseases on leafy vegetables", the presented efficacy data against *Bremia lactucae* and *Peronospora* spp. on the indicator crops lettuce and spinach can be extrapolated to the targeted crops: baby leaves, chards and beet leaves, chicory, chives, common purslane, cress, endive, escarole, herbs and edible flowers, lamb's lettuce, parsley, purple-vein rocket, watercress, iceberg lettuce under field as well as under greenhouse conditions.

Extract from EPPO extrapolation table 14/19578: Leafy vegetables

Pathogen species	Disease group name	Indicator crops	Extrapolation to other crops
Bremia sp. BREMSP	Downy Mildew	Lettuce LACSS	Leafy vegetables of the Asteraceae 1COMF, Prickly lettuce LACSE, Dandelion TAROF, Endive CICEN, chicory CICIN
Peronospora sp.		Spinach or Rocket	Crucifereae 1CRUF, Chenopodioideae 1CHES (Spinach SPQOL, Chard BEAVV), Rocket ERUVE, Lamb's lettuce VLLLO, Italian corn salad VLLER

Asteraceae: LACSA lettuce *Lactuca sativa*, LACSE prickly lettuce *Lactuca serriola*, CICEN endive *Cichorium endivia*, CICIN chicory *Cichorium intybus*, CICIF chicory witloof *Cichorium intybus* var. foliosum, TAROF dandelion *Taraxacum officinale*. **Crucifereae** : LEPSA garden cress *Lepidium sativum*, BARVE landcress *Barbarea verna*, DIPER Rockets *Diplotaxis erucoides* and ERUVE *Eruca vesicaria* subsp. Sativa, NAAOF watercress *Nasturtium officinale*, BRSJU leaf mustard *Brassica juncea*. **Chenopodioideae** : SPQOL spinach *Spinacia oleracea*, BEAVV chard *Beta vulgaris* subsp. vulgaris. **Other**: VLLLO lamb's lettuce *Valerianella locusta*, SANMI burnet *Sanguisorba minor*, VERBE cow cress *Veronica beccabunga*, VLLER Italian corn salad *Valerianella eriocarpa*, POROS purslane *Portulaca oleracea* subsp. sativa

Comments of zRMS:

9 protected efficacy trials have been submitted in lettuce. Based on PESSEV assessment, the test product at 0,5 l/ha achieved very high effectiveness after 1 application following appearance of disease in 4 out of 5 trials. Also 1 result after 2 applications confirms efficacy >90%. No significant differences between test and reference products have been observed. A23019A achieved superior result compared to Revus for PESSEV index in 6 trials. Similar trend was visible also for PESINC assessment with very high efficacy in all trials. In opinion of zRMS, A23109A at 0,5 l/ha can be accepted for use control of *Bremia lactucae* on lettuce under protected condition. ~~Because all trials were carried out only on lettuce, the cMSs are kindly asked to consider other leafy vegetables on national level.~~

Taking into account the extrapolation table for minor crops, cMSs are kindly asked to consider other species indicated in the GAP table on national level.

3.2.3.2 Minor use

Minor uses are those uses of plant protection products (defined in relation to crops and pests) in which either the crop is considered of low economic importance at national level (minor crop), or the pest is of limited importance on a major crop (minor pest). It should be noted that a minor use in one country may be a major use in another country (each country is responsible for defining its minor uses).
For details on major and minor status of intended crops in intended Member States, please refer to Table 3.2-4.

3.2.3.1 Yield (and relevant quality indicators), from efficacy trials (in the presence of challenging pest populations)

3.2.3.1.1 Lettuce

A summary of the quality data from efficacy trials is presented in Table 3.2-18.

A total of 5 trials were carried out under protected conditions (Belgium (4x) and France (1x)) between 2019 and 2020. As supportive data, 11 trials were carried out between 2019 and 2020 in Belgium (2x), France (2x), Germany (1x), Italy (1x), Poland (5x). The objective was to confirm the quality response of A23109A in presence of disease.

It is to note that the rate of MFX in A23109A based on EU MFX definition is 87.2 g ai/ha although it is indicated 90 g ai/ha in the trial reports and the tables of results, which is calculated based on global definition (R+S enantiomer).

Table 3.2-18: Quality data of A23109A in efficacy trials on lettuce in presence of *Bremia lactucae*

Assessment type	EPPO zone	Number of trials ~~Number of assessments~~	Untreated control		A23109A at 0.5 L PR/ha		Standard Revus at 0.6 L PR/ha	
			Mean	Min & Max	Mean	Min & Max	Mean	Min & Max
			Absolute figures (kg/plant)		Absolute figures (kg/plant)			
Weight of marketable plants	Protected conditions	n=5; N=5	0.040	0.000-0.200	0.412	0.300-0.701	0.379	0.300-0.690
	~~MAR~~	~~n=5; N=5~~	~~0.183~~	~~0.000-0.500~~	~~0.371~~	~~0.040-0.600~~	~~0.326~~	~~0.040-0.600~~
	~~MED~~	~~n=1; N=1~~	~~12.4~~	~~-~~	~~14.2~~	~~-~~	~~13.8~~	~~-~~
	~~NE~~	~~n=5; N=5~~	~~0.181~~	~~0.000-0.400~~	~~0.672~~	~~0.262-1500~~	~~0.525~~	~~0.227-1.100~~
			Absolute figures (%)		Absolute figures (%)			
Percentage of marketable plants	Protected conditions	n=5; N=5	14.6	0-73.1	99.8	99.2-100	94.4	85.0-99.8
	~~MAR~~	~~n=5; N=5~~	~~32.6~~	~~0-86.3~~	~~64.3~~	~~10.0-100~~	~~60.9~~	~~7.0-97.9~~
	~~MED~~	~~n=1; N=1~~	~~100~~	~~-~~	~~100~~	~~-~~	~~100~~	~~-~~
	~~NE~~	~~n=5; N=5~~	~~50.500~~	~~0-100~~	~~97.9~~	~~89.4-100~~	~~89.900~~	~~72.7-100~~

A23109A at the proposed label rate of 0.5 L PR/ha had no negative effects on the lettuce quality in presence of disease (*Bremia lactucae*) under ~~field and~~ protected conditions. Quality increases were even observed over the untreated under ~~both field and~~ protected conditions.

Comments of zRMS:

Yield has been evaluated in 5 efficacy trials under protected conditions. No special selectivity trials were carried out in any EPPO zones. A23109A at dose rate of 0,5 l/ha had not negative impact on lettuce. Yield increase was observed in the submitted trials.

3.2.3.2 Summary and conclusion

A23109A contains 30 g/L OXTP + 174.4 g/L MFX (EU definition only R enantiomer or 180 g/L MFX global definition R+S enantiomer) and brings at its targeted rate of 0.5 L PR/ha, 15 g/ha OXTP + 87.2 - 90 g/ha MFX (EU - global MFX definition).
It is to note that the rate of MFX in A23109A based on EU MFX definition is 87.2 g ai/ha although it is indicated 90 g ai/ha in the trial reports and the tables of results, which is calculated based on global definition (R+S enantiomer).

A total of 9 protected efficacy trials and 20 field supportive trials were carried out to evaluate the efficacy of A23109A for the control of the *Bremia lactucae* on lettuce. 9 trials were carried out under protected conditions in Belgium, France, Italy and Portugal between 2019 and 2020. 20 trials have been conducted in field conditions as supportive data in Maritime EPPO zone (Belgium, Germany and France), Mediterranean EPPO zone (France, Italy and Spain), North-East EPPO zone (Poland) between 2019 and 2020.
A23109A was tested at 0.5 L PR/ha.
Data from protected and field conditions demonstrated that the efficacy of the A23109A at the proposed rate of 0.5 L PR/ha was superior to the efficacy of standard Revus (A12946B) at 0.6 L PR/ha against *Bremia lactucae* on lettuce. This trend is well confirmed when considering only the efficacy achieved after the maximum number of two applications following disease appearance in the North-East EPPO zone.

According to the presented results and in function of the target disease, the dose rate of 0.5 L PR/ha of A23109A provided an optimum overall control and should be considered as effective under a wide range of environmental conditions against the disease for which activity of A23109A is claimed.

3.3 Information on the occurrence or possible occurrence of the development of resistance (KCP 6.3)

The capacity of target pathogens to become resistant to fungicide treatments varies greatly with respect to the different fungicide classes when single site fungicides are compared to multi-site fungicides, and it varies also between different genera or species of target fungi comparing different single site fungicides.

In the following sections it is referred to the mode of action and mechanism of resistance for oxathiapiprolin and metalaxyl-M baseline sensitivity and cross resistance patterns for grapes and vegetable targets. General measures and specifics guidelines are proposed to prevent resistance development against oxathiapiprolin and metalaxyl-M.

Oxathiapiprolin (OSBPI fungicide class) (FRAC 49)

Oxathiapiprolin belongs to the chemical class of the piperidinyl thiazole – isooxazoline.

Oxathiapiprolin and fluoxapiprolin are the two members of the FRAC group 49 named Oxysterol binding protein homologue inhibitors (OSBPI). The OSBPI fungicides are not cross resistant to the other FRAC fungicide classes as for example CAA, PA or QoI. Oxathiapiprolin blocks the sterol-binding domain of an OSBP homologue, preventing it from picking up sterols and making the inter-membrane transfer. Inhibiting OSBP disrupts many further processes in the cell, such as signalling, maintaining

cell membranes, and the formation of more complex lipids that are essential for the cell to survive.

Some lab studies were conducted to elucidate the mechanisms of resistance related to the OSBPI fungicide class. In the list below the amino acid changes are unified to the annotation of the oxathiapiprolin target protein of *P. infestans*.

P. capsici was recently used to generate lab mutants resistant to OSBPI either by spontaneous, UV or CRISPR/Cas9 approaches. Some point mutations in the oxysterol binding protein-related protein 1 (ORP1) were observed. In *P. capsici* ultraviolet mutagenesis mutants, L733W, S768I/F/K/Y, G770A/I/P/V/L, N837I/F/Y, G839W, P861H, L863W/F, and I877F/Y were detected.

P. sojae transformants were recovered using the CRISPR–Cas9 system. The following mutations were associated to high OSBPI resistance L733W, S768F, S768Y, N837Y, N837F, P861H, L863W, and I877Y

Some grape downy mildew isolates collected from field trials where oxathiapiprolin had been continuously used for 4 years showed resistance to OSBPI and harboured the following amino acid changes G770V, N837I and L863W.

The resistant alleles G770V and DG818/F819 were observed in *P. nicotianae* resistant mutants produced by UV radiation.

So far little is known about the possible fitness cost associated to resistance in field, however mutants harbouring G770V showed significantly reduced fitness in the lab.

The resistance risk for OSBPI is considered medium to high by FRAC.

Monitoring data has been established for the oomycetes P*lasmopara.viticola* in grapes, *Phytophthora infestans* in potatoes and *Bremia lactucae* in lettuce.

Metalaxyl-M (Phenylamide fungicide class) (FRAC 4)

Metalaxyl-M belongs to the phenylamides (PAs) (FRAC 4) which are a highly active class of fungicides specifically controlling plant pathogens of the Oomycetes (the downy mildews of the *Peronosporales* and *Sclerosporales*, as well as most members of the *Pythiales* (e.g., *Phytophthora* and *Pythium* spp.) and *Saprolegniales*[2]. Metalaxyl-M penetrates the plant tissue rapidly, is translocated acropetally within the plant and as all PAs inhibits rRNA biosynthesis (polymerase complex I) in the target pathogens. The use strategies for PAs have been well established. The presence of resistant subpopulations at varying proportions is well documented in several plant pathogen species of Oomycetes on a range of crops worldwide[3,4]. However, sensitive subpopulations have not disappeared, even though PA-containing products have been used continuously in similar quantities and intensities over the past 30 years. This strongly suggests that the recommended anti-resistance strategies are successful and that biological processes (e.g., sexual reproduction, fitness, winter survival) of the pathogens may contribute to equilibrate sensitivity in populations. Sampling and testing methods for resistance monitoring have been published through FRAC in 1992 and are still valid[5].

Sensitivity data to oxathiapiprolin (OSBPI fungicide class)

Monitoring data

Bioassay sensitivity monitoring conducted by Syngenta since 2015 showed the European population of *P. viticola* is largely sensitive to OSBPI. In total 388 *P. viticola* samples were analysed from 16 European countries since 2015. Samples showing decreased sensitivity to oxathiapiprolin was found at single locations in four European regions.

[2] Gisi, U. 2002. Chemical control of downy mildews. pp.119-159 in P.T.N.Spencer, U. Gisi, A. Lebeda, eds., Advances in Downy Mildew Research, Kluwer, Dordrecht.

[3] Gisi, U., Cohen, Y. 1996 Resistance to phenylamide fungicides: A case study with Phytophthora infestans involving mating type and race structure. Annual Review of Phytopathology34, 549-572.

[4] Gisi, U., Sierotzki, H. 2008. Fungicide modes of action and resistance in downy mildews. European Journal Plant Pathology 122: 157-167

[5] Sozzi, D., Schwinn, F.J., Gisi, U. 1992. Determination of the sensitivity of Phytophthora infestans to phenylamides: a leaf disc method. EPPO Bullettin 22: 306-309

Molecular analysis conducted to the less sensitive populations highlighted the presence of G770V in a single population and L863W in the other less sensitive samples.

Bioassay sensitivity monitoring conducted by Syngenta since 2015 showed the European population of *P. infestans* is largely sensitive to OSBPI. In total 302 *P. infestans* strains were analysed from 21 European countries from 2015 to 2020. No strains showing decreased sensitivity to oxathiapiprolin were monitored.

For *B. lactucae*, a total of 7 samples collected in 2019 from six European countries (Belgium, Spain, Greece, Italy, Portugal and Poland) were monitored. All samples were fully sensitive to oxathiapiprolin showing low EC50 values. No reports of *B. lactucae* decreased sensitivity to oxathiapiprolin have been reported so far.

For more details on monitoring data, please refer to the Biological Assessment Dossier, Annex Point IIIA 3.3 (KCP 6.3).

Mechanism of resistance to metalaxyl-M

The mechanism of resistance against metalaxyl-M and other PAs may involve one (or two) major gene(s) and potentially several minor genes. Therefore, there are no exhaustive molecular methods for the screening of the metalaxyl-resistance. Genetic studies to determine the nature of insensitivity to metalaxyl-M have involved crosses between insensitive and sensitive isolates of various *Phytophthora* sp. Segregation patterns of the trait among progeny revealed a range of insensitivity levels, with many intermediate between parental isolates[6]. Insensitivity is proposed to be conditioned by one or sometimes two incompletely dominant loci, called MEX1 and MEX2. Additional minor genes may also contribute to the level of insensitivity.
Recently, a sequencing approach for the determination of resistance against metalaxyl-M has been carried out[7]. The subunits of RNA polymerase I (RNApolI) were sequenced from sensitive and insensitive isolates and F1 progeny. Single nucleotide polymorphisms (SNPs) specific to insensitive field isolates were identified in the gene encoding the large subunit of RNApolI. In a survey of field isolates, SNP T1145A (Y382F) showed an 86% association with metalaxyl-M insensitivity. Isolates not showing this association belonged predominantly to one *P. infestans* genotype. The transfer of the 'insensitive' allele of RPA190 to a sensitive isolate yielded transgenic lines that were insensitive to metalaxyl-M. These results demonstrate that sequence variation in RPA190 contributes to insensitivity to metalaxyl-M in *P. infestans*.
For pathogens which undergo sexual recombination every winter, the genetic diversity of the primary inoculum is very high[8] and resistance is inherited according to Mendelian rules, i.e. all F1 progeny isolates are intermediate (i) in sensitivity. The proportion of sensitive, intermediate and resistant isolates in F2 progeny should then be 1 : 2 : 1 (theoretical). The sensitivity of field populations fluctuates from year to year and within the season. Sensitive, intermediate and resistant isolates can be detected in fields that have been treated with PAs or remained untreated and are often in a "dynamic equilibrium" with each other. In *Plasmopara viticola*, the proportion of sensitive isolates declines during the epidemics every year. Dynamics of resistance evolution are driven not only by the selection through PA fungicides; equally important are the Mendelian type of inheritance and the genetic background of resistance, as well as high fitness and rate of migration of isolates.

Evidence of resistance to metalaxyl-M

Metalaxyl-M and PA resistant isolates of *Phytophthora infestans* and *Plasmopara viticola* existed at low proportions in wild type populations already before PA fungicides were used commercially

[6] Gisi and Sierotzki. 2008. Fungicide modes of action and resistance in downy mildews. Eur. J. Plant Pathol. 122, 157–167.
[7] Randall et al 2014. Sequence diversity in the large subunit of RNA polymerase I contributes to Mefenoxam insensitivity in Phytophthora infestans. Mol Plant Pathol. DOI: 10.1111/mpp.12124
[8] Gobbin et al. 2007. Epidemiology and population genetics of grape vine downy mildew. pp. 205-209 in A. Lebeda and P.T.N. Spencer-Phillips, eds., Advances in Downy Mildew Research, Vol. 3, Proceedings 2 nd International Downy Mildew Symposium, JOLA, Kostelec na Hané, Olomouc, Czech

(1977/78) suggesting that recurrent mutations give rise to resistant individuals at different locations and time periods. Resistant isolates have been selected through the use of PAs, increased in frequency, survived during over-wintering periods and migrated to other regions through transport of sporangia in rain droplets and infected plant material (tubers, seedlings). Resistant isolates can compete successfully with sensitive isolates even in the absence of PA treatments. Therefore, resistant isolates can be detected in current field populations that were treated with PAs or remained untreated.
Samples for sensitivity analyses should be taken as early in the epidemic cycle as possible. Those taken towards the end of the season will provide results which are a result of selection, migration, mating and competition occurring during epidemics. Consequently, resistance frequencies are often overestimated. Standard sensitivity test methods (e.g., leaf disc assay) provide a fully resistant response to PAs (used as active ingredients) when as little as 1% of the sporangia in bulk samples of field populations are resistant. Since sensitivity tests are made with active ingredients of PAs but products are used for disease control in the field in mixture with multi-site fungicides there is no direct correlation between sensitivity test results in the laboratory and product performance in the field.
The current sensitivity test methods provide valuable information on the distribution of isolates over a certain period in a given agronomic area but should not be used to predict product performance. In most cases mixed populations can be controlled adequately by PA-containing products if the proportion of resistant isolates is not too high and if the number of applications is limited.
In general, PA-tolerance has been associated with a fitness cost for the resistant phenotype over the susceptible phenotype. This fitness coast indirectly justifies the registration of products containing metalaxyl-M and other active ingredients belonging to different class of resistance. A recent study found that the fitness cost of resistance is a crucial parameter to determine the outcome of competition between the sensitive and resistant pathogen strains and to assess the usefulness of a mixture. If fitness costs are absent, then the use of the high-risk fungicide in a mixture selects for resistance and the fungicide eventually becomes non-functional. If there is a cost of resistance, then an optimal ratio of fungicides in the mixture may be found at which selection for resistance is expected to vanish and the level of disease control can be optimized[9].

Cross resistance

There is full cross resistance among all members of PA fungicides (metalaxyl, metalaxyl-M (=mefenoxam), furalaxyl and oxadixyl, benalaxyl and benalaxyl-M (=kiralaxyl) and ofurace) but there is no cross resistance between PAs and fungicides of other chemical classes like cyanoacetamide oximes (Cymoxanil), QoIs (e.g. Azoxystrobin, Famoxadone), phosphonates (Fosetyl-Al), carboxylic acid amide (CAA) fungicides (Dimethomorph, Iprovalicarb, Mandipropamid), carbamates (Propamocarb), dinitroanilines (Fluazinam) and multisite inhibitors (e.g. dithiocarbamates like Mancozeb).

Sensitivity data

- *Phytophthora infestans* on tomato and potato

Phytophthora infestans on tomato and potato in considered by FRAC a high-risk disease for resistance development. Resistance in field to metalaxyl-M and to all the active ingredients belonging to the PA-group of fungicides (Phenylamides) is well known worldwide. The sensitivity of *P. infestans* populations fluctuates from year to year and within the season. In many cases, sensitive isolates predominate early and resistant isolates predominate late in the season for both PA-treated and untreated fields.

Results from recent monitoring conducted by Syngenta since 2007 are presented in the Biological Assessment Dossier, Annex Point IIIA 3.3 (KCP 6.3).

Comparison of the sensitivity in European populations to metalaxyl-M over several years demonstrates strong fluctuation in the frequency on sensitive, moderately sensitive and resistant isolates. Since 2007,

[9] Mikaberidze et al 2014. Can High-Risk Fungicides be Used in Mixtures Without Selecting for Fungicide Resistance? Analytical and Theoretical Plant Pathology. 104 (4): 324-331

the frequency of less sensitive isolates seems to decrease.

Results clearly demonstrate that different situations can be observed in the different regions of Europa where the samples were collected. Resistant isolates of *P. infestans* were detected in 2012 in populations of Portugal, Spain, Germany, Check Republic, Denmark and Netherlands. In 2014, monitoring studies revealed a slightly different scenario where different frequency in resistant isolates was observed in the different countries when compared to 2012. Similar observations can be done on the data available for 2015. In general, monitoring studies revealed a slightly different scenario where different frequency in resistant isolates was observed in the different countries and different frequencies over seasons.

- *Plasmopara viticola* on grape

Much less information on resistance to PAs is available for *Plasmopara viticola* compared to *Phytophthora infestans.* In countries where sensitivity analyses have been conducted recently (e.g. France, Switzerland, Spain, Germany), the proportion of resistant *P. viticola* isolates has remained high (50 – 80%) but more or less stable for many years[10].
Plasmopara viticola on grape is considered by FRAC a high-risk disease for resistance development. The EPPO Guideline PP1/213(3) list this pathogen as high-risk pathogen of which baseline sensitivity is requested.

Results from recent monitoring conducted by Syngenta in 2014 and 2015 are presented in the Biological Assessment Dossier, Annex Point IIIA 3.3 (KCP 6.3).

Results clearly demonstrate that different situations can be observed in the different regions of Europa where the samples were collected. In general, resistant isolates of *Plasmopara viticola* are present in populations of the Mediterranean EPPO zone (France, Italy, Spain and Portugal) and in south-west Germany. A limited number of isolates resistant to metalaxyl-M was detected in populations of the South-East EPPO zone.

Comparison of the sensitivity in European populations to metalaxyl-M over several years demonstrates strong variability in the frequency on sensitive, moderately sensitive and resistant isolates. The situation remained stable in 2014 and 2015 if compared to 2013.

- Other crops

The presence of resistant isolates in field populations has been confirmed in other pathogens including *Bremia lactucae* (e.g. UK, Italy) (FRAC Resistance Survey List, www.frac.info). However, the proportion of resistant isolates in field populations is not well documented. Resistance levels are not uniform and do not necessarily correlate with product performance problems.
Bremia lactucae on lettuce is considered by FRAC a medium risk disease for resistance development. Resistance in field to metalaxyl-M and to all the active ingredients belonging to the PA-group of fungicides (Phenylamides) is known.
Peronospora destructor on onion, *Phytophthora porri* on leek and *Peronospora parasitica* (=*Hyaloperonospora brassicae*) on brassica are considered by FRAC a medium risk disease for resistance development. The EPPO Guideline PP1/213(3) does not list this pathogen as high-risk pathogen of which baseline sensitivity is requested.

Resistance risk associated with unrestricted use pattern

The actual risk for the evolution of resistance towards metalaxyl-M and oxathiapiprolin depends on three different parameters: mechanism of resistance against the compound (intrinsic fungicide risk), biology of the pathogen (pathogen risk) and on agronomical factors (agronomic risk). Additionally, to the risk to the individual fungicides also the combined risk towards the mixture needs to be evaluated.

[10] Gisi U, Sierotzki H. 2008. Fungicide modes of action and resistance in downy mildews. European Journal of Plant Pathology 122:157-167.

Oxathiapiprolin and metalaxyl-M are single site inhibitors. OSBPI resistance has been generated in the lab to a range of pathogens, but in field is found sporadically in single pathogens. Only little is known about the dynamics of OSBPI resistance evolution, such as stability, spread and fitness cost. Based on our knowledge today, the intrinsic fungicide risk for oxathiapiprolin is moderate to high.

The intrinsic resistance risk of phenylamide fungicides is considered as high (FRAC).

The overall resistance risk for phenylamides and OSBPI including metalaxyl-M and oxathiapiprolin should be considered between medium and high depending on the agronomic risk associated to each pathogen/crop system (Figure 3.3-1).

SDHI
OXTP

Fungicide Risk		Pathogen Risk: 1 – Low risk	Pathogen Risk: 2 – Medium risk	Pathogen Risk: 3 – High risk	Agronomic Risk	
High risk Benzimidazoles QoIs Phenylamides	3	3	6	9	1	High risk
		1,5	3	4,5	0,5	Medium risk
		0,75	1,5	2,25	0,25	Low Risk
Medium risk CAA DMIs / APs Morpholines MBI-D Phenylpyrrol	2	2	4	6	1	High risk
		1	2	3	0,5	Medium risk
		0,5	1	1,5	0,25	Low Risk
Low risk Multi sites MBI-R Resistance Ind.	0,5	0,5	1	1,5	1	High risk
		0,25	0,5	0,75	0,5	Medium risk
		0,125	0,25	0,375	0,25	Low Risk
		Low risk *S. vesicarium* *Rhizoctonia* spp. Rust spp. *Fusarium* spp. Soil borne fungi Seed borne fungi Smuts & Bunts	**Medium risk** *B. lactucae* *A. brassicicola* *A. brassicae* *C. beticola* *A. solani* *P. infestans* *R. secalis*	**High risk** *P. viticola* *P. cubensis* *S. fuliginea* *Erysiphe* spp *R. collo-cygni* *Corynespora* *Magnaporthe*		

Adapted from Grimmer et al. 2014. Pest Management Science 70:1008-1016

Figure 3.3-1: Resistance risk assessment matrix considering i) Fungicide, ii) Pathogen and iii) Agronomic risk for the discussed pathogen and fungicide classes.

Management strategy

The actual performance of products depends on the strength of the evolved reduced sensitivity and its frequency in a particular population. Monitoring of oxathiapiprolin and metalaxyl-M sensitivity will continue as appropriate for the pathogens discussed above and any change in sensitivity will be reported through FRAC and the relevant country resistance management bodies. Through this process Syngenta can adapt to any changes in sensitivity and readily adopt alternative resistance management strategies as appropriate.

The summaries and recommendations included in this report are based upon data generated by members of the FRAC-OSBPI (FRAC 49) and FRAC-PA Working Group. The working group concentrates its resources on the major crop/pathogen targets from the point of view of resistance risk. To help in making recommendations for crops and pathogens the following general recommendations can be made:

The use of two fungicides in a mixture is considered as valuable anti-resistance strategy compared to the use of solo compounds.

To prevent the development and spread of resistance, applications of A23109A, for both field and

protected uses, should be included in program, in alternation with products containing different mode of actions or in bloc system where:

OSBPI products (FRAC 49):

- Make no more than four applications or maximum of 33% of the total period pf protection needed per crop, whichever is the more restrictive.
- Where to total number of fungicide applications targeting oomycetes is less than three, apply no more than 1 application of an OSBPI product.
- Application of OSBPI fungicides to be made no more than three times in sequence before applying a fungicide of a different MoA.
- OSBPI fungicides can be made in alternation with a fungicide with a different MoA.
- In case of multicrop growing systems, do not use more than six (6) applications of OSBPI fungicides per year in the same area for the same pathogen.
- In cases where a OSBPI fungicide is used in seed treatment or soil application, foliar application of OSBP-containing products should not be carried out
- OSBPI fungicides should not be used in nursery production of transplanted crops.

Phenylamide products (FRAC 4):

- The number of phenylamide applications should be limited (two to four consecutive applications per crop and year).
- Application of Phenylamide fungicides to be made no more than two times in sequence before applying a fungicide of a different MoA
- The application intervals should not exceed 14 days and may be shorter in cases of high disease pressure
- Phenylamide sprays are recommended early season or during the period of active vegetative growth of the crop

Conclusion

The resistance management strategy for A23109A is therefore based on limitation of exposure of the pathogen to the fungicide by limiting the number of applications permitted in a program and promoting the use of alternation with products from different MoA cross resistance groups.

- Applications of A23109A to be applied according to label recommendations and can be made in alternation with products containing different cross-resistance group with satisfactory efficacy against the targeted pathogen(s).
- Maximum 2 applications A23109A at 0.5 l/ha per crop and per year.
- Exposure to A23109A should not exceed thirty-three percent (33%) of the total period of protection needed per crop.
- A23109A applications are to be made preventively.

Comments of zRMS:

A23109A contains two active substances: oxathiapiprolin (belonging to the chemical group of piperidinyl-thiazole-isoxazolines, MoA group of OSBPI fungicides) and metalaxyl-M (belonging to the chemical group of acylalanines, MoA group of PA-fungicides). According to FRAC classification, the resistance risk for metalaxyl-M is considered high risk and for oxathiapiprolin - medium to high. Furthermore, the target pathogens indicated in the GAP table are medium risk developed of resistance (*Phytophthora porri, Albugo candida*). The overall resistance risk for phenylamides and OSBPI including metalaxyl-M and oxathiapiprolin should be considered between medium and high depending on the agronomic risk associated to each pathogen/crop system. Due to that the resistance management is required. Taking into account data generated by members of the FRAC-OSBPI (FRAC 49) and FRAC-PA Working Group, the resistance management strategy for A23109A proposed by the applicant is sufficient in opinion of zRMS. The below recommendations should be included to the product label:
- *applications of A23109A to be applied according to label recommendations*

- use A23109A in rotation with other product containing active substances belonging to other chemical group with different mode of action
- maximum 2 applications A23109A at 0,5 l/ha per crop and per year
- exposure to A23109A should not exceed thirty-three percent (33%) of the total period of protection needed per crop
- A23109A applications are to be made preventively

3.4 Adverse effects on treated crops (KCP 6.4)

Information on trials submitted (3.4: Adverse effects on treated crops)

Table 3.4-1: Presentation of selectivity trials

Crop(s) *	Country	Years	Type of trial**	Number of trials		GEP, non-GEP, official***	Comments (any other relevant information)
				Mediterranean zone	Protected conditions		
Lettuce	Belgium	2020	S+Q	-	2	GEP	Selectivity trial
	~~Spain~~	~~2020~~	~~S+Q~~	~~2~~	~~-~~	~~GEP~~	~~Selectivity trial~~
~~**TOTAL**~~	~~-~~	~~**2020**~~	~~-~~	~~**2**~~	~~**2**~~	~~–~~	~~–~~

* According to the GAP table

** S = selectivity trial, Y = trial with yield assessment, Q = trial with quality assessment, T = trial on the basis of the study of impact on transformation process (TP: Physical transformation, TF: transformation involving microbial fermentation), P = trial with assessment of impact on propagation

*** Official: carried out by a national official organisation

Table 3.4-2: Presentation of reference standards used in trials (selectivity trials)

Crop(s)	EPPO ZONE	Reference standard	Country(ies) where the product is registered (1)	Authorization number	Active substance(s)	Formulation		Registered application rate (3)	Application rate in trials (per treatment)	Remark(4)
						Type (2)	Concentration of a.s.			
Lettuce	Greenhouse	Revus (A12946B)	Belgium	9604P/B	Mandipropamid	SC	250 g/L	0.6 L/ha	0.6 L/ha	-
	~~Mediterranean~~	~~Revus (A12946B)~~	~~Spain~~	~~25186~~	~~Mandipropamid~~	~~SC~~	~~25%~~	~~0.4-0.6 L/ha~~	~~0.6 L/ha~~	-

(1) only on use(s) applied for (with the test product)
(2) e.g.WP (wettable powder), EC (emulsifiable concentrate), etc.
(3) Dose / dose range authorized in the country
(4) Other relevant information (e.g. uses, number of applications, spray volume, method of application…)

3.4.1 Phytotoxicity to host crop (KCP 6.4.1)

According to Table 1 of EPPO standard PP 1/135(4), specific selectivity trials and yield assessments are not required for fungicides when no adverse phytotoxic effects are observed in direct efficacy trials.

Phytotoxicity of A23109A was thus evaluated in efficacy trials presented in this dossier including efficacy and pest free trials.

In addition, ~~4~~ 2 crop safety trials were conducted on lettuce under protected ~~and field~~ conditions.

Table 3.4-3: Details on selectivity trials methodology
Selectivity on lettuce under protected conditions

Guidelines	General guidelines	EPPO PP 1/181(4), EPPO PP 1/152(4), EPPO PP 1/135(4)
	Specific guidelines	n.a.
Experimental design	Plot design	Randomized Complete Block (RCB) (2 trials)
	Plot size	9 m²
	Number of replications	4 (2 trials)
Crop	Trials per crop	Lettuce (LACSA) (2 trials)
	Varieties per crop	Lucrecia (1 trial), Walha (1 trial)
	Planting date	July 2020 (1 trial), November 2020 (1 trial)
Application	Crop stage (BBCH) at application	From BBCH 15 to BBCH 19
	Number of applications Intervals between applications	2 appl. (2 trials) with intervals of 7 days
	Spray volumes	500 L/ha
Assessment	Assessment types	Phytotoxicity - general/injury (%) on plant, yield (kg/plant) marketable plants, count (%) marketable plants, inhibition (%) on plant, deposit (nb) on leaf, phytotoxicity - necrosis/burn (%) on plant
	Assessment dates	4-88 DALA*
Other relevant information	Soil type, pH (in case of soil active substance …)	Fine sandy loam (1 trial), loamy sand (1 trial)
	Natural / artificial innoculation…	n.a.
	Field / Greenhouse...	Protected conditions (2 trials)

* DALA = Days After Last Application

Selectivity on lettuce in Mediterranean EPPO zone

Guidelines	General guidelines	EPPO PP 1/181(4), EPPO PP 1/152(4), EPPO PP 1/135(4)
	Specific guidelines	n.a.
Experimental design	Plot design	Randomized Complete Block (RCB) (2 trials)
	Plot size	10-16 m²
	Number of replications	4 (2 trials)
Crop	Trials per crop	Lettuce (LACSA) (2 trials)
	Varieties per crop	Ximenes (1 trial), Iceberg (1 trial)
	Planting date	May 2020 (1 trial), September 2020 (1 trial)
Application	Crop stage (BBCH) at application	From BBCH 14 to BBCH 33
	Number of applications Intervals between applications	2 appl. with intervals of 7-8 days
	Spray volumes	300-625 L/ha
Assessment	Assessment types	Count (%) marketable plants, phytotoxicity (%) on plant, yield marketable plants (kg/plant), phytotoxicity – general/injury (%) on plant
	Assessment dates	0-51 DALA*
Other relevant information	Soil type, pH (in case of soil active substance …)	Clay loam (1 trial), loamy clay (1 trial)
	Natural / artificial innoculation…	n.a.
	Field / Greenhouse...	Field (2 trials)

* DALA = Days After Last Application

3.4.1.1 Lettuce

Table 3.4-4: Phytotoxicity of product

Number of trials with…		Selectivity trials (4 2 trials)				Efficacy trials (31 9 trials)	
		A23109A/EXF16956C		Revus (=A12946B)		A23109A/EXF16956C	Revus (=A12946B)
		N	2N (or other)	N	2N (or other)	N	N
Maximum of phytotoxicity recorded during the trials	0% to 5%	4 2	4 2	4 2	4 2	31 9	31 9
	>5% to 10%	0	0	0	0	0	0
	>10% to 15%	0	0	0	0	0	0
	>15 %	0	0	0	0	0	0
Level of symptoms at the last assessments	0% to 5%	4 2	4 2	4 2	4 2	31 9	31 9
	>5% to 10%	0	0	0	0	0	0
	>10% to 15%	0	0	0	0	0	0

Number of trials with…		Selectivity trials (~~4~~ 2 trials)				Efficacy trials (~~31~~ 9 trials)	
		A23109A/EXF16956C		Revus (=A12946B)		A23109A/EXF16956C	Revus (=A12946B)
		N	2N (or other)	N	2N (or other)	N	N
	>15 %	0	0	0	0	0	0

A total of ~~24 field and~~ 11 protected trials were carried out on lettuce in ~~Belgium, France, Germany, Italy, Portugal, and Spain (field conditions) and in~~ Belgium, France, Italy and Portugal (protected conditions) from 2019 to 2020 on a wide range of commercially grown varieties.

No phytotoxicity symptom caused by A23109A at the proposed dose rate of 0.5 L/ha was recorded in all ~~35~~ 11 trials.

Further evidence of crop safety is illustrated by considering the time of year when the applications were made to the lettuce crop under protected conditions. It is known that the risk of phytotoxicity is increased when Plant Protection Products are applied to lettuce crops under Low Light Intensity. Of the nine lettuce efficacy trials conducted under protected conditions, six trials received applications in the months October to February when light intensity is known to be reduced. Despite applications being made during these autumn and winter months no phytotoxicity was seen.

Efficacy trials (Protected)	Variety	Application Months
ITSOZF1002019	Lettuce, Gennarì	November -December
FRQUZF9312019	Lettuce, Etincel	October - November
FRQUZF0262020	Lettuce, Goldorac	May-June
BESKZF0062020	Lettuce, Cosmopolia	May - June
FRSYZF0332020	Lettuce, Panisse	May-June
PTSTZF0152020	Lettuce, Séminis (6621)	January - February
BESKZF0052020	Lettuce, Gardia	October-November
BESKZF9112019	Lettuce, Soupiraï	September - October
BESKZF9122019	Lettuce, Gardia	September- October

Comments of zRMS:

2 selectivity trials were carried out in greenhouses. The phytotoxicity assessment was also provided in the efficacy trials under protected conditions. No negative symptoms were observed in all trials. A23109A at dose rate of 0,5 l/ha is safe for lettuce.

3.4.1.2 Other crops, including minor crops

The crop safety data presented above were conducted on a representative major crop from the leafy vegetables group (lettuce). Perfect selectivity observed in this crop may be fully extrapolated to a range of other major and minor crops of this crop group. For details on major and minor status of intended crops in intended Member States, please refer to Table 3.2-4.

Considering the use in crops belonging to leafy vegetables, full selectivity of A23109A was demonstrated at proposed label rate on lettuce. This is in accordance with EPPO extrapolation table for effectiveness in leafy vegetables (14/19578) that considers lettuce as indicator crop for *Bremia* sp.

efficacy experiment. See https://www.eppo.int/media/uploaded_images/ACTIVITIES/plant_protect_products/minor_uses/fungicides/PP1-19578FEET_2014_Leafy_vegetables-effectiveness.pdf.
EPPO crop safety extrapolation table is not available for leafy vegetables.

According to the Dutch Board for the Authorisation of Plant Protection Products and Biocides, document "Chapter 8 efficacy: Appendix E: Extrapolation possibilities - versie2.0", it is advised to test head lettuce for crop safety purpose. The selectivity results obtained on head lettuce may be extrapolated to *Lactuca sativa* sp., endive, green Belgian endive and fresh herbs. See https://english.ctgb.nl/plant-protection/documents/assessment-framework-ppp/2016/09/30/8.-appendices-dutch-extrapolation-document-in-english-em2.1
Head lettuce is indeed a susceptible crop showing thin leaves and can therefore serve as phytotoxicity model for other leafy vegetable crops.

As A23109A appears to be a fully selective fungicide in lettuce in the frame of this dossier, and further to extrapolations possibilities, it is reasonable to conclude that A23109A will be fully selective, when applied at recommended label rate, with all the whole supported group of leafy vegetables as lettuce, baby leaves, chicory, cress, endive, escarole, herbs & edible flowers, iceberg lettuce, lamb's lettuce, purple-vein rocket and watercress.

In conclusion, A23109A at recommended label rate is expected to be fully selective on all intended crops.

Comments of zRMS:

No efficacy trials have been submitted for other minor crops intended in the GAP table. Because no special selectivity trials were available for these crops, the cMSs are kindly asked to consider safety of these crops on national level.

3.4.2 Effect on the yield of treated plants or plant product (KCP 6.4.2)

According to Table 1 of EPPO standard PP 1/135(4), specific selectivity trials and yield assessments are not required for fungicides when no adverse phytotoxic effects are observed in direct efficacy trials.
A23109A appeared fully selective with the supported crops with not any significant symptoms of phytotoxicity (see 3.4.1), therefore no negative effects are expected on yield when A23109A is used as recommended.
No quantitative yield assessments were therefore performed neither in selectivity trials conducted in disease-free conditions nor in efficacy trials conducted in the absence of disease pressure.
Some qualitative yield assessments on marketable plants were however made on lettuce under protected and field conditions and are discussed in Point 3.4.3.

Comments of zRMS:

Accepted.

3.4.3 Effects on the quality of plants or plant products (KCP 6.4.3)

According to Table 1 of EPPO standard PP 1/135(4), specific selectivity trials and yield assessments are not required for fungicides when no adverse phytotoxic effects are observed in direct efficacy trials.
A23109A appeared fully selective with the supported crops with not any symptoms of phytotoxicity (see 3.4.1), therefore no negative effects are expected on yield quality when A23109A is used as recommended.

Some qualitative yield assessments on marketable plants were however made to confirm the absence of

adverse effect caused by A23109A on quality of field and protected lettuces in disease-free selectivity trials.

A summary of the quality data from selectivity trials is presented in Table 3.4-5.

A total of ~~4~~ 2 trials were carried out in 2020 in ~~Spain~~ Belgium (2x) ~~and~~ under protected conditions ~~(Belgium (2x))~~. The objective was to confirm the quality response of A23109A in the absence of disease.

Table 3.4-5: Quality data of A23109A on lettuce under disease-free conditions (quality relative to the untreated)

Assessment type	EPPO zone	Number of trials; Number of assessments	Untreated control		% Quality relative to the untreated 100%					
					A23109A at 0.5 L PR/ha N dose rate		A23109A at 1 L PR/ha 2 N dose rate		Standard Revus at 0.6 L PR/ha	
			Mean	Min & Max	Mean	Min & Max	Mean	Min & Max	Mean	Min & Max
			Absolute figures (kg/plant)							
Weight of marketable plants	Protected conditions	n=2~~, N=2~~	0.401	0.400-0.402	97.6	96.6-98.5	101.7	99.3-104.0	99.4	98.6-100.1
	~~MED~~	~~n=2; N=2~~	~~0.399~~	~~0.300-0.498~~	~~104.1~~	~~100.2-107.9~~	~~104.5~~	~~99.9-109.0~~	~~103.5~~	~~99.9-107.1~~
			Absolute figures (%)							
Percentage of marketable plants	Protected conditions	n=2~~, N=2~~	100	100-100	100	100-100	100	100-100	100	100-100
	~~MED~~	~~n=2; N=2~~	~~84~~	~~67.5-100~~	~~102.8~~	~~100-105.6~~	~~103.7~~	~~100-107.4~~	~~102.8~~	~~100-105.6~~

In all ~~4~~ 2 trials, the weight of marketable plants as well as the percentage of marketable plants was statistically equivalent to the one of untreated control and the standard Revus.
A23109A at the proposed label rate of 0.5 L PR/ha had no negative effects on the quality of lettuce in the absence of disease

Comments of zRMS:

Quality data has been evaluated in 2 selectivity trials under protected conditions. A23109A at dose rate of 0,5 l/ha had not negative impact on lettuce. Yield increase was observed in the submitted trials at double dose (1 L PR/ha). Based on percentage of marketable plants, no significant differences between untreated control and treated objects were noted.

3.4.4 Effects on transformation processes (KCP 6.4.4)

Reference is given to Part B Section 7 for information on residues in harvested/processed parts of plant.

To address transformation process questions, EPPO standard PP 1/243(2) – '*Effects of plant protection products on transformation processes'* provides an indication of the circumstances under which data on transformation processes are required. Additionally, taint tests requirements are further discussed in standard PP 1/242(2) – '*Taint tests'*.

Processing procedures are not relevant for leafy vegetable crops.

Comments of zRMS:

Accepted.

3.4.5 Impact on treated plants or plant products to be used for propagation (KCP 6.4.5)

According to Table 2 of EPPO standard PP 1/135(4), no data are normally required for fungicides on plants parts for propagation except when the plant protection product has systemic activity, is applied close to harvest and some phytotoxic effects are seen on some crops.

Because A23109A has no herbicidal activity and no phytotoxicity was reported from the trials with no negative impact on quality and yield, no data on plant parts for propagation are required.

Comments of zRMS:

Accepted.

3.5 Observations on other undesirable or unintended side-effects (KCP 6.5)

3.5.1 Impact on succeeding crops (KCP 6.5.1)

Due to the good selectivity of formulated product A23109A, no negative impacts on succeeding crops can be expected if the product is applied according to good agricultural practice (GAP).
Based on this evidence and the risk assessment for non-target terrestrial plants as provided in **Part B, Section 8** (Environmental Fate), it is concluded that the risk to succeeding crops is low.

Table 3.5-1: Endpoints and effect values relevant for the risk assessment for non-target terrestrial plants – metalaxyl-M

Species	Substance	Exposure System	Results	Reference
Brassica napus d *Avena fatua* m *Beta vulgaris* d *Zea mays* m *Glycine max* d *Allium cepa* m	RIDOMIL GOLD (A9651D)	Screening study	No effects on seedling emergence or vegetative vigour at 4.5 kg/ha	EFSA Journal 2015;13(3):3999; Walder, L., 2001, report no. CGA329351/1457

m: monocotyledonous; d: dicotyledonous
EFSA Journal 2015 ;13(3):3999. [105 pp.] doi: 10.2903/j.efsa.2015.3999

Table 3.5-2: Endpoints and effect values relevant for the risk assessment for non-target terrestrial plants – oxathiapiprolin

Species	Substance	Exposure System	Results	Reference
Zea mays m *Avena sativa* m *Allium cepa* m *Lolium perenne* m *Cucumis sativus* d *Pisum sativum* d *Brassica napus* d *Glycine max* d *Beta vulgaris* d *Lycopersicon esculentum* d	Oxathiapiprolin (formulated as 100 g/L OD)	21 d Seedling emergence	ER_{50} > 600 g a.s./ha for all species tested	EFSA 2016;14(7):4504, DuPont-32478

Species	Substance	Exposure System	Results	Reference
Zea mays m *Avena sativa* m *Allium cepa* m *Lolium perenne* m *Cucumis sativus* d *Pisum sativum* d *Brassica napus* d *Glycine max* d *Beta vulgaris* d *Lycopersicon esculentum* d	Oxathiapiprolin (formulated as 100 g/L OD)	21 d Vegetative vigour	ER_{50} > 600 g a.s./ha for all species tested	EFSA 2016;14(7):4504, DuPont-32479

m: monocotyledonous; d: dicotyledonous
EFSA Journal 2016 ;14(7):4504. [19 pp.] doi:10.2903/j.efsa.2016.4504.

Table 3.5-3: Endpoints and effect values relevant for the risk assessment for non-target terrestrial plants – A23109A

Species	Substance	Exposure System	Results	Reference
*Allium cepa*m *Triticum aestivum*m *Beta vulgaris*d *Brassica napus*d *Cucumis sativus*d *Glycine max*d	A23109A	28 d phytotoxicity screen, seedling emergence	No phytotoxic effects at rates up to and including 1 000 mL/ha, the highest rate tested	Jones 2020; Syngenta file no. VV-890173
*Allium cepa*m *Triticum aestivum*m *Beta vulgaris*d *Brassica napus*d *Cucumis sativus*d *Glycine max*d	A23109A	21 d phytotoxicity screen, vegetative vigour	No phytotoxic effects at rates up to and including 1 000 mL/ha, the highest rate tested	Jones 2020; Syngenta file no. VV-890173

m: monocotyledonous; d: dicotyledonous

Conclusion

Screening test rates up to and including 1000 mL/ha were tested with formulation A23109A and effects were below the critical threshold as defined by the "Guidance Document on Terrestrial Ecotoxicology", (SANCO/10329/2002 rev.2 final, 2002). There were no phytotoxic effects based on seedling emergence or vegetative vigour up to and including the highest test rate of 1000 mL A23109A/ha.

The test rates exceed the highest field application rate of 500 mL A23109A/ha and are thus considered an indicator for an acceptable risk.

Comments of zRMS:

The trial results submitted in Section 8 show that A23109A at dose rate of 0,5 l/ha does not negative influence on the tested crop species: onion, wheat, beet, rapeseed, cucumber and soybean. No phytotoxic symptoms were observed in case of seedling emergence and vegetative vigour. However, no information about selectivity of formulated product in situation of earlier plowing of the crops has been presented. Also no date about intervals between using of A23109A and sowing succeeding crops was given. Due to that, no recommendations to the product label are proposed. The assessment conducted in Section 8 is precedent in this case.

3.5.2 Impact on other plants including adjacent crops (KCP 6.5.2)

In accordance with EPPO Standard PP 1/256 'Effects on adjacent crops', a step-wise approach should be taken to assess the impact on other plants including adjacent crops.

A23109A is a foliar spray fungicide for which no phytotoxic effects were observe at any point during

profiling or development. Following the decision-support scheme for the risk assessment for adjacent crops proposed in Appendix 2 of EPPO Standard PP 1/256, the data produced for the risk assessment for non-target terrestrial plants, presented in Part B, section 9, is relevant to assess the impact on other plants including adjacent crops. For ease of reference a summary and interpretation of the data are presented in Table 3.5-3.

Screening test rates up to and including 1000 mL/ha were tested with formulation A23109A and effects were below the critical threshold as defined by the "Guidance Document on Terrestrial Ecotoxicology", (SANCO/10329/2002 rev.2 final, 2002). There were no phytotoxic effects based on seedling emergence or vegetative vigour up to and including the highest test rate of 1000 mL A23109A/ha.

It is the applicant's conclusion that A23109A will cause no adverse effects on adjacent crops.
Since no effects are observed on sensitive crops in field trials, nor in the risk assessment studies for non-target terrestrial plants, authorization should be granted without restrictions concerning adjacent crops.

Tank cleaning

In agreement with the EPPO guideline PP1/292(1) *"Cleaning pesticide application equipment (PAE) – efficacy aspects"*, which provides a stepwise, tiered guide to identify the risk of crop damage from tank residues, *Tier I* data to assess the efficiency of tank cleaning procedures can usually be taken even from efficacy studies if a range of sensitive crops have been tested.

A23109A has fungicide activity and no herbicidal activity, therefore the risk from tank residues is of no relevance and no testing of cleaning method are required. Furthermore, A23109A causes no phytotoxic symptoms on the plant species tested.

However, one test (Report Number: 450796; VV-Number: VV-903870) was carried out with the objective to investigate the effectiveness of the conventional (rinsing the tank three times with tapwater, no use of detergents) tank cleaning procedure.

Data to determine the effectiveness of the tank cleaning procedure for A23109A showed that after applying the cleaning procedure, 0.06 % residue was found in the refilled spray tank. These data demonstrate that the rinsing procedure sufficiently reduced the amount of residue in the spray tank. Further details in the relative dRR section.

For all these reasons, when applied according to the recommendations, traces of residues of A23109A remained in the application equipment after cleaning should pose no risk to subsequently treated crops.

Cleaning Procedure

Immediately after use, clean the spray equipment thoroughly. Drain the system completely and rinse spray tank, boom, and nozzles two to three times with clean water until the foam and all traces of the formulation have been removed.

Comments of zRMS:

The trial results submitted in Section 9 show that A23109A at dose rate of 1 l/ha does not cause negative symptoms on the tested crops: onion, wheat, sugar beet, oilseed rape, cucumber and soybean. It can be considered that the test product is safe for sensitive crops and no special recommendations in the label in case of adjacent crops are required. Based on the test results, tank cleaning procedure proposed by the applicant is justified. Rinsing with clean water two to three times removes residues to a safe level. The below recommendation can be included to the product label:
"*Immediately after use, clean the spray equipment thoroughly. Drain the system completely and rinse spray tank, boom, and nozzles two to three times with clean water until the foam and all traces of the formulation have been removed*."

3.5.3 Effects on beneficial and other non-target organisms (KCP 6.5.3)

No impacts on the fauna in general and/or beneficials were observed, nor could any negative impacts on the environment be noticed in the trials summarized in this dossier. Also, no adverse effects on natural predators or other organisms are reported, applying Metalaxyl-M formulations since the '80 on a range of crops as well as for Oxathiapiprolin. Therefore, it can be concluded that A23109A does not have adverse effects on beneficial organisms.

Detailed studies on the possible adverse effects to beneficial organisms are submitted and summarised in **Part B, Section 9** (Ecotoxicology).

Compatibility with current management practices including IPM

There are no specific tests presented in this dossier using A23109A in strategies of application with other partner fungicides.

The principles of the Integrated Pest Management (IPM) are listed and described in Annex III of the Directive 2009/128/EC.

In IPM, integrated control seeks to identify the best mix of chemical and biological controls for a given disease.

In compliance with this approach, A23109A is a suitable candidate for inclusion in IPM thanks to its profile and characteristics

Summary and conclusion

A23109A applied on leafy vegetables grown under protected conditions and in open field, according to recommendations, does not lead to unacceptable risk to succeeding crops, adjacent crops, beneficial insects and non–target organisms. Further details are given in Part B Section 8 and Section 9 of the dRR.

Furthermore, it's demonstrated the effectiveness of the conventional tank cleaning procedure following the application of A23109A.

Finally, A23109A is a suitable candidate for inclusion in IPM thanks to its profile and characteristics.

Comments of zRMS:
Accepted.

3.6 Other/special studies (KCP 6.6)

No special studies.

3.7 List of test facilities including the corresponding certificates

The following table gives information about the testing facilities where trials were done. All facilities are certified, and the trials conducted according to GEP.

The corresponding certificates are available in the GEP Certificate Database System (Certibase) (http://www.gepcertibase.eu) via the hyperlinks provided in the table below.

Table 3.7-1: List of test facilities

Hyperlink to certificate	Test facility	Country	Address	Number of trials		
				2019	2020	2021
~~1d6cb032edb (2021-2024)~~	~~Agri2000 Hellas Ltd.~~	~~Greece~~	~~Venizelou 45 (81), 57009 Kalochori~~	-	-	4

Hyperlink to certificate	Test facility	Country	Address	Number of trials		
				2019	2020	2021
1d6cb032d07 (2016-2021)	Agroblu Romania SRL	Romania	Calea Bucurestilor, no. 30 B, Saftica, 077015 Ilfov, Saftica	-	-	3
1d6cb032dd6 (2018-2023)	Anadiag Polska	Poland	Sadowa 16/22, 95-100 Zgierz	-	-	1
1d6cb032d06 (2017-2022)	Anadiag Portugal	Portugal	Rua dos Olivais, 3 R\C Dto, 3780-229 Anadia	-	-	1
1d6cb032c76 (2017-2022)	Anadiag SAS	France	8, route de Gray, 21490 Varois-et-Chaignot	-	-	1
1d6cb032cd2 (2019-2024)	BioChem agrar GmbH	Germany	Kupferstraße 6, 04827 Gerichshain	-	-	2
1d6c95f8d6d (2015-2100)	Biochem agrar Polska Spółka z.o.o.	Poland	Kozielska 48, 47-270 Urbanowic	1	-	-
1d6c9ca5f06 (2018-2023)	Biotek Agriculture España S.L	Spain	Pol. Ind. Oeste, C/ Uruguay. Parcela 14. Nave C7B, 30820 Alcantarilla	-	1	-
1d6c95f8d86 (2015-2100)	Eurofins Agroscience Services Sp. Z o.o	Poland	Parkowa 6, 64-530 Kaźmierz	-	1	-
1d6c9ca5dca (2016-2022)	Exploras Agro Development	The Netherlands	Eindsestraat 38, 5105 AC Dongen	-	1	-
1d6c9ca5fb3 (2019-2024)	F.S. Trials S.L.L.	Spain	C. del Metal, 27, 30149 Siscar, Murcia	-	1	-
1d6cb032b0d (2016-2021) 1d6cb032e25 (2021-2026)	Gemerprodukt Valice - OVD, Rimavska Sobota	Slovakia	Okruzna 3771, 97901 Rimavska Sobota	-	-	1
1d6cba1dc31	Syngenta Agro GmbH	Germany	Am Technologiepark 1, 63477 Maintal	1	-	-
1d6c9ca5e23 (2017-2021)	Inagro vzw	Belgium	Ieperseweg 87, 8800 Rumbeke-Beitem	-	1	-
1d6c95f907b (2021-2026)	Institut of Horticulture in Skierniewice	Poland	3, Konstytucji 3 Maja 1, 96-100 Skierniewice	1	1	-
1d6c9ca5f16 (2017-2100)	Research Institute of Horticulture	Poland	3, Konstytucji 3 Maja 1, 96-100 Skierniewice	1	2	-
1d6c9ca5e28 (2018-2023)	InTec Agro Trials, s.r.o.	Czech Republic	Blatnická 179, 687 24 Uherský Ostroh	-	1	-
1d6c9ca5db9 (2015-2021)	Martin – Feldversuchswesen	Germany	Im Grund 20, 78359 Orsingen-Nenzingen	-	1	-
1d6c95f8f76 (2019-2020) 1d6c95f8e40 (2017-2019)	PCG (Provinciaal Proefcentrum voor de Groenteteelt Oost-Vlaanderen vzw)	Belgium	Karreweg 6, 9770 Kruishoutem	2	2	-
1d6c9ca5ded (2015-2021)	Proeftuin Zwaagdijk (Stichting Proeftuin Zwaagdijk)	The Netherlands	Tolweg 13, 1681 ND Zwaagdijk	2	2	-
1d6c95f904b (2019-2020) 1d6c95f8fca (2020-2021) 1d6c95f904b (2020-2024)	PSG SKW (Proefstation voor de Groenteteelt VZW)	Belgium	Duffelsesteenweg 101, 2860 Sint-Katelijne-Waver	3 2	5 2	-
1d6c95f8fb6 (2018-2023)	Qualiphyt	France	80 chemin de Riboulin, 26270 Loriol sur Drôme	1	2 1	-
1d6c9ca5dd7 (2016-2021)	Staphyt	France	23 Rue de Moeuvres, 62860 Inchy-en-Artois	1	-	-
1d6c95f8d51 (2016-2021)	Syngenta Agro GmbH	Germany	Am Technologiepark 1, 63477 Maintal	1	-	-
1d6c95f8de9 (2016-2021)	Syngenta España, S.A.	Spain	C. de la Ribera del Loira, 8, 10, 28042 Madrid	5	1	-
1d6c95f8f45 (2018-2023)	Syngenta France SAS	France	1 avenue des Près, CS 10537, 78286 Guyancourt	1	2	-

Hyperlink to certificate	Test facility	Country	Address	Number of trials		
				2019	2020	2021
1d6cb032de7 (2020-2022) 1d6c95f8f31 (2018-2020) 1d6c95f9007 (2020-2022)	Syngenta Italia S.p.A	Italy	Via Montesanto, 16, Monestirolo, 44100 Ferrara	-	-	2
	Syngenta Italia S.p.A	Italy	via Gallarate n. 139, 20151 Milano	1	-	-
1d6c95f8f31 (2018-2020) 1d6c95f9007 (2020-2022)	Syngenta Italia S.p.A.	Italy	Viale Fulvio Testi, 280/6, 20126 Milano MI	2	2 1	-
1d6c95f8ff4 (2014-2021)	Syngenta Polska Sp.z o.o.	Poland	Szamocka 8, 01-748 Warszawa	-	2	-
1d6c95f8f4f (2019-2024)	SynTech Research France SAS	France	613 route du Bois de Loyse, 71570 La Chapelle de Guinchay	-	1	-
1d6c95f8cee (2015-2100) 1d6c95f900e (2020-2100)	SynTech Research Poland	Poland	Bajeczna 6, 05-870 Bramki	-	1	-
1d6c95f8e78 (2018-2023)	SynTech Research Portugal	Portugal	Rua Antonio de Oliveira, no 21, Zona Industrial de Caldas da Rainha, 2500-916 Santo Onofre	-	1	1
1d6c9ca5e47 (2017-2022)	SynTech Research Spain S.L.	Spain	Camino de los Huertos s/n, 46210 Picanya, Valencia	-	1	-
Uniwersytet Przyrodniczy, ZDD Gorzyn (2021-2026)	Uniwersytet Przyrodniczy, ZDD Gorzyn	Poland	Mazowiecka 45, 60-623 Poznań	1	-	-
1d6cb032e88 (2021-2027)	Vertify	The Netherlands	Tolweg 13, 1681 ND Zwaagdijk-Oost, Noord-Holland	-	-	1
Wageningen Plant Research (2017-2022)	Wageningen Plant Research	The Netherlands	Radix, Droevendaalsesteeg 1, 6708 PB Wageningen	-	1	-

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Source Company Report No. GLP or GEP status Published or Unpublished Syngenta File No.	Vertebrate study Y/N	Owner SYN = Syngenta
KCP 6	Redebel Regulatory Affairs scrl, Syngenta	2022	Biological Assessment Dossier <A23109A> Syngenta -,- non GEP Unpublished VV-882408	N	SYN
Trial Reports					
~~KCP 6.1~~	~~Apahidean A.~~	~~2021~~	~~Efficacy trials with A13947B (MFX solo) in brassicas against downy mildew in Europe OF~~ ~~Agroblu Romania SRL~~ ~~ROANZF9102021~~ ~~GEP~~ ~~Unpublished~~ ~~VV-944371~~	~~N~~	~~SYN~~
~~KCP 6.1~~	~~Apahidean A.~~	~~2021~~	~~Efficacy trials with A13947B (MFX solo) in brassicas against downy mildew in Europe OF~~ ~~Agroblu Romania SRL~~ ~~ROANZF9012021~~ ~~GEP~~ ~~Unpublished~~ ~~VV-944370~~	~~N~~	~~SYN~~
~~KCP 6.1~~	~~Apahidean A.~~	~~2021~~	~~Efficacy trials with A13947B (MFX solo) in onion against DM Peronospora destructor – 2021~~ ~~Agroblu Romania SRL~~ ~~ROANZF9342021~~ ~~GEP~~ ~~Unpublished~~ ~~VV-944372~~	~~N~~	~~SYN~~

Data point	Author(s)	Year	Title Source Company Report No. GLP or GEP status Published or Unpublished Syngenta File No.	Vertebrate study Y/N	Owner SYN = Syngenta
KCP 6.1	Bertin B.	2021	EAME Registration of A23109A in allium against Peronospora destructor in open field in EU – 2020 Syngenta France SAS FRBEZF0352020 GEP Unpublished VV-938002	N	SYN
KCP 6.1	Cap N.	2019	Profiling & registration of EXF16939C / EXF16956C -in onion in EAME 2019 PC Groententeelt Kruishoutem BEKHZF9082019 GEP Unpublished VV-937960	N	SYN
KCP 6.1	Commandeur I.	2019	Profiling & registration of EXF16956C / EXF16939C (OXTP + MFX) against Peronospora brassicae in brassicae in EAME 2019 Stichting Proeftuin Zwaagdijk NLZWZF9142019 GEP Unpublished VV-938046	N	SYN
KCP 6.1	Commandeur I.	2021	Efficacy trials with A13947B (MFX solo) in brassicas against downy mildew in Europe OF Vertify NLA2ZF9032021 GEP Unpublished VV-944367	N	SYN
KCP 6.1	Darwich S.	2020	EAME Registration of A23109A against Peronospora parasitica in brassicae in EAME 2020 Inagro vzw BEINZF0032020 GEP Unpublished VV-937957	N	SYN

Data point	Author(s)	Year	Title Source Company Report No. GLP or GEP status Published or Unpublished Syngenta File No.	Vertebrate study Y/N	Owner SYN = Syngenta
KCP 6.1	de Vries H.	2019	Profiling & registration of EXF16939C / EXF16956C (OXTP + MFX) in onion in EAME 2019 Proeftuin Zwaagdijk NLZWZF9062019 GEP Unpublished VV-938042	N	SYN
KCP 6.1	de Vries H.	2021	EAME Registration of A23109A in allium against Peronospora destructor in open field in EU – 2020 Proeftuin Zwaagdijk NLZWZF9042020 GEP Unpublished VV-938041	N	SYN
KCP 6.1	Evenhuis B.	2020	EAME Registration of A23109A in allium against Peronospora destructor in open field in EU – 2020 Wageningen Plant Research NLPPZF9032020 GEP Unpublished VV-938040	N	SYN
KCP 6.1	Hoitink R.	2020	EAME Registration of A23109A against Peronospora parasitica in brassicae in EAME 2020 Proeftuin Zwaagdijk NLZWZF9092020 GEP Unpublished VV-938045	N	SYN
KCP 6.1	Ingenerf M.	2021	Efficacy trials with A13947B (MFX solo) in onion against DM Peronospora destructor – 2021 BioChem agrar GmbH, Branch office Agroplan DEANZF9292021 GEP Unpublished VV-944357	N	SYN

Data point	Author(s)	Year	Title Source Company Report No. GLP or GEP status Published or Unpublished Syngenta File No.	Vertebrate study Y/N	Owner SYN = Syngenta
KCP 6.1	Jarecka-Boncela A.	2020	Profiling & registration of EXF16956C / EXF16939C (OXTP + MFX) against Peronospora brassicae in brassicae in EAME 2019 Instytut Sadownictwa i Kwiaciarstwa, Skierniewice PLIWZF1122019 GEP Unpublished VV-938059	N	SYN
KCP 6.1	Jarecka-Boncela A.	2020	EAME Registration of A23109A (OXTP + MFX) against Peronospora parasitica in brassicae in EAME 2020 Institut of Horticulture in Skierniewice PLIWZF1072020 GEP Unpublished VV-938057	N	SYN
KCP 6.1	Jarecka-Boncela A.	2020	EAME Registration OXTP + MFX (A23109A) in onion against DM in open field in EU – 2020 Instytut Ogrodnictwa Skierniewice PLIWZF1042020 GEP Unpublished VV-938056	N	SYN
KCP 6.1	Jateczak K.	2021	Efficacy trials with A13947B (MFX solo) in brassicas against downy mildew in Europe OF Anadiag Polska PLANZF9042021 GEP Unpublished VV-944368	N	SYN
KCP 6.1	Krosschell A.	2020	EAME Registration of A23109A in allium against Peronospora destructor in open field in EU – 2020 Exploras Agro Development NLEXZF9022020 GEP Unpublished VV-938037	N	SYN

Data point	Author(s)	Year	Title Source Company Report No. GLP or GEP status Published or Unpublished Syngenta File No.	Vertebrate study Y/N	Owner SYN = Syngenta
KCP 6.1	Marques M.	2020	Profiling & registration of EXF16939C / EXF16956C (OXTP + MFX) in onion in EAME 2019 Syngenta España S.A. ESEAZF1142019 GEP Unpublished VV-937994	N	SYN
KCP 6.1	Marques M.	2020	Profiling & registration of EXF16939C / EXF16956C (OXTP + MFX) in onion in EAME 2019 Syngenta España S.A. ESEAZF1132019 GEP Unpublished VV-937993	N	SYN
KCP 6.1	Martin T.	2020	EAME Registration of A23109A (OXTP + MFX) against Peronospora parasitica in brassicae in EAME 2020 Martin – Feldversuchswesen DEFMZF1022020 GEP Unpublished VV-937990	N	SYN
KCP 6.1	Matusiak J.	2020	EAME Registration OXTP + MFX (A23109A) in onion against DM in open field in EU – 2020 Syngenta Polska Sp. z o.o. PLDSZF5202020 GEP Unpublished VV-938051	N	SYN
KCP 6.1	Oliveira M.	2021	Efficacy trials with A13947B (MFX solo) in brassicas against downy mildew in Europe OF Anadiag Portugal PTANZF9112021 GEP Unpublished VV-944369	N	SYN
KCP 6.1	Otrhalkova P.	2020	EAME Registration OXTP + MFX (A23109A) in onion against DM in open field in EU – 2020 InTec Agro Trials, s.r.o. CZITZF1052020 GEP Unpublished VV-937986	N	SYN

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KCP 6.1	Palmieri N.	2020	EAME Registration OXTP + MFX (A23109A) in onion against DM in open field in EU - 2020 Syngenta Italia S.p.A. ITSOZF1122020 GEP Unpublished VV-938035	N	SYN
KCP 6.1	Palmieri N.	2021	Efficacy trials with A13947B (MFX solo) in onion against DM Peronospora destructor - 2021 Syngenta Italia SpA ITSOZF2902021 GEP Unpublished VV-944366	N	SYN
KCP 6.1	Reinhard R.	2019	Profiling & registration of EXF16956C / EXF16939C (OXTP + MFX) against Peronospora brassicae in brassicae in EAME 2019 Syngenta Agro GmbH DEDSZF5572019 GEP Unpublished VV-937989	N	SYN
KCP 6.1	Renovell A.	2020	EAME Registration OXTP + MFX (A23109A) in onion against DM in open field in EU - 2020 SynTech Research Spain ESSTZF0142020 GEP Unpublished VV-938000	N	SYN
KCP 6.1	Szymanska B.	2019	Profiling & registration of EXF16939C / EXF16956C (OXTP + MFX) in onion in EAME 2019 Uniwersytet Przyrodniczy PLUPZF1022019 GEP Unpublished VV-938063	N	SYN

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KCP 6.1	Toth F.	2021	Efficacy trials with A13947B (MFX solo) in onion against DM Peronospora destructor – 2021 Gemerprodukt Valice – OVD, Rimavska Sobota, Slovakia SKANZF9332021 GEP Unpublished VV-944373	N	SYN
KCP 6.1	Tselikis I.	2021	Efficacy trials with A13947B (MFX solo) in onion against DM Peronospora destructor – 2021 Agri 2000 Hellas GRA2ZF9262021 GEP Unpublished VV-944363	N	SYN
KCP 6.1	Tselikis I.	2021	Efficacy trials with A13947B (MFX solo) in onion against DM Peronospora destructor – 2021 Agri 2000 Hellas GRA2ZF9332021 GEP Unpublished VV-944364	N	SYN
KCP 6.1	Tsopelopoulos K.	2021	Efficacy trials with A13947B (MFX solo) in brassicas against downy mildew in Europe OF Agri2000 Hellas Ltd. GRA2ZF9012021 GEP Unpublished VV-944361	N	SYN
KCP 6.1	Tsopelopoulos K.	2021	Efficacy trials with A13947B (MFX solo) in brassicas against downy mildew in Europe OF Agri2000 Hellas Ltd. GRA2ZF9022021 GEP Unpublished VV-944362	N	SYN
KCP 6.1	Viard J.	2021	Efficacy trials with A13947B (MFX solo) in onion against DM Peronospora destructor – 2021 Anadiag SAS France FRANZF9312021 GEP Unpublished VV-944360	N	SYN

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KCP 6.1	Visentin F.	2021	Efficacy trials with A13947B (MFX solo) in onion against DM Peronospora destructor – 2021 Syngenta Italia SpA ITNOZF3052021 GEP Unpublished VV-944365	N	SYN
KCP 6.1	Willocq B.	2019	Profiling & registration of EXF16939C / EXF16956C in onion in EAME 2019 Staphyt FRSTZF9082019 GEP Unpublished VV-938028	N	SYN
KCP 6.1	Zappe C.	2021	Efficacy trials with A13947B (MFX solo) in brassicas against downy mildew in Europe OF BioChem agrar GmbH DEANZF9072021 GEP Unpublished VV-944356	N	SYN
KCP 6.1 KCP 6.2 KCP 6.4.1	Cap N.	2021	EAME Registration of A23109A and A22773A for lettuce against bremia in FIELD in EU – 2020 PCG BEKHZF0012020 GEP Unpublished VV-937958	N	SYN
KCP 6.1 KCP 6.2 KCP 6.4.1	Carstens H.	2020	EAME Profiling & registration_OXTP+AZT – Orondis Evo (A22773A) and OXTP+MFX for Lettuce against Bremia in the field 2019 Syngenta Agro GmbH DEDSZF1452019 GEP Unpublished VV-937988	N	SYN

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~~KCP 6.1 KCP 6.2 KCP 6.4.1~~	~~Chatelier B.~~	~~2020~~	~~EAME Registration of A23109A and A22773A for lettuce against bremia in FIELD in EU – 2020 Qualiphyt – France FRQUZF0232020 GEP Unpublished VV-938007~~	~~N~~	~~SYN~~
~~KCP 6.1 KCP 6.2 KCP 6.4.1~~	~~Fortusini M.~~	~~2020~~	~~EAME Registration OXTP + MFX (A23109A) and OXTP+AZT (A22773A) for lettuce against bremia in FIELD in EU – 2020 Syngenta Italia S.p.A. ITNOZF1012020 GEP Unpublished VV-938033~~	~~N~~	~~SYN~~
~~KCP 6.1 KCP 6.2 KCP 6.4.1~~	~~Jarecka-Boncela A.~~	~~2019~~	~~EAME Profiling & registration OXTP+AZT - Orondis Evo (A22773A) and OXTP+MFX for Lettuce against Bremia in the field 2019 Institut of Horticulture in Skierniewice PLIWZF1102019 GEP Unpublished VV-938058~~	~~N~~	~~SYN~~
~~KCP 6.1 KCP 6.2 KCP 6.4.1~~	~~Jarecka-Boncela A.~~	~~2020~~	~~EAME Registration OXTP + MFX (A23109A) and OXTP+AZT (A22773A) for lettuce against bremia in FIELD in EU – 2020 Institut of Horticulture in Skierniewice PLIWZF1022020 GEP Unpublished VV-938054~~	~~N~~	~~SYN~~
~~KCP 6.1 KCP 6.2 KCP 6.4.1~~	~~Matusiak J.~~	~~2020~~	~~EAME Registration OXTP + MFX (A23109A) and OXTP+AZT (A22773A) for lettuce against bremia in FIELD in EU – 2020 Syngenta Polska Sp. z o.o. PLDSZF5172020 GEP Unpublished VV-938050~~	~~N~~	~~SYN~~

Data point	Author(s)	Year	Title Source Company Report No. GLP or GEP status Published or Unpublished Syngenta File No.	Vertebrate study Y/N	Owner SYN = Syngenta
~~KCP 6.1 KCP 6.2 KCP 6.4.1~~	~~Mesange C.~~	~~2020~~	~~EAME Registration of A23109A and A22773A for lettuce against bremia in FIELD in EU – 2020 Syngenta SAS FRCMZF0322020 GEP Unpublished VV-938003~~	~~N~~	~~SYN~~
KCP 6.1 KCP 6.2 KCP 6.4.1	Ripaud H.	2019	EAME Profiling & registration of A22773A and EXF16956C for Lettuce against Bremia GH 2019 Qualiphyt FRQUZF9312019 GEP Unpublished VV-938009	N	SYN
KCP 6.1 KCP 6.2 KCP 6.4.1	Ripaud H.	2020	EAME Registration of A23109A and A22773A for lettuce against bremia in GH in EU – 2020 Qualiphyt FRQUZF0262020 GEP Unpublished VV-938008	N	SYN
~~KCP 6.1 KCP 6.2 KCP 6.4.1~~	~~Slowiak K.~~	~~2019~~	~~EAME Profiling & registration OXTP+AZT - Orondis Evo (A22773A) and OXTP+MFX for Lettuce against Bremia in the field 2019 Biochem agrar Polska Spólka z o.o. PLBCZF1082019 GEP Unpublished VV-938048~~	~~N~~	~~SYN~~
~~KCP 6.1 KCP 6.2 KCP 6.4.1~~	~~Vega P.~~	~~2019~~	~~EAME Profiling & registration OXTP+AZT - Orondis Evo (A22773A) and OXTP+MFX for Lettuce against Bremia in the field 2019 Syngenta España S.A. ESSEZF3122019 GEP Unpublished VV-937997~~	~~N~~	~~SYN~~

Data point	Author(s)	Year	Title Source Company Report No. GLP or GEP status Published or Unpublished Syngenta File No.	Vertebrate study Y/N	Owner SYN = Syngenta
~~KCP 6.1 KCP 6.2 KCP 6.4.1~~	~~Vega P.~~	~~2020~~	~~EAME Registration OXTP + MFX (A23109A) and OXTP+AZT (A22773A) for lettuce against bremia in FIELD in EU – 2020 Syngenta España S.A. ESSEZF3052020 GEP Unpublished VV-937996~~	~~N~~	~~SYN~~
KCP 6.1 KCP 6.2 KCP 6.4.1	Venneman S.	2019	EAME Profiling & registration of A22773A and EXF16956C for Lettuce against Bremia GH 2019 PSG SKW BESKZF9112019 GEP Unpublished VV-937974	N	SYN
KCP 6.1 KCP 6.2 KCP 6.4.1	Venneman S.	2019	EAME Profiling & registration of A22773A and EXF16956C for Lettuce against Bremia GH 2019 PSG SKW BESKZF9122019 GEP Unpublished VV-937975	N	SYN
~~KCP 6.1 KCP 6.2 KCP 6.4.1~~	~~Venneman S.~~	~~2019~~	~~EAME Profiling & registration of A22773A and EXF16956C for Lettuce against Bremia in the field 2019 PSG SKW BESKZF9102019 GEP Unpublished VV-937973~~	~~N~~	~~SYN~~
KCP 6.1 KCP 6.2 KCP 6.4.1	Venneman S.	2020	EAME Registration of A23109A and A22773A for lettuce against bremia in GH in EU – 2020 PSG SKW BESKZF0062020 GEP Unpublished VV-937966	N	SYN

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KCP 6.1 KCP 6.2 KCP 6.4.1	Venneman S.	2020	EAME Registration of A23109A and A22773A for lettuce against bremia in GH in EU – 2020 PSG SKW BESKZF0052020 GEP Unpublished VV-937965	N	SYN
~~KCP 6.1 KCP 6.2 KCP 6.4.1~~	~~Venneman S.~~	~~2020~~	~~EAME Registration of A23109A and A22773A for lettuce against bremia in FIELD in EU – 2020 PSG SKW BESKZF0042020 GEP Unpublished VV-937964~~	~~N~~	~~SYN~~
~~KCP 6.1 KCP 6.2 KCP 6.4.1~~	~~Wachowiak P.~~	~~2020~~	~~EAME Registration OXTP + MFX (A23109A) and OXTP+AZT (A22773A) for lettuce against bremia in FIELD in EU – 2020 Eurofins Agroscience Services Sp. Z o.o PLEUZF1072020 GEP Unpublished VV-938052~~	~~N~~	~~SYN~~
KCP 6.2 KCP 6.4.1	Aversa A.	2020	EAME Profiling OXTP+AZT - Orondis Evo (A22773) for Lettuce against Bremia GH 2019 Syngenta Italia S.p.A ITSOZF1002019 GEP Unpublished VV-938034	N	SYN
~~KCP 6.2 KCP 6.4.1~~	~~Berti L.~~	~~2019~~	~~EAME Profiling & registration- OXTP+AZT - Orondis Evo (A22773A) and OXTP+MFX for Lettuce against Bremia in the field 2019 Syngenta Italia SpA ITNOZF0992019 GEP Unpublished VV-938032~~	~~N~~	~~SYN~~

Data point	Author(s)	Year	Title Source Company Report No. GLP or GEP status Published or Unpublished Syngenta File No.	Vertebrate study Y/N	Owner SYN = Syngenta
~~KCP 6.2 KCP 6.4.1~~	~~Cánovas M.~~	~~2019~~	~~EAME Profiling & registration OXTP+AZT - Orondis Evo (A22773A) and OXTP+MFX for Lettuce against Bremia in the field 2019 Syngenta Agro, Madrid, Spain ESSEZF4012019 GEP Unpublished VV-937998~~	~~N~~	~~SYN~~
~~KCP 6.2 KCP 6.4.1~~	~~Kasperek M.~~	~~2020~~	~~EAME Registration OXTP + MFX (A23109A) and OXTP+AZT (A22773A) for lettuce against bremia in FIELD in EU – 2020 SynTech Research Poland PLSYZF1012020 GEP Unpublished VV-938061~~	~~N~~	~~SYN~~
~~KCP 6.2 KCP 6.4.1~~	~~Neukermans J.~~	~~2019~~	~~EAME Profiling & registration of A22773A and EXF16956C for Lettuce against Bremia in the field 2019 PC Groententeelt Kruishoutem BEKHZF9122019 GEP Unpublished VV-937962~~	~~N~~	~~SYN~~
~~KCP 6.2 KCP 6.4.1~~	~~Neukermans J.~~	~~2019~~	~~EAME Profiling & registration of A22773A and EXF16956C for Lettuce against Bremia in the field 2019 PC Groententeelt Kruishoutem BEKHZF9132019 GEP Unpublished VV-937963~~	~~N~~	~~SYN~~
KCP 6.2 KCP 6.4.1	Oriol B.	2020	EAME Registration of A23109A and A22773A for lettuce against bremia in GH in EU – 2020 SynTech Research France SAS FRSYZF0332020 GEP Unpublished VV-938030	N	SYN

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~~KCP 6.2 KCP 6.4.1~~	~~Speyer M.~~	~~2020~~	~~EAME Profiling & registration of A22773A and EXF16956C for Lettuce against Bremia in the field 2019 Syngenta France SAS FRSMZF9142019 GEP Unpublished VV-938026~~	~~N~~	~~SYN~~
KCP 6.2 KCP 6.4.1	Spreckelsen G.	2021	EAME Registration OXTP + MFX (A23109A) and OXTP+AZT (A22773A) for lettuce against bremia in GH in EU – 2020 Syntech Research Portugal PTSTZF0152020 GEP Unpublished VV-938066	N	SYN
~~KCP 6.4.1~~	~~Cánovas M.~~	~~2019~~	~~EAME Profiling & registration- OXTP+AZT - Orondis Evo (A22773A) and OXTP+MFX for Lettuce against Bremia in the field 2019 Syngenta Agro, Madrid, Spain ESSEZF4022019 GEP Unpublished VV-937999~~	~~N~~	~~SYN~~
~~KCP 6.4.1~~	~~Pisco A.~~	~~2019~~	~~EAME Profiling & registration- OXTP+AZT - Orondis Evo (A22773A) and OXTP+MFX for Lettuce against Bremia in the field 2019 Syngenta CP Italy ITNOZF0982019 GEP Unpublished VV-938031~~	~~N~~	~~SYN~~
KCP 6.4.1 KCP 6.4.3	Espinosa A.	2020	EAME Registration OXTP+MFX (A23109A) and MFX+CU (A15605D) on Lettuce - Crop safety trials 2020 BIOTEK Agricluture España S.L ESBTZF0052020 GEP Unpublished VV-937992	N	SYN

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KCP 6.4.1 KCP 6.4.3	Soto Espinosa F.	2020	EAME Registration OXTP+MFX (A23109A) and MFX+CU (A15605D) on Lettuce - Crop safety trials 2020 FS Trials S.L ESFSZF0092020 GEP Unpublished VV-937995	N	SYN
~~KCP 6.4.1 KCP 6.4.3~~	~~Venneman S.~~	~~2020~~	~~EAME Registration of A23109A and A15605D on Lettuce – Crop safety trials 2020 PSG SKW BESKZF0082020 GEP Unpublished VV-937967~~	~~N~~	~~SYN~~
~~KCP 6.4.1 KCP 6.4.3~~	~~Venneman S.~~	~~2021~~	~~EAME Registration of A23109A and A15605D on Lettuce – Crop safety trials 2020 PSG SKW BESKZF0092020 GEP Unpublished VV-937968~~	~~N~~	~~SYN~~

List of data submitted by the applicant and not relied on

Data point	Author(s)	Year	Title Source Company Report No. GLP or GEP status Published or Unpublished Syngenta File No.	Vertebrate study Y/N	Owner
-	-	-	-	-	-

List of data relied on not submitted by the applicant but necessary for evaluation

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-	-	-	-	-	-