REGISTRATION REPORT

Part A

Risk Management

Product code: A12946B

Product name: REVUS

Chemical active substance:

Mandipropamide, 250 g/L

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

Label extension according to Art. 51

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Minor uses

Applicant: SYNGENTA FRANCE SAS

Date: 09/07/2024

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PART A – Risk Management

The company SYNGENTA FRANCE SAS has requested a label extension in France for the REVUS (formulation code: A12946B) according to article 51 Regulation (EC) no 1107/2009[1]

This document describes the specific conditions of use and labelling required for extension of the registration of REVUS (A12946B) containing Mandipropamid in France.

The conclusions of the risk assessment are based on the already existing registration of the preparation in France. Therefore, the evaluation of the current application is limited to the points not covered by the existing registration.

Appendix 1 of this document provides a copy of the French Decision.

Appendix 2 of this document is a copy of the draft product label as proposed by the applicant.

Appendix 3 of this document is a copy of the letter(s) of access.

1 DETAILS OF THE APPLICATION

1.1 Application background

REVUS (A12946B) is a concentrated suspension product containing 250 g/L of mandipropamid, for use as a fungicide for control of downy mildew. The aim of this registration application is to gain a label extension for crops of leafy cabbages, vegetables for seed production and fresh herbs.

The complete GAP for the national application in France is provided below, under point 2.3.

1.2 Active substance approval

Mandipropamid

Commission Implementing Regulation (EU) No 188/2013 of 5 March 2013 approving the active substance mandipropamid, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011
Specific provisions of Regulation (EU) No 188/2013 were as follows: For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on mandipropamid, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 1 February 2013 shall be taken into account. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit confirmatory information as regards the potential for preferential enantiomeric transformation or racemisation of mandipropamid at the soil surface as a result of soil photolysis. The applicant shall submit to the Commission, the Member States and the Authority that information by 31 July 2015.
An EFSA conclusion is available (EFSA Journal 2012; 10(11):2935). A Review Report is available (SANCO/ 12991/2012 rev 4 - 1 February 2013).

[1] REGULATION (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

1.3 Regulatory approach

The present application (n°2022-0240) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses)[2].

The current document based on Anses' assessment of the application submitted for this product is in compliance with Regulation (EC) no 1107/2009, implementing regulations and French regulations.

Since the application is intended for use in France only, the draft Part A was not circulated for comments.

According to the French law and procedures, specific conditions of use are set out in the Decision letter.
The French Order of 4th May 2017[3] provides that:

- unless formally stated in the product authorisation, the pre harvest interval (PHI) is at least 3 days;
- unless formally stated in the product authorisation, the minimum buffer zone alongside a water body is 5 m;
- unless formally stated in the product authorisation, the minimum re-entry period is 6 hours for field uses and 8 hours for indoor uses.

Drift reduction measures such as low-drift nozzles are not considered within the decision making process in France. However, drift buffer zones may be reduced under some circumstances as explained in appendix 3 of the above-mentioned French order.

The data taken into account are those deemed to be valid either at European Union level or at zonal/national level. This part A presents a summary of essential scientific points upon which recommendations are based and is not intended to show the assessment in detail.

The conclusions relating to the acceptability of risk are based on the criteria indicated in Regulation (EU) N°546/2011[4], and are expressed as "acceptable" or "not acceptable" in accordance with those criteria.

Finally, the French Order of 12 April 2021[5] provides that:

- an authorisation granted for a « reference » crop applies also for "linked" crops unless formally stated in the decision
- the "reference" and "linked crops are defined in appendix 1 of that French order. .

Thus, at French national level, possible extrapolation of submitted data and the corresponding assessment from "reference" crops to "linked" ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is reached on the acceptability of the intended uses on those "linked" crops. The aim of this Order, mainly based on the EU document on residue data extrapolation[6] is to supply "minor" crops with registered plant protection products.

Therefore the GAP table (Section 2.3) and Decision may include uses on crops not originally requested by the applicant. The Decision, as reproduced in Appendix 1, takes also into account national provisions, including national mitigation measures.

1.4 Data protection claims

There is no new data submitted with this application.

1.5 Letter(s) of access

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2 French Food Safety Agency, Afssa, before 1 July 2010

3 Arrêté du 4 mai 2017 relatif à la mise sur le marché et à l'utilisation des produits phytopharmaceutiques et de leurs adjuvants visés à l'article L. 253-1 du code rural et de la pêche maritime, amended by the arrêté du 27 décembre 2019 relatif aux mesures de protection des personnes lors de l'utilisation de produits phytopharmaceutiques https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGRG1632554A/jo/texte ; https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000039686039&categorieLien=id

4 COMMISSION REGULATION (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products

5 https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000043401456

6 SANCO document "guidance document:- Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs": SANCO/ 7525/VI/95 - rev.9

Not relevant for this application.

2 DETAILS OF THE AUTHORISATION

2.1 Product identity

Product name (code)	REVUS (A12946B)
Authorisation number	2080098
Function	fungicide
Applicant	SYNGENTA FRANCE SAS
Composition	250 g/L mandipropamid
Formulation type (code)	Concentrated suspension (SC)
Packaging	Not relevant for extension of authorisation according article 51.

2.2 Classification and labelling

2.2.1 Classification and labelling under Directive 99/45/EC

Not relevant for extension of authorisation according article 51.

2.2.2 Classification and labelling in accordance with Regulation (EC) No1272/2008

Not relevant for extension of authorisation according article 51.

2.2.3 Other phrases in compliance with Regulation (EU) No 547/2011

Refer to the decision of product authorization.

2.2.4 Other phrases linked to the preparation

Wear suitable personal protective equipment[7]: refer to the Decision in Appendix 1 of product authorisation.
Re-entry period[8] : 6 hours in field and 8 hours in greenhouse.
Pre-harvest interval[9] : 14 days (leafy cabbages); 7 days (fresh herbs)
Other mitigation measures: Do not feed animal with kale treated with REVUS. The by-products from crops used for seed production must not be used for food or animal feed purposes.
The label must reflect the conditions of authorisation.

[7] If a tractor with cab is used, wearing gloves during application is only required when working with the spray mixture

[8] The legal basis for this is **Titre I Article 3** of the French Order of 4th May 2017concerning the marketing and use of products encompassed by article L. 253-1 of the rural code [that is, plant protection products/pesticides]

[9] According to the French Order of 4th May 2017, PHI cannot be lower than 3 days unless specifically stated in the assessment and decision.

2.3 Product uses

Please note: The GAP Table below reports the intended uses proposed by the applicant, and possible extrapolation according to French Order of 12 April 2021 (highlighted in green), evaluated and concluded as safe uses by France as zRMS. Those uses are then granted in France.
When the conclusion is "not acceptable" , the intended use is highlighted in grey and the main reason(s) reported in the remarks.
When a use is "acceptable" with GAP restrictions, the modifications of the GAP are in bold.
Use should be crossed out when the applicant no longer supports this use.

GAP rev. 1, date: 2024-07-25

PPP (product name/code):	REVUS / A12946B	Formulation type:	SC [a, b]
Active substance 1:	Mandipropamid	Conc. of a.s. 1:	250 g/L [c]
Safener:	/	Conc. of safener:	/
Synergist:	/	Conc. of synergist:	/
Applicant:	SYNGENTA FRANCE SAS	Professional use:	☒
Zone(s):	Southern Zone [d]	Non-professional use:	☐
Verified by MS:	Yes		
Field of use:	Fungicide		

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/or situation (crop destination/purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:**
					Method/Kind	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		e.g. g safener/synergist per ha [f]
Minor uses according to Article 51 (zonal uses)													
1	FR	Leafy cabbages: kale (BRSOA), Chinese cabbages (BRSPK) and others leafy cabbages	F	*Peronospora* sp. (PEROSP), *Pseudoperonospora cubensis* (PSPECU)	Foliar spraying	BBCH 16-49	a) 2 b) 2	10	a) 0.6 L/ha b) 1.2 L/ha	a) 150 g mandipropamid/ha b) 300 g mandipropamid/ha	200-800	14	**Acceptable**

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/or situation (crop destination/purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f]
					Method/Kind	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
2a	FR	Vegetables for seed production	F	*Peronospora* sp. (PEROSP), *Pseudoperonospora* sp. (PSPESP), *Plasmopara* sp. (PLASSP), *Phytophthora* sp. (PHYTSP), *Bremia* sp. (BREMSP), *Albugo* sp (ALBUSP)	Foliar spraying	BBCH 12-79	a) 2 b) 2	10	a) 0.6 L/ha b) 1.2 L/ha	a) 150 g mandipropamid/ha b) 300 g mandipropamid/ha	200-400	NA	**Acceptable**
2b	FR	Vegetables for seed production	G	*Peronospora* sp. (PEROSP), *Pseudoperonospora* sp. (PSPESP), *Plasmopara* sp. (PLASSP), *Phytophthora* sp. (PHYTSP), *Bremia* sp. (BREMSP), *Albugo* sp (ALBUSP)	Foliar spraying	BBCH 12-79	a) 1 b) 1	-	a) 0.6 L/ha b) 0.6 L/ha	a) 150 g mandipropamid/ha b) 150 g mandipropamid/ha	200-400	NA	**Acceptable**
3	FR	Fresh herbs	F	*Peronospora sp*. (PEROSP), *Plasmopara crustosa* (PLASCR)	Foliar spraying	BBCH 11-49	a) 4 (max 2 app per cycle) b) 4 (max 2 app per cycle)	7	a) 0.6 L/ha b) 2.4 L/ha (max 1.2 L/ha per cycle)	a) 150 g mandipropamid/ha b) 600 g mandipropamid (max 300 g mandipropamid/ha per cycle)	200-600	7	**Acceptable**

Remarks table heading:

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

Remarks columns:

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

3 RISK MANAGEMENT

3.1 Reasoned statement of the overall conclusions taken in accordance with the Uniform Principles

3.1.1 Physical and chemical properties

Not relevant for extension of authorisation according article 51.

3.1.2 Methods of analysis

3.1.2.1 Analytical method for the formulation

Not relevant for extension of authorisation according article 51.

3.1.2.2 Analytical methods for residues

Further data for this application are not necessary.

3.1.3 Mammalian Toxicology

For the leafy cabbages and vegetable for seed production (field and greenhouse) uses, the exposure assessment for operators, residents, bystanders and workers are covered by the previous assessment at 1.2 L/ha and 0.6 L/ha.

For the fresh herbs use (0.6 L/ha), an updated risk assessment was submitted by the applicant and the exposure was below the AOEL of the active substance as detailed below:

Endpoints used in risk assessment

Active substance	**Mandipropamid**
AOEL systemic	0.17 mg/kg bw per day
AAOEL	-
Oral absorption	70 %
Vapour pressure	100 %
Reference	EFSA Journal 2012;10(11):2935
Dermal absorption values	Concentrate : 0.13 % Dilution: 1.85 %

3.1.3.1 Operator exposure

Considering the proposed use (fresh herbs), the operator systemic exposure was estimated using the EFSA model[10]:

[10] AOEM – Agricultural Operator Exposure Model (EFSA Journal 2022;20(1):7032)

Model data		Mandipropamid
	Level of PPE	**% AOEL**
Application : Fresh herbs (Low vegetables) Tractor / *down spraying* outdoor		
Application rate		0.15 kg a.s./ha
Spray application (AOEM; 75th percentile) Body weight: 60 kg	Work wear (arms, body and legs covered) M/L and A	0.7

According to the exposure assessment using the EFSA model, the operator exposure to REVUS (A12946B) is below the AOEL value of Mandipropamid, with a working coverall during mixing/loading and application.

For details of personal protective equipment for operators, refer to the Decision in Appendix 1.

3.1.3.2 Worker exposure

Workers may have to enter into treated areas after treatment for crop reaching and picking activities. Therefore, the estimation of worker exposure was calculated according to EFSA model.

Model data		Mandipropamid
	Level of PPE	**% AOEL**
Use: Fresh herbs (Low vegetables) Activity: Reaching, picking Outdoor Work rate: 8 hours/day Number of applications : 4 Interval between treatments: 7 days		
DT50:		30 days
DFR:		3 µg/cm^2/kg a.s./ha
Application rate (kg as/ha)		0.15 kg a.s./ha
Body weight: 60 kg	Work wear (arms, body and legs covered) + gloves TC: 580 cm^2/person/h	1.2

According to the exposure assessment using the EFSA model, the worker exposure to REVUS (A12946B) is below the AOEL value of Mandipropamid, with a working coverall and gloves.

For details of personal protective equipment for workers, refer to the Decision in Appendix 1.

3.1.3.3 Bystander exposure

Only the resident exposure is provided since, according to EFSA Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (**EFSA Journal 2022;20(1):7032**):
"*When an acute risk assessment is not triggered (i.e. for PPPs containing active substances that are not acutely toxic, and for which the setting of an AAOEL was not necessary), no bystander risk assessment is required. Exposure in this case will be determined by average exposure over a longer duration, and higher exposures on one day will tend to be offset by lower exposures on other days. Therefore, exposure assessment for residents also covers bystander exposure*".

3.1.3.4 Resident exposure

Resident exposure was assessed according to EFSA model.

Model data		**Mandipropamid**
		% AOEL
Use: Fresh herbs (Low vegetables) Scenario: Buffer zone: 2-3 (m) Drift reduction technology: no Number of applications : 4 Interval between treatments: 7 days		
DT_{50}		30 days
DFR		3 µg/cm^2/kg a.s./ha
Resident (children) Body weight: 10 kg	Drift (75th perc.)	0.2
	Vapour (75th perc.)	0.5
	Deposits (75th perc.)	0.2
	Re-entry (75th perc.)	0.9
	Sum (mean)	1.5
Resident (adults) Body weight: 60 kg	Drift (75th perc.)	0.05
	Vapour (75th perc.)	0.2
	Deposits (75th perc.)	0.04
	Re-entry (75th perc.)	0.5
	Sum (mean)	0.6

According to the exposure assessment performed by the EFSA model, the resident exposure to REVUS (A12946B) is below the AOEL value of Mandipropamid.

3.1.3.5 Combined exposure

Not relevant. The product contains only one active substance.

3.1.4 Residues and Consumer Exposure

The residue behaviour of the active substance mandipropamid has been evaluated within the EU review process. Information about metabolism is sufficient to evaluate the intended uses in leafy cabbages, fresh herbs and vegetables for seed production.

3.1.4.1 Leafy cabbages

Four mandipropamid residues trials were carried out on leafy crops (two on kales and two on Pak-Choi) in 2018 in France to support this dossier. The GAP in the four residues trials was the same as the GAP claimed is this dossier: 2 applications at 150 g mandipropamid/ha, PHI 14 days. Residue analysis report is provided in Appendix 2G.1.

Summary of global information:

Comparative trials (between formulations, with and adjuvant/safener/synergist)	No	
Number of applications	2 applications with 9-10 days interval	
Dose mandipropamid (g as/ha)	Nominal:150 g/ha	Effective: 149-156 g/ha
Mode of application	Foliar application	
PHI (days) and/or growth stage (BBCH)	Application stage: min.BBCH14-max BBCH 49 Samples harvested at 7, 14 and 21d	
Analytical method (Code +Type)	GRM001.7A- LC-MS/MS	
LoQ (mg/kg)	0.01	

Summary of the study

N° Trial		S18-03418-01	S18-03418-02	S18-03418-03	S18-03418-04
North/South/Indoor		North	North	North	North
Matrix		Kale	Kale	Pak-Choi	Pak-Choi
Decline (D)/Harvest (H) trial?		D	D	D	D
Formulation		SC	SC	SC	SC
Equivalence between formulations		Y	Y	Y	Y
Accordance with intended GAP		Y	Y	Y	Y
Correct sampling		Y	Y	Y	Y
Samples frozen within 24h		Y	Y	Y	Y
Max storage period (in days)	Sample	19	33	64	53
	Extract(1)	2	6	1	1
Storage T°<-18°C		Y	Y	Y	Y
Validated analytical method		N	N	N	N
Negative controls		Y	Y	Y	Y
Considered trial		**Y**	**Y**	**Y(3)**	

Remarks	(1): Procedural recoveries were performed concurrently. (2): Analytical method not validated (For accuracy, reduced sample is not acceptable as the method GRM001.7A is not independently validated and as the test facility of the analytical phases between the report of residue trials and the report of the method in the dossier 2016-0197 is different) (3): For trials S18-03418-03 and S18-03418-04, the sites are too close (only a distance of 1.3 km between them) to be considered as independent trials.

The table below presents the levels of residues observed in those trials.

Report No. Trial No. Location / Region) / Country Year	Commodity/ Variety	Date of 1.Sowing or planting 2.Flowering 3. Harvest	Method of Treatment	Application rate per treatment			Dates of treatment or no. of treatments and last date	Growth stage at last treatment or date	Portion analyzed	Residues	PHI (days)	Details on trial
				L PR/ha	Water (L/ha)	g a.s./ha				Mandipropamid (mg/kg)		
S18-03418-01 Villejuif / Essonne / France 2018	Kale Reflex	1. 15.07.2018 2. - 3. 02.11.2018 09.11.2018 16.11.2018	Foliar spray	0.59 0.64	198 214	149 161	16.10.2018 26.10.2018	BBCH 47 BBCH 48	Leaves Leaves Leaves Leaves	1.2 1.3 <u>1.4</u> 0.44	7 14 NCH <u>14 NCH</u> 21	Analytical method: GRM001.7A (LC-MS/MS, LOQ = 0.01 mg/kg)
S18-03418-02 Dampierre en Burly, / Loiret / France 2018	Kale Winterbor F1	1. 20.07.2018 2. - 3. 19.10.2018 26.10.2018 02.11.2018	Foliar spray	0.65 0.60	215 201	1561 151	02.10.2018 12.10.2018	BBCH 47 BBCH 47	Leaves Leaves Leaves	1.4 <u>1.1</u> 0.76	7 <u>14 NCH</u> 21	Analytical method: GRM001.7A (LC-MS/MS, LOQ = 0.01 mg/kg)
S18-03418-03 Innenheim / Bas-Rhin / France 2018	Pak-Choi Pacifiko F1	1. 25.07.2018 2. - 3. 18.09.2018 26.09.2018 04.10.2018	Foliar spray	0.62 0.60	311 301	156 151	03.09.2018 12.09.2018	BBCH 19-41 BBCH 45	Leaves Leaves Leaves	0.069 <u>0.011</u> < 0.01	7 <u>14 NCH</u> 21	Analytical method: GRM001.7A (LC-MS/MS, LOQ = 0.01 mg/kg) Not retain as conducted as same location than S-18-03418-03
S18-03418-04 Innenheim / Bas-Rhin / France 2018	Pak-Choi Bilko F1	1. 01.08.2018 2. - 3. 12.10.2018 19.10.2018 26.10.2018	Foliar spray	0.62 0.61	312 303	156 151	26.09.2018 05.10.2018	BBCH 41 BBCH 43	Leaves Leaves Leaves	0.028 <u>0.025</u> < 0.01	7 <u>14 NCH</u> 21	Analytical method: GRM001.7A (LC-MS/MS, LOQ = 0.01 mg/kg)

The table below summarises the mandipropamid residue levels on leafy cabbages.

Commodity	Source	Region zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg)	HR (mg/kg) (a)	STMR (mg/kg) (b)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg)	MRL compliance
Leafy cabbages (kale, Pak-Choi)	New trials	NEU	Trials GAP: 2 x 150 g a.s./ha PHI 14 days ~~0.011~~, 0.025, 1.1, 1.4	1.4	0.63	3.13	25	Yes

(a): Highest residue.
(b): Supervised trials median residue.

According SANTE_2019_12752, four residue trials minimum are needed per zone for minor crop. Leafy cabbages are minors crops which mainly grow in the North zone.

Analytical method used in the submitted residue trials are not validated and has to be regarded only as supportive data. Nevertheless the inforce MRL is based on an import tolerance which lead to an MRL 5 more higher than the national intended use. Therefore even though there is still one trial missing and data on leafy brassica have to be regarded as not fully validated, no MRL exceedance is expected for application on REVUS (A12946B) on leafy brassica at the intended GAP.

The available residue information is sufficient to perform an adequate assessment.

The use is acceptable and residues that are expected from the intended use of REVUS (A12946B) on leafy cabbages will not exceed the MRL at ~~25~~ 50 mg/kg voted for Mandipropamid (Reg. (EU) N° ~~2020/1565~~ 2024/344).

3.1.4.2 Fresh herbs

REVUS (A12946B) has been registered in France on fresh herbs at 2 applications at 150 g mandipropamid/ha (BBCH 11-49) since 2018. This dossier supports the increase of number of applications per year: 2 applications at 150 g mandipropamid/ha (BBCH 11-49) per crop cycle and maximum 4 applications per year. As Mandipropamid is not a systemic active ingredient, regarding residues and consumer risk, the crop cycles are independent of each other.

We consider, regarding residues and consumer risk, that there is no change compare to the current registered GAP for fresh herbs. The registered GAP and the supported GAP in this dossier are compliant with the current EU mandipropamid MRLs of 30 mg/kg for fresh herbs (Reg EU N° 2020/1565)

For information we present, the fresh herbs data extracted from final RR of REVUS (A12946B) (2013-0182 & 2014-0329) evaluated by France in 2018.

Extract from final RR REVUS® (2013-0182 & 2014-0329) 2018
Comparison of intended and critical EU GAPs

Crop	Type of GAP	Number of applications	Application rate per treatment (kg as/ha)	Interval between application	Growth stage at last application	PHI (days)
Parsley, fresh herbs	EU (DAR)	-	-	-	-	-
	Intended FR	2	0.150	7	BBCH 11-49	7
	Intended IT	2	0.150	7	BBCH 11-49	7

The EU critical GAP for mandipropamid on herbs is identical to the one for lettuce and other salad plants. Therefore, according to guidance document **7525/VI/95 – rev.9 24/03/2011**, residue data for open-leaf/open-head lettuce can be extrapolated to herbs.

The guidance document 7525/VI/95 – rev.9 24/03/2011 is currently replace by the guidance document **SANTE_2019_12752**. However, in the current version, the rule for extrapolation from residue data for open-leaf/open-head lettuce to fresh herbs is still valid.

Summary of monograph and new data supporting the intended use on fresh herbs and conformity to existing MRL

Commodity	Source	EU zone	Evaluation GAP Residue levels (mg/kg)	STMR (mg/kg)	HR (mg/kg)	Rber (mg/kg)	Rmax (mg/kg)	OECD calculator MRL (mg/kg)	In force EU MRL (mg/kg)	MRL compliance resulting / in force
Lettuce → fresh herbs	Monograph	North (8)	Trials GAP: 2 x 0.150 kg as/ha, PHI 7d 0.11, 0.27, 0.43, 0.47, 0.50, 1.20, 1.30, 1.60	0.485	1.6	0.760	2.485	3 (2.931)	~~10~~ current MRL 30 mg/kg (Reg EU n°2024/344~~2020/1565~~)	Yes
		South (8)	Trials GAP: 2 x 0.150 kg as/ha, PHI 7d 0.10, 0.66, 0.83, 0.96, 0.98, 1.30, 1.90, 2.20	0.970	2.2	3.500	3.268	4 (3.829)		

Herb is a minor crop in both Northern and Southern EU. 4 SEU trials are required to support the intended use in southern Europe. In France, 4 SEU or 4 NEU trials are required.

A total of 6 SEU trials are available on lettuce (open leaf varieties). According to document SANCO 7525/VI/95-rev.9, Appendix D, "Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs", extrapolation is possible from lettuce (open leaf) to herbs.

The guidance document 7525/VI/95 – rev.9 24/03/2011 is currently replace by the guidance document **SANTE_2019_12752**. However, in the current version, the rule for extrapolation from residue data for open-leaf/open-head lettuce to fresh herbs is still valid.

According to the available data, MRL (~~10 mg/kg~~, current MRL according Reg EU n°2024/344~~2020/1565:~~ 30 mg/kg) is not expected to be exceeded. The proposed cGAP on herbs will not result in MRL exceedance and is then considered as fully supported in the southern part of Europe and in France.

3.1.4.3 Vegetables for seeds production

No EU MRL are required for vegetables for seed production.

The use concerned by this application is only for vegetable seeds production. It is not for human consumption. Therefore, the use is not concerned by residues in food commodities. Mandipropamid is not accumulating.

3.1.4.4 Consumer exposure

The proposed uses of mandipropamid do not represent unacceptable acute and chronic risks for the consumer.

No data is available on the possible transfer of residues of mandipropamid in animal commodities. Therefore the following mitigation measure is proposed: do not feed animal with kale treated with REVUS (A12946B).

3.1.5 Environmental fate and behaviour

According to previous risk assessments performed by Anses, no unacceptable risk for groundwater is expected. Similar mitigation measures as defined for previous risk assessment apply.

3.1.6 Ecotoxicology

According to previous risk assessments performed by Anses, no unacceptable risk for terrestrial and aquatic non-target organisms is expected. Similar mitigation measures as defined for previous risk assessment apply.

3.1.7 Efficacy

According to Article 51 of Regulation (EC) No 1107/2009, the efficacy assessment and the absence of any phytotoxicity risk on the crop is not necessary.

3.2 Conclusions arising from French assessment

Taking into account the above assessment, an authorisation can be granted as proposed in Appendix 1 – Copy of the product Decision.

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

No further information is required.

Appendix 1 – Copy of the French Decision

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Décision relative à une demande d'extension d'usages d'un produit phytopharmaceutique

Vu les dispositions du règlement (CE) n° 1107/2009 du 21 octobre 2009 et de ses textes d'application,

Vu le code rural et de la pêche maritime, notamment le chapitre III du titre V du livre II des parties législative et règlementaire,

Vu la demande d'extension d'usages mineurs du produit phytopharmaceutique ***REVUS***

de la société *SYNGENTA FRANCE S.A.*

enregistrée sous le *n° 2022-0240*

Vu les conclusions de l'évaluation de l'Anses du 24 juin 2024,

L'autorisation de mise sur le marché du produit référencé ci-après **est étendue** aux usages décrits dans la présente décision.

La présente décision s'applique sans préjudice des autres dispositions applicables.

Avertissement :

Le non-respect des conditions décrites ci-dessous peut entraîner le retrait ou la modification de l'autorisation ainsi que toute action incluant des poursuites judiciaires.

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Informations générales sur le produit	
Noms du produit	REVUS MDI 3 MDI 2 MDI 4 MDI 1 EVAGIO
Type de produit	Produit de référence
Titulaire	SYNGENTA FRANCE S.A. 1228 Chemin de l'Hobit 31790 SAINT-SAUVEUR France
Formulation	Suspension concentrée (SC)
Contenant	250 g/L - mandipropamide
Numéro d'intrant	2060345
Numéro d'AMM	2080098
Fonction	Fongicide
Gamme d'usage	Professionnel

L'échéance de validité de la présente décision correspond à celle de l'autorisation du produit.

La présente décision peut être retirée ou modifiée si des éléments le justifient.

A Maisons-Alfort, le 09/07/2024

DocuSigned by:
Charlotte Grastilleur
AE261A85A42454...

Directrice générale déléguée
en charge du pôle produits réglementés
Agence nationale de sécurité sanitaire de
l'alimentation, de l'environnement et du travail (ANSES)

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ANNEXE : Modalités d'autorisation du produit

Liste des nouveaux usages et des usages modifiés autorisés
En l'absence de mention spécifique, les usages autorisés correspondent à une utilisation en plein champ.
En l'absence de restriction, les usages sont autorisés sur l'ensemble des cultures de la portée de l'usage.

Usages	Dose maximale d'emploi	Nombre maximum d'applications	Stade d'application BBCH	Délai avant récolte (jours)	Zone Non Traitée aquatique (mètres)	Zone Non Traitée arthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Culture attractive en floraison (arrêté du 20/11/2021) (1)
00516049 Choux feuillus*Trt Part.Aer.*Mildiou(s)	**0,6 L/ha**	**2/an**	entre les stades BBCH 16 et BBCH 49	14	5	-	-	-
	Intervalle minimum entre les applications : 10 jours. Usage autorisé dans le cadre de l'article 51 du règlement (CE) n° 1107/2009.							
19153202 Fines Herbes*Trt Part.Aer.*Mildiou(s)	**0,6 L/ha**	**4/an**	entre les stades BBCH 11 et BBCH 49	7	5	-	-	-
	2 applications maximum par coupe ou par cycle cultural. Intervalle minimum entre les applications : 7 jours. Augmentation du nombre d'application autorisée dans le cadre de l'article 51 du règlement (CE) n° 1107/2009.							
10993213 Porte graine - PPAMC, Florales et Potagères*Trt Part.Aer.*Mildiou et rouille blanche	**0,6 L/ha**	**2/an**	entre les stades BBCH 12 et BBCH 79	Non applicable	5	-	-	-
	Intervalle minimum entre les applications : 10 jours. Usage autorisé dans le cadre de l'article 51 du règlement (CE) n° 1107/2009.							

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Liste des nouveaux usages et des usages modifiés autorisés
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Usages	Dose maximale d'emploi	Nombre maximum d'applications	Stade d'application BBCH	Délai avant récolte (jours)	Zone Non Traitée aquatique (mètres)	Zone Non Traitée arthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Culture attractive en floraison (arrêté du 20/11/2021) (1)
10993213 Porte graine - PPAMC, Florales et Potagères*Trt Part.Aer.*Mildiou et rouille blanche	**0,6 L/ha**	**1/an**	entre les stades BBCH 12 et BBCH 79	Non applicable	-	-	-	-
	Uniquement autorisé sous abri. Usage autorisé dans le cadre de l'article 51 du règlement (CE) n° 1107/2009.							

(1) : En attente du renouvellement de l'AMM

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Conditions d'emploi du produit

Protection de l'opérateur et du travailleur

Des informations générales relatives aux bonnes pratiques de protection pourront être mises à disposition de l'utilisateur :

- l'utilisation d'un matériel adapté et entretenu et la mise en œuvre de protections collectives constituent la première mesure de prévention contre les risques professionnels, avant la mise en place de protections individuelles ;
- le port de combinaison de travail dédiée ou d'EPI doit être associé à des réflexes d'hygiène (ex : lavage des mains, douche en fin de traitement) et à un comportement rigoureux (ex : procédure d'habillage/déshabillage) ;
- les modalités de nettoyage et de stockage des combinaisons de travail et des EPI réutilisables doivent être conformes à leur notice d'utilisation.

Pour l'opérateur, porter

Dans le cadre d'une application effectuée à l'aide d'un pulvérisateur à rampe

• pendant le mélange/chargement

- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A) ;
- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 ;
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus l'EPI vestimentaire précité ;

• pendant l'application - Pulvérisation vers le bas

Si application avec tracteur avec cabine

- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 ;
- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN ISO 374-2 (types A, B ou C) à usage unique, dans le cas d'une intervention sur le matériel pendant la phase de pulvérisation. Dans ce cas, les gants ne doivent être portés qu'à l'extérieur de la cabine et doivent être stockés après utilisation à l'extérieur de la cabine ;

Si application avec tracteur sans cabine

- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 ;
- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN ISO 374-2 (types A, B ou C) à usage unique, dans le cas d'une intervention sur le matériel pendant la phase de pulvérisation ;

• pendant le nettoyage du matériel de pulvérisation

- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A) ;
- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 ;
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus l'EPI vestimentaire précité.

Pour le travailleur, porter

- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 et, en cas de contact avec la culture traitée, des gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A).

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Délai de rentrée en application de l'arrêté du 4 mai 2017 :

- 6 heures pour les usages en plein champ et 8 heures pour les applications en milieu fermé.

Protection des personnes présentes et des résidents (au sens du règlement (UE) N°284/2013)

Respecter une distance d'au moins 3 mètres entre la rampe de pulvérisation et :
- l'espace fréquenté par les personnes présentes lors du traitement ;
- l'espace susceptible d'être fréquenté par des résidents.

Respect des limites maximales de résidus (LMR)

- Pour chaque usage figurant dans la liste des usages autorisés, les conditions d'utilisation du produit permettent de respecter les limites maximales de résidus.
- Ne pas utiliser les sous-produits des cultures porte-graines traitées en alimentation humaine ou animale.
- Ne pas utiliser les choux verts en alimentation animale.

Protection de l'environnement (milieux, faune et flore)

Protection de la faune

- SPe 3 : Pour protéger les organismes aquatiques, respecter une zone non traitée de 5 mètres par rapport aux points d'eau.

Recommandations relatives à l'étiquette du produit

Il est recommandé de faire figurer l'information suivante sur l'étiquette :

- Pour les usages mineurs dont l'autorisation a été accordée dans le cadre de l'article 51 du règlement (CE) n° 1107/2009, l'attention de l'utilisateur est attirée sur les risques éventuels de phytotoxicité ou de manque d'efficacité. Avant tout emploi du produit, il est recommandé à l'utilisateur de s'assurer de son efficacité ou de l'absence de risques éventuels de phytotoxicité sur la culture.

Les autres modalités d'autorisation du produit restent inchangées.

Appendix 2 – Copy of the draft product label as proposed by the applicant

REVUS® (AMM n°2080098)
Extension d'usage sur choux feuillus, porte graine - PPAMC, florales et potagères et Chicorées - Production de chicons
Projet d'étiquette

Les tableaux ci-dessous viennent se substituer aux tableaux de l'étiquette existante.

Etiquette DOS ou Pavé réglementaire :

CULTURES AUTORISEES, UNIQUEMENT	CIBLES, DOSES AUTORISEES et DAR
Pomme de terre, Tomate, Aubergine, Melon, Pastèque, Potiron, Potimarron, Laitue, Scarole, Frisée, Mâche, Roquette, Epinard, Feuille de bettes, Pourpier, Choux de Bruxelles, Chou-fleur, Brocoli, Choux feuillus, Radis et Pois écossés frais, Chicorée production de chicons, Fines herbes, Houblon, Arbustes, Cultures florales et plantes vertes, Rosier, Porte graine - PPAMC, florales et potagères	Voir tableau des usages à l'intérieur du livret

Etiquette Livret (page 4 du PDF joint) :

En traitement des parties aériennes

CULTURES AUTORISEES, UNIQUEMENT :	CIBLES	DOSES AUTORISEES	NOMBRES MAX. D'APPLICATIONS	INTERVALLES MINIMUM ENTRE APPLICATIONS	STADES D'APPLICATION	DELAI AVANT RECOLTE	ZNT AQUATIQUE(1)
Cultures légumières							
Pomme de terre	Mildiou(s)	0,6 L/ha	4	7 jours	BBCH 31-91	21 jours	5 mètres
Tomate Aubergine *Plein champ et sous abri*			4	7 jours	BBCH 21-89 en plein champ BBCH 11-89 sous abri	3 jours	
Melon Pastèque Potiron Potimarron *Plein champ et sous abri*			4	7 jours	BBCH 11-89	3 jours	
Laitue Scarole Frisée Mâche Roquette *Plein champ et sous abri*			2(2) (plein champ) 1 (sous abri)	7 jours	BBCH 11-49	7 jours	
Chou-fleur(3), brocoli(3)			2	10 jours	BBCH 16-49	14 jours	

CULTURES AUTORISEES, UNIQUEMENT :	CIBLES	DOSES AUTORISEES	NOMBRES MAX. D'APPLICATIONS	INTERVALLES MINIMUM ENTRE APPLICATIONS	STADES D'APPLICATION	DELAI AVANT RECOLTE	ZNT AQUATIQUE(1)
Choux de Bruxelles(3)			2	10 jours	BBCH 16-49	14 jours	
Choux feuillus			2	10 jours	BBCH 16-49	14 jours	
Epinard(3), feuille de bettes(3), pourpier(3)			2	7 jours	BBCH 14-45	7 jours	
Radis(3)			2/culture avec 6 applications maximum par an et par parcelle	7 jours	BBCH 12-49	7 jours	
Pois écossés frais(3)			2	14 jours	BBCH 35-59	14 jours	
Chicorée - production de chicons Traitements des plants, en chambre de forçage		0,5 mL/m²	1	-	BBCH 00	21 jours	-
Fines herbes *Plein champ et sous abri*		0,6 L/ha	4 app/culture et pas plus de 2 app/coupe (ou cycle) (plein champ) 1 (sous abri)	7 jours	BBCH 11-49	7 jours	5 mètres
Cultures porte-graines							
Porte-graines – PPAMC(5), florales et potagères,	Mildiou(s), rouille blanche	0,6 L/ha	2(2) (plein champ) 1 (sous abri)	10 jours	BBCH 12-79	-	5 mètres
Cultures ornementales							
Arbustes	Mildiou(s)	0,6 L/ha	4	7 jours	-	-	5 mètres
Cultures florales et plantes vertes *Plein champ et sous abri*			4	7 jours	-	-	
Rosier *Plein champ et sous abri*			4	7 jours	-	-	
Autres cultures							
Houblon(4)	Mildiou(s)	1,6 L/ha	2	10 jours	BBCH 31-87	14 jours	5 mètres

(1) ZNT aquatique : Zone Non Traitée par rapport à un point d'eau temporaire ou permanent.

(2) Nombre d'applications maximal par cycle et par an

(3) Pour ces cultures, respecter une distance d'au moins 3 mètres entre la rampe de pulvérisation et l'espace fréquenté par les personnes présentes lors du traitement ou l'espace susceptible d'être fréquenté par des résidents.

(4) Usage mineur autorisé dans le cadre de l'article 51 du règlement (CE) n°1107/2009.

(5) Plantes à Parfum Aromatiques Médicinales et Condimentaires

Appendix 3 – Letter(s) of Access

Not applicable