REGISTRATION REPORT

Part A

Risk Management

Product code: FLP+IPV WG 65.3

Product name: SIRBEL UD

Active substances:

iprovalicarb, 90 g/kg

folpet, 563 g/kg

COUNTRY: FRANCE

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(Authorisation renewal according to Art. 43)

Applicant: BAYER S.A.S.

Date: 25/10/2022

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Décision relative à une demande de renouvellement de l'autorisation de mise sur le marché d'un produit phytopharmaceutique et aux demandes associées

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 les demandes de renouvellement de l'autorisation de mise sur le marché, suite au renouvellement de l'approbation de la substance active iprovalicarbe, d'ajout d'emballage, de modification des informations et les données fournies en réponse aux demandes de post-autorisation, du produit phytopharmaceutique ***SIRBEL UD***

de la société *BAYER SAS*

enregistrées sous les *n°2012-1506, 2016-2206, 2017-0619, 2017-2471 et 2021-3996*

Vu les conclusions de l'évaluation de l'Anses du 1er juillet 2021 et du 26 août 2022,

Considérant qu'un risque d'effet nocif pour les travailleurs, lié à l'utilisation du produit, ne peut être exclu,

Considérant qu'en conséquence, les exigences mentionnées à l'article 29 du règlement (CE) n°1107/2009 ne sont plus remplies,

L'autorisation de mise sur le marché du produit phytopharmaceutique désigné ci-après **n'est pas renouvelée** en France.

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Informations générales sur le produit	
Noms du produit	SIRBEL UD ODENA UD
Type de produit	Produit de référence
Titulaire	BAYER SAS CS 90106 16 rue Jean-Marie Leclair 69266 LYON CEDEX 09 France
Formulation	Granulé dispersable (WG)
Contenant	563 g/kg - folpet 90 g/kg - iprovalicarbe
Numéro d'intrant	2010552
Numéro d'AMM	2010552
Fonction	Fongicide
Gamme d'usage	Professionnel

A Maisons-Alfort, le 25/10/2022

DocuSigned by:
Charlotte Grastilleur
AE281A865A42454...

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

SIRBEL UD
AMM n°2010552

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ANNEXE : Conditions de mise sur le marché

Liste des usages retirés

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)	Délai accordé pour la vente et la distribution	Délai accordé pour le stockage et l'utilisation des stocks
12703203 Vigne*Trt Part.Aer.* Mildiou(s)	1,3 kg/ha	2/an	28	6 mois à compter de la présente décision	18 mois à compter de la présente décision
Motivation du retrait : L'usage est retiré car les données disponibles ne permettent pas d'exclure un risque d'effet nocif pour les travailleurs.					

SIRBEL UD
AMM n°2010552

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zRMS NOTE

In order to comply with the provisions of Regulation (EC) No 1107/2009 (Commission Implementing Regulation (EU) 2015/2033) and according to Art. 43 of Regulation (EC) No 1107/2009, and in accordance with the guidance document SANCO/2010/13170, the outcome of the risk assessment for the re-registration of plant protection product only applies to the active substance iprovalicarb following its renewal of approval. For folpet and fosetyl-Al, provisions of the initial authorization remain.

PART A – Risk Management

The company BAYER S.A.S. has requested renewal of the marketing authorisation in France for the product SIRBEL UD (formulation code: FLP+IPV WG 65.3; marketing authorisation n° 2010552), containing 90 g/kg iprovalicarb and 563 g/kg folpet, for use as a fungicide.

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 1-7 and Part C, and where appropriate the addenda for France. The information, data and assessments provided in Registration Report, Part B include assessment of further data or information as required at national registration by the EU peer review. It also includes assessment of data and information relating to SIRBEL UD (FLP+IPV WG 65.3) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of SIRBEL UD (FLP+IPV WG 65.3) have been made using endpoints agreed in the EU peer review(s) of both iprovalicarb and folpet.

This document describes the specific conditions of use and labelling required for France for the registration of SIRBEL UD (FLP+IPV WG 65.3).

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

The present registration report concerns the evaluation of BAYER S.A.S's application to market SIRBEL UD (FLP+IPV WG 65.3) in France as a fungicide (product uses described under point 2.3). France acted as a zonal Rapporteur Member State (zRMS) for this request and assessed the application submitted for the renewal of authorisation after approval of iprovalicarb of this product in France and in other MSs of the Southern zone.

1.2 Active substance approval

Iprovalicarb

Commission Implementing Regulation (EU) 2016/147 of 4 February 2016 renewing the approval of the active substance iprovalicarb 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 Implementing Regulation (EU) No 540/2011.
Specific provisions of Regulation (EU) 2016/147 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 iprovalicarb, and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the protection of groundwater from the relevant soil metabolite PMPA (*) when the active substance is applied in regions with low clay containing soil types, — the safety of operators and workers, — the protection of aquatic organisms in the case of formulated products containing other active substances. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit to the Commission, the Member States and the Authority, confirmatory information as regards the genotoxic potential of soil metabolite PMPA. This information shall be submitted by 30 September 2016. (*) *p*-methyl-phenethylamine

An EFSA conclusion is available (EFSA Journal 2015; 13(4):4060) plus the Outcome of the consultation with Member States, the applicant and EFSA on the pesticide risk assessment for iprovalicarb in light of confirmatory data (EFSA Supporting publication 2017:EN-1216). A Review Report is available (SANCO/11968/2015 Rev 3, 20 July 2018).

Folpet

Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances.
Specific provisions of Regulation (EU) No 540/2011 were as follows : PART A Only uses as fungicide can be authorised. PART B In assessing applications to authorise plant protection products containing folpet for uses other than winter wheat Member States shall pay particular attention to the criteria in Article 4(3) of Regulation (EC) No 1107/2009, and shall ensure that any necessary data and information is provided before such an authorisation is granted. 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 folpet, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 29 September 2006 shall be taken into account. In this overall assessment Member States must pay particular attention to: — operators and workers safety. Authorised conditions of use must prescribe the application of adequate personal protective equipment; — the dietary exposure of consumers in view of future revisions of Maximum Residue Levels; — the protection of birds, mammals, aquatic and soil organisms. Conditions of authorisation should include risk mitigation measures. The Member States concerned shall request the submission of further studies to confirm the risk assessment for birds, mammals and earthworms. They shall ensure that the notifiers at whose request folpet has been included in this Annex provide such studies to the Commission within two years from the approval.
An EFSA conclusion is available (EFSA Scientific Report (2009) 297, 1-80). A Review Report is available (SANCO/10032/2006 rev 5, 11 July 2008).

1.3 Regulatory approach

The present applications (2016-2206, 2017-0619, 2017-2471, 2012-1506) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses)[1] in the context of the zonal procedure for all Member States of the Southern zone, taking into account the worst-case uses ("risk envelope approach")[2] – the highest application rates over the Southern Zone. Additional data concerning the worker's risk have been submitted and evaluated at national level (application 2021-3996). When risk mitigation measures were necessary, they are adapted to the situation in France. According to the French law and procedures, specific conditions of use are set out in the Decision letter.

The French Order of 4 May 2017[3] provides that:

- unless formally stated in the product authorisation, the pre harvest interval (PHI) is at least three days;

[1] French Food Safety Agency, Afssa, before 1 July 2010

[2] SANCO document "risk envelope approach", European Commission (14 March 2011). Guidance document on the preparation and submission of dossiers for plant protection products according to the "risk envelope approach"; SANCO/11244/2011 rev. 5

[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 https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGRG1632554A/jo/texte

- unless formally stated in the product authorisation, the minimum buffer zone alongside a water body is five metres;
- unless formally stated in the product authorisation, the minimum re-entry period is six hours for field uses and eight 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 current document (RR) based on Anses's assessment of the application submitted for this product is in compliance with Regulation (EC) No 1107/2009[4], implementing regulations, and French regulations.

The data taken into account are those deemed to be valid either at European Union level or at zonal/national level. This part A of the RR 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) No 546/2011[5], and are expressed as "acceptable" or "not acceptable"/"not finalised" in accordance with those criteria.

Moreover, the French Order of 12 April 2021[6] 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[7] is to supply "minor" crops with registered plant protection products.

Finally, the French Order of 20 November 2021[8] on the protection of bees and other pollinating insects and the preservation of pollination services when using plant protection products provides that unless otherwise stated in the product authorisation, use on attractive culture[9] when in flower and on foraging area is forbidden. Specific conditions of application on flowering crops should be respected. As consequences specific Spe 8 may include reference to this order.
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

Where protection for data is being claimed for information supporting registration of SIRBEL UD (FLP+IPV WG 65.3), it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

1.5 Letter(s) of Access

The applicant has provided a letter of access for folpet data.

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[4] 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

[5] 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

[6] http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGRG1407093A/jo

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

[8] https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000044346734

[9] List of culture considered as unattractive to bees and other pollinators insects defined by French Agricultural ministry and published in Bulletin Officiel du ministère chargé de l'agriculture.

2 DETAILS OF THE AUTHORISATION

2.1 Product identity

Product name (code)	SIRBEL UD (FLP+IPV WG 65.3) Second trade name: ODENA UD.
Authorisation number	2010552
Function	Fungicide
Applicant	BAYER S.A.S.
Composition	90 g/kg iprovalicarb 563 g/kg folpet
Formulation type (code)	Water-dispersible granule (WG)
Packaging	Al composite foil–paper/LDPE/Al/LDPE cardboard (1.5 kg) Al composite foil–paper/LDPE/Al/LDPE bag (6 kg, 10 kg, 12 kg, 15 kg) LDPE/PA/Al/LDPE cardboard (1.5 kg) LDPE/PA/Al/LDPE bag (6 kg, 10 kg, 12 kg, 15 kg)

2.2 Classification and labelling

2.2.1 Classification and labelling in accordance with Regulation (EC) No 1272/2008

Physical hazards	-	
Health hazards	Serious eye damage, Hazard Category 1 Sensitisation — Skin, Hazard Category 1 Carcinogenicity, Hazard Category 2 Specific Target Organ Toxicity – Repeated Exposure, Hazard Category 2	
Environmental hazards	Hazardous to the aquatic environment — Acute Hazard, Category 1	
Hazard pictograms		
Signal word	Danger	
Hazard statements	H318	Causes serious eye damage.
	H317	May cause an allergic skin reaction.
	H351	Suspected of causing cancer.
	H373	May cause damage to organs (lung).
	H400	Very toxic to aquatic life.
Precautionary statements –	***For the P phrases, refer to the extant legislation***	

Supplementary information (in accordance with Article 25 of Regulation (EC) No 1272/2008)	-	Contains 1,2-benzisothiazol-3(2H)-one. May produce an allergic reaction.

See Part C for justifications of the classification and labelling proposals.

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

N/A : marketing authorisation withdrawn.

2.2.3 Other phrases linked to the preparation

N/A : marketing authorisation withdrawn

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 March 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: 2022-10-25

PPP (product name/code):	**SIRBEL UD / FLP+IPV WG 65.3**	Formulation type:	**WG** [a, b]
Active substance 1:	iprovalicarb (IPV)	Conc. of as 1:	**90 g/kg** [c]
Active substance 2:	folpet (FLP)	Conc. of as 2:	**563 g/kg** [c]
Applicant:	**BAYER S.A.S.**	Professional use:	☒
Zone(s):	southern [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:** e.g. g safener/synergist per ha [f]
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg product / ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	France	Grape (table)	F	PLASVI	Spray	BBCH 07 - 69	a) 2 b) 2	10 days	a) 1.3 b) 2.6	a) IPV : 117 FLP : 732 b) IPV : 234 FLP : 1464	200 - 400	70	**Not acceptable** (risk for workers)
2	France	Grape (wine)	F	PLASVI	Spray	BBCH 07 - 81	a) 2 b) 2	10 days	a) 1.3 b) 2.6	a) IPV : 117 FLP : 732 b) IPV : 234 FLP : 1464	200 - 400	28	**Not acceptable** (risk for workers)

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

SIRBEL UD (FLP+IPV WG 65.3) is a water-dispersible granule formulation (WG). All studies have been performed in accordance with the current requirements and the results are deemed acceptable. The appearance of the product is that of dark brown solid granules, with a mouldy, slightly, pungent odour. The formulation is not explosive, has no oxidising properties and is not flammable. It has a self-ignition temperature of 305 °C. In aqueous solution (1 %), it has a pH value of 9.2 at room temperature. There is no effect of low and high temperatures on the stability of the formulation, since after 14 days at 54 °C and eight weeks at 40 °C, neither the active substances' content nor the technical properties were changed. The stability data indicate a shelf life of at least two years at ambient temperature when stored in Al composite foil-paper/LDPE/AL/LDPE and LDPE/PA/Al/LDPE commercial packaging.

Its technical characteristics are acceptable for a WG formulation.

The formulation is not classified for the physico-chemical aspect.

3.1.2 Methods of analysis

3.1.2.1 Analytical method for the formulation

Analytical methods for the determination of the active substances in the formulation are available and validated.

Analytical methods for the determination of relevant impurities (toluene, carbon tetrachloride and perchloromethyl mercaptan) in the formulation are available and validated.

3.1.2.2 Analytical methods for residues

Analytical methods are available in the Draft Assessment Report (DAR)/this dossier and validated for the determination of residues of folpet and iprovalicarb in plants (acidic), soil, water (surface and drinking) and air.

Analytical methods for the determination of residues of the active substances in foodstuffs of animal origin are not necessary.

The active substances are neither toxic nor very toxic, hence no analytical method is required for the determination of residues in biological fluids and tissues.

3.1.3 Mammalian Toxicology

Endpoints used in risk assessment

<table>
<tr><td colspan="5">Active substance: folpet (FLP)</td></tr>
<tr><td>ADI</td><td colspan="2">0.1 mg/kg bw/d</td><td colspan="2" rowspan="3">EU (2007)</td></tr>
<tr><td>ARfD</td><td colspan="2">0.2 mg/kg bw</td></tr>
<tr><td>AOEL</td><td colspan="2">0.1 mg/kg bw/d</td></tr>
<tr><td rowspan="5">Dermal absorption</td><td colspan="4">Based on an in vitro human study performed on formulation:</td></tr>
<tr><td rowspan="2"></td><td rowspan="2">Concentrate (tested)
572 g/kg</td><td colspan="2">Diluted formulation (tested)</td></tr>
<tr><td>3.65 g/L</td><td>0.688 g/L</td></tr>
<tr><td>In vitro (human) %</td><td>3</td><td>5</td><td>14</td></tr>
<tr><td></td><td>Concentrate
(used in formulation)
563 g/kg</td><td colspan="2">Spray dilution
(used in formulation)
0.98 g/L (min.)</td></tr>
<tr><td></td><td>Dermal absorption endpoints %</td><td>3 %</td><td colspan="2">14 %</td></tr>
<tr><td>Oral absorption</td><td colspan="2">100 % (> 80 %)</td><td colspan="2"></td></tr>
</table>

<table>
<tr><td colspan="5">Active substance: iprovalicarb (IPV)</td></tr>
<tr><td>ADI</td><td colspan="2">0.015 mg/kg bw/d</td><td colspan="2" rowspan="3">EU (renewal 2016)</td></tr>
<tr><td>ARfD</td><td colspan="2">Not necessary</td></tr>
<tr><td>AOEL</td><td colspan="2">0.015 mg/kg bw/d</td></tr>
<tr><td rowspan="5">Dermal absorption</td><td colspan="4">Based on an in vitro human study performed on formulation:</td></tr>
<tr><td rowspan="2">Concentrate (tested)
90 g/kg</td><td colspan="2">Diluted formulation (tested)</td></tr>
<tr><td>1.2 g/L</td><td>0.07 g/L</td></tr>
<tr><td>In vitro (human) %</td><td>0.3%</td><td>4%</td><td>17%</td></tr>
<tr><td></td><td>Concentrate
(used in formulation)
90 g/kg</td><td colspan="2">Spray dilution
(used in formulation)
0.15 g/L (min.)</td></tr>
<tr><td></td><td>Dermal absorption endpoints %</td><td>0.3%</td><td colspan="2">17%</td></tr>
<tr><td>Oral absorption</td><td colspan="2">100% (91%)</td><td colspan="2"></td></tr>
</table>

3.1.3.1 Acute Toxicity

SIRBEL UD (FLP+IPV WG 65.3) containing 90 g/kg iprovalicarb and 563 g/kg folpet has a low acute oral, inhalational and dermal toxicity. The product is not irritating to the rabbit skin but is irritating to the eye and a skin sensitiser.

The classification proposed in accordance with Regulation (EC) No 1272/2008 is shown in Section 2.2.2.

3.1.3.2 Operator Exposure

Summary of critical use patterns (French GAP):

Crop type	**F/G**[10]	**Equipment** ***Application method***	**Maximum application rate** **kg as /ha**	**Minimum volume water** **(L/ha)**
Grapevines	F	Vehicle-mounted *Upward spraying*	1.3 kg product/ha (732 g FLP/ha 117 g IPV/ha)	200

Considering the proposed uses, operator systemic exposure was estimated using the AOEM model[11]:

Crop	**Equipment**	**PPE and/or working coverall**	**% AOEL FLP**	**% AOEL IPV**
Grapevines	Vehicle-mounted	Working coverall and gloves during mixing/loading and application	26.9	41.0

According to the model calculations, it may be concluded that the risk for the operator using SIRBEL UD (FLP+IPV WG 65.3) is acceptable with a working coverall (90 % protection factor) and gloves during mixing/loading and application.

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

3.1.3.3 Bystander Exposure

[10] Open field or glasshouse
[11] AOEM – Agricultural Operator Exposure Model (EFSA Journal 2014:12 (10):3874)

Consideration of acute exposure should only be made where an AAOEL has been established during an approval, review or renewal evaluation of an active substance, i.e. no acute operator and bystander exposure assessments can be performed with the AOEM model where no AAOEL has been set[12].

Only 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 2014;12(10):3874): "*No bystander risk assessment is required for PPPs that do not have significant acute toxicity or the potential to exert toxic effects after a single exposure. 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

Residential exposure was assessed according to AOEM model incorporating a distance of 10 metres from the spray boom and drift reducing nozzles. Resident exposure is below respective AOEL of folpet and iprovalicarb, both for children and adults:

Model (AOEM) - All pathways (mean)	**% AOEL FLP**	**% AOEL IPV**
Resident (children)	49.6%	48.4%
Resident (adults)	27.0%	24.2%

For folpet, default DFR and DT50 values according to EFSA Journal 2014;12(10):3874 have been used. For iprovalicarb, DFR and DT50 values have been calculated based on data from a DFR study that applicant submitted, and details for these calculations are reported in Vol. 3 Section IIIA 7.7

3.1.3.5 Worker Exposure

For folpet, default DFR and DT50 values according to EFSA Journal 2014;12(10):3874 have been used. For iprovalicarb, DFR and DT50 values have been calculated based on data from a DFR study that applicant submitted, and details for these calculations are reported in Vol. 3 Section IIIA 7.7.

Workers may have to enter treated areas after treatment for grapevines for harvesting and other activities (e.g. leaf pulling and tying). Therefore, estimation of worker exposure was calculated according to the AOEM model. Exposure is estimated to be 315 % of the AOEL of iprovalicarb and 742.63% of the AOEL of folpet when workwear is worn (arms, body and legs covered). According to the EFSA guidance, there is no transfer coefficient (TC) (cm^2/h) available when workwear and gloves (PPE) are worn for grapevines, and no further refinement is possible. Therefore, it may be concluded that there is unacceptable risk anticipated for the worker.

New data submitted in application n°2021-3996 did not allowed to change the worker exposure estimation. Risk for workers cannot be excluded.

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

3.1.4 Residues and Consumer Exposure

The data available are considered sufficient for risk assessment. Any exceedence of the current MRL on wine and table grapes as laid down in Reg. (EU) 396/2005 is not expected.

The chronic and short-term intakes of folpet and iprovalicarb residues resulting from the uses proposed in the framework of this application are unlikely to present a public health concern.

[12] Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (SANTE-10832-2015 rev. 1.7, 2017)

As far as consumer health protection is concerned, France, zRMS, agrees with the continued authorisation of the proposed uses.

According to the available data, no specific mitigation measures should apply.

Summary for folpet

Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance Reg. EU 2016/156	Chronic risk for consumers identified?	Acute risk for consumers identified?	Comments
Wine grapes	Yes	Yes (6 NEU and 8 SEU)	Yes	Yes	Yes	No	No	
Table grapes	Yes	Yes (4 SEU)	Yes	Yes	Yes		No	

The effects of processing on the nature of folpet residues have been investigated. Data on effects of processing on the amount of residue have been submitted. These data were considered for risk assessment.

Residues in succeeding crops have been sufficiently investigated taking into account the specific circumstances of the cGAP uses being considered here. It is very unlikely that residues will be present in succeeding crops.

Considering dietary burden and based on the intended uses, no significant modification of the intake was calculated for livestock. Further investigation of residues as well as the modification of MRLs in commodities of animal origin are therefore not necessary.

Summary for iprovalicarb

Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance Reg. EU 777/2013	Chronic risk for consumers identified?	Acute risk for consumers identified?	Comments
Wine grapes	Yes	Yes (8 NEU and a minimum of 25 SEU)	Yes	Yes	Yes	No	No	
Table grapes	Yes	Yes (8 NEU and a minimum of 25 SEU)	Yes	Yes	Yes		No	

The effects of processing on the nature of iprovalicarb residues have been investigated. Data on effects of processing on the amount of residue have been submitted.

These data were not considered for risk assessment.

Residues in succeeding crops have been sufficiently investigated taking into account the specific circumstances of the cGAP uses being considered here. It is very unlikely that residues will be present in succeeding crops.

Considering dietary burden and based on the intended uses, no significant modification of the intake was calculated for livestock. Further investigation of residues as well as the modification of MRLs in commodities of animal origin are therefore not necessary.

Summary for SIRBEL UD

Crop	PHI for SIRBEL UD requested by applicant	PHI/withholding period* sufficiently supported for		PHI for SIRBEL UD proposed by zRMS	zRMS Comments (if different PHI proposed)
		Folpet	Iprovalicarb		
Wine grapes	28 days for France	Yes	Yes	28 days for France	
Table grapes	70 days for France	Yes	Yes	70 days for France	

NR: not relevant
* Purpose of withholding period to be specified
** F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop).

Waiting periods before planting succeeding crops

Waiting period before planting succeeding crops			Overall waiting period proposed by zRMS for SIRBEL UD
Crop group	Led by folpet	Led by iprovalicarb	
All crop group	NR	NR	NR

NR: not relevant

3.1.5 Environmental fate and behaviour

The fate and behaviour in the environment have been evaluated according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU conclusions were used to calculate predicted environmental concentration (PEC) values for the active substance and its metabolites for the intended use patterns. In cases where deviations from the EU agreed endpoints were considered appropriate (for example when additional studies are provided), such deviations were highlighted and justified accordingly.

In order to comply with the provisions of Regulation (EC) No 1107/2009 (Commission Implementing Regulation (EU) 2015/2033) and according to Art. 43 of Regulation (EC) No 1107/2009, and in accordance with the guidance document SANCO/2010/13170, this risk assessment report for the sections “Fate and behaviour in the Environment / Ecotoxicology” only applies for the active substance iprovalicarb following its renewal of approval. For the other active substance, provisions of the initial authorization remain.

The PEC values of iprovalicarb and its metabolites in soil, surface water and groundwater have been assessed according to FOCUS guidance documents, with standard FOCUS scenarios to obtain outputs from the FOCUS models, and the endpoints established in the EU conclusions or agreed in the assessment based on new data provided.

PECsoil and PECsw values derived for iprovalicarb and its metabolites are used for the ecotoxicological risk assessment, and mitigation measures are proposed.

PECgw values for iprovalicarb and its metabolites (except metabolite PMPA [M10]) do not occur at levels exceeding those mentioned in Regulation (EC) No 1107/2009 and guidance document SANCO 221/2000 on the relevance of metabolites in groundwater.

For metabolite PMPA (M10), as the EFSA conclusions states a correlation of the leaching and the clay content of soil, PECgw values were provided by the applicant according to EFSA recommendations with the average Kfoc of 290.2 L/kg and another set of simulations with the lowest Kfoc (i.e., 117.9 L/kg) to account for potential leaching in soils

that have a low clay content. PECgw values are predicted to be below 0.1 µg/L for all scenarios with a Kfoc value of 290.2 L/kg. With a Kfoc value of 117.9 L/kg, PECgw values are predicted to be above 0.1 µg/L for all scenarios (PECgw max = 1.805 µg/L). A mitigation measure restricting uses to vineyards with soil clay content above 8 % is proposed by the applicant. This is considered acceptable and consistent with provisional measures, as proposed in the review report.

MSs may wish to consider a different approach where relevant.

Therefore no unacceptable risk of groundwater contamination is expected for the intended uses.

Based on vapour pressure, information on volatilisation from plants and soil, and DT_{50} calculation, no significant contamination of the air compartment is expected for the intended uses.

3.1.6 Ecotoxicology

The ecotoxicological risk assessment of the formulation was performed according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU review for active substances and their metabolites were used for the intended use patterns. In cases where deviations from the EU agreed endpoints were considered appropriate (for example when additional studies are provided), such deviations were highlighted and justified accordingly.

In order to comply with the provisions of Regulation (EC) No 1107/2009 (Commission Implementing Regulation (EU) 2015/2033) and according to Art. 43 of Regulation (EC) No 1107/2009, and in accordance with the guidance document SANCO/2010/13170, this risk assessment report for the sections “Fate and behaviour in the Environment / Ecotoxicology” only applies for the active substance iprovalicarb following its renewal of approval. For the other active substance, provisions of the initial authorization remain.

Based on the guidance documents, the risks for birds, mammals, bees and other non-target arthropods, earthworms and other soil macro-organisms, micro-organisms and non-target plants are acceptable for the intended uses.

For aquatic organisms, the risks are acceptable in France when a 5 metres spray drift and runoff buffer is considered.

3.1.7 Efficacy

Considering the claim under Article 43 and the data provided on the risk of resistance development:

- SIRBEL UD (FLP+IPV WG 65.3)’s efficacy is still considered as satisfactory. However, regarding the resistance situation to carboxylic acid amides (CAAs) in France (high frequency of resistance, associated with efficacy failures), it should be noted that iprovalicarb may have no usefulness on plots where there is CAA resistance (folpet alone will provide an equivalent efficacy).
- SIRBEL UD (FLP+IPV WG 65.3)’s risk of phytotoxicity is considered negligible.
- SIRBEL UD (FLP+IPV WG 65.3)’s risk of negative impact on yield, quality, the wine-making process and adjacent crops are considered negligible.
- The risk of resistance developing to folpet does not require monitoring. However, there is a risk of resistance developing or appearing to iprovalicarb for *Plasmopara viticola*, requiring both monitoring and the setting-up of efficacy trials in situations of characterised resistance. To avoid the development of resistance of *P. viticola* to iprovalicarb, the number of application is limited to two applications per crop cycle [year] (preferably not consecutive).

3.2 Conclusions arising from French assessment

Taking into account the above assessment, an **authorisation renewal cannot be granted**. A copy of the Decision issued can be found in Appendix 1 – Copy of the product Decision.

3.3 Substances of concern for national monitoring

No information stated.

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

3.4.1 Post-authorisation monitoring

None.

3.4.2 Post-authorisation data requirements

None

3.4.3 Label amendments

The draft label proposed by the applicant in Appendix 2 may be corrected with consideration of any new element under points 2.2.1 (or 2.2.2), 2.2.3 and 2.2.4.

The label shall reflect the detailed conditions stipulated in the Decision.

Appendix 1 – Copy of the French Decision

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RÉPUBLIQUE FRANÇAISE
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Décision relative à une demande de renouvellement de l'autorisation de mise sur le marché d'un produit phytopharmaceutique et aux demandes associées

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 réglementaire,

Vu les demandes de renouvellement de l'autorisation de mise sur le marché, suite au renouvellement de l'approbation de la substance active iprovalicarbe, d'ajout d'emballage, de modification des informations et les données fournies en réponse aux demandes de post-autorisation, du produit phytopharmaceutique ***SIRBEL UD***

de la société *BAYER SAS*

enregistrées sous les *n°2012-1506, 2016-2206, 2017-0619, 2017-2471 et 2021-3996*

Vu les conclusions de l'évaluation de l'Anses du 1er juillet 2021 et du 26 août 2022,

Considérant qu'un risque d'effet nocif pour les travailleurs, lié à l'utilisation du produit, ne peut être exclu,

Considérant qu'en conséquence, les exigences mentionnées à l'article 29 du règlement (CE) n°1107/2009 ne sont plus remplies,

L'autorisation de mise sur le marché du produit phytopharmaceutique désigné ci-après **n'est pas renouvelée** en France.

SIRBEL UD
AMM n°2010552

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Informations générales sur le produit	
Noms du produit	SIRBEL UD ODENA UD
Type de produit	Produit de référence
Titulaire	BAYER SAS CS 90106 16 rue Jean-Marie Leclair 69266 LYON CEDEX 09 France
Formulation	Granulé dispersable (WG)
Contenant	563 g/kg - folpet 90 g/kg - iprovalicarbe
Numéro d'intrant	2010552
Numéro d'AMM	2010552
Fonction	Fongicide
Gamme d'usage	Professionnel

A Maisons-Alfort, le 25/10/2022

DocuSigned by:
Charlotte Grastilleur
AE281A955A42454...

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 : Conditions de mise sur le marché

Liste des usages retirés

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)	Délai accordé pour la vente et la distribution	Délai accordé pour le stockage et l'utilisation des stocks
12703203 Vigne*Trt Part.Aer.* Mildiou(s)	1,3 kg/ha	2/an	28	6 mois à compter de la présente décision	18 mois à compter de la présente décision
	Motivation du retrait : L'usage est retiré car les données disponibles ne permettent pas d'exclure un risque d'effet nocif pour les travailleurs.				

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

Sirbel® UD

Contient 9 % iprovalicarbe soit 9.0 % (m/m)
56.25 % folpel soit 56.25 % (m/m)
sous forme de granulés dispersibles dans l'eau (WG)

AMM N° : 2010552

RESERVE A UN USAGE EXCLUSIVEMENT PROFESSIONNEL

SIRBEL UD est un fongicide à base d'iprovalicarbe, substance active qui appartient à la famille chimique des amino-acide amide carbamates, et de folpel.
Il est doté de propriétés pénétrantes et diffusantes.
SIRBEL UD possède une action préventive importante et une action curative sur les champignons de la famille des oomycètes et notamment le mildiou.

Tableaux des usages :

Culture	Cibles / Usages	Doses	Spécifications d'usage	DAR (en jours)ou Stades cultures(NC=non concerné)	Précautions environnement (voir légendes)
Vigne - raisin de cuve	Mildiou	1.3 kg/ha	2 trait./an non consécutifs	28	1a 2a
Vigne - raisin de table	Mildiou	1.3 kg/ha	2 trait./an non consécutifs	BBCH 69	1a 2a

Utilisé suivant les Bonnes Pratiques Agricoles et dans le respect du Délai Avant Récolte, SIRBEL UD n'a aucune incidence néfaste sur la vinification, et ne modifie pas les qualités organoleptiques des vins.
SIRBEL UD peut s'utiliser jusque début véraison sur les vignes destinées à la production d'alcools et eaux-de-vie.

Limites maximales en résidus de substances actives : se reporter aux LMR en vigueur au niveau de l'Union Européenne et consultables à l'adresse :http://ec.europa.eu/sanco_pesticides/public/index.cfm

Bayer SAS ne préconise l'utilisation de ce produit que sur les cultures et usages mentionnés dans le tableau des usages ci-dessus et, à ce titre, décline toute responsabilité concernant l'élargissement de son utilisation à d'autres usages tels que prévus par l'arrêté du 26 mars 2014 et ses arrêtés modificatifs.

1. Organismes aquatiques
1a. Pour protéger les organismes aquatiques, respecter une zone non traitée de 5 mètres comportant un dispositif végétalisé permanent par rapport aux points d'eau.

Le tableau ci-dessus fait apparaître les précautions à prendre pour l'environnement, fixées par l'autorisation de mise en marché de la spécialité.
Si ZNT aquatique non fixée (en l'absence sur l'étiquette de zone non traitée par rapport aux points d'eau), respecter, selon les dispositions de l'arrêté du 12 septembre 2006, la valeur minimale suivante : Zone non traitée 5 mètres.

2. Arthropodes
2a. Pour protéger les arthropodes non cibles, respecter une zone non traitée de 5 mètres par rapport à la zone non cultivée adjacente.

Une tolérance a été accordée pour l'iprovalicarbe aux USA, au Canada et au Japon, facilitant l'accès aux marchés à l'exportation pour les vins issus de vignes traitées avec SIRBEL UD.

Champ d'activité :

Mode d'emploi :

- *Préparation de la bouillie*

Verser SIRBEL UD, présenté sous forme de granulés dispersibles, dans la cuve du pulvérisateur à demi remplie d'eau, le système d'agitation étant en marche pour obtenir une bonne mise en suspension. Compléter avec la quantité d'eau nécessaire à l'application en maintenant l'agitation.

- *Mélanges et Compatibilités*

Les mélanges doivent être mis en oeuvre conformément à la réglementation en vigueur. Pour connaître le détail pratique de cette mise en oeuvre, il est nécessaire de contacter au préalable le 0 800 25 35 45

- *Dose(s) préconisée(s)*

1,3 kg/ha dès le premier traitement anti-mildiou.

- *Conditions de traitement (époque, stade, seuil d'intervention)*

Attention : en cas de recours à des techniques culturales nouvellement mises en oeuvre par l'utilisateur ou présentant une quelconque spécificité, l'utilisateur doit en informer son fournisseur avant toute utilisation du produit, afin que ce dernier puisse en vérifier la faisabilité avec le fabricant du produit.
SIRBEL UD s'applique préférentiellement en préventif, avant les contaminations de mildiou. Se conformer aux observations des organisations professionnelles diffusées sur votre zone. SIRBEL UD est sélectif de la plupart des cépages.
Sur raisin de table, l'application doit se faire au plus tard au stade BBCH 69.
Ne pas utiliser SIRBEL UD sous serre.
Ne pas appliquer SIRBEL UD sur des sols de faible teneur en argile (< 8 %).

SIRBEL UD est classé Neutre à Faiblement Toxique sur les typhlodromes T. pyri.

- *Programme de traitement*

-Utilisation préventive sur mildiou :
L'intervalle entre les applications sera de 10 à 12 jours, selon les conditions climatiques, la pression parasitaire et la pousse de la vigne. En cas de forte pression du mildiou, le délai entre les traitements sera ramené à 10 jours maximum.
En fin de saison, le renouvellement du traitement dépend de la fréquence et de l'intensité des épisodes pluvieux.

-Intervention exceptionnelle en curatif sur mildiou :
La curativité de l'iprovalicarbe permet également de traiter la vigne avec SIRBEL UD dans les 1 à 2 jours après une contamination par le mildiou, dans la limite de 25 % de la période d'incubation du pathogène.
Si l'application de SIRBEL UD intervient sur attaque déclarée (taches de mildiou visibles), renouveler la protection 5 à 6 jours après avec un fongicide mettant en oeuvre un autre mode d'action, tel que VALIANT Flash (consulter l'étiquette de VALIANT Flash). Tant que les conditions restent favorables au champignon, la couverture anti-mildiou doit être rigoureusement maintenue en resserrant les intervalles entre traitements.Ne pas appliquer SIRBEL UD plus de deux fois, non consécutives, par campagne. Il est également conseillé d'alterner des produits à base de substances actives de familles chimiques différentes et à modes d'action différents lors de la mise en oeuvre des programmes de protection de la vigne contre le mildiou.

- *Application (matériel, pression)*

Compte-tenu du mode de distribution des substances actives de SIRBEL UD :
- action pénétrante de l'iprovalicarbe
- action de contact du folpel
une pulvérisation face par face sur chaque rang est fortement conseillée.

Bayer S.A.S. interdit formellement les applications réalisées à l'aide d'un pulvérisateur à dos, la qualité de pulvérisation étant trop irrégulière. Ainsi, Bayer S.A.S. décline toute responsabilité en cas d'utilisation du SIRBEL UD à l'aide d'un appareil de ce type.

- *Conditions du milieu*

Eviter de traiter aux heures chaudes de la journée.

Précautions à prendre :

- Pour le stockage

- Conserver le produit dans son emballage d'origine, dans des locaux fermés à clé, à l'écart de tout aliment et boisson y compris ceux pour les animaux, et hors de portée des enfants. Les locaux doivent être frais et ventilés.

- Mesures de protection des individus

Pour protéger l'opérateur, porter:

Pendant le mélange / chargement
-Gants en nitrile certifiés EN 374-3 réutilisables;
-Combinaison de travail tissée en polyester 65% /coton 35% avec un grammage de 230g/m2 ou plus avec un traitement déperlant;
-EPI partiel (blouse) de catégorie III et de type PB (3) à porter par-dessus la combinaison précitée;
-Bottes de protection conforme à la réglementation et selon la norme EN 13 832-3;
-Lunettes norme EN 166 ou EN 170 (CE, sigle 3).

Pendant l'application
-Combinaison de travail cotte en polyester 65% /coton 35% avec un grammage d'au moins 230 g/m2 avec traitement déperlant;
Si application avec tracteur sans cabine :
-Gants en nitrile certifiés EN 374-2 à usage unique pendant l'application et dans le cas d'une intervention sur le matériel pendant la phase de pulvérisation;
-Bottes de protection conforme à la réglementation et selon la norme EN 13 832-3;
-Lunettes norme EN 166 ou EN 170 (CE, sigle 3).
Si application avec tracteur avec cabine:
-Gants en nitrile certifiés EN 374-2 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;
-Bottes de protection conforme à la réglementation et selon la norme EN 13 832-3;

Pendant le nettoyage du matériel de pulvérisation
-Gants en nitrile certifiés EN 374-3;
-Combinaison de travail tissée en polyester 65% /coton 35% avec un grammage de 230g/m2 ou plus avec un traitement déperlant;
-EPI partiel (blouse) de catégorie III et de type PB (3) à porter par-dessus la combinaison précitée;
-Bottes de protection conforme à la réglementation et selon la norme EN 13 832-3;
-Lunettes norme EN 166 ou EN 170 (CE, sigle 3).

Pour le travailleur
Après respect du délai de rentrée et s'il doit intervenir sur une parcelle traitée, porter une combinaison de travail tissée en polyester 65% /coton 35% avec un grammage de 230g/m2 ou plus avec un traitement déperlant et des gants en nitrile certifiés EN 374-3.

- Pour l'emploi

- Eviter l'inhalation de gouttelettes de bouillie.
- Eliminer les fonds de cuve conformément à la réglementation en vigueur.

- Pour l'élimination du produit et de l'emballage

- Pour l'élimination des produits non utilisables, faire appel à une entreprise habilitée pour la collecte et l'élimination des produits dangereux.
- Ne pas réutiliser les emballages vides et les éliminer via une collecte organisée par les distributeurs partenaires de la filière Adivalor ou un autre service de collecte spécifique.

Sirbel® UD AMM N° : 2010552

9 % iprovalicarbe, soit 9.0% (m/m)
56.25 % folpel, soit 56.25% (m/m)

Danger

H351 - Susceptible de provoquer le cancer.

H318 - Provoque des lésions oculaires graves.

H317 - Peut provoquer une allergie cutanée.

H400 - Très toxique pour les organismes aquatiques.

P280 - Porter des gants de protection/des vêtements de protection/un équipement de protection des yeux/du visage.

P305+P351+P338 - EN CAS DE CONTACT AVEC LES YEUX : rincer avec précaution à l'eau pendant plusieurs minutes. Enlever les lentilles de contact si la victime en porte et si elles peuvent être facilement enlevées. Continuer à rincer.

P308+P313 - EN CAS d'exposition prouvée ou suspectée : consulter un médecin.

P501 - Eliminer le contenu/récipient dans le lieu d'élimination conformément à la réglementation locale

Substance classée sensibilisante : Contient du Folpel. Peut produire une réaction allergique.

Délai de réentrée des travailleurs dans la zone traitée : 48 heures après traitement.

SPe3 - Pour protéger les organismes aquatiques, respecter une zone non traitée de 5 mètres comportant un dispositif végétalisé permanent par rapport aux points d'eau et pour protéger les arthropodes non cibles respecter une zone non traitée de 5 mètres par rapport à la zone non cultivée adjacente.

Ne pas polluer l'eau avec le produit ou son emballage.

Respectez les instructions d'utilisation afin d'éviter les risques pour la santé humaine et l'environnement.

Premiers secours
Conseils généraux
S'éloigner de la zone dangereuse. Enlever immédiatement tout vêtement souillé et le mettre à l'écart. Maintenir et transporter la victime en position latérale de sécurité.

Inhalation
Appeler immédiatement un médecin ou un centre AntiPoison. Amener la victime à l'air libre. Garder la victime au repos et la maintenir au chaud.

Contact avec la peau Laver immédiatement avec du polyéthylèneglycol 400 puis avec beaucoup d'eau. Appeler immédiatement un médecin ou un centre AntiPoison.

Contact avec les yeux Rincer immédiatement et abondamment à l'eau, y compris sous les paupières, pendant au moins 15 minutes. Après les 5 premières minutes, enlever les lentilles cornéennes, si présentes, continuer à rincer l'oeil. Appeler immédiatement un médecin ou un centre AntiPoison.

Ingestion Appeler immédiatement un médecin ou un centre AntiPoison. Ne PAS faire vomir. Rincer la bouche.

En cas de perte de la Fiche de données de sécurité, celle-ci peut vous être à nouveau fournie sur simple appel au 0 800 25 35 45 ou être consultée sur les sites internet : www.bayer-agri.fr et www.quickfds.com .

En cas d'urgence, appeler le 15 ou le centre antipoison puis signalez vos symptômes au réseau "Phyt'attitude" n° vert 0 800 887 887 (appel gratuit depuis un poste fixe).

Point gélif : -10 °C
40 °C

UN : 3077


9 - Matières et objets dangereux divers


- Dangereux pour l'environnement

® Marque déposée Bayer
Bayer SAS
Division Crop Science - 16, rue Jean-Marie Leclair - CS 90106 - 69266 Lyon Cedex 09 France
Fabrication CEE

Date de fabrication/n° de lot : voir sur l'emballage

BPP_2

Important
Respecter les usages, doses, conditions et précautions d'emploi mentionnés sur l'emballage qui ont été déterminés en fonction des caractéristiques du produit et des applications pour lesquelles il est préconisé. Conduisez sur ces bases, la culture et les traitements selon la bonne pratique agricole en tenant compte, sous votre responsabilité, de tous facteurs particuliers concernant votre exploitation, tels que la nature du sol, les conditions météorologiques, les méthodes culturales, les variétés végétales, la résistance des espèces...
Le fabricant garantit la qualité de ses produits vendus dans leur emballage d'origine ainsi que leur conformité à l'autorisation de mise sur le marché.
Compte tenu de la diversité des législations existantes, il est recommandé, dans le cas où les denrées issues des cultures protégées avec cette spécialité sont destinées à l'exportation, de vérifier la réglementation en vigueur dans le pays importateur.

Appendix 3 – Letter(s) of Access

Provided upon request.