REGISTRATION REPORT

Part A

Risk Management

Product code: IBE-4025

Product name(s): VIDERYO F

Active Substance(s):

Cyazofamid, 40 g/L

Folpet, 400 g/L

COUNTRY: FRANCE

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(New application)

Applicant: ISK Biosciences Europe N.V.

Date: 2019-06-21

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PART A – Risk Management

The company ISK Biosciences Europe N.V. has requested a new application in France for the product VIDERYO F (formulation code: IBE-4025), containing 40 g/L cyazofamid and 400 g/L 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 VIDERYO F (IBE-4025) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of VIDERYO F (IBE-4025) have been made using endpoints agreed in the EU peer review of both cyazofamid and folpet.

This document describes the specific conditions of use and labelling required for France for the registration of VIDERYO F (IBE-4025).

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 ISK Biosciences Europe N.V.'s application to market VIDERYO F (IBE-4025) 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 first authorisation of this product in France and in other MSs of the Southern zone.

1.2 Active substance approval

Cyazofamid

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 : Only uses as fungicide may be authorised. 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 cyazofamid, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 3 December 2002 shall be taken into account. In this overall assessment: - Member States must pay particular attention to the protection of aquatic organisms; - Member States must pay particular attention to the degradation kinetics of the metabolite CTCA in soil, especially for Northern European regions. Risk mitigation measures or use restrictions should be applied where appropriate.
A Review Report is available (SANCO/10379/2002-final, 27 November 2002).

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 application (2012-2439) 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. 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 4th May 2017[3] provides that:
- unless formally stated in the product authorisation, the pre harvest interval (PHI) is at least three days;
- 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.

[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
[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

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" in accordance with those criteria.

Finally, the French Order of 26 March 2014[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.

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 VIDERYO F (IBE-4025), 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 letter(s) of access.

[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

2 DETAILS OF THE AUTHORISATION

2.1 Product identity

Product name (code)	VIDERYO F (IBE-4025)
Authorisation number	Not applicable
Function	fungicide
Applicant	ISK Biosciences Europe N.V.
Composition	40 g/L cyazofamid 400 g/L folpet
Formulation type (code)	Suspension Concentrate (SC)
Packaging	N/A: not registered in France.

2.2 Classification and labelling

2.2.1 Classification and labelling under Directive 99/45/EC

Not applicable after 1st June 2015.

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

Physical hazards	-	
Health hazards	Skin Sensitisation Cat. 1 Acute Toxicity (Inhalation) Cat. 4 Carcinogenicity Cat. 2	
Environmental hazards	Aquatic Acute 1 Aquatic Chronic 1	
Hazard pictograms		
Signal word	Warning	
Hazard statements	H317	May cause an allergic skin reaction
	H332	Harmful if inhaled
	H351	Suspected of causing cancer
	H400	Very toxic to aquatic life
	H410	Toxic to aquatic life with long lasting effects
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

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

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

N/A: not registered in France.

2.2.4 Other phrases linked to the preparation

N/A: not registered in France.

2.3 Product uses

Please note:
When the conclusion is "not acceptable", the intended use is highlighted in grey and the main reason(s) reported in the remarks.

PPP (product name/code):	**VIDERYO F (IBE-4025)**	Formulation type:	**SC** [a, b]
Active substance 1:	Cyazofamid	Conc. of as 1:	**40 g/L** [c]
Active substance 2:	Folpet	Conc. of as 2:	**400 g/L** [c]
Applicant:	**ISK Biosciences Europe N.V.**	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)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
	FR	Grape (wine grape)	F	*Plasmopara viticola* (PLASVI)	Foliar application	BBCH 15 to PHI	6	10-12	2.5	100 g cyazofamid, 1000 g folpet	200-1000	28	**Non acceptable** (resistance, risk for consumer)
		Grape (table grape)										70	
	FR	Grape (wine grape)	F	*Plasmopara viticola* (PLASVI)	Foliar application	BBCH 15 to PHI	**2**	10-12	2.5	100 g cyazofamid, 1000 g folpet	200-1000	28	**Not acceptable** (risk for consumer)
		Grape (table grape)				BBCH 15-**69**						**F**	

Remarks table heading:

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

Remarks columns:

1 Numeration necessary to allow references
2 Use official codes/nomenclatures of EU Member States
3 use For crops, the EU and Codex classifications (both) should be used; when relevant, the 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

VIDERYO F (IBE-4025) is a suspension concentrate (SC). All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is an opaque beige clear liquid, with a faint chemical odour. It is not explosive and has no oxidising properties. It has a self-ignition temperature above 600 °C. In aqueous solution (1%), it has a pH value around 6.0 at 20.7°C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0°C and 14 days at 54 °C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in HDPE. As the stability was performed on HDPE packaging, all the packaging can be considered as acceptable. Its technical characteristics are acceptable for a SC formulation.

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

The formulation must be shaken before use.

3.1.2 Methods of analysis

3.1.2.1 Analytical method for the formulation

Analytical methods for the determination of active substances and relevant impurities (perchloromethylmercaptan and carbon tetrachloride for folpet) in the formulation are available and validated.

3.1.2.2 Analytical methods for residues

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

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

To update the dossier, a confirmatory method is required for the determination of cyazofamid in acid matrices in post-authorization.

According to the EFSA conclusions, an analytical method for the determination of cyazofamid residue in air (with a LOQ<0.14 µg/m3) should be required in post-authorization.

The active substances are neither toxic nor very toxic. Nevertheless, in the framework of the renewal of the active substance cyazofamid, an analytical method fully validated for the determination of residues of cyazofamid in biological fluids and tissues is required in post-authorisation.

3.1.3 Mammalian Toxicology

The following endpoints were used for the risk assessment.

Active Substance: cyazofamid		
ADI	0.17 mg kg bw/d	EU 2003
ARfD	not applicable	
AOEL	0.3 mg/kg bw/d	
New AOEL	0.045 mg/kg bw/d	EU 2016
Dermal	Based on default values (oral bioavailability) according to SANCO guidance (2004):	

absorption		Concentrate (used in formulation) 40 g/L	Spray dilution (used in formulation) 0.1 g/L
	Dermal absorption endpoints	**15%**	**15%**

Active Substance: folpel			
ADI	0.1 mg kg bw/d		EU 2007
ARfD	0.2 mg/kg bw/d		
AOEL	0.1 mg/kg bw/d		
Dermal absorption	Based on an *in vitro* human study performed on formulation according to guidance on dermal absorption (EFSA 2012):		
		Concentrate (tested) 384 g/L	Diluted formulation (tested) 0.94 g/L
	In vitro (human)	0.3%	5.4%
		Concentrate (used in formulation) 400 g/L	Spray dilution (used in formulation) 1 g/L
	Dermal absorption endpoints	**0.3%**	**5.4%**

3.1.3.1 Acute Toxicity

VIDERYO F (IBE-4025) containing 40 g/L of cyazofamid and 400 g/L of folpel has a low toxicity in respect to acute oral and dermal toxicity, is not irritating to the rabbit skin or eye, and is a skin sensitizer. VIDERYO F (IBE-4025) is harmful via inhalation route.

3.1.3.2 Operator Exposure

Summary of critical use patterns (worst cases):

Crop	**F/G[8]**	**Equipment**	**Application rate L product/ha (g as/ha)**	**Spray dilution (L/ha)**	**Model**
Grape	F	Tractor mounted broadcast air-assisted sprayer	2.5 L/ha (100 g cyazofamid/ha and 1000 g folpel/ha)	200-1000	BBA
		Hand-held sprayer (high level target)	2.5 L/ha (100 g cyazofamid/ha and 1000 g folpel/ha)	200-1000	BBA

Considering proposed use, operator systemic exposure was estimated using the German BBA model:

Crop	**Equipment**	**PPE and/or working coverall**	**% AOEL cyazofamid**	**% AOEL folpel**	**% new AOEL cyazofamid**
Grape	Tractor mounted broadcast air-assisted sprayer	Working coverall and gloves during mixing/loading and application	1.5%	16%	9.9%
	Hand-held sprayer (high level target)	Working coverall and gloves during mixing/loading and application	2.2%	12%	15%

According to the model calculations, it can be concluded that the risk for the operator using VIDERYO F (IBE-4025) 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

[8] Open field or glasshouse

Bystander exposure was assessed according to EUROPOEM II. Exposure is estimated to be 0.3% of the AOEL of cyazofamid and 3.7% of the AOEL of folpel. It is concluded that there is no unacceptable risk to the bystander after incidental short-term exposure to VIDERYO F (IBE-4025).

Considering the new AOEL for cyazofamid, bystander exposure was assessed according to EUROPOEM II. Exposure is estimated to be 2.1% of the AOEL of cyazofamid and 3.7% of the AOEL of folpel. It is concluded that there is no unacceptable risk to the bystander after incidental short-term exposure to VIDERYO F (IBE-4025).

3.1.3.4 Worker Exposure

Workers may have to enter treated areas after treatment for crop harvesting activities. Therefore, estimation of worker exposure was calculated according to EUROPOEM II. Exposure is estimated to be 3.0 % of the AOEL of cyazofamid and 32.4% of the AOEL of folpel. It is concluded that without taking into account a re-entry period, there is no unacceptable risk anticipated for workers wearing a working coverall and gloves, when re-entering crops treated with VIDERYO F (IBE-4025).

Considering the new AOEL for cyazofamid, worker exposure is estimated to be 20.0% of the AOEL of cyazofamid and 32.4% of the AOEL of folpel.

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

3.1.4 Residues and Consumer Exposure

3.1.4.1 Residues

Primary crop metabolisms were sufficiently investigated to define residues of both active substances for enforcement and risk assessment in crops under consideration.

Regarding the magnitude of residues in wine and table grapes, a sufficient number of residue trials are available to support the intended GAPs in France. These data allowed confirming that no MRL exceedance will result from intended uses.

The effects of processing on the nature of folpet and cyazofamid residues have been investigated. Data on effect of processing on the amount of residue have been submitted and considered for risk assessment.

Residues in succeeding crops have been sufficiently investigated; it is very unlikely that residues of folpet or cyazofamid will be present in succeeding crops.

As grape is not fed to animals, livestock metabolism and livestock feeding studies are not necessary.

3.1.4.2 Consumer exposure

The toxicological profile of folpet and cyazofamid were evaluated at EU level, which resulted in the proposal of ADIs (0.1 mg/kg for folpet and 0.17 mg/kg for cyazofamid) and ARfD (0.2 mg/kg for folpet) that were considered in the frame of this evaluation.

Chronic consumer exposure resulting from the uses proposed in the framework of this application was calculated for both active substances. Nether the less, it should be noted that in EFSA conclusion (2016), the consumer dietary risk assessment could not be finalised for processed commodities as the genotoxic potential of metabolite CCIM (4-chloro-5-(4-methylphenyl)-1H-imidazole-2-carbonitrile) could not be ruled out.

Based on these conclusions, an unacceptable risk for consumer cannot be excluded

3.1.4.3 Mitigation measures

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

3.1.5 Environmental fate and behaviour

The fate and behaviour in the environment of the formulation have been evaluated according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU review were used to calculate PECs for the active substances and their 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.

The PECs of cyazofamid, folpet and their 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 review or agreed in the assessment based on new data provided.

The PEC soil and PEC surface water derived for the active substances and their metabolites are used for the eco-toxicological risk assessment, and mitigation measures are proposed.

The PEC groundwater for cyazofamid, folpet and their metabolites do not occur at levels exceeding those mentioned in regulation EC 1107/2009 and guidance document SANCO 221/2000.

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

3.1.6.1 Effects on Terrestrial Vertebrates

The risk assessment for birds and mammals was carried out according to the 'EFSA Guidance Document on Risk Assessment for Birds and Mammals (2009)[9]' and considering the EU agreed endpoints of folpet and cyazofamid.

The TER values, calculated for recommended scenarios, all exceed the trigger values of 10 for acute risk and 5 for long-term risk, indicating that the risk to birds and mammals[10] is acceptable following use of VIDERYO F (IBE-4025) according to the proposed use patterns.

3.1.6.2 Effects on Aquatic Species

The risk assessment for aquatic organisms was carried out according to the Guidance Document on Aquatic Ecotoxicology (SANCO/3268/2001) and considering the EU agreed endpoints of folpet, cyazofamid, their metabolites and data on the formulation VIDERYO F (IBE-4025).

The TER for folpet and cyazofamid exceed the relevant triggers, indicating that the risk to aquatic organisms is acceptable following use of VIDERYO F (IBE-4025) when a buffer zone of 20 meters and permanent vegetated filter strip is used.

3.1.6.3 Effects on Bees and Other Arthropod Species

Based on the guidance documents, the risks for bees and other non-target arthropods are acceptable for the intended uses.

[9] European Food Safety Authority; Guidance Document on Risk Assessment for Birds and Mammals on request from EFSA. EFSA journal 2009; 7(12):1438. [139 pp.]

[10] From direct dietary exposure, drinking water and secondary poisoning.

3.1.6.4 Effects on Earthworms and Other Soil Macro-organisms

The risk assessment for earthworms and other soil macro-organisms was carried out according to the Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002) and considering the EU agreed endpoints of folpet, cyazofamid and data on the formulation VIDERYO F (IBE-4025).

The acute and chronic TER values for folpet, cyazofamid and data on the formulation are greater than the triggers of 10 and 5 respectively, indicating that the risk to earthworms and other soil macro-organisms is acceptable according to the proposed use pattern.

3.1.6.5 Effects on Soil Non-target Micro-organisms

The risk of VIDERYO F (IBE-4025) to soil micro-organisms was evaluated by comparison of no-effect concentrations, derived from laboratory tests, with PECS.

The no effect levels exceed the relevant PECS values, indicating that the risk to soil micro-organisms is acceptable following use of VIDERYO F (IBE-4025) according to the proposed use pattern.

3.1.6.6 Assessment of Potential for Effects on Other Non-target Organisms (Flora and Fauna)

The risk assessment for non-target plants was carried out according to the Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002) and considering the endpoints of the formulation VIDERYO F (IBE-4025).

The application VIDERYO F (IBE-4025) does not cause unacceptable effects on non-target terrestrial plants when applied at a maximum application rate of 3000 g formulation/ha.

3.1.7 Efficacy

The product complies with the Uniform Principles.

Considering the data submitted:

- The efficacy of VIDERYO F (IBE-4025) is considered as satisfying for downy mildew control on vine,
- The selectivity of VIDERYO F (IBE-4025) is considered as satisfying,
- The risk of negative impact (processing procedure, yield, adjacent crop and beneficial organisms) is considered as negligible,
- The risk of resistance development or appearance is considered as low to moderate and some measures of management have been settled (**limitation of number of applications (max. 2/year) in France**).
-

- **Crops**	**Pest**	**Dose**	**Max. n° of appli. (interval)**	**French efficacy section opinion**	**Remarks**
Grape (**wine and table grapes**) in France	Downy mildew (*Plasmopara viticola*)	2.0 - 2.5 L/ha	~~6~~ **2** (10 days)	Favourable	Limitation to 2 applications per year **in France** Each country should establish its own resistance management strategy regarding number of applications
Grape (**wine and table grapes**) in rest of southern regulatory zone			~~6~~ **3** (10 days)	Favourable	

3.2 Conclusions arising from French assessment

Taking into account the above assessment, an authorisation 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

N/A: not registered in France.

3.4.2 Post-authorisation data requirements

N/A: not registered in France.

3.4.3 Label amendments

N/A: not registered in France.

Appendix 1 – Copy of the French Decision

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anses
agence nationale de sécurité sanitaire alimentation, environnement, travail

Décision relative à une demande d'autorisation de mise sur le marché 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'autorisation de mise sur le marché et les demandes associées du produit phytopharmaceutique ***VIDERYO F***

de la société	*ISK BIOSCIENCES EUROPE S.A.*
enregistrées sous les	*n°2012-2439, 2012-2440 et 2012-2441*

Vu les conclusions de l'évaluation de l'Anses du 7 juin 2018,

Considérant que le potentiel génotoxique du métabolite CCIM de la substance active cyazofamide contenue dans le produit ne peut être exclu,

Considérant qu'en conséquence, un risque d'effet nocif pour le consommateur ne peut être exclu,

Considérant qu'il ne peut pas être établi que les exigences mentionnées à l'article 29 du règlement (CE) n°1107/2009 sont respectées,

La mise sur le marché du produit phytopharmaceutique désigné ci-après **n'est pas autorisée** en France.

VIDERYO F
AMM n°-

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anses
agence nationale de sécurité sanitaire
alimentation, environnement, travail

Informations générales sur le produit	
Noms du produit	VIDERYO F VINCYA F DAIMYO F
Type de produit	Produit de référence
Titulaire	ISK BIOSCIENCES EUROPE S.A. Pegasus park, De Kleetlaan 12B - Bus 9 B-1831 DIEGEM Belgique
Formulation	Suspension concentrée (SC)
Contenant	40 g/L - cyazofamide 400 g/L - folpel
Numéro d'intrant	9914-2012.01
Numéro d'AMM	-
Fonction	Fongicide
Gamme d'usage	Professionnel

A Maisons-Alfort le, 21 JUIN 2019

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

VIDERYO F
AMM n°-

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ANNEXE I : Conditions de mise sur le marché demandées

Liste des usages refusés

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
12703203 Vigne*Trt Part.Aer.*Mildiou(s)	2,5 L/ha	6/an	-
	Motivation du refus : L'usage est refusé au motif qu'un risque d'effet nocif pour le consommateur ne peut être exclu et en raison d'un risque d'apparition ou de développement de la résistance vis-à-vis du cyazofamide.		

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

IBE 4025 ®

Proposed trade name : **Vidéryo® F, Daimyo® F and Vincya® F**

Fongicide destiné au contrôle du Mildiou de la vigne (raisins de cuve et raisins de table ; applications préventives)

Contient 400 g/l de folpel + 40g/l de cyazofamide sous forme de suspension concentrée (SC)

Autorisation de mise sur le marché n° XXX délivrée le XXX

Contenu: 1, 2.5, 5, 10 (et 20L) litre e

Date de fabrication et numéro de lot: voir emballage

PRODUITS POUR LES PROFESSIONNELS : UTILISEZ LES PRODUITS PHYTOPHARMACEUTIQUES AVEC PRÉCAUTION. AVANT TOUTE UTILISATION, LISEZ L'ÉTIQUETTE ET LES INFORMATIONS CONCERNANT LE PRODUIT.

BELCHIM
–Crop Protection–

Détenteur de l'autorisation de mise sur le marché:
ISK Biosciences Europe N.V.
Pegasus Park – De Kleetlaan 12B
1831 Diegem
Belgique
Tél.: +32 (0)2 627 86 11

ISK

® = Marque déposée ISHIHARA SANGYO KAISHA, Ltd, Japon. Produit de ISK Biosciences Europe N.V.

IBE 4025® contient 400 g/l de folpel + 40g/l de cyazofamide
sous forme de suspension concentrée (SC)

Xn - Nocif

N – Dangereux pour l'environnement

PHRASES DE RISQUE

R 20 – Nocif par inhalation.

R 40 – Effet cancérogène suspecté – preuves insuffisantes.

R 43 – Peut entraîner une sensibilisation par contact avec la peau.

R 50/53 – Très toxique pour les organismes aquatiques, peut entraîner des effets néfastes à long terme pour l'environnement aquatique.

CONSEILS DE PRUDENCE

S2 - Conserver hors de la portée des enfants.

S13 - Conserver à l'écart des aliments et boissons, y compris ceux pour animaux.

S20/21 - Ne pas manger, ne pas boire et ne pas fumer pendant l'utilisation.

S35 - Ne se débarrasser de ce produit et de son récipient qu'en prenant toutes précautions d'usage.

S36/37 - Porter un vêtement de protection et des gants appropriés.

S46 – En cas d'ingestion, consulter immédiatement un médecin et lui montrer l'emballage ou l'étiquette.

S57 - Utiliser un récipient approprié pour éviter toute contamination du milieu ambiant.

S61 - Eviter le rejet dans l'environnement. Consulter les instructions spéciales/la fiche de données de sécurité.

Délai de rentrée sur la parcelle : 6 heures après le traitement.

Respecter les instructions d'utilisation pour éviter les risques pour l'homme et l'environnement.

SP1 - Ne pas polluer l'eau avec le produit ou son emballage. [Ne pas nettoyer le matériel

d'application près des eaux de surface. /Eviter la contamination via les systèmes d'évacuation des eaux à partir des cours de ferme ou des routes]. SPe3 - Pour protéger les organismes aquatiques, respecter une zone non traitée de 20 mètres par rapport aux points d'eau.
Distribué par : Belchim Crop Protection France S.A. Parc Tertiaire de Bois Dieu - 3, Allée des Chevreuils - 69380 LISSIEU Tel. 04 78 83 40 66 - Fax 04 78 83 49 23

Fiche de données de sécurité disponible sur le site www.quickfds.com

En cas d'urgence
En cas d'intoxication humaine, appeler le 15 (depuis un téléphone fixe) ou le 112 (depuis un téléphone mobile) ou le centre antipoison et consulter la Fiche de Données de Sécurité puis signalez vos symptômes au réseau Phyt'attitude, n° vert 0 800 887 887 (appel gratuit depuis un poste fixe).
Vous pouvez également appeler au 00 32 14 58 45 45 (24h/24 n° d'appel d'urgence).

MODE D'ACTION
Les substances actives de IBE 4025, cyazofamide (code FRAC 21) et folpel, agissent par contact avec les spores du Mildiou de la vigne (*Plasmopara viticola*), induisant leur éclatement ou inhibant leur germination. L'application doit être réalisée préventivement à la contamination de la vigne par le champignon.

USAGES ET DOSES D'EMPLOI

Culture	Dose du produit	N^{bre} maximal d'applications	Intervalle entre application (jours)	Délai avant récolte (jours)
Vigne Raisins de cuve	Maximum 2.5 L/ha	6	10 à 12 (selon pression maladie)	28
Raisins de table		1-2		70

Les limites maximales de résidus sont consultables à l'adresse suivante : hhtp://ec.europa.eu/sanco_pesticides/public/index.cfm

PREPARATION DE LA BOUILLIE
Avant de débuter le remplissage de la cuve du pulvérisateur pour préparer la bouillie de pulvérisation, s'assurer que celle-ci ne contient aucun résidu liquide ou solide d'un traitement précédent.
Remplir à 50% du volume requis le réservoir du pulvérisateur avec de l'eau propre. Mettre en marche le système d'agitation ou d'incorporation puis ajouter progressivement le produit. Ajouter enfin le reste du volume d'eau requis. Maintenir la bouillie en état d'agitation jusqu'à la fin de la pulvérisation. Ne préparez jamais plus de bouillie qu'il n'en est nécessaire.

CONDITIONS D'EMPLOI

Volume de bouillie : Le volume d'eau utilisé dépend du type de matériel de pulvérisation. Un volume de bouillie de 200 à 1000 Litres est recommandé pour IBE 4025® contre le mildiou de la vigne. L'applicateur veillera à ce que l'ensemble du feuillage ait reçu le traitement, et particulièrement lors de croissances rapides de la végétation.

La première application contre le mildiou doit être réalisée quand les systèmes d'avertissements agricoles (les Bulletins de Santé du Végétal) prévoient une situation à risque de développement de la maladie à partir du stade 4 à 6 feuilles (BBCH 15) et jusqu'à maturation des baies (BBCH 85).

Pour les **raisins de table** maximum 1 à 2 traitements sont possible afin de garantir le respect du stade (avant la fin floraison) et du délai avant récolte de 70 jours.

IBE 4025 est un produit de contact basé sur 2 matières actives qui se complètent et le produit s'utilise de façon préventive (avant l'arrivée de la maladie dans les champs).
IBE 4025® s'utilise en pulvérisation de l'ensemble de la végétation et peut être appliqué jusqu'à six fois par année sur une parcelle de vigne. Remarque : pour raisins de table le nombre maximum de traitement est limité à 2 et ceux sont positionnés avant la fin de la floraison de la culture.

Un intervalle de 12 jours maximum est recommandé entre deux applications consécutives. Cet intervalle doit être réduit à 10 jours en cas de forte pression maladie (présence de mildiou généralisée dans l'environnement de la parcelle) ou de période de pousse végétative importante (croissance de + de 15 cm par semaine).

Dose d'emploi : La dose d'application est au maximum de 2.5 Litre de produit formulé par hectare. La concentration de la bouillie dépend du type d'équipement de pulvérisation utilisé et du stade de développement de la culture. Dans des conditions standards (1000 L d'eau par hectare), la concentration recommandée est de 0.25% (250 mL pour 100 L d'eau).

Sélectivité

IBE 4025® est sélectif des cépages couramment plantés en vigne pour la production de raisin de cuve ou de table et en pépinières de vigne (plants mères). Aucun effet négatif sur cultures voisines n'a été observé.

Effets non intentionnels:

IBE 4025® n'a pas d'effet négatif sur la fermentation et la qualité du vin. Les populations d'acariens auxiliaires ne sont pas affectées par des applications d'IBE 4025®

MELANGES

Les mélanges doivent être mis en œuvre conformément à la réglementation en vigueur et aux recommandations des guides de bonnes pratiques officiels.
Nous attirons votre attention sur la nécessité de faire un test de compatibilité physique en procédant à une pulvérisation sur une surface appropriée de la culture.
Si les tests sont concluants (aspects physiques et biologiques), le mélange pourra être appliqué sur une plus grande étendue.

GESTION DU RISQUE DE RÉSISTANCE

Appliquer IBE 4025® selon les instructions données pour le traitement du mildiou de la vigne, à la dose et aux stades de traitement préconisés.
Réaliser un maximum de 3 traitements consécutifs par saison avec un intervalle entre application de 10 à 12 jours.
L'utilisation répétée sur une même parcelle, de préparations à base de substances actives de la même famille chimique, ou ayant le même mode d'action, peut conduire à l'apparition d'organismes résistants.

Pour réduire ce risque, il est conseillé d'alterner ou d'associer, sur une même parcelle, des préparations à base de substances actives de familles chimiques différentes ou à modes d'action différents, tant au cours d'une saison culturale que dans la rotation.
Consultez votre distributeur pour connaître les cas avérés de résistance au niveau de votre région.

PRECAUTIONS D'EMPLOI
Avant l'application :
- Conserver le produit uniquement dans le récipient d'origine, dans un local phytopharmaceutique conforme à la réglementation en vigueur et fermé à clé, à l'abri de l'humidité, du gel, dans un endroit frais, aéré et ventilé, à l'écart des aliments et boissons y compris ceux pour animaux et hors de portée des enfants.

Pendant la préparation de la bouillie et en cours d'application :
- Ne pas manger, boire, fumer.
- Porter un vêtement de protection approprié, des gants et un appareil de protection des yeux et du visage, selon la réglementation en vigueur.
- Vérifier régulièrement et maintenir le bon état et le réglage du matériel d'application, en conformité avec la législation.
- Surveiller le remplissage de la cuve du pulvérisateur et ajuster le volume de bouillie (clapet anti-retour, dispositif de surverse).
- Ne pas souffler dans les buses pour tenter de les déboucher.
- Ne pas respirer les vapeurs, ni le brouillard de pulvérisation.
- Ne pas pulvériser à proximité des points d'eau (mares, cours d'eau, fossés...).
- Ne pas traiter en présence de vent (selon la réglementation en vigueur).

Après application :
- Eliminer les fonds de cuve et les eaux de rinçage conformément à la réglementation en vigueur.
- Ne pas conserver la bouillie de pulvérisation dans la cuve plus de 48 heures.
- Nettoyer très soigneusement avec un produit adapté (type Phytnet) et rincer le pulvérisateur aussitôt après le traitement conformément à la réglementation en vigueur.
- Immédiatement après l'application, nettoyer les équipements de protection, se laver les mains à l'eau savonneuse, prendre une douche et changer de vêtements.

ELIMINATION DU PRODUIT ET DES EMBALLAGES
Lors de l'utilisation du produit, rincer le bidon 3 fois en veillant à verser l'eau de rinçage dans la cuve du pulvérisateur.
Pour l'élimination des produits non utilisables, faire appel à une entreprise habilitée pour la collecte et l'élimination des produits dangereux.
Réutilisation de l'emballage interdite. Eliminer les emballages vides via une collecte organisée par un service de collecte spécifique.

PREMIER SOINS
- En **cas d'ingestion :** Ne pas provoquer le vomissement. Consulter immédiatement un médecin.
- **En cas de contact avec les yeux :** Rincer les yeux immédiatement et abondamment à l'eau courante pendant au moins 15 minutes et maintenir le patient sous surveillance médicale.
- **En cas de contact avec la peau :** Laver immédiatement et soigneusement à l'eau pendant 15 minutes.

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 vente du Ministère de l'Agriculture.
- 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.

GARANTIE - Le fabricant ne donne aucune garantie, explicite ou implicite, relative à l'utilisation du produit d'une autre manière que celle indiquée sur l'étiquette. L'utilisateur sera responsable des risques liés à l'utilisation et/ou la manipulation et/ou l'entreposage de ce produit en cas de non-respect des recommandations de l'étiquette.

RESPONSABILITES - En cas de non-respect de la garantie ou de négligence, le recours de l'utilisateur sera limité au remboursement de dommages et intérêts, à concurrence du prix d'achat, à l'exclusion de tout autre dommage.

Appendix 3 – Letter(s) of Access

Provided upon request.