REGISTRATION REPORT
Part A
Risk Management

Product code: IKF-1216 500 SC
Product name: ONIBI
Chemical active substance:
fluazinam, 500g/L

Southern Zone
Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE
(New application)

Applicant: ISK Biosciences Europe N.V.
Date: 08/06/2020

Table of Contents

PART A
RISK MANAGEMENT

1 Details of the application

The company ISK Biosciences Europe N.V. has requested a marketing authorisation in France for the product ONIBI (product code: IKF-1216 500 SC), containing 500g/L fluazinam; as a fungicide for professional.

The risk assessment conclusions provided in this document are based on the information, data and assessments provided in the Registration Report, Part B Sections 1-10 and Part C, and where appropriate the addendum/addenda for France. The information, data and assessments provided in the Registration Report, Part B include assessment of further data or information as required at national registration by EU regulations. It also includes assessment of data and information related to ONIBI (IKF-1216 500 SC) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of ONIBI (IKF-1216 500 SC) have been made using endpoints agreed in the EU peer review of fluazinam.

This document describes the specific conditions of use and labelling required for France for the registration of ONIBI (IKF-1216 500 SC).

Appendix 1 of this document provides a copy of the product authorisation.

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

Appendix 3 of this document contains a copy of the Letter(s) of Access.

1.1 Application background

The present registration report concerns the evaluation of ISK Biosciences Europe N.V.'s application to market ONIBI (IKF-1216 500 SC) 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 under the trade name of ONIBI (IKF-1216 500 SC) of this product in France and in other MSs of the Southern zone.

The present application (2016-2538) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses) 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")[1] – the highest application rates applied for in the Southern Zone. When risk mitigation measures were necessary, they are adapted to the situation in France.

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[2], 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

[1] 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.

[2] 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.

are based and is not intended to show the assessment in detail.

The conclusions on the acceptability of risk are based on the criteria provided in Regulation (EU) No 546/2011[3], and are expressed as "acceptable" or "not acceptable" in accordance with those criteria.

1.2 Letters of Access

Not necessary: the applicant is the owner of the active substance and/or PPP data.

1.3 Justification for submission of tests and studies

According to the applicant: "*No new vertebrate studies were conducted to support this application. A new dislodgeable foliar residue study was triggered by the worker exposure risk assessment and is submitted. Reference was made to EU evaluated data where possible. All other data were generated to fulfil the requirements of Regulation (EU) 284/2013.*"

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of ONIBI (IKF-1216 500 SC), it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

2 Details of the authorisation decision

2.1 Product identity

Product code	IKF-1216 500 SC
Product name in MS	ONIBI
Authorisation number	N/A : no marketing authorisation granted
Low risk (article 47)	No
Function	Fungicide
Applicant	ISK Biosciences Europe N.V.
Active substance(s) (incl. content)	Fluazinam, 500g/L.
Formulation type	Suspension concentrate (SC).
Packaging	N/A : no marketing authorisation granted
Coformulants of concern for national authorisations	-
Restrictions related to identity	-
Mandatory tank mixtures	None.
Recommended tank mixtures	-

[3] 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.

2.2 Conclusion

The evaluation of the application for ONIBI (IKF-1216 500 SC) resulted in the decision **to refus**e the authorisation.

2.3 Substances of concern for national monitoring

Refer to 5.1.1.

2.4 Classification and labelling

2.4.1 Classification and labelling under Regulation (EC) No 1272/2008

N/A : no marketing authorisation granted.

2.4.2 Standard phrases under Regulation (EU) No 547/2011

N/A : no marketing authorisation granted.

2.4.3 Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)

None.

2.5 Risk management

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[4] provides that:

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

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

Finally, the French Order of 26 March 2014[5] provides that:

- an authorisation granted for a “reference” crop applies also for “linked” crops, unless formally stated in the Decision
- the “reference” and “linked” crops are defined in Appendix 1 of that French Order.

[4] 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, modifié par l’arrêté du 27 décembre.

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

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

Therefore the GAP table (Section 2.3) and Decision may include uses on crops not originally requested by the applicant.

The Decision, as reproduced in Appendix 1, takes also into account national provisions, including national mitigation measures.

2.5.1 Restrictions linked to the PPP

N/A : no marketing authorisation granted.

2.5.2 Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions in addition to those listed under point

2.5.3 (mandatory labelling):

None.

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

2.6 Intended uses (only NATIONAL GAP)

Please note: The GAP Table below reports the intended uses proposed by the applicant, 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.

GAP rev. 1, date: 2020-06-08

PPP (product name/code):	ONIBI/IKF-1216 500 SC	Formulation type:	suspension concentrate (SC) [a, b]
Active substance 1:	Fluazinam	Conc. of a.s. 1:	500g/L [c]
Applicant:	ISK Biosciences Europe N.V.	Professional use:	☒
Zone(s):	Southern Zone [d]	Non-professional use:	☐
Verified by MS:	Yes		
Field of use:	fungicide		

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/ or situation** **(crop destination/purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** 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)	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	FR	Wine grapes	F	*Botrytis cinerea;* (BOTRCI)	broadcast air-assisted sprayer (including atomiser)	In the period of the critical development stages susceptible to disease: from stage "A" (end of flowering), to stage "D" (21 days before harvest*; period from June to September.	1	not relevant	1.2 L/ha	600	100-1200	21*	**Not Acceptable** (Risk for bystanders, residents, and worker) (Risk for operator using an open cab)

* BBCH stages: (A) end of flowering, (B) bunch closure, (C) colour change and (D) 21 days before harvest [stated by applicant].

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 Background of authorisation decision and risk management

3.1 Physical and chemical properties (Part B, Section 2)

ONIBI (IKF-1216 500 SC) is a suspension concentrate (SC). All studies have been performed in accordance with the current requirements and the results are deemed acceptable. The appearance of the product is a homogeneous light-yellow suspension with no characteristic odour. It is not explosive and has no oxidising properties. The product is not flammable and does not self-ignite. In aqueous solution (1%), it has a pH value of 5.4-6.6 at ambient temperature. There is no effect of low and high temperatures on the stability of the formulation, since after seven days at 0°C and 14 days at 54°C, neither the active substance 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 HDPE, PET, HDPE-f and HDPE/PA/EVOH. The technical characteristics are acceptable for an SC formulation.

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

3.2 Efficacy (Part B, Section 3)

3.3 Efficacy data

Considering the data submitted:

o The efficacy level of ONIBI (IKF-1216 500 SC) is considered satisfactory for the requested use.

3.3.1 Information on the occurrence or possible occurrence of the development of resistance

Considering the data submitted:

o There is a risk of resistance developing or appearing to fluazinam for the control of grey mould on wine grape but this does not require monitoring.

Restrictions: None.

Resistance monitoring data: None.

Post-authorisation data: None.

3.3.2 Adverse effects on treated crops

Considering the data submitted:

o The phytotoxicity level of ONIBI (IKF-1216 500 SC) is considered negligible for the requested use.

3.3.3 Observations on other undesirable or unintended side-effects

Considering the data submitted:

- The risks of negative impact on yield, quality, transformation processes, propagation and adjacent crops are considered negligible for the requested use.

4 Methods of analysis (Part B, Section 5)

4.1.1 Analytical method for the formulation

Analytical methods for the determination of the active substance and relevant impurity in the formulation are available and validated.

4.1.2 Analytical methods for residues

Analytical methods are available in the Draft Assessment Report (DAR) and in this dossier and validated for the determination of residues of fluazinam in plants (grapes, apples), foodstuffs of animal origin, soil, water (surface and drinking) and air.

An analytical method is available in the DAR and validated for the determination of residues of fluazinam in tissues and body fluids.

4.2 Mammalian toxicology (Part B, Section 6)

Active substance: **fluazinam**			
ADI	0.01 mg/kg body weight/day		EU (2009)
ARfD	0.07 mg/kg body weight		
AOEL	0.004 mg/kg body weight/day		
AAOEL	None		
Dermal absorption	Based on an *in vivo* rat and a comparative *in vitro* rat and human studies performed on formulation (using a "triple pack" approach):		
		Concentrate (tested) 500g/L	Diluted formulation (tested) 0.5g/L
	In vivo (rat) %	1	5
	In vitro (rat) %	11	59
	In vitro (human) %	5	61
	In vivo human	0.63	5.2
		Concentrate (used in formulation) 500g/L	Spray dilution (used in formulation) 0.5-6g/L
	Dermal absorption end-points %	**0.6**	**5**
Oral absorption	**35**		**EFSA (2008)**

4.2.1 Acute toxicity

ONIBI (IKF-1216 500 SC), containing 500g/L fluazinam, has a low acute oral, inhalational and dermal toxicity, is not irritating to the rabbit skin or eye but is a skin sensitiser.

4.2.2 Operator exposure

Summary of critical use patterns (worst cases):

Crop type	F/G[7]	Equipment *Application method*	Maximum application rate kg product/ha (g a.s./ha)	Minimum volume water (L/ha)
Grapes	F	Vehicle-mounted *Upward spraying*	1.2 L IKF-1216 500 SC/ha (fluazinam: 600 g/ha)	100

Considering the proposed use, operator systemic exposure was estimated using the EFSA model a field study:

- **EFSA model**

Crop	Equipment	PPE and/or working coverall	% AOEL fluazinam
Grapes	Vehicle-mounted *Upward spraying*	Working coverall and gloves during mixing/loading and application	**241**
		Working coverall and gloves during mixing/loading and application and closed cab	30

According to the EFSA model calculations, it may be concluded that the risk for the operator using ONIBI (IKF-1216 500 SC) is acceptable with a working coverall and gloves during mixing/loading and application and with the **use of a closed cab.**

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

Since operator exposure estimations carried out indicated that the acceptable operator exposure level (AOEL) was exceeded under conditions of intended uses according to the German BBA model as well as the UK POEM, a field study measuring the operator exposure (Spence & Just, 2011, KCP 7.2.1/01) was provided by the applicant. As the risk for the operator is acceptable with a working coverall and gloves during mixing/loading and application and with the use of a closed cab according to the EFSA model, this study was not assessed by France as zRMS.

[7] Open field or glasshouse

4.2.3 Worker exposure

EFSA model: Workers may have to enter treated areas after treatment for crop hand-harvesting. Therefore estimation of worker exposure was calculated according to the AOEM model. **Exposure is estimated to be 3030 % of the AOEL of fluazinam with PPE (work wear only). It may therefore be concluded that there is an unacceptable risk anticipated for the worker.**

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

4.2.4 Bystander and resident exposure

EFSA model (no AAOEL): 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 or bystander exposure assessments can be performed with the AOEM model where no AAOEL has been set.

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.*"

Residential exposure was assessed according to the EFSA model[8] incorporating a distance of 10 metres from the spray boom and a drift reduction technology and exposure to vapours refinement*. An unacceptable risk was determined for residents (adult and child):

Model (AOEM) - All pathways (mean)	**% AOEL fluazinam**
Resident (children)	**454**
Resident (adults)	**247**

*Exposure to vapours recalculated according to data provide in a field study (concentration in air of fluazinam at 10 m = 34.5 ng/m³).

4.3 Residues and consumer exposure (Part B, Section 7)

4.3.1 Residues

Toxicological reference values for the dietary risk assessment of fluazinam

Reference value	**Source**	**Year**	**Value**	**Study relied upon**	**Safety factor**
Fluazinam					

8 *EFSA Journal 2014;12(10):3874*

Reference value	Source	Year	Value	Study relied upon	Safety factor
ADI	Review Report	2009	0.01 mg/kg bw/d	2-year mouse, supported by 1-year dog	100
ARfD	Review Report	2009	0.07 mg/kg bw	Rabbit, developmental	100

4.3.1.1 Summary for fluazinam

Summary for fluazinam

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
1	Wine grapes	Yes	Yes	Yes	Yes(1)	Yes (NEU & SEU)	No	No

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1

(1) Covered by storage stability data for fluazinam and AMGT[9] in grapes. Pending storage stability data of AMPA[10]-fluazinam in high-acid-content matrices, it is assumed by France as zRMS that no degradation of AMPA-fluazinam is expected during the storage period of the samples.

Quantifiable residues of fluazinam are expected in wine grapes, therefore an adequate study investigating the effects of processing on the nature of fluazinam residues under standard processing conditions would be desirable.

Data on effects of processing on the amount of residues have been submitted for wine grapes. These data indicate that there is no residues concentration of fluazinam, AMPA-fluazinam and AMGT in must or wine. These data have not been considered for risk assessment as they were not considered to be robust, due to the absence of a study on the effect of processing on the *nature* of the residue.

Since the intended use of IKF-1216 500 SC (ONIBI) on wine grapes only pertain to permanent crops, studies investigating the metabolism in rotational crops are not needed.

Considering dietary burden and based on the intended use, 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.

9 3-[[4-amino-3-[[3-chloro-5-(trifloromethyl)-2-pyridinyl]amino]-2-nitro-6-(trifluoromethyl) phenyl] thio]-2-(beta-D-glucopyranosyloxy) propionic acid.

10 4-chloro-N2-[3-chloro-5- (trifluoromethyl)-2-pyridyl]-3-nitro-5-(trifluoromethyl)-1,2-benzenediamine.

4.3.1.2 Summary for ONIBI (IKF-1216 500 SC)

Information on ONIBI (IKF-1216 500 SC)

Crop	PHI for IKF-1216 500 SC requested by applicant	PHI/withholding period* sufficiently supported for fluazinam	PHI for IKF-1216 500 SC proposed by zRMS	zRMS Comments (if different PHI proposed)
Wine grapes	21 days (FR)	Yes	21 days	-

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

Not relevant.

4.3.2 Consumer exposure

Critical GAP(s) and overall conclusion

The critical GAPs with respect to consumer intake and risk assessment for the preparation IKF-1216 500 SC are presented above. They have been selected from the individual GAPs in the Southern zone for apple and wine grape. A list of all intended uses within the SEU is given in Part B, Section 0.

Overall conclusion

The data available are considered sufficient for risk assessment. No exceedence of the current MRL of 3 mg/kg on wine grapes as laid down in Reg. (EU) 396/2005 is expected.

The chronic and short-term intakes of fluazinam residues are unlikely to present a public health concern. As far as consumer health protection is concerned, France as zRMS agrees with the authorisation of the intended use in France.

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

Data gaps

Noticed data gaps are:

- data on the nature of the residue of fluazinam in processed commodities;
- stability data of AMPA-fluazinam in grapes (high-acid commodities) covering the storage period of residue trial samples.

4.4 Environmental fate and behaviour (Part B, Section 8)

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.

The PEC values of fluazinam and its metabolite 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 the active substance and its metabolites are used for the ecotoxicological risk assessment, and mitigation measures are proposed.

PECgw values for fluazinam and its metabolite 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. Therefore no unacceptable risk of groundwater contamination is expected for the intended use.

4.5 Ecotoxicology (Part B, Section 9)

The ecotoxicological risk assessment of the formulation was performed according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU conclusions for the active substance and its/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.

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

According to new requirements of Reg. No. 284/2013, data on chronic effects on adult bees and on development of bees should have been submitted by the applicant, as exposure of bees to the formulation cannot be excluded. Therefore, the risk to bees cannot be completely fulfilled. Thus, Member States may consider the risk for bees as “not finalised”, or require mitigation measures to avoid exposure of bees, and/or request chronic adult and larvae toxicity studies at post-registration. **At national level, France as zRMS will conclude that the risk for bees is not finalised.**

4.6 Relevance of metabolites (Part B, Section 10)

Not relevant.

5 Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)

The active substance is not approved as a candidate for substitution, therefore a comparative assessment is not foreseen.

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

When the conclusions of the assessment is “Not acceptable”, please refer to relevant summary under point 3 “Background of authorisation decision and risk management”.

6.1.1 Post-authorisation monitoring

N/A : no marketing authorisation granted.

Appendix 1 Copy of the product authorisation

Liberté • Égalité • Fraternité
RÉPUBLIQUE FRANÇAISE

anses

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 la demande associée du produit phytopharmaceutique ***ONIBI***

de la société	*ISK BIOSCIENCES EUROPE N.V*
enregistrées sous les	*n°2016-2538 et 2017-1416*

Vu les conclusions de l'évaluation de l'Anses du 30 avril 2020,

Considérant que l'exposition liée à l'utilisation du produit est supérieure au niveau acceptable d'exposition au fluazinam pour le travailleur, les résidents et les personnes présentes,

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.

ONIBI
AMM n°-

Page 1 sur 3

Liberté • Égalité • Fraternité
RÉPUBLIQUE FRANÇAISE

anses

Informations générales sur le produit	
Nom du produit	ONIBI
Type de produit	Produit de référence
Titulaire	ISK BIOSCIENCES EUROPE N.V Pegasus Park De Kleetlaan 12B - Box 9 B-1831 Diegem Belgique
Formulation	Suspension concentrée (SC)
Contenant	500 g/L - fluaziname
Numéro d'intrant	728-2016.01
Numéro d'AMM	-
Fonction	Fongicide
Gamme d'usage	Professionnel

A Maisons-Alfort le, 08 JUIN 2020

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)

Liberté • Égalité • Fraternité
RÉPUBLIQUE FRANÇAISE

anses

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)**
12703205 Vigne*Trt Part.Aer.* Pourriture grise	1,2 L/ha	1/an	21
	Motivation du refus : L'usage sur raisin de cuve, est refusé en raison d'un risque d'effet nocif pour le travailleur, les résidents, les personnes présentes et pour l'opérateur dans le cas d'un traitement avec tracteur sans cabine.		

Appendix 2 Copy of the product label

Proposed draft label

FONGICIDE

Sekoya

Contient : 500 g/l de fluazinam

Pour la vigne.
Contre la pourriture grise.
Distribué par :
Syngenta France SAS
12, Chemin de l'Hobit, 31790 Saint-Sauveur
SAS au capital de 111 447 427 EUR
R.C.S. – RSAC Toulouse 443 716 832
Numéro de TVA intra-com. : FR 11 443 716 832
N° d'agrément MP02249 : distribution de produits phytopharmaceutiques
à des utilisateurs professionnels

Product names marked ® or ™, the ALLIANCE FRAME
The SYNGENTA Logo and the PURPOSE ICON are Trademarks of a Syngenta Group Company
4 x 5 litres

CRAINT LE GEL

POIDS BRUT/
27,60 KG
EN CAS D'ACCIDENT DE TRANSPORT SERVICE D'URGENCE
TEL: 06 11 07 32 81
®1 Marque enregistrée par
ISK Biosciences Europe NV.

4x5 litres

1002724

FRAN/10S 7-3105-200-160-13/15

Appel en cas d'urgence : 15 ou centre antipoison puis signalez vos symptômes au réseau Phyt'attitude (appel gratuit depuis un poste fixe).
500 g/l (38,8 %) de fluazinam - Suspension concentrée (SC)
AMM n° 9700467

CARACTÉRISTIQUES DU PRODUIT

SEKOYA®1 (formulation suspension concentrée) est le premier fongicide anti-botrytis ayant une action multi-site. Le fluazinam (famille des Pyridinamines) bloque une étape clé de la respiration des

mitochondries, site de production d'énergie de la cellule. Il agit également sur la perméabilité des membranes cellulaires à l'eau et aux ions potassium. Ces mécanismes conduisent à la mort du champignon.

Il agit par contact et inhibe le champignon à différents stades de son développement (germination et croissance mycélienne). Il a une action préventive.

Le mode d'action du fluazinam étant multi-site, la probabilité d'apparition de résistance est trés faible. SEKOYA a donc un intérêt dans la stratégie anti-résistance. Comme pour tous les anti- botrytis, il est recommandé de ne pas utiliser SEKOYA plus d'une fois par saison.

SEKOYA respecte les auxiliaires comme les typhlodromes.
SEKOYA est sélectif des variétés de raisins de cuve.
®1 Marque enregistrée par ISK Biosciences Europe NV. Détenteur de l'Autorisation : ISK Biosciences Europe NV.

PRÉCONISATIONS D'EMPLOI

TABLEAU DES USAGES

Nouveau catalogue des usages (arrêté du 26 mars 2014) : L'utilisation de ce produit est préconisée uniquement sur les cultures et cibles ci-dessous.

Syngenta France SAS décline en conséquence toute responsabilité en cas d'utilisation du produit sur des cultures ou pour des cibles non préconisées.

En traitement des parties aériennes

CULTURE	USAGE	DOSE PRÉCONISÉE	NOMBRE D'APPLICATION	DAR	ZNT*
Vigne (uniquement sur raisin de cuve)	Pourriture grise	1,0-1,2 l/ha	1	21 jours	5 mètres minimum

Zone non traitée par rapport à un point d'eau temporaire ou permanent.
Les limites maximales de résidus sont consultables à l'adresse suivante :
http://ec.europa.eu/sanco_pesticides/public/index.cfm

PÉRIODES D'APPLICATION
Conseils d'utilisation: SEKOYA peut s'appliquer au stade A (chute des capuchons floraux), B (fermeture de la grappe), C (début véraison) ou D (21 jours avant récolte).

MÉLANGES
Respecter la réglementation en vigueur selon l'arrêté du 7 avril 2010.

CONDITIONS D'EMPLOI POUR LA PROTECTION DE L'OPERATEUR ET DU TRAVAILLEUR
Lors de l'utilisation du produit, porter le vêtement de travail et les Equipements de Protection Individuelle (EPI) suivants :

Vêtement de travail et EPI	Au mélange/ chargement	A l'application	Au nettoyage du matériel de pulvérisation
Gants en nitrile certifiés réutilisables (EN 374-3) ou à usage unique (EN 374-2)	Réutilisables	A usage unique en l'absence de cabine ou en cas d'intervention sur le matériel de pulvérisation*	Réutilisables
Combinaison de travail tissée en polyester 65% / coton 35% avec un grammage de 230 g/m2 ou plus et traitement déperlant	oui	oui	oui
EPI partiel (tablier à manches longues ou blouse) de catégorie III type PB (3) à porter par-dessus la combinaison de travail précitée	oui	-	oui
Combinaison de protection de catégorie III type 4 avec capuche	-	En l'absence de cabine	-
Lunettes de sécurité ou écran facial certifié EN 166 (CE, sigle 3) ou EN 170 (protection des yeux) Bottes de protection certifiées	oui	En l'absence de cabine	oui
EN 13832-3	oui	oui	oui

Ces gants ne doivent être portés qu'à l'extérieur de la cabine et stockés après utilisation à l'extérieur de la cabine

Lors de la rentrée du travailleur sur la parcelle traitée, porter le vêtement de travail et l'EPI suivant:

Combinaison de travail tissée en polyester 65% / coton 35% avec un grammage de 230 g/m2 ou plus, et traitement déperlant.
Gants en nitrile certifiés EN 374-3

Attention
H317 - Peut provoquer une allergie cutanée.
H361d - Susceptible de nuire au fœtus.
H410 - Très toxique pour les organismes aquatiques, entraîne des effets néfastes à long terme.
P202 - Ne pas manipuler avant d'avoir lu et compris toutes les précautions de sécurité.
P280 - Porter des gants de protection/des vêtements de protection (se reporter au livret de l'étiquette pour le détail des protections aux différentes phases).

P302 + P352 : EN CAS DE CONTACT AVEC LA PEAU : laver abondamment à l'eau et au savon.
P308 + P313 : EN CAS d'exposition prouvée ou suspectée : consulter un médecin.
P321 - Traitement spécifique (voir l'information sur l'étiquette).
P333 + P313 : En cas d'irritation ou d'éruption cutanée : consulter un médecin.
Combustible à l'état sec.
Informations supplémentaires santé humaine :
Délai de rentrée dans la parcelle : 48 heures
Pour le travailleur qui serait amené à intervenir sur les parcelles traitées, porter des gants en nitrile certifiés EN 374-3 et une combinaison de travail tissée en polyester 65 % / coton 35 % avec un grammage de 230 g/m2 ou plus, et traitement déperlant.
Informations supplémentaires environnement :
SPe3 - Pour protéger les organismes aquatiques, respecter une zone non traitée de 5 mètres au minimum par rapport aux points d'eau.
SP1 - Ne pas polluer l'eau avec le produit ou son emballage.
EUH401 - Respectez les instructions d'utilisation pour éviter les risques pour la santé humaine et l'environnement.
Autres conditions d'utilisation et précautions d'usage : lire attentivement le livret.

PRODUIT POUR LES PROFESSIONNELS

www.syngenta.fr

®1 Marque enregistrée par ISK Biosciences Europe NV.
Détenteur de l'Autorisation : ISK Biosciences Europe NV.

FICHES DE DONNÉES DE SÉCURITÉ : www.quickfds.com

CRAINT LE GEL

Appendix 3 Letter of Access

Not applicable.