

REGISTRATION REPORT

Part A

Risk Management

Product code: IKF-309 180SC

Product name(s): PROPERTY 180SC

Chemical active substance(s):

pyriofenone, 180g/L

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(Label extension)

Applicant: ISK Biosciences Europe N.V

Date: 22/05/2019

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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 PROPERTY 180 SC (formulation code: IKF-309 180SC), containing 180g/L pyriofenone as a fungicide for professional uses.

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 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 PROPERTY 180 SC (IKF-309 180SC) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of PROPERTY 180 SC (IKF-309 180SC) have been made using endpoints agreed in the EU peer review of pyriofenone.

This document describes the specific conditions of use and labelling required for France for the registration of PROPERTY 180 SC (IKF-309 180SC).

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 PROPERTY 180 SC (IKF-309 180SC) 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 label extension and the modification of conditions of use of this product in France and in other MSs of the Southern zone.

The present application (2017-3261 and 2017-3262) 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 assessment of the application submitted for this product is in compliance with Regulation (EC) no 1107/2009², 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 on the acceptability of risk are based on the criteria provided in Regulation (EU)

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.

No 546/2011³, 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 PPP data.

1.3 Justification for submission of tests and studies

According to the applicant: “*Since this product was previously registered there have been changes in data requirements; therefore where necessary in order to amend the conditions of the authorization and extend the label new tests and study reports are provided.*”

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of PROPERTY 180 SC (IKF-309 180SC), 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-309 180SC
Product name in MS	PROPERTY 180 SC
Authorisation number	2140180
Low risk (article 47)	No
Function	Fungicide
Applicant	ISK Bioscience Europe N.V
Active substance(s) (incl. content)	Pyriofenone, 180g/L
Formulation type	Suspension concentrate (SC)
Packaging	-
Coformulants of concern for national authorisations	-
Restrictions related to identity	-
Mandatory tank mixtures	None
Recommended tank mixtures	None

2.2 Conclusion

The evaluation of the application for PROPERTY 180 SC (IKF-309 180SC) resulted in the decision **to grant** the authorization.

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.

2.3 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

Classification not changed.

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

SP 1	Do not contaminate water with the product or its container. Do not clean application equipment near surface water. Avoid contamination <i>via</i> drains from farmyards and roads.
SPe 3	To protect aquatic organisms respect an unsprayed buffer zone of 5 metres to surface water bodies.
	For other restrictions refer to 2.5

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 4th May 2017⁴ 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 2014⁵ 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

⁴ Arrêté du 4 mai 2017 relatif à la mise sur le marché et à l'utilisation des produits phytopharmaceutiques et de leurs adjutants 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/AGR1632554A/jo/texte>.

⁵ <http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGR1407093A/jo>

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 extrapolation⁶ 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

The authorisation of the PPP is linked to the following conditions:

Operator protection:	
-	refer to the Decision in Appendix 1 for the details
Worker protection:	
-	refer to the Decision in Appendix 1 for the details
Integrated pest management (IPM)/sustainable use:	
	-
Environmental protection	
SPe 3	To protect aquatic organisms, respect an unsprayed buffer zone of 5 meters to surface water bodies.
Other specific restrictions	
Re-entry period	48 hours

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 2.5.1 (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 a use is "acceptable" with GAP restrictions, the modifications of the GAP are in bold.

PPP (product name/code):	PROPERTY 180SC (IKF-309 180SC)	Formulation type:	Suspension concentrate (SC) ^(a, b)
Active substance 1:	pyriofenone	Conc. of as 1:	180g/L ^(c)
Safener:	-	Conc. of safener:	- ^(c)
Synergist:	-	Conc. of synergist:	- ^(c)
Applicant:	ISK Biosciences Europe N.V	Professional use:	<input checked="" type="checkbox"/>
Zone(s):	southern ^(d)	Non professional use:	<input type="checkbox"/>
Verified by MS:	Yes		
Field of use:	fungicide		

GAP rev. 1, date: 2019-05-22

^(a) Suspension concentrate (SC)

^(b) 180g/L

^(c) -

^(d) -

^(e) -

^(f) -

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ^(e)	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha ^(f)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg 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	Wheat, rye, triticale, spelt (TRZAW TRZAS SECCW SECCS, TTLSO TTLSS TTLWI TRZSP)	F	Powdery mildew (<i>Blumeria graminis</i>)	Tractor mount- ed/ trailed boom sprayer fitted with hydrau- lic noz- zles	BBCH 30 to 65	a) 1 b) 1		a) 0.5L/ha b) 0,5L/ha	a) 90 g as/ha b) 90 g as/ha	200 / 300	nr	Acceptable with further restriction Restriction to 1 application per crop and season for resistance management in France. Monitoring on <i>B.</i> <i>graminis</i> f. sp

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ^(e)	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha ^(f)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
													<i>tritici</i> and f. sp <i>hordei</i> required.
2	FR	Barley, Oats (HORVW HORVS AVESS)	F	Powdery mildew (<i>Blumeria graminis</i>)	Tractor mount- ed/ trailed boom sprayer fitted with hydrau- lic noz- zles	BBCH 30 to 50	a) 1 b) 1		a) 0.5L/ha b) 0,5L/ha	a) 90 g as/ha b) 90 g as/ha	200 / 300	nr	Acceptable with further restriction Restriction to 1 application per crop and campaign for resistance management in France. Monitoring on <i>B.</i> <i>graminis</i> f. sp <i>tritici</i> and f. sp <i>hordei</i> required.

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/homelacatures 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)

PROPERTY 180 SC (IKF-309 180SC) is a suspension concentrates (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 a beige, odourless SC, It is not explosive and has no oxidising properties. The product is not flammable. It has a self- ignition temperature $> 400^{\circ}\text{C}$. In aqueous solution (1%), it has a pH value of 7.2 at 20°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. Its technical characteristics are acceptable for a SC formulation.

The physico-chemical properties of the formulation have been evaluated and considered acceptable during the registration of this formulation. The intended concentrations claimed for the extension uses (concentrations from 0.1% to 0.25 v/v) are covered by the concentrations authorized during the registration of this 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:

- The efficacy level of PROPERTY 180 SC (IKF-309 180SC) is considered as satisfactory for the claimed uses. In France, the control of powdery mildew in cereals generally not exceeding one fungicide treatment per season, and **regarding the risk of resistance of powdery mildew to molecules of the phenyl-ketone family, the number of applications of PROPERTY 180 SC (IKF-309 180SC) is limited to one application per campaign in cereal crops.**
- The phytotoxicity level of PROPERTY 180 SC (IKF-309 180SC) is considered as negligible for all the claimed uses.
- The risks of negative impact on yield, quality and propagation are considered as negligible.
- The risk of negative impact on processing procedures (bread and beer-making) is considered as acceptable.
- The risks of negative impact on succeeding and adjacent crops are considered as negligible.
- The risk of resistance development of powdery mildew to pyriofenone requires monitoring data in wheat and barley.

3.4 Methods of analysis (Part B, Section 5)

3.4.1 Analytical method for the formulation

Analytical method for the determination of the active substance in the formulation is available and validated. As the active substance pyriofenone does not contain relevant impurity, no analytical method is required.

3.4.2 Analytical methods for residues

Analytical methods are available in the Draft Assessment Report and in this dossier and validated for the determination of residues of pyriofenone in plants (high oil content), soil, water (surface and drinking) and air.

3.5 Mammalian toxicology (Part B, Section 6)

Endpoints used in risk assessment

Active Substance: pyriofenone			
ADI	0.07 mg/kg body weight/day	EU (2014)	
ARfD	not required		
AOEL	0.15 mg/kg body weight/day		
Dermal absorption	Based on an <i>in vitro</i> human study performed on formulation (DAR representative formulation):	Concentrate (tested) 180g/L	Diluted formulation (tested) 0.18g/L
	<i>In vitro</i> (human) %	0.3%	12%
		Concentrate (used in formulation) 180g/L	Spray dilution (used in formulation) 0.3-0.45g/L
	Dermal absorption endpoints %	0.3%	12%

3.5.1 Acute toxicity

PROPERTY 180 SC (IKF-309 180SC) containing 180g/L pyriofenone has a low toxicity in respect to acute oral, inhalation and dermal toxicity and is not irritating to the rabbit skin or eye and is not a skin sensitisier.

3.5.2 Operator exposure

Summary of critical use patterns (worst cases):

Crop type	F/G ⁷	Equipment Application method	Maximum application rate kg as /ha	Minimum volume water (L/ha)	Max. number (min. interval between applications)
Cereals (wheat, rye, triticale, spelt, barley, oats)	F	Vehicle mounted <i>Downward spraying</i>	0.5L product/ha (0.09kg pyriofenone/ha)	200	2 (14 days)

Considering proposed uses, operator systemic exposure was estimated using the EFSA model⁸:

Crop	Equipment	PPE and/or working coverall	% AOEL pyriofenone
Cereals	Vehicle mounted <i>Downward spraying</i>	Working coverall and gloves during mixing/loading and application	0.27

According to the model calculations, it can be concluded that the risk for the operator using PROPERTY 180 SC (IKF-309 180SC) is acceptable with a working coverall and gloves during mixing/loading and application.

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

3.5.3 Worker exposure

Workers may have to enter treated areas after treatment for crop inspection activities. Therefore, estimation of worker exposure was calculated according to AOEM model. Exposure is estimated to 1.74 % of the AOEL of pyriofenone without PPE.

It is concluded that there is no unacceptable risk anticipated for the worker.

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

3.5.4 Bystander and resident exposure

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 set⁹.

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*

⁷ Open field or glasshouse.

⁸ AOEM – Agricultural Operator Exposure Model (EFSA Journal 2014;12 (10):3874).

⁹ 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).

covers bystander exposure.”

Residential exposure was assessed according to EFSA model. An acceptable risk was determined for residents (adult and/or child) when no drift reduction technology or mitigation measures such as a buffer zone of 3 meters are taken:

Model (AOEM) - All pathways (mean)	% AOEL pyriofenone
Resident (children)	3.11
Resident (adults)	1.25

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

The data available are considered sufficient for risk assessment. An exceedance of the current MRLs for pyriofenone as laid down in Reg. (EU) 396/2005 is not expected.

The chronic and the short-term intakes of pyriofenone residues are unlikely to present a public health concern.

As far as consumer health protection is concerned, France, zRMS agrees with the authorization of the intended uses on wheat, rye, triticale and spelt.

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

Summary for active substance pyriofenone

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	BBCH sufficiently supported?	Sample storage covered by stability data?	MRL compliance (reg 2016/1)	Chronic risk for consumers identified?	Acute risk for consumers identified?
2	Barley (winter and spring)	Yes	Yes	Yes	Yes	Yes	No	No
2	Oats	Yes	Yes	Yes	Yes	Yes		No
1	Triticale	Yes	Yes	Yes	Yes	Yes		No
1	Spelt	Yes	Yes	Yes	Yes	Yes		No
1	Rye	Yes	Yes	Yes	Yes	Yes		No

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

Information on PROPERTY 180 SC (IKF-309 180SC) (KCA 6.8)

Crop	PHI for PROPERTY 180 SC (IKF-309 180SC) proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for PROPERTY 180 SC (IKF-309 180SC) proposed by zRMS	zRMS Comments (if different PHI proposed)
		Pyriofenone		
Barley (winter and spring)	<BBCH 50	Yes	/	
Oat	<BBCH 50	Yes	/	
Wheat	<BBCH 65	Yes	/	
Triticale	<BBCH 65	Yes	/	
Spelt	<BBCH 65	Yes	/	
Rye	<BBCH 65	Yes	/	

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).

3.6.1 Residues

As residues of pyriofenone do not exceed the trigger values defined in Reg (EU) No 283/2013, there is no need to investigate the effect of industrial and/or household processing.

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.

3.6.2 Consumer exposure

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 is therefore not necessary.

3.7 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 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 of pyriofenone 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.

PEC soil and PECsw derived for the active substance and its metabolites are used for the ecotoxicological risk assessment.

PECgw for pyriofenone and its metabolites do not occur at levels exceeding those mentioned in regulation EC 1107/2009 and guidance document SANCO 221/2000¹⁰.

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 DT₅₀ calculation, no significant contamination of the air compartment is expected for the intended uses.

3.8 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 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, aquatic organisms, mammals, bees and other non-target arthropods, earthworms, other soil macro-organisms and micro-organisms and terrestrial plants are acceptable for the intended uses.

For aquatic organisms, risk is acceptable with an unsprayed buffer zone of 5 meters.

3.9 Relevance of metabolites (Part B, Section 10)

The active substance pyriofenone and metabolites 3HDPM and 2MDPM are predicted to occur in groundwater at concentrations below 0.1µg/L.

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

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

5 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”.

5.1.1 Post-authorisation monitoring

A monitoring of powdery mildew resistance to pyriofenone in wheat and barley should be put in place. Any information that could affect the resistance risk analysis should immediately be provided to ANSES. In all cases, the results of the monitoring put in place should be provided at the time of the renewal of PROPERTY 180 SC (IKF-309 180SC).

¹⁰ Guidance document on the assessment of the relevance of metabolites in groundwater of substances regulated under Council directive 91/414/EEC. Sanco/221/2000-rev10-final, 25 February 2003.

5.1.2 Post-authorisation data requirements

None.

Appendix 1 Copy of the product authorisation



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

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 la demande d'extension d'usage majeur et la demande de modification des conditions d'emploi du produit phytopharmaceutique PROPERTY 180 SC

de la société *ISK BIOSCIENCES EUROPE N.V*
enregistrées sous les n°*2017-3261 et 2017-3262*

Vu les conclusions de l'évaluation de l'Anses du 24 avril 2019,

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

La modification de l'autorisation de mise sur le marché du produit désigné ci-après **est autorisée** dans les conditions précisées dans la présente décision.

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

Avertissement :

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



Informations générales sur le produit	
Noms du produit	PROPERTY 180 SC PROFINITY
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	180 g/L - pyriofénone
Numéro d'intrant	2140296
Numéro d'AMM	2140180
Fonction	Fongicide
Gamme d'usage	Professionnel

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

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

A Maisons-Alfort le,

22 MAI 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)



ANNEXE I : Modalités d'autorisation du produit

Liste des nouveaux usages autorisés

En l'absence de restriction, les usages sont autorisés sur l'ensemble des cultures de la portée de l'usage.

Usages	Dose maximale d'emploi	Nombre maximum d'applications	Stade d'application BBCH	Délai avant récolte (jours)	Zone Non Traitée aquatique (mètres)	Zone Non Traitée arthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Mention abeilles
15103206 Avoine*Ttr Part.Aer.* Oidium(s)	0,5 L/ha	1/an	entre les stades BBCH 30 et BBCH 50	F (BBCH 50)	5	-	-	-
Diminution du nombre maximal d'applications de 2 à 1 en raison d'un risque de résistance de l'oidium à la pyriofénone.								
15103225 Orge*Ttr Part.Aer.* Oidium(s)	0,5 L/ha	1/an	entre les stades BBCH 30 et BBCH 50	F (BBCH 50)	5	-	-	-
Diminution du nombre maximal d'applications de 2 à 1 en raison d'un risque de résistance de l'oidium à la pyriofénone.								



Liste des usages autorisés concernés par la modification de l'autorisation

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

Usages	Dose maximale d'emploi	Nombre maximum d'applications	Stade d'application BBCH	Délai avant récolte (jours)	Zone Non Traitée aquatique (mètres)	Zone Non Traitée arthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Mention abeilles
15103209 Blé*Trt Part.Aer.* Oridium(s)	0,5 L/ha	1/an	entre les stades BBCH 30 et BBCH 65	F (BBCH 65)	5	-	-	-
L'augmentation du nombre maximal d'applications de 1 à 2 est refusée en raison d'un risque de résistance de l'oidium à la pyriofénone.								
00125016 Seigle*Trt Part.Aer.* Oridium(s)	0,5 L/ha	1/an	entre les stades BBCH 30 et BBCH 65	F (BBCH 65)	5	-	-	-
L'augmentation du nombre maximal d'applications de 1 à 2 est refusée en raison d'un risque de résistance de l'oidium à la pyriofénone.								



Conditions d'emploi du produit

Protection de l'opérateur et du travailleur

Les équipements de protection individuelle ci-après sont applicables à tous les usages du produit.

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

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

Pour l'opérateur, porter

Dans le cadre d'une application avec un pulvérisateur à rampe

• pendant le mélange/chargement

- Gants en nitrile certifiés EN 374-3 ;
- Combinaison de travail en polyester 65 %/coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant ;
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus la combinaison précitée ;

• pendant l'application

Si application avec tracteur avec cabine

- Combinaison de travail en polyester 65 %/coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant ;
- 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 ;

Si application avec tracteur sans cabine

- Combinaison de travail en polyester 65 %/coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant ;
- Gants en nitrile certifiés EN 374-2 à usage unique, dans le cas d'une intervention sur le matériel pendant la phase de pulvérisation ;

• pendant le nettoyage du matériel de pulvérisation

- Gants en nitrile certifiés EN 374-3 ;
- Combinaison de travail en polyester 65 %/coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant ;
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus la combinaison précitée.

Pour le travailleur, porter

- Une combinaison de travail (cotte en coton/polyester 35 %/65 % - grammage d'au moins 230 g/m²) avec traitement déperlant et, en cas de contact avec la culture traitée, des gants en nitrile certifiés EN 374-3.



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

- 48 heures.

Protection des personnes présentes et des résidents

Respecter une distance d'au moins :

- 3 mètres entre la rampe de pulvérisation et l'espace susceptible d'être fréquenté par des personnes présentes ou des résidents pour les usages autorisés.

Respect des limites maximales de résidus (LMR)

Pour chaque usage figurant dans la liste des usages autorisés, les conditions d'utilisation du produit permettent de respecter les limites maximales de résidus.

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

Protection de l'eau

- SP 1 : Ne pas polluer l'eau avec le produit ou son emballage. Ne pas nettoyer le matériel d'application près des eaux de surface. Éviter la contamination via les systèmes d'évacuation des eaux à partir des cours d'eau ou des routes.

Protection de la faune

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

Exigences complémentaires post-autorisation

A défaut de transmission de ces données dans les délais impartis à compter de la date de la présente décision, la présente décision pourra être retirée ou modifiée.

Détail de la demande post autorisation	Délai (mois)	Référence (mois)
Mettre en place un suivi de la résistance à la pyriofénone pour l'oïdium du blé et de l'orge. Fournir, aux autorités compétentes, toute nouvelle information susceptible de modifier l'analyse du risque de résistance.	-	-

Appendix 2 Copy of the product label

The draft product label as proposed by the applicant is reported below. The draft label may be corrected with consideration of any new element. The label shall reflect the detailed conditions stipulated in the Decision.



Customer name:
ISK Biosciences Europe N.V.

CCL reference:
177711

Customer reference:
7-319-200-202-13/17

Product description:
316710 - PROPERTY BCP 4 x 5L
FR

Dimensions:
180 x 297 mm

Dimensions insert/label:
0 x 0 mm

Dimensions finished box/label:
180 x 297 mm

Colors:
Cyan Magenta Yellow Black

Page number:
1

Date / date:
14-10-2016
14-10-17

Customer report:
Edwin Vullings

We request you to verify this PDF version in text, dimensions, layout and colors. The values in this PDF give only an indication of the final result, depending on the printing technique and the use to be joined material/label separator that you do not accept responsibility for the outcome of the printing. We do not accept any responsibility for problems with printed approvals.

Approved by customer:
Approved by CCL:
Date: Date:

CCL Label B.V.
[redacted]
P.O. Box 104
5340 AC Helmond
The Netherlands
customerservice@cclabel.com





Customer name:
ISK Biosciences Europe N.V.

CCL reference:
177710

Customer reference:
7-3119-200-202-11/17

Product description:
316709 - PROPERTY BCP 5L FR

Dimensions:
140 x 130 mm

Dimensions insert folded:
0 x 0 mm

Dimensions finished booklet / insert:
140 x 130 mm

Colors:
Cyan Magenta Yellow Black

Page number:
1

Date / time:
11-10-2016
14:33:03

Customer support:
Edwin Vullings

We request you to verify this PDF-proof on text, illustrations, lay-out and colors. The colors in this PDF give only an indication of the final result, depending on the printing technique and the to be printed material. We emphasize that you as client are responsible for the correctness of the delivered artwork, the check on test adoption and other relevant. We do not accept any responsibility for problems with incorrect artwork.

Approved by customer	Approved by CCL
	OKE MODEL
_____ _____ _____ _____	_____ _____ _____ _____
Date: _____._____.2016	Date: _____._____.2016

CCL Label Oss B.V.
IJsselstraat 15
P.O. Box 104
5340 AC Oss
The Netherlands
customerservice@cclind.com

PROPERTY[®]
180 SC



Fongicide anti-oïdium des céréales

Property[®] 180SC est un fongicide à action préventive, curative (dans la phase latente du cycle d'infection) et anti-sporulante.

Contient 180 g/l (16,7% p/p) de pyriofénone sous forme de Suspension Concentrée (SC).

Autorisation de mise sur le marché n° 2140180 délivrée le 14/11/14

PRODUITS POUR LES PROFESSIONNELS | UTILISEZ LES PRODUITS PHOTOPHARMACEUTIQUES AVEC PRÉCAUTION, ARRETEZ TOUTE UTILISATION, LISEZ ET RESPECTEZ LES INFORMATIONS CONCERNANT LE PRODUIT.

Contenu: 5 L e

5 1414572 022893

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

* Marque déposée ISHIIKAWA SANKEI KAISHA, LTD, Japon. Produit de ISK Biosciences Europe N.V.

Distribué par : Belchim Crop Protection France S.A.
Parc Tertiaire de Bois Dieu - 3, Allée des Chevreuils - 69340 LISSIEU

BELCHIM
BC-Crop Protection



Customer name:
ISK Biosciences Europe N.V.
CCL reference:
177715
Customer reference:
7-3119-200-202-14/17
Product description:
316715 - BKL PROPERTY BCP SL
FR INSEAL
Dimensions:
140 x 325 mm
Dimensions insert folded:
0 x 0 mm
Dimensions finished bottle/label:
140 x 130 mm / 140 x 110 mm
Color:
Cyan Magenta Yellow Black

Page number:
Date / time:
1-10-2016
5:42:34
Customer report:

We request you to verify this PDF yourself, illustrations, layout and styling. The colors in this PDF give only an indication of the final result, depending the printing method and the to be printed material. We emphasize that you, as client, are responsible for the correctness of the delivered artwork at the client, as well as the print, web and other applications. We do not accept any responsibility for problems with these materials.

Approved by customer	Approved by CCL OKE MODEL
_____	_____
Date: _____	Date: _____
_____	_____

CCL Label One B.V.
[redacted] 15
P.O. Box 104
5340 AC Oss
The Netherlands
customerservice@cclid.com

ÉLIMINATION DU PRODUIT ET DES ÉMBALLAGES:
 Lors de l'utilisation du produit, rincer le bâton 3 fois en utilisant 1 seau pour le rinçage dans la cuve de préparation.
 Pour l'élimination du produit sans utilisable, faire appel à une entreprise habilitée pour la collecte et l'élimination des produits dangereux.

Réutilisation de l'emballage intérieur: Réutiliser les emballages vides via une collecte organisée par un service de collecte spécifique.

PREMIER SOIN:

- En cas d'ingestion: Il ne pas provoquer le vomissement. Consulter immédiatement un médecin.
- En cas de contact avec les yeux: Rincer les yeux immédiatement et abondamment 15 à 20 minutes pendant au moins 15 minutes et maintenir le patient sous surveillance médicale.
- En cas de contact avec la peau : Laver immédiatement et suffisamment à l'eau pendant 15 minutes.

PROTECTION DE L'OPÉRATEUR ET DU TRAVAILLEUR:
 Pour pratiquer l'application, porter :

- Pantalon de protection/élastique/shorts :
- Gants en nitrile conforme à la norme EN 374-3 ;
- Blouson de protection conforme à la réglementation et selon la norme EN 13 812-3 ;
- Lotisseur et fourrière conforme à la réglementation et selon la norme EN 13 812-3 ;
- Combinaison de tissu 45 % polyéthylène 35% coton d'un grammage d'au moins 250 g/m² grec avec traitement déperlant ;
- EPRI (pétale bleue) ou similaire à la main et échangée de catégorie III et de type PB (3) à porter pendant la combinaison prédictive.
- Pantalon d'application :
- Étagère/collier avec bâton sans cabine :
- Combinaison de travail entoilé en polyester 65% / coton 35% avec un grammage d'au moins 250 g/m² grec avec traitement déperlant;
- Blouson de protection conforme à la réglementation et selon la norme EN 13 812-3 ;
- Gants en nitrile certifiés EN 374-3 2 stages unique dans le cas d'une intervention sur le matériau prédictif et portés après l'extinction de la cabine et doivent être stériles après utilisation à l'extinction de la cabine.
- Stérilisation avec bâton sans cabine :
- Combinaison de travail entoilé en polyester 65% / coton 35% avec un grammage d'au moins 250 g/m² grec avec traitement déperlant;
- Blouson de protection conforme à la réglementation et selon la norme EN 13 812-3;
- Gants en nitrile certifiés EN 374-3 2 stages unique pendant l'application et dans le cas d'une intervention sur le matériau pendant la phase de préparation.

- Pendant le nettoyage du matériel de granuléation :
 - Gants en nitrile certifiés EN 174-2;
 - Bérets de protection conforme à la réglementation et selon norme EN 13 833-2;
 - Lunettes de sécurité conforme à la réglementation et selon norme EN 166;
 - Continuation de travail (bois en pelleteuse 15% / sol 35% avec un grammage de 280 g/m² et plus avec toutes personnes dépourvues de protection);
 - Un patiné bleu ou noir à manche longue de calque III et de type PB 13 à peur par-dessus la cimaise-préfixe.

Pour protéger le travailleur, porter une combinaison de travail 45% polyester/55% coton d'un grammage d'au moins 250 g/m² avec traitement déportant et des gants en nitrile certifiés EN 174-2.

IMPORTEANT

- Respecter les usages, doses, conditions et précautions d'emploi indiqués sur l'étiquetage qui est toujours délivré en fonction de la caractéristique du produit et des applications pour lesquelles il est préparé.
- Conduire sur nos bases, la culture et les traitements nécessaires pour la bonne pratique agricole, en tenant compte, notamment, de la taille factuelle, particulières concernant la variété, la nature du sol, les conditions météorologiques, les maladies, les parasites, les cultures, la récolte et la récolte des engrangements.
- Le fabricant garantit la qualité de ses produits vendus dans le commerce et échange ainsi que leur conformité à l'admission en 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, vérifier la réglementation en vigueur dans le pays importateur.

GARANTIE - Le fabricant, en dehors d'autre garantie, applique sa garantie, relative à l'utilisation du produit d'une manière qui est indiquée sur l'étiquetage. L'utilisateur se responsabilise des risques liés à l'utilisation même de la préparation et/ou l'enseignement de sa utilisation en cas de non-respect des recommandations de l'étiquetage.

RESPONSABILITÉS - En cas de non-respect de la garantie ou de n'importe quelles autres obligations de l'utilisateur, le remède de l'utilisateur sera limité au remboursement de dommages et intérêts, la convocation du propriétaire d'achat, à l'exclusion de tout autre dommage.

   	ATTENTION PROPERTY 180 SC contient 180 g/l (16,7% p/p) de pyridofrone sous forme de suspension concentrée (SC)	<p>Phrases H</p> <p>H311 Susceptible de provoquer le cancer.</p> <p>H411 Toxique pour les organismes aquatiques, avec des effets à long terme.</p> <p>Phrases P</p> <p>P102 Tenir hors de portée des enfants.</p> <p>P202 Ne pas manipuler avant d'avoir lu et compris toutes les précautions de sécurité.</p> <p>P270 Ne pas manger, boire ou fumer en manipulant ce produit.</p> <p>P272 Les vêtements de travail contaminés ne devraient pas sortir du lieu de travail.</p> <p>P280 Porter des gants de protection, des vêtements de protection et un équipement de protection des yeux/du visage.</p> <p>P363 Laver les vêtements contaminés avant réutilisation.</p> <p>P273 Éviter le rejet dans l'environnement.</p> <p>P304 + P313 EN CAS D'EXPOSITION PRÉSUMÉE OU SUSPECTÉE: consulter un médecin.</p> <p>P391 Recueillir le produit répandu.</p> <p>EUH401 Respecter les instructions d'utilisation pour éviter les risques pour la santé humaine et l'environnement.</p> <p>SP1 Ne pas polluer l'eau avec le produit ou son emballage. [Ne pas nettoyer le matériel d'application près des eaux de surface. (Éviter la contamination via les systèmes d'évacuation des eaux à partir des cours de eau ou des ruisseaux).]</p> <p>SP63 Pour protéger les organismes aquatiques, respecter une zone non traitée de 5 mètres par rapport aux points d'eau.</p> <p>Délai de rentrée: 6 heures</p> <p>Distribué par: Beldim Crop Protection France S.A. Parc Tertiaire du Bois Dival - 3, Allée des Chevaliers - 69360 LISSIEUX</p> <p>En cas d'urgence En cas d'intoxication humaine, APPELER LE 15 (appeler un téléphone fixe) OU LE 112 (appeler un téléphone mobile). OU LE CENTRE ANTIVENIN ou contacter la Fédération Française de Sécurité pour signaler vos symptômes au réseau ressources-santeesecurite.fr</p>
6602-40	7-2119-260-202-3-4/17	échéance validité: 16/07/2016

Appendix 3 Letter of Access

Not applicable.