REGISTRATION REPORT

Part A

Risk Management

Product code: 102000023092

Product name: SUBLIEM

Active substances:

pencycuron, 400 g/L

fluoxastrobin, 130 g/L

COUNTRY: FRANCE

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(new application)

Applicant: BAYER S.A.S.

Date: 2019/09/06

Table of Contents

PART A – Risk Management

The company BAYER S.A.S. has requested the marketing authorisation in France for the product SUBLIEM (102000023092), containing 400 g/L pencycuron and 130 g/L fluoxastrobin, 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 SUBLIEM (102000023092) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of SUBLIEM (102000023092) have been made using endpoints agreed in the EU peer reviews of both pencycuron and fluoxastrobin.

This document describes the specific conditions of use and labelling required for France for the registration of SUBLIEM (102000023092).

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.

1 DETAILS OF THE APPLICATION

1.1 Application background

The present registration report concerns the evaluation of BAYER S.A.S.'s application to market SUBLIEM (102000023092) 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

Pencycuron

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 may be authorised. PART B 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 pencycuron, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 March 2011 shall be taken into account. In this overall assessment Member States shall pay particular attention to the protection of large omnivorous mammals. Conditions of use shall include risk mitigation measures, where appropriate. The Member States concerned shall request the submission of confirmatory information as regards: (1) the fate and behaviour in soil of the chlorophenyl and cyclopentyl portions of pencycuron; (2) the fate and behaviour in natural surface water and sediment systems of the chlorophenyl and phenyl portions of pencycuron; (3) the long-term risk to large omnivorous mammals. The Member States concerned shall ensure that the applicant submits to the Commission the information set out in points (1), (2) and (3) by 31 May 2013.

An EFSA conclusion is available (EFSA Journal 2010;8(10):1828). A Review Report is available (SANCO/10188/2011 final rev 1, 20 March 2014).

Fluoxastrobin

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 may be authorised. PART B 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 fluoxastrobin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 22 January 2008 shall be taken into account. In this overall assessment Member States must pay particular attention to: - the operator safety, in particular when handling the undiluted concentrate. Conditions of use shall include adequate protective measures, such as wearing a face shield, - the protection of aquatic organisms. Risk mitigation measures such as buffer zones shall be applied, where appropriate, - the levels of residues of the metabolites of fluoxastrobin, when straw from treated areas is used as animal feeding stuff. Conditions of use shall include restrictions for feeding to animals, where appropriate, - the risk of accumulation in the soil surface, if the substance is used in perennial crops or in succeeding crops in crop rotation. Conditions of use shall include risk mitigation measures, where appropriate. The concerned Member States shall request the submission of: - data to allow a comprehensive aquatic risk assessment to be made taking into account spray drift, run-off, drainage and the effectiveness of potential risk mitigation measures, - data on toxicity of non-rat metabolites if straw from treated areas is to be used as feedstuff. They shall ensure that the notifier at whose request fluoxastrobin 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 (2007) 102, 1-84). A Review Report is available (SANCO/3921/07 final, 28 September 2012).

1.3 Regulatory approach

The present application (2015-6582) 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 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 4 May 2017[2] provides that:
- unless formally stated in the product authorisation, the pre harvest interval (PHI) is at least three days;

[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] Arrêté du 4 mai 2017 relatif à la mise sur le marché et à l'utilisation des produits phytopharmaceutiques et de leurs adjuvants visés à l'article L. 253-1 du code rural et de la pêche maritime https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGRG1632554A/jo/texte

- unless formally stated in the product authorisation, the minimum buffer zone alongside a water body is five metres;
- unless formally stated in the product authorisation, the minimum re-entry period is six hours for field uses and eight hours for indoor uses.

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

The current document (RR) based on Anses's assessment of the application submitted for this product is in compliance with Regulation (EC) no 1107/2009[3], implementing regulations, and French regulations.

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

The conclusions relating to the acceptability of risk are based on the criteria indicated in Regulation (EU) No 546/2011[4], and are expressed as "acceptable" or "not acceptable" in accordance with those criteria.

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.

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

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

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

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of SUBLIEM (102000023092), 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

Not necessary: the applicant is the owner of the active substances and product data.

[3] 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

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

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

[6] 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	SUBLIEM (102000023092)
Authorisation number	-
Function	Fungicide
Applicant	BAYER S.A.S.
Composition	400 g/L pencycuron 130 g/L fluoxastrobin
Formulation type (code)	Suspension concentrate (SC)
Packaging	-

2.2 Classification and labelling

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

Physical hazards	-	
Health hazards	Carcinogenicity, category 2.	
Environmental hazards	Hazardous to the aquatic environment, Acute Hazard, Category 1. Hazardous to the aquatic environment, Chronic Hazard, Category 1.	
Hazard pictograms		
Signal word	Warning	
Hazard statements	H351	Suspected of causing cancer.
	H400	Very toxic to aquatic life.
	H410	Very 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)	EUH208	Contains 1,2-benzisothiazol-3(2H)-one (CAS No. 2634-33-5). May cause an allergic reaction.

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

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

N/A: not registered in France:

2.2.3 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.

GAP, date: 2019-09-06

PPP (product name/code):	SUBLIEM / 102000023092	Formulation type:	SC [a, b]
Active substance 1:	pencycuron (PCC)	Conc. of a.s. 1:	400 g/L [c]
Active substance 2:	fluoxastrobin (FXA)	Conc. of a.s. 2:	130 g/L [c]
Safener:	-	Conc. of safener:	- [c]
Synergist:	-	Conc. of synergist:	- [c]
Applicant:	BAYER S.A.S.	Professional use:	☒
Zone(s):	Southern [d]	Non-professional use:	☐
Verified by MS:	yes		
Field of use:	Fungicide		

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f]
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	France	Potato	F	*Rhizoctonia solani*, *Colletotrichum coccodes*	In furrow	BBCH 00-BBCH 03	a) 1 b) 1	-	a) 3 L/ha b) 3 L/ha	Pencycuron a)b) 1200 g/ha Fluoxastrobin a)b) 390 g/ha	50 - 250	F	**Not acceptable** (MRL)

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 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

SUBLIEM (102000023092) 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 white suspension, with a musty odour. It is not explosive, has no oxidising properties, is not flammable and has a self-ignition temperature of 455 °C. In aqueous solution (1 %), it has a pH value of 6.3. 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 substances' content nor the technical properties were changed. The stability data indicate a shelf life of at least two years at ambient temperature when stored in HDPE. As the stability was performed in HDPE packaging, HDPE/EVOH and HDPE/PA packaging can also be considered acceptable. The technical characteristics are acceptable for an SC formulation.

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

3.1.2 Methods of analysis

Analytical method for the determination of the active substances in the formulation is available and validated. As the active substances fluoxastrobin and pencycuron do not contain any relevant impurity, no analytical method is required.

Analytical methods are available in the Draft Assessment Report (DAR) and this dossier and validated for the determination of residues of fluoxastrobin and pencycuron in plants (high-water-content crops), foodstuffs of animal origin, soil, water (surface and drinking) and air.

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

3.1.3 Mammalian Toxicology

The following endpoints were used for risk assessment purposes.

Active substance: **fluoxastrobin**			
ADI	0.015 mg/kg bw/d		EU (2008)
ARfD	0.3 mg/kg bw		
AOEL	0.03 mg/kg bw/d		
AAOEL	-		
Dermal absorption	Based on default values according to guidance on dermal absorption (EFSA 2012):		
		Concentrate (130 g/L)	Spray dilution (1.6 - 7.8 g/L)
	Dermal absorption endpoints %	**25**	**75**
Oral absorption	80 – 92 % (bile + urine)		

Active substance: **pencycuron**		
ADI	0.2 mg/kg bw/d	EU (2011)
ARfD	Not applicable	
AOEL	0.15 mg/kg bw/d	
AAOEL	-	
Dermal	Based on default values according to guidance on dermal absorption (EFSA 2012):	

absorption		Concentrate (400 g/L)	Spray dilution (4.8 - 24 g/L)
	Dermal absorption endpoints %	**25**	**46**
Oral absorption	46 % (bile, urine, tissues and organs)		

3.1.3.1 Acute Toxicity

The studies on the acute toxicity (oral, dermal and inhalational; skin and eye irritation and sensitisation) were performed in 2004-2006 with an old formulation. Full details of the formulation specification and related bridging statements can be found in the confidential part of the Registration Report (Part C).

SUBLIEM (102000023092) is of very low acute toxicity by the oral, dermal and inhalational routes of exposure in Wistar rats. It is not irritating when applied to the skin and eyes of New Zealand White rabbits. SUBLIEM (102000023092) shows no skin sensitising potential in the (9x) Buehler Patch Test on guinea pigs and in the modified Local Lymph Node Assay on mice.

France (zRMS) has classified fluoxastrobin as a category 2 carcinogen (H351) pending the harmonised European classification. Since SUBLIEM (102000023092) contains more than 1 % of this active substance, the same classification applies.

The classification proposed in accordance with Regulation (EC) No 1272/2008 is shown in Section 2.2.

3.1.3.2 Operator Exposure

The intended use is the treatment of potato tubers during the planting process via in-furrow application. Single tubers are sprayed while directed from the hopper into the furrow. The treated tubers fall into the furrow and soil in the furrow is treated. The planting hill is closed immediately after the treatment (= in-furrow spray application).

The critical use patterns (worst cases) are summarised below:

Crop type	F/G[7]	Equipment application method	Maximum application rate (g a.s./ha)	Minimum volume water
Potato (in-furrow application at planting)	F	Vehicle-mounted/ downward/upward spraying	3 L product/ha (390 g FXA/ha and 1200 g PCC/ha)	50 L/ha

No official model is available that contains this specific exposure scenario. Exposure of operators during spray treatment of potato tubers during planting was investigated in two operator exposure studies. These studies were performed 2001 in the Netherlands during loading and application of a liquid formulation to potato tubers during planting. The two studies were performed with MONCEREN 250 SC (a.s.: pencycuron only) and their data applied to the preparation SUBLIEM (102000023092) for both pencycuron and fluoxastrobin (physico-chemical properties are considered similar).

Summary for pencycuron

WITHOUT ANY COVERALL/GLOVES						
Individual values	Dermal exposure (mg/kg a.s.)	Systemic dermal exposure (corrected by dermal absorption(1)) (mg/kg a.s.)	Inhalational exposure (mg/kg a.s.) (2)	Total systemic exposure (mg/kg a.s.)	Total systemic exposure, normalised (mg/kg bw/d) (3)	% AOEL (4)
min	1.89	0.869	0.00364	0.873	0.105	70
max	7.76	3.57	0.05866	3.63	0.436	**291**

[7] Open field or glasshouse

WITH A COVERALL/GLOVES						
Individual values	Dermal exposure (mg/kg a.s.)	Systemic dermal exposure (corrected by dermal absorption(1)) (mg/kg a.s.)	Inhalational exposure (mg/kg a.s.) (2)	Total systemic exposure (mg/kg a.s.)	Total systemic exposure, normalised (mg/kg bw/d) (3)	% AOEL (4)
min	0.0724	0.0333	0.00364	0.0369	0.004	3
max	0.5724	0.2633	0.05866	0.3220	0.039	26

(1) Default value of 46 % considered for all phases
(2) Considers a breathing rate of 20.8 L/minute
(3) Upon the following assumptions: a max treated area of 6 ha (max value in the studies) corresponding to a handled amount of pencycuron of 7.2g/day, a worst-case body weight of 60 kg
(4) AOEL of pencycuron : 0.15 mg/kg bw/d

Summary for fluoxastrobin

WITHOUT ANY COVERALL/GLOVES						
Individual values	Dermal exposure (mg/kg a.s.kg a.s.)	Systemic dermal exposure (corrected by dermal absorption(1)) (mg/kg a.s.)	Inhalational exposure (mg/kg a.s.) (2)	Total systemic exposure (mg/kg a.s.)	Total systemic exposure, normalised (mg/kg bw/d) (3)	% AOEL (4)
min	1.89	1.42	0.00364	1.424	0.056	**187**
max	7.76	5.82	0.05866	5.88	0.229	**763**
WITH A COVERALL/GLOVES						
Individual values	Dermal exposure (mg/kg a.s.)	Systemic dermal exposure (corrected by dermal absorption(1)) (mg/kg a.s.)	Inhalation exposure (mg/kg a.s.) (2)	Total systemic exposure (mg/kg a.s.)	Total systemic exposure, normalised (mg/kg bw/d) (3)	% AOEL (4)
min	0.0724	0.0543	0.00364	0.0579	0.002	7
max	0.5724	0.4293	0.05866	0.4880	0.019	63

(1) Default value of 75 % considered for all phases
(2) Considers a breathing rate of 20.8 L/minute
(3) Upon the following assumptions: a max treated area of 6 ha (max value in the studies) corresponding to a handled amount of fluoxastrobin of 2.34kg/day, a worst-case body weight of 60 kg
(4) AOEL of fluoxastrobin : 0.03 mg/kg bw/d

According to the study data, it may be concluded that the risk for the operator using SUBLIEM (102000023092) 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.

3.1.3.3 Bystander Exposure

Not relevant considering the intended use.

3.1.3.4 Worker Exposure

Not relevant considering the intended use.

3.1.3.5 Resident Exposure

Not relevant considering the intended use.

3.1.4 Residues and Consumer Exposure

An exceedence of the current MRL of 0.1 mg/kg for pencycuron on potato as laid down in Regulation (EU) No 396/2005 cannot be excluded.

Summary for pencycuron

Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance Reg. 149/2008	Chronic risk for consumers identified?	Acute risk for consumers identified?	Comments
Potato	Yes	Yes	Yes	Yes	**No**	/	/	

Summary for fluoxastrobin

Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance Reg. 2016/1016	Chronic risk for consumers identified?	Acute risk for consumers identified?	Comments
Potato	Yes	Yes	Yes	Yes	Yes	/	/	Risk for consumers not assessed due to MRL exceedence for pencycuron

3.1.5 Environmental fate and behaviour

The fate and behaviour in the environment have been evaluated according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU conclusions were used to calculate predicted environmental concentration (PEC) values for the active 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 PEC values of pencycuron, fluoxastrobin 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 conclusions or agreed in the assessment based on new data provided.

PECsoil and PECsw values derived for the active substances and their metabolites are used for the ecotoxicological risk assessment.

PECgw values for pencycuron, fluoxastrobin and their metabolites 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, when used once every three years. Therefore no unacceptable risk of groundwater contamination is expected for the intended use under these conditions.

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 use.

3.1.6 Ecotoxicology

3.1.6.1 Effects on Terrestrial Vertebrates

Exposure of birds at time of application following in-furrow treatment of potato is unlikely.

For mammals, the risk assessment showed that the toxicity-to-exposure-ratios (TER) for the species of concern, the wild boar, meet the acceptability criteria. An unacceptable risk to mammals from dietary exposure after in-furrow application on potato is thus unlikely.

In addition, the risk from drinking water and secondary poisoning of birds and mammals via prey like fish and earthworms is considered, overall, to be acceptable.

3.1.6.2 Effects on Aquatic Species

All aquatic TER values based on PECsw values correspond with the trigger values, indicating that the use of the product does not raise any direct concern when applied according to the proposed use pattern.

3.1.6.3 Effects on Bees and Other Arthropod Species

Due to the use of the product, no exposure for bees is expected. Therefore the risk can be considered acceptable.

3.1.6.4 Effects on Earthworms and Other Soil Macro-organisms

As demonstrated by acute and chronic studies, no unacceptable effects on earthworms are to be expected from the application of the product according to the proposed use pattern.

The tests with *Folsomia* and *Hypoaspis* also indicate that no adverse effects on other soil non-target macro-organisms are to be expected from the use of the product.

3.1.6.6 Effects on Soil Non-target Micro-organisms

The risk assessment indicates that no adverse effects on soil micro-organisms are to be expected when the product is applied according to the proposed use pattern.

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

Studies with soil-dwelling arthropods conducted with fluoxastrobin and pencycuron "straight" (i.e., single a.s.) formulations show that no unacceptable effects are expected when the product is used as recommended.

In the case of an in-furrow application to potato tubers, no exposure of non-target terrestrial plants to the tuber dressing product in the off-crop area is expected. Therefore a risk assessment is not necessary.

3.1.7 Efficacy

Considering the data submitted:

- The efficacy level of SUBLIEM (102000023092) is considered satisfactory for *Rhizoctonia solani* and acceptable for *Colletotrichum coccodes*.
- The phytotoxicity level of SUBLIEM (102000023092) is considered acceptable for the requested use.
- The risks of negative impact on yield, quality, propagation and succeeding crops are considered acceptable.
- The risk of resistance developing or appearing to fluoxastrobin and pencycuron does not require monitoring for the requested use.

3.2 Conclusions arising from French assessment

Taking into account the above assessment, an authorisation cannot be granted (due to MRL exceedence). 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

3.4.2 N/A: not registered in France. Post-authorisation data requirements

3.4.3 N/A: not registered in France. Label amendments

N/A: not registered in France.

Appendix 1 – Copy of the French Decision

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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 du produit phytopharmaceutique ***SUBLIEM***

de la société *BAYER SAS*

enregistrée sous le *n°2015-6582*

Vu les conclusions de l'évaluation de l'Anses du 29 juillet 2019,

Considérant le risque de dépassement des limites maximales de résidus de pencycuron,

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.

SUBLIEM
AMM n°-

Page 1 sur 3

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anses

Informations générales sur le produit	
Nom du produit	SUBLIEM
Type de produit	Produit de référence
Titulaire	BAYER SAS Département Homologation 16, rue Jean-Marie Leclair CS 90106 69266 LYON CEDEX 09 FRANCE
Formulation	Suspension concentrée (SC)
Contenant	130 g/L - fluoxastrobine 400 g/L - pencycuron
Numéro d'intrant	9863-2015.01
Numéro d'AMM	-
Fonction	Fongicide
Gamme d'usage	Professionnel

A Maisons-Alfort le, 06 SEP. 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)

SUBLIEM
AMM n°-

Page 2 sur 3

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)
01141024 Pomme de terre*Trt Sol*Champignons autres que pythiacées	3 L/ha	1/an	-
	Motivation du refus : L'usage est refusé en raison d'un risque de dépassement des limites maximales de résidus de pencycuron.		

SUBLIEM
AMM n°-

Page 3 sur 3

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

SIDE 1

Subliem
Contient 400 g/l de pencycuron
130 g/l de fluoxastrobine
sous forme de suspension concentrée (concentré fluidifiable) (SC)

Fongicide pour traitement de sol par pulvérisation dans la raie de plantation à la plantation pour lutter contre le rhizoctone et la dartrose
10 L
5.35 / 36° - Viusel Pomme de Terre = PDT

Etiqueté CLP

RESERVE A UN USAGE EXCLUSIVEMENT PROFESSIONNEL

SIDE 2

Tableau(x) des usages :

Culture	Cibles / Usages	Doses	Spécifications d'usage	DAR (en jours) ou Stades cultures (NC=non concerné)	Précautions environnement (voir légendes)
Pomme de terre	Rhizoctone brun, Dartrose	3.0 l/ha	1 trait./campagne pulvérisation dans la raie de plantation	stade BBCH 00 à BBCH 03	1a , 1b

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

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

1. Organismes aquatiques

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

1b. Pour protéger les organismes aquatiques, ne pas appliquer ce produit plus d'une fois tous les deux ans sur pomme de terre uniquement.

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

Champ d'activité

Subliem est destiné au contrôle de deux maladies fongiques de la pomme de terre (usage 01141024 : traitement du sol, champignons autres que pythiacées) :

* le rhizoctone brun (*Rhizoctonia solani*)
* la dartrose (*Colletotrichum cocoodes*)

Mode d'emploi

- *Préparation de la bouillie*

La préparation doit se faire dans un matériel de pulvérisation en bon état de fonctionnement, propre, ne contenant aucun résidu de bouillie d'une pulvérisation précédente.

- *Mélanges et compatibilités*

Pas de mélange recommandé.
Pour connaître le détail pratique de cette mise en oeuvre, il est nécessaire de contacter au préalable le 0 800 25 35 45

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

- *Dose(s) préconisée(s)*

La dose préconisée est la dose homologuée, soit 3 litres par hectare.

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

Application par pulvérisation dans la raie de plantation à la plantation des semences de pomme de terre (volume conseillé de 150 à 250 litres de bouillie par hectare).
Il est indispensable d'équiper la planteuse d'un système de pulvérisation adapté qui permettra de traiter le sol de la raie à l'avant du tubercule ainsi qu'à l'arrière de celui-ci, avant recouvrement.

Attention : en cas de recours à des techniques culturales nouvellement mises en oeuvre par l'utilisateur ou présentant une quelconque spécificité, l'utilisateur doit en informer son fournisseur avant toute utilisation du produit, afin que ce dernier puisse en vérifier la faisabilité avec le fabricant du produit.

- *Programme de traitement*

Une seule application à l'implantation de la culture de pomme de terre

- *Application*

La pulvérisation au niveau du sol dans la raie de plantation doit être bien répartie.

Précautions à prendre

- *Pour le stockage*

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

- *Mesures de protection des individus*

Opérateur
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 :
- Combinaison de travail en polyester 65 %/coton 35 % avec un grammage d'au moins 230 g/m² 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

Travailleur
Après respect du délai de rentrée et dans les cas où le travailleur serait amené à intervenir sur les parcelles traitées : combinaison de travail polyester 65 %/coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant et gants en nitrile certifiés EN 374-3.

- *Pour l'emploi*

- Eliminer les fonds de cuve conformément à la réglementation en vigueur.

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

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

Subliem
400 g/l de pencycuron , soit 36.0% (m/m)
130 g/l de fluoxastrobine , soit 11.7% (m/m)

Attention

H410 - Très toxique pour les organismes aquatiques, entraîne des effets néfastes à long terme.

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

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

Contient du 1,2-Benzisothiazolin-3-one. Peut produire une réaction allergique.

Délai de rentrée des travailleurs dans la zone traitée

6 heures après traitement.

SPe2 - Pour protéger les eaux souterraines, ne pas appliquer ce produit plus d'une fois tous les deux ans sur pomme de terre uniquement.

SPe3 - Pour protéger les organismes aquatiques, respecter une zone non traitée de 5 mètres par rapport aux points d'eau.

Mesures de protection des individus :
Se reporter impérativement au paragraphe de l'étiquette intitulé Précautions à prendre

Ne pas polluer l'eau avec le produit ou son emballage.
Respectez les instructions d'utilisation afin d'éviter les risques pour la santé humaine et l'environnement.

Premiers secours

Conseils généraux :
S'éloigner de la zone dangereuse. Maintenir et transporter la victime en position latérale de sécurité. Enlever immédiatement tout vêtement souillé et le mettre à l'écart.
Inhalation :
Amener la victime à l'air libre. Garder la victime au repos et la maintenir au chaud. Appeler immédiatement un médecin ou un centre AntiPoison.
Contact avec la peau :
Nettoyer avec une grande quantité d'eau et du savon, si disponible, avec du polyéthylèneglycol 400, puis rincer avec de l'eau. Faire appel à une assistance médicale en cas d'apparition d'une irritation qui persiste.
Contact avec les yeux :
Rincer immédiatement et abondamment à l'eau, y compris sous les paupières, pendant au moins 15 minutes. Après les 5 premières minutes, enlever les lentilles cornéennes, si présentes, continuer à rincer l'oeil. Faire appel à une assistance médicale en cas d'apparition d'une irritation qui persiste.
Ingestion :
Ne PAS faire vomir. Appeler immédiatement un médecin ou un centre AntiPoison. Rincer la bouche.

En cas de perte de la Fiche de données de sécurité, celle-ci peut vous être à nouveau fournie sur simple appel au 0 800 25 35 45 ou être consultée sur les sites internet : www.bayer-agri.fr et www.quickfds.com .
En cas d'urgence, appeler le 15 ou le centre antipoison puis signalez vos symptômes au réseau "Phyt'attitude" n° vert 0 800 887 887 (appel gratuit depuis un poste fixe).

Point gélif : -10°C
40°C

Subliem10L33115_V1

81726132
u 3526550024381
g 3526550024404

UN :3082

9 - Matières et objets dangereux divers

Dangereux pour l'environnement

® Marque déposée Bayer
Bayer S.A.S - Bayer CropScience
16, rue Jean-Marie Leclair - CS 90106 - F-69266 Lyon Cedex 09
Fabrication CEE

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

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

Appendix 3 – Letter(s) of Access

Not applicable.