REGISTRATION REPORT

Part A

Risk Management

Product code: SAP100H

Product name(s): JEXTIRP

Active Substance(s):

Clodinafop-propargyl, 100 g/L

Cloquintocet-mexyl, 25 g/L

COUNTRY: FRANCE

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(New application)

Applicant: SAPEC Agro S.A.

Date: 09/01/2019

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PART A – Risk Management

The company SAPEC Agro S.A. has requested marketing authorisation in France for the product JEXTIRP (product code: SAP100H), containing 100 g/L clodinafop-propargyl and 25 g/L cloquintocet-mexyl (safener) for use as an herbicide.

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 JEXTIRP (SAP100H) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of JEXTIRP (SAP100H) have been made using endpoints agreed in the EU peer review(s) of both clodinafop-propargyl and cloquintocet-mexyl.

This document describes the specific conditions of use and labelling required for France for the registration of JEXTIRP (SAP100H).

Appendix 1 of this document provides a copy of the French Decision.

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

Appendix 3 of this document is a copy of the letter(s) of Access.

1 DETAILS OF THE APPLICATION

1.1 Application background

The present registration report concerns the evaluation of SAPEC Agro S.A.'s application to market JEXTIRP (SAP100H) in France as an herbicide (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

Clodinafop-propargyl

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 herbicide 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 clodinafop, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 27 January 2006 shall be taken into account.
An EFSA conclusion is available (EFSA Scientifi report (2005) 34, 1-78 A Review Report is available (SANCO/10530/2005 – rev. 3, 27 January 2006).

1.3 Regulatory approach

The present application (2014-1900) was evaluated in France by the French Agency for Food, Environmental and

Occupational Health & Safety (Anses)[1] in the context of the zonal procedure for all Member States of the Southern zone, taking into account the worst-case uses ("risk envelope approach")[2] – the highest application rates over the Southern Zone. When risk mitigation measures were necessary, they are adapted to the situation in France.

According to the French law and procedures, specific conditions of use are set out in the Decision letter.

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

- unless formally stated in the product authorisation, the pre harvest interval (PHI) is at least three days;
- unless formally stated in the product authorisation, the minimum buffer zone alongside a water body is five metres;
- unless formally stated in the product authorisation, the minimum re-entry period is six hours for field uses and eight hours for indoor uses.

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

The current document (RR) based on Anses's assessment of the application submitted for this product is in compliance with Regulation (EC) no 1107/2009[4], implementing regulations, and French regulations.

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

The conclusions relating to the acceptability of risk are based on the criteria indicated in Regulation (EU) No 546/2011[5], and are expressed as "acceptable" or "not acceptable" in accordance with those criteria.

Finally, the French Order of 26 March 2014[6] provides that:

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

Thus, at French national level, possible extrapolation of submitted data and the corresponding assessment from "reference" crops to "linked" ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is reached on the acceptability of the intended uses on those "linked" crops. The aim of this Order, mainly based on the EU document on residue data extrapolation[7] is to supply "minor" crops with registered plant protection products.

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

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1 French Food Safety Agency, Afssa, before 1 July 2010.

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

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

4 REGULATION (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC.

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

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

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

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 JEXTIRP (SAP100H), 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.

2 DETAILS OF THE AUTHORISATION

2.1 Product identity

Product name (code)	JEXTIRP (SAP100H)
Authorisation number	N/A : no marketing authorisation granted
Function	Herbicide
Applicant	SAPEC Agro S.A.
Composition	100 g/L Clodinafop-propargyl 25 g/L Cloquintocet-mexyl
Formulation type (code)	Emulsifiable concentrate (EC)
Packaging	-

2.2 Classification and labelling

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

Physical hazards		
Health hazards	Skin sens. 1 Eye dam. 1 STOT RE 2 Asp Tox 1	
Environmental hazards	Aquatic Chronic 2	
Hazard pictograms		
Signal word	Danger	
Hazard statements	H304 H317 H318 H373 H411	May be fatal if swallowed and enter airways May cause an allergic skin reaction. Causes serious eye damage. May cause damage to organs through prolonged or repeated exposure if swallowed. 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)	EUH066	Repeated exposure may cause skin dryness or cracking

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: 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: 2019-01-09

PPP (product name/code)	**SAP100H**	**Formulation type:**	**EC**
active substance 1	**clodinafop-propargyl**	**Conc. of as 1:**	**100 g/L**
safener cloquintocet-mexyl		**Conc. of safener:**	**25 g/L**
synergist	**N.A.**	**Conc. of synergist:**	**N.A.**
Applicant:	**SAPEC AGRO S.A.**	**professional use**	☒
Zone(s):	**Southern**	**non professional use**	☐

Verified by MS: **y**

1	2	3	4	5	6	7	8	10	11	12	13	14
Use-No.	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F G 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. safener/synergist per ha e.g. recommended or mandatory tank mixtures
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
1	FR	Wheat (durum and soft) Triticale Rye	F	*Alopecurus myosuroides* *Lolium* spp. *Avena* spp. *Phalaris* spp.	Tractor mounted boom spraying	BBCH13-39	a) 1 b) 1	a) 0.600 b) 0.600	a) 60 b) 60	200-300	**F**	**Not acceptable** **(selectivity for spring cereals and risk for earthworms and other soil macroorganisms)**

Remarks:

(a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.* fumigation of a structure).
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I).
(c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds.
(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR).
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989.
(f) All abbreviations used must be explained.
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench.
(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.
(i) g/kg or g/l.
(j) Growth stage at 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.
(k) The minimum and maximum number of application possible under practical conditions of use must be provided.
(l) PHI - minimum pre-harvest interval.
(m) 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

JEXTIRP (SAP100H) is a brown, with organic solvent odour, emulsifiable concentrate, containing 100 g/L of clodinafop-propargyl and 25 g/L of cloquintocet-mexyl. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. It is not explosive and has no oxidising properties. The product has a flash point of 86°C. It has a self- ignition temperature of 361°C. In aqueous solution (1%), it has a pH value of 5.7 at ambient temperature. 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/EVOH packaging. Its technical characteristics are acceptable for an EC formulation.

The content of H304 compounds is >10% and kinematic viscosity is below 20.5 mm^2/s. Therefore, the formulation is classified H304 Cat.1.

3.1.2 Methods of analysis

3.1.2.1 Analytical method for the formulation

Analytical methods for the determination of the active substances in the formulation are available and validated. As the active substance clodinafop-propargyl and the safener cloquintocet-mexyl do not contain relevant impurity, no analytical method is required.

3.1.2.2 Analytical methods for residues

Analytical methods are available in the Draft Assessment Report and validated for the determination of residues of clodinafop propargyl in plants (dry commodities), food of animal origin, soil, water (surface and drinking) and air.

To update the dossier, a fully validated method and its ILV are required for the determination of cloquintocet mexyl residues (cloquintocet) in dry commodities.

3.1.3 Mammalian Toxicology

Endpoints used in risk assessment

Active Substance: **Clodinafop-propargyl**			
ADI	0.003 mg / kg body weight/day		EU (2007)
ARfD	0.05 mg/kg body weight		
AOEL	0.026 mg/kg body weight/day		
Dermal absorption	Based on default values according to guidance on dermal absorption (Efsa 2012):		
		Concentrate (used in formulation) 100 g/L	Spray dilution (used in formulation) 0.2 g/L
	Dermal absorption endpoints %	**25%**	**75%**
Active Substance: **Cloquintocet-mexyl** (safener)			
ADI	0.04 mg/kg body weight/day		EU agreed endpoint (2016)
ARfD	1 mg/kg body weight		
AOEL	0.05 mg/kg body weight/day		
Dermal absorption	Based on default values according to guidance on dermal absorption (Efsa 2012):		
		Concentrate (used in formulation)	Spray dilution (used in formulation)

		25 g/L	0.05 g/L
	Dermal absorption endpoints %	**25%**	**75%**

3.1.3.1 Acute Toxicity

JEXTIRP (SAP100H) containing 100 g/L clodinafop-propargyl and 25 g/L cloquintocet-mexyl has a low toxicity in respect to acute oral, inhalation and dermal toxicity, is not irritating to the rabbit skin.
It is irritating to the rabbit and it is a skin sensitizer.

3.1.3.2 Operator Exposure

Summary of critical use patterns (worst cases):

Crop	F/G	Equipment	Application rate kg/L product/ha (g as/ha)	Spray dilution (L/ha)	Model
Cereals	F	Tractor mounted/trailed boom sprayer, hydraulic nozzles	0.25 L SAP100H 60 g clodinafop/ha 15 g cloquintocet/ha	-	BBA

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

Crop	Equipment	PPE and/or working coverall	% AOEL clodinafop (0.026 mg/kg bw/d)	% AOEL cloquintocet (0.05 mg/kg bw/d)
Cereals	Tractor mounted/trailed boom sprayer, hydraulic nozzles	Working coverall and gloves during mixing/loading and application	17%	2.2%

According to the model calculations, it can be concluded that the risk for the operator using JEXTRIRP (SAP100H) is acceptable with a working coverall (90% protection factor) and gloves during mixing/loading and application.
For details of personal protective equipment for operators, refer to the Decision in Appendix 1.

3.1.3.3 Bystander Exposure

Bystander exposure was assessed according to EUROPOEM II. Exposure is estimated to 1.2% of the AOEL of clodinafop-propargyl and to 0.2% of the AOEL of cloquintocet-mexyl.
It is concluded that there is no unacceptable risk to the bystander after incidental short-term exposure to JEXTIRP (SAP100H).

3.1.3.4 Worker Exposure

JEXTIRP (SAP100H) is used as herbicidal treatment on several crops where there is no need to re-enter the treated area after application. Worker exposure is considered not relevant.
For details of personal protective equipment for workers, refer to the Decision in Appendix 1.

3.1.4 Residues and Consumer Exposure

Critical GAP(s) and overall conclusion

The data available are considered sufficient for risk assessment. An exceedance of the current MRL of 0.02 mg/kg for clodinafop-propargyl as laid down in Reg. (EU) 396/2005 is not expected; nor an exceedance of the current French MRL of 0.05* mg/kg for the safener cloquintocet-mexyl as laid down in the « Arrêté du 8 novembre 1996 modifiant l'arrêté du 10 février 1989 relatif aux teneurs maximales en résidus de pesticides admissibles dans et sur

les céréales destinées à la consommation humaine ».
The chronic and the short-term intakes of clodinafop-propargyl and the safener cloquintocet-mexyl 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 use(s).

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

Data gaps: None.

Data required in post-authorization: None.

Summary of the evaluation

Summary for clodinafop-propargyl

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance Reg EU 777/2013	Chronic risk for consumers identified?	Acute risk for consumers identified?	Comments
1	Wheat, triticale and rye	Yes	Yes (22 NEU +7 SEU)	Yes	Yes	Yes	No	No	See (1)

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

(1) 22 SEU trials and only 7 SEU trials on wheat grain were carried out according to the intended SEU GAP of JEXTIRP (SAP100H). However, a total of 64 supervised residue trials were carried out on cereals in both Northern and Southern regions, encompassing 4 growing seasons in the framework of the peer review and residues of clodinafop (CGA 193 469) in grains were always below the LOQ, even under more critical conditions than the proposed representative use (later growth stage of application – BBCH 69-73). Therefore, the number of NEU and SEU residue trials on wheat grain is considered as sufficient.

As residues of clodinafop-propargyl 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.

Considering dietary burden and based on the intended uses, a significant intake was calculated for ruminants. However, no modification of MRLs in commodities of animal origin is awaited.

Summary for Cloquintocet-mexyl (safener)

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	French MRL compliance**	Chronic risk for consumers identified?	Acute risk for consumers identified?	Comments
1	Wheat, triticale and rye	Yes	Yes (4 NEU + 4 SEU) (1)	Yes	Yes	Yes	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

** Arrêté du 8 novembre 1996 modifiant l'arrêté du 10 février 1989 relatif aux teneurs maximales en résidus de pesticides admissibles dans et sur les céréales destinées à la consommation humaine

(1) Only 4 NEU trials and 4 SEU trials on wheat were available. However as all residue levels of cloquintocet were below LOQ of 0.02 mg/kg, is considered to be sufficient.

As residues of cloquintocet-mexyl 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 not been investigated but taking into account the specific circumstances of the cGAP uses being considered here, it is very unlikely that residues will be present in succeeding crops.

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

Summary for JEXRIRP (SAP100H)

Crop	**PHI for JEXTIRP (SAP100H) proposed by applicant**	**PHI/ Withholding period* sufficiently supported for**		**PHI for JEXTIRP (SAP100H) proposed by zRMS**	**zRMS Comments (if different PHI proposed)**
		Clodinafop-propargyl	**Cloquintocet-mexyl (safener)**		
Wheat, triticale and rye	NA BBCH 13-39	Yes	Yes	F BBCH 13-39	

NR: not relevant

* Purpose of withholding period to be specified

** F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop).

Waiting periods before planting succeeding crops

Waiting period before planting succeeding crops			**Overall waiting period proposed by zRMS for JEXTIRP (SAP100H)**
Crop group	**Led by clodinafop-propargyl**	**Led by Cloquintocet-mexyl (safener)**	
Not relevant	-	-	-

NR: not relevant

3.1.5 Environmental fate and behaviour

The fate and behaviour in the environment have been evaluated according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU conclusions were used to calculate PEC values for the active substance, the safener 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 of clodinafrop-propargyl, cloquintocet-mexyl 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 derived for the active substance, the safener and their metabolites are used for the ecotoxicological risk assessment.

PECgw for clodinafrop-propargyl, cloquintocet-mexyl and their metabolites do not occur at levels exceeding those mentioned in regulation EC 1107/2009 and guidance document SANCO 221/2000[8]. Therefore, no unacceptable risk of groundwater contamination is expected for the intended uses.

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

3.1.6 Ecotoxicology

The ecotoxicological risk assessment of the formulation was performed according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU conclusions for the active substance(s) 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 terrestrial vertebrates, bees and other non-target arthropods, and micro-organisms can be considered acceptable for the intended uses.

The risk to aquatic organisms following the intended use of JEXTIRP (SAP100H) can be considered acceptable with a 5m unsprayed buffer zone for the uses on cereals.

Since toxicity data for the chronic risk for earthworms and others soil macro-organisms are not available, it is not possible to finalise the risk assessment for these organisms. Therefore it is not possible to conclude to an acceptable risk for earthworms and others soil macro-organisms.

The risk to non-target plants following the intended use of JEXTIRP (SAP100H) can be considered acceptable with a 5 m unsprayed buffer zone.

3.1.7 Efficacy

- The efficacy level of JEXTIRP (SAP100H) is considered acceptable for all the claimed uses.
- The selectivity level of JEXTIRP (SAP100H) is considered acceptable for all the claimed uses, except for spring cereals for which no crop safety trials were submitted.
- The risks of negative impact of JEXTIRP (SAP100H) on quality, bread-making processes and propagation are considered acceptable for the claimed uses.
- The risks of negative impact of JEXTIRP (SAP100H) on succeeding crops are considered acceptable for the claimed uses. Nevertheless, specific attention should be paid to the establishment of replacement and succeeding crops.
- The risks of negative impact of JEXTIRP (SAP100H) on adjacent crops are considered acceptable for the claimed uses. Nevertheless, specific attention should be paid in case of adjacent grass crops regarding the nature of the herbicide.
- The risk of resistance development to JEXTIRP (SAP100H) requires monitoring data for all the claimed uses.

Monitoring data: None.

[8] 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.

3.2 Conclusions arising from French assessment

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

3.3 Substances of concern for national monitoring

No information stated.

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

3.4.1 Post-authorisation monitoring

N/A: Not registered in France.

3.4.2 Post-authorisation data requirements

N/A: Not registered in France.

3.4.3 Label amendments

N/A: Not registered in France.

Appendix 1 – Copy of the French Decision

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anses
agence nationale de sécurité sanitaire alimentation, environnement, travail

Décision relative à une demande d'autorisation de mise sur le marché d'un produit phytopharmaceutique

Vu les dispositions du règlement (CE) N° 1107/2009 du 21 octobre 2009 et de ses textes d'application,

Vu le code rural et de la pêche maritime, notamment le chapitre III du titre V du livre II des parties législative et règlementaire,

Vu la demande d'autorisation de mise sur le marché du produit phytopharmaceutique ***JEXTIRP***

de la société	*SAPEC AGRO France*
enregistrée sous le	*n°2014-1900*

Vu les conclusions de l'évaluation de l'Anses du 16 octobre 2018,

Considérant que les données fournies ne permettent pas d'exclure un risque inacceptable pour les vers de terre et autres macroorganismes du sol,

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.

JEXTIRP
AMM n°-

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Informations générales sur le produit	
Nom du produit	JEXTIRP
Type de produit	Produit de référence
Titulaire	SAPEC AGRO France 2/12 Rue du Chemin des Femmes Immeuble l'Odyssée – Bâtiment A – 3ème Etage 91300 MASSY France
Formulation	Concentré émulsionnable (EC)
Contenant	100 g/L - clodinafop-propargyl 25 g/L - cloquintocet-mexyl
Numéro d'intrant	9637-2014.01
Numéro d'AMM	-
Fonction	Herbicide
Gamme d'usage	Professionnel

A Maisons-Alfort le, 09 JAN. 2019

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

JEXTIRP
AMM n°-

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Liste des usages refusés

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
15105912 Blé*Désherbage	0,6 L/ha	1/an	-
	Motivation du refus : L'usage est refusé en raison d'un manque de données de toxicité chronique permettant d'exclure un risque inacceptable pour les vers de terre et autres macroorganismes du sol. Il est également refusé sur céréales de printemps en raison de l'absence de données de sélectivité.		
15105915 Seigle*Désherbage	0,6 L/ha	1/an	-
	Motivation du refus : L'usage est refusé en raison d'un manque de données de toxicité chronique permettant d'exclure un risque inacceptable pour les vers de terre et autres macroorganismes du sol. Il est également refusé sur céréales de printemps en raison de l'absence de données de sélectivité.		

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

PROJET D'ETIQUETTE

(SURFACE PRINCIPALE)

HERBICIDE

JEXTIRP

Concentré Emulsionnable (EC)

COMPOSITION:

Clodinafop-propargyl 100 g/L (10% p/v)

Numéro d'Autorisation de Mise sur le Marché : XXX

CONTENU NET: XXX

Date de production / numéro de lot : voir emballage

HOMOLOGUE and DISTRIBUE PAR:

SAPEC Agro S.A.
Alameda dos Oceanos
Lote 1.0601.1 -3°A
Parque das Nações
1990-207 Lisboa
Portugal

LIRE TOUTES LES INSTRUCTIONS DE CETTE ETIQUETTE AVANT D'UTILISER LE PRODUIT

USAGE PROFESSIONNEL

(PARTIE GAUCHE)
DONNEES DE SECURITE

Xn

Nocif

R36 Irritant pour les yeux.
R43 Peut entraîner une sensibilisation par contact avec la peau.
R48/22 Nocif : risque d'effets graves pour la santé en cas d'exposition prolongée par ingestion.
R66 L'exposition répétée peut provoquer dessèchement ou gerçures de la peau.
S2 Conserver hors de la portée des enfants.
S13 Conserver à l'écart des aliments et boissons, y compris ceux pour animaux.
S23 Ne pas respirer les vapeurs/aérosols.
S24/25 Éviter le contact avec la peau et les yeux.
S26 En cas de contact avec les yeux, laver immédiatement puis consulter un ophtalmologiste.
S37 Porter des gants appropriés.
S45 En cas d'accident ou de malaise consulter immédiatement un médecin et lui montrer l'emballage ou l'étiquette.

RECOMMENDATIONS EN CAS D'INTOXICATION OU D'ACCIDENT

Premiers soins:
Transporter la personne à l'écart de la zone contaminée.
Enlever immédiatement les vêtements souillés ou éclaboussés.
En cas de contact avec les yeux, rincer avec une grande quantité d'eau pendant au minimum 15 minutes ; ne pas oublier d'enlever les lentilles de contact si la victime en porte.
Laver la peau avec beaucoup d'eau et du savon, sans frotter.
N'administrer aucune substance par voie orale à la victime.
En cas d'ingestion ne pas provoquer de vomissement.
Garder la victime au calme.
Maintenir la température corporelle de la victime.
Vérifier la respiration et pratiquer la respiration artificielle si besoin.
Si la personne est inconsciente, allongez-la sur le côté avec la tête plus basse que le reste du corps et les genoux à demi fléchis (Position Latérale de Sécurité, PLS).
Transporter la victime à l'hôpital et, si possible, apporter l'étiquette ou l'emballage du produit avec elle.

EN AUCUN CAS NE LAISSER LA VICTIME SEULE

EN CAS D'INTOXICATION COMPOSER LE NUMERO DE TELEPHONE D'URGENCE (SAMU : 15 / numéro d'appel d'urgence dans l'ensemble de l'Union Européenne : 112)

N

Dangereux pour l'environnement

R51/53 Toxique pour les organismes aquatiques, peut entraîner des effets néfastes à long terme pour l'environnement aquatique.

POUR EVITER LES RISQUES POUR L'HOMME ET L'ENVIRONNEMENT RESPECTER LES CONSIGNES D'UTILISATION

SP1: NE PAS POLLUER L'EAU AVEC LE PRODUIT OU SON EMBALLAGE (Ne pas nettoyer le matériel près de point d'eau/éviter de contaminer les fossés)

Mesures d'atténuation des risques environnementaux:
Non requis

Mesures d'atténuation des risques de manipulations:
L'utilisateur doit porter des gants de protection durant le phase de préparation et de chargement.

Ne pas entrer dans les champs/cultures traités avant que le produit épandu soit totalement sec.

Elimination de l'emballage: Les emballages vides doivent être rincés trois fois. Les emballages vides doivent être éliminés en accord avec la réglementation locale/nationale en vigueur.

(PARTIE DROITE)

INSTRUCTIONS D'EMPLOI

CARACTERISTIQUES:

Clodinafop-propargyl appartient à la famille chimique des Aryloxyphenoxy-propionate (FOPs).
La matière active clodinafop-propargyl et le phytoprotecteur cloquintocet-mexyl sont absorbés par les feuilles et les plantules. Ces substances sont rapidement transloquées et stockées dans les tissus méristématiques.

L'effet obtenu est l'inhibition de l'enzyme acetyl CoA carboxylase (ACC-ase). 48 heures après l'application, le développement cellulaire des plantes sensibles cesse. Les plantes meurent sous 2 à 3 semaines.

DOSE ET INSTRUCTIONS D'EMPLOI:

Appliquer directement par aspersion en direction du sol pour une couverture totale du produit sur les parties vertes des plantes.

Les doses et volumes recommandés sont:

Culture	Stade de la culture	Dose	Volume	Nombre de traitements
Blé (dur et tendre) Triticale Riz	BBCH 13-39	0.600 L/ha	200-300 l/ha	1

PLANTES CIBLES:

Alopecurus myosuroides (BBCH 13-29), *Avena* spp. (BBCH 13-32), *Lolium* spp. (BBCH 13-32) et *Phalaris* spp. (BBCH 13-29); *Poa annua* (BBCH 13-29).

Préparation de la bouillie:
Commencer à remplir la cuve de pulvérisation avec de l'eau tout en ajoutant la quantité recommandée de produit, puis compléter au volume d'eau requis en tenant compte de la surface à traiter. Maintenir une agitation constante du réservoir pendant la préparation et l'application. Ne pas préparer plus de solution de pulvérisation que nécessaire.

DELAI APRES RECOLTE:

Non requis.

ATTENTION : Toutes les recommandations données ci-dessus résultent d'investigations multiples et rigoureuses. Néanmoins, un nombre de facteurs indépendants de notre volonté (préparation du mélange, application, climatologie, etc) peut influencer les effets. La compagnie garantie la composition, la formulation et le contenu du produit. L'utilisateur est responsable des dommages causés (manque d'efficacité, toxicité en général, résidus, etc) en cas d'inobservance totale ou partielle des instructions de la présente étiquette.

Appendix 3 – Letter(s) of Access

Not applicable.