REGISTRATION REPORT Part A

Risk Management

Product code: CA2134

Product name: CORASIL E P

Chemical active substance:

Dichlorprop-p 2-EHE, 37.4 g/L (25 g/L dichlorprop-p equivalents)

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

Label extension according to Art. 51

Minor uses

Applicant: NUFARM SAS

Date: 2023-04-14

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PART A – Risk Management

The company NUFARM SAS has requested a label extension in France for the CORASIL E P (formulation code: CA2134) according to article 51 Regulation (EC) no 1107/2009¹

This document describes the specific conditions of use and labelling required for extension of the registration of CORASIL E P (CA2134) containing dichlorprop-P in France.

The conclusions of the risk assessment are based on the already existing registration of the preparation in France. Therefore, the evaluation of the current application is limited to the points not covered by the existing registration.

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

CORASIL E P (CA2134) is an emulsifiable concentrate (EC) product containing 25 g/L of dichlorprop-P, for use as a plant growth regulator. The aim of this registration application is to gain a label extension for crops of elementine.

The complete GAP for the national application in France is provided below, under point 2.3.

1.2 Active substance approval

Dichlorprop-P

Commission Implementing Regulation (EU) No 1166/2013 of 18 November 2013 amending Implementing Regulation (EC) No 540/2011 as regards the conditions of approval of the active substance dichlorprop-P.

Specific provisions of Regulation (EU) No 1166/2013 were as follows:

PART A

Only uses as herbicide may be authorised.

As regards cereals, only application in spring may be authorised, at rates not exceeding 800 g active substance per hectare per application.

Use on grassland shall not 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 dichlorprop-P, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 23 May 2006 shall be taken into account.

In this overall assessment Member States shall pay particular attention to the protection of birds, mammals, aquatic organisms and non-target plants.

Conditions of authorisation shall include risk mitigation measures, where appropriate.

An EFSA conclusion is available (EFSA Journal 2012;10(11):2950).

A Review Report is available (SANCO/10016/2006 rev 4, 3rd October 2013).

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

1.3 Regulatory approach

The present application (n°2022-1205) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses)².

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

Since the application is intended for use in France only, the draft Part A was not circulated for comments.

According to the French law and procedures, specific conditions of use are set out in the Decision letter. The French Order of 4th May 2017³ provides that:

- unless formally stated in the product authorisation, the pre harvest interval (PHI) is at least 3 days;
- unless formally stated in the product authorisation, the minimum buffer zone alongside a water body is 5 m;
- unless formally 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, drift buffer zones may be reduced under some circumstances as explained in appendix 3 of the above-mentioned French order.

The data taken into account are those deemed to be valid either at European Union level or at zonal/national level. This part A 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) $N^{\circ}546/2011^{4}$, and are expressed as "acceptable" or "not acceptable" in accordance with those criteria.

Finally, the French Order of 12 April 2021⁵ 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 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.

1.4 Data protection claims

There is no new data submitted with this application.

² French Food Safety Agency, Afssa, before 1 July 2010

Arrêté du 4 mai 2017 relatif à la mise sur le marché et à l'utilisation des produits phytopharmaceutiques et de leurs adjuvants visés à l'article L. 253-1 du code rural et de la pêche maritime, modifié par l'arrêté du 27 décembre 2019.

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

https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000043401456

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

1.5 Letter(s) of access

Not relevant for this application.

2 DETAILS OF THE AUTHORISATION

2.1 Product identity

Product name (code)	CORASIL E P (CA 2134)			
Authorisation number	2030337			
Function	Plant growth regulator			
Applicant	NUFARM SAS			
Composition	25 g/L dichlorprop-P			
Formulation type (code)	Emulsifiable concentrate (EC)			
Packaging	Not relevant for extension of authorisation according article 51.			

2.2 Classification and labelling

2.2.1 Classification and labelling under Directive 99/45/EC

Not relevant for extension of authorisation according article 51.

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

Not relevant for extension of authorisation according article 51.

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

Refer to the decision of product authorization.

2.2.4 Other phrases linked to the preparation

Wear suitable personal protective equipment⁷: refer to the Decision in Appendix 1 of product authorisation.

Re-entry period⁸: 48 hours.

Pre-harvest interval⁹: F (BBCH 73).

Other mitigation measures:

SPe 3: To protect aquatic organisms, respect an unsprayed buffer zone of 5 meters to surface water bodies.

The label must reflect the conditions of authorisation.

If a tractor with cab is used, wearing gloves during application is only required when working with the spray mixture

The legal basis for this is **Titre I Article 3** of the <u>French Order of 4th May 2017concerning the marketing and use of products encompassed by article L. 253-1 of the rural code</u> [that is, plant protection products/pesticides]

According to the French Order of 4th May 2017, PHI cannot be lower than 3 days unless specifically stated in the assessment and decision.

2.3 Product uses

Please note: The GAP Table below reports the intended uses proposed by the applicant, and possible extrapolation according to French Order of 12 April 2021 (highlighted in green), 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.

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

Use should be crossed out when the applicant no longer supports this use.

GAP rev. 1, date: 2023-04-14

EC (a, b)

25 g/L (c)

_ (c)

_ (c)

PPP (product name/code): CORASIL E P / CA2134

Active substance 1: Dichlorprop-P

Safener: -

Synergist: -

Applicant: NUFARM SAS
Zone(s): Southern Zone (d)

Verified by MS: Yes

Field of use: Plant growtg regulator

1	2	3	4	5	6	7	8	9	10	11	12	13	14				
		•	,						Application	n			Application rate	;			Remarks:
No. (6)	state(s)	or situation (crop destination/purpos e of crop)	Fpn G, Gn, Gpn	Fpn G, Gn,	controlled (additionally: developmental stages of the pest or pest group)	Method/K ind	Timing/Growth stage of crop & season	a) per use	applications (days)	a) max. rate per appl.	a) max. rate per appl.	L/ha min/ma	sa h	e.g. g safener/synergist per ha (f)			
Mino	Minor uses according to Article 51 (zonal uses)																
1	FR	Clementine	F		High volume spray	BBCH 71-73	a) 1 b) 1	-	a) 2.5 b) 2.5	a) 62.5 b) 62.5	1500- 2500	F	Acceptable				

Remarks table heading:

- 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

Formulation type:

Conc. of a.s. 1:

Conc. of safener: Conc. of synergist:

Professional use:

Non-professional use:

- (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.

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FRANCE

Remarks columns:

- Numeration necessary to allow references
- 2 Use official codes/nomenclatures of EU Member States
- 3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)
- F: professional field use, Fn: non-professional field use, Fpn: professional and nonprofessional field use, G: professional greenhouse use, Gn: non-professional greenhouse use. Gpn: professional and non-professional greenhouse use. I: indoor application
- 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.
- 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.

- 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
- 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
- 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.
- The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, 11 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

Not relevant for extension of authorisation according article 51.

3.1.2 Methods of analysis

3.1.2.1 Analytical method for the formulation

Not relevant for extension of authorisation according article 51.

3.1.2.2 Analytical methods for residues

A new analytical method for the determination of dichlorprop in orange has been furnished to support the new use (Clementine (High acid content)). This analytical method is not validated.

3.1.3 Mammalian Toxicology

The preparation is already registered in France. If used properly and according to the intended conditions of use, adverse health effects for operators, workers, bystanders and residents will not be expected.

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

3.1.4 Residues and Consumer Exposure

The residue behaviour of the active substance Dichlorprop-p 2-EHE has been evaluated within the EU review process under Article 10 of Regulation (EC) 396/2005 (EFSA, 2017). Information about metabolism is sufficient to evaluate the intended uses in clementine.

3.1.4.1 Residues

Clementines (small citrus) are a major crop in southern Europe and France require only southern residue data in accordance with SANTE/2019/12752. New studies on the magnitude of residue have been submitted by the applicant in the framework of this application. Previously evaluated residue trials are also relied upon.

New data

In total, 4 trials in Southern France, conducted according to a more critical GAP than the intended one are available (1 x 74-77 g a.s./ha instead of 1 x 50-62.5 g as/ha). These new trials submitted in the present dossier have been evaluated but not considered acceptable in the present assessment, since, the analytical method used cannot be considered validated for dichlorprop-P, please, see Section B5 of this fRR.

EU data

In total, 6 trials in Southern Europe, conducted according to a more critical GAP than the intended one are available (1 x 66-89 g a.s./ha instead of 1 x 50-62.5 g as/ha). These trials were previously evaluated and accepted in the EU renewal evaluation (EFSA, 2018).

Moreover, in EFSA, 2017: « In support of the MRL application, the applicant submitted residue trials on mandarins. The fruit samples were analysed according to the residue definitions for enforcement and risk assessment. According to the assessment of the EMS, the methods used were sufficiently validated and fit for purpose. Mandarin samples of these residue trials were stored under conditions (maximum storage of 193 days) for which integrity of the samples has been demonstrated (Spain, 2016). Decline of residues during storage of the trial samples is therefore not expected. In support of the SEU use, 12 residue trials on mandarins were submitted. Four residue trials were disregarded as incompliant with the intended good agricultural practices (GAP) in terms of a number of

applications. The remaining eight trials were conducted in Spain in 2010, 2011 and 2015. The residue trials provide information on residues in the peel, pulp and/or whole fruit at the prehar-vest intervals (PHI) of 0, 14–15 and 44–45 days, thus deviating from the PHI of 20 days of the intended GAP. Nevertheless, the trials were considered acceptable as the growth stages at the time of application were consistent with the GAP. The residue values selected for the MRL estimate were those at the PHI of 14–15 days, unless higher at a longer PHI of 44–45 days. »

These trials (8 trials) were already assessed at EU level in the framework of MRL modification (EFSA 2017) and they were at the origin of the current MRL on mandarin (group of citrus fruits). The access to these data from EFSA, 2017 is verified and accepted, since, the applicant, Nufarm, who submitted the application to the competent national authority in Spain to modify the existing maximum residue levels (MRL) for the active substance dichlorprop-P in citrus fruits (except oranges) (EFSA, 2017) is the same applicant of this submission. Sufficient trials were conducted at a more critical GAP ($2 \times 56,3 - 75 \text{ g}$ a.s./ha, BBCH 73, outdoor), than the intended cGAP, and therefore suitable to rely on in this dossier.

For clarity all studies are summarized in the Table below.

Summary of EU reported and new data supporting the intended uses of CORASIL E P (CA2134) and conformity to existing MRL

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) E = RA ^(a)	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg)	MRL compliance
cGAP: 1 x	EFSA, 2018 ^(b) Ireland, 2018 ^(b)	S-EU	Trials GAP: 1 x 66-89 g a.s./ha, BBCH 73-75, outdoor E/RA: 3x <0.02, 0.05, 0.06, 0.08	0.04	0.08	0.144	0.3	Yes
62.5 g a.s./ha, BBCH 71- 73	New trials	S EU	Trials GAP: 1 x 74 77 g a.s./ha, BBCH 73, oudoor E/RA: 2x 0.01, 0.03, 0.05	0.02	0.05	0.102		
	EFSA, 2017	S-EU	Trials GAP: 2 x 56,3 – 75 g a.s./ha, BBCH 73, outdoor E/RA: 0.06; 0.06; 0.06; 0.07; 0.08; 0.08; 0.12; 0.17	0.08	0.17	0.263		
	Overall supporting data for eGAP	S EU	2x 0.01, 3x <0.02, 0.03, 2x 0.05, 0.06, 0.08	0.03	0.08	0.130		

^{*} Source of EU MRL: Reg. (EU) No. 2017/1777

Therefore, the assessment was based on EU data in order to support the intended use on clementines.

⁽a) Residue definitions for enforcement and risk assessment are identical: Dichlorprop (Sum of dichlorprop (including dichlorprop-P), its salts, esters and conjugates, expressed as dichlorprop).

⁽b) The rationale behind the selection of residue data in the EFSA conclusion is not clear, therefore these previously evaluated trials supporting the intended GAP are presented in Appendix 2 based on the summaries provided in the RAR Volume 3 B.7 (Ireland, 2018).

In accordance with SANTE/2019/12752, data on small citrus (lemons and mandarins) can be extrapolated to support the other small citrus commodities including clementines (0110050-002), which is the case here. In this case, sufficient residue trials are available to support the use of CORASIL E P (CA2134) on clementines in the SEU zone.

→ Sufficient data is available to conclude that results comply with the in-force MRL of 0.3 mg/kg on clementines.

The data available are considered sufficient for risk assessment. An exceedance of the current MRL of 0.3 mg/kg for dichlorprop-p as laid down in Reg. (EU) 396/2005 is not expected.

Citrus dried pulp does contribute to the animal dietary burden. However, a dietary burden calculation was conducted in the 2017 Reasoned Opinion (EFSA, 2017), which remains relevant. EFSA, 2017 included a use on large citrus that results in more critical endpoints (STMR = 0.08 mg/kg). Therefore, the intended use on clementines will not impact the previously assessed animal dietary burden and the conclusions from EFSA, 2017 remain relevant. Further investigation of residues as well as the modification of MRLs in commodities of animal origin is therefore not necessary in the frame of this dossier.

Regarding magnitude of residues in processed commodities, new data on the distribution of residues between peel and pulp were submitted in the framework of this application. However, this new data cannot be assessed in the present dossier, since the study was considered unacceptable due to invalid analytical method. Despite the available data on the processed factors, peeling factor was not used to refine consumer risk assessment calculations, since the contribution of small citrus fruits to the TMDI is <10% of the ADI and the IESTI is <10% of the ARfD.

The crop (clementine) under evaluation is a permanent crop. Further investigation of residues in rotational crops is therefore not required.

According to SANTE/11956/2016 rev. 9, clementine is a melliferous crop. Moreover, dichlorprop-p is reported as a systemic molecule (Table 7.2). However, zRMS is of the opinion that no studies on honey are required on clementine, since CORASIL E P (CA2134) is applied after the flowering period (BBCH 71-73). Therefore, dichlorprop-p residues are not expected to be transferred to honey.

3.1.4.2 Consumer exposure

Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo (rev. 3.1)	5 % (based on NL toddler)
IEDI (% ADI) according to EFSA PRIMo (rev. 3.1)	Not required (TMDI <100 %)
IESTI (% ARfD) according to EFSA PRIMo* (rev. 3.1)	Mandarin: 2 % (based on NL toddler) Mandarin: 0.6 % (based on CZ male 15-17 years)
NTMDI (% ADI) **	Not required
NEDI (% ADI)**	Not required
NESTI (% ARfD) **	Not required

^{*} include raw and processed commodities if both values are required for PRIMo

The proposed uses of dichlorprop-p 2-EHE in the formulation CORASIL E P (CA2134) do not represent unacceptable acute and chronic risks for the consumer.

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

As far as consumer health protection is concerned, France agrees with the authorization of the intended use on clementine.

3.1.5 Environmental fate and behaviour

According to previous risk assessments performed by Anses, no unacceptable risk for groundwater is expected. Similar mitigation measures as defined for previous risk assessment apply.

^{**} if national model is available

3.1.6 Ecotoxicology

According to previous risk assessments performed by Anses, no unacceptable risk for terrestrial and aquatic non-target organisms is expected. Similar mitigation measures as defined for previous risk assessment apply.

3.1.7 Efficacy

According to Article 51 of Regulation (EC) No 1107/2009, the efficacy assessment and the absence of any phytotoxicity risk on the crop is not necessary.

3.2 Conclusions arising from French assessment

Taking into account the above assessment, an authorisation can be granted as proposed in Appendix 1 – Copy of the product Decision.

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

No further information is required.

Appendix 1 - Copy of the French Decision

DocuSign Envelope ID: 09A77839-8813-4F35-8387-9AFB1CF1B0C0





Décision relative à une demande d'extension d'usage 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'extension d'usage mineur du produit phytopharmaceutique CORASIL E P

de la société NUFARM SAS

enregistrée sous le n° 2022-1205

Vu les conclusions de l'évaluation de l'Anses du 16 mars 2023,

L'autorisation de mise sur le marché du produit référencé ci-après est étendue aux usages décrits 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.



Liberté Égalité Fraternité



Informations générales sur le produit						
Nom du produit	CORASIL E P					
Type de produit	Produit de référence					
Titulaire	NUFARM SAS Immeuble West Plaza 11 rue du Débarcadère 92700 COLOMBES France					
Formulation	Concentré émulsionnable (EC)					
Contenant	37,4 g/L – dichlorprop-P 2-EHE (équivalent à 25 g/L de dichlorprop-P acide)					
Numéro d'intrant	2030337					
Numéro d'AMM	2030337					
Fonction	Régulateur de croissance					
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 13/04/2023

—Bocusigned by: Charlotte Grastilleur

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 : Modalités d'autorisation du produit

	Liste des nouveaux usages autorisés En l'absence de mention spécifique, les usages autorisés correspondent à une utilisation en plein champ.									
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)	Culture attractive en floraison (arrêté du 20/11/2021)		
12053813 Agrumes*Trt Part,Aer,*Act,	2,5 L/ha	1/an	entre les stades BBCH 71 et BBCH 73	F (BBCH 73)	5	-	-	Non concerné		
Qual. Fruits	Uniquement su	Dose d'emploi de 0,1 L/hL avec un volume de bouillie maximal de 2500 L/ha. Uniquement sur clémentinier. Usage autorisé dans le cadre de l'article 51 du règlement (CE) n°1107/2009.								

CORASIL E P AMM n°2030337

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Liberté Égalité Fraternité



Conditions d'emploi du produit

Protection de l'opérateur et du travailleur

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

Les équipements de protection individuelle ci-après sont applicables à tous les usages du produit utilisant ce mode d'application.

Dans le cadre d'une application à l'aide d'un pulvérisateur à jet projeté :

• pendant le mélange/chargement

- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A);
- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1;
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter pardessus l'EPI vestimentaire précité ;
- Lunettes ou écran facial certifié norme EN 166 (CE, sigle 3);

• pendant l'application - Pulvérisation vers le haut

Si application avec tracteur avec cabine

- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1;
- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN ISO 374-2 (types A, B ou C) 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

- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 ;
- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN ISO 374-2 (types A, B ou C) 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 NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A);
- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1;
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter pardessus l'EPI vestimentaire précité.

Pour le travailleur, porter

- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 et, en cas de contact avec la culture traitée, des gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A).

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

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

- 48 heures.

CORASIL E P AMM n°2030337



Liberté Égalité Fraternité



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 la faune

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

Recommandations relatives à l'étiquette du produit

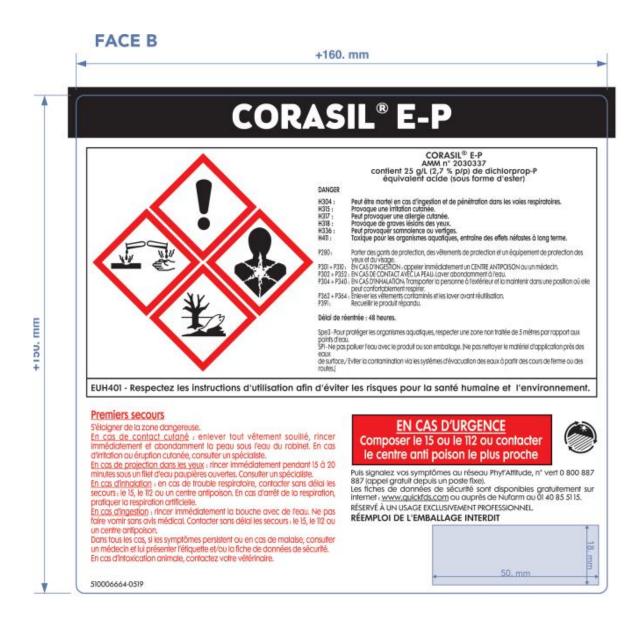
Il est recommandé de faire figurer l'information suivante sur l'étiquette :

- Pour les usages mineurs dont l'autorisation de mise sur le marché a été accordée dans le cadre de l'article 51 du règlement (CE) n°1107/2009, l'attention de l'utilisateur est attirée sur les risques éventuels de phytotoxicité ou de manque d'efficacité.

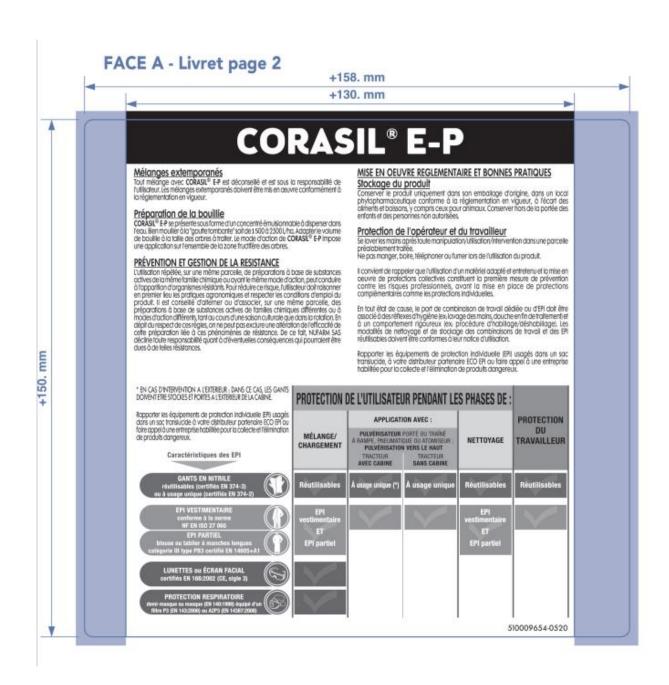
Avant tout emploi du produit, il est recommandé à l'utilisateur de s'assurer de son efficacité ou de l'absence de risques éventuels de phytotoxicité sur la culture.

Les autres modalités d'autorisation du produit restent inchangées.

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











Appendix 3 – Letter(s) of Access

Not applicable