REGISTRATION REPORT

Part A

Risk Management

Product code: DPX-B0634 80 WP

Product name(s): VENZAR

Chemical active substance(s):

Lenacil, 800 g/kg

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

Application for a label extension according to Art. 51

-

Minor uses

Applicant: FMC France

Date: 04 July 2025

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PART A – Risk Management

The company FMC FRANCE has requested a label extension in France for the VENZAR (formulation code: DPX-B0634 80 WP) according to article 51 Regulation (EC) no 1107/2009[1]

This document describes the specific conditions of use and labelling required for extension of the registration of VENZAR (DPX-B0634 80 WP) containing lenacil 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.

1 DETAILS OF THE APPLICATION

1.1 Application background

VENZAR (DPX-B0634 80 WP) is a wettable powder (WP) product containing 800 g/kg of Lenacil, for use as a herbicide for the control of various weeds. The aim of this registration application is to gain a label extension for crops of non-food perfume, aromatic and medicinal plants.

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

1.2 Active substance approval

Lenacil

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 lenacil, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 11 May 2010 shall be taken into account. In this overall assessment Member States must pay particular attention to: -the risk to aquatic organisms, especially algae and aquatic plants. Conditions of authorisation shall include risk mitigation measures, such as bufferzones between treated areas and surface water bodies; -the protection of the groundwater, where the active substance is applied in regions with vulnerable soil or climatic conditions. Conditions of authorisation shall include risk mitigation measures and monitoring programmes shall be initiated to verify potential groundwater contamination from the metabolites IN-KF 313, M1, M2 and M3 in vulnerable zones, where appropriate. The Member States concerned shall ensure that the notifier submits to the Commission confirmatory information on the identity and characterisation of soil metabolites Polar B and Polars and metabolites M1, M2 and M3 which occurred in lysimeter studies and confirmatory data on rotational crops, including possible phytotoxic effects. They shall ensure that the notifier provides such information to the Commission by 30 June 2012.

[1] 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

If a decision on the classification of lenacil under Regulation (EC) No 1272/2008 of the European Parliament and of the Council (3) identifies the need for further information on the relevance of the metabolites IN-KE 121, IN-KF 313, M1; M2, M3, Polar B and Polars, the Member States concerned shall request the submission of such information. They shall ensure that the notifier provides that information to the Commission within six months from the notification of such a classification decision.
An EFSA conclusion is available (EFSA Journal 2009; 7(10):1326). A Review Report is available (SANCO/833/08 – rev. 4, 16 May 2014).

1.3 Regulatory approach

The present application (n°2022-2444) 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 2017[3] 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°546/2011[4], and are expressed as "acceptable" or "not acceptable" in accordance with those criteria.

Moreover, the French Order of 12 April 2021[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.

Finally, the French Order of 20 November 2021[7] on the protection of bees and other pollinating insects and the preservation of pollination services when using plant protection products provides that unless otherwise stated in the

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

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, amended by the arrêté du 27 décembre 2019 relatif aux mesures de protection des personnes lors de l'utilisation de produits phytopharmaceutiques https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGRG1632554A/jo/texte ; https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000039686039&categorieLien=id

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

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

7 https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000044346734

product authorisation, use on attractive crop[8] when in flower and on foraging area is forbidden. Specific conditions of application on flowering crops should be respected. As consequences specific SPe 8 may include reference to this order.

1.4 Data protection claims

There is no new data submitted with this application.

[8] List of culture considered as unattractive to bees and other pollinators insects defined by French Agricultural ministry and published in Bulletin Officiel du ministère chargé de l'agriculture.

1.5 Letter(s) of access

Not relevant for this application.

2 DETAILS OF THE AUTHORISATION

2.1 Product identity

Product name (code)	VENZAR (DPX-B0634 80 WP)
Authorisation number	6400401
Function	Herbicide
Applicant	FMC FRANCE
Composition	Lenacil , 800 g/kg
Formulation type (code)	Wettable powder (WP)
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 equipment[9]: refer to the Decision in Appendix 1 of product authorisation.
Re-entry period[10] : 48 h
Pre-harvest interval[11] : refer to the decision of product authorisation.
Other mitigation measures: refer to the decision of product authorisation. - The by-products from crops must not be used for food or animal feed purposes
The label must reflect the conditions of authorisation.
Respect an unsprayed zone of 3 meters from the extremity of the boom and: - areas where bystanders are present during treatment

[9] If a tractor with cab is used, wearing gloves during application is only required when working with the spray mixture
[10] The legal basis for this is **Titre I Article 3** of the French Order of 4th May 2017concerning the marketing and use of products encompassed by article L. 253-1 of the rural code [that is, plant protection products/pesticides]
[11] According to the French Order of 4th May 2017, PHI cannot be lower than 3 days unless specifically stated in the assessment and decision.

- areas where residents could be present
SPe 1: To protect groundwater, do not use this or any other product containing lenacil more than one year in three on the same field.
SPe 2: To protect aquatic organisms, respect an unsprayed buffer zone of 20 metres and a planted buffer strip of 20 metres to adjacent surface water bodies.
After an application of the product, specify the time periods to be respected after treatment for planting the following crops (replacement or rotation crop) according to their levels of sensitivity to the product.

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: 04/07/2025

PPP (product name/code):	VENZAR / DPX-B0634 80 WP	Formulation type:	WP [a, b]
Active substance 1:	lenacil	Conc. of a.s. 1:	800 g/kg [c]
Safener:	-	Conc. of safener:	- [c]
Synergist:	-	Conc. of synergist:	- [c]
Applicant:	FMC FRANCE	Professional use:	☒
Zone(s):	Southern Zone[d]	Non-professional use:	☐
Verified by MS:	Yes		
Field of use:	Herbicide		

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:**
					Method/Kind	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg 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		e.g. g safener/synergist per ha [f]
Minor uses according to Article 51 (zonal uses)													
1	Fr	PPAM not used for any human consumption	F	Grass and broad-leaved weeds	Tractor mounted sprayer, Broadcast, ground directed spraying	Pre-planting, pre-emergence or post-emergence, post-planting, depending on the crop	a) 1 b) 1	NA 1 application every 3 years	a) 0.625 b) 0.625	a) 500 b) 500		-	**Acceptable**

Remarks table heading:

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008
(c) g/kg or g/l
(d) Select relevant
(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
(f) No authorisation possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

Remarks columns:

1 Numeration necessary to allow references
2 Use official codes/nomenclatures of EU Member States
3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)
4 F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application
5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.
6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.
7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
8 The maximum number of application possible under practical conditions of use must be provided.
9 Minimum interval (in days) between applications of the same product
10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product/ha).
12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
13 PHI - minimum pre-harvest interval
14 Remarks may include: Extent of use/economic importance/restrictions

3 RISK MANAGEMENT

3.1 Reasoned statement of the overall conclusions taken in accordance with the Uniform Principles

3.1.1 Physical and chemical properties

The physico-chemical properties of the formulation have been evaluated taken into account the concentration of uses (concentration from 0.026 % w/v to 0.31 % w/v) and considered acceptable during the registration of this formulation.
The concentrations of uses claimed for this extension of uses (concentration from 0.16% w/v to 0.42% w/v) are not covered by this previously assessment. However, physico-chemical properties provided during the renewal of the preparation were performed at use rates compliant with the proposed claimed concentrations for this use extension (0.43% w/v for persistent foaming and 0.015-0.425% w/v for suspensibility). Data are considered sufficient for this use extension.

3.1.2 Methods of analysis

3.1.2.1 Analytical method for the formulation

Not relevant for extension of authorization according article 51.

3.1.2.2 Analytical methods for residues

No MRL/residue definition is fixed for the proposed uses (PPAMC, not for food/feeding). So, no analytical method is necessary for the determination of residues in these matrices. The intended uses are not used in animal feed. So, no analytical method is necessary for the determination of residues in these matrices.

3.1.3 Mammalian Toxicology

3.1.3.1 Acute toxicity

VENZAR (DPX-B0634 80 WP) containing 800 g lenacil/kg has a low toxicity in respect to acute oral, inhalation and dermal toxicity, is not irritating to the rabbit skin or eye and is not a skin sensitiser.

3.1.3.2 Operator Exposure

Considering proposed uses, operator systemic exposure was estimated using the EFSA model[12]:

Long term exposure

Model data		**Lenacil**
	Level of PPE	**% AOEL**
Application: Vehicle mounted, *Downward spraying* Outdoor Non-edible perfume, medicinal and aromatic crops (low vegetables)		
Application rate		0,5 kg a.s./ha
Spray application (AOEM; 75th percentile) Body weight: 60 kg	Work wear (arms, body and legs covered) M/L and A + gloves	51
Application: Manual Hand held, *Downward spraying* Outdoor Non-edible perfume, medicinal and aromatic crops (low vegetables)		

[12] AOEM – Agricultural Operator Exposure Model (EFSA Journal 2022;20(1):7032)

Application rate		0,5 kg a.s./ha
Spray application (AOEM; 75th percentile) Body weight: 60 kg	Work wear (arms, body and legs covered) M/L and A + gloves	44
Application: Manual knapsack, *Downward spraying* Outdoor Non-edible perfume, medicinal and aromatic crops (low vegetables)		
Application rate		0,5 kg a.s./ha
Spray application (AOEM; 75th percentile) Body weight: 60 kg	Work wear (arms, body and legs covered) M/L and A + gloves	22

According to the exposure assessment using EFSA model, operator exposure to VENZAR (DPX-B0634 80 WP) is below the AOEL value of lenacil, 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

Only resident exposure is provided since, according to EFSA Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (**EFSA Journal 2022;20(1):7032**):
"*When an acute risk assessment is not triggered (i.e. for PPPs containing active substances that are not acutely toxic, and for which the setting of an AAOEL was not necessary), no bystander risk assessment is required. Exposure in this case will be determined by average exposure over a longer duration, and higher exposures on one day will tend to be offset by lower exposures on other days. Therefore, exposure assessment for residents also covers bystander exposure*".

3.1.3.4 Resident Exposure

Resident exposure was assessed according to EFSA model[13] without mitigation measures (i.e. without drift reduction technology and a buffer zone of 3 meters).

Model data		Lenacil
		% AOEL
Scenario: low vegetables Buffer zone: 3 (m) Drift reduction technology: no Number of applications 1 Interval between treatments: 365 days DT50: 30 days DFR: 3 µg/cm2/kg a.s./ha		
Resident (children) Body weight: 10 kg	Drift (75th perc.)	11.3
	Vapour (75th perc.)	0.2
	Deposits (75th perc.)	1
	Re-entry (75th perc.)	10.5
	Sum (mean)	15.5

[13] AOEM – Agricultural Operator Exposure Model (EFSA Journal 2022;20(1):7032)

Resident (adults) Body weight: 60 kg	Drift (75th perc.)	2.7
	Vapour (75th perc.)	0.07
	Deposits (75th perc.)	0.4
	Re-entry (75th perc.)	5.9
	Sum (mean)	6.3

According to the exposure assessment using EFSA model, resident exposure to VENZAR (DPX-B0634 80 WP) is below the AOEL value of lenacil, without risk mitigation measures.

3.1.3.5 Worker Exposure

Workers may have to enter into treated areas after treatment for crop reaching and picking activities. Therefore, estimation of worker exposure was calculated according to EFSA model[14].

Model data		**Lenacil**
	Level of PPE	**% AOEL**
Activity: Reaching, picking Outdoor Work rate: 8 hours/day Number of applications: 1 Interval between treatments: 365 days DT50: 30 days DFR: 3 µg/cm2/kg a.s./ha		
Application rate (kg as/ha)		0,5 kg a.s./ha
Body weight: 60 kg	Work wear (arms, body and legs covered) TC: 2500 cm2/person/h	63

According to the exposure assessment using EFSA model, worker exposure to VENZAR (DPX-B0634 80 WP) is below the AOEL value of lenacil, with a working coverall.

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

3.1.4 Residues and Consumer Exposure

As PPAM not used for any human consumption are non edible commodities, the respective intended uses were not assessed. Furthermore, as per EFSA 2009, significant residues of lenacil above 0.01 mg/kg are not expected in rotational crops following the authorised uses.

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.

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.

[14] AOEM – Agricultural Operator Exposure Model (EFSA Journal 2022;20(1):7032)

3.2 Conclusions arising from French assessment

Taking into account the above assessment, a label extension 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

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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 ***VENZAR***

de la société *FMC FRANCE*

enregistrée sous le *n° 2022-2444*

Vu les conclusions de l'évaluation de l'Anses du 3 mars 2025,

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.

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Informations générales sur le produit	
Noms du produit	VENZAR LENAZAR VARAPE
Type de produit	Produit de référence
Titulaire	FMC FRANCE 11 bis quai Perrache 69002 LYON France
Formulation	Poudre mouillable (WP)
Contenant	800 g/kg - lénacile
Numéro d'intrant	6400401
Numéro d'AMM	6400401
Fonction	Herbicide
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 04/07/2025

DocuSigned by:
Charlotte Grastilleur
AE281A955A42454...

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

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

Usages	Dose maximale d'emploi	Nombre maximum d'applications	Stade d'application BBCH	Délai avant récolte (jours)	Zone Non Traitée aquatique (mètres)	Zone Non Traitée arthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Culture attractive en floraison (arrêté du 20/11/2021) (1)
19335901 PPAM - non alimentaires*Désherbage	**0,625 kg/ha**	**1/an**	-	Non applicable	20 (dont DVP 20)	-	-	-
	Usage autorisé dans le cadre de l'article 51 du règlement (CE) n° 1107/2009.							

DVP : Dispositif Végétalisé Permanent.

(1) : Usage non évalué au regard des exigences de l'arrêté du 20/11/2021.

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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

Dans le cadre d'une application effectuée à l'aide d'un pulvérisateur à rampe du produit sous forme de poudre mouillable

• 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 par-dessus l'EPI vestimentaire précité ;
- Protections respiratoires certifiées : demi-masque certifié (EN 140) équipé d'un filtre P3 (EN 143) ou A2P3 (EN 14387) ;
- Lunettes ou écran facial certifié norme EN 166 (CE, sigle 3) ;

• pendant l'application

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 par-dessus l'EPI vestimentaire précité.

Dans le cadre d'une application effectuée à l'aide d'un pulvérisateur à rampe du produit sous forme de sachets hydrosolubles

• 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 par-dessus l'EPI vestimentaire précité ;

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• pendant l'application

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 par-dessus l'EPI vestimentaire précité.

Pour le travailleur, porter

- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1.

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

- 48 heures.

Protection des personnes présentes et des résidents (au sens du règlement (UE) n° 284/2013)

Respecter une distance d'au moins 3 mètres entre la rampe de pulvérisation et :
- l'espace fréquenté par les personnes présentes lors du traitement ;
- l'espace susceptible d'être fréquenté par des résidents.

Respect des limites maximales de résidus (LMR)

- Ne pas utiliser les sous-produits des cultures de PPAM – non alimentaires en alimentation humaine ou animale.

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

Protection de l'eau

- SPe 1 : Pour protéger les eaux souterraines, ne pas utiliser ce produit ou tout autre produit contenant du lénacile plus d'une année sur trois sur la même parcelle.

Protection de la faune

- SPe 3 : Pour protéger les organismes aquatiques, respecter une zone non traitée de 20 mètres par rapport aux points d'eau comportant un dispositif végétalisé permanent non traité d'une largeur de 20 mètres en bordure des points d'eau.

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Recommandations relatives à l'étiquette du produit

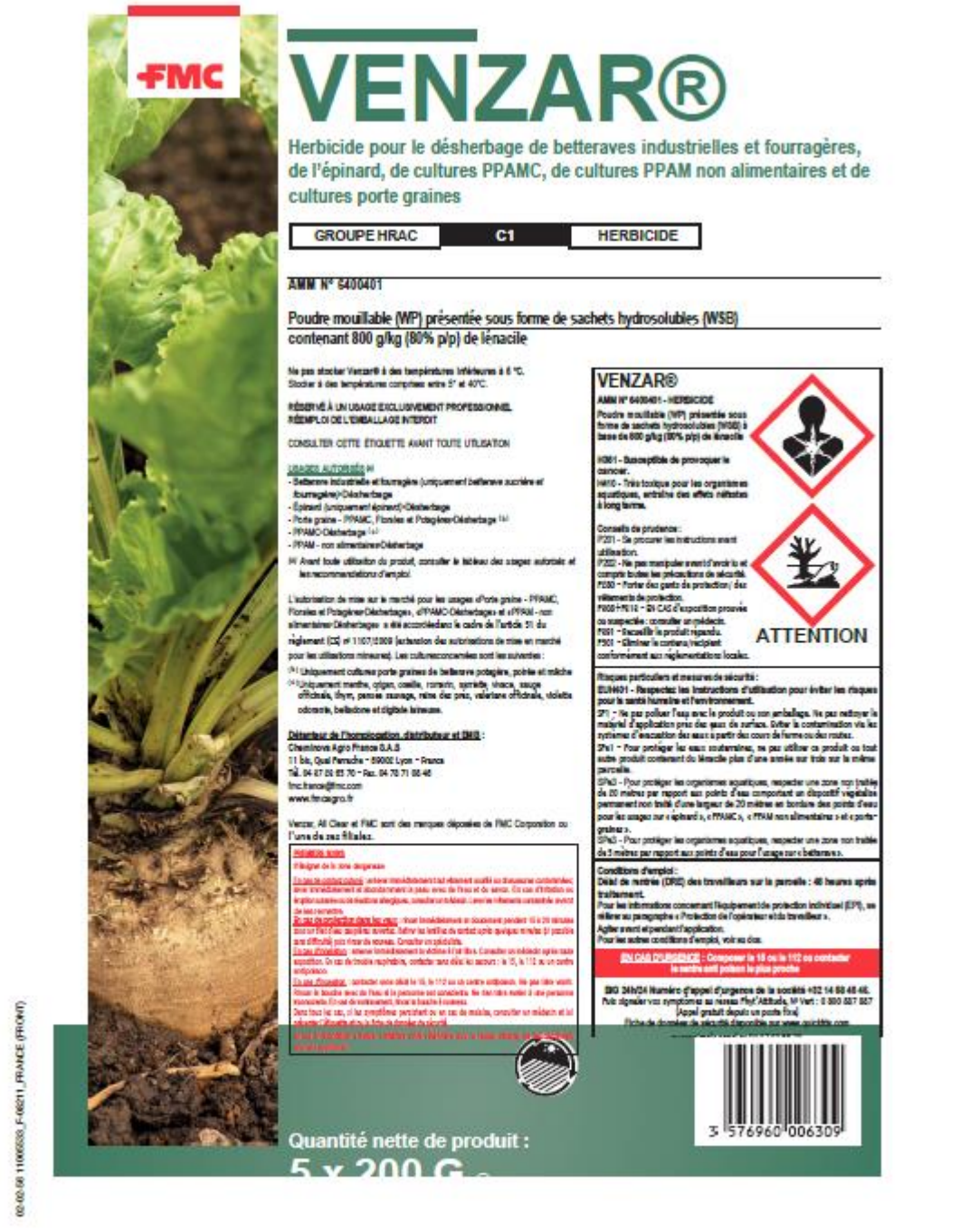
Il est recommandé de faire figurer l'information suivante sur l'étiquette :

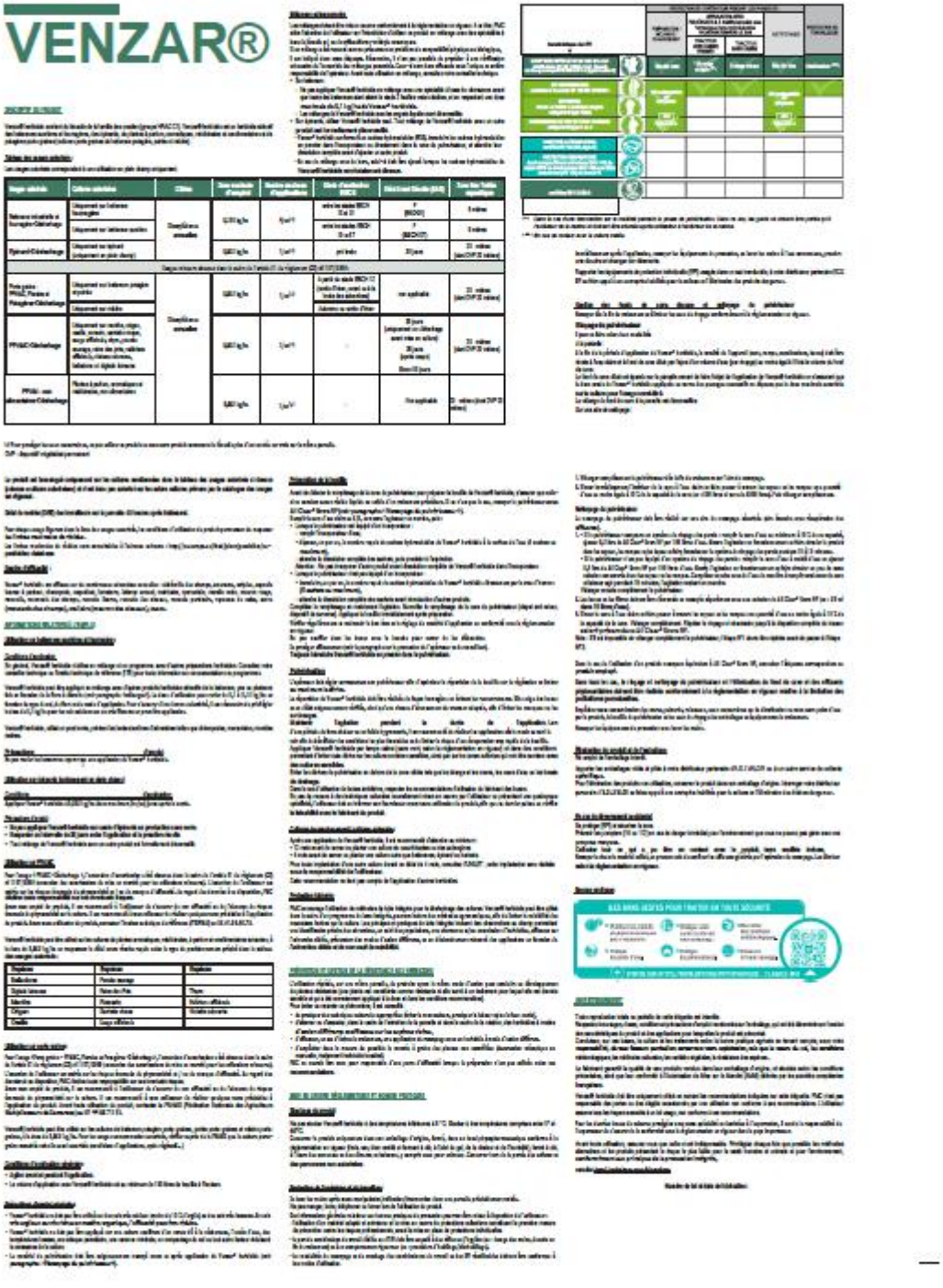
- Pour les usages mineurs dont l'autorisation a été accordée dans le cadre de l'article 51 du règlement (CE) n°1107/2009, l'attention de l'utilisateur est attirée sur les risques éventuels de phytotoxicité ou de manque d'efficacité.

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.

- Après une application du produit, préciser les délais à respecter après traitement pour implanter les cultures suivantes (culture de remplacement ou de rotation) en fonction de leurs niveaux de sensibilité au produit.

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

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