REGISTRATION REPORT

Part A

Risk Management

Product code: CA2262

Product name: PAVANETT EV

Chemical active substances:

glyphosate, 72 g/L
dichlorprop-P, 54 g/L
MCPA, 54 g/L

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(authorisation renewal according to art 43)

Applicant: Nufarm S.A.S.

Date: 17 December 2021

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PART A
RISK MANAGEMENT

1 Details of the application

The company Nufarm SAS has requested a marketing authorisation in France for the product PAVANETT EV (formulation code: CA2262), containing 72 g/L glyphosate[1], 54 g/L, dichlorprop-P[2] and 54 g/L MCPA[3] as a herbicide for professional uses.

Appendix 1 of this document provides a copy of the product authorisation.

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

1.1 Application background

The present registration report concerns the evaluation of Nufarm SAS's application submitted on 18/03/2018 to market PAVANETT EV (CA2262) in France (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 re-registration of authorisation after the renewal of approval of the active substance glyphosate of this product in France and in other Member States (MSs) of the Southern zone.

The present applications (2018-0666, 2018-1206, 2019-4952 & 2020-0045) were evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses), according to the Regulation (EC) no 1107/2009[4], the implementing regulations, and French regulations. This application was assessed in the context of the zonal procedure for all MSs of the Southern zone, taking into account the worst-case uses ("risk envelope approach")[5]. When risk mitigation measures were necessary, they are adapted to the situation in France.

The data taken into account are those deemed to be valid either at European level (Review Report and EFSA conclusion) or at zonal/national level. The assessment of PAVANETT EV (CA2262) has been made using endpoints agreed in the EU peer reviews of glyphosate, dichlorprop-P and MCPA. It also includes assessment of data and information related to PAVANETT EV (CA2262) where those data have not been considered in the EU peer review process.

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 risk assessment conclusions provided in this document are based on the information, data and assessments provided in the Registration Report, Part B Sections 1-10 and Part C, and where appropriate the addendum for France.

In order to comply with the provisions of Regulation (EC) No 1107/2009 (Commission Implementing Regulation (EU) 2015/2033) and according to Art. 43 of Regulation (EC) No 1107/2009, and in accordance with the guidance document SANCO/2010/13170, the outcome of the risk assessment for the re-registration

[1] Commission Implementing Regulation (EU) 2017/2324 of 12 December 2017, renewing the approval of the active substance glyphosate in accordance with Regulation (EC) N°1107/2009 of the European Parliament and the Council concerning the placing of plant protection products on the market, and amending the Annex to commission Implementing Regulation (EU) N°540/2011.

[2] Implementing Regulation (EU) No 1166/2013 of 18 November 2013 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance dichlorprop-P Text with EEA relevance

[3] 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 Text with EEA relevance

[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] 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

of plant protection product only applies to glyphosate following its renewal of approval. For dichlorprop-P and MCPA, provisions of the initial authorisation remain.

The conclusions on the acceptability of risk are based on the criteria provided in Regulation (EU) No 546/2011[6], and are expressed as "acceptable" or "not acceptable" in accordance with those criteria.

This document also describes the specific conditions of use and labelling required for France for the registration of PAVANETT EV (CA2262).

1.2 Letters of Access

NUFARM SAS is part of the Glyphosate Task Force so NUFARM SAS is co-owner of the protected Glyphosate data used in this application. A letter of acces from Monsanto dated on 23 November 2017 has been provided and is available upon request.

Not necessary for dichlorprop-P and MCPA: active substance data are not protected any more.

1.3 Justification for submission of tests and studies

According to the applicant: "The tests and study reports are necessary in order to support the authorisation of CA2262 as a new product (i.e. Article 43 renewal in the EU)."

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of PAVANETT EV (CA2262), it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7. Details of the authorisation decision

1.5 Product identity

Product code	CA2262
Product name in MS	PAVANETT EV
Authorisation number	2010319
Kind of use	Professional use
Low risk product (article 47)	No
Function	Herbicide
Applicant	Nufarm S.A.S.
Active substances (incl. content)	glyphosate, 72 g/L dichlorprop-P, 54 g/L MCPA, 54 g/L
Formulation type	Soluble Concentrate [SL]
Packaging	HDPE[7](1 L, 5 L, 10 L, 20 L, 25 L)

[6] 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

[7] High density polyethylene

Coformulants of concern for national authorisations	-
Restrictions related to identity	-
Mandatory tank mixtures	None
Recommended tank mixtures	None

1.6 Conclusion

The evaluation of the application for PAVANETT EV (CA2262) resulted in the decision **to withdraw** the authorisation.

1.7 Substances of concern for national monitoring

Refer to 5.1.1.

1.8 Classification and labelling

1.8.1 Classification and labelling under Regulation (EC) No 1272/2008

N/A : marketing authorisation withdrawn

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

N/A : marketing authorisation withdrawn

1.8.3 Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)

N/A : marketing authorisation withdrawn
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1.9 Risk management

According to the French law and procedures, specific conditions of use are set out in the Decision letter. The French Order of 4 May 2017[8] provides that:

- unless otherwise stated in the product authorisation, the pre harvest interval (PHI) is at least 3 days;
- unless otherwise stated in the product authorisation, the minimum buffer zone alongside a water body is 5 metres for products applied through spraying or dusting;

[8] 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

- unless otherwise stated in the product authorisation, the minimum re-entry period is 6 hours for field uses and 8 hours for indoor uses.

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

Moreover, for glyphosate-based products, the official statement[9] of 8 October 2004 provides specific restrictions (applied doses and/or conditions of use) for uses on crops, in non-agricultural or industrial areas or in forestry.

Finally, the French Order of 21 april 2021[10] provides that:
- an authorisation granted for a "reference" crop applies also for "related" crops, unless formally stated in the Decision
- the "reference" and "related" 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 "related" ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is also reached on the acceptability of the intended uses on those "related" crops. The aim of this Order, mainly based on the EU document on residue data extrapolation[11] 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.

1.9.1 Restrictions linked to the PPP

N/A : marketing authorisation withdrawn

1.9.2 Specific restrictions linked to the intended uses

N/A : marketing authorisation withdrawn

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[9] Avis du 8 octobre 2004 à tous les détenteurs d'autorisations de mise sur le marché pour des spécialités commerciales à base de glyphosate, https://www.legifrance.gouv.fr/jo_pdf.do?id=JORFTEXT000000445445

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

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

1.10 Intended uses (only NATIONAL GAP)

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: 2021-12-17

PPP (product name/code):	CA2262 / PAVANETT EV	Formulation type:	SL [a, b]
Active substance 1:	glyphosate	Conc. of a.s. 1:	72 g/L [c]
Active substance 2:	dichloprop-P	Conc. of a.s. 2:	54 g/L [c]
Active substance 3:	MCPA	Conc. of a.s. 3:	54 g/L [c]
Safener:	-	Conc. of safener:	-
Synergist:	-	Conc. of synergist:	-
Applicant:	Nufarm S.A.S.	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 or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		e.g. g safener/synergist per ha [f]
Zonal uses (field or outdoor uses, certain types of protected crops)													

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1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. (e)	**Member state(s)**	**Crop and/ or situation (crop destination/purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha (f)
					Method/Kind	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
1	FR	Total weed control on public gardens, pathways (professional use)	F	Annual and broad-leaved weeds	Truck-mounted tank with a hand-held lance or Backpack sprayer	Spot application on emerged weeds From spring to autumn	N/A	N/A	15 litres product per ha	Glyphosate : max 1080 Dichlorprop-p : max 810 MCPA : max 810	500 L/ha	N/A	**Not acceptable** (relevant impurity, genotoxic potential, (*)) Registered rate : 15 L CA2262/ha
2	FR	Total weed control (including railways)	F	Annual and broad-leaved weeds	Truck-mounted tank with a hand-held lance or Backpack sprayer	Spot application on emerged weeds From spring to autumn	N/A	N/A	15 litres of product per ha	Glyphosate : max 1080 Dichlorprop-p : max 810 MCPA : max 810	500 L/ha	N/A	**Not acceptable** (relevant impurity, genotoxic potential) Registered rate : 15 L CA2262/ha Actual rate applied to railway = 70% surface within 1/3 total rail area = 23% total rate = 3.45 L CA2262/ha

(*) Risk to diversity and abundance of non-target terrestrial arthropods (other than bees) and vertebrates *via* trophic interactions.

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

2 Background of authorisation decision and risk management

2.1 Physical and chemical properties (Part B, Section 2)

The appearance of the product is that of homogenous caramel coloured translucent liquid. It is neither explosive nor oxidising, has no flash point up to 110°C and no auto-ignition temperature up to 600°C. The product has a relative density of 1.141 and in aqueous solution, it has a pH value of 7.05 at 20°C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0 °C, 14 days at 54 °C and 2 years at room temperature, neither the content of the active substances nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in 1L HDPE packaging. The technical characteristics of the product are acceptable for a soluble concentrate formulation. The intended concentration of use is 1.4% v/v to 7.5% v/v.
The product is not intended for tank mixing.

The active substance glyphosate contains two relevant impurities, formaldehyde and N-nitrosoglyphosate. The relevant impurity formaldehyde is considered as a by-product of the manufacturing process for glyphosate and as such cannot be formed by storage of the formulation. The monitoring of this impurity in the storage studies is not necessary.

Concerning the relevant impurity N-nitrosoglyphosate, based on the conditions of formation of this impurity, it is unlikely that this impurity is formed during the formulation and storage of the preparation.
No monitoring of the concentration of this impurity during storage of the preparation was provided.

The following data would have been required to update the dossier:
- An accelerated storage stability study and a shelf life study with the content of NNG before and after the storage should be provided. The NNG should be determined with a validated method with a limit of quantification in accordance with the maximum concentration limit of this NNG impurity in the preparation
- A demonstration that the formation of the foam is no risk for the operator should be provided in post-authorisation

2.2 Efficacy (Part B, Section 3)

PAVANETT EV (CA2262) is a preparation based on glyphosate (72 g/L), dichlorprop-p (54 g/L) and MCPA (54 g/L) for the weeding in non-cropped areas. This dossier is a request for the renewal of the product, the claimed uses are the same as those currently authorized.
Considering the data submitted:
- The efficacy level of PAVANETT EV (CA2262) is considered satisfactory for all the claimed uses.
- Glyphosate having an herbicidal activity on all types of plants (known as “total weed killer”), the preparation PAVANETT EV (CA2262) cannot therefore be considered selective. Given the foliar penetration of glyphosate, the preparation should not be directed on the green part of non-target plants.
- The risk of negative impact on adjacent crops is considered acceptable, as long as the preparation does not reach the green parts of adjacent crops. Specific attention should be paid to the spraying conditions close to adjacent crops.
- The risk of development resistance or appearance to MCPA and dichlorprop-p used in non cropped areas should not be increased in comparison with the agricultural uses in cereals and rapeseed and does not require a monitoring for these particular uses.

- There is a risk of resistance development or appearance to glyphosate for ryegrass (*Lolium multiflorum, Lolium perenne* and *Lolium rigidum*), fleabanes (*Conyza sp*.), and common ragweed (*Ambrosia artemisiifolia*) requiring a survey of resistance.
The survey of resistance to glyphosate should be continued based on analysis of field efficacy failures (one monitoring for all products based on glyphosate), and especially on ryegrass (*Lolium multiflorum, Lolium perenne* and *Lolium rigidum*), fleabanes (*Conyza* sp.) and common ragweed (*Ambrosia artemisiifolia*). Any new information which would change the resistance risk analysis should be provided to authorities. In all cases, a report on the results of the survey put in place should be provided at the time of the next renewal of glyphosate.

2.3 Methods of analysis (Part B, Section 5)

Analytical methods for the determination of actives substance in the formulation are available and considered as acceptable.
Analytical method for the determination of relevant impurity formaldyde is available and considered as acceptable.

The following data would have been required to update the dossier:
An analytical method for the determination of relevant impurity NNG in the formulation with LOQ below the acceptable limit (LOQ ≤ 0.066mg/kg for NNG) is required.

Methods for the determination of active substance residue environmental matrices are available and validated.
Considering the uses, analytical methods for the determination of actives substances residue are not necessary in plant and animal matrices.

2.4 Mammalian toxicology (Part B, Section 6)

Endpoints used in risk assessment

Formulation type	SC
Active substance(s) (incl. content)	**Glyphosate** 72 g/L
AOEL systemic AAOEL	0.01 mg/kg bw/d none
Inhalation absorption	100%
Oral absorption	20%
Dermal absorption	Concentrate: 0.12 % Dilution: 1.2 %
Model	EFSA model

2.4.1 Acute toxicity

PAVANETT EV (CA2262) containing 72 g/L glyphosate, 54 g/l Dichloprop-P and 54 g/L MCPA, has a low toxicity in respect to acute oral, inhalation and dermal toxicity and is not irritating to the rabbit skin or eye and is not a skin sensitiser.

2.4.2 Genotoxic potential

In the EC review report for glyphosate (SANTE/10441/2017 Rev 2), the following toxicity studies were requested (see page 6 of the review report):
"As outlined in the EFSA conclusion on glyphosate, the peer review recognised that some genotoxicity studies on formulations presented positive results, and therefore, that the genotoxic potential of formulations should be addressed dur-ing renewal or first authorisation of plant protection products."

According to EFSA scientific opinion on genotoxicity testing strategies (EFSA Journal 2011; 9(9):2379), a combination of two tests is needed to "*[fulfil] the basic requirements to cover the three genetic endpoints: the bacterial reverse mutation assay covers gene mutations and the in vitro micronucleus test covers both structural and numerical chromosome aberrations*".

The genotoxicity tests were not provided for the formulation PAVANETT EV (CA2262). Hence the genotoxic potential of PAVANETT EV (CA2262) cannot be finalised.

2.4.3 Operator exposure

Crop type	F/G[12]	Equipment *Application method*	Maximum application rate g as /ha	Minimum volume water (L/ha)
Non crop area	F	Hand held /knapsack *Downward spraying*	1080 (glyphosate)	500

Crop	Equipment	PPE and/or working coverall	% AOEL glyphosate
Non crop area	Hand held *Downward spraying*	Working coverall and gloves during mixing/loading and application	0.18
	Knapsack *Downward spraying*		3.22

According to the model calculations, it can be concluded that the risk for the operator using PAVANETT EV (CA2262) is acceptable with a working coverall and gloves during mixing/loading and application.

2.4.4 Worker exposure

[12] Open field or glasshouse

		Glyphosate	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**
Maintenance Outdoor Work rate: 8 hours/day, DT_{50}: 30 days DFR: 3 µg/cm²/kg a.s./ha			
Number of applications and application rate		1 × 1.080 kg a.s./ha	
Body weight: 60 kg	Potential TC: 5800 cm²/person/h	0.0300672	30.07
	Work wear (arms, body and legs covered) TC: 2500 cm²/person/h	0.0129600	12.96

No unacceptable risk was identified for workers re-entering into total weed control on public gardens, pathways at a dose of 1*1.080 kg sa/ha dose of CA2262/ PAVANETT® EV
For details of personal protective equipment for workers, refer to the Decision in Appendix 1.

2.4.5 Bystander exposure

Consideration of acute exposure should only be made where an AAOEL has been established during an approval, review or renewal evaluation of an active substance, i.e. no acute operator or bystander exposure assessments can be performed with the AOEM model where no AAOEL has been set[13].
Only resident exposure is provided since, according to EFSA Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (EFSA Journal 2014;12(10):3874): "*No bystander risk assessment is required for PPPs that do not have significant acute toxicity or the potential to exert toxic effects after a single exposure. Exposure in this case will be determined by average exposure over a longer duration, and higher exposures on one day will tend to be offset by lower exposures on other days. Therefore, exposure assessment for residents also covers bystander exposure*."

Recreational exposure was assessed according to EFSA model. Exposure is estimated to 7 % and 0.8 % of the AOEL of glyphosate for children and adults, respectively. It is concluded that there is no unacceptable risk anticipated for recreational exposure.

2.4.6 Resident exposure

Recreational exposure was assessed according to EFSA model. Exposure is estimated to 6.50 % and 1.58 % of the AOEL of glyphosate for children and adults, respectively. It is concluded that there is no unacceptable risk anticipated for recreational exposure.

2.4.7 Combined exposure

Not relevant

[13] Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (SANTE-10832-2015 rev. 1.7, 2017)

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

The uses for which renewal is sought only relate to non-edible crops and there will not be any edible crops planted subsequently. As a consequence, a consideration of residues for this plant protection product is irrelevant.

2.6 Environmental fate and behaviour (Part B, Section 8)

The fate and behaviour in the environment have been evaluated according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU conclusions were used to calculate PEC values for the active substance and its metabolites for the intended use patterns. In cases where deviations from the EU agreed endpoints were considered appropriate (for example when additional studies are provided), such deviations were highlighted and justified accordingly.

The PEC of glyphosate and its metabolites in soil, surface water and groundwater have been assessed according to FOCUS guidance documents and the endpoints established in the EU conclusions or agreed in the assessment based on new data provided.

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

PECgw for glyphosate and its metabolite do not occur at levels exceeding those mentioned in regulation EC 1107/2009. 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.

2.7 Ecotoxicology (Part B, Section 9)

The ecotoxicological risk assessment of the formulation was performed according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU conclusions for the active substance(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.

Given the intended uses on non-agricultural areas, national addendum may be requested at national level. zRMS considers at national level in FR that:

- For the uses in railways, a risk assessment is performed for aquatic and terrestrial organisms in the edge of the railway lines by considering that protection of the treated area is not relevant. Drift of 2.8 % of the full dose is then considered in the risk assessment (according to HardSPEC) only when the risk assessment at the full dose is not sufficient to conclude on the acceptability of risk for those non-agricultural areas. No specific TER calculations are conducted for non-target plants, therefore to protect non-target plants, the following safety phrase is applied in FR and may be adapted at national level: «avoid spray drift to the non-target plants in the edge of the railway lines».
- For the uses in industrial sites, a risk assessment for aquatic organisms is considered relevant. In view of the specificity of the treated area, a risk assessment for the other non-target species is not deemed necessary.

- For the uses in pathways in public parks and sidewalk, applications are realised by professionals with specific directed equipments limiting the transfer via drift. A risk assessment for aquatic organisms and bees is considered relevant. In view of the specificity of the treated area, a risk assessment for the other non-target species is not deemed necessary.

As glyphosate belongs to the AIR II program and CA2262 is a formulation under renewal, the Regulation (EU) No 284/2013 do not apply.

Risk mitigation measures are required in order to protect aquatic organisms.

Concerning the risk to diversity and abundance of non-target terrestrial arthropods and vertebrates via trophic interactions (Regulation (EU) 2017/2324), no new information has been provided by the notifier to assess this risk compared to the UE review (EFSA Journal 2015;13(11):4302; Pesticides Peer Review Meeting 128; Renewal Assessment Report).
Among the intended uses, this information is not considered necessary for some uses made in highly anthropized area (weed control of railways for application via a train and of industrial sites).
For bees and other pollinators, new toxicity data (adult honey bees, bumble bees and solitary bees) in others zRR assessed by FR and available on CIRCA. Given the risk to divertsity, and the new data available, zRMS proposed a risk assessment in the other zRR based on the Efsa guidance document (2013) on risk assessment for bees.
In view of the maximal application rate of glyphosate intended for the formulation, no unacceptable risk for bees and other pollinators is expected.

2.8 Relevance of metabolites (Part B, Section 10)

An assessment was conducted according to the SANCO/221/2000 guidance document. Please refer to environmental fate and behaviour above for conclusion on the risk of groundwater contamination.

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

The active substance glyphosate is not approved as a candidate for substitution, however a comparative assessment according to Art. 50(2) is undertaken.

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

When the conclusions of the assessment is “Not acceptable”, please refer to relevant summary under point 3, “Background of authorisation decision and risk management”.

4.1.1 Post-authorisation monitoring

N/A : marketing authorisation withdrawn

4.1.2 Post-authorisation data requirements

N/A : marketing authorisation withdrawn

Appendix 1 Copy of the product authorisation

DocuSign Envelope ID: 98CD6425-B8D9-4984-A7D2-02221B299666

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AGENCE NATIONALE DE SÉCURITÉ SANITAIRE de l'alimentation, de l'environnement et du travail

Décision relative à une demande de renouvellement de l'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 règlement d'exécution (UE) 2017/2324 de la Commission du 12 décembre 2017 renouvelant l'approbation de la substance active «glyphosate» conformément au règlement (CE) no 1107/2009 du Parlement européen et du Conseil concernant la mise sur le marché des produits phytopharmaceutiques et modifiant l'annexe du règlement d'exécution (UE) no 540/2011 de la Commission,

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 les demandes de renouvellement de l'autorisation de mise sur le marché, suite au renouvellement de l'approbation de la substance active glyphosate, de changement de classification, de modification des informations déclarées et les données fournies en réponse aux demandes post autorisation du produit phytopharmaceutique ***PAVANETT EV***

de la société	*NUFARM SAS*
enregistrées sous les	*n°2018-0666, 2020-0045, 2018-1206 et 2019-4952*

Vu les conclusions de l'évaluation de l'Anses du 4 novembre 2021,

Considérant que les données fournies ne permettent pas d'évaluer le potentiel génotoxique du produit,

Considérant qu'un effet génotoxique ne peut être exclu,

Considérant que les données fournies ne permettent pas d'exclure la formation de l'impureté pertinente N-nitrosoglyphosate au cours du stockage du produit,

Considérant qu'en conséquence un risque d'effet nocif pour la santé humaine ne peut pas être exclu,

Considérant que les conditions mentionnées à l'article 29 du règlement (CE) n°1107/2009 ne sont donc pas respectées,

L'autorisation de mise sur le marché du produit phytopharmaceutique désigné ci-après **n'est pas renouvelée** en France.

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Informations générales sur le produit	
Noms du produit	PAVANETT EV ALLEE NET EV PAVANESS
Type de produit	Produit de référence
Titulaire	NUFARM SAS Immeuble West Plaza 11, rue du Débarcadère 92700 COLOMBES France
Formulation	Concentré soluble (SL)
Contenant	72 g/L - glyphosate 54 g/L - MCPA 54 g/L - dichlorprop P 2-EHE
Numéro d'intrant	9800201
Numéro d'AMM	9800201
Fonction	Herbicide
Gamme d'usage	Professionnel

A Maisons-Alfort, le 17/12/2021

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 : Conditions de mise sur le marché demandées

Liste des usages retirés

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)	Délai accordé pour la vente et la distribution	Délai accordé pour le stockage et l'utilisation des stocks
11015903 JEVI*Désherbage* All. PJT, Cimet., Voies	15 L/ha	1/an	Non applicable	6 mois à compter de la présente décision	12 mois à compter de la présente décision
	Motivation du retrait : L'usage, évalué comme les usages 10015907 JEVI*Désherb. Total*Sites industriels et autres infrastructures, 01001001 JEVI*Désherbage*Voies ferrées et 10015908 JEVI*Désherbage*PJT, est retiré au motif que les données disponibles ne permettent pas d'évaluer le potentiel génotoxique du produit, ni d'exclure la formation de l'impureté pertinente N-nitrosoglyphosate au cours du stockage du produit.				

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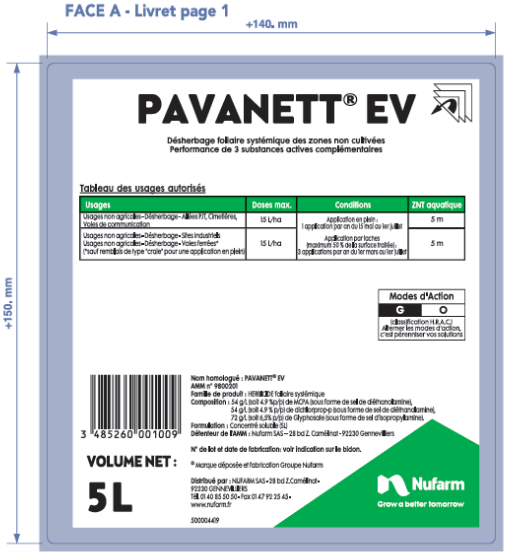
Appendix 2 Copy of the product label

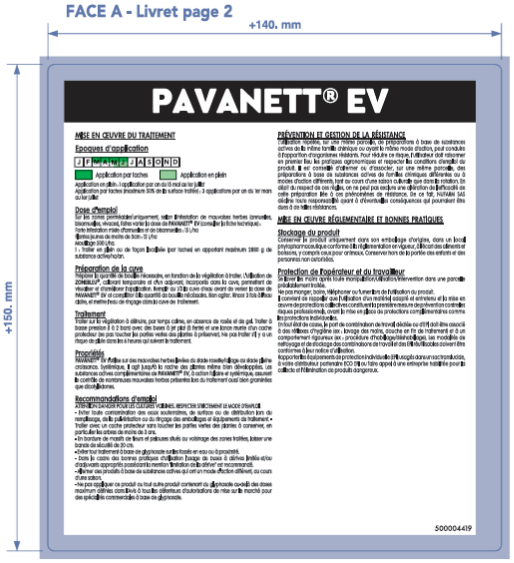
The draft product label as proposed by the applicant is reported below. The draft label may be corrected with consideration of any new element. The label shall reflect the detailed conditions stipulated in the Decision.

FACE B

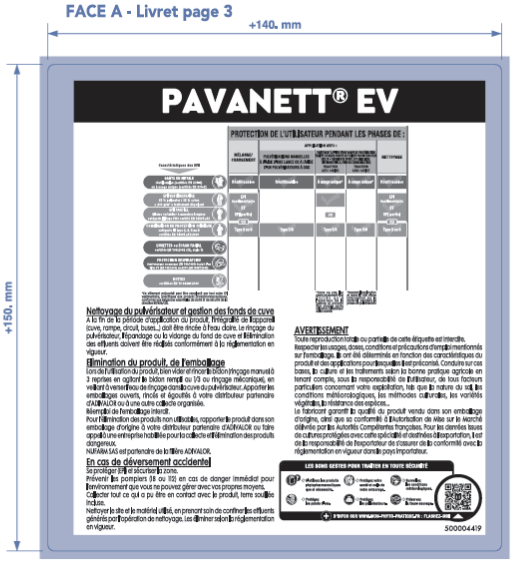
FACE A - Livret page 1



FACE A - Livret page 2



FACE A - Livret page 3



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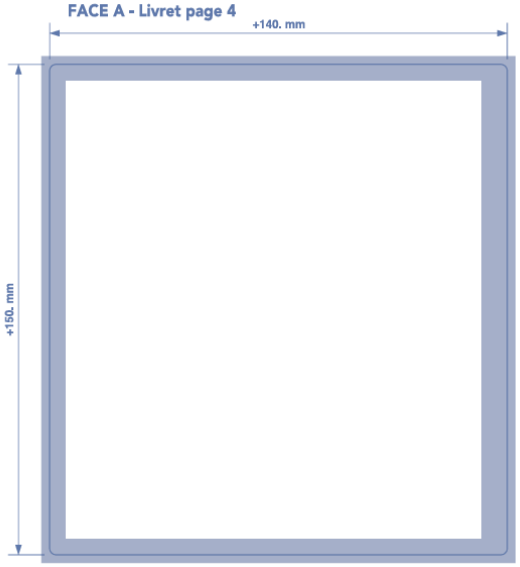
FACE A - Livret page 4



FACE A - BASE LABEL

FACE A - Livret page 6