

REGISTRATION REPORT

Part A

Risk Management

Product code: CA2036

Product name(s): CHARDOL 600

Chemical active substance(s):

2,4-D, 600 g/L

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(label extension)

Applicant: NUFARM S.A.S.

Date: 12/12/2022

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PART A

RISK MANAGEMENT

1 Details of the application

The company NUFARM S.A.S. has requested a marketing authorisation in France for the product CHARDOL 600 (FORMULATION CODE: CA2036), (FORMULATION CODE: CA2036), (FORMULATION CODE: CA2036), (formulation code: CA2036), containing 600 g/L 2,4-D¹ 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 S.A.S.'s application submitted on 25/06/2021 to market CHARDOL 600 (FORMULATION CODE: CA2036), 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 the label extension of this product in France and in other Member States (MSs) of the Southern zone.

The present application (2021-2558) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses), according to the Regulation (EC) no 1107/2009², 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")³. 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 CHARDOL 600 (FORMULATION CODE: CA2036), has been made using endpoints agreed in the EU peer review of 2,4-D. It also includes assessment of data and information related to CHARDOL 600 (FORMULATION CODE: CA2036), 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.

The conclusions on the acceptability of risk are based on the criteria provided in Regulation (EU) No 546/2011⁴, and are expressed as "acceptable" or "not acceptable" in accordance with those criteria.

¹ Commission Implementing Regulation (EU) 2015/2033 of 13 November 2015 renewing the approval of the active substance 2,4-D in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011.

² 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

³ 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](#)

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

This document also describes the specific conditions of use and labelling required for France for the registration of CHARDOL 600.

1.2 Letters of Access

Not necessary: the applicant is the owner of data which support the renewal of approval of the active substance.

1.3 Justification for submission of tests and studies

Justification not submitted by the applicant.

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of CHARDOL 600 (CA2036), it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections Details of the authorisation decision

1.5 Product identity

Product code	CA2036
Product name in MS	CHARDOL 600
Authorisation number	9100296
Kind of use	Professional use
Low risk product (article 47)	No
Function	Herbicide
Applicant	NUFARM S.A.S.
Active substance(s) (incl. content)	2,4-D, 600 g/L
Formulation type	Soluble concentrate [SL]
Packaging	Packaging not changed
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 CHARDOL 600 (FORMULATION CODE: CA2036), resulted in the decision **to grant 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**

Classification not changed.

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

SP 1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).
	For other restrictions refer to 2.5

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

None.

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 2017⁵ 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;
- 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.

Finally, the French Order of 12 April 2021⁶ 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”

⁵ 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/AGRGI632554A/jo/texte> ; <https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000039686039&categorieLien=id>

⁶ <https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000043401456>

crops. The aim of this Order, mainly based on the EU document on residue data extrapolation⁷ 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 2021⁸ 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 product authorisation, use on attractive culture⁹ 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

1.9.1 Restrictions linked to the PPP

The authorisation of the PPP is linked to the following conditions:

Operator protection:	
-	Refer to the Decision in Appendix 1 for the details.
Worker protection:	
-	Refer to the Decision in Appendix 1 for the details.
Integrated pest management (IPM)/sustainable use:	
	-
Environmental protection	
SPe 2	To protect aquatic organisms do not apply to artificially drained soils with clay content higher than or equal to 45% ..
SPe 3	To protect aquatic organisms respect an unsprayed buffer zone of 20 meters ¹⁰ to surface water bodies and settle measures to limit transfer by runoff in sugar cane fields (for example increase crop cover in the field).
SPe3	To protect aquatic organisms respect an unsprayed buffer zone of 5 m to surface water bodies for the uses on Aromatic plant.
bystander and resident protection	Respect an unsprayed zone of 3 meters from the extremity of the boom and : - areas where bystanders are present during treatment - areas where residents could be present
Other specific restrictions	
Re-entry period	Not changed

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

⁸ <https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000044346734>

⁹ 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.

¹⁰ in consistency with French Order of 4 May 2017 (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), modified by the French Order of 27 December 2019.

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Storage	-
Risk mitigation measures	None

The other conditions of use specified in the previous evaluations are not changed.

1.9.2 Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions in addition to those listed under point 1.9.1 (mandatory labelling):

None.

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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” or “not finalised”, 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. 2, date: 2022-12

PPP (product name/code): CHARDOL 600 (FORMULATION CODE: CA2036),
(FORMULATION CODE: CA2036), / CA2036

Formulation type: SL ^(a, b)

Active substance 1: 2,4-D

Conc. of as 1: 600 g/L ^(c)

Safener: -

Conc. of safener: - ^(c)

Synergist: -

Conc. of synergist: - ^(c)

Applicant: Nufarm S.A.S.

Professional use: ☒

Zone(s): southern^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 or (crop destination/purpose of crop)	F, Fn, 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/Ki nd	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		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	FR	Sugar cane	F	Annual and perennial broadleaved weeds	Overall treatment	BBCH 29 – 32	1		a) 1.25 b) 1.25	a) 750 b) 750	150 – 500	F(BBC H 32)	Acceptable
2a	FR	Pome fruit (apple tree, pear tree, etc.)	F	Annual and perennial broadleaved weeds	Directed spray treatment on weeds*	June – July	1		a) 1.25 b) 1.25	a) 750 b) 750	150 – 500	30	Not acceptable (efficacy)

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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 or situation (crop destination/purpose of crop)	F, Fn, 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/Ki nd	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/ma x		
2b	FR	Pome fruit (apple tree, pear tree, etc.)	F	Annual and perennial broadleaved weeds	Directed spray treatment on weeds*	After harvest	1		a) 1.25 b) 1.25	a) 750 b) 750	150 – 500	30	Not acceptable (efficacy) (aquatic organisms)
3a	FR	Stone fruit, established crop (apricot tree, peach tree, plum tree, cherry tree, etc.)	F	Annual and perennial broadleaved weeds	Directed spray treatment on weeds*	June – July	1		a) 1.25 b) 1.25	a) 750 b) 750	150 – 500	30	Not acceptable (efficacy)
3b	FR	Stone fruit, established crop (apricot tree, peach tree, plum tree, cherry tree, etc.)	F	Annual and perennial broadleaved weeds	Directed spray treatment on weeds*	After harvest	1		a) 1.25 b) 1.25	a) 750 b) 750	150 – 500	30	Not acceptable (efficacy) (aquatic organisms)
4a	FR	Tree nuts (almond, chestnut, hazel, wal- nut, pistachio)	F	Annual and perennial broadleaved weeds	Directed spray treatment on weeds*	June – July		1	a) 1.25 b) 1.25	a) 750 b) 750	150 – 500	30	Not acceptable (efficacy)
4b	FR	Tree nuts (almond, chestnut, hazel, wal- nut, pistachio)	F	Annual and perennial broadleaved weeds	Directed spray treatment on weeds*	After harvest		1	a) 1.25 b) 1.25	a) 750 b) 750	150 – 500	30	Not acceptable (efficacy) aquatic organisms)
5	FR	Aromatic plant: Lavender, lavandin	F	Annual and perennial broadleaved weeds	Overall treatment	Vegetative rest (BBCH 14) with floral stalk at 10 cm (BBCH 32) March - May		1	a) 0.6 b) 0.6	a) 360 b) 360	150 – 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.

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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 or situation (crop destination/purpose of crop)	F, Fn, 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/Ki nd	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		
Remarks columns:	1	Numeration necessary to allow references					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					
	2	Use official codes/nomenclatures of EU Member States					8	The maximum number of application possible under practical conditions of use must be provided.					
	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)					9	Minimum interval (in days) between applications of the same product					
	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					10	For specific uses other specifications might be possible, e.g.: g/m ³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.					
	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.					11	The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product/ha).					
	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.					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 physico-chemical properties of the formulation have been evaluated and considered acceptable during the registration of this formulation. The intended concentrations claimed for the extension uses (concentrations from 0.12% to 0.83% v/v) are closely covered by the concentrations authorized during the registration of this formulation (from 0.14% to 0.83% v/v).

Therefore, the physico-chemical properties were not reviewed in the aim of this extension of uses.

2.2 Efficacy (Part B, Section 3)

Based on the submitted data, it can be concluded that:

The efficacy of the product CA2036 applied at 1.15 l/ha is considered acceptable on sugarcane when applied in post emergence.

The efficacy of the product CA2036 applied at 1.25 l/ha on pome fruit, stone fruit and nut trees in post emergence is considered insufficient.

The selectivity of the product CA 2036 is considered acceptable on sugarcane, pome fruit, stone fruit and nut trees.

The risk of negative effect on following crops and adjacent crops is covered by the current authorised uses in each country. Please refer to national label. The risk of resistance is considered as acceptable on the requested uses for the product CA2036.

The risk of resistance apparition to 2,4D on the intended uses is considered as acceptable and does not require a survey of resistance.

2.3 Methods of analysis (Part B, Section 5)

2.3.1 Analytical method for the formulation

The analytical methods for the determination of the active substance in the formulation in the dossier of the preparation meet the regulatory requirements.

2.3.2 Analytical methods for residues

The analytical methods for the determination of the active substance residues in matrices (plants and food of animal origin) submitted at European level and in the dossier of the preparation meet the regulatory requirements.

2.4 Mammalian toxicology (Part B, Section 6)

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Product name and code	CA2036 (2,4-D DMA 600 SL)
Formulation type	SL
Category	Herbicide
Container size(s), short description	Not applicable*
Active substance(s) (incl. content)	2,4-D 600 g/L
AOEL systemic	0.02 mg/kg bw/d
Inhalation absorption	100 %
Oral absorption	100 %
Dermal absorption	Concentrate: 0.14 % Dilution: 4% (Dilution rate: 1:400) Dilution : 8.33% (Dilution rate: 1:833)

2.4.1 Acute toxicity

CHARDOL 600, containing 600 g/L of 2,4-D, is not harmful by oral, dermal or inhalation route, is a serious eye damage active substance, is not classified for skin irritation and not classified for skin sensitisation either.

2.4.2 Operator exposure

Considering proposed uses, operator systemic exposure was estimated using the EFSA model¹¹:

Model data		
	Level of PPE	% AOEL
Application : Tractor mounted <i>downward spraying</i> Outdoor Sugar cane		
Application rate: kg/ha		0.75 kg 2,4-D / ha
Spray ap-plica-tion (AOEM; 75th percentile) Body weight: 60 kg	Working coverall and gloves during mix/loading and application	3.46

Model data		
	Level of PPE	% AOEL
Application : Tractor mounted <i>downward spraying</i> Outdoor Lavender		
Application rate: kg/ha		0.36 kg 2,4-D / ha

¹¹ AOEM – Agricultural Operator Exposure Model (EFSA Journal 2014;12 (10):3874)

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Spray application (AOEM; 75th percentile) Body weight: 60 kg	Working coverall and gloves during mix/loading and application	2.65
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Model data		
	Level of PPE	% AOEL
Application : Tractor mounted downward spraying Outdoor Pome fruit, stone fruit, tree nuts		
Application rate: kg/ha		0.75 kg 2,4-D / ha
Spray application (AOEM; 75th percentile) Body weight: 60 kg	Working coverall and gloves during mix/loading and application	3.08

According to the model calculations, it can be concluded that the risk for the operator using CHARDOL 600 (FORMULATION CODE: CA2036), (is acceptable with a working coverall and gloves during mixing/loading and application.

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

2.4.3 Worker exposure

Workers may have to enter into treated areas after treatment for crop inspection activities. Therefore, estimation of worker exposure was calculated according to AOEM model.

Model data		2,4-D
	Level of PPE	%AOEL
Crop : Sugar cane Activity: Inspection, irrigation Outdoor Work rate: 2 hours/day Number of applications : 1 Interval between treatments: -		
DT50:		30 days
DFR:		3 µg/cm ² /kg a.s./ha
Application rate (kg as/ha)		0.75 kg /ha
Body weight: 60 kg	Work wear (arms, body and legs covered) TC: 1400 cm ² /person/h	21.00

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Model data		2,4-D
	Level of PPE	%AOEL
Crop : Lavender Activity: Cutting, sorting, bundling, carrying Outdoor Work rate: 8 hours/day Number of applications : 1 Interval between treatments: -		
DT50:		30 days
DFR:		3 µg/cm ² /kg a.s./ha
Application rate (kg as/ha)		0.36 kg /ha
Body weight: 60 kg	Work wear (arms, body and legs covered) TC: 1400 cm ² /person/h	83.97

CA2036 is used as herbicide in Pome fruit, stone fruit and tree nut. For these use, the EFSA model does not take into account worker tasks such as inspection and irrigation. In accordance with the TCs proposed in the EFSA Guidance and the default value of 2 hours for inspection activities, the following formula is applied:

$$\text{Systemic exposure [mg a.s/kg bw/day]} = (\text{AR (kg sa/ha)} \times \text{DFR } [\mu\text{g/cm}^2] \times \text{TC [cm}^2/\text{h}] \times \text{T [h/day]}) \times \text{MAF} / 1\,000 \times \text{DA [\%]} / \text{BW}$$

Where:

Dislodgeable foliar residue (DFR): 3 µg/cm² of foliage/kg a.s. applied/ha × application rate [kg a.s./ha]

Transfert coefficient (TC): 12500 cm²/h (total potential exposure) and 1400 cm²/h (arms, body and legs covered)

Work rate (T): 2 hours

Multiple application factor (MAF): x

Dermal absorption (DA): x %

Body weight (BW): 60 kg

	Potential exposure	Work wear - arms, body and legs covered
Total systemic exposure (mg a.s./day)	2,25	0,252
Total systemic exposure per kg body weight (mg/kg bw/day)	0,0375	0,0042
% of RVNAS	187,50%	21,00%

For all uses, worker exposure reentering into treated crops has been calculated to be below the AOEL.

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

2.4.4 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 2,4D, i.e. no acute operator or bystander exposure assessments can be performed with the AOEM model where no AAOEL has been set¹².

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.”

Bystander exposure was assessed according to EFSA model without mitigation measures (2,4D)

2.4.5 Resident exposure

Resident exposure was assessed according to EFSA model without mitigation measures, a distance of 3 metres from the spray boom and no drift reduction technology was considered.

Model data		2,4-D
		% AOEL
Scenario: Sugar cane Buffer zone: 3 (m) Drift reduction technology: no Number of applications : 1 Interval between treatments: -		
DT ₅₀		30 days
DFR		3 µg/cm²/kg a.s./ha
Resident (children) Body weight: 10 kg	Spray drift (75th percentile)	27.36
	Vapour (75th percentile)	5.35
	Surface deposits (75th percentile)	5.23
	Entry into treated crops (75th percentile)	25.31
	All pathways (mean)	44.55
Resident (adults) Body weight: 60 kg	Spray drift (75th percentile)	6.47
	Vapour (75th percentile)	1.15
	Surface deposits (75th percentile)	1.02
	Entry into treated crops (75th percentile)	14.06
	All pathways (mean)	16.20
Model data		2,4-D
		% AOEL
Scenario: Lavender		

¹² 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)

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Buffer zone: 3 (m) Drift reduction technology: no Number of applications : 1 Interval between treatments: -		
DT ₅₀		30 days
DFR		3 µg/cm ² /kg a.s./ha
Resident (children) Body weight: 10 kg	Spray drift (75th percentile)	27.36
	Vapour (75th percentile)	5.35
	Surface deposits (75th percentile)	22.37
	Entry into treated crops (75th percentile)	25.31
	All pathways (mean)	58.42
Resident (adults) Body weight: 60 kg	Spray drift (75th percentile)	6.47
	Vapour (75th percentile)	1.15
	Surface deposits (75th percentile)	4.37
	Entry into treated crops (75th percentile)	14.06
	All pathways (mean)	18.91

Model data		2,4-D
		% AOEL
Scenario: Pome fruit, stone fruit, tree nuts Buffer zone: 3 (m) Drift reduction technology: no Number of applications : 1 Interval between treatments: -		
DT ₅₀		30 days
DFR		3 µg/cm²/kg a.s./ha
Resident (children) Body weight: 10 kg	Spray drift (75th percentile)	27.36
	Vapour (75th percentile)	5.35
	Surface deposits (75th percentile)	22.37
	Entry into treated crops (75th percentile)	25.31
	All pathways (mean)	58.42
Resident (adults) Body weight: 60 kg	Spray drift (75th percentile)	6.47
	Vapour (75th percentile)	1.15
	Surface deposits (75th percentile)	4.37
	Entry into treated crops (75th percentile)	14.06
	All pathways (mean)	18.91

For aforementioned uses and scenarios, resident exposure (children and adults) is below the AOEL.

2.4.6 Combined exposure

Not relevant

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

An exceedance of the current MRL of 0.05* mg/kg on sugar cane, pome fruit, stone fruit and tree nuts for 2,4-D as laid down in Reg. (EU) 396/2005 is not expected.

According to magnitude of residue trials presented in this dossier, a PHI F- BBCH 29-32 is proposed for the use on sugar cane.

Considering that the active substance 2,4-D is systemic, in the absence of residue trials with honey, an exceedance of the current MRL of 0.05 mg/kg in honey, as laid down in Reg. (EU) 396/2005, cannot be excluded for the use on lavender and lavandin.

The chronic and the short-term intakes of 2,4-D residues are unlikely to present a public health concern.

As far as consumer health protection is concerned, zRMS agrees with the authorization of the intended uses.

Table 2.5-1: Information on CA2036 (2,4-D DMA 600 SL) (KCP 8.7)

Crop	PHI for CA2036 proposed by applicant	PHI/ Withholding period* sufficiently supported for 2,4-D	PHI for CA2036 proposed by zRMS	zRMS Comments (if different PHI proposed)
Sugar cane	15 days	No	F – BBCH 29-32	Insufficient residue data supporting the intended PHI of 15 days
Pome fruits	30 days	Yes	30 days	
Stone fruit	30 days	Yes	30 days	
Tree nuts	30 days	Yes	30 days	
Aromatic plant: Lavender, lavandin	No concern.			

* Purpose of withholding period to be specified

Waiting periods before planting succeeding crops

Not relevant.

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 2,4-D and its metabolites in soil, surface water and groundwater have been assessed according to FOCUS guidance documents, with standard FOCUS scenarios to obtain outputs from the FOCUS models and the endpoints established in the EU conclusions or agreed in the assessment based on new data provided.

PEC soil and PEC_{sw} derived for the active substance and its metabolites are used for the ecotoxicological risk assessment, and mitigation measures are proposed.

For the intended uses on orchards, the PEC_{sw} and PEC_{sed} calculations do not cover the application period post-harvest. Therefore, the risk assessment for non-target aquatic organisms cannot be finalized for this application period for these uses.

PEC_{gw} for 2,4-D and its metabolites do not occur at levels exceeding those mentioned in regulation EU No 546/2011. 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 DT₅₀ 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 review for active substances and their metabolites were used for the intended use patterns. In cases where deviations from the EU agreed endpoints were considered appropriate (for example when additional studies are provided), such deviations were highlighted and justified accordingly.

Based on the guidance documents, the risks for birds, mammals, bees and non-target arthropods, soil macro- and micro-organisms and non-target plants are acceptable for the intended uses.

For aquatic organisms, the risk is acceptable for all requested uses **excepted for orchards at post-harvest** when the mitigation measures as reported in point “ 2.5.1 Restrictions linked to the PPP” are applied.

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 2,4-D is not approved as a candidate for substitution, therefore a comparative assessment is not foreseen.

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

None.

4.1.2 Post-authorisation data requirements

For authorisation renewal, provide data permitting to ensure respect of MLR of 2,4D in honey (consult guidelines SANTE/11956/2016).

Appendix 1 Copy of the product authorisation

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Décision relative à une demande d'extension d'usages 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 réglementaire,

*Vu la demande d'extension d'usages majeurs du produit phytopharmaceutique **CHARDOL 600***

de la société NUFARM SAS

enregistrée sous le n°2021-2558

Vu les conclusions de l'évaluation de l'Anses du 22 septembre 2022,

Vu la décision du Directeur général de l'Anses du 3 octobre 2022,

Vu le recours gracieux formé le 10 novembre 2022 par la société NUFARM SAS,

Considérant les dispositions nationales relatives à la mise en œuvre du document guide européen sur les LMR dans le miel du 12 août 2022,

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

La présente décision abroge et remplace la décision du 3 octobre 2022 et 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	CHARDOL 600 U 600 D U 46 PRO U 600 PRO DICOPUR 600 SPECIAL LISERONS CHARDONS EV
Type de produit	Produit de référence
Titulaire	NUFARM SAS Immeuble West Plaza 11 rue du Débarcadère 92700 COLOMBES France
Formulation	Concentré soluble (SL)
Contenant	600 g/L - 2,4-D
Numéro d'intrant	9100296
Numéro d'AMM	9100296
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 14/12/2022

DocuSigned by:

 AE2B1A955A42454...
 Directrice générale déléguée
 en charge du pôle produits réglementés
 Agence nationale de sécurité sanitaire de
 l'alimentation, de l'environnement et du travail (ANSES)

CA2036 / CHARDOL 600
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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)
13205901 Canne à sucre* Désherbage	1,25 L/ha	1/an	entre les stades BBCH 29 et BBCH 32	F (BBCH 32)	20	-	-	Non concerné
	-	-	-	-	-	-	-	-
19335901 PPAM - non alimentaires* Désherbage	0,6 L/ha	1/an	entre les stades BBCH 14 et BBCH 32	Non applicable	5	-	-	Non concerné
	Uniquement sur lavande et lavandin. Usage autorisé dans le cadre de l'article 51 du règlement (CE) n°1107/2009.							

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Liste des usages refusés			
Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
12455901 Fruits à coque*Désherbage* Cult. Installées	1,25 L/ha	1/an	30
	Motivation du refus : L'usage est refusé car l'efficacité du produit n'a pas été démontrée et les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les organismes aquatiques lors d'un traitement après récolte.		
12555902 Fruits à noyau*Désherbage* Cult. Installées	1,25 L/ha	1/an	30
	Motivation du refus : L'usage est refusé car l'efficacité du produit n'a pas été démontrée et les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les organismes aquatiques lors d'un traitement après récolte.		
12605905 Fruits à pépins*Désherbage* Cult. Installées	1,25 L/ha	1/an	30
	Motivation du refus : L'usage est refusé car l'efficacité du produit n'a pas été démontrée et les données disponibles ne permettent pas d'exclure un risque d'effet inacceptable pour les organismes aquatiques lors d'un traitement après récolte.		

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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

• 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 ;
- 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.
- Lunettes ou écran facial certifié norme EN 166 (CE, sigle 3).

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 :

- 24 heures.

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**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)

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 2 : Pour protéger les organismes aquatiques, ne pas appliquer ce produit sur sol artificiellement drainé ayant une teneur en argile supérieure ou égale à 45 %.

- SPE 3 : Pour protéger les organismes aquatiques, respecter une zone non traitée de 20 mètres par rapport aux points d'eau pour l'usage sur « canne à sucre » et mettre en place des mesures (ou dispositifs) limitant les transferts par ruissellement.

- SPE 3 : Pour protéger les organismes aquatiques, respecter une zone non traitée de 5 mètres par rapport aux points d'eau pour l'usage sur « PPAM - non alimentaires ».

Exigences complémentaires post-autorisation

A défaut de transmission de ces données dans les délais impartis à compter de la date de la présente décision, la présente décision pourra être retirée ou modifiée.

Détail de la demande post autorisation	Délai (mois)	Récurrence (mois)
Fournir les éléments permettant de garantir le respect des limites maximales de résidus de 2,4-D fixées dans le miel (consulter le document guide SANTE/11956/2016).	A fournir au renouvellement de l'AMM	-

Recommandations relatives à l'étiquette du produit

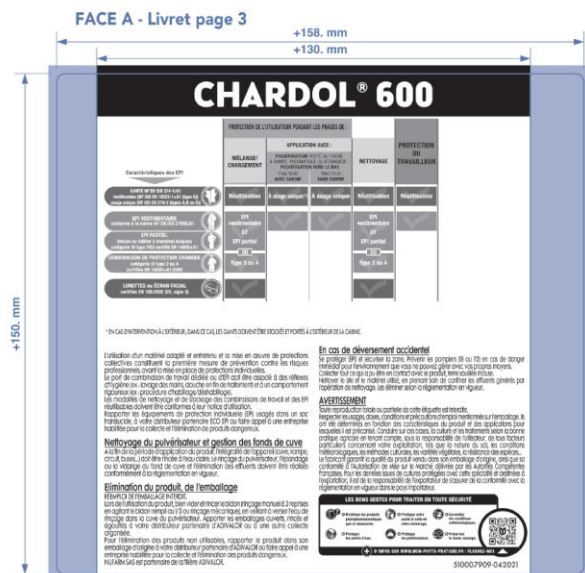
Il est recommandé de faire figurer l'information suivante sur l'étiquette :

- 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 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.



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miller GRAPHICS GROUP 10 - 12, rue Léon Walras Z.I. de Magré - 87100 Limoges FRANCE Tél. 05 55 30 04 55 www.millergraphics.com	CLIENT NUFARM SAS	C 1.33% M 6.65% Y 1.37% K 6.78% VERNIS UV 100%	UNIT SIZE 150 x 160 mm INK NUMBER 4 SH2 DEVELOPMENT PLATE SCREEN RULING 120 PRINTING SIDE surface DATE	FOR APPROVAL Please verify the proof carefully, returning by ink, size, text, and barcode. For the Personal Colour, please refer to the colour Personal Colour guide. After your approval on the above we can proceed to the next stage of your project. Please send this proof by signature and send it back to us. Thank you. CLIENT SIGNATURE Date:
	REFERENCE 3485263-001-013	ORDER N° 00154777-001-013 BARCODE N° 3485263-001-013 CSR Marion Champelovier OPERATOR BLA PROOF / DATE Approval N°1 - 04-Mai-21	UNIT SIZE 150 x 160 mm INK NUMBER 4 SH2 DEVELOPMENT PLATE SCREEN RULING 120 PRINTING SIDE surface DATE	FOR APPROVAL Please verify the proof carefully, returning by ink, size, text, and barcode. For the Personal Colour, please refer to the colour Personal Colour guide. After your approval on the above we can proceed to the next stage of your project. Please send this proof by signature and send it back to us. Thank you. CLIENT SIGNATURE Date:
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