REGISTRATION REPORT

Part A

Risk Management

Product code: 1 31080 00

Product name: REMARCABLE

Active substance:

2,4-D, 250 g/L

COUNTRY: FRANCE

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(new application)

Applicant: PHYTEUROP

Date: 2022-01-03

Table of Contents

PART A – Risk Management

The company PHYTEUROP has requested marketing authorisation in France for the product REMARCABLE (product code: 1 31080 00), containing 250 g/L 2,4-D, as a herbicide for professional use.

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report (RR), Part B Sections 1-7 and Part C, and where appropriate the addenda for France. The information, data and assessments provided in Registration Report, Part B include assessment of further data or information as required at national registration by the EU peer review. It also includes assessment of data and information relating to REMARCABLE (1 31080 00) where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of REMARCABLE (1 31080 00) have been made using endpoints agreed in the EU peer review of 2,4-D.

This document describes the specific conditions of use and labelling required for France for the registration of REMARCABLE (1 31080 00).

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

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

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

1 DETAILS OF THE APPLICATION

1.1 Application background

The present registration report concerns the evaluation of PHYTEUROP's application to market REMARCABLE (1 31080 00) in France as a herbicide (product uses described under point 2.3). France acted as a zonal Rapporteur Member State (zRMS) for this request and assessed the application submitted for the first authorisation of this product in France and in other MSs of the Southern zone.

1.2 Active substance approval

2,4-D

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.
Specific provisions of Regulation (EU) No 2015/2033 were as follows: 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 2,4-D, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to the risk to aquatic organisms, terrestrial organisms and consumers in cases of uses above 750 g/ha. Conditions of use shall include risk mitigation measures, where appropriate. The notifier shall submit to the Commission, the Member States and the Authority: (1) confirmatory information in the form of the submission of the complete study results from the existing extended one-generation study; (2) confirmatory information in the form of the submission of the Amphibian Metamorphosis Assay (AMA) (OECD (2009) Test No 231) as to verify the potential endocrine properties of the substance. The information set out in point (1) shall be submitted by 4 June 2016 and the information set out in point (2) by 4 December 2017.

An EFSA conclusion is available (EFSA Journal 2014; 12(9):3812).

A review report is available in the form of a Revised Renewal report (SANCO/11961/2014 Rev 5 of 6 October 2017).

1.3 Regulatory approach

The present application (2015-2637) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses) in the context of the zonal procedure for all Member States of the Southern zone, taking into account the worst-case uses ("risk envelope approach")[1] – the highest application rates over the Southern Zone. When risk mitigation measures were necessary, they are adapted to the situation in France.

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

The French Order of 4 May 2017[2] provides that:
- unless formally stated in the product authorisation, the pre harvest interval (PHI) is at least three days;
- unless formally stated in the product authorisation, the minimum buffer zone alongside a water body is five metres;
- unless formally stated in the product authorisation, the minimum re-entry period is six hours for field uses and eight hours for indoor uses.

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

The current document (RR) based on Anses's assessment of the application submitted for this product is in compliance with Regulation (EC) no 1107/2009[3], implementing regulations, and French regulations.

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

The conclusions relating to the acceptability of risk are based on the criteria indicated in Regulation (EU) No 546/2011[4], and are expressed as "acceptable" or "not acceptable" in accordance with those criteria.

Finally, 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.

---

1 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

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

3 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

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 Arrêté du 12 avril 2021 relatif à la mise en œuvre du catalogue national des usages phytopharmaceutiques visés dans les décisions d'autorisation de mise sur le marché et de permis de commerce parallèle des produits phytopharmaceutiques et des adjuvants

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

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

The Decision, as reproduced in Appendix 1, takes also into account national provisions, including national mitigation measures.

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of REMARCABLE (1 31080 00), it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

1.5 Letter(s) of Access

The applicant has provided letter(s) of access for the active substance.

2 DETAILS OF THE AUTHORISATION

2.1 Product identity

Product name (code)	REMARCABLE (1 31080 00).
Authorisation number	Not applicable
Function	Herbicide.
Applicant	PHYTEUROP.
Composition	250 g/L 2,4-D.
Formulation type (code)	Emulsifiable concentrate (EC).
Packaging	N/A : not registered in France

2.2 Classification and labelling

2.2.1 Classification and labelling in accordance with Regulation (EC) No 1272/2008

Physical hazards		
Health hazards	Acute Toxicity, category 4. Skin irritation, category 2. Eye irritation, category 2. Skin sensitisation, category 1. Specific target organ toxicity - single exposure, hazard category 3, respiratory tract irritation.	
Environmental hazards	Hazardous to the aquatic environment, chronic hazard, category 2.	
Hazard pictograms		
Signal word	Warning	
Hazard statements	H302	Harmful if swallowed.
	H315	Causes skin irritation.
	H317	May cause an allergic skin reaction.

	H319	Causes serious eye irritation.
	H335	May cause respiratory irritation.
	H411	Toxic to aquatic life with long-lasting effects.
Precautionary statements –	***For the P phrases, refer to the extant legislation***	
Supplementary information (in accordance with Article 25 of Regulation (EC) No 1272/2008)	-	-

See Part C for justifications of the classification and labelling proposals.

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

N/A : not registered in France.

2.2.3 Other phrases linked to the preparation

N/A : not registered in France.

2.3 Product uses

Please note: The GAP Table below reports the intended uses proposed by the applicant, 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: 2022-01-03

PPP (product name/code) **1 31080 00**
active substance **2,4-D**
Applicant: **PHYTEUROP**
Zone(s): **Southern EU**

Formulation type: **EC**
Conc. of a.s. **250 g/L**
professional use ☒
non-professional use ☐

Verified by MS: **no**

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)	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]
1	France	Grassland (3GRLC) (including pastures)	F	Dicotyledons	Broadcast: High and low volume sprays - overall	March - September	1	-	3.0	750	200 - 500	15 days	**Not acceptable** (risk to consumers)
2	France	Grass turf (3AMGC)	F	Dicotyledons	Broadcast: High and low volume sprays - overall	March - September	1	-	2.9	725	200 - 500	-	**Not acceptable** (risk to operators (for hand-held lance applications), bystanders, residents, workers)
3	France	Inter-crop (3INTCO°	F	Dicotyledons	Broadcast: High and low volumes spray - overall	March - May August - October	1	-	1.7	425	100 - 300	-	**Not acceptable** (risk to bystanders, residents)

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)	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		
4	France	Winter cereals (NNNGW) (wheat, triticale, spelt, barley, oat, rye)	F	Dicotyledons	Broadcast: High and low volume sprays - overall	February – April BBCH 29-32	1	-	3.0	750	100 - 300	F	**Not acceptable** (risk to bystanders, residents, workers)
5	France	Spring cereals (NNNGS) (wheat, triticale, barley, oat, rye)	F	Dicotyledons	Broadcast: High and low volume sprays - overall	March - June BBCH 21-32	1	-	1.7	425	100 - 300	F	**Not acceptable** (risk to bystanders, residents, workers)
6	France	Maize (ZEAMX)	F	Dicotyledons	Broadcast: High volume spray - between plants	April – August BBCH 11-**16 (between plant rows only)**	1	-	2.4	600	100 - 400	F	**Not acceptable** (risk to bystanders, residents, workers)

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

REMARCABLE (1 31080 00) is an emulsifiable concentrate (EC). All studies have been performed in accordance with the current requirements and the results are deemed acceptable. The appearance of the product is that of a yellowish liquid, with a terpene-like odour. It is not explosive and has no oxidising properties. The product is not flammable and has a flash point of 95.5 °C. It has a self-ignition temperature of 368 °C. In 1 % aqueous solution, it has a pH value of 3.03 at 21 °C. There is no effect of low and high temperatures on the stability of the formulation, since after seven days at 0 °C and 14 days at 54 °C, neither the active substance content nor the technical properties were changed. The stability data indicate a shelf life of at least two years at ambient temperature when stored in HDPE. As the stability was performed on HDPE packaging, all packaging can be considered acceptable. The technical characteristics are acceptable for an EC formulation.

The formulation is not classified for the physico-chemical aspect.

The product must be shaken before use and the spray mixture stirred/agitated during application.

3.1.2 Methods of analysis

Analytical methodology for the determination of the active substance in the formulation is available and validated.

No analytical method for the determination of the relevant impurities of the active substance 2,4-D (dioxins and furans expressed as 2,3,7,8-tetrachlorodibenzodioxin (TCDD) equivalent toxic < 10 ppb) has been submitted for the product; this is required post-authorisation.

Analytical methods are available in the Draft Renewal Assessment Report (DRAR) and validated for the determination of residues of 2,4-D in plants (dry matrices), animal products, soil, water (surface and drinking) and air.

To update the dossier:

According to the EFSA conclusion, further data on the hydrolysis step and extraction efficiency for the animal and plant analytical methods was identified as missing; this is required.

The active substance is neither toxic nor very toxic, hence no analytical method is required for the determination of residues in biological fluids and tissues.

3.1.3 Mammalian Toxicology

Endpoints used in risk assessment

Active substance: **2,4-D**		
ADI	0.02 mg/kg bw/d	EU 2017 (2,4-D SANCO/11961/2014 Rev 4 final; 6 October 2017)
ARfD	0.3 mg/kg bw	
AOEL	0.02 mg/kg bw/d	
AAOEL	-	
Dermal absorption	Based on an *in vitro* human study performed on the formulation REMARCABLE (1 31080 00) [2,4-D 250 g/L EC], at two in-use diluted rates of the product and default value for concentrate (EFSA 2012):	

		Spray dilution (6 g/L)	Spray dilution (1.42 g/L)
	Dermal absorption (%)	**50**	**42**
		Concentrate (250 g/L)	Spray dilution (1.5 g/L)
	Dermal absorption endpoints (%)	**25**	**42**
Oral absorption **(%)**			**> 90**

* Remark: the first dermal absorption endpoint proposed by the applicant used the dermal absorption values determined for the representative product (2,4-D DMA 600 SL) in the RAR of 2,4-D. However, this product cannot be considered similar to REMARCABLE (1 31080 00) according to the EFSA guidance on dermal absorption (2012). REMARCABLE (1 31080 00) is a solvent-based formulation (EC) whereas 2,4-D DMA 600 SL is a water-based formulation. In addition, REMARCABLE (1 31080 00) is classified as a skin irritant and a skin sensitiser whereas 2,4-D DMA 600 SL is not. Therefore the default values of 25 % for the concentrate and 75 % for the dilution have been proposed as dermal absorption endpoints.

Since the exposure assessment was not acceptable, the applicant submitted an *in vitro* human study performed on the diluted formulation REMARCABLE (1 31080 00). According to this study, the dermal absorption is 42 % for the diluted formulation.

3.1.3.1 Acute Toxicity

REMARCABLE (1 31080 00), containing 250 g/L 2,4-D, has a low acute inhalational and dermal toxicity, is an acute oral toxicant, is irritating to skin, respiratory tract and eye, and is a skin sensitiser.

The classification proposed in accordance with Regulation (EC) No 1272/2008 is shown in Section 2.2.

3.1.3.2 Operator Exposure

Summary of critical use patterns (worst cases):

Crop type	F/G[7]	Equipment *Application method*	Maximum application rate (product, L/ha) [g a.s./ha]	Minimum volume water (L/ha)
Winter and spring cereals and Maize	F	Vehicle-mounted - downward spraying	3 [750]	100
Bare soil (post-harvest – pre-emergence)	F	Vehicle-mounted - downward spraying	1.7 [425]	100
Grassland (including pasture) and grass turf	F	Vehicle-mounted	3 [750]	200
	F	Knapsack		
	F	Hand-held		

[7] Open field or glasshouse

Considering the proposed uses, operator systemic exposure was estimated using the EFSA model[8]:

Crop	Equipment	PPE and/or working coverall	% AOEL 2,4-D
Cereals, maize, bare soil			
Winter and spring cereals and maize	Vehicle-mounted drift reduction	Working coverall and gloves during mixing/loading and application	64
Bare soil (Post harvest - pre emergence)	Vehicle-mounted drift reduction	Working coverall and gloves during mixing/loading and application	38
Grassland (including pasture) and grass turf			
Grassland and lawns Golf, turf or other sports lawns	Vehicle-mounted drift reduction	Working coverall and gloves during mixing/loading and working coverall during application	64
	Manual knapsack	Working coverall and gloves during mixing/loading and working coverall during application	**317**
	Manual hand-held lance	Working coverall and gloves during mixing/loading and working coverall during application	**635**

Considering the proposed uses on "pasture and grass turf" are non-agricultural areas, operator systemic exposure was also estimated using the French study from UPJ 2009-2010[9] dedicated to such uses:

Crop	Equipment	PPE and/or working coverall	% AOEL 2,4-D
Pasture and Grass turf	<u>Scenario 5 :</u> Downward applications, low-level target with tractor-mounted/trailed boom sprayer: hydraulic nozzles (Treated surface: 4 ha)	Working coverall and gloves during mixing/loading and working coverall during application	**153**
	<u>Scenario 2a :</u> Hand-held applications hydraulic nozzles "small devices" – low-level target (Treated surface: 0.14 ha)	Working coverall and gloves during mixing/loading and application	15

[8] AOEM – Agricultural Operator Exposure Model (EFSA Journal 2014:12 (10):3874)

[9] Studies and models that can be used to estimate operator exposure during the use of plant protection products in non- agricultural areas. Report from expert group "produits phytosanitaires : substances et préparations chimiques" Working group "évaluation de l'exposition des utilisateurs de produits phytopharmaceutiques en zones non agricoles" - June 2011.

	Scenario 1a : Hand-held applications "large devices" – low-level target (Treated surface: 1.4 ha)	Working coverall and gloves during mixing/loading and application	**217**

EFSA model:

According to the EFSA model calculations and concerning the application of REMARCABLE (1 31080 00) on bare soil and cereals, grassland (including pasture) and grass turf using a vehicle-mounted- drift reduction equipment, it can be concluded that the risk for the operator is acceptable with a working coverall and gloves during mixing/loading and application.

Concerning the application of REMARCABLE (1 31080 00) on grass turf using a manual knapsack or hand-held equipment, the risk for the operator is unacceptable even with coverall and gloves during mixing/loading and application.

MONOP-ZNA model:

According to MONOP-ZNA model and concerning the application of REMARCABLE (1 31080 00) on pasture and grass turf with vehicle-mounted or manual hand-held equipment (grass turf), the risk for the operator is unacceptable with appropriate personal protective equipment.

The risk for the operator is acceptable only for the application of REMARCABLE (1 31080 00) using a manual knapsack equipment on grass turf (low surface area, .i.e., 0.14 ha) when they wear working coverall and gloves during mixing/loading and application.

Considering the assessments done according to the EFSA calculator and to MODOP-ZNA:

- Considering vehicle-mounted equipment, MODOP-ZNA includes data from the BBA model which are no longer considered applicable for this scenario. Then the evaluation done with the EFSA model is more relevant than this done with MODOP-ZNA. The risk of operators during mixing/loading and application on pastures and grass turf using vehicle-mounted equipment is acceptable with a working coverall and gloves during mixing/loading and application.
- Considering manual knapsack equipment, MODOP-ZNA is more appropriate than the EFSA calculator as it includes data generated under conditions applicable to uses on grass turf. The risk to operators during mixing/loading and application on grass turf using vehicle-mounted equipment is acceptable with a working coverall during mixing/loading and application and gloves during mixing/loading.

Finally, acceptable scenarios are met for operators except for application using manual hand-held equipment with lance on grass turf.

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

3.1.3.3 Bystander Exposure

In the absence of an AAOEL determined for 2,4-D, it is considered that the risk assessment for the bystander is covered by the resident risk assessment.

Indeed, 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*."

3.1.3.4 Worker Exposure

Workers may have to enter treated areas after treatment for crop inspection/irrigation or maintenance activities. Therefore, estimation of worker exposure was calculated according to the EFSA model. Exposure is estimated to be more than 221 % of the AOEL of 2,4-D with at least working clothing.

Uses (EFSA scenario)	**Tasks**	**PPE and/or working coverall**	**% AOEL**
Cereals	Inspection, irrigation	Working clothing	**226**
Grassland and lawns	Inspection, irrigation	Working clothing	**221**
Golf course, turf or other sports lawns	Maintenance	Working clothing and gloves	**365**
Bare soil	Not relevant	Not relevant	-

It may be concluded that there is an unacceptable risk anticipated for the worker regarding the application of REMARCABLE (1 31080 00) on cereals, grassland and lawns.

However, REMARCABLE (1 31080 00) is used as herbicidal treatment on some crops or situations where there is no need to re-enter the treated area after application. Estimation of worker exposure is considered to be not necessary for bare soil (post-harvest – pre-emergence) and grassland.

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

3.1.3.5 Resident Exposure

<u>EFSA model:</u> Residential exposure was assessed according to the EFSA model:

e.g. Tractor-mounted boom spray application outdoors to low crops
Buffer zone: 10 m
Drift-reduction technology: yes
DT_{50}: 30 days
DFR: 3µg/cm^2/kg a.s./ha
Interval between treatments: 365 days

Crop			% AOEL 2,4-D
Bare soil	Resident child Body weight: 10 kg	**Sum (all pathways)**	**163**
	Resident adult Body weight: 60 kg	**Sum (all pathways)**	75
Winter and spring cereals and maize	Resident child Body weight: 10 kg	**Sum (all pathways)**	**291**
	Resident adult Body weight: 60 kg	**Sum (all pathways)**	**134**
Grassland and lawns Golf, turf or other sports lawns	Resident child Body weight: 10 kg	**Sum (all pathways)**	91
	Resident adult Body weight: 60 kg	**Sum (all pathways)**	32

e.g. manual hand-held or knapsack application outdoors to low crops
Buffer zone: 10 m
DT_{50}: 30 days
DFR: 3µg/cm^2/kg a.s./ha
Interval between treatments: 365 days

Crop			% AOEL 2,4-D
Grassland and lawns Golf, turf or other sports lawns	Resident child Body weight: 10 kg	**Sum (all pathways)**	**126**
	Resident adult Body weight: 60 kg	**Sum (all pathways)**	39

EFSA model:
For applications on bare soil and cereals, an unacceptable risk was determined for residents (adult or/and child) even when drift-reduction technology and mitigation measures such as a buffer zone of 10 metres are taken to reduce the resident exposure.

For applications using manual knapsack or hand-held, on pastures and grass turf, an unacceptable risk was determined for child. Whereas the risk is acceptable for child and adult after application using vehicle-mounted with drift-reduction technology and mitigation measures such as a buffer zone of 10 metres.

EFSA model: Recreational exposure was assessed according to the EFSA model
EFSA model (Golf course, turf or other sports lawns): Recreational exposure was assessed according to the EFSA model. Exposure is estimated to be 463 % and 192 % of the AOEL of 2,4-D for children and adults, respectively. For Golf course, turf or other sports lawns, there is an unacceptable risk anticipated for recreational exposure.

Conclusion:
It may be concluded that there is an unacceptable risk to the resident exposed to REMARCABLE (1 31080 00), except for use on grassland.

3.1.4 Residues and Consumer Exposure

The data available are considered sufficient for risk assessment. No exceedance of the current MRL for 2,4-D as laid down in Reg. (EU) 396/2005 is expected.

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, France agrees with the authorisation of the requested uses.

The intended use of 2,4-D on grassland/pasture is likely to lead to livestock exposure to 2,4-D, which was shown to be potentially metabolised to 2,4-DCP (in liver and kidney), a metabolite for which further toxicological information and further data on the consumer exposure is needed. Since no such data were submitted, the risk assessment relating to use on pasture cannot be considered as acceptable.

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

Data gaps: none.

Data required in post-authorisation: none.

Summary of the evaluation

REMARCABLE (1 31080 00) contains 2,4-D.

Summary for 2,4-D

Use-No.*	**Crop**	**Plant metabolism covered?**	**Sufficient residue trials?**	**PHI sufficiently supported?**	**Sample storage covered by stability data?**	**MRL compliance Reg. (EU) no 1317/2013**	**Chronic risk for consumers identified?**	**Acute risk for consumers identified?**	**Comments**
	Winter and spring cereals	Yes	Yes	Yes	Yes	Yes	No	No	-
	Maize	Yes (but - see comment)	Yes(2)	Yes(2)	Yes	Yes	No	No	Only up to BBCH 16 and PHI F
	Grassland/ pasture	Yes	Yes	Yes	Yes	N.R.	**Not finalised**	**Not finalised**	Risk assessment for this requested use cannot be finalised.
	General treatment	-	-	-	-	-	-	-	

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

As residues of 2,4-D do not exceed the trigger values defined in Reg. (EU) No 283/2013, there is no need to investigate the effect of industrial and/or household processing.

Residues in succeeding crops have been sufficiently investigated taking into account the specific circumstances of the cGAP uses being considered here. It is very unlikely that residues will be present in succeeding crops.

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

During the re-approval process (EFSA, 2014) it was concluded that consumer exposure to 2,4-DCP through animal commodities needs to be reassessed for other uses that those assessed at EU level (i.e., cereals and maize uses with the application rate limited to 750 g/ha). Since no further data were submitted to estimate consumer exposure to 2,4-DCP and as no additional toxicological data are available to conclude on the genotoxic or carcinogenic potential of 2,4-DCP, the risk assessment relating to use on pasture cannot be finalised.

Summary for REMARCABLE (1 31080 00)

Information on REMARCABLE (1 31080 00) (KCA 6.8)

Crop	**PHI for REMARCABLE (1 31080 00) requested by applicant**	**PHI/withholding period* sufficiently supported for 2,4-D**	**PHI for REMARCABLE (1 31080 00) proposed by zRMS**	**zRMS Comments (if different PHI proposed)**
Spring and winter cereals	BBCH 32	Yes	BBCH 32	-
Maize	BBCH 59	No	BBCH 16	No residue trials to support an application up to BBCH 59. Acceptable for consumers with a latest timing of BBCH 16.
General treatment (Post-harvest and before seeding)	NA	-	-	-

* Purpose of withholding period to be specified

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

NR: not relevant

3.1.5 Environmental fate and behaviour

The fate and behaviour in the environment have been evaluated according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU conclusions were used to calculate predicted environmental concentration (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 values 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.

PECsoil and PECsw values derived for the active substance and its metabolites are used for the ecotoxicological risk assessment and mitigation measures are proposed.

PECgw values for 2,4-D and its metabolites do not occur at levels exceeding those mentioned in Regulation (EC) no 1107/2009 and guidance document SANCO 221/2000[10]. Therefore, no unacceptable risk of groundwater contamination is expected for the intended uses.

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

3.1.6 Ecotoxicology

The ecotoxicological risk assessment of the formulation was performed according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU review for active substances and their metabolites were

[10] Guidance document on the assessment of the relevance of metabolites in groundwater of substances regulated under Council directive 91/414/EEC. Sanco/221/2000-rev10-final, 25 February 2003.

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 other non-target arthropods, earthworms and other soil macro- and micro-organisms are acceptable for the intended uses.

For aquatic organisms and non-target plants, risk mitigation measures are required.

3.1.7 Efficacy

Considering the submitted data:

- The efficacy level of REMARCABLE (1 31080 00) is considered satisfactory for all the requested uses.
- The selectivity level of REMARCABLE (1 31080 00) is considered satisfactory for all the requested uses. It is important to note that the application of REMARCABLE (1 31080 00) on maize should always be done *between* plant rows, to avoid phytotoxicity.
- The risks of negative impact on yield, quality, transformation processes, propagation, succeeding and adjacent crops are considered negligible.
- The risk of resistance developing or appearing to 2.4 D does not require monitoring for the requested use.
- Regarding the risk of phytotoxicity on maize lines for seed production, it is recommended to the user to take advice from specific seed producing institute and/or to follow the recommendation of the seed production company.

3.2 Conclusions arising from French assessment

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

3.3 Substances of concern for national monitoring

No information stated.

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

3.4.1 Post-authorisation monitoring

N/A : not registered in France.

3.4.2 Post-authorisation data requirements

N/A : not registered in France.

3.4.3 Label amendments

N/A : not registered in France

Appendix 1 – Copy of the French Decision

RÉPUBLIQUE
FRANÇAISE
Liberté
Égalité
Fraternité

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

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

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

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

Vu la demande d'autorisation de mise sur le marché et la demande associée du produit phytopharmaceutique ***REMARCABLE***

de la société	*PHYTEUROP*
enregistrées sous les	*n°2015-2637 et 2015-2638*

Vu les conclusions de l'évaluation de l'Anses du 28 avril 2021,

Considérant que l'utilisation du produit peut entraîner un risque d'effet nocif pour les personnes présentes et les résidents ainsi que pour les travailleurs pour les usages sur gazons de graminées et sur céréales,

Considérant par ailleurs, qu'un risque d'effet nocif pour le consommateur, lié à l'utilisation du produit sur les prairies, ne peut être exclu,

Considérant qu'il ne peut pas être établi que les exigences mentionnées à l'article 29 du règlement (CE) n°1107/2009 sont respectées,

La mise sur le marché du produit phytopharmaceutique désigné ci-après **n'est pas autorisée** en France.

RÉPUBLIQUE FRANÇAISE
Liberté
Égalité
Fraternité

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

Informations générales sur le produit	
Noms du produit	REMARCABLE PRIVILEGE
Type de produit	Produit de référence
Titulaire	PHYTEUROP 83 avenue de la Grande Armée 75016 PARIS France
Formulation	Concentré émulsionnable (EC)
Contenant	250 g/L - 2,4-D
Numéro d'intrant	510-2015.01
Numéro d'AMM	-
Fonction	Herbicide
Gamme d'usage	Professionnel

A Maisons-Alfort, le 03/01/2022

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)

REMARCABLE
AMM n°-

Page 2 sur 3

RÉPUBLIQUE FRANÇAISE
Liberté
Égalité
Fraternité

anses

ANNEXE : Conditions de mise sur le marché demandées

Liste des usages refusés

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
15105911 Avoine*Désherbage	1,7 L/ha	1/an	F
	Motivation du refus : L'usage est refusé en raison d'un risque d'effet nocif pour les travailleurs, les personnes présentes et les résidents.		
15105912 Blé*Désherbage	1,7 L/ha	1/an	F
	Motivation du refus : L'usage est refusé en raison d'un risque d'effet nocif pour les travailleurs, les personnes présentes et les résidents.		
18505901 Gazons de graminées* Désherbage	2,9 L/ha	1/an	-
	Motivation du refus : L'usage est refusé en raison d'un risque d'effet nocif pour les travailleurs, les personnes présentes, les résidents et pour les opérateurs dans le cadre d'une application par lance.		
15555901 Maïs*Désherbage	2,4 L/ha	1/an	F
	Motivation du refus : L'usage est refusé en raison d'un risque d'effet nocif pour les travailleurs, les personnes présentes et les résidents.		
15105913 Orge*Désherbage	1,7 L/ha	1/an	F
	Motivation du refus : L'usage est refusé en raison d'un risque d'effet nocif pour les travailleurs, les personnes présentes et les résidents.		
15705914 Prairies*Désherbage	3 L/ha	1/an	-
	Motivation du refus : L'usage est refusé car les données disponibles ne permettent pas d'exclure un risque d'effet nocif pour le consommateur.		
15105915 Seigle*Désherbage	1,7 L/ha	1/an	F
	Motivation du refus : L'usage est refusé en raison d'un risque d'effet nocif pour les travailleurs, les personnes présentes et les résidents.		
11015924 Traitements généraux*Désherbage* Avt Mise Cult.	1,7 L/ha	1/an	-
	Motivation du refus : L'usage est refusé en raison d'un risque d'effet nocif pour les personnes présentes et les résidents.		

REMARCABLE

AMM n°-

Page 3 sur 3

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

REMARCABLE®

NOM HOMOLOGUE :	REMARCABLE
N° D'AMM :	xxxxxxx
DETENTEUR DE L'AMM :	Phyteurop - 55 rue Raspail 92300 Levallois-Perret
TYPE D'ACTION :	Herbicide (HRAC O)
FORMULATION :	Emulsion concentrée (EC)
COMPOSITION :	250 g/L (22,44%) 2,4-D

Usages autorisés	Cultures recommandées	Doses	Spécifications d'emploi	ZNT
Avoine * désherbage	Avoine	- Cultures d'hiver : 3,0 L/ha - Cultures de printemps : 1,7 L/ha	- Cultures d'hiver : BBCH 29 à 32 - Cultures de printemps : BBCH 21 à 32	5m
Blé * désherbage	Blé, triticale, épeautre			
Orge * désherbage	Orge			
Seigle * désherbage	Seigle			
Maïs * désherbage	Maïs	2,4 L/ha	- Traitement dirigé sur l'inter-rang uniquement - BBCH 11 à 59	
Traitements généraux * Désherbage * Avt Mise Cult.	-	1,7 L/ha	-	
Prairies * désherbage	Prairies	3,0 L/ha	Délai réintroduction du bétail / fauche : 15 jours	
Gazons de graminées* désherbage	Gazons de graminées	2,9 L/ha	-	

L'utilisation de ce produit sur ses usages autorisés n'est recommandée que sur les cultures et cibles indiquées dans le tableau ci-dessus. PHYTEUROP décline en conséquence toute responsabilité en cas d'utilisation du produit sur des cultures ou pour des cibles non recommandées.

- Limites maximales de résidus : se reporter aux LMR définies au niveau de l'Union Européenne, consultables à l'adresse : http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database
- Les mélanges doivent être mis en œuvre conformément à la réglementation en vigueur.
- Délai de rentrée : 48 heures.

Performances

REMARCABLE est un herbicide antidicotylédones à large spectre d'action.
REMARCABLE, absorbé par le système foliaire, se déplace à l'intérieur de la plante et agit même sur les organes souterrains, si bien qu'il est actif à la fois sur les plantes annuelles, jeunes ou développées et sur des espèces vivaces. Il agit essentiellement sur les mauvaises herbes présentes lors du traitement. Annuelles les plus sensibles : Bleuet, Capselle, Coquelicot, Géranium : au stade plantule ; Laiteron, Lamier, Moutarde, Myosotis, Ravenelle, Renoncule. Vivaces : Chardons et Liserons.

Périodes et doses d'emploi

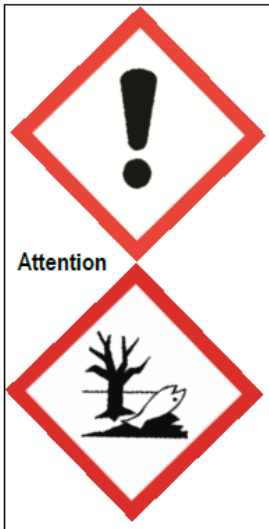
Traiter en période de croissance des mauvaises herbes, par temps doux.
REMARCABLE est actif à partir de 10-12°C. Ne pas traiter au-dessus de 25°C. Ne pas traiter par temps pluvieux, l'efficacité étant diminuée par une pluie survenant moins de 5 heures après l'application. Eviter tout traitement par temps froid ou sur des cultures en mauvais état végétatif.
Céréales : traiter du début du tallage à deux noeuds. Des applications plus précoces peuvent être en effet toxiques pour la céréale et elles peuvent, en outre, provoquer de nombreuses déformations d'épis.
Maïs : Traiter de manière localisée sur l'inter-rang sans toucher les feuilles du maïs afin d'éviter toute phytotoxicité.
Pour un résultat satisfaisant, la lutte contre les vivaces doit se gérer sur plusieurs campagnes à l'échelle de la rotation.
Gazons de graminées : Traiter au moins 3 jours après une tonte et attendre 2 à 3 jours avant de tondre.
Ne pas traiter :- Si le gazon est sur le point d'être ressemé ou sursemé.
- Si des massifs ou des arbres, des plantes bulbeuses et des arbustes sont établis dans les pelouses.
- La première année suivant le semis.

Préparation

REMARCABLE, versé directement dans la cuve du pulvérisateur à demi remplie d'eau, se mélange rapidement par simple brassage. Maintenir l'agitation pendant la pulvérisation, surtout en cas d'application à ultra bas volume. Volume d'eau généralement recommandé : autour de 150 L/ha.

Bonnes pratiques phytosanitaires

- **ATTENTION DANGER POUR LES CULTURES VOISINES. RESPECTER STRICTEMENT LE MODE D'EMPLOI.**
- Toujours conserver le produit dans son emballage d'origine. Le stocker dans un local réservé à cet usage, frais, sec, bien ventilé et fermant à clé, à l'abri du gel et de la chaleur.
- **Réservé à un usage professionnel.**



Attention

REMARCABLE®
Contient : 2,4-D

H302 **Nocif en cas d'ingestion.**
H315 **Provoque une irritation cutanée.**
H319 **Provoque une sévère irritation des yeux.**
H317 **Peut provoquer une allergie cutanée.**
H335 **Peut irriter les voies respiratoires.**
H411 **Toxique pour les organismes aquatiques, entraîne des effets néfastes à long terme.**
P260 Ne pas respirer les aérosols.
P272 Les vêtements de travail contaminés ne devraient pas sortir du lieu de travail.
P273 Éviter le rejet dans l'environnement.
P280 Porter des gants de protection/des vêtements de protection.
P305+P351+P338 EN CAS DE CONTACT AVEC LES YEUX: rincer avec précaution à l'eau pendant plusieurs minutes. Enlever les lentilles de contact si la victime en porte et si elles peuvent être facilement enlevées. Continuer à rincer.
P333+P313 En cas d'irritation ou d'éruption cutanée: consulter un médecin.
SP1 Ne pas polluer l'eau avec le produit ou son emballage. [Ne pas nettoyer le matériel d'application près des eaux de surface. Eviter la contamination via les systèmes d'évacuation des eaux à partir des cours de ferme ou des routes.]
SPe2 Pour protéger les organismes aquatiques, ne pas appliquer ce produit sur sols artificiellement drainés contenant plus de 45% d'argile pour les usages prairies, gazons de graminées, traitements généraux et céréales d'hiver.
SPe3 Pour protéger les plantes non cibles, respecter une zone non traitée de 5 mètres par rapport à la zone non cultivée adjacente.
EUH401 Respectez les instructions d'utilisation afin d'éviter les risques pour la santé humaine et l'environnement.

Distribué par : PHYTEUROP - 55, rue Raspail - 92300 Levallois-Perret
Tél. : 01 47 59 77 00. Fax. : 01 47 37 54 52. www.phyteurop.com

Elimination du produit et de l'emballage :
- Pour l'élimination des produits non utilisables, faire appel à une entreprise habilitée pour la collecte et l'élimination des produits dangereux.
- Réemploi de l'emballage interdit. Lors de l'utilisation du produit, bien vider et rincer le bidon en veillant à verser l'eau de rinçage dans la cuve du pulvérisateur. Eliminer les emballages vides via les collectes organisées par les distributeurs partenaires de la filière ADIVALOR.
- Eliminer les fonds de cuve conformément à la réglementation en vigueur.
-

Premiers soins :
- Enlever immédiatement les vêtements contaminés par le produit
- Après inhalation : donner de l'air frais
- Après contact avec la peau : laver immédiatement et abondamment à l'eau et au savon. Bien rincer.
- Après contact avec les yeux : rincer les yeux pendant plusieurs minutes, sous l'eau courante en écartant bien les paupières.
- Après ingestion : rincer la bouche à l'eau. Ne pas faire vomir.
- Dans tous les cas, si les symptômes persistent ou en cas de malaise, consulter un médecin et lui présenter l'étiquette et/ou la fiche de données de sécurité.

La fiche de données de sécurité peut être obtenue gratuitement sur Internet à l'adresse www.quickfds.com.

PHYTEUROP
un éclairage différent

EMB : 49215 F

N° et lot et date de fabrication : voir sur l'emballage.
® Marque déposée Phyteurop

Volume net : **5 L**

Appendix 3 – Letter(s) of Access

Provided upon request.