

REGISTRATION REPORT

Part A

Risk Management

Product code: COM 503 15 H GR

Active substances:

2,4-D 3.3 g/kg

dicamba 1.6 g/kg

COUNTRY: FRANCE

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(marketing authorisation)

Applicant: COMPO EXPERT FRANCE S.A.S.

Date: 2021-12-31

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PART A – Risk Management

The company COMPO EXPERT FRANCE S.A.S. has requested a marketing authorisation in France for the product COM 503 15 H GR¹ (the product's code and name are the same), containing 3.3 g/kg 2,4-D and 1.6 g/kg dicamba, as a herbicide and a fertiliser.

The risk assessment conclusions provided in this document are based on the information, data and assessments provided in the Registration Report, Part B Sections 1-8 and Part C, and where appropriate the addenda for France. The information, data and assessments provided in the Registration Report, Part B include assessment of further data or information as required at national registration by EU regulations. It also includes assessment of data and information related to COM 503 15 H GR where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of COM 503 15 H GR have been made using endpoints agreed in the EU peer reviews of 2,4-D.

This document describes the specific conditions of use and labelling required for France for the registration of COM 503 15 H GR.

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

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

Appendix 3 of this document contains a copy of the Letter(s) of Access.

1 DETAILS OF THE APPLICATION

1.1 Application background

The present registration report (RR) concerns the evaluation of COMPO EXPERT FRANCE S.A.S.'s application to market COM 503 15 H GR in France as a herbicide and a fertiliser (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 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;

¹ An identical formulation, for non-professional use, is FLORANID DESHERBANT GAZON LD

(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).

Dicamba

Commission Implementing Regulation (EU) No 1100/2011 of 31 October 2011 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substances dicamba, difenoconazole, and imazaquine.

Specific provisions of Regulation (EU) No 540/2011 were as follows:

PART A

Only uses as herbicide may be authorised.

PART B

For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on dicamba, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health shall be taken into account.

Specific provisions of Regulation (EU) No 1100/2011 were to amend Part B as follows:

PART B

For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on dicamba, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 27 September 2011 shall be taken into account.

In this overall assessment Member States shall pay particular attention to the protection of non-target plants.

Conditions of use shall include adequate risk mitigation measures, where appropriate.

The notifier shall submit confirmatory information as regards:

- (a) the identification and quantification of a group of soil transformation products formed in a soil incubation study;
- (b) the potential for long range transport through the atmosphere.

The notifier shall submit this information to the Member States, the Commission and the Authority by 30 November 2013.

An EFSA conclusion is available (EFSA Journal 2011; 9(1): 1965) plus the outcome of the consultation on confirmatory data used in the risk assessment (Efsa technical report, 1 April 2016).

A review report is available (SANCO/829/08 – final rev. 2 of 12 July 2016).

1.3 Regulatory approach

The present application (2013-0174 and 2020-3391) 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”)² – the highest application rates applied for in the Southern Zone. When risk mitigation measures were necessary, they are adapted

² 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

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 2017³ provides that:

- unless otherwise stated in the product authorisation, the pre harvest interval (PHI) is at least three days;
- unless otherwise stated in the product authorisation, the minimum buffer zone alongside a water body is five metres;
- unless otherwise 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, non-spraying 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 1107/2009⁴, 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 on the acceptability of risk are based on the criteria indicated in Regulation (EU) No 546/2011⁵, and are expressed as “acceptable” or “not acceptable” or “not finalised” in accordance with those criteria.

Finally, the French Order of 12 April 2021⁶ 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 “related” ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is also reached on the acceptability of the intended uses on those “related” crops. The aim of this Order, mainly based on the EU document on residue data 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.

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of COM 503 15 H GR, 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

³ Arrêté du 4 mai 2017 relatif à la mise sur le marché et à l'utilisation des produits phytopharmaceutiques et de leurs adjuvants visés à l'article L. 253-1 du code rural et de la pêche maritime, modifié par l'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>

⁴ REGULATION (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

⁵ 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

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

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

The applicant has provided the supporting data in Document K; the ownership of the data is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-8. The applicant has provided Letter(s) of Access for 2,4-D.

2 DETAILS OF THE AUTHORISATION

2.1 Product identity

Product name / code	COM 503 15 H GR.
Authorisation number	2210586
Function	Herbicide and fertiliser (NPK and MgO). Professional use.
Applicant	COMPO EXPERT FRANCE S.A.S.
Composition	3.3 g/kg 2,4-D. 1.6 g/kg dicamba.
Formulation type (code)	Granule [GR].
Packaging	PE (polyester) / PA (polyamide) / PE (polyester) bags in cardboard box, containing 1 kg, 1.5 kg, 3 kg or 6 kg product. PE / PA / PE bags or sacks containing 0.5 kg, 7.5 kg, 12 kg, 15 kg or 21 kg product. PET (polyethylene terephthalate) / OPA (polyamide nylon) / LDPE (low-density polyethylene) sacks containing 6 kg or 12 kg product. PET / PET / PE sacks containing 14 kg or 21 kg product. PP (polypropylene) buckets containing 5 kg, 6 kg, 7.5 kg or 10 kg product.

2.2 Classification and labelling

2.2.1 Classification and labelling under Directive 99/45/EC

Not applicable after 1st June 2015.

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

Physical hazards	-
Health hazards	-
Environmental hazards	-
Hazard pictograms	-
Signal word	-
Hazard statements	-
Precautionary statements –	<i>For the P phrases, refer to the existant legislation.</i>

Supplementary information (in accordance with Article 25 of Regulation (EC) No 1272/2008)	EUH 208	Contains 2,4-D. May produce an allergic reaction ⁸ .
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See Part C for justifications of the classification and labelling proposals.

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

The authorisation of the preparation is linked for professional uses only to the following conditions:

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).
SPe 6	To protect birds and wild mammals, remove spillages.
SPe 3	To protect aquatic organisms respect a vegetated buffer zone of 5 meters to surface water bodies.

2.2.4 Other phrases linked to the preparation

Wear suitable personal protective equipment ⁹ : refer to the Decision in Appendix 1 for the details.
Re-entry period ¹⁰ : 6 hours
Pre-harvest interval ¹¹ : Not applicable.
Other mitigation measures: -
<p>The label may include the following recommendations:</p> <p>Precise the conditions of use of mowing waste as mulch or compost.</p> <p>Precise the optimal conditions for using the product in order to limit the risk of phytotoxicity on adjacent crops.</p> <p>This product is a mixed product: NPK fertilizer complying with a mandatory application standard (to be recalled) and herbicide.</p> <p>The label must reflect the conditions of authorisation.</p>

⁸ COM 503 15 H GR contains ≥ 0.1 % of 2,4-D acid (classified as a skin sensitizer category 1 in the CLP Regulation). This concentration limit for elicitation is used to protect already-sensitized individuals.

⁹ If a tractor with cab is used, wearing gloves during application is only required when working with the spray mixture.

¹⁰ The legal basis for this is **Titre I Article 3** of the French Order of 4th May 2017 concerning the marketing and use of products encompassed by article L. 253-1 of the rural code [that is, plant protection products/pesticides]

¹¹ According to the French Order of 4th May 2017, PHI cannot be lower than 3 days unless specifically stated in the assessment and decision.

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.

date: 2021-12-31

PPP (product name/code) **COM 503 15 H GR**
active substance 1 **2,4-D**
active substance 2 **dicamba**

Formulation type: **GR**
Conc. of a.s. 1: **3.3 g/kg**
Conc. of a.s. 2: **1.6 g/kg**

Applicant: **COMPO EXPERT FRANCE S.A.S.**
Zone(s): **Southern EU**
Verified by MS: **yes**

professional use ☒
non-professional use ☐

1	2	3	4	5	6	7	8	10	11	12	13	14	15
Use- No.	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F G or I (a)	Pests or Group of pests controlled (b) (additionally: developmental stages of the pest or pest group)	Application			Application rate			PHI (days) (g)	Remarks: e.g. g safener/synergist per ha (h)	zRMS Conclusion
					Method / Kind (c-e)	Timing / Growth stage of crop & season (f)	Max. number (min. interval between applications) a) per use b) per crop/ season	g, product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			
1	France	Managed amenity turf (professional uses) (non- agricultural zones: parks and municipal gardens, sports grounds, golf courses, cemeteries)	F	Dicotyledonous weeds	Granule applicator or manual application	During growth period (May to August)	a) 1 b) 1	a) 3000 g/ha b) 3000 g/ha	a) 2,4-D: 990 g/ha Dicamba: 480 g/ha b) 2,4-D: 990 g/ha Dicamba: 480 g/ha	N/A	N/A	Professional uses. On established turf only. st.	Acceptable

- Remarks:**
- (a) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
 - (b) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds
 - (c) All abbreviations used must be explained
 - (d) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
 - (e) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
 - (f) Growth stage at 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
 - (g) PHI - minimum pre-harvest interval
 - (h) Remarks may include: Extent of use/economic importance/restrictions
N/A: not applicable.

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

COM 503 15 H GR is a granule (GR). All studies have been performed in accordance with the current requirements and the results are deemed acceptable. The appearance of the product is a pale brown solid, with a characteristic odour. It is not explosive and has no oxidising properties. The product is not flammable or auto-flammable. In aqueous solution (1 %), it has a pH value of 7.33 at ambient temperature. There is no effect of high temperature on the stability of the formulation, since 14 days at 54 °C, neither the active substances' 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 PE/PA/PE. As the formulation is a granule, all packaging can be considered acceptable. The technical characteristics are likewise acceptable for a granule (GR) formulation.

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

3.1.2 Methods of analysis

Analytical methodology for the determination of the active substances in the formulation is available and validated. As the active substance dicamba does not contain any relevant impurity, no pertinent analytical method is required.

Nevertheless the relevant impurities of the active substance 2,4-D (dioxins and furans expressed as TCDD equivalent toxic < 10 µg/kg) cannot be formed during the production and storage of the product. The contents of its relevant impurities are below the specifications in the active substance. The analytical methods for the determination of these impurities in the technical active substance are validated. However, no analytical method for the determination of these relevant impurities has been submitted for the product and confirmation of the applicability of the method for the technical a.s. to the product is therefore required post-authorisation.

Analytical methods are available in the Draft or Renewal Assessment Reports (DAR/RAR) and validated for the determination of residues of dicamba and 2,4-D in soil, water (surface and drinking) and air.

Based on to the specific use, analytical methods for the determination of the residues of dicamba and 2,4-D in plants and foodstuffs of animal origin are not necessary.

The active substances are 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 ¹²)
ARfD	0.3 mg kg bw/d		
AOEL	0.02 mg/kg bw/d <i>No correction for oral absorption needed.</i>		
Dermal absorption	Based on an <i>in vitro</i> human study performed on a similar formulation:		
		Concentrate (tested) 3.3 g/kg	Diluted formulation (tested) x g/L
	<i>In vitro</i> (human) %	0.5	
		Concentrate (used in formulation) 3.3 g/kg	Spray dilution (used in formulation) x g/L
	Dermal absorption endpoints %	0.5	
Active substance: dicamba			
ADI	0.3 mg/kg bw/d		EU (2009)
ARfD	0.3 mg/kg bw		
AOEL	0.3 mg/kg bw/d		
Dermal absorption	Based on an <i>in vitro</i> human study performed on the formulation:		
		Concentrate (tested) 1.6 g/kg	Diluted formulation (tested) x g/L
	<i>In vitro</i> (human) %	9	
		Concentrate (used in formulation) 1.6 g/kg	Spray dilution (used in formulation) x g/L
	Dermal absorption endpoints %	9	

3.1.3.1 Acute Toxicity

COM 503 15 H GR, containing 3.3 g/kg 2,4-D and 1.6 g/kg dicamba, has a low acute oral, inhalational and dermal toxicity, is not irritating to the rabbit skin or eye and is not a skin sensitiser.

3.1.3.2 Operator Exposure

¹² Revised Renewal report for the active substance 2,4-D; SANCO/11961/2014 Rev 5, 6 October 2017: "On 6 October 2017, the Standing Committee on Plant, Animals, Food and Feed took note of the revision of this review report after the amendment by EFSA of the human reference toxicological endpoints.

That amendment has been considered appropriate in the light of the further consideration by the peer review experts of studies common to the evaluation of the active substances 2,4-D and 2,4-DB (of which 2,4-D on its turn is a major metabolite). The current revision of the renewal report has been carried out in line with the Guidance document on the evaluation of new active substance data post approval.

The following reference values have been finalised as part of this evaluation:

ADI: 0.02 mg/kg bw per day,

ARfD: 0.3 mg/kg bw,

AOEL: 0.02 mg/kg bw per day.

At the time of adoption of revision 4 of this document, some Member States had already renewed authorisations according to Article 43 of Regulation (EC) No 1107/2009 or granted new authorisations based on endpoints which are no longer valid. With a view to harmonise the implementation of the new endpoints, due to this exceptional circumstance, Member States should review the authorisations referred to above according to the new endpoints by 22 March 2019. Article 44 should apply and applicants may be asked to update their dossiers, as appropriate. Member States can take advantage of the standard zonal procedure for the evaluation of plant protection products."

Summary of critical use patterns (worst cases):

Crop	F/G ¹³	Equipment	Application rate kg product/ha (g a.s./ha)	Spray dilution (L/ha)	Model
Turf	F	Vehicle-mounted	300 kg/ha (2,4-D: 990 g/ha; dicamba: 480 g/ha)	Not applicable	PHED model reviewed by CRD
		Hand-held equipment (granular spreader)			
		Manual spreading	30 g/m ² (2,4-D: 0.099 g/m ² ; dicamba: 0.048 g/m ²)		French garden studies (UPI, 2005)

Considering the proposed use, operator systemic exposure was estimated using the PHED model reviewed by CRD and the French study of 2005 dedicated to amateur use:

Crop	Equipment	PPE and/or working coverall	% AOEL 2,4-D (0.15 mg/kg bw/d) (0.02 mg/kg bw/d)	% AOEL dicamba (0.3 mg/kg bw/d)
Turf	Vehicle-mounted	Gloves and normal workwear during loading and application	12 % 90 %	3.2 %
	Hand-held equipment	Gloves and normal workwear during loading and application	10 % 77 %	24 %
	Manual spreading	No PPE	0.1 % 1.1 %	0.6 %

According to the model calculations, it can be concluded that the risk for the operator using COM 503 15 H GR is acceptable with a working coverall (90 % protection factor) and gloves during mixing/loading and application, for applications by professional operators with vehicle-mounted or hand-held equipment.

3.1.3.3 Bystander Exposure

Due to the application technique for COM 503 15 H GR, where the granular formulation is applied directly to turf, no drift is expected. In addition, the active substances are not volatile in this formulation type and the formulation is a solid non-dusty granule. Consequently, it is considered unnecessary to assess the risk of bystander exposure.

3.1.3.4 Resident Exposure

The amount of granules to be ingested by toddlers without unacceptable effects is such high that it can be considered unrealistic, and it can be reasonably concluded that there is no unacceptable risk anticipated for toddlers accidentally ingesting granules of COM 503 15 H GR.

3.1.3.5 Worker Exposure

COM 503 15 H GR is a solid non-dusty granule applied directly to the turf.

¹³ Open field or glasshouse

Worker exposure following spray application is usually through contact with dislodgeable foliar or plant residues; this scenario is not relevant to the use of this product, where granules are applied directly to the turf.

Professional users re-entering the field after application are considered not to be exposed by oral, dermal or inhalational routes. Therefore it can be concluded that there is no unacceptable risk anticipated for the worker when re-entering the area treated with COM 503 15 H GR.

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

3.1.4 Consumer exposure

Given the proposed use, no exposure of consumers is anticipated.

3.1.5 Environmental fate and behaviour

The fate and behaviour in the environment of the formulation have been evaluated according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU review were used to calculate predicted environmental concentrations (PECs) for the active substance and its/their 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, dicamba and their 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 review or agreed in the assessment based on new data provided.

PEC_{soil} and PEC_{sw} values derived for the active substances and their metabolites are used for the ecotoxicological risk assessment and mitigation measures are proposed.

PEC_{gw} values for 2,4-D, dicamba and their metabolites do not occur at levels exceeding those mentioned in Regulation (EC) no 1107/2009 and guidance document SANCO 221/2000¹⁴. 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.

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 the 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 terrestrial vertebrates, aquatic organisms, bees and other non-target arthropods, earthworms and other soil macro- and micro-organisms and non-target plants are acceptable for the intended uses.

COM 503 15 H GR is used as a herbicide and fertiliser. Thus, a risk of eutrophication of aquatic ecosystems due to phosphorus cannot be excluded. In view of their national requirements, Member States may recommend a vegetated buffer zone of 5 metres, to protect the aquatic ecosystems from eutrophication following the use of COM 503 15 H GR. Depending on their national requirements, Member States may recommend the following precaution:

¹⁴ Guidance document on the assessment of the relevance of metabolites in groundwater of substance regulated under Council directive 94/414/EEC. Sanco/2000-rev10-final, 25 February 2003.

3.1.7 Efficacy

Considering the data submitted:

- ✓ The efficacy of COM 503 15 H GR is considered acceptable on broadleaved weeds.
- ✓ The selectivity level of COM 503 15 H GR is considered acceptable for the requested use, for turf established more than one year.
- ✓ The risk of negative impact on adjacent and succeeding crops is considered acceptable. The product should not be directed on to adjacent ornamental crops. Due to the presence of dicamba, it is advisable not to use grass clippings as mulch or compost.
- ✓ The risk of resistance developing or appearing to dicamba and 2,4-D does not require monitoring for the requested use.

3.2 Conclusions arising from French assessment

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

3.3 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

No further information is required.

3.4.2 Post-authorisation data requirements

No further information is required.

3.4.3 Label amendments

The draft label proposed by the applicant in Appendix 2 may be corrected with consideration of any new element under points 2.2.1 (or 2.2.2), 2.2.3 and 2.2.4.

The label shall reflect the detailed conditions stipulated in the Decision.

Appendix 1 – Copy of the French Decision

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

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

*Vu la demande d'autorisation de mise sur le marché et la demande associée du produit mixte **COM 503 15 H GR***

de la société COMPO EXPERT France

enregistrées sous les n°2013-0174 et n°2020-3391

Vu les conclusions de l'évaluation de l'Anses du 25 octobre 2021,

La mise sur le marché du produit phytopharmaceutique désigné ci-après **est autorisée** en France, sous réserve du respect de la composition du produit autorisée dans les conclusions de l'évaluation, pour les usages et dans les conditions précisés dans la présente décision et son annexe.

La présente décision s'applique sans préjudice des autres dispositions applicables.

Avertissement :

Le non-respect des conditions décrites ci-dessous peut entraîner le retrait ou la modification de l'autorisation ainsi que toute action incluant des poursuites judiciaires.

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Informations générales sur le produit	
Nom du produit	COM 503 15 H GR
Type de produit	Produit de référence
Titulaire	COMPO EXPERT France 49, Avenue George Pompidou 92593 LEVALLOIS-PERRET France
Formulation	Granulé (GR)
Contenant	1,93 g/kg - dicamba sel de diméthylamine (équivalent à 1,6 g/kg de dicamba) 3,97 g/kg - 2,4-D sel de diméthylamine (équivalent à 3,3 g/kg de 2,4-D) Engrais fertilisant (NPK et MgO) déclaré conforme à une norme d'application obligatoire
Numéro d'intrant	9872-2013.01
Numéro d'AMM	2210586
Fonction	Engrais (NPK et MgO) et herbicide
Gamme d'usage	Professionnel

L'échéance de validité de la présente décision est fixée à trois mois à compter de la date d'expiration de l'approbation de la substance active qui arrive à échéance le plus tôt. A titre indicatif, dans l'état actuel du calendrier d'approbation des substances actives, l'échéance de l'autorisation est fixée au 31 décembre 2023.

A défaut pour le titulaire de demander le renouvellement conformément à l'article 43 du règlement (CE) 1107/2009 dans les trois mois suivant le renouvellement de l'approbation de la substance active, l'autorisation de mise sur le marché est échue de plein droit. Le dépôt d'une demande de renouvellement prolonge de plein droit la durée de validité de l'autorisation de mise sur le marché de la durée nécessaire pour mener à bien l'examen et adopter une décision sur le renouvellement.

La présente décision peut être retirée ou modifiée avant cette échéance si des éléments le justifient.

A Maisons-Alfort, le 31/12/2021

DocuSigned by:

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)

COM 503 15 H GR
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ANNEXE : Modalités d'autorisation du produit

Vente et distribution	
Le titulaire de l'autorisation peut mettre sur le marché le produit uniquement dans les emballages :	
Emballage	Contenance
Sacs en polyester / polyamide / polyester	500 g ; 7,5 kg ; 12 kg ; 15 kg ; 21 kg
Carton contenant un sac en polyester / polyamide / polyester	1 kg ; 1,5 kg ; 3 kg ; 6 kg ;
Sacs en polyéthylène téréphtalate / polyamide orienté / polyéthylène basse densité	6 kg ; 12 kg
Sacs en polyéthylène téréphtalate / polyéthylène téréphtalate / polyester	14 kg ; 21 kg
Seaux en polypropylène	5 kg ; 6 kg ; 7,5 kg ; 10 kg

Teneurs garanties retenues en éléments fertilisants
Indiquer sur l'étiquette la teneur (en % MB) des éléments fertilisants revendiqués : N (et ses différentes formes), P ₂ O ₅ (et ses différentes formes), K ₂ O soluble dans l'eau et MgO, conformément à la norme d'application obligatoire qui encadre le produit.
Il est de la responsabilité du détenteur de s'assurer de la conformité à la norme à laquelle il se réfère.

Classification du produit
La classification retenue est la suivante : Sans classement.
EUH208 : Contient du 2,4-D. Peut produire une réaction allergique.
Pour les phrases P se référer à la réglementation en vigueur.
Le titulaire de l'autorisation est responsable de la mise à jour de la fiche de données de sécurité et de la classification du produit en tenant compte de ses éventuelles évolutions.

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Liste des 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)	Mention abeilles
18505901 Gazons de graminées*Désherbage	300 kg/ha	1/an	-	Non applicable	DVP 5	-	-	-
Application durant la phase de croissance du gazon, de mai à août. Uniquement sur gazons installés								

DVP : Dispositif Végétalisé Permanent.

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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 équipement manuel :

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

Dans le cadre d'une application effectuée à l'aide d'un tracteur équipé d'un microgranulateur

• pendant le chargement du matériel d'épandage

- 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 ;

• pendant l'épandage

- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN ISO 374-2 (types A, B ou C) à usage unique en cas d'intervention sur semoir, épandeur à engrais ou microgranulateur ;
- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 ;

• pendant le nettoyage du matériel d'épandage

- 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 ;
- Combinaison catégorie III Type 5/6 ou EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus l'EPI vestimentaire précité.

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

- 6 heures

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

Protection de l'eau

- SP 1 : Ne pas polluer l'eau avec le produit ou son emballage. Ne pas nettoyer le matériel d'application près des eaux de surface. Éviter la contamination *via* les systèmes d'évacuation des eaux à partir des cours de ferme ou des routes.

Protection de la faune

- SPe 3 : Pour protéger les organismes aquatiques, respecter une zone non traitée comportant un dispositif végétalisé permanent non traité d'une largeur de 5 mètres en bordure des points d'eau.
- SPe 6 : Pour protéger les oiseaux et les mammifères sauvages, récupérer tout produit accidentellement répandu.

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Recommandations relatives à l'étiquette du produit

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

- Préciser les conditions optimales d'utilisation du produit afin de limiter le risque de phytotoxicité sur les cultures adjacentes.
- Préciser les conditions d'utilisation des déchets de tonte comme mulch ou compost.
- Ce produit est un produit mixte : engrais (NPK et MgO) conforme à une norme d'application obligatoire (à rappeler) et herbicide.

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

**Draft Label
COM 503 15 H GR –professional use
France**

20.03.2016

COM 503 15 H GR is a lawn fertiliser with herbicidal activity formulated as a fine granulate to control broad-leaved weeds in established lawns and turfs. The product is a premium speciality product for the lawn with an optimal combination of weed control and adequate long-term lawn fertilization. The valuable lawn fertilizer contains all important primary and secondary nutrients.

For PROFESSIONAL USE

DIRECTIONS FOR USE:

When to apply:

J	F	M	A	M	J	J	A	S	O	N	D

1. Once per year from May to August at temperatures higher than 14°C
2. Do not apply during the first year after sowing.
3. Do not apply on windy days, in frost or during periods of draught.

How to apply:

Strewing 30 g/m² by hand (wearing protective gloves) or using a spreader in the following sequence:

1. Mow lawn.
2. Wait for 3 to 4 days for the grass and weeds to regrow.
3. Apply in the morning on a rain-free day on the grass wet with dew or water it in an appropriate way short before application. Do not enter the treated lawn directly after application.
4. Afterwards allow the active ingredients at least one day, better 2 days, to take effect via the leaves.
5. Water the treated lawn in an appropriate way after 2 to 3 days if it has not rained.
6. Mow lawn not earlier than 7 days after treatment.

Dosage: 10 kg are sufficient to treat 333 m². Do not strew overlapping. (Do not over-dose).

Re-sowing of grass is generally possible in case larger spots of bare soil occur due to death of weeds after product application. Prior to re-sowing the dead weeds should be thoroughly mechanically removed from the treated area at the earliest 4 weeks after application. As a huge variety of grass seed mixture is commercially available and due to the diverse local conditions we cannot guarantee the successful growth or the reseedling.

Efficacy:

Susceptible weed species: Andryala integrifolia, Field chamomile, Daisy, Canada horseweed, Prickly lettuce, Common mallow, Bristly oxtongue, Prostrate knotweed, Vipergrass, Perennial sowthistle, Annual sowthistle, Common chickweed, Common dandelion, Clover, Yellow Trefoil, Selfheal, Creeping buttercup, Buttercup, Perennial sowthistle, Ivy-leaved speedwell, Bird's-eye speedwell

Less susceptible weed species: Sticky chickweed, Common fumitory, Cat's-ear dandelion, California burclover, Narrow-leaved plantain, Broadleaf plantain, Red clover, Common yarrow, Yarrow, Common bugle, Little mouse-ear, Ground ivy, Plantago major intermedia

No sufficient control of: Mud plantain, Cut-leaved cranesbill, Bird's-foot trefoil, Buck's-horn plantain, Berseem clover, Corn speedwell, Meadow cranesbill, Creeping cinquefoil, Golden dock, Rabbit-foot clover, Trigonella monspeliaca

COM 503 15 H GR

Active substances: 1,6 g/kg (0,16 %) Dicamba
3,3 g/kg (0,33 %) 2,4-D

To avoid risks to man and the environment, comply with the instructions for use. Contains 2,4-D. May produce an allergic reaction. Keep locked up and out of the reach of children. Keep away from food, drink and animal foodstuffs. Do not empty into drains. If swallowed, seek medical advice immediately and show this container or label.

Net weight: **X kg e**

Approval holder:
address

Distributor:
address

Amount of nutrients: 15% total nitrogen (N), 5% phosphorous pentoxide (P₂O₅), 8% potassium oxide (K₂O), 3% magnesium oxide (MgO).

Bees:

Used at the recommended rate, the product is not dangerous to bees.

Protection of plants and bulbs:

When spreading take care that granules are not spread onto sensitive plants such as flowers, ornamentals, vegetables, etc. Do not feed cut grass during the first year after application to animals. Do not use the first two clippings for mulching other plants/areas.

Special information:

Approval holder is not responsible for improper application.

Storage

Store in a safe, cool, dry place away from frost

Reg.-No. XXX

Manufacturing date

Appendix 3 – Letter(s) of Access

Provided upon request.