

# **REGISTRATION REPORT**

## **Part A**

### **Risk Management**

**Product code: GF-3730**

**Product name(s): PROCLOVA**

**Chemical active substance(s):**

**Florpyrauxifen-benzyl, 75.49 g/kg**

**Amidosulfuron, 360.00 g/kg**

**Southern Zone**

**Zonal Rapporteur Member State: France**

**NATIONAL ASSESSMENT FRANCE**

**(new application)**

**Applicant: Corteva Agriscience**

**Date: 29 April 2025**

## Table of Contents

|          |   |           |
|----------|---|-----------|
| <b>1</b> | <b>Details of the application .....</b>   | <b>4</b>  |
| 1.1      | Application background.....   | 4         |
| 1.2      | Letters of Access .....   | 5         |
| 1.3      | Justification for submission of tests and studies .....   | 5         |
| 1.4      | Data protection claims .....  | 5         |
| <b>2</b> | <b>Where protection for data is being claimed for information supporting registration of PROCLOVA (GF-3730), it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.Details of the authorisation decision .....</b> | <b>5</b>  |
| 2.1      | Product identity .....  | 5         |
| 2.2      | Conclusion .....  | 6         |
| 2.3      | Substances of concern for national monitoring .....   | 6         |
| 2.4      | Classification and labelling.....   | 6         |
| 2.4.1    | Classification and labelling under Regulation (EC) No 1272/2008 .....   | 6         |
| 2.4.2    | N/A : no marketing authorisation granted.Standard phrases under Regulation (EU) No 547/2011 .....   | 6         |
| 2.4.3    | Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009) .....   | 6         |
| 2.5      | Risk management.....  | 7         |
| 2.5.1    | Restrictions linked to the PPP.....   | 7         |
| 2.5.2    | Specific restrictions linked to the intended uses .....   | 7         |
| 2.6      | Intended uses (only NATIONAL GAP) .....   | 9         |
| <b>3</b> | <b>Background of authorisation decision and risk management .....</b>   | <b>12</b> |
| 3.1      | Physical and chemical properties (Part B, Section 2) .....  | 12        |
| 3.2      | Efficacy (Part B, Section 3) .....  | 12        |
| 3.3      | Methods of analysis (Part B, Section 5).....  | 12        |
| 3.3.1    | Analytical method for the formulation .....   | 12        |
| 3.3.2    | Analytical methods for residues.....  | 12        |
| 3.4      | Mammalian toxicology (Part B, Section 6) .....  | 13        |
| 3.4.1    | Acute toxicity.....   | 13        |
| 3.4.2    | Operator exposure .....   | 13        |
| 3.4.3    | Worker exposure .....   | 14        |
| 3.4.4    | Bystander exposure .....  | 14        |
| 3.4.5    | Resident exposure .....   | 15        |
| 3.4.6    | Combined exposure .....   | 16        |
| 3.5      | Residues and consumer exposure (Part B, Section 7).....   | 16        |
| 3.6      | Environmental fate and behaviour (Part B, Section 8) .....  | 17        |
| 3.7      | Ecotoxicology (Part B, Section 9) .....   | 18        |
| 3.8      | Relevance of metabolites (Part B, Section 10) .....   | 18        |

|                   |   |           |
|-------------------|---|-----------|
| <b>4</b>          | <b>Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009) .....</b>  | <b>18</b> |
| <b>5</b>          | <b>Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorisation.....</b> | <b>19</b> |
| 5.1.1             | Post-authorisation monitoring.....  | 19        |
| 5.1.2             | Post-authorisation data requirements .....  | 19        |
| <b>Appendix 1</b> | <b>Copy of the product authorisation .....</b>  | <b>20</b> |
| <b>Appendix 2</b> | <b>Copy of the product label .....</b>  | <b>23</b> |

# **PART A**

## **RISK MANAGEMENT**

### **1 Details of the application**

The company CORTEVA AGRISCIENCE has requested a marketing authorisation in France for the product PROCLOVA (product code: GF-3730), containing 360 g/kg Amidosulfuron<sup>1</sup> and 75.49 g/kg florpyrauxifen-benzyl<sup>2</sup> 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 CORTEVA AGRISCIENCE's application submitted on 30/12/2021 to market PROCLOVA (GF-3730) in France (product uses described under point 2.3). France acted as a zonal Rapporteur Member State (zRMS) for this request and assessed the application submitted for the first authorisation of this product in France and in other Member States (MSs) of the Southern zone.

The present application (2021-3706) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses), according to the Regulation (EC) no 1107/2009<sup>3</sup>, 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")<sup>4</sup>. 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 PROCLOVA (GF-3730) has been made using endpoints agreed in the EU peer reviews of amidosulfuron and florpyrauxifen-benzyl. It also includes assessment of data and information related to PROCLOVA (GF-3730) 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.

---

<sup>1</sup> COMMISSION IMPLEMENTING REGULATION (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances

<sup>2</sup> COMMISSION IMPLEMENTING REGULATION (EU) 2019/1138 of 3 July 2019 approving the active substance florpyrauxifen-benzyl 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

<sup>3</sup> 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

<sup>4</sup> 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](#)

GF-3730/ PROCLOVA  
Part A - National Assessment  
FRANCE

The conclusions on the acceptability of risk are based on the criteria provided in Regulation (EU) No 546/2011<sup>5</sup>, and are expressed as “acceptable” or “not acceptable” in accordance with those criteria.

This document also describes the specific conditions of use and labelling required for France for the registration of PROCLOVA (GF-3730).

## 1.2 Letters of Access

The applicant has provided letters of access for active substance. These letters of access are available upon request.

## 1.3 Justification for submission of tests and studies

According to the applicant: « The tests and studies submitted are necessary for first authorisation in France and are in accord-ance with Reg. (EU) No. 284/2013 ».

## 1.4 Data protection claims

## 2 Where protection for data is being claimed for information supporting registration of PROCLOVA (GF-3730), it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.Details of the authorisation decision

### 2.1 Product identity

|  |   |
|--|---|
| Product code   | GF-3730   |
| Product name in MS                                     | PROCLOVA  |
| Authorisation number                                   | N/A : no marketing authorisation granted                      |
| Kind of use  | Professional use  |
| Low risk product (article 47)                          | No  |
| Function   | Herbicide   |
| Applicant  | CORTEVA AGRISCIENCE FRANCE S.A.S.                             |
| Active substance(s)<br>(incl. content)                 | Amidosulfuron , 360 g/kg<br>Florpyrauxifen-benzyl, 75.49 g/kg |
| Formulation type                                       | Water-dispersible granule [WG]                                |
| Packaging  | N/A : no marketing authorisation granted                      |
| Coformulants of concern for<br>national authorisations | -   |
| Restrictions related to identity                       | -   |

<sup>5</sup> 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

GF-3730/ PROCLOVA  
Part A - National Assessment  
FRANCE

|                           |      |
|---------------------------|------|
| Mandatory tank mixtures   | None |
| Recommended tank mixtures | None |

## 2.2 Conclusion

The evaluation of the application for PROCLOVA (GF-3730) resulted in the decision **to refuse** the authorisation.

## 2.3 Substances of concern for national monitoring

Refer to 5.1.1.

## 2.4 Classification and labelling

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

### 2.4.2 N/A : no marketing authorisation granted. Standard phrases under Regulation (EU) No 547/2011

N/A : no marketing authorisation granted

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

None.

## 2.5 Risk management

According to the French law and procedures, specific conditions of use are set out in the Decision letter. The French Order of 4 May 2017<sup>6</sup> 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.

Moreover, the French Order of 12 April 2021<sup>7</sup> provides that:

- an authorisation granted for a “reference” crop applies also for “related” crops, unless formally stated in the Decision
- the “reference” and “related” crops are defined in Appendix 1 of that French Order.

Thus, at French national level, possible extrapolation of submitted data and the corresponding assessment from “reference” crops to “related” ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is also reached on the acceptability of the intended uses on those “related” crops. The aim of this Order, mainly based on the EU document on residue data extrapolation<sup>8</sup> 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.

Finally, the French Order of 20 November 2021<sup>9</sup> 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 crop 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. The Decision, as reproduced in Appendix 1, takes also into account national provisions, including national mitigation measures.

### 2.5.1 Restrictions linked to the PPP

N/A : no marketing authorisation granted.

### 2.5.2 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 2.5.1 (mandatory labelling):

<sup>6</sup> Arrêté du 4 mai 2017 relatif à la mise sur le marché et à l'utilisation des produits phytopharmaceutiques et de leurs adjuvants visés à l'article L. 253-1 du code rural et de la pêche maritime, amended by the arrêté du 27 décembre 2019 relatif aux mesures de protection des personnes lors de l'utilisation de produits phytopharmaceutiques <https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGRG1632554A/jo/texte> ; <https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000039686039&categorieLien=id>

<sup>7</sup> <https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000043401456>

<sup>8</sup> SANCO document “guidance document:- Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs”: SANCO/ 7525/VI/95 - rev.9

<sup>9</sup> <https://www.legifrance.gouv.fr/loda/id/LEGISCTA000044349452>

GF-3730/ PROCLOVA  
Part A - National Assessment  
FRANCE

---

None.



GF-3730/ PROCLOVA  
Part A - National Assessment  
FRANCE

## 2.6 Intended uses (only NATIONAL GAP)

**Please note:** The GAP Table below reports the intended uses proposed by the applicant, and possible extrapolation according to French Order of 12 April 2021 (highlighted in green), evaluated and concluded as safe uses by France as zRMS. Those uses are then granted in France.

When the conclusion is “not acceptable”, the intended use is highlighted in grey and the main reason(s) reported in the remarks.

When a use is “acceptable” with GAP restrictions, the modifications of the GAP are in bold.

Use should be crossed out when the applicant no longer supports this use.

29 April 2025

PPP (product name/code): GF-3730  
Active substance 1: Florpyrauxifen-benzyl  
Active substance 2: Amidosulfuron  
Safener: -  
Synergist: -  
Applicant: Corteva Agriscience  
Zone(s): South Zone  
Verified by MS: YES  
Field of use: herbicide

Formulation type: WG  
Conc. of as 1: 75.49 g as/kg (60 g ae/kg)  
Conc. of as 2: 360 g as/kg  
Conc. of safener: - (c)  
Conc. of synergist: - (c)  
Professional use: ☒  
Non professional use: ☐

| 1  | 2                  | 3   | 4   | 5   | 6               | 7  | 8   | 9  | 10  | 11   | 12                       | 13            | 14   |
|--|--------------------|---|---|---|-----------------|--|---|--|---|--|--------------------------|---------------|--|
| Use-<br>No. <sup>(e)</sup>   | Member<br>state(s) | Crop<br>or<br>situation<br><br>(crop<br>destination/purpose<br>of crop) | F,<br>Fn,<br>Fpn<br>G,<br>Gn,<br>Gpn<br>or<br>I | Pests or Group of pests<br>controlled<br><br>(additionally:<br>developmental stages of<br>the pest or pest group) | Application     |  |   |  | Application rate  |  |                          | PHI<br>(days) | Remarks:<br><br>e.g. g safener/synergis<br>per ha<br>(f) |
|  |                    |   |   |   | Method/Ki<br>nd | Timing/Growth<br>stage of crop &<br>season | Max. number<br>a) per use<br>b) per crop/<br>season | Min. interval<br>between<br>applications<br>(days) | kg or L<br>product/ha<br>a) max. rate per<br>appl.<br>b) max. total rate<br>per crop/season | g<br>a.s./ha<br>a) max. rate per<br>appl.<br>b) max. total rate<br>per crop/season | Water<br>L/ha<br>min/max |               |  |
| Zonal uses (field or outdoor uses, certain types of protected crops) |                    |   |   |   |                 |  |   |  |   |  |                          |               |  |

GF-3730/ PROCLOVA  
Part A - National Assessment  
FRANCE

| 1                          | 2                  | 3   | 4  | 5   | 6                                   | 7  | 8   | 9  | 10  | 11  | 12                               | 13            | 14   |
|----------------------------|--------------------|---|--|---|-------------------------------------|--|---|--|---|---|----------------------------------|---------------|--|
| Use-<br>No. <sup>(e)</sup> | Member<br>state(s) | Crop<br>or<br>situation<br><br>(crop<br>destination/purpose<br>of crop) | F,<br>Fn,<br>G,<br>Gn,<br>Gpn<br>or<br>I | Pests or Group of pests<br>controlled<br><br>(additionally:<br>developmental stages of<br>the pest or pest group) | Application                         |  |   |  | Application rate  |   |                                  | PHI<br>(days) | Remarks:<br><br>e.g. g safener/synergist<br>per ha<br><sup>(f)</sup>               |
|                            |                    |   |  |   | Method/Ki<br>nd                     | Timing/Growth<br>stage of crop &<br>season | Max. number<br>a) per use<br>b) per crop/<br>season | Min. interval<br>between<br>applications<br>(days) | kg or L<br>product/ha<br>a) max. rate per<br>appl.<br>b) max. total rate<br>per crop/season | g a.s./ha<br>a) max. rate per<br>appl.<br>b) max. total rate<br>per crop/season | Water<br>L/ha<br><br>min/ma<br>x |               |  |
| 1                          | France             | Newly sown<br>grassland<br><br>Fodder leguminous                        | F  | Broadleaved weeds   | Broadcast<br>applicatio<br>n foliar | BBCH 13-39<br>1April – 31<br>October       | 1 per calendar<br>year                              | N/A  | 0.085 kg/ha   | 6.417 gas/ha +<br>30.6 gas/ha   | 200-<br>400                      | 7days         | <b>Not acceptable</b><br>(MRL, MRL<br>honeygroundwater,<br>aquatic organisms)      |
| 1'                         | France             | Newly sown<br>grassland<br><br>Fodder gramineous                        | F  | Broadleaved weeds   | Broadcast<br>applicatio<br>n foliar | BBCH 13-39<br>1April – 31<br>October       | 1 per calendar<br>year                              | N/A  | 0.085 kg/ha   | 6.417 gas/ha +<br>30.6 gas/ha   | 200-<br>400                      | 7days         | <b>Not acceptable</b><br>(MRLgroundwater,<br>aquatic organisms)                    |
| 1''                        | France             | Newly sown<br>grassland<br><br>Grassland                                | F  | Broadleaved weeds   | Broadcast<br>applicatio<br>n foliar | BBCH 13-39<br>1April – 31<br>October       | 1 per calendar<br>year                              | N/A  | 0.085 kg/ha   | 6.417 gas/ha +<br>30.6 gas/ha   | 200-<br>400                      | 7days         | <b>Not acceptable</b><br>(MRLgroundwater,<br>aquatic organisms)                    |
| 2                          | France             | Established<br>grassland<br><br>Fodder leguminous                       | F  | Broadleaved weeds   | Broadcast<br>applicatio<br>n foliar | 1March<br>31October                        | - 1 per calendar<br>year                            | N/A  | 0.125 kg/ha   | 9.436 gas/ha +<br>45 gas/ha   | 200-<br>400                      | 7 days        | <b>Not acceptable</b><br>(MRL, MRL<br>honeygroundwater,<br>aquatic organisms)<br>* |
| 2'                         | France             | Established<br>grassland<br><br>Fodder gramineous                       | F  | Broadleaved weeds   | Broadcast<br>applicatio<br>n foliar | 1March<br>31October                        | - 1 per calendar<br>year                            | N/A  | 0.125 kg/ha   | 9.436 gas/ha +<br>45 gas/ha   | 200-<br>400                      | 7 days        | <b>Not acceptable</b><br>(MRLgroundwater,<br>aquatic organisms)                    |
| 2''                        | France             | Established<br>grassland<br><br>Grassland                               | F  | Broadleaved weeds   | Broadcast<br>applicatio<br>n foliar | 1March<br>31October                        | - 1 per calendar<br>year                            | N/A  | 0.125 kg/ha   | 9.436 gas/ha +<br>45 gas/ha   | 200-<br>400                      | 7 days        | <b>Not acceptable</b><br>(MRLgroundwater,<br>aquatic organisms)<br>*               |

\* The application is possible during the flowering period in line with the application of the French Order of November 20, 2021 (arrêté du 20 novembre 2021 relatif à la protection des abeilles et des autres insectes pollinisateurs et à la préservation des services de pollinisation lors de l'utilisation des produits phytopharmaceutiques).

**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.

GF-3730/ PROCLOVA  
Part A - National Assessment  
FRANCE

---

|                         |   |  |    |  |
|-------------------------|---|--|----|--|
| <b>Remarks columns:</b> | 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 <sup>3</sup> 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   | 12 | If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under "application: method/kind".  |
|                         |   | Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.  | 13 | PHI - minimum pre-harvest interval   |
|                         |   |  | 14 | Remarks may include: Extent of use/economic importance/restrictions  |
|                         |   |  |    |  |
|                         |   |  |    |  |
|                         |   |  |    |  |
|                         |   |  |    |  |
|                         |   |  |    |  |
|                         |   |  |    |  |

### **3 Background of authorisation decision and risk management**

#### **3.1 Physical and chemical properties (Part B, Section 2)**

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The plant protection product GF-3730 is a WG formulation containing a nominal concentration of 7.6 % w/w florpyrauxifen-benzyl and 36 % w/w amidosulfuron by weight. The appearance of the product is that of a tan granule with a mild odour. The bulk density is 0.4956 g/mL and a tap density of 0.5635 g/mL. It is not explosive, nor does it have oxidising properties. The product is not highly flammable. Its relative self-ignition temperature is greater than 400°C. When diluted in aqueous solution (1% w/w), it has a pH value of 6.2 at ambient temperature.

There is no effect of high temperature on the stability of the formulation, since after 14 days at 54 °C, neither the active ingredient content nor the technical properties were changed. This is confirmed by the results of a 2 years stability study at room temperature in HDPE. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in HDPE. Its technical characteristics are acceptable for a WG formulation.

#### **3.2 Efficacy (Part B, Section 3)**

Considering the data provided:

- GF-3730 efficacy level is considered as satisfying for the intended use.
- GF-3730 selectivity level is considered as acceptable for the intended use.
- The risks of negative impact on yield, quality and propagation are considered as acceptable.
- The risk of negative impact on succeeding crops is considered as acceptable. Nevertheless, specific attention should be paid to susceptible succeeding crops.
- The risk of negative impact on adjacent crops is considered as acceptable. Nevertheless, specific attention should be paid to susceptible succeeding crops.
- The risk of resistance development or appearance to florpyrauxifen does not require a monitoring for the claimed use. There is a risk of resistance development or appearance to amidosulfuron which does not require a monitoring considering the claimed uses.

#### **3.3 Methods of analysis (Part B, Section 5)**

##### **3.3.1 Analytical method for the formulation**

Validated analytical methods for the determination of the active substances florpyrauxifen-benzyl and amidosulfuron in the product GF-3730 are available.

##### **3.3.2 Analytical methods for residues**

Validated analytical methods for the determination of florpyrauxifen-benzyl residues in matrices of vegetal origin, matrices of animal origin, water (surface and drinking), soil, air and body fluids and tissues are available.

GF-3730/ PROCLOVA  
Part A - National Assessment  
FRANCE

Validated analytical methods for the determination of amidosulfuron residues in matrices of vegetal origin, matrices of animal origin, water (surface and drinking), soil, air and body fluids and tissues are available.

### 3.4 Mammalian toxicology (Part B, Section 6)

|                       |  |  |
|-----------------------|--|--|
| Product               | PROCLOVA   |  |
| Formulation type      | Water dispersible granule (WG)   |  |
| Active substance (s)  | Florpyrauxifen-benzyl<br>75.49 g.a.s/kg  | Amidosulfuron<br>360 g/kg  |
| AOEL systemic (RVNAS) | 0.13 mg/kg bw/d  | 1.40 mg/kg bw/d  |
| Inhalation absorption | 100%   | 100%   |
| Oral absorption       | 25%  | 90%  |
| Dermal absorption     | Concentrate: 10%<br>Dilution: 50%<br>Default values (EFSA Journal 2017; 15 (6):4873) | Concentrate: 10%<br>Dilution: 50%<br>Default values (EFSA Journal 2017; 15 (6):4873) |

#### 3.4.1 Acute toxicity

PROCLOVA (GF-3730) containing 75.49 g/kg of Florpyrauxifen-benzyl and 360 g/kg of Amidosulfuron presents no acute oral, inhalation and dermal toxicity, its not irritating to the skin and the eye and its not a skin sensitiser.

#### 3.4.2 Operator exposure

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

|   |   | <i>Florpyrauxifen-benzyl</i>         |                    | <i>Amidosulfuron</i>            |                    |
|---|---|--------------------------------------|--------------------|---------------------------------|--------------------|
| Model data  | Level of PPE  | Total absorbed dose (mg/kg/day)      | % of systemic AOEL | Total absorbed dose (mg/kg/day) | % of systemic AOEL |
| Critical use: Established grassland (max. 0.125 kg product/ha)              |   |                                      |                    |                                 |                    |
| Tractor mounted boom spray application outdoors to low crops                |   |                                      |                    |                                 |                    |
| Application rate  |   | 0.009436 kg a.s./ha ( 1 application) |                    | 0.045 kg a.s/ha (1 application) |                    |
| Spray application (AOEM; 95 <sup>th</sup> percentile)<br>Body weight: 60 kg | Without RPE/PPE   | 0,0039                               | 2,98               | 0,0130                          | 0,93               |
|   | Work wear (arms, body and legs covered) M/L and A                   | 0,0024                               | 1,82               | 0,0079                          | 0,56               |
|   | Work wear (arms, body and legs covered) and gloves during M/L and A | 0,0008                               | 0,62               | 0,0016                          | 0,12               |

Conclusion: According to the EFSA model calculations, it can be concluded that the risk for the operator using GF 3730 is below the AOEL value of active substance Florpyrauxifen-benzyl and active substance Amidosulfuron for all intended uses without PPE.

### 3.4.3 Worker exposure

Estimation of worker exposure was calculated according to AOEM model. Exposure is summarized in table below:

| Grasslands   |   |        |   |        |
|--|---|--------|---|--------|
|  | Florpyrauxifen-benzyl                                     |        | Amidosulfuron   |        |
|  | Total systemic exposure per kg body weight (mg/kg bw/day) | % AOEL | Total systemic exposure per kg body weight (mg/kg bw/day) | % AOEL |
| Searching, reaching, picking,<br>Outdoor<br>Work rate: 8 hours/day<br>DT <sub>50</sub> : 30 days<br>DFR: 3 µg/cm <sup>2</sup> / kg a.s/ha<br>Interval between treatments: 365 days |   |        |   |        |
| Number of application and application rate   | 0.009436 kg a.s./ha                                       |        | 0.045 kg a.s./ha  |        |
| Potential exposure   | 0,0059  | 4,54   | 0,0281  | 2,01   |
| Work wear - arms, body and legs covered  | 0,0007  | 0,51   | 0,0032  | 0,23   |

Conclusion: According to the model-calculation results, worker exposure levels are below the systemic AOEL value for both active substances after exposure to GF 3730.

### 3.4.4 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, i.e. no acute operator or bystander exposure assessments can be performed with the EFSA model where no AAOEL has been set.

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.”*

GF-3730/ PROCLOVA  
Part A - National Assessment  
FRANCE

### 3.4.5 Resident exposure

Residential exposure was assessed according to EFSA model with mitigation measures:

| Grasslands   |                                   |                                    |  |                                    |   |
|--|-----------------------------------|------------------------------------|--|------------------------------------|---|
|  |                                   | Florpyrauxifen-benzyl              |  | Amidosulfuron                      |   |
| Model data   |                                   | Total absorbed dose (mg/kg bw/day) | % of systemic AOEL<br>% of systemic AA-OEL | Total absorbed dose (mg/kg bw/day) | % of systemic AOEL<br>% of systemic AAOEL |
| e.g. Tractor mounted boom spray application outdoors to low crops<br>Buffer zone: 2-3 m<br>Drift reduction technology: no<br>DT <sub>50</sub> : 30 days<br>DFR: 3 µg/cm <sup>2</sup> /kg a.s./ha<br>Interval between treatments: NA days |                                   |                                    |  |                                    |   |
| Number of applications and application rate  |                                   | 0.009436 kg a.s./ha                |  | 0.045 kg a.s./ha                   |   |
| Resident child<br>Body weight: 10 kg   | Drift (75 <sup>th</sup> perc.)    | 0,0006                             | 0,49                                       | 0,0030                             | 0,22                                      |
|  | Vapour (75 <sup>th</sup> perc.)   | 0,0011                             | 0,82                                       | 0,0011                             | 0,08                                      |
|  | Deposits (75 <sup>th</sup> perc.) | 0,0001                             | 0,05                                       | 0,0004                             | 0,03                                      |
|  | Re-entry (75 <sup>th</sup> perc.) | 0,0002                             | 0,13                                       | 0,0010                             | 0,07                                      |
|  | <b>Sum (mean)</b>                 | 0,0016                             | 1,25                                       | 0,0037                             | 0,27                                      |
| Resident adult<br>Body weight: 60 kg   | Drift (75 <sup>th</sup> perc.)    | 0,0002                             | 0,12                                       | 0,0007                             | 0,05                                      |
|  | Vapour (75 <sup>th</sup> perc.)   | 0,0002                             | 0,18                                       | 0,0002                             | 0,02                                      |
|  | Deposits (75 <sup>th</sup> perc.) | 0,0000                             | 0,02                                       | 0,0002                             | 0,01                                      |
|  | Re-entry (75 <sup>th</sup> perc.) | 0,0001                             | 0,06                                       | 0,0003                             | 0,02                                      |
|  | <b>Sum (mean)</b>                 | 0,0004                             | 0,31                                       | 0,0010                             | 0,07                                      |

#### Conclusion:

According to the EFSA model calculations, it can be concluded that the risk using GF-3730 is below the AOEL for resident (adult and child) for both active substances.

### 3.4.6 Combined exposure

| Grasslands                |   |   |   |                                    |
|---------------------------|---|---|---|------------------------------------|
| Population groups and PPE |   | Florpyrauxifen-benzyl<br>Estimated exposure / AOEL (HQ) | Amidosulfuron<br>Estimated exposure / AOEL (HQ) | Cumulative Exposure – Hazard Index |
| Operators                 | Working coverall and gloves during mixing/loading and application | 0.0062  | 0.0012  | 0.0074                             |
| Worker                    | Working coverall and gloves during mixing/loading and application | 0.0051  | 0.0023  | 0.0074                             |
| Resident - child          | Drift   | 0.0049  | 0.0022  | 0.0071                             |
|                           | Vapour  | 0.0082  | 0.0008  | 0.0090                             |
|                           | Deposits  | 0.0005  | 0.0003  | 0.0008                             |
|                           | Re-entry  | 0.0013  | 0.0007  | 0.0020                             |
|                           | Sum of all pathways   | 0.0125  | 0.0027  | 0.0152                             |
| Resident – adult          | Drift   | 0.0012  | 0.0005  | 0.0017                             |
|                           | Vapour  | 0.0018  | 0.0002  | 0.002                              |
|                           | Deposits  | 0.0002  | 0.0001  | 0.0003                             |
|                           | Re-entry  | 0.0006  | 0.0002  | 0.0008                             |
|                           | Sum of all pathways   | 0.0031  | 0.0007  | 0.0038                             |

#### Conclusion:

The Hazard Index is < 1. Thus, combined exposure to both active substances in GF 3730 is not expected to present a risk for operators, workers, residents and bystanders.

### 3.5 Residues and consumer exposure (Part B, Section 7)

The data available are not considered sufficient for risk assessment.

**Due to invalid residue trials (lack of validation data for hydrolysis efficiency), no conclusions can be drawn on the magnitude of residues on grassland and compliance to existing MRLs for florpyrauxifen-benzyl cannot be performed.** An exceedance of the current MRLs for animal commodities for amidosulfuron as laid down in Reg. (EU) 396/2005 is not expected.

Considering that active substances florpyrauxifen-benzyl and amidosulfuron are 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 leguminous plants.**

The chronic and the short-term intakes of residues of amidosulfuron are unlikely to present a public health concern. Due to the shortcomings on the residue trials and the lack of data to address the genotoxicity and general toxicity of the metabolites X12568215 and X12393505, the chronic and the short-term intakes of florpyrauxifen-benzyl (XDE-848) residues cannot be finalized.

**As far as consumer health protection is concerned, France, zRMS does not agree with the authorization of the intended uses on fodder gramineous and fodder leguminous.**



GF-3730/ PROCLOVA  
Part A - National Assessment  
FRANCE

#### Information on GF-3730 (KCA 6.8)

| Crop                 | PHI for GF-3730<br>proposed by applicant | PHI/ Withholding period* sufficiently supported for |               | PHI for GF-3730<br>proposed by zRMS | zRMS Comments<br>(if different PHI proposed)   |
|----------------------|--|---|---------------|-------------------------------------|--|
|                      |  | florpyrauxifen-benzyl                               | amidosulfuron |                                     |  |
| Fodder<br>gramineous | 7 days                                   | No  | Yes           | /                                   | Use not supported<br>(hydrolysis efficiency<br>and residue trials)                               |
| Fodder<br>leguminous | 7 days                                   | No  | No            | /                                   | Use not supported<br>(hydrolysis efficiency<br>and residue trials)<br>MRL exceedance in<br>honey |

NR: not relevant

\* 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).

#### Waiting periods before planting succeeding crops

Not relevant

### 3.6 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 substances and 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 of the active substances 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 conclusions or agreed in the assessment based on new data provided.

PEC soil derived for the active substances and their metabolites are used for the ecotoxicological risk assessment, and mitigation measures are proposed.

PECgw for florpyrauxifen-benzyl do not occur at levels exceeding those mentioned in regulation EU No 546/2011 for all the intended uses. PECgw for amidosulfuron and its metabolites, with the exception of guanidine, do not occur at levels exceeding those mentioned in regulation EU No 546/2011 and guidance document SANCO 221/2000<sup>10</sup> for applications every year on established grassland and for applications every three years on newly sown grassland from BBCH 20.

However, PECgw for all florpyrauxifen-benzyl metabolites and amidosulfuron metabolite guanidine were not considered reliable due to major deviations identified in the selection of the input parameters related to degradation in soil that are not in accordance with the recommendations of the current guidance documents

<sup>10</sup> 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.

GF-3730/ PROCLOVA  
Part A - National Assessment  
FRANCE

(EFSA, 2014<sup>11</sup> and FOCUS 2014<sup>12</sup>). **Therefore, the risk of groundwater contamination for florypyrauxifen-beznyl metabolites and amidosulfuron metabolite guanidine, cannot be finalized for all intended uses.**

PEC<sub>sw/sed</sub> for the active substances and their metabolites were not considered reliable mostly due to major deviations identified in the selection of the input parameters related to degradation in water/sediment system that are not in accordance with the recommendations of the current guidance documents (EFSA, 2015<sup>13</sup>). In addition, the crop interception specific for the use on newly sown layers was not correctly implemented in all FOCUS scenarios needed for the risk assessment. Finally, not all PEC<sub>sw/sed</sub> modelling files were made available. **Consequently, the exposure assessment for surface water compartment for the active substances and their metabolites cannot be finalized for all the intended uses.**

Based on vapour pressure, information on volatilisation from plants and soil, and DT<sub>50</sub> calculation, no significant contamination of the air compartment is expected for the intended uses.

### 3.7 Ecotoxicology (Part B, Section 9)

For all uses, the exposure levels for non-target aquatic species provided by the applicant, for the use of preparation PROCLOVA (GF-3730), could not be used for the active substances and metabolites. **Therefore, the risk assessment for non-target aquatic species, for the use of product PROCLOVA (GF-3730), cannot be finalised.**

The estimated exposure levels for non-target terrestrial species, related to the use of PROCLOVA (GF-3730) product are lower than the reference toxicity values for each group of organisms, under the conditions of use specified below.

### 3.8 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.

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

Active substances amidosulfuron and florypyrauxifen-benzyl are not approved as a candidate for substitution, therefore a comparative assessment is not foreseen.

<sup>11</sup> EFSA (2014) European Food Safety Authority, 2014. EFSA Guidance Document for evaluating laboratory and field dissipation studies to obtain DegT<sub>50</sub> values of active substances of plant protection products and transformation products of these active substances in soil. EFSA Journal 2014;12(5):3662, 37 pp., doi:10.2903/j.efsa.2014.3662

<sup>12</sup> FOCUS (2014) Generic guidance for Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration, Version: 1.1 Date: 18 December 2014

<sup>13</sup> FOCUS (2015) Generic guidance for FOCUS surface water Scenarios, Version: 1.4, Date: May 2015

**5 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”.

**5.1.1 Post-authorisation monitoring**

None.

**5.1.2 Post-authorisation data requirements**

None.

## Appendix 1 Copy of the product authorisation



### 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 réglementaire,*

*Vu la demande d'autorisation de mise sur le marché du produit phytopharmaceutique PROCLOVA*

de la société **CORTEVA AGRISCIENCE FRANCE S.A.S.**  
enregistrée sous le n° 2021-3706

*Vu les conclusions de l'évaluation de l'Anses du 26 décembre 2024,*

*Considérant que le nombre d'essais résidus valides disponibles est insuffisant pour vérifier le respect des limites maximales de résidus dans les denrées d'origine animale,*

*Considérant qu'en l'absence d'étude de toxicité sur deux métabolites du floupyrauxifène-benzyle et d'essai résidu valide, l'évaluation du risque pour le consommateur lié à l'utilisation du produit ne peut être effectuée,*

*Considérant qu'un risque inacceptable de contamination des eaux souterraines, lié à l'utilisation du produit, ne peut être exclu,*

*Considérant enfin qu'un risque d'effet inacceptable pour les organismes aquatiques, lié à l'utilisation du produit, 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.

GF-3730/ PROCLOVA  
Part A - National Assessment  
FRANCE



| Informations générales sur le produit |   |
|---------------------------------------|---|
| Nom du produit                        | PROCLOVA  |
| Type de produit                       | Produit de référence  |
| Titulaire                             | CORTEVA AGRISCIENCE FRANCE S.A.S.<br>1 bis avenue du 8 mai 1945<br>Immeuble Equinoxe II<br>78280 GUYANCOURT<br>France |
| Formulation                           | Granulé dispersable (WG)  |
| Contenant                             | 75,40 g/kg - florpyrauxifène-benzyle<br>360 g/kg - amidosulfuron  |
| Numéro d'intrant                      | 830-2021.01   |
| Numéro d'AMM                          | -   |
| Fonction                              | Herbicide   |
| Gamme d'usage                         | Professionnel   |

A Maisons-Alfort, le

Directrice générale déléguée  
en charge du pôle produits réglementés  
Agence nationale de sécurité sanitaire de  
l'alimentation, de l'environnement et du travail (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) |
| <b>15305905</b><br>Graminées fourragères*Désherbage    | 0,085 kg/ha   | 1/an                          | 7                           |
|  | L'usage est refusé car, compte tenu du nombre insuffisant d'essais résidus valides, le respect des limites maximales de résidus de flupyrauxifène-benzyle dans les denrées d'origine animale ne peut être vérifié, et car, en l'absence d'étude de toxicité sur deux métabolites du flupyrauxifène-benzyle et d'essai résidu valide, une évaluation du risque pour le consommateur ne peut être effectuée, et au motif que les données disponibles ne permettent pas d'exclure un risque inacceptable de contamination des eaux souterraines, ni un risque d'effet inacceptable pour les organismes aquatiques. |                               |                             |
| <b>15455911</b><br>Légumineuses fourragères*Désherbage | 0,085 kg/ha   | 1/an                          | 7                           |
|  | L'usage est refusé car, compte tenu du nombre insuffisant d'essais résidus valides, le respect des limites maximales de résidus de flupyrauxifène-benzyle dans les denrées d'origine animale ne peut être vérifié, et car, en l'absence d'étude de toxicité sur deux métabolites du flupyrauxifène-benzyle et d'essai résidu valide, une évaluation du risque pour le consommateur ne peut être effectuée, et au motif que les données disponibles ne permettent pas d'exclure un risque inacceptable de contamination des eaux souterraines, ni un risque d'effet inacceptable pour les organismes aquatiques. |                               |                             |
| <b>15705914</b><br>Prairies*Désherbage                 | 0,085 kg/ha   | 1/an                          | 7                           |
|  | L'usage est refusé car, compte tenu du nombre insuffisant d'essais résidus valides, le respect des limites maximales de résidus de flupyrauxifène-benzyle dans les denrées d'origine animale ne peut être vérifié, et car, en l'absence d'étude de toxicité sur deux métabolites du flupyrauxifène-benzyle et d'essai résidu valide, une évaluation du risque pour le consommateur ne peut être effectuée, et au motif que les données disponibles ne permettent pas d'exclure un risque inacceptable de contamination des eaux souterraines, ni un risque d'effet inacceptable pour les organismes aquatiques. |                               |                             |

## **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.



1G.1\_PROCLOVA\_G  
F-3730\_draft label.d