REGISTRATION REPORT Part A Risk Management

Product code: F7B-39-30 Product name(s): RINPODE Chemical active substance(s): florpyrauxifen-benzyl, 25 g/L

Southern Zone Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE (new application)

Applicant: Corteva Agriscience France S.A.S. Date: 23/12/2024

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| 5 | Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorisation |
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PART A RISK MANAGEMENT

1 Details of the application

The company Corteva Agriscience France S.A.S. has requested a marketing authorisation in France for the product RINPODE (product code: F7B-39-30), containing 25 g/L florpyrauxifen-benzyl¹ as an 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 France S.A.S.'s application submitted on 12/04/2023 to market RINPODE (F7B-39-30) 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 (2023-1389) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses), according to the Regulation (EC) no 1107/2009², the implementing regulations, and French regulations. This application was assessed in the context of the zonal procedure for all MSs of the Southern zone, taking into account the worst-case uses ("risk envelope approach")³. When risk mitigation measures were necessary, they are adapted to the situation in France.

The data taken into account are those deemed to be valid either at European level (Review Report and EFSA conclusion) or at zonal/national level. The assessment of RINPODE (F7B-39-30)has been made using endpoints agreed in the EU peer review of florpyrauxifen-benzyl. It also includes assessment of data and information related to RINPODE (F7B-39-30) where those data have not been considered in the EU peer review process.

This part A of the RR presents a summary of essential scientific points upon which recommendations are based and is not intended to show the assessment in detail. The risk assessment conclusions provided in this document are based on the information, data and assessments provided in the Registration Report, Part B Sections 1-10 and Part C, and where appropriate the addendum for France.

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

¹ 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

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

³ SANCO document "risk envelope approach", European Commission (14 March 2011). <u>Guidance document on the preparation and submission</u> of dossiers for plant protection products according to the "risk envelope approach"; SANCO/11244/2011 rev. <u>5</u>

⁴ COMMISSION REGULATION (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products

This document also describes the specific conditions of use and labelling required for France for the registration of RINPODE (F7B-39-30).

1.2 Letters of Access

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

1.3 Justification for submission of tests and studies

According to the applicant: « The studies submitted are necessary for first authorisation in Southern EU zone and are in accordance with Reg. (EU) No. 284/2013. Relevant studies (as listed in SanCo Guidance Document 7109/VI/1995) have been conducted in compliance with the principles of GLP or GEP ».

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of RINPODE (F7B-39-30), it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7

2 Details of the authorisation decision

2.1 **Product identity**

| | FTD 20 20 |
|---|--|
| Product code | F7B-39-30 |
| Product name in MS | RINPODE |
| 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) (incl. content) | florpyrauxifen-benzyl, 25 g/L |
| Formulation type | Emulsifiable concentrate [EC] |
| Packaging | N/A : no marketing authorisation granted |
| Coformulants of concern for national authorisations | - |
| Restrictions related to identity | - |
| Mandatory tank mixtures | None |
| Recommended tank mixtures | None |

2.2 Conclusion

The evaluation of the application for RINPODE (F7B-39-30) 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 2017⁵ provides that:

- unless otherwise stated in the product authorisation, the pre harvest interval (PHI) is at least 3 days;
- unless otherwise stated in the product authorisation, the minimum buffer zone alongside a water body is 5 metres for products applied through spraying or dusting;
- unless otherwise stated in the product authorisation, the minimum re-entry period is 6 hours for field uses and 8 hours for indoor uses.

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

Finally, the French Order of 12 April 2021⁶ provides that:

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

Thus, at French national level, possible extrapolation of submitted data and the corresponding assessment from "reference" crops to "related" ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is also reached on the acceptability of the intended uses on those "related"

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

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

crops. The aim of this Order, mainly based on the EU document on residue data extrapolation⁷ is to supply "minor" crops with registered plant protection products.

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

Finally, the French Order of 20 November 2021^{s9} 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

 $N\!/\!A$: no marketing authorisation granted.

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

⁹ 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 - Légifrance (legifrance.gouv.fr)

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.

| | | | GAP rev. 1, date: 2024/12/24 |
|--------------------------|-----------------------------------|-----------------------|------------------------------|
| PPP (product name/code): | RINPODE / F7B-39-30 | Formulation type: | EC ^(a, b) |
| Active substance 1: | florpyrauxifen-benzyl | Conc. of a.s. 1: | 25 g/L ^(c) |
| Applicant: | Corteva Agriscience France S.A.S. | Professional use: | \boxtimes |
| Zone(s): | Southern Zone ^(d) | Non-professional use: | |
| Verified by MS: | Yes | | |
| Field of use: | Herbicide | | |

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 |
|--------------------|-------------|---|---|--|--------------------------|--|---|--|---|---|-------------|-----|--|
| () | Member | Crop and/ | | Pests or Group of pests | Application | n | | | Application rate | | | PHI | Remarks: |
| No. ^(e) | state(s) | or situation (crop destination/purpose of crop) | Fn, Fpn G, Gn, Gpn or I | controlled (additionally: developmental stages of the pest or pest group) | Method/Ki nd | Timing/Growth stage of crop & season | Max. number a) per use b) per crop/ season | Min. interval between applications (days) | product/ha a) max. rate per appl. b) max. total rate | g a.s./ha a) max. rate per appl. b) max. total rate per crop/season | min/ma | | e.g. g safener/synergist per ha |
| Zonal | uses (field | or outdoor uses, ce | ertain t | ypes of protected crops) | | | | | | | | | |
| 1 | FR | Sugar beet: Beta vulgaris (BEAVA). Fodder beet (BEAVC) | | Abutilon teophrasti (ABUTH) Chenopodium album (CHEAL) Aethusa cynapium (AETCY) Papaver rhoeas (PAPRH) Datura stramonium (DATST) and other species | Overall, foliar spray | BBCH 10 to 19 | a) 1 b) 1 | - | a) 0.08 L pr/ha b) 0.08 L pr/ha | a) 2.0 b) 2.0 | 100- 300 | F | Notacceptable (groundwater, aquatic organisms) |

F7B-39-30 / RINPODE

Part A - National Assessment

FRANCE

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | | | | | | |
|--------------------|----------|---|---------------------|--|---------------------------|-------------------------|-------------------------|-------------------------|-------------------------------------|--|-------------|--|---|--|---|--|----------------|--------|------------------------------------|
| Use- | Member | Crop and/ | F, | Pests or Group of pests controlled | Application | 1 | | | Application rate | | | PHI | Remarks: | | | | | | |
| No. ^(e) | state(s) | or situation (crop destination/purpose of crop) | Fpn G, se Gn, | Fpn G, Se Gn, Gpn | Fpn G, e Gn, Gpn | Fpn G, Gn, Gpn | Fpn G, Gn, Gpn | Fpn G, Gn, Gpn | Fpn G, Gn, Gpn | on(additionally:n,developmental stages ofpnthe pest or pest group) | nd | Timing/Growth stage of crop & season | Max. number a) per use b) per crop/ season | Min. interval between applications (days) | product/ha a) max. rate per appl. | | L/ha min/ma | (days) | e.g. g safener/synergist per ha |
| 2 | FR | Sugar beet: Beta vulgaris (BEAVA). Fodder beet (BEAVC) | | Abutilon teophrasti (ABUTH) Chenopodium album (CHEAL) Aethusa cynapium (AETCY) Papaver rhoeas (PAPRH) Datura stramonium (DATST) and other species | Overall, foliar spray | BBCH 10 to 19 | a) 2 b) 2 | | | a) 1.0 b) 2.0 | 100- 300 | F | Not acceptable (groundwater, aquatic organisms) | | | | | | |
| 3 | FR | Sugar beet: Beta vulgaris (BEAVA). Fodder beet (BEAVC) | F | Abutilon teophrasti (ABUTH) Chenopodium album (CHEAL) Aethusa cynapium (AETCY) Papaver rhoeas (PAPRH) Datura stramonium (DATST) and other species) and other species | Overall, foliar spray | BBCH 10 to 19 | a) 3 b) 3 | 5 days | a) 0.026 L pr/ha b) 0.08 L pr/ha | a) 0.66 b) 2.0 | 100- 300 | F | Not acceptable (groundwater, aquatic organisms) | | | | | | |
| 4 | FR | Sugar beet: Beta vulgaris (BEAVA). Fodder beet (BEAVC) | F | Abutilon teophrasti (ABUTH) Chenopodium album (CHEAL) Aethusa cynapium (AETCY) Papaver rhoeas (PAPRH) Datura stramonium (DATST) and other species | Overall, foliar spray | BBCH 10 to 19 | a) 4 b) 4 | 5 days | a) 0.02 L pr/ha b) 0.08 L pr/ha | a) 0.5 b) 2.0 | 100- 300 | F | Not acceptable (groundwater, aquatic organisms) | | | | | | |

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Part A - National Assessment

of equipment used must be indicated.

FRANCE

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 |
|--------------------|--------------|---|---|--|--------------------------|--|---|--|--|---|----------------|-----------|--|
| | Member | Crop and/ | F, | Pests or Group of pests | Application | n | | 1 | Application rate | | | PHI | Remarks: |
| No. ^(e) | state(s) | or situation (crop destination/purpose of crop) | Fn, Fpn G, Gn, Gpn or I | controlled (additionally: developmental stages of the pest or pest group) | Method/Ki nd | Timing/Growth stage of crop & season | Max. number a) per use b) per crop/ season | Min. interval between applications (days) | product/ha a) max. rate per appl. | g a.s./ha a) max. rate per appl. b) max. total rate per crop/season | L/ha min/ma | (days) | e.g. g safener/synergist per ha |
| 5 | FR | Sugar beet: Beta vulgaris (BEAVA). Fodder beet (BEAVC) | F | Abutilon teophrasti (ABUTH) Chenopodium album (CHEAL) Aethusa cynapium (AETCY) Papaver rhoeas (PAPRH) Datura stramonium (DATST) and other species | Overall, foliar spray | BBCH 10 to 19 | a) 1 - 4 b) 1 - 4 | 5 days | a) 0.02 – 0.08 L pr/ha b) 0.02 - 0.08 L pr/ha | a) 0.5 – 2.0 b) 0.5 – 2.0 | 100- 300 | F | Not relevant (covered by the above uses) |
| Remark able | s (a) (b) | | | mulsifiable concentrate (EC), mulation types and internat | | | () | Select relevant | accordance with th | e list of all intended | d GADe in | Dort B S | ection 0 should be given |
| heading | (-) | | | ograph n°2, 6th Edition Revis | | | | n column 1 | accordance with th | e list of all intended | | Tart D, S | section o should be given |
| | (c) | g/kg or g/l | | | - | | | | possible for uses w no longer supports | | hlighted in | n grey, U | se should be crossed out |
| Remark | s 1 | Numeration necessary | to allo | w references | | | 7 (| Frowth stage at | first and last treat | tment (BBCH Mo | nograph | Growth | Stages of Plants, 1997, |
| columns | | | | ures of EU Member States | | | | | | | | | n on season at time of |
| | 3 | | | x classifications (both) should | | nen relevant, the use | | pplication | | | | | |
| | | | | (e.g. fumigation of a structur | | c · · · · | | | | | | | of use must be provided. |
| | 4 | | | Fn: non-professional field u fessional greenhouse use, Gn: | | | | | al (in days) between | | | | of fumigation of empty |
| | | 1 | - | rofessional greenhouse use, I: | 1 | 0 | | | EPPO-Guideline PP | | | | |
| | 5 | | | Codes of target pests/disease | | | | | | | | | per treatment (usually g, |
| | | common names of the | e pest g | roups (e.g. biting and sucking | g insects, soi | l born insects, foliar | k | g or L product/h | na). | | | | |
| | | | | pmental stages of the pests a | nd pest grou | ps at the moment of | | | | | ments (e.g | g. ULVA | or LVA) it should be |
| | C | application must be na | | annovina law volum- | ing | na dustina del- | | | "application: metho | | | | |
| | 6 | | | spraying, low volume spray | | | | | ore-harvest interval | | nce/restric | rtions | |
| | | Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type 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)

The appearance of F7B-39-30 is that of a green clear liquid with fruity odour. The density is 0.924 g/mL and the pH of an aqueous dilution (1%) is 5.5 at 19 °C. The product showed a Newtonian behaviour.

The F7B-39-30 physical properties, other than the appearance, are not anticipated to change significantly as a result of the colorant. Confirmative GLP physical properties studies on F7B-39-30 to evaluate oxidizing properties, explosive properties, and flammability are still being finalized and the corresponding final report is expected to be available in May 2023. In the meantime, the GF-3206 results are reported: GF-3206 is not explosive, has no oxidizing properties, is not flammable (flashpoint higher than 100°C) and it is not liable to ignite under normal storage conditions.

F7B-39-30 is anticipated to be stable under accelerated and ambient storage conditions in commercial packaging: the addition of the food-grade dye is not anticipated to impact the active ingredient stability nor technical performance properties. The GLP storage stability studies for confirming the stability of F7B-39-30 formulation under accelerated conditions in PET packaging are provided. Based on these studies, there is no effect of low and high temperature on the stability of the formulation, since at 54°C for 14 days (and at 40°C for 2 weeks) and at 0°C for 7 days, no significant change in active substance content or in physicalchemical properties occurred.

Ambient storage stability (24 months) and shelf-life data (36 months) in commercial packaging (PET and HDPE/PA) are leveraged from studies conducted from GF-3206. Based on these data, a shelf life of minimum two years in commercial packagings is assigned.

F7B-39-30 technical characteristics are acceptable for an emulsifiable concentrate (EC) formulation.

Stability studies were carried out in HDPE/PA (1 L), PET (250 mL) and HDPE-f (1 L) containers. Given the formulation type (EC), extrapolation to HDPE packaging, HDPE/PA packaging with a volume of less than 1 L and PET packaging with a volume of less than 250 mL is not acceptable.

3.2 Efficacy (Part B, Section 3)

The effectiveness level of RINPODE (F7B-39-30) applied post-emergence is considered satisfactory for broadleaf weed control for all the intented uses.

The selectivity level of RINPODE (F7B-39-30) applied post-emergence is considered acceptable for all the uses claimed.

The risk of negative impact on yield and quality is considered acceptable.

The risk of negative impact on multiplication is considered negligible.

The risk of negative impact on following and adjacent crops is considered acceptable.

The risk of resistance to florpyrauxifen-benzyl does not require monitoring for the uses claimed.

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 substance florpyrauxifen-benzyl and its relevant impurity toluene in the product RINPODE (F7B-39-30) 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.

3.4 Mammalian toxicology (Part B, Section 6)

3.4.1 Acute toxicity

The product has a low toxicity in respect to acute oral, inhalation and dermal toxicity and is not irritating to the skin or the eye and is not a skin sensitiser

3.4.2 Operator exposure

Considering the proposed uses, the operator systemic exposure was estimated using the EFSA model¹⁰:

| | | Florpyrauxifen-benzyl | | | | |
|--|---|------------------------------------|--------|--|--|--|
| Model data | Level of PPE | Total absorbed dose (mg/kg/day) | % AOEL | | | |
| Sugar beet Tractor mounted boom spray Application rate: 2g as/ha | application outdoors, downward | | | | | |
| EFSA Operator Model (75 th quantile regression) Body weight: 60 kg | Work wear - arms, body and legs covered and gloves during M/L and A | 0.00013 | 0.1 | | | |

| | | Florpyrauxifen-benzyl | | | | | | | |
|--|---|------------------------------------|--------|--|--|--|--|--|--|
| Model data | Level of PPE | Total absorbed dose (mg/kg/day) | % AOEL | | | | | | |
| Sugar beet Tractor mounted boom spray Application rate: 0.5g as/ha | Sugar beet Tractor mounted boom spray application outdoors, downward | | | | | | | | |
| EFSA Operator Model (75 th quantile regression) Body weight: 60 kg | Work wear - arms, body and legs covered and gloves during M/L and A | 0.000065 | 0.05 | | | | | | |

According to the exposure assessment using the EFSA model, the operator exposure to RINPODE (F7B-39-30) is below the AOEL value of Florpyrauxifen-benzyl, with a working coverall and gloves during mixing/loading and application.

¹⁰ AOEM – Agricultural Operator Exposure Model (EFSA Journal 2022;20(1):7032)

3.4.3 Worker exposure

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

| | | Florpyrauxifen-benzyl | | | | |
|--|---|------------------------------------|-----------------------|--|--|--|
| Model data | Level of PPE | Total absorbed dose (mg/kg/day) | % of systemic AOEL | | | |
| Sugar beet Mission : inspection, irriga Outdoor Work rate: 2 hours/day DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha | ation | | | | | |
| 1 of applications and appli | cation rate: | 0.002 kg a.s./ha | | | | |
| Body weight: 60 kg | Work wear (arms, body and legs covered) and gloves TC: 1250 cm ² /person/h | 0.0001 | 0.08 | | | |

| | | Florpyrauxifen-benzyl | | | |
|---|---|------------------------------------|-----------------------|--|--|
| Model data | Level of PPE | Total absorbed dose (mg/kg/day) | % of systemic AOEL | | |
| Sugar beet Mission : inspection, irrig Outdoor Work rate: 2 hours/day DT ₅₀ : 30 days DFR: 3 µg/cm ² /kg a.s./ha | | | | | |
| 4 of applications and app | lication rate: | 0.0005 kg a.s./ha | | | |
| Body weight: 60 kg | Work wear (arms, body and legs covered) and gloves TC: 1250 cm ² /person/h | 0.0002 | 0.1 | | |

3.4.4 Bystander exposure

In the absence of AAOEL determined for Florpyrauxifen-benzyl, it is considered that the risk assessment for the bystander is covered by the resident risk assessment.

Indeed, only resident exposure is provided since, according to EFSA Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (EFSA Journal 2022;20(1):7032): "When an acute risk assessment is not triggered (i.e. for PPPs containing active substances that are not acutely toxic, and for which the setting of an AAOEL was not necessary), no bystander risk assessment is required. Exposure in this case will be determined by average exposure over a longer duration, and higher exposures on one day will tend to be offset by lower exposures on other days. Therefore, exposure assessment for residents also covers bystander exposure."

3.4.5 Resident exposure

Resident exposure was assessed according to the EFSA model.

| M. J.I | | Florpyrauxife | n-benzyl |
|--|---|------------------------------------|----------|
| Model data | | Total absorbed dose (mg/kg/day) | % AOEL |
| Buffer zone Drift reduct Number of Interval bet | unted – downward application : 3 meters ion technology: no applications : 1 ween treatments: - rate : 0.002 kg a.s./ha | | |
| DT ₅₀ | | 30 days | |
| DFR | | 3 µg/cm ² /kg a.s./ha | |
| Resident | Spray drift (75th percentile) | 0.0002 | 0.2 |
| (children) Body weight: 10 kg | Vapour (75th percentile) | 0.0008 | 0.6 |
| | Surface deposits (75th percentile) | 1e-05 | 0.01 |
| | Entry into treated crops (75th percentile) | 0.0001 | 0.1 |
| | All pathways (mean) | 0.001 | 0.8 |
| Resident | Spray drift (75th percentile) | 5e-05 | 0.04 |
| (adults) Body | Vapour (75th percentile) | 0.0003 | 0.2 |
| weight: 60 | Surface deposits (75th percentile) | 6e-06 | 0.004 |
| kg | Entry into treated crops (75th percentile) | 8e-05 | 0.06 |
| | All pathways (mean) | 0.0004 | 0.3 |
| | | Florpyrauxife | n-benzyl |
| Model | | Total absorbed dose (mg/kg/day) | % AOEL |

Number of applications : 4 Interval between treatments: 5 days Application rate : 0.0005 kg a.s./ha

| DT ₅₀ | | 30 days | | |
|--------------------|--|----------------------------------|------|--|
| DFR | | 3 µg/cm ² /kg a.s./ha | | |
| Resident | Spray drift (75th percentile) | 0.0001 | 0.08 | |
| (children) Body | Vapour (75th percentile) | 0.0008 | 0.6 | |
| weight: 10 | Surface deposits (75th percentile) | 2e-05 | 0.01 | |
| kg | Entry into treated crops (75th percentile) | 0.0002 | 0.2 | |
| | All pathways (mean) | 0.001 | 0.8 | |
| Resident | Spray drift (75th percentile) | 2e-05 | 0.02 | |

| (adults) | Vapour (75th percentile) | 0.0003 | 0.2 |
|--------------------|--|--------|-------|
| Body weight: 60 | Surface deposits (75th percentile) | 9e-06 | 0.007 |
| kg | Entry into treated crops (75th percentile) | 0.0001 | 0.09 |
| | All pathways (mean) | 0.0004 | 0.3 |

3.4.6 Combined exposure

Not relevant. The product contains only one active substance.

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

The data available are considered sufficient for risk assessment.

An exceedance of the current EU MRLs of 0.01* mg/kg for florpyrauxifen-benzyl as laid down in Reg. (EU) 396/2005 is not expected.

The chronic and the short-term intakes of florpyrauxifen-benzyl residues are unlikely to present a public health concern.

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

Summary for RINPODE (F7B-39-30)

| Table : | Information on F7B-39-30 |
|---------|--------------------------|
| | |

| Сгор | PHI for F7B-39-30 proposed by appli- | PHI/ Withholding period* sufficiently supported for | PHI for F7B-39-30 | zRMS Comments (if different PHI pro- |
|------------|---|--|-------------------|---|
| | cant | Florpyrauxifen-benzyl | proposed by zRMS | posed) |
| Sugar beet | F – BBCH 10-19 | Yes | F-BBCH 19 | - |

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.

The PEC of florpyrauxifen-benzyl and its metabolites in soil, surface water and groundwater have been assessed according to FOCUS guidance documents, with standard FOCUS scenarios to obtain outputs from the FOCUS models, and the endpoints established in the EU conclusions.

PECsoil and PECsw/sed derived for the active substance and its metabolites are used for the ecotoxicological risk assessment. However, PECsw/sed for metabolite X11438848 was derived following an approach that is not in line with the recommandations of the FOCUS documentation (FOCUS, 2014¹¹; FOCUS, 2015¹²) related to the selection of the input parameters for degradation in soil of parent. **Consequently the exposure assessment for surface water compartment for metabolite X11438848 cannot be finalized for all the intended uses.**

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 florpyrauxifen-benzyl metabolites were not considered reliable due to major deviations identified in the selection of the input parameters related to degradation in soil of parent that are not in accordance with the recommendations of the current guidance documents (FOCUS, 2014 and FOCUS 2021¹³). Therefore, the risk of groundwater contamination for florpyrauxifen-benzyl metabolites cannot be finalized for all intended uses.

3.7 Ecotoxicology (Part B, Section 9)

The ecotoxicological risk assessment of the formulation was performed according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU conclusions for the active substance(s) and its/their metabolites were used for the intended use patterns. In cases where deviations from the EU agreed endpoints were considered appropriate (for example when additional studies are provided), such deviations were highlighted and justified accordingly.

Based on the guidance documents, the risks for birds, mammals, bees and other non-target arthropods, earthworms, other soil macro-organisms and micro-organisms and terrestrial plants are acceptable for the intended uses in the conditions of uses described under 2.5.

For aquatic organisms, the ratio PEC/RAC are above 1 with the PEC Step 2 indicating a possible risk for metabolite X11438848. However, it is not possible to refine the risk assessment for this metabolite since the PECsw Step 3 are not acceptable. **Therefore, the risk assessment cannot be finalized for aquatic organisms.**

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.

¹¹ 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.

¹² FOCUS (2015) Generic guidance for FOCUS surface water Scenarios, Version: 1.4, Date: May 2015.

¹³ FOCUS (2021) "Generic guidance for Tier 1 FOCUS groundwater assessments". Version 2.3, June 2021

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

The active substance florpyrauxifen-benzyl is not approved as a candidate for substitution, therefore a comparative assessment is not foreseen.

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

Docusign Envelope ID: 738558EF-D2EF-4C7E-A904-1BCB85DAD217

RÉPUBLIQUE FRANÇAISE Libert Égalia Fotternité



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

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

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

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

| de la société | CORTEVA AGRISCIENCE FRANCE S.A.S. |
|---------------------|-----------------------------------|
| enregistrée sous le | n° 2023-1389 |

Vu les conclusions de l'évaluation de l'Anses du 6 novembre 2024,

Considérant qu'un risque inacceptable de contamination des eaux souterraines par les métabolites du florpyrauxifène-benzyle, lié à l'utilisation du produit, ne peut être exclu,

Considérant également, qu'un risque d'effet inacceptable pour les organismes aquatiques par le métabolite X11438848 du florpyrauxifène-benzyle, 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.

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Docusign Envelope ID: 738558EF-D2EF-4C7E-A904-1BC885DAD217





| Informations générales sur le produit | | | | |
|---------------------------------------|---|--|--|--|
| Nom du produit | RINPODE | | | |
| Type de produit | Produit de référence | | | |
| Titulaire | CORTEVA AGRISCIENCE FRANCE S.A.S. Immeuble Equinoxe II 1 bis avenue du 8 mai 1945 78280 GUYANCOURT France | | | |
| Formulation | Concentré émulsionnable (EC) | | | |
| Contenant | 25 g/L - florpyrauxifène-benzyle | | | |
| Numéro d'intrant | 364-2023.01 | | | |
| Numéro d'AMM | | | | |
| Fonction | Herbicide | | | |
| Gamme d'usage | Professionnel | | | |

A Maisons-Alfort, le 23/12/2024

cuSigned by: Charlotte Grastilleur

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

RINPODE AMM n°-

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Docusign Envelope ID: 738558EF-D2EF-4C7E-A904-1BCB85DAD217





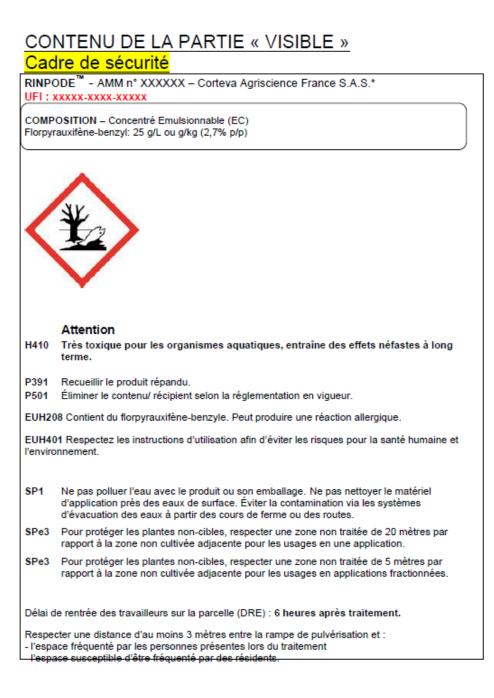
| Liste des usages refusés | | | | | | | |
|--|--|------|---------------------|--|--|--|--|
| Usages | Dose d'emploi Nombre maximum d'applications | | Délai avant récolte | | | | |
| | | | (jours) | | | | |
| 15055011 | 0,08 L/ha | 1/an | F (BBCH 19) | | | | |
| 15055911 Betterave industrielle et fourragère*Désherbage | Motivation du refus : L'usage est refusé, pour l'ensemble des modalités d'application revendiquées, car 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. | | | | | | |

RINPODE AMM n° -

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Appendix 2: Copy of the product label

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





Détenteur de l'Autorisation de Mise sur le Marché, Référent Emballeur et Distributeur : Corteva Agriscience France S.A.S. * 1 bis avenue du 8 mai 1945, Bâtiment Equinoxe II, 78280 Guyancourt, France Distributeur :

BONNES PRATIQUES



PREMIERS SOINS

S'éloigner de la zone dangereuse.

En cas de contact cutané : enlever tout vêtement souillé, rincer immédiatement et abondamment la peau sous l'eau du robinet. En cas d'irritation ou éruption cutanée, consulter un spécialiste.

En cas de projection dans les yeux : rincer immédiatement pendant 15 à 20 minutes sous un filet d'eau paupières ouvertes. Consulter un spécialiste. En cas d'inhalation : en cas de trouble respiratoire, contacter sans délai les secours : le 15, le 112 ou un centre antipoison. En cas d'ingestion : rincer immédiatement la bouche avec de l'eau. Ne pas faire vomir sans avis médical. Contacter sans délai les secours : le 15, le 112 ou un centre antipoison.

Dans tous les cas, si les symptômes persistent ou en cas de malaise, consulter un médecin et lui présenter l'étiquette et/ou la fiche de données de sécurité.

En cas d'intoxication animale, contactez votre vétérinaire.

S'éloigner de la zone dangereuse.

<u>Contact cutané</u>: rincer immédiatement et abondamment sous l'eau. <u>Contact oculaire</u>: rincer immédiatement pendant 15 à 20 minutes sous un filet d'eau paupières ouvertes. <u>Inhalation</u>: sortie la personne à l'air frais. En cas de trouble respiratoire, contacter sans délai les secours : le 15, le 112 ou un centre antipoison. <u>Ingestion</u>: contacter sans délai les secours : le 15, le 112 ou un centre antipoison. Ne pas faire vomir sauf sur ordre médical. Voir les premiers soins détaillés à l'intérieur du livret.

> Partie centrale RINPODE™ HERBICIDE

GROUPE 4(O) HERBICIDE

Mode d'action autorisé sur betteraves industrielles et fourragères Consulter le tableau exhaustif des cultures et des usages dans ce livret / la notice ci-jointe.

RÉSERVÉ À UN USAGE EXCLUSIVEMENT PROFESSIONNEL. Consulter ce livret avant toute utilisation Lire les instructions ci-jointes avant l'emploi



®™ Marques déposées de Corteva Agriscience et sociétés affiliées.

N° de lot, date de fabrication : voir sur l'emballage. Code barre (code EAN) + 2D Datamatrix Version de l'étiquette 1 L **e**

CONTENU DE LA PARTIE « LIVRET »

PREMIERS SOINS :

- DESCRIPTIF DU PRODUIT :

RINPODE est une solution innovante pour le désherbage de la betterave en post-levée sur tous types de sol. Il est composé d'une substance active de mode d'action auxinique (groupe HRAC 4 (anciennement O)) le Florpyrauxifène-benzyl (Rinskor[™]) de la famille des acides arylpicolinates. Son mode d'action foliaire implique une intervention sur adventices levées. Cette substance active est dotée de propriétés systémiques.

RINPODE[™] peut être appliqué aussi bien sur les variétés conventionnelles que sur CONVISO SMART du stade cotylédon jusqu'au stade 9 feuilles de la betterave ou 10 -15% de couverture de l'inter-rang.

⇒ Tableau des usages autorisés

Le produit RINPODE est autorisé pour le traitement des parties aériennes.

| Cultures | Cible | Dose maximum d'emploi | Nombre maximum d'applications | Stade d'application / conditions d'emploi | Délai avant récolte (DAR) et Stade limite d'application sur la culture ⁽²⁾ | Précautions environnement : Zone Non Traitée Aquatique (mètres), mention abeille, | Protection des personnes présentes et des résidents |
|-----------|---------------|-----------------------------|-------------------------------------|--|---|---|--|
| Betterave | Dicotylédones | 0,08 L/ha | 1 | BBCH 10 - BBCH 19 | DAR F (BBCH 19 ⁽³⁾) | Eau : 20 m | 3 mètres |
| Betterave | Dicotylédones | 0,04 L/ha | 2 | BBCH 10 - BBCH 19 | DAR F (BBCH 19 ⁽³⁾) | Eau:5m | 3 mètres |
| Betterave | Dicotylédones | 0,026 L/ha | 3 | BBCH 10 - BBCH 19 | DAR F (BBCH 19 ⁽³⁾) | Eau:5m | 3 mètres |
| Betterave | Dicotylédones | 0,02 L/ha | 4 | BBCH 10 – BBCH 19 | DAR F (BBCH 19 ⁽³⁾) | Eau:5m | 3 mètres |

| Betterave | Dicotylédones | 0,02- 0,08 ⁽¹⁾ | 1-4 | BBCH 10 - BBCH 19 | DAR F (BBCH 19 ⁽³⁾) | Eau: 20 m | 3 mètres |
|-----------|---------------|------------------------------|-----|----------------------|------------------------------------|-----------|----------|
|-----------|---------------|------------------------------|-----|----------------------|------------------------------------|-----------|----------|

(1) Il est possible de fractionner l'application en 4 applications maximum sans dépasser la dose maximale de 0.08 L/ha

(2) Délai avant récolte (DAR) en jours : non fixé. Respecter le stade limite d'application sur la culture.

(3) Stade 9 feuilles de la betterave ou 10 -15% de couverture de l'inter-rang.

Corteva Agriscience France ne préconise l'utilisation de ce produit que sur les cultures et cibles mentionnées ci-dessus et, à ce titre, décline toute responsabilité concernant son utilisation aux autres usages prévus par le catalogue des usages en vigueur.

Limites maximales de résidus : se reporter aux LMR définies au niveau de l'Union Européenne, consultables à l'adresse : <u>http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database</u>

⇒ Mode d'action

Le Florpyrauxifène-benzyl (Rinskor[™]) est une substance active herbicide, non volatile, utilisée pour le contrôle des adventices dicotylédones sur les cultures de betteraves sucrières et fourragères.

Le Florpyrauxifène-benzyl (Rinskor[™]) est un herbicide systémique principalement absorbé par les feuilles et appartenant à la famille des acides arylpicolinates au sein des auxines synthétiques (groupe HRAC 4, anciennement HRAC 0). Il représente un mode d'action innovant pour la culture de la betterave.

Le Florpyrauxifène-benzyl (RinskorTM) agit de manière systémique sur l'adventice en se liant aux récepteurs hormonaux cibles. Il s'accumule dans les tissus méristématiques des plantes après transport par le xylème et le phloème et entraîne la perturbation du processus de croissance de la plante (division cellulaire anarchique) entrainant la mort de l'adventice. Les symptômes engendrés par le Florpyrauxifènebenzyl (RinskorTM) sur les adventices sensibles sont des déformations caractéristiques des auxines de synthèse.

⇒ Spectre d'efficacité

RINPODE[™] est efficace sur les adventices dicotylédones levées au moment du traitement. Les meilleures efficacités sont obtenues sur des adventices au stade jeune.

| Nom commun | Nom latin (EPPO CODE) | RINPODE™ 0,08L/ha x 1 | RINPODE™ 0,04L/ha x 2 | RINPODE™ 0.026 L/ha x 3 | RINPODE™ 0,02 L/ha x 4 |
|-------------|-----------------------------|--------------------------|--------------------------|----------------------------|---------------------------|
| Ethuse | Aethusa cynapium (AETCY) | S | S | S | S |
| Ammi élevée | Ammi majus (AMIMA) | MS | S | S | S |

| Abutilon de théophrase | Abutilon theophrasti (ABUTH) | HS | H | IS | HS | HS | |
|------------------------------|--|-----------------------------|----|----------|------------------------|-------------------|--|
| Chénopode blanc | Chenopodium album (CHEAL) | MS | N | IS | MS | MS | |
| Gaillet gratteron | Galium aparine (GALAP) | MS | | S | MS | S | |
| Mercuriale | Mercurialis annua (MERAN) | MS | N | IS | MS | MS | |
| Coquelicot | Papaver rhoeas (PAPRH) | S | | S | S | S | |
| Datura | Datura stramonium (DATST) | S | H | IS | HS | HS | |
| Galinsoga | Galinsoga parviflora (GASPA) | MS | H | IS | HS | HS | |
| Lamier pourpre | Lamium purpureum (LAMPOU) | MS | HS | | HS | HS | |
| Les adventices sont classifi | Les adventices sont classifiées selon l'échelle ci-dessous : | | | | | | |
| Hautement sensible (HS) | Sensible (S) | Modérément sensible (MS) | | Partiell | ement Sensible (PS) | Non Sensible (NS) | |
| 95-100% | 85-94.9% | 75-84.99 | 6 | 60-74.9% | | <60% | |

Le niveau de contrôle dépend des espèces et du stade de croissance des adventices et des conditions environnementales.

- RECOMMANDATIONS D'EMPLOI :

⇒ Conditions d'application

RINPODE[™] peut être utilisé uniquement en post levée des betteraves sucrières et fourragères du stade cotylédon (BBCH 10) jusqu'au stade 9 feuilles de la betterave (BBCH 19) ou 10 -15% de couverture de l'inter-rang. RINPODE[™] peut être appliqué jusqu'à 4 fois par saison à une dose maximale cumulée de 2 g substance active / ha.

RINPODE™ est recommandé en association avec d'autres herbicides disposant de l'usage betterave, dans le cadre d'un programme de désherbage en post-levée des adventices. Pour une efficacité optimale, 2, 3 ou 4 applications fractionnées sont nécessaires. Les applications doivent être raisonnées avec un intervalle minimal de 5 jours ou lors de la levée de nouvelles adventices. Le stade de l'adventice cible est très importante pour une efficacité optimale. Les meilleurs résultats ont été obtenus pour des applications de RINPODE[™] sur des adventices aux stades cotylédon à 4 feuilles.

⇒ Précautions d'emploi

Conditions météorologiques :

Ne pas appliquer RINPODE™ si des précipitations sont annoncées dans l'heure suivant l'application. Traiter par temps calme, sans vent (inférieur à 3 sur l'échelle de Beaufort) afin d'éviter toute dérive sur les cultures voisines. Intervenir avec une hygrométrie supérieure à 60%.

Température :

Ne pas appliquer RINPODE[™] lorsque la température est en dessous de 0°C, et/ou lorsque l'amplitude thermique entre le jour et la nuit est supérieure à 12°C le jour de l'application. Sous ces conditions, la croissance normale de la culture peut être stoppé et des symptômes tels qu'une décoloration des feuilles peut apparaître.

Ne pas appliquer le produit sur des betteraves sucrières ou fourragères en situation de stress tel que des températures élevées (supérieur à 25°C)

Sol:

RINPODE™ peut être utilisé sur tous les types de sol.

Sélectivité :

Intervenir avec des cultures en bon état végétatif. Ne pas appliquer le produit sur des betteraves sucrières ou fourragères en situation de stress tel que des températures élevées (supérieur à 25°C), des attaques de ravageurs ou parasites, une déficience en minéraux et oligoéléments ou une asphyxie des racines.

RINPODE[™] est un herbicide sélectif de toutes les variétés de betteraves sucrières et fourragères (or multiplication de semences). Des déformations des feuilles transitoires peuvent apparaître mais elles demeurent sans aucune incidence sur la croissance future de la culture, ni sur le rendement ou le taux de sucre (richesse).

➡ Mélanges extemporanés

Les mélanges extemporanés doivent être mis en œuvre conformément à la réglementation en vigueur. Ne pas mélanger RINPODE[™] avec des oligoélément type bore.

Apporter les emballages vidés et fermés à votre distributeur partenaire d'A.D.I.VALOR ou à un autre service de collecte spécifique.

Pour l'élimination des produits non utilisables, conserver le produit dans son emballage d'origine. Interroger votre distributeur partenaire d'A.D.I.VALOR ou faites appel à une entreprise habilitée pour la collecte et l'élimination des déchets dangereux.

En cas de déversement accidentel

Se protéger (EPI) et sécuriser la zone.

Prévenir les pompiers (18 ou 112) en cas de danger immédiat pour l'environnement que vous ne pouvez gérer avec vos propres moyens. Collecter tout ce qui a pu être en contact avec le produit, terre souillée incluse.

Nettoyer le site et le matériel utilisé, en prenant soin de confiner les effluents générés par l'opération de nettoyage. Les éliminer selon la réglementation en vigueur.





AVERTISSEMENT

Toute reproduction totale ou partielle de cette étiquette est interdite.

Respecter les usages, doses, conditions et précautions d'emploi mentionnés sur l'emballage. Ils ont été déterminés en fonction des caractéristiques du produit et des applications pour lesquelles il est préconisé. Conduire sur ces bases, la culture et les traitements selon la bonne pratique agricole en tenant compte, sous la responsabilité de l'utilisateur, de tous facteurs particuliers concernant votre exploitation, tels que la nature du sol, les conditions météorologiques, les méthodes culturales, les variétés végétales, la résistance des espèces...

Le fabricant garantit la qualité du produit vendu dans son emballage d'origine et stocké selon les conditions préconisées, ainsi que sa conformité à l'Autorisation de Mise sur le Marché délivrée par les Autorités Compétentes françaises. Pour les denrées issues de cultures protégées avec cette spécialité et destinées à l'exportation, il est de la responsabilité de l'exportateur de s'assurer de la conformité avec la réglementation en vigueur dans le pays importateur.