REGISTRATION REPORT
Part A
Risk Management

Blood meal, 998 g/kg
CERTASOL

Southern Zone
Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE
(authorisation renewal)
Art.43

Applicant: Flügel GmbH
Date: 23/02/2023

Table of Contents

PART A

RISK MANAGEMENT

1 Details of the application

The company Flügel GmbH has requested a marketing authorisation in France for the product CERTASOL (product code: -), containing 998 g/kg Blood meal[1] as an repellent 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 Flügel GmbH's application submitted on 25/06/2021 to market CERTASOL 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 re-registration of authorisation after the renewal of approval of the active substance Blood meal of this product in France and in other Member States (MSs) of the Southern zone.

Blood meal is a low risk active substance, therefore CERTASOL shall be authorised as a low risk plant protection product where compliant with Article 47 of Regulation (EC) no 1107/2009.

The present application (2021-2799) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses), according to the Regulation (EC) no 1107/2009[2], 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 CERTASOL has been made using endpoints agreed in the EU peer review(s) of blood meal. It also includes assessment of data and information related to CERTASOL 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.

In order to comply with the provisions of Regulation (EC) No 1107/2009 (Commission Implementing Regulation (EU) 2015/2033) and according to Art. 43 of Regulation (EC) No 1107/2009, and in accordance with the guidance document SANCO/2010/13170, the outcome of the risk assessment for the re-registration of plant protection product only applies to blood meal following its renewal of approval.

---

1 COMMISSION IMPLEMENTING REGULATION (EU) 2021/413 of 8 March 2021 renewing the approval of the low-risk active substance blood meal in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011

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

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

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.

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

1.2 Letters of Access

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

1.3 Justification for submission of tests and studies

No new tests or study reports will be provided with this application.

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of CERTASOL, 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

Product code	-
Product name in MS	Certasol
Authorisation number	2110195
Kind of use	Professional
Low risk product (article 47)	**Yes**
Function	repellent
Applicant	Flügel GmbH
Active substance(s) (incl. content)	Blood meal 998 g/kg
Formulation type	Wettable powder [Code: WP]
Packaging	Polyethylene (PEBD) bags (1 kg)
Coformulants of concern for national authorisations	None
Restrictions related to identity	None
Mandatory tank mixtures	None

[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

Recommended tank mixtures	None

2.2 Conclusion

The evaluation of the application for CERTASOL resulted in the decision **to grant** 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

The following classification is proposed in accordance with Regulation (EC) No 1272/2008:

Physical hazards		
Health hazards	No classification	
Environmental hazards	No classification	
Hazard pictograms	-	
Signal word	-	
Hazard statements	-	
Precautionary statements –	***For the P phrases, refer to the extant legislation***	
Supplementary information (in accordance with Article 25 of Regulation (EC) No 1272/2008)		-

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

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

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

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[5] 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 2021[6] 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[7] 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[8] 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 culture[9] 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

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

---

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

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

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

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

9 List of culture considered as unattractive to bees and other pollinators insects defined by French Agricultural ministry and published in Bulletin Officiel du ministère chargé de l'agriculture.

The applicant is required to comply with the current applicable standard for PPEs..

Operator protection:	
-	Refer to the Decision in Appendix 1 for the details.
Worker protection:	
-	Refer to the Decision in Appendix 1 for the details.
Integrated pest management (IPM)/sustainable use:	
Environmental protection	
SPe 3	To protect aquatic organisms, respect an unsprayed buffer zone of 5 metres to surface water bodies.
Other specific restrictions	
Re-entry period	6 hours.
Storage	It is necessary to shake the plant protection product containing Blood meal before use.
Risk mitigation measures	-
Risk mitigation measures	-

The conditions of use of the active substance Blood meal specified in the previous evaluations are not changed.

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):

None.

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. 01, date: 2023-February-23

PPP (product name/code):	CERTASOL	Formulation type:	WP [a, b]
Active substance 1:	blood meal	Conc. of as 1:	998 g/kg)
Active substance 2:	-	Conc. of as 2:	-
Safener:	-	Conc. of safener:	-
Synergist:	-	Conc. of synergist:	-
Applicant:	Flügel GmbH	Professional use:	☒
Zone(s):	southern zone [d]	Non professional use:	☐
Verified by MS:	yes/no		

Field of use: repellent

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

- / CERTASOL
Part A - National Assessment
FRANCE

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. (e)	**Member state**	**Crop and/ or situation** (crop destination / purpose of crop)	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate***			**PHI (days)**	**Remarks:** e.g. g safener/synergist per ha (f) RMS CONCLUSION
					Method / Kind	**Timing / Growth stage of crop & season**	**Max. number a) per use b) per crop/ season**	**Min. interval between applications (days)**	**kg product / ha a) max. rate per appl. b) max. total rate per crop/season**	**kg a.i./ha a) max. rate per appl. b) max. total rate per crop/season**	**Water L/ha min / max**		
1	FR	Deciduous and coniferous trees in forestry, Fruit trees and shrubs in orchard, Ornamentals	F	Cervus sp. (CERVSP), fallow deer (DAMADA), roe deer (CAPRCA)	Spraying, painting, dipping (single plant treatment)	All season	a) 1 b) 1	-	a) 20 kg/ha b) 20 kg/ha	a) 19.96 kg/ha b) 19.96 kg/ha	5 - 200 L/ha*	1	**Acceptable**
2	FR	Deciduous and coniferous trees in forestry, Fruit trees and shrubs in orchard, Ornamentals	F	Rabbits (OVIMUS), lapin (ORYTSP), common hare (LEPUEU)	Spraying, painting, dipping (single plant treatment)	All season	a) 1 b) 1	-	a) 20 kg/ha b) 20 kg/ha	a) 19.96 kg/ha b) 19.96 kg/ha	5 - 200 L/ha*	1	**Acceptable**

* As some standards may have undergone changes, it is the responsibility of the applicant to update the references.
** Possible application during the flowering period according to the order of 20 November 2021 on the protection of bees and other pollinating insects and the preservation of pollination services when using plant protection products

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.

- / CERTASOL
Part A - National Assessment
FRANCE

Remarks columns:	1	Numeration necessary to allow references
	2	Use official codes/nomenclatures of EU Member States
	3	For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)
	4	F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application
	5	Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.
	6	Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.
	7	Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
	8	The maximum number of application possible under practical conditions of use must be provided.
	9	Minimum interval (in days) between applications of the same product
	10	For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
	11	The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product/ha).
	12	If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
	13	PHI - minimum pre-harvest interval
	14	Remarks may include: Extent of use/economic importance/restrictions

3 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 CERTASOL is dark red brown fine powder, almost odourless with tingle of fish. The product does not exhibit any explosive or oxidising properties, and is non-flammable and does not self-ignite. It has a pH of 7.56 (1% w/w suspension). In addition, the wet sieve test showed that the CERTASOL distributed differently on the surface of water. Persistent foaming is within the range. The human pathogenic germs are below the limit values before and after storage. The product is stable for 2 years at 20°C.
Swirling is necessary to wet the product. This has to be declared on the product label. The product should be diluted in water under continuous swirling to avoid clumping.
Its technical characteristics are acceptable for a wettable powder (WP) formulation. PE material will be used for the packaging of CERTASOL.

data gap:
The wet sieve test is outside acceptable limits, evidence must be submitted showing that the product will not block application equipment during the application.

Implications for labelling: none
Compliance with FAO specifications:
There is no FAO specification for blood meal
Compliance with FAO guidelines:
The formulation complies with the general requirements according to the FAO/WHO manual (2010) with exception of wettability and wet sieve test, but this is acceptable based on the intended appli-cation of the product.
Compatibility of mixtures:
No tank mixtures are intended for CERTASOL.
Nature and characteristics of the packaging:
Information with regard to type, dimensions, capacity, size of opening, type of closure, strength, leakproofness, resistance to normal transport & handling, resistance to & compatibility with the contents of the packaging, have been submitted, evaluated and is considered to be acceptable.
Nature and characteristics of the protective clothing and equipment:
Information regarding the required protective clothing and equipment for the safe handling of CERTASOL has been provided and is considered to be acceptable.

3.2 Efficacy (Part B, Section 3)

The efficacy level of CERTASOL is still considered satisfactory for all the requested uses under renewal process.

The phytotoxicity level of CERTASOL is considered negligible for all the requested uses.

3.3 Methods of analysis (Part B, Section 5)

3.3.1 Analytical method for the formulation

In the formulation the content of Iron can be determined by ICP or AAS.
Analytical method proposed for quantification of the active substance in the plant protection product are based on the determination of the iron content, considering the relationship between the iron content and the corresponding haemoglobin content. These methods have previously been reviewed and accepted at EU level. No other data are required.

3.3.2 Analytical methods for residues

Residue analytical methods for the determination of blood meal are not required.
According Reg. EU 2021/413, a residue definition is proposed only for surface water. An ICP-OES method exists for the determination of the residues in water expressed as iron content with a LOQ of 1.0 µg/L. The reference method for measuring haemoglobin by the International Committee for Standardization in Haematology (ICSH) is the hemoglobincyanide (HiCN) test.

3.4 Mammalian toxicology (Part B, Section 6)

Endpoints used in risk assessment

Agreed EU endpoints	
Active substance	**Blood meal**
AOEL systemic	Not required
AAOEL	Not required
Oral absorption	No data
Vapour pressure	Not relevant
Reference	EFSA Journal 2020;18(2):6006 SANTE/11236/2020 Rev
Dermal absorption	No data

3.4.1 Acute toxicity

According to the European assessment of blood meal (EU 2020[10] and EFSA 2020[11]) no toxicological data are required considering the properties of the active substance.

3.4.2 Operator exposure

[10] Review report SANTE/11236/2020 Rev

[11] European Food Safety Authority, 2020. Peer review of the pesticide risk assessment of the active substance blood meal

According to the European assessment of blood meal (EU 2020[10] and EFSA 2020[11]), based on the properties of the active substance, there is no need for establishing toxicological reference values.

Therefore, no risk assessment is necessary for theoperator exposure.

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

3.4.3 Worker exposure

According to the European assessment of blood meal (EU 2020[10] and EFSA 2020[11]), based on the properties of the active substance, there is no need for establishing toxicological reference values.

Therefore, no risk assessment is necessary for the worker exposure.

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

3.4.4 Bystander and resident exposure

According to the European assessment of blood meal (EU 2020[10] and EFSA 2020[11]), based on the properties of the active substance, there is no need for establishing toxicological reference values.

Therefore, no risk assessment is necessary for the bystander and resident exposure.

3.4.5 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. No MRLs are defined for the active substance blood meal.
The chronic and the short-term intakes of blood meal residues are unlikely to present a public health concern.
As far as consumer health protection is concerned, zRMS agrees with the authorization of the intended use(s).

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

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 substance for the intended use patterns. In cases where deviations from the EU agreed end-points were considered appropriate (for example when additional studies are provided), such deviations were highlighted and justified accordingly.

The PEC of blood meal in surface water 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.

PECsw derived for the active substance are used for the ecotoxicological risk assessment, and mitigation measures are proposed.

Due to the nature of the active substance for the preparation CERTASOL, exposure of soil and groundwater to the active substance is considered negligible. Consequently, no risk assessment for groundwater and soil non-target organisms is deemed necessary.

Blood meal is non-volatile powder and no significant contamination of the air compartment is expected for the 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, aquatic organisms, mammals, bees and other non-target arthropods, earthworms, other soil macro-organisms and micro-organisms and terrestrial plants are acceptable for the intended uses. Risk mitigations are required for aquatic organisms.

3.8 Relevance of metabolites (Part B, Section 10)

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)

The active substance blood meal 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

The French Decision requests the submission of post-authorisation confirmatory pieces of information within 24 months regarding:

- The wet sieve test is outside acceptable limits, evidence must be submitted showing that the product will not block application equipment during the application.

Appendix 1 Copy of the product authorisation

RÉPUBLIQUE FRANÇAISE
Liberté
Égalité
Fraternité

anses

Décision relative à une demande de renouvellement de l'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 de renouvellement de l'autorisation de mise sur le marché, suite au renouvellement de l'approbation de la substance active farine de sang, du produit phytopharmaceutique CERTASOL

de la société *FLÜGEL GMBH*

enregistrée sous le *n°2021-2799*

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

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

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

Avertissement :

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

CERTASOL
AMM n°2110105

Page 1 sur 7

RÉPUBLIQUE FRANÇAISE
Liberté
Égalité
Fraternité

anses

Informations générales sur le produit	
Nom du produit	CERTASOL
Type de produit	Produit de référence
Titulaire	FLÜGEL GMBH Eisdorfer Str. 21 37520 OSTERODE AM HARZ Allemagne
Formulation	Poudre mouillable (WP)
Contenant	998 g/kg - farine de sang
Numéro d'intrant	2100179
Numéro d'AMM	2110195
Fonction	Répulsif
Gamme d'usage	Professionnel
Mention particulière	Produit à faible risque au sens de l'article 47 du règlement (CE) n°1107/2009

L'échéance de validité de la présente décision est fixée à douze mois à compter de la date d'expiration de l'approbation de la substance active. A titre indicatif, dans l'état actuel du calendrier d'approbation des substances actives, l'échéance de l'autorisation est fixée au 31 mars 2037.

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

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

A Maisons-Alfort, le 23/02/2023

DocuSigned by:
Charlotte Grastilleur
AE281A855A42454...

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

RÉPUBLIQUE FRANÇAISE
Liberté
Égalité
Fraternité

anses

ANNEXE : Modalités d'autorisation du produit

Vente et distribution	
Le titulaire de l'autorisation peut mettre sur le marché le produit uniquement dans les emballages :	
Emballage	**Contenance**
Sacs en polyéthylène basse densité	1 kg

Classification du produit
La classification retenue est la suivante : Sans classement.
Pour les phrases P se référer à la règlementation en vigueur. **Le titulaire de l'autorisation est responsable de la mise à jour de la fiche de données de sécurité et de la classification du produit en tenant compte de ses éventuelles évolutions.**

- / CERTASOL
Part A - National Assessment
FRANCE

RÉPUBLIQUE FRANÇAISE
Liberté
Égalité
Fraternité

anses

Liste des usages autorisés

En l'absence de mention spécifique, les usages autorisés correspondent à une utilisation en plein champ.
En l'absence de restriction, les usages sont autorisés sur l'ensemble des cultures de la portée de l'usage.

Usages	Dose maximale d'emploi	Nombre maximum d'applications	Stade d'application BBCH	Délai avant récolte (jours)	Zone Non Traitée aquatique (mètres)	Zone Non Traitée arthropodes non cibles (mètres)	Zone Non Traitée plantes non cibles (mètres)	Culture attractive en floraison (arrêté du 20/11/2021)
21014051 Traitements généraux* Trt Répulsif* Grands mammifères	**20 kg/ha**	**1/an**	-	1	5	-	-	Emploi possible
	1 application maximum par an et par culture.							
21014048 Traitements généraux* Trt Répulsif* Lapin et lièvre	**20 kg/ha**	**1/an**	-	1	5	-	-	Emploi possible
	1 application maximum par an et par culture.							

Emploi possible ou interdit = usage autorisé ou interdit durant la floraison et sur les zones de butinage, pour les cultures attractives en plein champ ou sous abri ouvert, dans les conditions fixées par l'arrêté du 20/11/2021.

Liste des usages retirés

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)	Délai accordé pour la vente et la distribution	Délai accordé pour le stockage et l'utilisation des stocks
21014044 Traitements généraux* Trt Répulsif*Cervidés	20 kg/ha	1/an	-	-	-
	Motivation du retrait : L'usage est retiré car transitoire et transformé en l'usage 21014051 Traitements généraux*Trt Répulsif*Grands mammifères				

RÉPUBLIQUE FRANÇAISE
Liberté
Égalité
Fraternité

anses

Conditions d'emploi du produit

Protection de l'opérateur et du travailleur

Des informations générales relatives aux bonnes pratiques de protection pourront être mises à disposition de l'utilisateur :

- l'utilisation d'un matériel adapté et entretenu et la mise en œuvre de protections collectives constituent la première mesure de prévention contre les risques professionnels, avant la mise en place de protections individuelles ;
- le port de combinaison de travail dédiée ou d'EPI doit être associé à des réflexes d'hygiène (ex : lavage des mains, douche en fin de traitement) et à un comportement rigoureux (ex : procédure d'habillage/déshabillage) ;
- les modalités de nettoyage et de stockage des combinaisons de travail et des EPI réutilisables doivent être conformes à leur notice d'utilisation.

Pour l'opérateur, porter

Dans le cadre d'une application effectuée par trempage

- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A);
- EPI vestimentaire conforme à la norme NF EN ISO 27065/A ;
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus l'EPI vestimentaire précité ;
- Protections respiratoires certifiées : demi-masque certifié (EN 140) équipé d'un filtre P3 (EN143) ou A2P3 (EN 14387).

Dans le cadre d'une application effectuée à l'aide d'un pulvérisateur à gâchette ou d'un pinceau

• pendant le mélange/chargement

- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A);
- Combinaison de protection de catégorie III type 4 ;
- Protections respiratoires certifiées : demi-masque certifié (EN 140) équipé d'un filtre P3 (EN143) ou A2P3 (EN14387) ;

• pendant l'application

- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A) ;
- Combinaison de protection de catégorie III type 4 avec capuche ;
- Bottes de protection certifiées EN 13 832-3 ;

• pendant le nettoyage du matériel de pulvérisation

- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A) ;
- Combinaison de protection non tissée de catégorie III type 4.

Dans le cadre d'une application effectuée à l'aide d'un pulvérisateur à rampe

• pendant le mélange/chargement

- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A) ;
- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 ;
- EPI partiel (blouse ou tablier à manches longues) de catégorie III et de type PB (3) à porter par-dessus l'EPI vestimentaire précité ;
- Protections respiratoires certifiées : demi-masque certifié (EN 140) équipé d'un filtre P3 (EN 143) ou A2P3 (EN 14387) ;

• pendant l'application

Si application avec tracteur avec cabine

- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1 ;

RÉPUBLIQUE FRANÇAISE
Liberté
Égalité
Fraternité

anses

• pendant l'application

- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A) ;
- Combinaison de protection de catégorie III type 4 certifiée EN 14605+A1 avec capuche ;
- Bottes de protection certifiées EN 13 832-3 ;

• pendant le nettoyage du matériel de pulvérisation

- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A) ;
- Combinaison de protection de catégorie III type 4 certifiée EN 14605+A1 4.

Pour le travailleur, porter

- EPI vestimentaire conforme à la norme NF EN ISO 27065/A110 et, en cas de contact avec la culture traitée, des gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A).

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

- 6 heures.

Respect des limites maximales de résidus (LMR)

Le délai avant récolte est fixé à 1 jour en fonction des pratiques agricoles sur la culture et afin de limiter l'exposition potentielle des consommateurs.

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

Protection de l'eau

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

Protection de la faune

- SPe 3 : Pour protéger les organismes aquatiques, respecter une zone non traitée de 5 mètres par rapport aux points d'eau.

- Peut être dangereux pour les abeilles. Application possible durant la floraison et sur les zones de butinage selon les conditions fixées par l'arrêté du 20 novembre 2021 pour les usages caractérisés par « emploi possible ».

Le produit peut être utilisé sur les usages autorisés, conformément aux conditions d'emploi antérieures à la présente décision pendant une période de 6 mois.

Exigences complémentaires post-autorisation

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

Détail de la demande post autorisation	Délai (mois)	Récurrence (mois)
Fournir des éléments montrant que l'utilisation du produit dans les conditions réelles ne provoque pas de problème lors de l'application.	24	-

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.

Produit de
BIOCONTRÔLE

CERTASOL

• Chevreuil • Cerf • Lapin • Lièvre

ELAF solutions

FLÜGEL

CONTRE L'ABROUTISSEMENT CERVIDÉS
ET LES DÉGÂTS DES LAPINS ET DES LIÈVRES
EN TOUTES SAISONS



ELAF® solutions

CERTASOL®

APPLICATION PAR PULVÉRISATION, BADIGEON, TREMPAGE, POUDRAGE.

Propriétés

Ce répulsif gibier peut être appliqué en toutes saisons. Il agit par son odeur. Il permet de protéger les plantations ou les régénérations forestières contre les dégâts d'abroutissement des cervidés. Il est aussi actif contre les dégâts de rongement et de sectionnement des lapins et lièvres. Efficacité : une seule application à l'automne suffit jusqu'au départ de la végétation au printemps. En cours de végétation, en cas de forte croissance des nouvelles pousses, il peut être judicieux d'effectuer un second traitement. Du fait de la diffusion de l'odeur, le traitement de la pousse terminale suffit par exemple à protéger le 1er verticille dans le cas des résineux.

Mode d'emploi

Dans la majeure partie des cas le produit s'applique par pulvérisation, après filtrage, avec tous types de pulvérisateur. Aussi applicable par trempage, badigeon, poudrage.

Avantage très important : le produit peut également être pulvérisé sur les plants en jauge avant plantation, ce qui permet un gain de temps très conséquent.

20 kg/ha (en plein) arbres et arbustes forestiers, d'ornements et fruitiers.
Pulvérisation et badigeon : 0,5 kg / 1 000 plants (pousse terminale). 0,75 kg si trempage.

Domaines d'application

Le produit peut être utilisé sur toutes les essences, feuillus et résineux, en toutes saisons, sans risque de phytotoxicité.

Précautions

Préparer la quantité de bouille pouvant être appliquée dans un délai de 1 à 2 jours. Conserver la poudre dans son sachet bien fermé et dans un local tempéré, hors de portée des enfants.

Conditionnement - Toxicité

AMM n° 2110195 SSCL Sans classement toxicologique.

MODE D'EMPLOI

CERTASOL®

Usages :

Forêt :
Contre les dégâts d'abroutissement occasionnés au printemps, en été et en hiver par les chevreuils et le cerf, en milieu naturel, sur les feuillus et les conifères.

Plantations d'ornement :
Contre les dégâts d'abroutissement occasionnés, en toute saison, par le gibier sur les ligneux d'ornement dans les espaces verts. Contre les dégâts de rongements et les sectionnements occasionnés, en toute saison, par les lièvres et les lapins de garenne sur les ligneux d'ornement dans les espaces verts.

Arboriculture fruitière :
Contre les dégâts d'abroutissement occasionnés, en toute saison, par le gibier en arboriculture fruitière.
Contre les dégâts de rongements et les sectionnements occasionnés, en toute saison, par les lièvres et les lapins de garenne en arboriculture fruitière.

Propriétés et mode d'action :

CERTASOL est un produit de protection, constitué de **composants biologiques olfactifs**, contre les dégâts d'abroutissement, de rongement et de sectionnement dus au gibier, applicable toute l'année dans les domaines d'utilisations et les cultures