

REGISTRATION REPORT

Part A

Risk Management

Product code: -

Product name: RATRON GL JARDIN

Active substance:

zinc phosphide, 8 g/kg

COUNTRY: FRANCE

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

Non professional use

(New application)

Applicant: Frunol delicia GmbH

Date: 15/09/2017

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PART A – Risk Management

The company Frunol delicia GmbH has requested marketing authorisation in France for the product RATRON GL JARDIN (no formulation code is stated), containing 8 g/L zinc phosphide¹ for use as a rodenticide (non-professional use).

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

This document describes the specific conditions of use and labelling required for France for the registration of RATRON GL JARDIN.

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

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

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

1 DETAILS OF THE APPLICATION

1.1 Application background

The present registration report concerns the evaluation of Frunol delicia GmbH's application to market RATRON GL JARDIN in France as a rodenticide (product uses described under point 2.3). France acted as a zonal Rapporteur Member State (zRMS) for this request and assessed the application submitted for the first authorisation of this product in France and in other MSs of the Southern zone.

1.2 Active substance approval

Zinc phosphide

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.

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

PART A

Only uses as rodenticide in the form of ready-to-use baits placed in bait stations or target locations may be authorised.

PART B

For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on zinc phosphide, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 October 2010 shall be taken into account.

¹ The IUPAC name is trizinc diphosphide.

In this overall assessment Member States should pay particular attention to:

— the protection of non target organisms. Risk mitigation measures should be applied as appropriate in particular to avoid the spread of baits where only part of the content has been consumed.

An EFSA conclusion is available (EFSA Journal 2010; 8(7):1671).

A Review Report is available (SANCO/12548/2010 final, 28 October 2010).

1.3 Regulatory approach

The present application (2013-1299) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses)² in the context of the zonal procedure for all Member States of the Southern zone, taking into account the worst-case uses (“risk envelope approach”)³ – the highest application rates over the Southern zone. When risk mitigation measures were necessary, they are adapted to the situation in France.

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

The French Order 4th May 2017⁴ provides that:

- unless formally stated in the product authorisation, the pre harvest interval (PHI) is at least three days;
- unless formally stated in the product authorisation, the minimum buffer zone alongside a water body is five metres;
- unless formally stated in the product authorisation, the minimum re-entry period is six hours for field uses and eight hours for indoor uses.

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

The current document (RR) based on Anses’s assessment of the application submitted for this product is in compliance with Regulation (EC) no 1107/2009⁵, implementing regulations, and French regulations.

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

The conclusions relating to the acceptability of risk are based on the criteria indicated in Regulation (EU) No 546/2011⁶, and are expressed as “acceptable” or “not acceptable” in accordance with those criteria.

Finally, the French Order of 26 March 2014⁷ provides that:

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

Thus, at French national level, possible extrapolation of submitted data and the corresponding assessment from “reference” crops to “linked” ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is reached on the acceptability of the intended uses on those “linked” crops. The aim of this Order,

² French Food Safety Agency, Afssa, before 1 July 2010

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

⁴ 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 <https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGRG1632554A/jo/texte>

⁵ 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

⁶ 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

⁷ <http://www.legifrance.gouv.fr/eli/arrete/2014/3/26/AGRG1407093A/jo>

mainly based on the EU document on residue data extrapolation⁸ is to supply “minor” crops with registered plant protection products.

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

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

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of RATRON GL JARDIN, it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

1.5 Letter(s) of Access

Not necessary: the applicant has provided sufficient data to show that access is not required.

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

2 DETAILS OF THE AUTHORISATION

2.1 Product identity

Product name (code)	RATRON GL JARDIN (<i>synonym: RATRON GIFT-LINSEN</i>)
Authorisation number	N/A: authorization not granted in France
Function	Rodenticide (non-professional use)
Applicant	Frunol delicia GmbH
Composition	8 g/kg zinc phosphide
Formulation type (code)	Granular bait (GB)
Packaging	Polypropylene bucket with lid, containing 0.5 kg product. Multilayer polyethylene/card dosing container, holding 0.05 or 0.5 kg product Polyethylene terephthalate bottle, containing 0.750 kg product, connecting directly to the Ratron®-Appligun ⁹

2.2 Classification and labelling

2.2.1 Classification and labelling under Directive 99/45/EC

Not applicable after 1st June 2015.

2.2.2 Classification and labelling in accordance with Regulation (EC) No1272/2008

Physical hazards	-	
Health hazards	-	
Environmental hazards	Hazardous to the aquatic environment — Acute Hazard, Category 1 Hazardous to the aquatic environment — Chronic Hazard, Category 1	
Hazard pictograms		
Signal word	Warning	
	H400	Very toxic to aquatic life
	H410	Very toxic to aquatic life with long-lasting effects
Precautionary statements –	<i>For the P phrases, refer to the extant legislation</i>	
Supplementary information (in accordance with Article 25 of Regulation (EC) No 1272/2008)	EUH032	Contact with acids liberates very toxic gas

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

⁹ Editorial remark: the applicant had also originally proposed a polypropylene bucket with lid, containing 0.5 kg product, and a multilayer polyethylene/card dosing container, holding 0.05 or 0.5 kg product. However, these were found to be unsuitable on evaluation (cf. § 3.1.3.2)

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

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

N/A: authorization not granted in France
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2.2.4 Other phrases linked to the preparation

N/A: authorization not granted in France
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2.3 Product uses

Please note: The GAP Table below reports the intended uses proposed by the applicant,
When the conclusion is “not acceptable”, the intended use is highlighted in grey and the main reason(s) reported in the remarks.

PPP (product name/code)	RATRON GL JARDIN/(no product code)	Formulation type:	GAP rev. 1, date: 2017-september-19
active substance 1	zinc phosphide	Conc. of a.s. 1:	Granular bait (GB)
Applicant:	Frunol delicia GmbH	professional use	<input type="checkbox"/>
Zone(s):	southern EU	non-professional use	<input checked="" type="checkbox"/>
Verified by MS:	yes		
Field of use:	rodenticide		

1	2	3	4	5	6	7	8	10	11	12	13	14
Use- No.	Member state(s))**	Crop and/ or situation (crop destination/purpose of crop)	F G 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
					Method/Kin d	Timing/Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	kg, L product/ha a) max. rate per appl. b) max. total rate per crop/season	g, kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
21	France	Vegetables (non-professional use)	F	<i>Microtus arvalis</i> <i>Microtus agrestis</i>	placing of 5 baits in vole hole	all stages	a) n.a. b) n.a.)*	a) 2.0 b) n.a.)*	a) 0.016 b) n.a.)*	n.a.	n.a.	Not acceptable for non- professional users Packaging types are not able to assure a minimal exposure for non-professional users.
22	France	Vegetables (non-professional use)	F	<i>Microtus arvalis</i> <i>Microtus agrestis</i>	100 g bait per baiting place	all stages	a) n.a. b) n.a.)*	a) 2.5 b) n.a.)*	a) 0.020 b) n.a.)*	n.a.	n.a.	Not acceptable for non- professional users Packaging types are not able to assure a minimal exposure for non-professional users.
23	France	Orchard (non-professional use)	F	<i>Microtus arvalis</i> <i>Microtus agrestis</i> <i>Clethrionomys glareolus</i>	placing of 5 baits in vole hole	all stages	a) n.a. b) n.a.)*	a) 2.0 b) n.a.)*	a) 0.016 b) n.a.)*	n.a.	n.a.	Not acceptable for non- professional users Packaging types are not able to assure a minimal exposure for non-professional users.

1	2	3	4	5	6	7	8	10	11	12	13	14
Use- No.	Member state(s))**	Crop and/ or situation (crop destination/purpose of crop)	F G 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
					Method/Kin d	Timing/Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	kg, L product/ha a) max. rate per appl. b) max. total rate per crop/season	g, kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
24	France	Orchard (non-professional use)	F	<i>Microtus arvalis</i> <i>Microtus agrestis</i> <i>Clethrionomys glareolus</i>	100 g bait per baiting place	all stages	a) n.a. b) n.a.)*	a) 2.5 b) n.a.)*	a) 0.020 b) n.a.)*	n.a.	n.a.	Not acceptable for non- professional users Packaging types are not able to assure a minimal exposure for non-professional users.
25	France	Ornamentals (non-professional use)	F	<i>Microtus arvalis</i> <i>Microtus agrestis</i> <i>Clethrionomys glareolus</i>	placing of 5 baits in vole hole	all stages	a) n.a. b) n.a.)*	a) 2.0 b) n.a.)*	a) 0.016 b) n.a.)*	n.a.	n.a.	Not acceptable for non- professional users Packaging types are not able to assure a minimal exposure for non-professional users.
26	France	Ornamentals (non-professional use)	F	<i>Microtus arvalis</i> <i>Microtus agrestis</i> <i>Clethrionomys glareolus</i>	100 g bait per baiting place	all stages	a) n.a. b) n.a.)*	a) 2.5 b) n.a.)*	a) 0.020 b) n.a.)*	n.a.	n.a.	Not acceptable for non- professional users Packaging types are not able to assure a minimal exposure for non-professional users.

F: The pre-harvest interval for the envisaged area of application is covered by the application conditions and/or growing period remaining between the envisaged application and harvest; it is not necessary to lay down/indicate a pre-harvest interval in days (F)

N = pre-harvest interval not relevant due to the indication

Remarks:

- | | |
|--|--|
| <ul style="list-style-type: none"> (a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (e.g. fumigation of a structure) (b) Outdoor or field use (F), glasshouse application (G) or indoor application (I) (c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds (d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR) (e) GCPF Codes - GIFAP Technical Monograph No 2, 1989 (f) All abbreviations used must be explained (g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench (h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated | <ul style="list-style-type: none"> (i) g/kg or g/l (j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application (k) The minimum and maximum number of application possible under practical conditions of use must be provided (l) PHI - minimum pre-harvest interval (m) Remarks may include: Extent of use/economic importance/restrictions |
|--|--|

3 RISK MANAGEMENT

3.1 Reasoned statement of the overall conclusions taken in accordance with the Uniform Principles

3.1.1 Physical and chemical properties

The formulation RATRON GL JARDIN is a ready-to-use granular bait (GB) formulation. All studies have been performed in accordance with the current requirements and the results are deemed acceptable. The appearance of the product is that of grey-violet coloured bait grains, with no detectable odour. It is not explosive and has no oxidising properties. The product is not flammable and has no self-ignition properties. There is no effect of high temperature on the stability of the formulation, since after 14 days at 54 °C, neither the active substance content nor the technical properties were changed. The storage stability for two years at ambient temperature in the commercial packaging or equivalent must be provided post-authorisation. The technical characteristics are acceptable for a GB formulation.

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

3.1.2 Methods of analysis

3.1.2.1 Analytical method for the formulation

Analytical methodology for the determination of active substance in the formulation is available and validated. As the active substance zinc phosphide does not contain relevant impurities, no pertinent analytical method is required.

3.1.2.2 Analytical methods for residues

Considering the intended uses, analytical methods for the determination of residues in plants and in foodstuffs of animal origin are not necessary.

Analytical methods are available in the Draft Assessment Report (DAR)/this dossier and validated for the determination of residues of zinc phosphide in soil, water (surface and drinking) and air.

The active substance is very toxic (T+); however, no method is required for the determination of residues in tissues and body fluids as no exposure of operators, workers and bystanders is expected.

3.1.3 Mammalian Toxicology

Endpoints used in risk assessment

Active substance: zinc phosphide			
ADI	0.042 mg kg bw/d	EU (2011)	
ARfD	0.073 mg/kg bw		
AOEL	0.042 mg/kg bw/d		
Dermal absorption	Based on default values (expert judgement):		
		Concentrate (used in formulation) 8 g/kg	Spray dilution (used in formulation) x g/L
	Dermal absorption endpoints %	10%	

3.1.3.1 Acute Toxicity

RATRON GL JARDIN containing 8 g/kg of zinc phosphide has a low acute oral, inhalational and dermal toxicity, is not irritating to the rabbit skin or eye and is not a skin sensitiser.

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

3.1.3.2 Operator Exposure

Summary of critical use patterns (worst cases):

Application types	F/G ¹⁰	Equipment	Application rate kg product/ha (g a.s./ha)	Model
5 baits/vole hole	F and G	Lance application or Ratron® AppliGun	2 kg product/ha (16 g/ha)	Human Exposure to Rodenticides (PT 14), TNsG (2007) model RISKOFDERM model
100 g bait placed in baiting places or bait stations (worst case compared with 5 baits/vole hole)	F and G	No equipment	2.5 kg product/ha (20 g/ha)	

Considering the proposed uses, operator (i.e., user – non-professional) systemic exposure was estimated using the RISKOFDERM and Human Exposure to Rodenticides (PT 14), TNsG (2007) models:

Application types/model	Equipment	PPE and/or working coverall	% AOEL zinc phosphide (AOEL = 0.042 mg/kg bw/d)
100 g bait placed in baiting places or bait stations/Human Exposure to Rodenticides (PT 14), TNsG (2007) model	No equipment	No PPE	9.8
100 g bait placed in baiting places or bait stations/RISKOFDERM model	No equipment	Working coverall, no gloves	3.3

According to the model calculations, it may be concluded that the risk for the operator (i.e., user – non-professional) using RATRON GL JARDIN is acceptable without PPE.

The proposed packaging has been described in sufficient detail, and its compliance can therefore be assessed.

The composition and classification of RATRON GL JARDIN are compatible with a product of the type designated “authorised for use in home gardens”, in accordance with French Decree n°. 2010-1755 of 30 December 2010¹¹ and the Orders of 30 December 2010¹² which implement it.

¹⁰ Open field or glasshouse

¹¹ [Décret n° 2010-1755 du 30 décembre 2010 relatif à la cession des produits phytopharmaceutiques aux utilisateurs non professionnels et aux conditions de vente et d'emploi de ces produits](#)

The bucket, the dosing box and the bottle are not able to assure minimal exposure for the amateur gardener. These packaging types therefore do not comply with the above-mentioned Decree and Orders of 30 December 2010.

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

3.1.3.3 Bystander Exposure

In the context of use by non-professionals, it is considered that the assessment for bystanders is unnecessary.

3.1.3.4 Resident exposure

RATRON GL JARDIN is directly applied as loose grains into vole holes or placed in baiting places/bait stations. Therefore, exposure of residents (adults or children) to the product is considered unlikely. However, the accidental ingestion of baits by a child was assessed, by calculating the quantity of baits that could be ingested per day without unacceptable effect (reverse scenario).

For toddlers, the recommended daily intake is about 0.73 mg zinc phosphide/day, assuming a body weight of 10 kg and an ARfD value for zinc phosphide of 0.073 mg/kg bw. Considering that one granule contains a maximum of 0.146 mg of zinc phosphide which would be consumed per accidentally ingested granule, a toddler could ingest five granules per day without unacceptable effects.

Anses (France) recommends that a bittering agent be added to the formulation, to deter human ingestion.

3.1.3.5 Worker Exposure

RATRON GL JARDIN is intended to be used by non-professionals doing home garden applications. In this case of the non-professional user, the worker is also the user of the product. Moreover, RATRON GL JARDIN is a granular bait formulation; no work is expected to be practised after application. Therefore worker exposure estimation is considered to be not relevant.

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

3.1.4 Residues and Consumer Exposure

EFSA (2010¹³) concluded :

The submission of metabolism and residues data to support the representative use of zinc phosphide was not considered necessary. The product is applied in a targeted manner, exclusively as a bait against rodents, and therefore no significant residues in plant or animal matrices are expected. No residue definitions have therefore been set for plant or animal products, and no consumer risk assessments are required.

These conclusions apply to RATRON GL JARDIN as only rodenticide uses are intended.

3.1.5 Environmental fate and behaviour

The fate and behaviour in the environment have been evaluated according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU conclusions were used to calculate predicted environmental concentration (PEC) values for the active substance and its metabolites for the intended use patterns. In cases where deviations from the EU agreed endpoints were considered appropriate (for example when additional studies are provided), such deviations were highlighted and justified accordingly.

¹² Arrêté du 30 décembre 2010 relatif aux conditions d'emballage des produits phytopharmaceutiques pouvant être employés par des utilisateurs non professionnels and Arrêté du 30 décembre 2010 interdisant l'emploi de certains produits phytopharmaceutiques par des utilisateurs non professionnels

¹³ EFSA (European Food Safety Authority); 2010b; Conclusion on the peer review of the pesticide risk assessment of the active substance zinc phosphide. EFSA Journal 2010; 8(7):1671. [48 pp.]. doi:10.2903/j.efsa.2010.1671.

The PEC values of zinc phosphide and its metabolite in soil 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 values derived for the active substance and its metabolite are used for the ecotoxicological risk assessment.

According to the intended uses, PECsw calculations for zinc phosphide and its metabolite were not relevant. No unacceptable risk of groundwater contamination is expected for the intended uses. In both cases, this is in line with the European conclusions on the active substance for the same uses.

Based on vapour pressure, information on volatilisation from plants and soil, and DT₅₀ calculation, no significant contamination of the air compartment is expected for the intended uses.

3.1.6 Ecotoxicology

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

The risks for non-target organisms are covered by the assessments for professional uses. Therefore the risks are acceptable for the intended uses in home gardens.

3.1.7 Efficacy

Considering the data submitted:

- the efficacy of RATRON GL JARDIN is considered satisfactory in the requested conditions of use. Efficacy was not tested on *Arvicola terrestris*, but the efficacy data obtained on other vole species may be extrapolated to *A. terrestris*.
- the selectivity of RATRON GL JARDIN is considered satisfactory in the requested conditions of use.
- the risk of negative impact on yield, quality, transformation processes, propagation, succeeding and adjacent crops is considered negligible.
- the risk of resistance developing or appearing is considered to be low.

3.2 Conclusions arising from French assessment

Taking into account the above assessment, an authorisation cannot be granted as proposed in Appendix 1 – Copy of the product Decision.

3.3 Substances of concern for national monitoring

No information stated.

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

3.4.1 Post-authorisation monitoring

N/A: authorization not granted in France

3.4.2 Post-authorisation data requirements

N/A: authorization not granted in France

3.4.3 Label amendments

N/A: authorization not granted in France



Informations générales sur le produit		
Nom du produit	RATRON GL JARDIN	
Type de produit	Deuxième gamme	
Titulaire	FRUNOL DELICIA GMBH HANSASTRASSE 74 59425 UNNA ALLEMAGNE	
Formulation	Appât granulé (GB)	
Contenant	8 g/kg - phosphore de zinc	
Produit de référence	Nom commercial	RATRON GL
	N° AMM	2170697
Numéro d'intrant	915-2013.01	
Numéro d'AMM	-	
Fonction	Rodenticide	
Gamme d'usages	Amateur / emploi autorisé dans les jardins	

A Maisons-Alfort, le 15 SEP. 2017

Françoise WEBER
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 I : Conditions de mise sur le marché demandées

Classification du produit	
Catégorie de danger	Mention de danger
Dangers pour le milieu aquatique - Danger aigu, catégorie 1	H400 : Très toxique pour les organismes aquatiques
Dangers pour le milieu aquatique - Danger chronique, catégorie 1	H410 : Très toxique pour les organismes aquatiques, entraîne des effets néfastes à long terme
EUH032 : Au contact d'un acide, dégage un gaz très toxique	
Pour les phrases P se référer à la réglementation en vigueur.	



Liste des usages refusés

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
21011001 Traitements généraux*Trt Appat*Campagnols	2 kg/ha *	Non applicable	Non applicable
	* Pour des applications dans des trous de rongeurs, avec une dose d'emploi limitée à 5 granulés par trou. Motivation du refus : l'usage est refusé au motif que les emballages proposés ne sont pas en mesure de garantir une exposition minimale de l'utilisateur non professionnel.		
	2,5 kg/ha *	Non applicable	Non applicable
* Pour des applications dans des stations d'appâtage, avec une dose d'emploi limitée à 100 g par station d'appâtage. Motivation du refus : l'usage est refusé au motif que les emballages proposés ne sont pas en mesure de garantir une exposition minimale de l'utilisateur non professionnel.			

RATRON GL JARDIN

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



Information sur le produit

Ratron® GL Jardin

Appâts sous forme de lentilles agissant rapidement pour lutter contre le campagnol commun, le campagnol des champs et le campagnol roussâtre dans les cultures fruitières, dans les cultures légumières, dans les cultures ornementales. Autorisé sous serre et contre les souris domestiques dans les installations de stockage. Emploi autorisé dans les jardins.

Points fort du produit

- Nouveau développement unique.
- Sans poussière, résistant à l'eau et à la moisissure.
- Trois fois plus efficace que les produits traditionnels à base de blé empoisonné pour une quantité d'application égale (5 lentilles par terrier de rongeur).



N° d'AMM : XXXXXX délivrée le JJ/MM/AAAA

Détenteur de l'A.M.M. :

Frunol delicia GmbH
Hansastraße 74b
D-59425 Unna
Allemagne

Autorisé pour l'emploi en jardins d'amateurs.

Substance active

8 g/kg (0.8% m/m) de phosphure de zinc
Formulation : appât granulé (GB)

Caractéristiques et effets

Ratron® GL Jardin (lentilles pour souris) est un appât prêt à l'emploi, à action rapide dont la substance active est le phosphure de zinc (8 g/kg) pour contrôler le campagnol commun (*Microtus arvalis*), le campagnol des champs (*Microtus agrestis*), le campagnol roussâtre (*Clethrionomys glareolus*) et la souris domestique (*Mus musculus*). Ratron® GL Jardin résiste à la pluie.

La nouvelle formulation de Ratron® GL Jardin permet d'obtenir une efficacité optimale même avec une teneur en substance active moindre. De plus, il n'y a pas de dégradation de la substance active avant l'ingestion de l'appât par le rongeur. De ce fait, la méfiance des rongeurs est

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Information sur le produit

Ratron® GL Jardin

significativement réduite et l'attractivité de l'appât pour le rongeur reste optimale. L'efficacité et l'attractivité reste entière jusqu'à son ingestion par les rongeurs.

Après ingestion de l'appât, le phosphore de zinc (substance active) se transforme en phosphine (hydruure de phosphore) sous l'action des sucs gastriques de l'estomac du rongeur. La phosphine est une neurotoxine très active dans le métabolisme. La mort du campagnol survient dans un délai de 1 à 3 heures après ingestion de l'appât. Ensuite, la substance active est rapidement décomposée et ainsi ne peut provoquer aucun empoisonnement secondaire.

Recommandations d'utilisation

Ratron® GL Jardin est autorisé dans les jardins d'amateurs pour les usages en cultures fruitières, en cultures légumières et en cultures ornementales ainsi que lors de stockage (intérieur ou extérieur). Autorisé également sous serre.

Pour lutter contre les campagnols, 5 lentilles de Ratron® GL Jardin doivent être déposées dans chaque trou de rongeur. Pour une infestation moyenne, ce dosage correspond approximativement à une dose de 1 g/10 m² (la dose maximum d'application de produit par an est de 2 g/10 m²).

L'utilisation de Ratron® Appli-Gun, développé récemment, permet une application protégée de Ratron® GL Jardin. En utilisant cette méthode d'application dans chaque trou de rongeur, le temps de travail peut être considérablement réduit par rapport aux autres méthodes d'application. De plus, une application avec Ratron® Appli-Gun présente moins de risques pour l'utilisateur car elle minimise les contacts entre l'appât et l'utilisateur.

L'application de Ratron® GL Jardin dans les trous des rongeurs dans des stations d'appâts est possible avec 100 g par lieu d'appâtage (la dose maximum d'application de produit est de 2.5 g/10 m²) permettant ainsi une protection des appâts contre les organismes non-cibles.

Contre les souris domestiques dans les installations de stockage, le produit doit être appliqué dans stations d'appâts.

Il est interdit d'appliquer Ratron® GL Jardin de façon généralisée à la surface du sol. Ratron® GL Jardin comme tous les autres appâts à base de phosphore de zinc, doit être placé dans des endroits protégés/abrités (sous la surface du sol ou dans les stations d'appâtage).



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Information sur le produit

Ratron® GL Jardin

Usages homologués

Produit	Culture	Cible	Dose	Méthode d'application	Période d'application	Nb d'application (dose max par an)	DAR
Ratron® GL Jardin	Cultures ornementales ¹	Campagnol commun Campagnol des champs Campagnol roussâtre	5 lentilles par trou	Placer les appâts dans les trous	Lorsque l'infestation est détectée (tous les stades)	n.a. ² (2.0 g/10 m ²)	N
	Cultures ornementales ¹	Campagnol commun Campagnol des champs Campagnol roussâtre	100 g par station d'appâts	Station d'appâts		n.a. ² (2.5 g/10 m ²)	N
	Cultures fruitières ¹	Campagnol commun Campagnol des champs Campagnol roussâtre	5 lentilles par trou	Placer les appâts dans les trous	Lorsque l'infestation est détectée (tous les stades)	n.a. ² (2.0 g/10 m ²)	F
	Cultures fruitières ¹	Campagnol commun Campagnol des champs Campagnol roussâtre	100 g par station d'appâts	Station d'appâts		n.a. ² (2.5 g/10 m ²)	F
	Cultures légumières ¹	Campagnol commun Campagnol des champs	5 lentilles par trou	Placer les appâts dans les trous	Lorsque l'infestation est détectée (tous les stades)	n.a. ² (2.0 g/10 m ²)	F
	Cultures légumières ¹	Campagnol commun Campagnol des champs	100 g par station d'appâts	Station d'appâts		n.a. ² (2.5 g/10 m ²)	F
	Zone de stockage (intérieur)	Souris domestique	100 g par station d'appâts	Station d'appâts	Lorsque l'infestation est détectée (tous les stades)	n.a. ² (2.5 g/10 m ²)	N
	Zone de stockage (en plein air autour des bâtiments)	Souris domestique	100 g par station d'appâts	Station d'appâts		n.a. ² (2.5 g/10 m ²)	N

¹ : Usage extérieur et usage en serre

² : Nombre d'application : non applicable car les applications doivent être répétées jusqu'à ce que les appâts ne soient plus consommés (pour connaître la dose maximum en kg/ha de produit par an à appliquer, se référer au tableau).

F : Le délai avant récolte (DAR) pour les usages considérés est couvert par les conditions d'application et/ou le cycle de croissance de la culture. Par conséquent, il n'est pas nécessaire de proposer un DAR en jours.

N : Le délai avant récolte (DAR) n'est pas pertinent.

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Rodenticide



Information sur le produit

Ratron® GL Jardin

Conseils pour la protection de l'utilisateur et de l'environnement

IMPORTANT : Lire attentivement les instructions de cette section afin de garantir une utilisation sûre et efficace de ce produit.

Emploi autorisé dans les jardins.



N - Dangereux pour l'environnement

Ratron® GL Jardin

Contient du phosphore de zinc.

- R32:** Au contact d'un acide, dégage un gaz très toxique.
R50/53: Très toxique pour les organismes aquatiques, peut entraîner des effets néfastes à long terme pour l'environnement Aquatique
- S1/2:** Conserver sous clef et hors de portée des enfants.
S13: Conserver à l'écart des aliments et boissons, y compris ceux pour animaux.
S14: Conserver à l'écart des acides.
S26: En cas de contact avec les yeux, laver immédiatement et abondamment avec de l'eau et consulter un spécialiste.
S28: Après contact avec la peau, se laver immédiatement et abondamment avec de l'eau et du savon.
S35: Ne se débarrasser de ce produit et de son récipient qu'en prenant toutes précautions d'usage.
S37: Porter des gants appropriés.
S46: En cas d'ingestion, consulter immédiatement un médecin et lui montrer l'emballage ou l'étiquette.
S57: Utiliser un récipient approprié pour éviter toute contamination du milieu ambiant.

S'il y a lieu les conditions d'utilisation au niveau national doivent être incluses ici après l'enregistrement dans le pays concerné ainsi que la définition officiel des conditions.

Respecter les instructions d'utilisation pour éviter les risques pour l'homme et l'environnement.

- SP1:** 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.

Le nom et l'adresse du distributeur seront renseignés après l'autorisation

En cas d'urgence, appelez le 15 ou le centre anti-poison.

Fiche de Données de Sécurité disponible sur demande

N° de lot : voir emballage Contenu : XX kg e

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Rodentizide



Information sur le produit

Ratron® GL Jardin

Premiers soins:

En cas de contact avec les yeux, laver immédiatement et abondamment avec de l'eau et consulter un spécialiste. Après contact avec la peau, se laver immédiatement et abondamment avec de l'eau et du savon. En cas d'ingestion, consulter immédiatement un médecin et lui montrer l'emballage ou l'étiquette.

Stockage:

Stocker le produit dans son emballage d'origine, dans un endroit frais, sec et fermé à clé. Tenir hors de la portée des enfants. Conserver à l'écart des aliments et boissons, y compris ceux pour animaux et des substances odorantes. Après ouverture de l'emballage, une diminution de l'efficacité du produit stocké est possible.

Conseils supplémentaires:

Dangereux pour les chiens et/ou chats.

Ne pas traiter sur un terrain risquant un entraînement vers un point d'eau : ruisseau, étang, mare, puits... en particulier si le terrain est en pente.

Ne pas polluer l'eau avec le produit ou son emballage.

L'efficacité de Ratron® GL Jardin n'est assurée que pour les usages spécifiés sur cette étiquette et si les recommandations d'utilisation sont respectées. Compte-tenu des nombreux facteurs hors du contrôle du fabricant pouvant influencer l'efficacité du produit (application et stockage), le fabricant exclue toute responsabilité en cas de dommages pendant le stockage et l'application du produit. Le fabricant garantit la qualité de Ratron® GL Jardin à la date à laquelle il est livré. Le fabricant ne couvre pas les risques liés à son stockage et à son application.

Gestion et élimination des déchets:

Ne pas réutiliser l'emballage. Éliminer le produit non utilisé et les emballages souillés par le produit conformément à la réglementation locale en vigueur, par exemple par apport en déchetterie, et les emballages non souillés avec les ordures ménagères. Ne pas jeter dans les égouts et les cours d'eau.

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Rodenticide

Appendix 3 – Letter(s) of Access

Not applicable.