

REGISTRATION REPORT

Part A

Risk Management

Product code: -

Product name: RATRON GW JARDIN

Active substance:

zinc phosphide, 25 g/kg

COUNTRY: FRANCE

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

Non professional use

(marketing authorisation)

Applicant: Frunol delicia GmbH

Date: 15/09/2017 (Decision)

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PART A – Risk Management

The company Frunol delicia GmbH has requested marketing authorisation in France for the product RATRON GW JARDIN bait (ready for use [RB]) formulation, containing 25 g/kg 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 GW JARDIN where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of RATRON GW 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 GW 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 GW 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.

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

¹ The IUPAC name is trizinc diphosphide.

— 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 (2013-1297) 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 of 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/AGRGI1632554A/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/AGRGI1407093A/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 GW 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 GW JARDIN (-)
Authorisation number	N/A: authorization not granted in France
Function	Rodenticide (non-professional use)
Applicant	Frunol delicia GmbH
Composition	25 g/kg zinc phosphide
Formulation type (code)	Bait (ready for use) (RB)
Packaging	Cardboard/tinplate dispenser with synthetic dosing inset, holding 100 or 250 g product Polypropylene bucket holding 1 kg product

2.2 Classification and labelling

2.2.1 Classification and labelling under Directive 99/45/EC

Not applicable after 1st June 2015.

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

Physical hazards	-	
Health hazards	Acute toxicity, oral, Category 4	
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	
	H302	Harmful if swallowed
	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.

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

N/A : no authorisation granted in France

2.2.4 Other phrases linked to the preparation

N/A : no authorisation granted in France

2.3 Product uses

Please note: The GAP Table below reports the intended uses proposed by the applicant, and possible extrapolation according to French Order of 26 March 2014 (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.

PPP (product name/code) RATRON GW JARDIN/(-)
active substance 1 zinc phosphide
Applicant: Frunol delicia GmbH
Zone(s): southern EU
Verified by MS: yes
Field of use: rodenticide (non-professional)

Formulation type:
Conc. of a.s. 1: professional use
non-professional use

GAP rev. 1, date: 2017-september-15
Bait (ready for use) [RB]
25 g/kg

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 / Kind	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		
9	France	Ornamentals (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) 0.050 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.
10	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) 0.050 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 / Kind	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		
11	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) 0.050 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.

- Remarks:**
- (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

- (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

RATRON GW JARDIN is a ready-to-use bait (RB) 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 a reddish-violet coloured bait grains, with no odour. It is not explosive, has no oxidising properties, 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 stability data indicate a shelf life of at least two years at ambient temperature in the cardboard dispenser and the PP bucket. Its technical characteristics are acceptable for an RB formulation. The results obtained for the cardboard dispenser were considered transposable to dispensers in paper/PE, as cardboard was considered the worst case.

Its technical characteristics are acceptable for an RB formulation.

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

The attrition (wear) resistance must be determined.

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 any relevant impurity, 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

	Dermal absorption endpoints %	10 %	
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3.1.3.1 Acute Toxicity

RATRON GW JARDIN containing 25 g/kg zinc phosphide is harmful if swallowed, has a low acute 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 type	F/G ⁹	Equipment	Application rate kg product/ha (g a.s./ha)	Model
5 baits/vole hole	F and G	Lance application	2 kg product/ha (50 g/ha)	RISKOFDERM model

Considering the proposed uses, operator (i.e., user – non-professional) systemic exposure was estimated using RISKOFDERM model:

Crop	Equipment	PPE and/or working coverall	% AOEL zinc phosphide (AOEL = 0.042 mg/kg bw/d)
5 baits/vole hole	Lance application	Working coverall, no gloves	4.1

According to the model calculations, it may be concluded that the risk for the operator (i.e., user – non-professional) using RATRON GW 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 GW 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 2010¹⁰ and the Orders of 30 December 2010¹¹ which implement it.

The bucket and the dosing box 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.**

⁹ Open field or glasshouse

¹⁰ 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

¹¹ 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

For details of personal protective equipment for operators (i.e., 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 GW JARDIN is directly applied as loose grains into vole holes. Therefore, exposure of residents (adults or children) to the product is considered to be 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.

3.1.3.5 Worker Exposure

RATRON GW 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 GW 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.

3.1.4 Residues and Consumer Exposure

EFSA (2010¹²) 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 GW JARDIN as only rodenticide uses as 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.

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.

¹² 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.

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 substance 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 GW 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 GW JARDIN is considered satisfactory in the requested conditions of use.
- the risk of negative impact on yield, quality, transformation processes, propagation, succeeding or 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

N/A

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: no authorisation granted in France

3.4.2 Post-authorisation data requirements

N/A: no authorisation granted in France

3.4.3 Label amendments

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

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

Appendix 1 – Copy of the French Decision



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

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

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

*Vu la demande d'autorisation de mise sur le marché du produit phytopharmaceutique **RATRON GW JARDIN***

*de la société **FRUNOL DELICIA GMBH***

enregistrée sous le n°2013-1297

Vu les conclusions de l'évaluation de l'Anses du 31 août 2017,

Vu l'arrêté du 30 décembre 2010 relatif aux conditions d'emballage des produits phytopharmaceutiques pouvant être employés par des utilisateurs non professionnels,

Considérant que les emballages du produit ne permettent pas de garantir une exposition minimale de l'utilisateur non professionnel, conformément à l'article 1 de l'arrêté du 30 décembre 2010,

La mise sur le marché du produit phytopharmaceutique désigné ci-après **n'est pas autorisée** en France.



Informations générales sur le produit		
Nom du produit	RATRON GW JARDIN	
Type de produit	Deuxième gamme	
Titulaire	FRUNOL DELICIA GMBH HANSTRASSE 74 59425 UNNA ALLEMAGNE	
Formulation	Appât (prêt à l'emploi) (RB)	
Contenant	25 g/kg - phosphore de zinc	
Produit de référence	Nom commercial	RATRON GW
	N° AMM	2170698
Numéro d'intrant	913-2013.01	
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
Toxicité aiguë par voie orale - Catégorie 4	H302 : Nocif en cas d'ingestion
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.

RATRON GW JARDIN

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

Amateur use label

Ratron®
Rodenticide

Information sur le produit

Ratron® GW Jardin

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

Points forts du produit

- Nouvelle formulation empêchant la dégradation des appâts avant leur consommation.
- Aucun empoisonnement secondaire.



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

25 g/kg (2.5 % m/m) de phosphore de zinc
Formulation : appât (prêt à l'emploi) (RB)

Caractéristiques et effets

Ratron® GW Jardin est un appât prêt à l'emploi à base de blé, à action rapide, dont la substance active est le phosphore de zinc (25 g/kg). Il permet de lutter contre le campagnol commun (*Microtus arvalis*), le campagnol des champs (*Microtus agrestis*) et le campagnol roussâtre (*Clethrionomys glareolus*). Ratron® GW Jardin résiste à la pluie et ne germe pas.

Grâce à une nouvelle formulation, il n'y a pas de dégradation de la substance active avant l'ingestion de l'appât par le campagnol. De ce fait, la méfiance des rongeurs est 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 (hydrure 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

frunol delicia innovation
Hansastraße 74 b D-59425 Unna Tel.: +49 (0) 2303/25 360-0 Fax: +49 (0) 2303/25 360-50
Dübener Straße 145 D-04509 Delitzsch Tel.: +49 (0) 34202/65 300 Fax: +49 (0) 34202/65 309
Email: info@frunol-delicia.de Internet: www.frunol-delicia.de

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d'environ 1 à 3 heures après ingestion de l'appât. Ensuite, la substance active est rapidement éliminée et ainsi ne peut provoquer aucun empoisonnement secondaire.

Recommandations d'utilisation

Ratron® GW Jardin est autorisé dans les jardins amateurs pour les usages en cultures fruitières, en cultures légumières et en cultures ornementales.

Ratron® GW Jardin est autorisé également sous serre.

Pour lutter contre le campagnol des champs, le campagnol commun et le campagnol roussâtre, 2 à 5 grains de Ratron® GW Jardin doivent être déposés dans chaque trou de rongeurs. Pour une infestation moyenne, ce dosage correspond approximativement à une dose de 1 kg/ha (la dose maximum d'application de produit par an est de 2 kg/ha).

En utilisant un dispositif distributeur d'appâts pour Ratron® GW Jardin (permettant ainsi que les appâts soient abrités) dans le trou des rongeurs, le temps de travail est considérablement réduit par rapport aux autres méthodes d'application. De plus, cette méthode présente moins de risques pour l'utilisateur car elle minimise les contacts entre l'appât et l'utilisateur.

Il est interdit d'appliquer Ratron® GW Jardin de façon généralisée à la surface du sol. Ratron® GW Jardin, comme tous les autres appâts de blé à base de phosphure de zinc, doit être placé dans des endroits protégés/abrités (sous la surface du sol, dans les trous des rongeurs...).

Usages homologués

Culture / situation	Cible	Dose	Méthode d'application	Période d'application	Nombre d'applications	DAR
Cultures ornementales ¹	Campagnol commun Campagnol des champs	5 grains par trou	Déposer les appâts dans les trous	Lorsque l'infestation est détectée (tous les stades)	n.a. ²	N
Cultures fruitières ¹	Campagnol commun Campagnol des champs Campagnol roussâtre					F
Cultures légumières ¹	Campagnol commun Campagnol des champs					F

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 (dose max.: 2 g/10 m² de produit par an)

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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Hansastraße 74 b
Dübener Straße 145
Email: info@frunol-delicia.de

D-59425 Unna
D-04509 Delitzsch

Tel.: +49 (0) 2303/25 360-0
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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.

	<p>Ratron® GW Jardin Contient du phosphore de zinc.</p> <p>R22: Nocif en cas d'ingestion. 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.</p> <p>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.</p> <p><i>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.</i></p> <p>Respecter les instructions d'utilisation pour éviter les risques pour l'homme et l'environnement.</p> <p>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.</p>

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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Hansastraße 74 b
Dübener Straße 145
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D-04509 Delitzsch
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Tel.: +49 (0) 34202/65 300

Fax: +49 (0) 2303/25 360-50
Fax: +49 (0) 34202/65 309





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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 Ratron® GW Jardin 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® GW 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® GW 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.



English master label

Ratron® Rodentizide

Product Information

Ratron® Giftweizen

Fast acting cereal bait for the targeted control of common voles, field voles and bank voles in agriculture, on grassland (meadows and pastures), in forestry, in orchards, vegetables, vineyards, non-cultivated area and ornamentals as well as for the use in the home and garden sector and in greenhouses.

Product highlights

- New formulation technology prevents degradation before bait ingestion
- No secondary poisoning



Ingredient(s)

25 g/kg Zinc phosphide

Characteristics and effects

Ratron® Giftweizen (poison wheat) is a fast acting, ready-for-use wheat bait containing the active ingredient zinc phosphide (25 g/kg) for the control of common voles (*Microtus arvalis*), field voles (*Microtus agrestis*) and bank voles (*Clethrionomys glareolus*). **Ratron® Giftweizen** is rain-resistant and not viable.

Due to a new formulation technology a degradation of the active ingredient before ingestion of the bait is prevented. This means a significant reduction of bait shyness by mice. The full effectiveness and attractiveness remains until ingestion by mice.

After ingestion of the bait the active ingredient Zinc phosphide develops Phosphine (phosphorus hydride) in the stomach of mice under influence of the gastric acid. Phosphine is a very strong metabolism- and nerve poison and kills mice within approx. 1 to 3 hours. After this the active ingredient is rapidly decomposed and can therefore not cause secondary poisoning.

Instructions for use

Ratron® Giftweizen is approved for the use in agriculture, orchards, vegetables, ornamentals, on grassland, non-cultivated area, forestry and vineyards as well as for the home and garden sector and in greenhouses.

Against field, common and bank voles 2 to 5 grains **Ratron® Giftweizen** is applied into each mouse hole. At medium infestation this dosage equals to an application rate of approx. 1 kg/ha (max. application rate per year: 2 kg product/ha).

By usage of a bait placing device for the covered application of **Ratron® Giftweizen** into the mice holes the time effort is significantly reduced compared to other procedures. Furthermore the application with the bait placing device is of less risk for the user as there is virtually no contact between user and bait.

Please note that the open application is prohibited. This means that **Ratron® Giftweizen** as every other poison wheat product based on zinc phosphide must not be applied by broad spreading but only covered (sub-surface).



Rodentizide

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Hansastraße 74 b D-59425 Unna
Dübener Straße 145 D-04509 Delitzsch
Email: info@frunol-delicia.de

Tel.: +49 (0) 2303/25 360-0
Tel.: +49 (0) 34202/65 300
Internet: www.frunol-delicia.de

Fax: +49 (0) 2303/25 360-50
Fax: +49 (0) 34202/65 309



Product Information

Ratron® Giftweizen

Registered uses

Product	Crop / Situation	Pest	Dosage	Procedure	Application time	Number of applications	PHI
Ratron Giftweizen	Agriculture	Common vole Field vole	5 baits per hole	placing of baits in holes	at infestation (all stages)	n.a.) ¹	F
	Ornamentals) ¹) ²	Common vole Field vole	5 baits per hole	placing of baits in holes	at infestation (all stages)	n.a.) ¹	N
	Orchard) ¹) ²	Common vole Field vole Bank vole	5 baits per hole	placing of baits in holes	at infestation (all stages)	n.a.) ¹	F
	Vegetables) ¹) ²	Common vole Field vole	5 baits per hole	placing of baits in holes	at infestation (all stages)	n.a.) ¹	F
	Grassland	Common vole Field vole	5 baits per hole	placing of baits in holes	at infestation (all stages)	n.a.) ¹	F
	Forestry	Common vole Field vole Bank vole	5 baits per hole	placing of baits in holes	at infestation (all stages)	n.a.) ¹	N
	Non-cultivated area) ³	Common vole Field vole	5 baits per hole	placing of baits in holes	at infestation (all stages)	n.a.) ¹	N
	Vineyards	Common vole Field vole	5 baits per hole	placing of baits in holes	at infestation (all stages)	n.a.) ¹	F

)¹ professional and non-professional use (home and garden)

)² outdoor use and use in greenhouse

)³ For avoidance of immigration of voles to fields from surroundings, assurance of traffic security at airports, roads and stability of sea and river embankments.

)⁴ Number of applications: not applicable; application is to be repeated until no more baits are consumed (max. rate 2 kg product/ha, year)

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 use (e.g. harvest); it is not necessary to lay down a pre-harvest interval in days

N = The indication of a pre-harvest interval is not relevant.



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Tel.: +49 (0) 2303/25 360-0
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Ratron®
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Product Information

Ratron® Giftweizen

Advices for the protection of the user and the environment

Hazard classification: Xn (Harmful)

N (Dangerous for the environment)



Risk phrases

R22 Harmful if swallowed.
R32 Contact with acids liberates very toxic gas.
R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Safety phrases

S1/2 Keep locked up and out of the reach of children.
S13 Keep away from food, drink and animal feedingstuffs.
S14 Keep away from acids.
S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S28 After contact with skin, wash immediately with plenty of water and soap.
S35 This material and its container must be disposed of in a safe way.
S37 Wear suitable gloves
S46 If swallowed, seek medical advice immediately and show this container or label.
S57 Use appropriate containment to avoid environmental contamination.

[if applicable national use conditions are to be included here after registration in the respective countries and official definition of the conditions]

First aid

In case of contact with the eyes, rinse immediately with plenty of water and seek medical advice. After contact with skin, wash immediately with plenty of water and soap. If swallowed, seek medical advice immediately and show container or label.

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Hansastraße 74 b D-59425 Unna
Dübener Straße 145 D-04509 Delitzsch
Email: info@frunol-delicia.de

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Fax: +49 (0) 34202/65 309





Product Information

Ratron® Giftweizen

Storage

Store **Ratron® Giftweizen** in the original container cool, dry, locked up, out of the reach of children as well as separated from food, drink, animal feeding stuffs and odorous substances. After opening of packages losses of effectiveness must be taken into consideration.

Further advices

By due diligence it is proven that **Ratron® Giftweizen** is suitable for the recommended purposes if the instructions for use are followed. As storage and application are outside of our influence and we are not able to foresee all corresponding circumstances we exclude any liability for possible damages out of storage and application. We are liable for the proper quality of **Ratron® Giftweizen** at the delivery date, we do not bear the risk of storage and application.

Waste management / disposal

Do not further use empty packages. Pay attention to the national and regional regulations.

Delivery packages

0692-752	20 x 100 g dispenser	Pallet:	110 sales units
0692-070	20 x 250 g dispenser	Pallet:	64 sales units
0692-042	10 x 1 kg bucket	Pallet:	40 sales units
0692-040	4 x 5 kg bucket	Pallet:	18 sales units
0692-060	25 kg block bottom bag	Pallet:	35 sales units

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Dübener Straße 145 D-04509 Delitzsch
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Rodentizide

Appendix 3 – Letter(s) of Access

Not applicable.