REGISTRATION REPORT

Part A

Risk Management

Product code: -

Product name: RATRON GW

Active substance:

zinc phosphide, 25 g/kg

COUNTRY: FRANCE

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(New application)

Applicant: Frunol delicia GmbH

Date: 19/01/2018

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PART A – Risk Management

The company Frunol delicia GmbH has requested marketing authorisation in France for the product RATRON GW (RB), containing 25 g/kg zinc phosphide[1] for use as a rodenticide (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 where those data have not been considered in the EU peer review process. Otherwise assessments for the safe use of RATRON GW 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.

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 in France as a (professional use) 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 and label extension 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: — 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.

[1] The IUPAC name is trizinc diphosphide.

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 (2013-1291) 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 2017 [4] 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 1107/2009[5], 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 546/2011[6], and are expressed as "acceptable" or "not acceptable" in accordance with those criteria.

Finally, the French Order of 26 March 2014[7] 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, mainly based on the EU document on residue data extrapolation[8] is to supply "minor" crops with registered plant protection products.

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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

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

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, 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.

2 DETAILS OF THE AUTHORISATION

2.1 Product identity

Product name (code)	RATRON GW (-)
Authorisation number	2170698
Function	Rodenticide (professional use)
Applicant	Frunol delicia GmbH
Composition	25 g/kg zinc phosphide
Formulation type (code)	Bait (ready for use) (RB)
Packaging	Polypropylene (PP) bucket holding 1 or 5 kg product Paper/foil multilayer block bottom bag holding 5 or 25 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 –	***For the P phrases, refer to the extant legislation***	
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

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

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).
SPe 6	To protect birds/wild mammals, remove spillages.

2.2.4 Other phrases linked to the preparation

Wear suitable personal protective equipment[9]: refer to the Decision in Appendix 1 for the details
Re-entry period[10]: Not applicable for this type of product (ready-to-use bait).
Pre-harvest interval[11]: Not applicable.
Other mitigation measures: Usage of RATRON GW is limited to uses in plant protection encompassed by Regulation (EC) No 1107/2009.
The label must include the following recommendations: - The label must reflect the conditions of authorisation.

[9] If a tractor with cab is used, wearing gloves during application is only required when working with the spray mixture

[10] The legal basis for this is **Titre I Article 3** of the French Order of 4th May 2017 concerning the marketing and use of products encompassed by article L. 253-1 of the rural code [that is, plant protection products/pesticides]

[11] According to the French Order of 4th May 2017, PHI cannot be lower than 3 days unless specifically stated in the assessment and decision.

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.

GAP rev. 1, date: 2017-september-15

PPP (product name/code)	**RATRON GW/-**	**Formulation type:**	**Bait (ready for use) [RB]**
active substance 1	**zinc phosphide**	**Conc. of a.s. 1:**	**25 g/kg**
Applicant:	**Frunol delicia GmbH**	**professional use**	☒
Zone(s):	**southern EU**	**non-professional use**	☐
Verified by MS:	**yes**		
Field of use:	**rodenticide (professional)**		

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		
1	France	Ornamentals	F	*Microtus arvalis* *Microtus agrestis*	placing of 5 baits in vole hole	all stages	a) n.a. * b) n.a.	a) n.a. * b) 2.0	a) n.a. * b)0.050	n.a.	n.a.	acceptable
2	France	Agriculture	F	*Microtus arvalis* *Microtus agrestis*	placing of 5 baits in vole hole	all stages	a) n.a. * b) n.a.	a) n.a. * b) 2.0	a) n.a. * b) 0.050	n.a.	n.a.	acceptable
3	France	Orchard	F	*Microtus arvalis* *Microtus agrestis* *Clethrionomys glareolus*	placing of 5 baits in vole hole	all stages	a) n.a. * b) n.a.	a) n.a. * b) 2.0	a) n.a. * b) 0.050	n.a.	n.a.	acceptable
4	France	Vegetables	F	*Microtus arvalis* *Microtus agrestis*	placing of 5 baits in vole hole	all stages	a) n.a. * b) n.a.	a) n.a. * b) 2.0	a) n.a. * b) 0.050	n.a.	n.a.	acceptable
5	France	Grassland	F	*Microtus arvalis* *Microtus agrestis*	placing of 5 baits in vole hole	all stages	a) n.a. * b) n.a.	a) n.a. * b) 2.0	a) n.a. * b) 0.050	n.a.	n.a.	acceptable
6	France	Forestry	F	*Microtus arvalis* *Microtus agrestis* *Clethrionomys glareolus*	placing of 5 baits in vole hole	all stages	a) n.a. * b) n.a.	a) n.a. * b) 2.0	a) n.a. * b) 0.050	n.a.	n.a.	acceptable

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		
7	France	non-cultivated area	F	*Microtus arvalis* *Microtus agrestis*	placing of 5 baits in vole hole	all stages	a) n.a. * b) n.a.	a) n.a. * b) 2.0	a) n.a. * b) 0.050	n.a.	n.a.	acceptable
8	France	Vineyards	F	*Microtus arvalis* *Microtus agrestis*	placing of 5 baits in vole hole	all stages	a) n.a. * b) n.a.	a) n.a. * b) 2.0	a) n.a. * b) 0.050	n.a.	n.a.	acceptable
12	France	Orchard	G	*Microtus arvalis* *Microtus agrestis* *Clethrionomys glareolus*	placing of 5 baits in vole hole	all stages	a) n.a. * b) n.a.	a) n.a. * b) 2.0	a) n.a. * b) 0.050	n.a.	n.a.	acceptable
13	France	Vegetables	G	*Microtus arvalis* *Microtus agrestis*	placing of 5 baits in vole hole	all stages	a) n.a. * b) n.a.	a) n.a. * b) 2.0	a) n.a. * b) 0.050	n.a.	n.a.	acceptable
14	France	Ornamentals	G	*Microtus arvalis* *Microtus agrestis*	placing of 5 baits in vole hole	all stages	a) n.a. * b) n.a.	a) n.a. * b) 2.0	a) n.a. * b) 0.050	n.a.	n.a.	acceptable

*: applications should be repeated until baits are not consumed (respecting maximum total rate per crop/season)

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

The formulation RATRON GW is a bait (ready for use [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 reddish-violet coloured bait grains, without odour. The product 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. The product's technical characteristics are acceptable for an RB formulation. The results obtained for the cardboard dispenser were considered transposable to bags in paper/PE, as cardboard was considered the worst case.

The attrition (wear) resistance must be determined before and after accelerated storage and shelf life study.

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

<table>
<tr><td colspan="4">Active substance: zinc phosphide</td></tr>
<tr><td>ADI</td><td colspan="2">0.042 mg kg bw/d</td><td rowspan="3">EU (2011)</td></tr>
<tr><td>ARfD</td><td colspan="2">0.073 mg/kg bw</td></tr>
<tr><td>AOEL</td><td colspan="2">0.042 mg/kg bw/d</td></tr>
<tr><td rowspan="3">Dermal absorption</td><td colspan="3">Based on default values (expert judgement):</td></tr>
<tr><td></td><td>Concentrate
(used in formulation)
8 g/kg</td><td>Spray dilution
(used in formulation)
x g/L</td></tr>
<tr><td>Dermal absorption endpoints %</td><td>10%</td><td></td></tr>
</table>

3.1.3.1 Acute Toxicity

RATRON GW containing 25 g/kg of 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[12]	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)	EASE model RISKOFDERM model

Considering proposed uses, operator systemic exposure was estimated using the EASE and RISKOFDERM models:

Crop	Equipment	PPE and/or working coverall	% AOEL zinc phosphide (AOEL = 0.042 mg/kg bw/d)
5 baits/vole hole/EASE model	Lance application	Working coverall and gloves during mixing/loading and application	67
5 baits/vole hole/ RISKOFDERM model		Working coverall, no gloves	4.1

According to the model calculations, it may be concluded that the risk for the operator using RATRON GW is acceptable with a working coverall (90 % protection factor) and gloves during mixing/loading and application.

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

3.1.3.3 Bystander Exposure

RATRON GW is a bait (ready for use [RB]) formulation; no drift is expected. Therefore, bystander exposure estimation is considered to be unnecessary .

3.1.3.4 Resident Exposure

RATRON GW is a bait (ready for use [RB]) formulation; no drift is expected. Therefore, resident exposure estimation is considered to be not relevant.

[12] Open field or glasshouse

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 GW is a bait (ready for use [RB]) formulation; no drift is expected. Therefore, resident exposure estimation is considered to be unnecessary .

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

3.1.4 Residues and Consumer Exposure

EFSA (2010[13]) 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 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.

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.

[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.

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.
Risk assessments were performed for all indicator species relevant in the natural environment. In summary, no unacceptable risks were indicated for the indicator groups including aquatic and sediment-dwelling organisms, bees, other terrestrial non-target arthropods, soil macro- and micro-organisms, and terrestrial non-target plants under realistic conditions and in consideration of all GAP uses proposed for RATRON GW.
The only non-target species identified to be potentially at risk are terrestrial vertebrates feeding on the baits or on poisoned rodents. However birds are not expected to be exposed to an unacceptable risk, due to the application as ready-to-use bait (i) in bait stations, (ii) in vole holes or (iii) broadcast with baits enclosed in foil bags. The same can be expected for terrestrial mammals, with the exception of rodents (target pest and others). Fatal incidents by feeding on spilled bait material are considered to be restricted to rare and individual cases. Furthermore, the risk of secondary poisoning could largely be excluded.

3.1.7 Efficacy

Considering the data submitted:
The efficacy of RATRON GW 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 is considered as satisfactory in the claimed conditions.
- the risk of negative impact on yield, quality, transformation processes, propagation, succeeding crops, adjacent crops is considered as negligible.
- the risk of resistance development or appearance is considered as low.

3.2 Conclusions arising from French assessment

Taking into account the above assessment, an authorisation can 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

No further information is required.

3.4.2 Post-authorisation data requirements

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

- Determination of the wear (attrition) resistance of the formulation before and after the accelerated and long-term storage stability studies.

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

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anses

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

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

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

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

de la société *FRUNOL DELICIA GMBH*

enregistrée sous le *n°2013-1291*

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

Vu la décision du directeur général de l'Anses du 15 septembre 2017,

Considérant la nécessité de corriger l'intitulé de l'usage concerné,

La mise sur le marché du produit phytopharmaceutique désigné ci-après **est autorisée** en France pour les usages et dans les conditions précisés dans la présente décision et ses annexes.

La présente décision abroge et remplace la décision du 15 septembre 2017 et 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.

RATRON GW
AMM n°2170698

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anses
agence nationale de sécurité sanitaire alimentation, environnement, travail

Informations générales sur le produit	
Nom du produit	RATRON GW
Type de produit	Produit de référence
Titulaire	FRUNOL DELICIA GMBH HANSASTRASSE 74 59425 UNNA ALLEMAGNE
Formulation	Appât (prêt à l'emploi) (RB)
Contenant	25 g/kg - phosphure de zinc
Numéro d'intrant	914-2013.01
Numéro d'AMM	2170698
Fonction	Rodenticide
Gamme d'usages	Professionnel

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 30 avril 2022.

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 19 JAN. 2018

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)

RATRON GW
AMM n°2170698

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anses

ANNEXE I : 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 papier / polyéthylène	5 kg ; 25 kg
Seaux en polypropylène	1 kg ; 5 kg

Classification du produit	
La classification retenue est la suivante :	
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 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.**	

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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)	Mention abeilles
21011001 Traitements généraux* Trt Appât* Petits rongeurs	**2 kg/ha ***	Non applicable *	Tous les stades	Non applicable	-	-	-	-
	Egalement autorisé sous abri. *. Uniquement pour des applications dans des trous de rongeurs, avec une dose d'emploi limitée à 5 grains par trou. *. Les applications doivent être répétées jusqu'à ce que les appâts ne soient plus consommés, et en respectant la dose maximale de 2 kg/ha/an.							

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anses
agence nationale de sécurité sanitaire alimentation, environnement, travail

Conditions d'emploi du produit

Stockage et utilisation du produit

L'utilisation de la préparation RATRON GW est limitée aux usages phytopharmaceutiques entrant dans le cadre du règlement (CE) n°1107/2009.

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 à l'aide d'un dispositif spécifique permettant le positionnement des granulés dans les trous (canne de distribution) :

• pendant le mélange/chargement et le nettoyage du matériel d'application

- Gants en nitrile certifiés EN 374-3 ;
- Combinaison de travail en polyester 65 %/coton 35 % avec un grammage de 230 g/m² ou plus avec traitement déperlant ;

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

- Non applicable

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 6 : Pour protéger les oiseaux et les mammifères sauvages, récupérer tout produit accidentellement répandu.

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	Récurrence (mois)
Fournir les résultats de l'étude concernant la résistance à l'usure avant et après stockage accéléré.	15/09/2019	-
Fournir les résultats de l'étude en cours de réalisation, concernant la résistance à l'usure avant et après stockage pendant 2 ans à température ambiante.	15/09/2019	-

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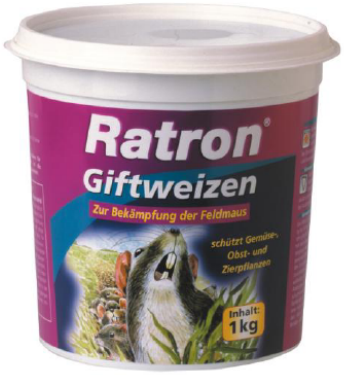
Appendix 2 – Copy of the draft product label as proposed by the applicant

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

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

Ratron® Rodentizide

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.)[4]	F
	Ornamentals)[1])[2]	Common vole Field vole	5 baits per hole	placing of baits in holes	at infestation (all stages)	n.a.)[4]	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.)[4]	F
	Vegetables)[1])[2]	Common vole Field vole	5 baits per hole	placing of baits in holes	at infestation (all stages)	n.a.)[4]	F
	Grassland	Common vole Field vole	5 baits per hole	placing of baits in holes	at infestation (all stages)	n.a.)[4]	F
	Forestry	Common vole Field vole Bank vole	5 baits per hole	placing of baits in holes	at infestation (all stages)	n.a.)[4]	N
	Non-cultivated area)[3]	Common vole Field vole	5 baits per hole	placing of baits in holes	at infestation (all stages)	n.a.)[4]	N
	Vineyards	Common vole Field vole	5 baits per hole	placing of baits in holes	at infestation (all stages)	n.a.)[4]	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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Ratron® Rodentizide

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.

Rodentizide

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Internet: www.frunol-delicia.de

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

Ratron® Rodentizide

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 odourous 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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Appendix 3 – Letter(s) of Access

Not applicable.