REGISTRATION REPORT

Part A

Risk Management

Product code: BW01 GB

Product name(s): VITROL GB

Chemical active substance(s):

Ferric pyrophosphate, 24 g/kg

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(new application)

Applicant: BROS SPÓŁKA Z OGRANICZONĄ ODPOWIEDZIALNOŚCIĄ

Date: 14/03/2024

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PART A

RISK MANAGEMENT

1 Details of the application

The company BROS SPÓŁKA Z OGRANICZONĄ ODPOWIEDZIALNOŚCIĄ has requested a marketing authorisation in France for the product VITROL GB (product code: BW01 GB), containing 24 g/kg Ferric pyrophosphate[1] as a molluscicide for non-professional uses.

Appendix 1 of this document provides a copy of the product authorisation.

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

1.1 Application background

The present registration report concerns the evaluation of BROS SPÓŁKA Z OGRANICZONĄ ODPOWIEDZIALNOŚCIĄ's application submitted on 31/03/2022 to market VITROL GB (BW01 GB) in France (product uses described under point 2.3). France acted as a zonal Rapporteur Member State (zRMS) for this request and assessed the application submitted for the first authorisation of this product in France and in other Member States (MSs) of the European Union.

Ferric pyrophosphate is a low risk active substance, therefore VITROL GB (BW01 GB) shall be authorised as a low risk plant protection product where compliant with Article 47 of Regulation (EC) no 1107/2009.

The present application (2022-1477) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses), according to the Regulation (EC) no 1107/2009[2], the implementing regulations, and French regulations. This application was assessed in the context of the zonal procedure for all MSs of the European Union, taking into account the worst-case uses ("risk envelope approach")[3]. When risk mitigation measures were necessary, they are adapted to the situation in France.

The data taken into account are those deemed to be valid either at European level (Review Report and EFSA conclusion) or at zonal/national level. The assessment of VITROL GB (BW01 GB) has been made using endpoints agreed in the EU peer review of Ferric pyrophosphate. It also includes assessment of data and information related to VITROL GB (BW01 GB) where those data have not been considered in the EU peer review process.

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

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1 Commission Implementing Regulation (EU) 2020/1018 of 13 July 2020 approving ferric pyrophosphate as low-risk active substance in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending Commission Implementing Regulation (EU) No 540/2011

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

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

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

This document also describes the specific conditions of use and labelling required for France for the registration of VITROL GB (BW01 GB).

1.2 Letters of Access

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

1.3 Justification for submission of tests and studies

According to the applicant: « All requested studies were submitted and accepted with dossier for approval of a new active substance according to 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. In addition studies on the effects of the formulation on sediment-dwelling organisms and non-target soil meso- and macrofauna are submitted to address the risk to the sediment-dwellers and soil compartment from Vitrol GB (BW01 GB). New trials reports to prove that plant protection product is sufficiently effective are also submitted. ».

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of VITROL GB (BW01 GB), it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7.

2 Details of the authorisation decision

2.1 Product identity

BW01 GB	BW01 GB
Vitrol GB in MS	VITROL GB
Authorisation number	2240078
Kind of use	Non-professional use
Low risk product (article 47)	Yes
Function	Molluscicide
Applicant	BROS SPÓŁKA Z OGRANICZONĄ ODPOWIEDZIALNOŚCIĄ
Active substance(s) (incl. content)	Ferric pyrophosphate, 24 g/kg
Formulation type	Ready-to-use bait [RB]

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

<table>
<tr><td>Packaging</td><td>
<table>
<tr><th>type</th><th>material</th><th>weight</th></tr>
<tr><td>bucket</td><td>PE or LDPE or HDPE or PP or PET or PCV</td><td>100 g, 150 g, 200 g, 250 g, 300 g, 350g, 400 g, 450 g, 500 g, 600 g,630 g,700 g, 800 g, 900 g, 1 kg</td></tr>
<tr><td>Carton</td><td>cardboard</td><td>100 g, 150 g, 200 g, 250 g, 300 g, 350g, 400 g, 450 g, 500 g, 600 g,630 g,700 g, 800 g, 900 g, 1 kg</td></tr>
<tr><td>Bottle</td><td>PE or LDPE or HDPE or PP or PET or PCV</td><td>100 g, 150 g, 200 g, 250 g, 300 g, 350g, 400 g, 450 g, 500 g, 600 g,630 g,700 g, 800 g, 900 g, 1 kg</td></tr>
</table>
The following packaging are not acceptable for the RMS since they are not considered in compliance with the provisions of French regulation relating to the conditions of authorisation of plant protection products by non-professional users (see page 14)
<table>
<tr><td>Sack/sachet</td><td>PE or HDPE or LDPE or PP or PA or laminate (PET/ALU/PE or PET/PET met PE or PA/PE or PAP/PE)</td><td>100 g, 150 g, 200 g, 250 g, 300 g, 350 g, 400 g, 450 g, 500 g, 600 g, 630 g</td></tr>
</table>
</td></tr>
<tr><td>Coformulants of concern for national authorisations</td><td>not applicable</td></tr>
<tr><td>Restrictions related to identity</td><td>-</td></tr>
<tr><td>Mandatory tank mixtures</td><td>None</td></tr>
<tr><td>Recommended tank mixtures</td><td>None</td></tr>
</table>

2.2 Conclusion

The evaluation of the application for VITROL GB (BW01 GB) resulted in the decision **to grant** the authorisation.

2.3 Substances of concern for national monitoring

Refer to 5.1.1.

2.4 Classification and labelling

2.4.1 Classification and labelling under Regulation (EC) No 1272/2008

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

Hazard class(es), categories:	Not classified
Hazard pictograms:	-
Signal word:	-
Hazard statement(s):	-

Precautionary statement(s):	***For the P phrases, refer to the existing legislation***
Additional labelling phrases:	

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

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

	Do not discharge into the sink, gutter or any other water source the non-used container leftovers and the washing water of the spreader.
	For other restrictions refer to 2.5

2.4.3 Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)

None.

2.5 Risk management

According to the French law and procedures, specific conditions of use are set out in the Decision letter. The French Order of 4 May 2017[5] provides that:

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

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

Moreover, the French Order of 12 April 2021[6] provides that:

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

Thus, at French national level, possible extrapolation of submitted data and the corresponding assessment from “reference” crops to “related” ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is also reached on the acceptability of the intended uses on those “related” crops. The aim of this Order, mainly based on the EU document on residue data extrapolation[7] is to supply “minor” crops with registered plant protection products.

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

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

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

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

Finally, the French Order of 20 November 2021[8] on the protection of bees and other pollinating insects and the preservation of pollination services when using plant protection products provides that unless otherwise stated in the product authorisation, use on attractive crop[9] when in flower and on foraging area is forbidden. Specific conditions of application on flowering crops should be respected. As consequences specific SPe 8 may include reference to this order.

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

2.5.1 Restrictions linked to the PPP

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

Operator protection:	
-	Refer to the Decision in Appendix 1 for the details.
Worker protection:	
-	Refer to the Decision in Appendix 1 for the details.
Integrated pest management (IPM)/sustainable use:	
	-
Environmental protection	
Other specific restrictions	
Re-entry period	-
Storage	-
SPa 1	-
Risk mitigation measures	None
Agricultural recommendations	-

2.5.2 Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions in addition to those listed under point 2.5.1 (mandatory labelling):

None.

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

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

2.6 Intended uses (only NATIONAL GAP)

Please note: The GAP Table below reports the intended uses proposed by the applicant, and possible extrapolation according to French Order of 12 April 2021 (highlighted in green), evaluated and concluded as safe uses by France as zRMS. Those uses are then granted in France.
When the conclusion is "not acceptable", the intended use is highlighted in grey and the main reason(s) reported in the remarks.
When a use is "acceptable" with GAP restrictions, the modifications of the GAP are in bold.
Use should be crossed out when the applicant no longer supports this use.

GAP rev. 1, date: 14/03/2024

PPP (name/code):	VITROL GB / BW01 GB	Formulation type:	RB (ready-to use bait) [a, b]
Active substance 1:	Ferric pyrophosphate	Conc. of a.s. 1:	24 g/kg [c]
Applicant:	BROS SPÓŁKA Z OGRANICZONĄ ODPOWIEDZIALNOŚCIĄ	Professional use:	☐
Zone(s):	Southern zone[d]	Non-professional use:	☒
Verified by MS:	Yes		
Field of use:	Molluscicide		

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. [e]	**Member state(s)**	**Crop and/ or situation (crop destination/purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha [f]
					Method/Kind	Timing/Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g a.s./ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
Zonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)													
1	FR, BG, EL, ES, IT, PT, HR	All edible and non edible crops	Fn, Gn, Cn	Slugs and snails	broadcast evenly, application by applicator for granular pesticides		a) 6 b) 6	2 weeks	a) 7 kg/ha b) 42 kg/ha	a) 0.17 kg/ha b) 1.02 kg/ha	n/a	1	Acceptable

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

Remarks table heading:	(a)	e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)	(d)	Select relevant
	(b)	Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008	(e)	Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
	(c)	g/kg or g/kg	(f)	No authorisation possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

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

3 Background of authorisation decision and risk management

3.1 Physical and chemical properties (Part B, Section 2)

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of turquoise granules, with a mild, characteristic odour. It is not explosive, has no oxidising properties. The product is not flammable. In aqueous solution, it has a pH value around 4.5 at 20 °C. There is no effect of high temperature on the stability of the formulation, since after 14 days at 54 °C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of 5 years at ambient temperature when stored in PE sachet. Its technical characteristics are acceptable for a ready-to-use bait (RB) formulation.

3.2 Efficacy (Part B, Section 3)

Considering the data submitted data:

- The efficacy of the product is considered satisfying for all intended uses.

- The phytotoxicity level of is considered negligible for all the intended uses.

- The risk of negative impact on yield, adjacent and succeeding crops are considered negligible for all the intended crops.

- The risk of resistance toward ferric phosphate in a non-professional use should not be amplified with regards to its professional use.

3.3 Methods of analysis (Part B, Section 5)

3.3.1 Analytical method for the formulation

Analytical method for the determination of the active substance ferric pyrophosphate in the formulation is available and validated. The method is however not specific to ferric pyrophosphate, therefore a complementary method should be provided to confirm the identity of the active substance.

Analytical method for the determination of relevant impurities (lead, cadmium and mercury) of ferric pyrophosphate in the formulation is available and validated. Nevertheless, the LOQs are higher than the maximum limits of relevant impurities authorized in the formulation. Another analytical method should be validated with appropriate LOQs.

3.3.2 Analytical methods for residues

Ferric pyrophosphate as active substance on Annex IV of EC Regulation no 396/2005 is exempt from MRL setting, therefore no analytical method is necessary for matrices of vegetal or animal origin.Mammalian toxicology (Part B, Section 6)

Endpoints used in risk assessment

Agreed EU endpoints	
Active substance	**Ferric pyrophosphate :** 24 g/kg (2.4%)
AOEL systemic (mg/kg bw/d)	0.4 mg/Kg bw/d
AAOEL	-
Inhalation absorption	100%
Oral absorption	50 %
Vapour pressure	n/a
Dermal absorption	10%

3.3.3 Acute toxicity

VITROL GB (BW01 GB) containing 24 g/kg ferric pyrophosphate shows a low toxicity in respect to acute oral, inhalation and dermal toxicity. VITROL GB (BW01 GB) is neither corrosive nor irritant to the eye or to the skin and is not a skin sensitiser.

3.3.4 Operator exposure

Estimation of the operator exposure has been amended by zRMS as presented in the table below :

		Fe equivalent to used ferric pyrophosphate	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**
Non-professional operator Outdoor/indoor Critical use: Bare soil, **manual application** of granules Application rate: 6 x 0.05 kg Fe/ha / area treated:1 ha/day			
PHED (Guidance EFSA Journal 2014;12(10):3874) Body weight: 60 kg	No PPE Potential exposure	0.81	**203.02**
Non-professional operator Outdoor/Indoor Critical use: Bare soil, **mechanical** (broadcast and in furrow) application of granules Application rate: 6 x 0.05 kg Fe./ha / area treated: 50 ha/day			
PHED (Guidance EFSA Journal 2014;12(10):3874) Body weight: 60 kg	No PPE Potential exposure	0.01	**2.60%**

No personal protective equipment is required for non-professional users.

Conclusion

According to the exposure assessment using EFSA (PHED) model, the operator exposure to VITROL GB (BW01 GB) is above the AOEL of Fe for manual application of granules and below the AOEL for mechanical (broadcast and in furrow) application .

3.3.5 Worker exposure

Comments of zRMS	zRMS considers that in the case of the non-professional user, the worker is also the user of the product. Therefore, the assessment of worker exposure is covered by the operator exposure.

There is no unacceptable risk for the worker for all the uses requered uses (all edible and inedible crops).

Packaging:

The claimed packaging (Sack/sachet (100-630 g), are not considered in compliance with the provisions of French regulation relating to the conditions of authorisation of plant protection products by non-professional users[10] since not able to guarantee minimal exposure of the non-professional user, within the conditions of use (no secure pouring system and closure device).

3.3.6 Bystander exposure

Comments of zRMS	Consideration of acute exposure should only be made where an AAOEL has been established during an approval, review or renewal evaluation of an active substance, i.e. no acute operator or bystander exposure assessments can be performed with the AOEM model where no AAOEL has been set[11]. Only resident exposure is provided since, according to EFSA Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (EFSA Journal 2014;12(10):3874): "*No bystander risk assessment is required for PPPs that do not have significant acute toxicity or the potential to exert toxic effects after a single exposure. Exposure in this case will be determined by average exposure over a longer duration, and higher exposures on one day will tend to be offset by lower exposures on other days. Therefore, exposure assessment for residents also covers bystander exposure*."

[10] Arrêté du 6 avril 2020 relatif aux conditions d'autorisation d'un produit phytopharmaceutique pour la gamme d'usages « amateur » JORF n°0088 du 10 avril 2020

[11] Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (SANTE-10832-2015 rev. 1.7, 2017)

3.3.7 Resident exposure

Comments of zRMS

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

There is no suitable model to assess residential exposure for non-professional uses. As a worst case the EFSA model for resident (recreational exposure) has been used by zRMS. The estimated recreational exposure for resident is presented in the table below:

Fe equivalent to used ferric pyrophosphate		
Model data	**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**
EFSA model- Recreational exposure Critical use: golf course, turf or other sports lawns Application rate: 6 x 0.05 kg Fe/ha		
1-3 year old child Body weight: 10 kg	**0.003**	**0.63%**
Adult	**0.001**	**0.18%**

Furthermore, to address the potential for ingestion by infants of the pellets a reverse reference approach has been used to calculate the number of VITROL GB pellets that, if consumed by an infant would result in an exceedance of the ADI of 0.8 mg/kg bw/day for iron and of the AOEL of 0.4 mg/kg bw/day.

Children are assumed to be 1 to 3 years old and have a body weight of 10 kg. VITROL GB is a granular plant protection product containing 24 g/kg (2.4% w/w) Ferric Pyrophosphate, corresponding to 7 g/kg (0.7 % w/w) iron (Fe). The individual pellet weight is confirmed as 15 mg (please refer to section B9). Using these parameters the number of pellets which would need to be consumed to reach an intake equivalent to the reference dose is calculated as follows:

$$\text{Number of pellets} = \frac{\text{ADI (mg/kg bw/day) x body weight (kg bw)}}{\text{Concentration of a.s. in product (\%) x weight of a single pellet (mg)}}$$

$$\text{Number of pellets} = \frac{\text{AOEL (mg/kg bw/day) x body weight (kg bw)}}{\text{Concentration of a.s. in product (\%) x weight of a single pellet (mg)}}$$

Number of pellets that if consumed would exceed the ADI and the AOEL:

		Iron (ADI = 0.8 mg/kg bw/day)
	Number of pellets	**74 pellets**
		Iron (AOEL = 0.4 mg/kg bw/day)
	Number of pellets	**37 pellets**

Conclusion:
Respectively 74 and 37 individual pellets are required to achieve an intake of iron which would be equivalent to the reference doses ADI and AOEL.

On the basis of this assessment to risk to residents (adults and children) is considered to be within acceptable levels. Consequently, there is no unacceptable risk to children.

3.3.8 Combined exposure

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

Ferric pyrophosphate is defined as an active substance for which no Maximum Residue Levels (MRLs) are required and listed in Annex IV to Regulation (EC) No 396/2005. Therefore estimation of consumer risk assessment is not necessary. The chronic and short-term intake of ferric pyrophosphate residues resulting from pesticide uses is unlikely to present a public health concern.

Summary for VITROL GB

Table : Information on VITROL GB (KCA 6.8)

Crop	PHI for BW01 GB proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for BW01 GB proposed by zRMS	zRMS Comments (if different PHI proposed)
		Ferric pyrophosphate		
All edible crops	Non necessary	Yes	Non necessary	
All inedible crops			Not applicable	Not assessed (non edible commodity)

NR: not relevant
* Purpose of withholding period to be specified
** F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop).

Waiting periods before planting succeeding crops

Not relevant

3.5 Environmental fate and behaviour (Part B, Section 8)

The applicant provided one core dossier for both preparations VITROL GB PRO (professional users) and VITROL GB (non professional users).

Due to the natural occurrence in the environment of ferric phosphate and its dissociation products (iron ions and phosphate ions), no specific study to address the fate and behavior of active substance in environment is needed.

Since the product VITROL GB (BW01 GB) is for non-professional uses, soil and surface water exposure are not considered requiring evaluation at FR national level.

Due to the nature of the active substance, no unacceptable risk of groundwater contamination by ferric pyrophosphate is expected for the intended uses.

3.6 Ecotoxicology (Part B, Section 9)

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

Since the product VITROL GB (BW01 GB) is applied as bait (ready-to-use product) for amateur uses, exposure of soil and surface water compartments to active substance is considered negligible. For other organisms for which an exposure could not be excluded, the risk was considered acceptable.

3.7 Relevance of metabolites (Part B, Section 10)

An assessment was conducted according to the SANCO/221/2000 guidance document. Please refer to environmental fate and behaviour above for conclusion on the risk of groundwater contamination.

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

The active substance Ferric pyrophosphate is not approved as a candidate for substitution, therefore a comparative assessment is not foreseen.

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

When the conclusions of the assessment is “Not acceptable”, please refer to relevant summary under point 3, “Background of authorisation decision and risk management”.

5.1.1 Post-authorisation monitoring

None.

Appendix 1 Copy of the product authorisation

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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 VITROL GB

de la société *BROS SPOLKA Z OGRANICZONA ODPOWIEDZIALNOSCIA*

enregistrée sous le *n° 2022-1477*

Vu les conclusions de l'évaluation de l'Anses du 2 novembre 2023,

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 son annexe.

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

Avertissement :

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

VITROL GB
AMM n° 2240078

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RÉPUBLIQUE FRANÇAISE
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anses

Informations générales sur le produit	
Nom du produit	VITROL GB
Type de produit	Produit de référence
Titulaire	BROS SPOLKA Z OGRANICZONA ODPOWIEDZIALNOSCIA Karpia 24 61-619 POZNAN Pologne
Formulation	Appât prêt à l'emploi (RB)
Contenant	24 g/kg - pyrophosphate ferrique
Numéro d'intrant	458-2022.01
Numéro d'AMM	2240078
Fonction	Molluscicide
Gamme d'usage	Amateur / emploi autorisé dans les jardins
Mention particulière	Produit à faible risque au sens de l'article 47 du règlement (CE) n° 1107/2009

L'échéance de validité de la présente décision est fixée à douze mois à compter de la date d'expiration de l'approbation de la substance active. A titre indicatif, dans l'état actuel du calendrier d'approbation des substances actives, l'échéance de l'autorisation est fixée au 3 août 2036.

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 14/03/2024

DocuSigned by:
Charlotte Grastilleur
AE281A955A42454...

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

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ANNEXE : Modalités d'autorisation du produit

Vente et distribution	
Le titulaire de l'autorisation peut mettre sur le marché le produit uniquement dans les emballages :	
Emballage	**Contenance**
Boîtes avec dispositif réducteur de débit en polychlorure de vinyle	100 g ; 150 g ; 200 g ; 250 g ; 300 g ; 350 g ; 400 g ; 450 g ; 500 g ; 600 g ; 630 g ; 700 g ; 800 g ; 900 g ; 1 kg
Boîtes avec dispositif réducteur de débit en polyéthylène basse densité	100 g ; 150 g ; 200 g ; 250 g ; 300 g ; 350 g ; 400 g ; 450 g ; 500 g ; 600 g ; 630 g ; 700 g ; 800 g ; 900 g ; 1 kg
Boîtes avec dispositif réducteur de débit en polyéthylène haute densité	100 g ; 150 g ; 200 g ; 250 g ; 300 g ; 350 g ; 400 g ; 450 g ; 500 g ; 600 g ; 630 g ; 700 g ; 800 g ; 900 g ; 1 kg
Boîtes avec dispositif réducteur de débit en polyéthylène téréphtalate	100 g ; 150 g ; 200 g ; 250 g ; 300 g ; 350 g ; 400 g ; 450 g ; 500 g ; 600 g ; 630 g ; 700 g ; 800 g ; 900 g ; 1 kg
Boîtes avec dispositif réducteur de débit en polypropylène	100 g ; 150 g ; 200 g ; 250 g ; 300 g ; 350 g ; 400 g ; 450 g ; 500 g ; 600 g ; 630 g ; 700 g ; 800 g ; 900 g ; 1 kg
Bouteilles avec opercule à trou en polychlorure de vinyle	100 g ; 150 g ; 200 g ; 250 g ; 300 g ; 350 g ; 400 g ; 450 g ; 500 g ; 600 g ; 630 g ; 700 g ; 800 g ; 900 g ; 1 kg
Bouteilles avec opercule à trou en polyéthylène basse densité	100 g ; 150 g ; 200 g ; 250 g ; 300 g ; 350 g ; 400 g ; 450 g ; 500 g ; 600 g ; 630 g ; 700 g ; 800 g ; 900 g ; 1 kg
Bouteilles avec opercule à trou en polyéthylène haute densité	100 g ; 150 g ; 200 g ; 250 g ; 300 g ; 350 g ; 400 g ; 450 g ; 500 g ; 600 g ; 630 g ; 700 g ; 800 g ; 900 g ; 1 kg
Bouteilles avec opercule à trou en polyéthylène téréphtalate	100 g ; 150 g ; 200 g ; 250 g ; 300 g ; 350 g ; 400 g ; 450 g ; 500 g ; 600 g ; 630 g ; 700 g ; 800 g ; 900 g ; 1 kg
Bouteilles avec opercule à trou en polypropylène	100 g ; 150 g ; 200 g ; 250 g ; 300 g ; 350 g ; 400 g ; 450 g ; 500 g ; 600 g ; 630 g ; 700 g ; 800 g ; 900 g ; 1 kg
Cartons avec dispositif verseur	100 g ; 150 g ; 200 g ; 250 g ; 300 g ; 350 g ; 400 g ; 450 g ; 500 g ; 600 g ; 630 g ; 700 g ; 800 g ; 900 g ; 1 kg

Les sacs et les sachets sont refusés car l'absence de système de versement sécurisé et de dispositif de fermeture ne permet pas de garantir une exposition minimale de l'utilisation non professionnel.

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

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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)	Culture attractive en floraison (arrêté du 20/11/2021)
11012903 Traitements généraux*Trt Sol*Limaces et escargots	**7 g/10 m²**	**6/an**	-	1	-	-	-	Non concerné
	Egalement autorisé sous abri. Intervalle minimum entre les applications : 14 jours.							

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Conditions d'emploi du produit

Stockage et manipulation du produit

- Application uniquement à l'aide d'un microgranulateur.

Respect des limites maximales de résidus (LMR)

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

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

Protection de l'eau

- Ne pas rejeter dans l'évier, le caniveau ou tout autre point d'eau les fonds d'emballage non utilisés et les eaux de lavage du microgranulateur.

Appendix 2 Copy of the product label

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

VITROL GB

Authorisation holder: BROS spółka z ograniczoną odpowiedzialnością., Ul. Karpia 24, 61 – 619 Poznań, Poland, Phone no: +48 61 826 25 12, e-mail: biuro@bros.pl, www.bros.pl

Follow the label instructions of the plant protection product to avoid risks for human health and the environment.

FOR USE ONLY AS AN AMATEUR USER
Rainproof formulation.

Active substance content:
ferric pyrophosphate - 24 g/kg (2.4%)

Authorisation number ..... dated on .....

EUH401 To avoid risks to human health and the environment, comply with the instructions for use.

MODE OF ACTION
Molluscicide - ready to use granular bait for control of slugs and snails by an amateur users. Due to specially selected food base, it attracts the slugs and snails and is eagerly eaten by them. It contains the active substance, which degrades to phosphorus and iron, which naturally occur in soil.. Suitable for protection of all edible and nonedible crops (both outdoor and protected). It causes an immediate inhibition of plant damage - after ingestion the pests stop feeding. Subsequently slugs and snails move to their hideaways and die thereafter, so dead slugs may not be visible in place of application, whereas lack of further plant damage is a visible effect of the product action. No pre-harvest interval enables crop gathering directly after the product application. The formulation has good resistance to damp conditions - mould, rain or watering.

APPLICATION OF THE PRODUCT

Apply after slug/snail infestation or when first damages caused by slugs/snails are observed. In case of freshly cultivated areas heavily infested with slugs/snails use the product immediately after planting.
REMARKS:

In the event of long period of rainy weather reapplication is recommended.
Lumpy soil should be flattened before product application to prevent falling of granules into crevices and assure its accessibility to slugs/snails.
When most of the applied bait is consumed reapplication is recommended.
Moderate wetting is advisable before application of the product on dry soil (moist granules are even more attractive for snails/slugs).
Best effects are obtained when the product is applied in the afternoon and evening.

Broadcast evenly directly from the pack or with use of applicator for granular products.
The maximum number of applications is 6 in one season. If needed, apply again after 2 weeks.

Crops	Pest	Maximum individual dose	Maximum number of treatments	Minimum interval between applications
All edible (outdoor & protected)	slugs & snails	0.7 g/m² 7 g / 10 m²	6	2 weeks

All nonedible (outdoor & protected)	slugs & snails	0.7 g/m² 7 g / 10 m²	6	2 weeks

CONDITIONS FOR SAFE USE OF THE PRODUCT

Precautions for people using the product:

Do not eat, drink or smoke while using the product. Wash hands and exposed skin before meals and after use.

Precautions for environmental protection:
Do not contaminate surface waters with the plant protection product or its packaging.

Period between the last use of the product and the day people can enter area where the product was applied and animals can be introduced (prevention period): not required

Prevention period for bees (period preventing poisoning): not applicable

Period between the last use of the product and harvesting of the crop (preharvest waiting period): not applicable

Contains active substance from low risk substances group

Period between the last use of the product on plants for feed and feeding animals on these plants
(preharvest waiting period for feed): not applicable

Period between the last use of the product and sowing or planting the succeeding crops: not applicable

CONDITIONS OF PLANT PROTECTION PRODUCT AND CONTAINER STORAGE AND SAFE REMOVAL
Keep out of reach of children
Store in original packaging in temp. 0ºC - 30ºC, away from food, beverages and feed.
Unused product should be handed over to the authorized waste disposal company according to local regulations.
Dispose of contents/container to a licensed hazardous-waste disposal contractor or collection site except for empty clean containers which can be disposed of as non-hazardous waste

FIRST AID
If a medical advice is necessary, the packaging or label should be presented.
Antidote: none, conduct symptomatic treatment.

Expiry date: 5 years
Date of production and lot number on the packaging.
Net content: .....