HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

BIJLAGE II bij het besluit d.d. 29 december 2017 tot toelating van het middel BRODITEC G-29, toelatingnummer NL-0018192-0000

Evaluation Report
Mutual Recognition

BRODITEC G-29
BRODILUX GRAAN
BRODITOP NEXT WHEAT
BRODITOP SENSITIVE WHEAT
DEVILTOP SENSITIVE WHEAT
MUSKIL EXCELLENT GRAAN
RODETOX BRODILO GRAAN
RODIBROD SENSITIVE WHEAT
ZED BF WHEAT

29-12-2017

Biocidal product assessment report related to product authorisation under (EU) Regulation 528/2012

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1 General information about the product application

Name and address of the authorisation holder	**Name**	Zapi SpA
	Address	Via Terza Strada 12, 35026, Conselve (PD), Italië
Authorisation number	NL-0018192-0000	
Date of the authorisation	22-12-2017	
Expiry date of the authorisation	27-01-2019	

Trade name(s)	BRODITEC G-29 BRODILUX GRAAN BRODITOP NEXT WHEAT BRODITOP SENSITIVE WHEAT DEVILTOP SENSITIVE WHEAT MUSKIL EXCELLENT GRAAN RODETOX BRODILO GRAAN RODIBROD SENSITIVE WHEAT ZED BF WHEAT
Evaluating member state	UK
Name of the product in RMS	Broditop Sensitive Wheat Bait R
Active substance	Brodifacoum
PT	PT14
User category	Professionals Non-professionals

2 Summary of the product assessment

2.1 Classification and labelling

For professional use

The identity of all substances in the mixture that contribute to the classification of the mixture *:		
Brodifacoum		
Pictogram:	GHS08	Signal word: warning
H-statements:	H373	May cause damage to the blood through prolonged or repeated exposure..
P-statements:	P101	If medical advice is needed, have product container or label at hand.
	P102	Keep out of reach of children.
	P103	Read label before use.
	P270	Do not eat, drink or smoke when using this

		product.
	P280	Wear protective gloves/protective clothing/eye protection/face protection.
	P301+310	IF SWALLOWED: Immediately call a POISON CENTER/doctor/...
	P405	Store locked up.
Supplemental Hazard information:	-	
Child-resistant fastening obligatory?		Not applicable
Tactile warning of danger obligatory?		Not applicable

For non-professional use

The identity of all substances in the mixture that contribute to the classification of the mixture *:			
Brodifacoum			
Pictogram:	GHS08	Signal word:	warning
H-statements:	H373	May cause damage to the blood through prolonged or repeated exposure.	
P-statements:	P101	If medical advice is needed, have product container or label at hand.	
	P102	Keep out of reach of children.	
	P103	Read label before use.	
	P270	Do not eat, drink or smoke when using this product.	
	P301+310	IF SWALLOWED: Immediately call a POISON CENTER/doctor/...	
	P405	Store locked up.	
Supplemental Hazard information:	-		
Child-resistant fastening obligatory?			No
Tactile warning of danger obligatory?			Yes

2.2 Packaging and shelf-life

For the information on packaging we refer to the SPC.

No rodenticides are authorised for use against rats for non-professional users in the Netherlands. Packaging types that are not accepted in the original authorisation, are not accepted.

The shelf life of the product is 24 months.
The product is tested in polyethylene bags. For solid formulations, extrapolation to all types of packaging is acceptable, except to more flexible packs. Therefore, all packaging materials are acceptable for this product.

2.3 Physico/chemical properties and analytical methods

For the assessment of the physical and chemical properties, analytical methods and risk assessment regarding physical and chemical properties we refer to the Product Assessment Report of the original authorisation.

2.4 Effectiveness against target organisms

For the assessment of the effectiveness against target organisms we refer to the Product Assessment Report of the original authorisation by the UK (Broditop Sensitive Wheat Bait R ,December 2016). The conclusions of the RMS are acceptable.

2.4.1 Authorised uses and use instructions

The applicant has provided a Dutch SPC. This has been adapted to our standards.

No rat control by non-professional users

Due to national specific policy (art. 37) use against rats by non-professional users is not authorised in NL.

Resistance management non-professionals

According to the SPC for non-professional use, use should be avoided in those areas where evidence of resistance is found and it is advised to alternate baits containing different anticoagulant active ingredients. NL is of the opinion that the proposed resistance management is not feasible for non-professional users. Instead the sentence is replaced by a harmonised sentence for the renewal in the risk mitigation measures. The new sentence recommends non-professional users to seek advice from the product supplier or call the pest control service when rodents are not eliminated within 35 days.

Outdoor use only for professionals with IPM training

The use of anticoagulants around buildings in the Netherlands is only allowed for professional users with additional IPM training. A sentence with this information has been included in the SPC.

2.5 Risk assessment for human health

For the risk assessment for human health we refer to the Product Assessment Report (PAR) of the original authorisation. The PAR was prepared by the RMS the UK.

The formulation BRODITEC G-29 is a rodenticide. It is a grain bait formulation, which contains 0.0029% w/w brodifacoum. The authorised use BRODITEC G-29 in the UK includes indoor and outdoor around buildings, by professional as well as non-professionals. The biocidal product will be supplied for professional and non-professional use in sachets (15 g tea-bag filter paper sachet and 25 g, 50 g, 100 g plastic transpiring sachets) and in pre-dosed tamper resistant bait stations. It is also supplied as a loose bait for professional use.

Please note that the PAR contains specific details for the UK market i.e. restrictions and authorisation requirements. The intended use of the product for submission in the Netherlands includes the professional control of house mice and brown rats in and around buildings and the non-professional control of house mice in buildings. These are the only types of use considered in the Netherlands.

No new studies with the product have been submitted. Instead, it has been proposed to read across to studies conducted with the test formulation, Broditop Wheat Bait R containing 0.005% Brodifacoum. Based on the compositions it has been proposed that the effects assessment for the test formulation provides a conservative assessment. This is accepted by the Ctgb. Based on the study outcome no classification is warranted for acute oral or acute dermal toxicity, for skin or eye irritation or for sensitising properties (LLNA). No study was submitted for acute inhalation. Inhalation exposure is not relevant because active substance has very low volatility and is only present at 0.0029% (w/w) in the solid bait product. Also, dustiness studies have shown that the wheat bait is nearly dust-free.

The company justification was accepted by the UK. The conclusion of the UK on formulation toxicity is accepted by the Ctgb.

No studies are available to evaluate the dermal absorption with the formulation BRODITEC G-29. A dermal absorption study (*in vitro* human conducted to OECD TG428) of brodifacoum as formulated in Brodifacoum 0.005 % (w/w) Pasta, was previously evaluated by the UK, and the UK concluded a dermal absorption value of 1.7 % (as a worst case) should be used in the risk characterisation when calculating the potential human systemic dose of brodifacoum following exposure to the test formulation. The UK accepted a direct read across dermal absorption of 1.7%. Dermal absorption of a solid grain will be no greater than that of a solid paste. Following the Guidance on Dermal Absorption the dermal absorption value of 1.7% is rounded to 2%. However, throughout the PAR the dermal absorption of 3% has been used without further explanation. The conversion of 2% to 3% may be due to the consideration of pro rata correction. With the application of pro rota correction the dermal absorption is calcualted to be 2.93%, which can be rounded to 3%. As 3% represents a worse case compared to 2% Ctgb accepts the use of 3% as applied by the UK.

For professional users, the loose bait is supplied in containers up to 25 kg, so decanting from the larger packs would be necessary. The grain bait is used either as loose bait placed in covered bait points / plastic bait boxes or supplied in sachets which may be fixed within a bait point/bait box. For exposure assessment exposure to loose grain was considered to represent the worst case. The exposure levels were estimated by the UK for dermal exposure during decanting, application and cleaning of the grain bait, and for inhalation exposure during decanting.

Based on the HEEG harmonisation paper (no. 12: Harmonised approach for the assessment of rodenticides (anticoagulants), endorsed TMII 2011), it was assumed that there will be 63 loading and 16 clean-up operations per day. For each loading 100 g of bait was assumed to be required. Without PPE, the exposure leads to 219% of the acute/chronic AEL (3.3×10^{-6} mg/kg). When gloves are worn for all the tasks, the predicted exposure was 61% of the AEL. The UK concluded that no adverse effects from exposure to brodifacoum are expected for the professional user when gloves are worn for all tasks (decanting, application, cleaning). This is accepted by the Ctgb.

For non-professional users the product is supplied in sachets. Although historically the number of manipulations assumed for non-professionals has been 5 each for loading and cleaning, for loading, the worst case is 4 manipulations (due to non-linearity in the exposure data). Assuming 4 times each for loading and cleaning, the predicted exposure was 14% of the acute/chronic AEL (3.3×10^{-6} mg/kg) for unprotected non-professional users. Based on this, the UK recommended product authorisation.

Although 4 manipulations per day has been assumed by the UK, the number should be 5 per day for a non-professional user according to HEEG opinion no.10. Therefore additional calculation was made by the Ctgb for the non-professional user. Assuming 5 times loading and 5 times cleaning per day the exposure level was calculated to be 5.86×10^{-7} mg/kg , corresponding to 18% of the acute/chronic AEL without the use of PPE. Based on this calculation the conclusion of the UK is accepted by the Ctgb.

The critical scenario for secondary exposure is the possibility of consumption of the formulation by infants. In the event that a child did gain access to the bait, the TNsG and the User Guidance indicate that an estimate of exposure can be made by assuming 5 g (mouthful) of bait is swallowed by a 10 kg child. Predicted exposure is 0.0145 mg/kg bw/d for infants ingesting bait, which corresponds to >439394% of the AEL (acute AEL of 3.3×10^{-6} mg/kg mg/kg bw/day). Additionally, exposure of child (10 kg)ingesting 0.01 g of bait is calculated by the Ctgb, in accordance with the TNsG (2002). The calculated exposure level was 0.0003 mg/kg bw/day, corresponding to 8788% of the acute/chronic AEL. These calculations indicate that infants are at significant risk of poisoning.

In order to reduce the chance of secondary exposure BRODITEC G-29 contains bittering agent. In addition, the following risk mitigation measures are added to reduce the risk of secondary exposure:
“Prevent access to bait by children, birds and non-target animals (particularly dogs, cats, pigs and poultry)”

“Keep out of reach of children”

"Baits must be securely deposited in a way so as to minimise the risk of consumption by other animals or children. Where possible, secure baits so that they cannot be dragged away".

Furthermore, the biocidal product does not contain any substance of concern. This is accepted by the Ctgb.

2.6 Risk assessment for the environment

BRODITEC G-29 is a rodenticide (PT 14) for use in and around buildings on domestic, industrial and commercial sites. The product is used for the control the population of Norway rat (*Rattus norvegicus*) and House mouse (*Mus musculus*).
The grain baits are used by professionals and non-professionals. The baits can be used in tamper-resistant bait stations or placed in inaccessible places such as inside pipes, under rocks etc, around industrial, commercial and residential buildings and empty buildings. BRODITEC G-29 is not authorised by the RMS for use in open areas, in waste dumps or in sewers.

For the risk assessment for the environment we refer to the Product Assessment Report of the original authorisation.

The product contains the active substance brodifacoum (0.0029% w/w). Due to the persistent (P), bioaccumulative (B) and toxic (T) properties of Brodifacoum, this substance fulfils the PBT criteria. Brodifacoum is not known to be endocrine disruptive. As the active substance is considered persistent, the risk assessment was also considered to cover possible metabolites.

The product does not contain any substances of concern for the environment.

Please note that the PAR contains specific details for the UK market i.e. restrictions and authorization requirements. The intended use of the product for submission in the Netherlands includes the professional control of house mice and brown rats in and around buildings and the non-professional control of house mice in buildings. For environmental reasons, the product needs to be applied in commercially available bait stations and not in covered bait stations. These are the only types of use considered in the Netherlands.

Dutch specific restrictions necessary to prevent access of non-target animals to the product are stated in the NL SPC.

Overall conclusion for the aspect environment: The conclusions in the risk assessment of the RMS are valid, considering the intended professional use of the product against house mice in buildings and rats in and around buildings and the non-professional use of the product against house mice in buildings. For environmental reasons, the product needs to be applied in commercially available bait stations and not in covered bait stations.

2.7 Measures to protect man, animals and the environment

For the measures to protect man, animals and the environment we refer to the Product Assessment Report of the original authorisation and the SPC of the CMS NL.

2.8 Substitution/exclusion criteria and comparative assessment

The active substance Brodifacoum meets the criteria for exclusion according to Article 5 (1) of Regulation (EU) 528/2012 and the criteria for substitution according to Article 10 of Regulation (EU) 528/2012. Therefore, in line with Article 23 (1) of Regulation (EU) 528/2012 a comparative assessment has to be conducted.
In line with Article 1 of Commission Implementing Decision (EU) 2017/1532, CMS Ctgb considered the information in the Annex on the comparative assessment of anticoagulant rodenticide biocidal products and came to the conclusion that in the absence of anticoagulant rodenticides, the use of rodenticides containing other active substances would lead to an inadequate chemical diversity to minimise the occurrence of resistance in the target harmful organisms.
Following an application for a major change, RMS UK has concluded that the conditions in Article 19 of Regulation (EU) 528/2012 are fulfilled. CMS NL agrees with the conclusions of UK.

3 Decision

The authorisation of BRODITEC G-29 is based on mutual recognition of the authorisation of RMS UK. For the evaluation we refer to the Product Assessment Report which has been composed by the RMS conform the Common Principles.

It is concluded that the application of BRODITEC G-29 according to the use instructions as stated in the SPC, will be effective and that there will be no harm for the health of humans and for the environment.