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 P-29F, toelatingnummer NL-0018191-0000

Evaluation Report
Mutual Recognition

BRODITEC P-29F
BRODILUX PASTA
BRODITOP NEXT PASTA FLUO-NP
BRODITOP NEXT PASTA PLUS FLUO-NP
BRODITOP SENSITIVE PASTA FLUO-NP
BRODITOP SENSITIVE PASTA PLUS FLUO-NP
DEVILTOP SENSITIVE PASTA FLUO
DEVILTOP SENSITIVE PASTA PLUS FLUO
RODETOX BRODILO PASTA
RODIBROD SENSITIVE PASTA FLUO
ZED BF SENSITIVE PASTA FLUO-NP
ZED BF SENSITIVE PASTA PLUS FLUO-NP
HGX TEGEN MUIZEN
MUSKIL EXCELLENT PASTA FLUO-NP

29-12-2017

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

Contents

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-0018191-0000	
Date of the authorisation	29-12-2017	
Expiry date of the authorisation	27-01-2019	

Trade name(s)	BRODITEC P-29F* BRODILUX PASTA BRODITOP NEXT PASTA FLUO-NP BRODITOP NEXT PASTA PLUS FLUO-NP BRODITOP SENSITIVE PASTA FLUO-NP BRODITOP SENSITIVE PASTA PLUS FLUO-NP DEVILTOP SENSITIVE PASTA FLUO DEVILTOP SENSITIVE PASTA PLUS FLUO HGX TEGEN MUIZEN MUSKIL EXCELLENT PASTA FLUO-NP RODETOX BRODILO PASTA RODIBROD SENSITIVE PASTA FLUO ZED BF SENSITIVE PASTA FLUO-NP ZED BF SENSITIVE PASTA PLUS FLUO-NP
Evaluating member state	UK
Name of the product in RMS	Broditop Sensitive pasta Fluo-NP R
Active substance	Brodifacoum
PT	14
User category	Professionals Non-professionals

*the trade name BRODITEC P-29F will be used in this document as representative for all trade names

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.	
	P264	Wash hands and exposed skin before meals and after use.	
	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.

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. However, since the flexible packs are packed in robust secondary packaging, it is reasonable to assume that stacking the products does not result in damage. 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 authorization by the eCA UK (Broditop Sensitive Pasta Fluo-NP 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 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 28 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 P-29F is a rodenticide. It is a solid, soft pasta formulation, which contains 0.0029% w/w brodifacoum. The authorised use BRODITEC P-29F in the UK includes indoor and outdoor around buildings, by professional as well as non-professionals. The biocidal product will be supplied in sachets (10 g and 15 g single dose edible paper tea-bags), plastic trays with printed peel-off covering (containing up to 100 g of bait for rats and up to 50 g for mice) and as pre-dosed (with 10/15 g sachets) tamper resistant bait stations (up to 100 g of bait for rats and up to 50 g for mice) for professional use and non-professional use. It will also be supplied in caulking guns (up to 600 g) for professional use only. The dose rate for rat infestations is to use bait points of up to 100 g and for mouse infestations use of bait points up to 50 g.

It should be noted 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 Pasta Fluo-NP 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/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. 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 P-29F. 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. Following the Guidance on Dermal Absorption, pro rata correction is considered, and dermal absorption for the formulation containing 0.0029% Brodifacoum is calculated to be 2.93%, which is rounded to 3%. Ctgb agrees with the conclusion of the UK to use 3% dermal absorption in the risk assessment.

Pasta baits are a non-dusty solid bait formulation containing the active substance, in this case brodifacoum which is not volatile. The risk of inhalation exposure to is not considered relevant due to the physical nature of the product.

For exposure assessment for the professional user using sachets, the most appropriate reference for the evaluation of rodenticide products is the HEEG harmonisation paper ‘HEEG opinion on a Harmonised approach for the assessment of rodenticides (anticoagulants)’ agreed at TM II 2011. There are no specific data for paste in sachets, but it is indicated that the data for wax blocks can reasonably be used. According to the HEEG opinion it was assumed that there will be 60 loading and 15 clean-up operations per day. Assuming 10 sachets per loading (10 g sachets to make up 100 g rat point) the exposure level exceeded the acute/chronic AEL (3.3×10^{-6} mg/kg) by 149% even with the use of PPE (gloves). When application of 6 sachets was assumed (15 g sachets to make up 90 g rat point), the exposure leads to 915% of the acute/chronic AEL without the use of PPE. When gloves are worn, the predicted exposure was 92% of the AEL. Considering that the actual exposure from handling a sachet is likely to be much less than from handling a wax block, the UK concluded that no adverse effects from exposure to brodifacoum are expected for the professional user when gloves are worn. This is accepted by the Ctgb.

Furthermore the formulation may be applied in the form of trays or by using caulking gun. The exposure by handling bait trays was expected to be lower than of sachets. For the use of caulking gun, reverse reference scenario was applied due to the lack of appropriate models. The calculation showed that up to 2.3 g of product may be deposited on the outside of the gloves. It is unlikely that a trained professional will get this much of paste formulation on his gloves as long as a spatula is used to scrape the bait out of the bait station during cleaning/disposal. Therefore the UK concluded professional use of a caulking gun is acceptable with the use of gloves with the addition of the following phrase for the professional product label: “Use a spatula for post-application (cleaning/disposal) of bait”. The conclusion of the UK is accepted by the Ctgb.

For non-professional users the product is supplied in either pre-baited, sealed bait stations, or loose sachets. Assuming 5 times loading and cleaning per day, and 6 sachets per

loading (15 g to make up 90 g rat bait point) the exposure was predicted to be 85% of the acute/chronic AEL (3.3×10^{-6} mg/kg) for unprotected non-professional users. The exposure levels from the control of mice (5 x 10 g sachets to make up 50 g mouse bait) will result in even lower %AEL. Based on these results, the UK has granted product authorisation. The use of sachets in pre-dosed tamper resistant bait stations for non-professional use to control mice is also considered acceptable. 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 P-29F 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 P-29F is a rodenticide (PT 14) for use in and around buildings. The product is used for the control the population of Norway rat (*Rattus norvegicus*) and House mouse (*Mus musculus*).
The solid, soft pasta bait formulation is used by professionals and non-professionals. The baits can be used in inaccessible places such as inside pipes, under rocks etc, around industrial, commercial and residential buildings and empty buildings.
BRODITEC P-29F 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 P29F 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 P-29F 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.