HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

BIJLAGE II bij het besluit d.d. 9 maart 2018 tot toelating van het middel IMIDASECT, NL-0018484-0000

Evaluation Report
Mutual Recognition

IMIDASECT

9 maart 2018

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**	Sharda Cropchem España S.L.
	Address	Carril Condomina Nº3 Planta 12 30006 MURCIA Spain
Authorisation number	NL-0018484-0000	
Date of the authorisation	9-3-2018	
Expiry date of the authorisation	29-6-2021	

Trade name(s)	IMIDASECT
Evaluating member state	DE
Name of the product in RMS	IMIDASECT
Active substance	Imidacloprid
PT	18
User category	Professionals and non-professionals

2 Summary of the product assessment

2.1 Classification and labelling

For the information regarding classification and labelling we refer to the SPC.

2.2 Packaging and shelf-life

Professional

	Packaging authorised/ evaluated by RMS	Packaging applied for in NL	Packaging authorised in NL
Packaging size and type	30g; 35g, 50g, 100g cartridge (Plastic (HDPE, COEX))	30g; 35g, 50g, 100g cartridge (Plastic (HDPE, COEX))	30g; 35g, 50g, 100g cartridge (Plastic (HDPE, COEX))
	0.75g, 1g, 1.2g, 1.4g bait tray (Plastic (HDPE, COEX))	0.75g, 1g, 1.2g, 1.4g bait tray (Plastic (HDPE, COEX))	0.75g, 1g, 1.2g, 1.4g bait tray (Plastic (HDPE, COEX))

Non-professional use

	Packaging authorised/ evaluated by RMS	Packaging applied for in NL	Packaging authorised in NL

Packaging size and type	3g, 5g, 10g, 15g syringe (Plastic (HDPE, COEX))	3g, 5g, 10g, 15g syringe (Plastic (HDPE, COEX))	3g, 5g, 10g, 15g syringe (Plastic (HDPE, COEX))
	0.75g, 1g, 1.2g, 1.4g bait tray (Plastic (HDPE, COEX))	0.75g, 1g, 1.2g, 1.4g bait tray (Plastic (HDPE, COEX))	0.75g, 1g, 1.2g, 1.4g bait tray (Plastic (HDPE, COEX))

The shelf life of the product is 24 months in the packaging applied for.

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 eCA Germany (IMIDASECT, 9-2-2017). The conclusions of the RMS are acceptable.

However, the target species of this product (*Blattella germanica & Blatta orientalis*) do not live outdoors in the Netherlands. Therefore, outdoor use of this product is not relevant in the Netherlands and will not be authorised (BPR art 37e).

2.4.1 Instructions for the use(s)

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

2.5 Risk assessment for human health

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

The ready-to-use gel IMIDASECT contains 2.15% w/w imidacloprid as active substance. The biocidal product is applied in cracks and crevices indoor and outdoor, against cockroaches. The product can be applied in open manner (syringe or cartridge) or in a bait tray. Various applications rates are included for low or high infestation, depending on the cockroach and the way of application. This is included in the use and is described in PAR and SPC. The product is intended for both professional and non-professional use. The Product Assessment Report (PAR) was prepared by the refMS Germany (DE).

Studies with the product have been submitted and 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 (LLN study). The applicant tried to perform an appropriate inhalation study with the biocidal product, however, failed in the production of appropriate dust. DE concluded that no further testing was required. As the product is a gel, and imidacloprid has low vapour pressure, no inhalation exposure is accepted. The conclusion on formulation toxicity by DE is accepted by the Ctgb.

A value equivalent to 8 % is used as dermal absorption rate for dilutions of imidacloprid in water, which has been derived from dilutions of the test substance containing between 0.07

% and 0.007 % imidacloprid (CAR, RMS DE 2011). As no co-formulants were present in the tested formulation, and none of the co-formulants of the IMIDASECT are expected to increase dermal absoption, this value is considered a worst case for the biocidal product containing 2.15 % imidacloprid. This is accepted by the Ctgb.

Based on the low vapour pressure of imidacloprid, only dermal exposure is envisaged by use of the product.

For professional exposure, the application of the product, cleaning of equipment and disposal of the biocidal product are considered by DE, resulting in a risk index of 0.06 for application of gel drops via cartridge/syringe/nozzle or 0.08 for application in bait trays for the unprotected professional user. Therefore, DE concluded that no adverse effects from exposure to imidacloprid are expected for the unprotected professional user during the application, cleaning equipment and disposal of IMIDASECT. This is accepted by the Ctgb.

For non-professional exposure, the application of the product and disposal of the biocidal product are considered by DE, resulting in 20% of $AEL_{long\text{-}term}$. Therefore, DE concluded that no adverse effects from exposure to imidacloprid are expected for the unprotected non-professional user during the application and disposal of IMIDASECT. This is accepted by the Ctgb.

For secondary exposure, dermal and oral contact of toddlers to the gel bait as worst case for children and adults was considered. For the assessment, the ingestion of the content of one bait tray was considered, ingestion if a gel bait drop (100 mg) and transient mouthing of 10 mg biocidal product. A risk has been identified for toddlers accidentally ingesting higher amounts of the gel bait. However, since the gel paste contains an aversive agent and is enclosed in a tamper-resistant bait tray or will be placed inaccessible for pets, other domestic animals and children there is
no concern against the intended use if the directions for use according to chapter 2.5 and if applicable to 2.4 of the SPC for protection of bystanders, the general public, pets and livestock animals and labelling elements are followed.
The consumption of one gel bait drop (0.1 g) will lead to an exposure of 0.215 mg/kg bw (54 % of
AEL_{acute}). Thus, the consumption of 2 drops would lead to an exceedance of the AEL_{acute}. However, the consumption of more than 1 spot is considered unlikely for the following reasons: (1) bait spots are hardly visible if dried; (2) The bait contains an aversive agent and (3) the bait is applied on places inaccessible for children. With these reasons taken in consideration, an overall conclusion of a safe use is not affected even if non-professional users do not comply with the instructions of use as exposure is very unlikely.

Furthermore, DE did not identify a substance of concern. This accepted by the Ctgb.

Based on this risk assessment, it was concluded that no adverse health effects are expected for the unprotected professional and non-professional user after dermal and respiratory exposure to imidacloprid as a result of the application of IMIDASECT, when used in accordance to the SPC.

Furthermore, when used according to the SPC, no adverse health effects are expected for the general public by indirect exposure to imidacloprid as a result of the application of IMIDASECT.

2.6 Risk assessment for the environment

The PAR consists of 8 uses, which are summarised below:

Intended uses
Use 1 & 2: Non prof resp. Professional use Indoor: Open bait application (cracks and crevices) for cockroaches. Max 6 applications per year. 0.1 – 0.2 g/m^2
Use 3 & 4: Non prof resp. Professional use Indoor: Open bait application (cracks and crevices) for cockroaches. Max 6 applications per year. 0.2 – 0.3 g/m^2
Use 5: Professional & non professional use Indoor: Open bait trays (”an open tray comparable to the product being applied on the floor”) for cockroaches. Max 6 applications per year. 0.1 – 0.2 g/m^2
Use 6: Professional & non professional use Indoor: Open bait trays for cockroaches. Max 6 applications per year. 0.2 – 0.3 g/m^2
Use 7: Professional & non professional use Outdoor: Bait trays for cockroaches, as a barrier at entry points. Max 6 applications per year. 0.1 – 0.2 g/m^2
Use 7: Professional & non professional use Outdoor: Bait trays for cockroaches, as a barrier at entry points. Max 6 applications per year. 0.1 – 0.2 g/m^2
Use 8: Professional & non professional use Outdoor: Bait trays for cockroaches, as a barrier at entry points. Max 6 applications per year. 0.2 – 0.3 g/m^2

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

The product contains the active substance imidacloprid (2.15%).
There are no substances of concern in the product.
There are no major metabolites detected in the water. Hence, the risk assessment does not describe these metabolites either.

In the Annex 1 decision, it is specifically noted that the following provisions are in place:
Products shall not be authorised for uses in animal housings where emission to a sewage treatment plant or direct emission to surface water cannot be prevented, unless data is submitted demonstrating that the product will meet the requirements of Article 5 and Annex VI, if necessary by the application of appropriate risk mitigation measures.
These provisions are included on the SPC.

The PEARL calculations result in low leaching potential, except for a single scenario (Piacenza). Kremsmuenster is safe (<0.01 g/L)

Mitigations:

General :

Instructions for use

1. Before treatment, remove all natural source of food for cockroaches (waste, food scraps ...) from the infested area to encourage the ingestion of the gel.
2. Apply the gel to identified areas but also between food sources as well as warm (<50 °C) and humid sheltered areas (corners, cracks, crevices, air ducts, behind baseboards and appliances, along pipes, close to water points ...).
3. During inspections, check the treated area and if necessary, replace the gel used as cockroaches leave secretions and faeces to attract conspecifics.
4. Dried out gel has to be replaced in order to maintain palatability of the product.
5. Inform the authorisation holder if the treatment is ineffective.

Risk Mitigations

1. Avoid any unnecessary contact to the preparation. Misuse may cause health damage.
2. Do not contaminate food, feed, eating utensils or food contact surfaces.
3. Keep out of reach of children.
4. Baits must be securely deposited in a way so as to minimise the risk of consumption by other animals or children.
5. Avoid release to the environment.

Indoor:

1. Apply the biocidal product only in cracks and crevices.
2. Do not expose bait drops to sunlight or heat source (i.e radiator).
3. If a large number of cockroaches is visible or is suspected, refer to the application rate for “high infestation”. If only a few or individual cockroaches have been seen, refer to the application rate for “low infestation”.

Outdoor:

1. The bait trays applied shall be tamper-resistant.
2. Do not force open the bait tray.
3. Do not use the product where release to drains (sewers) cannot be prevented.
4. Apply the product only in places where it is protected from rainfall events to prevent it from wash-out by rain.
5. Ensure that an accidental environmental release is avoided by unintentional movement of the product through wind, humans or larger animals.

In NL only indoor use (uses 1 to 6) is taken into consideration as we were informed by the KAD that the target organisms are not present in harmful quantities outdoor in the Netherlands. Therefore, the Ctgb derogates from the German authorisation according to article 37(e) of the BPR. This has been agreed and accepted by the applicant.

Overall conclusion for the aspect environment: The conclusions in the risk assessment for indoor use of the product are acceptable.

2.7 Substitution/exclusion criteria and comparative assessment

The active substance imidacloprid shall be considered a candidate for substitution using the criteria in Article 10(1) of the BPR, therefore a comparative assessment of IMIDASECT has been performed by RMS DE. The RMS has considered all authorised products for the relevant uses, and concluded that the comparative assessment for IMIDASECT can be finalised at the screening stage and that the product IMIDASECT can be authorised for a period not exceeding 5 years in accordance with Article 23(6) of the BPR.
As RMS DE has included in its assessment all products authorised according to the BPR in The Netherlands at the moment of the RMS authorisation, NL accepts the conclusion of the RMS.

3 Decision

The authorisation of IMIDASECT is based on mutual recognition of the authorisation of RMS DE. 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 IMIDASECT 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.