HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

BIJLAGE II (NL) bij het besluit d.d. 9 maart 2018 tot toelating van het biocide DELTASECT, toelatingsnummer NL-0018318-0000

Evaluation Report
Mutual Recognition

DELTASECT

9 March 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-0018318-0000	
Date of the authorisation	9 March 2018	
Expiry date of the authorisation	30 March 2027	

Trade name(s)	DELTASECT
Evaluating member state	United Kingdom
Name of the product in RMS	DELTASECT
Active substance	deltamethrin
PT	18
User category	Professional and non-professional

2 Summary of the product assessment

2.1 Classification and labelling

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

2.2 Packaging and shelf-life

Professional use

	Packaging authorised/ evaluated by RMS	Packaging applied for in NL	Packaging authorised in NL
Packaging size and type	25 – 5000mL HDPE or COEX bottles	25 – 5000mL HDPE or COEX bottles	25 – 5000mL HDPE or COEX bottles

Non-professional use

	Packaging authorised/ evaluated by RMS	Packaging applied for in NL	Packaging authorised in NL
Packaging size and type	25mL HDPE or COEX bottles	25mL HDPE or COEX bottles	25mL HDPE or COEX bottles

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 authorization by the eCA United Kingdom (DELTASECT, March 2017). The conclusions of the RMS are acceptable.

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 formulation DELTASECT is a suspension concentrate containing 2.394% deltamethrin, which is used againgst crawling insects including cockroaches and ants. The formulation is diluted before use, and applied in cracks and crevices by means of low pressure sprayer (handheld and backpack sprayer). The intended users include professionals as well as non-professionals. The Product Assessment Report (PAR) was prepared by the RMS UK.

Toxicity studies using Deltamethrin 2.5 SC have been supplied to address the acute oral, dermal and inhalation toxicity, skin and eye irritation and skin sensitisation. Based on these studies, no hazard classification of Deltamethrin 2.5 SC is required. However, DELTASECT contains preservatives (isothiazolones) at a concentration equal to or greater than one tenth of the relevant SCL. Therefore the following must be placed on the label: EUH208 ‘Contains 1,2-benzisothiazolin-3-one and a 3:1 mixture: 5-chlor-2-methyl-3(2H)-isothiazolone & 2-methyl-3(2H) isothiazolone). May produce an allergic reaction’. The conclusions of UK on formulation toxicity is accepted by the Ctgb.

No new dermal absorption data have been provided for Deltasect. The CAR for the active substance deltamethrin used a dermal absorption value of 2% as the worst case for a range of formulations and dilutions. This dermal absorption value is based on oil/water emulsion (EW) and emulsifiable concentrate (EC) tested formulations which usually show a higher skin penetration than water based formulations. Therefore, it is reasonable to use the dermal absorption value of 2% for the exposure calculations for Deltamethrin 2.5 SC. This is accepted by the Ctgb.

For primary exposure, exposure of professional and non-professional users were calculated using Spraying model 1 as the worst case, which presumes “Low pressure insecticide application. Professional operators mixing and loading liquids and powders in compression applicators, and applying at 1 or 3 bar pressure as a coarse or medium spray, indoors and outdoors, overhead and downwards”. Assuming working duration of 2 hours per day, the exposure level was calculated to be 0.0038 mg/kg bw/day for an adult of 60 kg, which is 51% of the short, medium and long-termAEL of deltamethrin (0.0075 mg/kg bw/day). UK concluded that no adverse effects from exposure to deltamethrin are expected for the unprotected professional and non-professional user during the application of DELTASECT for the control of insects. This is accepted by the Ctgb.

For secondary exposure, UK has considered 1) exposure of a toddler playing on treated surface including hand-to-mouth exposure, 2) inhalation exposure to residues dislodged from treated carpet, 3) sleeping on a treated mattress, and 4) laundering contaminated work clothing. Among these four scenarios the exposure in %AEL was the highest for the first scenario. For a toddler exposure was calculated to be 24% of the systemic short, medium and long-termAEL of deltamethrin. Therefore UK concluded risk is acceptable for the general public from the secondary exposure to deltamethrin. This conclusion is accepted by the Ctgb.

No local effects are expected as consequence of exposure to DELTASECT.

Furthermore, UK did not identify any 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 deltamethrin as a result of the application of DELTASECT, 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 deltamethrin as a result of the application of DELTASECT.

2.6 Risk assessment for the environment

DELTASECT is intended for the professional and non-professional control of crawling insects including ants and cockroaches as a crack and crevice treatment by low pressure spraying. The product is for indoor use in domestic, public and commercial premises.

Application rate: 50 mL of product diluted in 5L of water to treat 100 m2 surface.
Professional - Maximum 6-8 applications/year.
Non-Professional - Maximum 1-2 applications/year.
Treatment can be repeated after 2 months.

DELTASECT is similar to one of the representative products included in the deltamethrin assessment report. The representative product at EU review contained deltamethrin at a concentration of 26.25 g a.s/L and 12.5 mg a.s. was applied per m^2 of floor.

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

The product contains the active substance deltamethrin (2.4 % w/w). DELTASECT does not contain substances of concern for the environment.

In the public CAR, a major metabolite Br2CA is identified in water, sediment and soil compartments. Even if it is assumed that 100 % of metabolite could form in each of these compartments (noting that levels of only 13.3 % were identified in a microcosm study and 23 % were identified in a laboratory soil degradation study), then based on the lower molecular weight of Br2CA (298 g/mol as compared to deltamethrin at 505.2 g/mol) and reduced eco(toxicity) the level of risk posed by Br2CA can be considered to be negligible and covered by the risks calculated for the parent. Hence no assessment of the levels of, or the risk posed by, Br2CA have been calculated in the PAR of UK.

Overall conclusion for the aspect environment: The conclusions in the risk assessment of the RMS are valid.

2.7 Measures to protect man, animals and the environment

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

2.8 Substitution/exclusion criteria and comparative assessment

DELTASECT does not contain any active substances that are considered candidate for substitution.

3 Decision

The authorisation of DELTASECT is based on mutual recognition of the authorisation of RMS United Kingdom. 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 DELTASECT 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.