HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

BIJLAGE II bij het besluit d.d. 03-03-2017 tot toelating van het middel Autan protection plus dry spray, toelatingnummer NL-0011633-0000

Evaluation Report
Mutual Recognition

Autan protection plus dry spray

3-3-2017

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**	SC Johnson S.A.S.
	Address	10, Rue Saint-Hilaire 95004 Saint-Ouen-L'Aumone Cergy Pontoise FRANKRIJK
Authorisation number	NL-0011633-0000	
Date of the authorisation	03-03-2017	
Expiry date of the authorisation	20-02-2027	

Trade name	Autan protection plus dry spray
Evaluating member state	UK
Name of the product in RMS	Autan tropical dry spray
Active substance	DEET
PT	19
User category	Non-professionals

2 Summary of the product assessment

2.1 Classification and labelling

Based on the profile of the substance, the provided toxicology of the preparation, the characteristics of the co-formulants, the method of application and the risk assessment for the operator, as mentioned above, the following labeling of the preparation is proposed:

The identity of all substances in the mixture that contribute to the classification of the mixture *:			
-			
Pictogram:	GHS02 GHS07	Signal word:	Danger
H-statements:	H222	Extremely flammable aerosol.	
	H229	Pressurised container: May burst if heated.	
	H319	Causes serious eye irritation.	
	H412	Harmful to aquatic life with long lasting effects.	
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.	

	P210	Keep away from heat, hot surfaces, sparks, open flames, and other ignition sources. No smoking.
	P211	Do not spray on an open flame or other ignition source.
	P251	Pressurized container: Do not pierce or burn, even after use.
	P273	Avoid release to the environment.
	P305+P351+P338,	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
	P337+P313	If eye irritation persists: Get medical advice/attention.
	P410+P412	Protect from sunlight. Do not expose to temperatures exceeding 50°C/122°F
	P501	Dispose of contents/container to ....
Supplemental Hazard information:	-	
		No
Child-resistant fastening obligatory?		
Tactile warning of danger obligatory?		No

* according to Reg. (EC) 1272/2008, Title III, article 18, 3 (b)

2.2 Packaging and shelf-life

Non-professional use

	Packaging authorised/ evaluated by RMS	Packaging applied for in NL	Packaging authorised in NL
Packaging size and type	100mL steel/tin-plated aerosol cans	100mL steel/tin-plated aerosol cans	100mL steel/tin-plated aerosol cans

The provisional shelf life of the product is 24 months in steel/tin-plated aerosol cans.

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 Product Assessment Report of the original authorization by the RMS UK (Autan Tropical Dry Spray containing DEET, November 2016). NL does not agree with RMS UK that body parts to be treated are restricted due to the risk assessment performed by the UK. According to their use instructions only hands, face, neck, lower arms and upper parts of feet are treated. For example not treating the legs whereas this product has a claim against ticks is not a realistic use of a repellent, neither is this solved by adding a recommendation that clothing is used to cover any untreated areas of skin and so restrict access by biting insects. Therefore NL has adapted the use instructions on the SPC.

The other efficacy conclusions of the RMS are acceptable.

2.4.1 The label claim

The applicant has provided a Dutch SPC. NL has adapted the use instructions.

2.5 Risk assessment for human health

Autan protection plus dry spray is a ready-to-use aerosol containing 25.0% w/w DEET The product is intended for non-professional use. The Product Assessment Report (PAR) was prepared by the eCA United Kingdom (UK).

Formulation toxicity data for Autan protection plus dry spray studies with comparable products have been submitted for acute oral, acute dermal and acute inhalation studies and for skin and eye irritation. Overall, based on these data, the test materials and by read-across to Autan protection plus dry spray, the product requires classification for eye irritation (H319) under CLP. This is accepted by the Ctgb.
Furthermore, a skin sensitisation a Buehler study with the product was submitted, without argumentation on its acceptability (the Buehler test is known to be less sensitive). As the product is not classified for sensitising properties based on the classification rules as included in CLP, the use of the Buehler study can be accepted.

No dermal absorption was available for the product. A dermal absorption value of 20% is proposed by eCA UK for the assessment when applied alone, based on the outcome of the dermal absorption study from the CAR, as the product is comparable to the representative product in the CAR. However, a default dermal absorption value of 25% is included in the UK risk assessment the product is applied together with sun screens. The effect of sun lotions (or other dermal care products) on dermal absorption of PT19 products is not known. Therefore, it is unclear whether using the defaults according to the EFSA guidance will cover the combined effects. As more detailed information on the combined effect is lacking, NL CA does not agree to use this value in the risk assessment. , An assessment in line the CAR for DEET and in line with other NL authorisations for DEET containing PT19 products (i.e. use 20% for dermal absorption) will be performed.

Furthermore, the UK assessment is based on the applied amount from the efficacy studies, which only results in the safe use when the application is restricted to specific body parts once a day.
The NL CA does not consider that covering up body parts by clothing, that are excluded from treatment according to the instructions, as a realistic risk mitigation. NL CA assumes that people will treat this body parts instead. Furthermore, covering the body parts (and not treat these parts with the product) is not an effective risk mitigation measure, as insects can and will sting/bite through clothing anyway. This is also in line with the outcome of the CG-15 meeting.

As NL CA cannot agree with the UK , a risk assessment is performed comparing the applied product with national authorised products.
Based on comparable national authorised products with similar or higher concentration of DEET, the instructions for use must contain the following directions:

- Do not use more than once a day.
- Do not use on children (< 13 years old)
- Use only outdoors or in a well-ventilated area and do not inhale the product
- Keep this product away from children.

2.6 Risk assessment for the environment

Autan protection plus dry spray is a non-professional insect repellent (PT19) with N,N-diethyl-m-toluamide (DEET, 25% w/w) as active substance. It is to be marketed for topical application to skin of humans to repel various mosquito species. The product is sprayed onto hands, face, neck, lower arms, and upper part of feet twice per day. For the risk assessment for the environment we refer to Product Assessment Report of the original authorisation.

The risk assessment was made according to the latest draft version of the PT19 ESD as the final version was not yet available at the time of the assessment. Three scenarios were run, namely:

- Consumption approach in which DEET is discharged to the sewer during showering;
- Swimming model to calculate direct emission to surface water;
- Direct release to soil due to spray drift.

Endpoints (fate and ecotox) were in accordance with the CAR. No new data have been submitted meanwhile. As DEET is readily biodegradable and no metabolites >10% were identified, no risk assessment for metabolites was required. The risk assessment was entirely based on the physical-chemical and ecotoxicological properties of DEET.

For the showering scenario the UK CA:

- lowered the fraction released to water from 1 to 0.887 assuming a degree of loss by metabolism and emission to air;
- increased the fraction inhabitants using the product from 0.2 to 0.37;
- decreased the penetration factor from 0.5 to 0.28;
- decreased the skin area from 11240 cm^2 to 10000 cm^2;

, which is in accordance with the CAR. The above listened adapted parameters reduced the emission from 1.60 to 1.38 kg/d. Nevertheless, the PNECs in surface water, sediments, and soils as calculated by the UK CA are well below one (0.202, 0.202, and 0.221, respectively), the final conclusions will remain unaffected if emission was calculated according to the ESD (both draft and final version).

The UK CA has applied a lake volume of 1.2 Mm^3 while the volume was reduced to 0.435 Mm^3 in the final ESD. Furthermore, the concentration in surface water over 91 days was calculated according to PT08 instead of the ESD for PT19. Although the applied formula is correct, it calculates a time-weighted average concentration which is not feasible for concentrations that increase in time. Therefore, the concentration was underestimated as the PEC after 91 days is higher than the PEC averaged over 91 d. Nevertheless, the difference between plateau concentration and time-weighted average concentrations is a factor of two for active substances that do not degrade and negligible for fast degrading compounds like DEET. At last, the UK has applied a skin area of 10000 cm^3, while it may be expected that a major part of the body is unprotected. Therefore, the total skin area including trunks as suggested in the ESD (16600 cm^3) is more realistic. In the other hand, the UK CA has increased the number of daily applications from 1 to 2. Also note that concentrations were not corrected for sorption onto suspended matter. Although the calculated PECs are best-case, PEC calculations according to the ESD will not results in a different conclusion considering a PEC:PNEC ratios of 0.159.

Spray drift during application results in unacceptable risks for the soil compartment (PEC:PNEC are 4.7 for grassland and 23.3 for arable land). Without any scientific substantiation, the UK CA accepts these values as 10% spray drift (default) is unrealistic and 1% was considered more likely. Moreover, the soil area affected (1 m^2) is <1% of the overall area of a domestic garden. Therefore, repopulation would occur when degradation reduces concentrations below the PNEC. We consider the UK CA's argumentation plausible.

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

2.7 Measures to protect man, animals and the environment

Based on this risk assessment, it was concluded that no adverse health effects are expected for the unprotected non-professional user after dermal and respiratory exposure to DEET as a result of the application of Autan protection plus dry spray, 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 DEET as a result of the application of Autan protection plus dry spray.

The instructions for use in the SPC must contain the following directions:

- Do not use more than once a day.
- Do not use on children (< 13 years old)
- Use only outdoors or in a well-ventilated area and do not inhale the product
- Keep this product away from children.

2.8 Substitution/exclusion criteria and comparative assessment

Autan protection plus dry spray does not contain any active substances that are considered candidate for substitution.

3 Decision

The authorisation of Autan protection plus dry spray 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. By way of derogation from article 32(2), NL has proposed to adjust the terms and conditions of the authorisation to be granted, which is considered justified on grounds of the protection of health of humans. In accordance with article 37(2) the proposed derogation was communicated to the applicant and an agreement was reached.

It is concluded that the application of Autan protection plus dry spray 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.