

Draft scenario to estimate the indirect exposure via food by using insect repellents developed by the ARTFood ad hoc Working Group of the Biocidal Product Committee

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Insect Repellent with skin application

Assessment approach

Insect repellent products (PT 19) available for non-professional use can be applied directly on the skin (i.e. aerosol, pump spray, lotion). The product is applied using hands palms on different parts of the body (hands, arms, head, legs and feet). The a.s. may be transferred from the treated hands to the food¹.

Considering that the exposure to repellent residues via food is not negligible, a scenario to estimate the dietary exposure and risk via food is derived hereafter². Considering that repellents are not used year-round, only acute exposure is estimated (and ARfD should be used in the DRA). No assessment of chronic exposure is therefore considered necessary.

Assumptions

- The application rate, expressed as mg of BP per cm² of treated skin (mg product/cm²), is considered to estimate the exposure (one application just before food handling is considered relevant).
- The default values of hand surface that can be in contact with food are expressed as cm² and they represent 100% of hand surface areas for toddler and children (i.e. inside and outside of both hands), and 50% of hands surface area for adults³ (i.e. inside of both hands) (see Appendix 5-2 for default values)
- Transfer factor from hand to food: 50% (see Appendix 5-2 for default values)
- Exposure of all intended age groups (see Appendix 5-2)

¹ Food contamination were detected for some active substances. This might be related to the use of PT19 BP by worker harvesting food crops (EC 2018: Health and Food Safety Directorate General, sante.ddg2.g.5(2018)5591112, Summary Report of the Standing Committee on plants, animals, Food and Feed held in Brussels on 17 September 2018 (Section Novel Food and Toxicological Safety of the Food Chain), CIRCABC Link: <https://circabc.europa.eu/w/browse/6b693e53-a6ac-42e5-8922-b75d2661b3cb>)

² This scenario was agreed on at ARTFood meeting in November 2019.

³ in line with Recommendations no. 11 and 14 of the BPC Ad hoc Working Group on Human Exposure

- 42 • The frequency of hand contact with food should not be included in the
43 calculation.

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45 **Refinement options**

- 46• A retention factor of 10%⁴ after rinsing can be used to refine exposure if hands are
47 washed after application (see Appendix 5-2 for default values). Such a retention factor
48 should only be used if a RMM requiring to wash hands after use of the product appears
49 practicable for the product under evaluation.

50 **Estimation of indirect exposure via food**

51
$$\mathbf{Exp_{cons} = ApplRate * C * Hfood\ contact * TF (*RF) / bw}$$

52 **Where:**

53	Exp_{cons}	Dietary exposure (mg a.s./kg bw/d)
54	ApplRate	Application rate (mg product/cm ²)
55	C	Concentration of a.s. in the BP (% w/w or mg/100 mg)
56	Hfood contact	Hand surface in contact with food (cm ²)
57	TF	% of biocide residue transferred from hands surface to food
58	RF	% of biocide residue retained after hands washing
59	bw	Body weight (kg bw)

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4 in line with Notes of guidance for testing of cosmetic ingredients for their safety evaluation SCCNFP/0321/00
Final

Example : Insect Repellent with skin application

Biocidal product: a pump spray is used on human skin to repel mosquitos from non-professional users, on all age groups with the following RMM: "wash hands after use and before handling food"

Estimation of acute consumer exposure

ApplRate Application rate in mg of BP/cm²: 1.5 (value given by the Applicant)

C Concentration of a.s. in BP: 20% (value given by the Applicant)

Hfood contact 230.4 cm² for toddler (1-2 years old)
 330.9 cm² for children (2-6 years old)
 427.8 cm² for children (6-12 years old)
 410 cm² for adults
 (default values according to Headhoc Recommendation No. 14)

TF 50% (default value)

RF 10% (default value for refinement option)

bw 10 kg for toddler (1-2 years old)
 15.6 kg for children (2-6 years old)
 23.9 kg for children (6-12 years old)
 60 kg for adults
 (default values according to Headhoc Recommendation No. 14)

Toddler Exp_{cons} = 1.5 mg/cm² x 20% x 230.4 cm² x 50% x 10% ÷ 10 kg
 = 0.35 mg/kg bw/d

Children 2-6 years old Exp_{cons} = 1.5 mg/ cm² x 20% x 330.9 cm² x 50% x 10% ÷ 15.6 kg
 = 0.32 mg/kg bw/d

Children 6-12 year old Exp_{cons} = 1.5 mg/ cm² x 20% x 427.8 cm² x 50% x 10% ÷ 23.9 kg
 = 0.27 mg/kg bw/d

Adult Exp_{cons} = 1.5 mg/ cm² x 20% x 410 cm² x 50% x 10% ÷ 60 kg
 = 0.10 mg/kg bw/d

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Remark: the following precautionary advices are recommended to be added for all PT19 BP with skin application, independently from the results of the DRA:

- "Avoid contact of the treated skin or clothes with food."
- "Do not use the product near food and surfaces that may come into contact with food and feed or drinks for human consumption"

Additional standard sentences can be found at [Frequently used sentences in the SPC](#)

If the applicant proposed restriction for the biocidal product application, the exposure and risk should be assessed with the intended RMM (i.e. "For children 2 to 12 years: The repellent must be applied by adults", "Do not apply to children's hands", "wash hands before handling food", etc).

No.	Description	Default values	Background information: Remarks	References
6.5 Insect Repellent with skin application				
22	hand surface that can be in contact with food for children	100% Equivalent to: 230.4 cm ² for toddler	100% of hand surface areas for toddler and children (i.e. palms and backs of both hands) is the worst case for children.	Recommendations no. 11 and 14 of the BPC Ad hoc Working Group on Human Exposure ARTFood meeting in November 2019

		(1-2 years old) 330.9 cm ² for children (2-6 years old) 427.8 cm ² for children (6-12 years old)		
23	hand surface that can be in contact with food for adults	50% Equivalent to: 410 cm ²	50% of hand surface areas for adult (i.e. palms of both hands) is the reasonable worst case for adult.	Recommendations no. 11 and 14 of the BPC Ad hoc Working Group on Human Exposure ARTFood meeting in November 2019
24	Transfer factor from hand to food	50%	Considered as a reasonable worst case of transfer agreed by ArtFood members	ARTFood meeting in November 2019
25	retention factor after rinsing	10%	Considered as a reasonable refining factor in accordance with SCCNFP/0321/00 Final (p.60 for rinse-off products) and agreed by ArtFood 2019	Notes of guidance for testing of cosmetic ingredients for their safety evaluation SCCNFP/0321/00 Final (Scientific Committee on Cosmetic Products and Non-Food Products) ARTFood meeting in November 2019
26	Body weight	See HEEG opinion 17		Recommendations no. 11 and 14 of the BPC Ad hoc Working Group on Human Exposure
27	Body surfaces	See HEEG opinion 17		Recommendations no. 11 and 14 of the BPC Ad hoc Working Group on Human Exposure

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