Biocidal Products Committee (BPC)

Opinion on the application for approval of the active substance:

Icaridin

Product type: 19

ECHA/BPC/229/2019

Adopted

10 December 2019

Opinion of the Biocidal Products Committee

on the application for approval of the active substance icaridin for product type 19

In accordance with Article 89(1) of Regulation (EU) No 528/2012 of the European Parliament and of the Council 22 May 2012 concerning the making available on the market and use of biocidal products (BPR), the Biocidal Products Committee (BPC) has adopted this opinion on the approval in product type 19 of the following active substance:

Common name:	**Icaridin**
Chemical name:	***(RS)*-sec-butyl *(RS)*-2-(2-hydroxyethyl)piperidine-1-carboxylate**[1]
EC No.:	**423-210-8**
CAS No.:	**119515-38-7**
Existing active substance	

This document presents the opinion adopted by the BPC, having regard to the conclusions of the evaluating Competent Authority. The assessment report, as a supporting document to the opinion, contains the detailed grounds for the opinion.

Process for the adoption of BPC opinions

Following the submission of an application by Saltigo GmbH on 20 April 2006, the evaluating Competent Authority Danish EPA submitted an assessment report and the conclusions of its evaluation to the Commission on 14 January 2011. In order to review the assessment report and the conclusions of the evaluating Competent Authority, the Agency organised consultations via BPC (BPC-28 and BPC-33) and its Working Groups (WG 1 2017 and WG IV 2019). Revisions agreed upon where presented and the assessment report and the conclusions were amended accordingly.

[1] Original version of the BPC opinion contained the incorrect “Chemical name”. This has been replaced by the correct name in May 2020.

Adoption of the BPC opinion

Rapporteur: Denmark

The BPC opinion on the approval of the active substance Icaridin in product type 19 was adopted on 10 December 2019.

The BPC opinion was adopted by consensus. The opinion is published on the ECHA webpage at: http://echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances/bpc-opinions-on-active-substance-approval.

Detailed BPC opinion and background

1. Overall conclusion

The overall conclusion of the BPC is that icaridin in product type 19 may be approved. The detailed grounds for the overall conclusion are described in the assessment report.

2. BPC Opinion

2.1. BPC Conclusions of the evaluation

a) Presentation of the active substance including the classification and labelling of the active substance

This evaluation covers the use of icaridin in product type 19. Specifications for the reference source are established.

The physico-chemical properties of the active substance and biocidal product have been evaluated and are deemed acceptable for the appropriate use, storage and transportation of the active substance and biocidal product.

Validated analytical methods are available for the active substance as manufactured and for the relevant and significant impurities. Validated analytical methods are available for the relevant matrix soil. Validated analytical methods are missing and required at product authorisation for icaridin and icaridin-acid residues in surface water and groundwater, please refer to section 2.5.

A harmonized classification and labelling according to Regulation (EC) No 1272/2008 is not available for icaridin. A CLH dossier will be submitted end 2019.

The (proposed) classification and labelling for icaridin according to Regulation (EC) No 1272/2008 (CLP Regulation) is:

(Proposed) Classification according to the CLP Regulation	
Hazard Class and Category Codes	No classification is warranted to any hazard class
Labelling	
Pictogram codes	None
Signal Word	None
Hazard Statement Codes	None
Specific Concentration limits, M-Factors	None
Justification for the proposal	
-	

b) Intended use, target species and effectiveness

Icaridin is an insect repellent to be used by non-professional users of the general public.

The landing behaviour of target animals is strongly inhibited by the odour released by icaridin. Thus, the active substance reduces the host attractiveness and prevents landing and biting of insects. The repellent effect of the active substance starts immediately after application on skin and develops full performance within a few minutes. Due to the mode of action a development of resistance is neither to be expected nor has ever been observed.

The representative product contains 20% icaridin and is to be applied on face, neck, arms, hands, legs and feet which is the proper use, i.e. the use in compliance with the conditions on the label: once a day for adults and children (≥ 2 years).

Sufficient efficacy with a protection time of 4.9 hours with *Culex quinquefasciatus* as target organism was demonstrated. Efficacy requirements may be subject to national specificities as only efficacy against *Culex* may be insufficient in some Member States (MS) at authorisation stage.

c) Overall conclusion of the evaluation including need for risk management measures

Human health

Icaridin is of low acute toxicity. It is not irritating to the skin and only slightly eye irritating. The substance is not sensitising. The target organs for icaridin toxicity are liver and kidney both after oral and dermal repeated administration of icaridin to rats revealed increased organ weights and, hepatocellular hypertrophy and degenerative nephropathy. The substance is not a developmental toxicant, and no evidence of mutagenicity was reported. No effects were seen in studies of reproductive and carcinogenic effects. Icaridin is not classifiable according to the criteria rules of Regulation 1272/2008/EC.

The table below summarises the exposure scenarios assessed.

Summary table: human health scenarios			
Scenario	**Primary or secondary exposure and description of scenario[2]**	**Exposed group**	**Conclusion**
Non professionals	Primary Tier I, two dermal application per day Primary Tier II, one dermal application per day	adults and children (6-11 years) children (≥ 2-6 years)	Acceptable
Non professionals	Primary Tier I, two dermal applications and secondary Tier I (oral uptake) Primary Tier II, one dermal application and secondary Tier I (oral uptake)	toddlers (1-<2 years) infants (6-12 month)	Unacceptable

The overall outcome of the risk assessment for humans which covers the use of the representative product (containing 20% icaridin) on face, arms, hands, legs and feet (which is the proper use in compliance with the conditions on the label), shows acceptable risks for adults and children (2-11 years) applying the product twice a day. However, due to the environment risk assessment using the product once per day is currently only acceptable. An unacceptable risk for children younger than 2 years old was identified.

[2] The HEEG opinion 17 "Default human factor values for use in exposure assessments for biocidal products, RIVM report General Fact Sheet General Default parameters for estimating consumer exposure - Updated version 2014 and comparison with recent revised Recommendation 11 (Jan 2018) and the HEAdhoc recommendation "Proposal for harmonising the assessment of human exposure to repellents (PT19)". For age groups justification, please refer to footnote 3 in Document IIB.

Acceptable risks were identified for adults and children ≥ 2 years using the representative product twice a day applying an $AEL_{medium\text{-}term}$ of 1.4 mg/kg bw/day (AF 67 by using human data to adjust the value from an animal study).

However, an unacceptable risk has been identified for, toddlers and infants from the use of the representative product in both Tier I and Tier II.

For the endocrine-disrupting properties with respect to humans no conclusion can be drawn with the data currently available. It should be noted that there were no indications of ED properties in the available data.

Environment

Considering the hydrolytic stability of icaridin determined under relevant environmental pH and temperature conditions, it is not expected that hydrolytic processes will contribute to the degradation of icaridin in the environment. Due to its lack of UV absorbance in the sunlight region icaridin is not degradable by direct photodegradation in water.

Model calculations indicate a rapid degradation of icaridin when entering the atmosphere. Hence, air will not be an environmental compartment of concern for the compound used in repellents.

Icaridin is not ready biodegradable and it was also not inherently biodegradable. Biodegradation of icaridin in freshwater shows that icaridin is not persistent but that icaridin-acid is a P/vP substance. Degradation of icaridin in both compartments of a water sediment system proceeded via formation of icaridin-acid. The degradation of icaridin in soil incubated under aerobic conditions proceeds primarily via the formation of icaridin-acid and of bound residues. A fast degradation in soil was seen for both icaridin and icaridin-acid (hours to a few days).

Based on the estimated K_{oc} value icaridin can be assumed to have a high potential for mobility in soils. Icaridin-acid has a significant lower leaching potential; however icaridin-acid is still considered to have a moderate-high potential for mobility in soils.

The log K_{OW} for icaridin, indicate a low bioaccumulation potential. Measured BCF values indicates some potential for bioaccumulation, but since the depuration is rapid no risk for bioaccumulation is anticipated. The risk of secondary poisoning is therefore expected to be low via ingestion of potentially contaminated food (e.g., fish, earthworms) by birds or mammals. For icaridin-acid, the B criterion is not fulfilled.

Icaridin and icaridin-acid is not classified as very toxic to aquatic life and is not assumed to cause long lasting effects.

An application rate of 2.92 g product, corresponding to 0.584 g icaridin per person per day has been used for the environmental exposure assessment. This corresponds to one application per day. Two applications per day was not assessed in the environmental risk assessment.

The predicted environmental concentrations (PECs) for the consumption scenario have been estimated for the aquatic compartment including the sewage treatment plant (STP), surface water, and sediment, and for the terrestrial compartment including soil and groundwater. Stages of the product's lifecycle considered as relevant for the consumption scenario are surface application to human skin for non-professional use.

The table below summarises the exposure scenarios assessed.

Summary table: environment scenarios		
Scenario	**Description of scenario including environmental compartments**	**Conclusion**
Consumption based scenario		
Non-professional use via showering or bathing of humans who have used icaridin	STP is considered as primary receiving compartment with subsequent emissions to surface water, sediment, soil and groundwater.	Acceptable risk identified for all environmental compartments.
Via swimming outdoor	Direct release to surface water and sediment	Acceptable risk identified for both environmental compartments.

It can be concluded that the evaluated use of icaridin in PT 19 does not present a risk for the environment when applied once per day.

For the endocrine-disrupting properties with respect to non-target organisms no conclusion can be drawn with the data currently available.

Overall conclusion

Acceptable risks are identified for the environment and human health for non-professional use of the product if one application per day is used. The environment risk assessment has only assessed one application per day while the risk assessment for human health includes calculations for two application per day. Therefore, an overall conclusion can only be made for one application per day.

An unacceptable risk is identified for children under 2 years of age in the human health risk assesment.

2.2. Exclusion, substitution and POP criteria

2.2.1. Exclusion and substitution criteria

The table below summarises the relevant information with respect to the assessment of exclusion and substitution criteria:

Property		Conclusions	
CMR properties	Carcinogenicity (C)	No classification required	Icaridin does not fulfil criterion (a), (b) and (c) of Article 5(1)
	Mutagenicity (M)	No classification required	
	Toxic for reproduction (R)	No classification required	
PBT and vPvB properties	Persistent (P) or very Persistent (vP)	Icaridin: not P or vP Icaridin-acid: P and vP	Icaridin does not fulfil criterion (e) of Article 5(1) and
	Bioaccumulative	Icaridin and icaridin-	

	(B) or very Bioaccumulative (vB)	acid: not B or vB	does not fulfil criterion (d) of Article 10(1)
	Toxic (T)	Icaridin and icaridin-acid: not T	
Endocrine disrupting properties	Section A of Regulation (EU) 2017/2100: ED properties with respect to humans	No conclusion can be drawn based on the available data.	No conclusion can be drawn whether icaridin fulfils criterion (d) of Article 5(1) and/or criterion (e) of Article 10(1)
	Section B of Regulation (EU) 2017/2100: ED properties with respect to non-target organisms	No conclusion can be drawn based on the available data.	
	Article 57(f) and 59(1) of REACH	No	
	Intended mode of action that consists of controlling target organisms via their endocrine system(s).	No	
Respiratory sensitisation properties	Icaridin does not fulfil criterion (b) of Article 10(1).		
Concerns linked to critical effects other than those related to endocrine disrupting properties	For icaridin no concerns regarding critical effects according to criterion (e) of Article 10(1) are identified.		
Proportion of non-active isomers or impurities	Icaridin does not fulfil criterion (f) of Article 10(1).		

The exclusion and substitution criteria were assessed in line with the "Note on the principles for taking decisions on the approval of active substances under the BPR"[3], with "Further guidance on the application of the substitution criteria set out under Article 10(1) of the BPR"[4] and with "Implementation of scientific criteria to determine the endocrine-disrupting

[3] See document: Note on the principles for taking decisions on the approval of active substances under the BPR (available from https://circabc.europa.eu/d/a/workspace/SpacesStore/c41b4ad4-356c-4852-9512-62e72cc919df/CA-March14-Doc.4.1%20-%20Final%20-%20Principles%20for%20substance%20approval.doc)

[4] See document: Further guidance on the application of the substitution criteria set out under article 10(1) of the BPR (available from https://circabc.europa.eu/d/a/workspace/SpacesStore/dbac71e3-cd70-4ed7-bd40-fc1cb92cfe1c/CA-Nov14-Doc.4.4%20-%20Final%20-%20Further%20guidance%20on%20Art10(1).doc)

properties of active substances currently under assessment"[5] agreed at the 54th, 58th and 77th meeting respectively, of the representatives of Member States Competent Authorities for the implementation of Regulation 528/2012 concerning the making available on the market and use of biocidal products. This implies that the assessment of the exclusion criteria is based on Article 5(1) and the assessment of substitution criteria is based on Article 10(1)(a, b, d, e and f).

Consequently, the following is concluded:

Icaridin does not meet the exclusion criteria laid down in Article 5(1)(a, b, c and e) of Regulation (EU) No 528/2012. For the endocrine-disrupting properties as defined in Regulation (EU) No 2017/2100, no conclusion can be drawn on the available data. For reports submitted before 1 September 2013, it is mentioned in the CA meeting note mentioned above that the evaluating Competent Authority has to conclude based on the already available data and/or the data provided by the applicant and, in case the data is insufficient to reach a conclusion, the BPC may conclude in its opinion that no conclusion could be drawn. It is noted that the evaluation of icaridin for PT 19 was submitted before 1 September 2013. Consequently, no conclusion is drawn whether icaridin meets the conditions laid down in Article 5(1)(d) based on the available data.

Icaridin does not meet the conditions laid down in Article 10(1)(b, c,d and f) of Regulation (EU) No 528/2012**.** For the endocrine-disrupting properties as defined in Regulation (EU) No 2017/2100, no conclusion can be drawn on the available data. For reports submitted before 1 September 2013, it is mentioned in the CA meeting note mentioned above that the evaluating Competent Authority has to conclude based on the already available data and/or the data provided by the applicant and, in case the data is insufficient to reach a conclusion, the BPC may conclude in its opinion that no conclusion could be drawn. It is noted that the evaluation of icaridin for PT 19 was submitted before 1 September 2013. Consequently, no conclusion is drawn whether icaridin meets the conditions laid down in Article 10(1)(a and e) based on the available data.

2.2.2. POP criteria

Icaridin does not fulfil any of the PBT criteria and the long-range transport criterion according to the Stockholm convention (half-life in air of more than two days) is not fulfilled. Therefore, icaridin does not fulfil the POP criteria.

2.3. BPC opinion on the application for approval of the active substance Icaridin in product type 19

In view of the conclusions of the evaluation, it is proposed that icaridin shall be approved and be included in the Union list of approved active substances, subject to the following specific conditions:

1. Specification: minimum purity of the active substance evaluated: 97 % w/w.

   Maximum content of relevant impurities**:** toluene max 0.1 % w/w**.**

2. The authorisations of biocidal products are subject to the following condition(s):

   a. The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for

[5] See document: Implementation of scientific criteria to determine the endocrine-disrupting properties of active substances currently under assessment (available from https://circabc.europa.eu/ui/group/e947a950-8032-4df9-a3f0-f61eefd3d81b/library/48320db7-fc33-4a91-beec-3d93044190cc/details)

authorisation, but not addressed in the Union level risk assessment of the active substance.

b. For products that may lead to residues in food or feed, the need to set new or to amend existing maximum residue levels (MRLs) in accordance with Regulation (EC) No 470/2009 or Regulation (EC) No 396/2005 shall be verified, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded.

c. In view of the risks identified for the uses assessed, the product assessment shall pay particular attention to:

    i. Children younger than 2 years following dermal and secondary exposure.

The active substance does not fulfil the criteria according to Article 28(2) to enable inclusion in Annex I of Regulation (EU) 528/2012, as the major metabolite icaridin-acid is vP.

2.4. Elements to be taken into account when authorising products

The following recommendations and risk mitigation measures have been identified for the uses assessed. Authorities should consider these risk mitigation measures when authorising products, together with possible other risk mitigation measures, and decide whether these measures are applicable for the concerned product:

a. Efficacy was demonstrated against *Culex quinquefasciatus*. Efficacy requirements may be subject to national specifities as efficacy against *Culex alone* may be insufficient in some MS at authorisation stage.

b. An unacceptable risk is identified for children under 2 years of age with the representative product. If the risk cannot be reduced to an acceptable level by appropriate risk mitigation measures or by other means, these uses should not be authorised.

c. The daily number of applications should be considered carefully in relation to the concentration of the product. It is noted that acceptable use for both human health and the environment has only been demonstrated with one application per day, corresponding to 0.584 g icaridin per person per day (ensuring efficacy for 4.9 hours).

d. A bittering agent should be included in the product.

e. The label shall include information that the product should only be applied to face, arms, neck, hands, legs and feet and that contact to eyes should be avoided and that hands should be washed after use.

f. An assessment of the risk in food and feed areas may be required at product authorisation where use of the product may lead to contamination of food and feeding stuffs.

2.5. Requirement for further information

Sufficient data have been provided to verify the conclusions on the active substance, permitting the proposal for the approval of icaridin.

However further studies are required: further data on analytical methods for determining icaridin and icaridin-acid residues in surface water and groundwater must be provided as soon as possible but no later than 6 months before the date of approval to the evaluating Competent Authority (Denmark).

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