Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

**PRODUCT ASSESSMENT REPORT OF BIOCIDAL PRODUCT FAMILY FOR MINOR CHANGE OF NATIONAL AUTHORISATION APPLICATIONS**

(submitted by the evaluating Competent Authority)



CINQ SUR CINQ LOTION

Product type 19

Ethyl butylacetylaminopropionate (IR 3535)

Case Number (NA-APP) in R4BP: BC-KV020758-09  
Case Number (NA-MIC) in R4BP: BC-AR056140-44

Evaluating Competent Authority: France

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Table of Contents

[Table of Contents 2](#_Toc30683227)

[*1* CONCLUSION 7](#_Toc30683228)

[*2* ASSESSMENT REPORT 13](#_Toc30683229)

[2.1 Summary of the product assessment 13](#_Toc30683230)

[Part I.- First information level 13](#_Toc30683231)

[2.1.1 Administrative information 13](#_Toc30683232)

[**2.1.1.1** Identifier of the product / product family 13](#_Toc30683233)

[**2.1.1.2** Authorisation holder 13](#_Toc30683234)

[**2.1.1.3** Manufacturer(s) of the products of the family 13](#_Toc30683235)

[**2.1.1.4** Manufacturer(s) of the active substance(s) 13](#_Toc30683236)

[2.1.2 Product (family) composition and formulation 14](#_Toc30683237)

[**2.1.2.1** Identity of the active substance 14](#_Toc30683238)

[**2.1.2.2** Candidate(s) for substitution 14](#_Toc30683239)

[**2.1.2.3** Qualitative and quantitative information on the composition of the biocidal product family 14](#_Toc30683240)

[**2.1.2.4** Information on technical equivalence 14](#_Toc30683241)

[**2.1.2.5** Information on the substance(s) of concern 15](#_Toc30683242)

[Please see the confidential annex for further details. 15](#_Toc30683243)

[**2.1.2.6** Assessment of endocrine disruption (ED) properties of the biocidal products of BPF 15](#_Toc30683244)

[**2.1.2.7** Type of formulation 15](#_Toc30683245)

[Part II.- Second information level - meta SPC 1 15](#_Toc30683246)

[1. Meta SPC 1 administrative information 15](#_Toc30683247)

[1.1. Meta SPC identifier 15](#_Toc30683248)

[1.2. Suffix to the authorisation number 15](#_Toc30683249)

[1.3. Product type(s) 15](#_Toc30683250)

[2. Meta SPC 1 composition 16](#_Toc30683251)

[2.1. Qualitative and quantitative information on the composition of the meta SPC 1 16](#_Toc30683252)

[2.2. Type(s) of formulation of the meta SPC 1 16](#_Toc30683253)

[3. Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 1 16](#_Toc30683254)

[4. Authorised use(s) of the meta SPC 1 16](#_Toc30683255)

[4.1.1. Use-specific instructions for use 18](#_Toc30683256)

[The product must not be used for tropical species. 18](#_Toc30683257)

[4.1.2 Use-specific risk mitigation measures 18](#_Toc30683258)

[4.1.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment 18](#_Toc30683259)

[4.1.4 Where specific to the use, the instructions for safe disposal of the product and its packaging 18](#_Toc30683260)

[4.1.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage 18](#_Toc30683261)

[4.2.1. Use-specific instructions for use 19](#_Toc30683262)

[The product must not be used for tropical species. 19](#_Toc30683263)

[4.2.2 Use-specific risk mitigation measures 19](#_Toc30683264)

[4.2.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment 19](#_Toc30683265)

[4.2.4 Where specific to the use, the instructions for safe disposal of the product and its packaging 19](#_Toc30683266)

[4.2.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage 19](#_Toc30683267)

[5. General directions for use of the meta SPC 1 19](#_Toc30683268)

[*5.1. Instructions for use* 19](#_Toc30683269)

[*5.2. Risk mitigation measures* 20](#_Toc30683270)

[*5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment* 20](#_Toc30683271)

[*5.4. Instructions for safe disposal of the product and its packaging* 20](#_Toc30683272)

[*5.5. Conditions of storage and shelf-life of the product under normal conditions of storage* 21](#_Toc30683273)

[Part III - Third information level: individual products in the meta SPC 1 21](#_Toc30683274)

[1. Trade name(s), authorisation number and specific composition of each individual product 21](#_Toc30683275)

[Part II.- Second information level - meta SPC 2 21](#_Toc30683276)

[1.1. Meta SPC identifier 21](#_Toc30683277)

[1.2. Suffix to the authorisation number 21](#_Toc30683278)

[1.3. Product type(s) 21](#_Toc30683279)

[2. Meta SPC 2 composition 22](#_Toc30683280)

[2.1. Qualitative and quantitative information on the composition of the meta SPC 2 22](#_Toc30683281)

[2.2. Type(s) of formulation of the meta SPC 2 22](#_Toc30683282)

[4.1.1. Use-specific instructions for use 24](#_Toc30683283)

[The product must not be used for tropical species. 24](#_Toc30683284)

[4.1.2 Use-specific risk mitigation measures 24](#_Toc30683285)

[4.1.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment 24](#_Toc30683286)

[4.1.4 Where specific to the use, the instructions for safe disposal of the product and its packaging 24](#_Toc30683287)

[4.1.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage 24](#_Toc30683288)

[4.1.1. Use-specific instructions for use 25](#_Toc30683289)

[The product must not be used for tropical species. 25](#_Toc30683290)

[4.1.2 Use-specific risk mitigation measures 25](#_Toc30683291)

[4.1.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment 25](#_Toc30683292)

[4.1.4 Where specific to the use, the instructions for safe disposal of the product and its packaging 25](#_Toc30683293)

[4.1.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage 25](#_Toc30683294)

[5. General directions for use of the meta SPC 2 25](#_Toc30683295)

[*5.1. Instructions for use* 25](#_Toc30683296)

[*5.2. Risk mitigation measures* 26](#_Toc30683297)

[*5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment* 26](#_Toc30683298)

[*5.4. Instructions for safe disposal of the product and its packaging* 26](#_Toc30683299)

[*5.5. Conditions of storage and shelf-life of the product under normal conditions of storage* 27](#_Toc30683300)

[6. Other information 27](#_Toc30683301)

[Part III - Third information level: individual products in the meta SPC 2 27](#_Toc30683302)

[1. Trade name(s), authorisation number and specific composition of each individual product 27](#_Toc30683303)

[Part II.- Second information level - meta SPC 3 28](#_Toc30683304)

[1.1. Meta SPC identifier 28](#_Toc30683305)

[1.2. Suffix to the authorisation number 28](#_Toc30683306)

[1.3. Product type(s) 28](#_Toc30683307)

[2. Meta SPC 3 composition 28](#_Toc30683308)

[2.1. Qualitative and quantitative information on the composition of the meta SPC 3 28](#_Toc30683309)

[2.2. Type(s) of formulation of the meta SPC 3 28](#_Toc30683310)

[3. Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 3 28](#_Toc30683311)

[4. Authorised use(s) of the meta SPC 3 29](#_Toc30683312)

[4.1.1. Use-specific instructions for use 30](#_Toc30683313)

[4.1.2 Use-specific risk mitigation measures 30](#_Toc30683314)

[4.1.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment 30](#_Toc30683315)

[4.1.4 Where specific to the use, the instructions for safe disposal of the product and its packaging 31](#_Toc30683316)

[4.1.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage 31](#_Toc30683317)

[5. General directions for use of the meta SPC 3 31](#_Toc30683318)

[*5.1. Instructions for use* 31](#_Toc30683319)

[*5.2. Risk mitigation measures* 31](#_Toc30683320)

[*5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment* 31](#_Toc30683321)

[*5.4. Instructions for safe disposal of the product and its packaging* 32](#_Toc30683322)

[*5.5. Conditions of storage and shelf-life of the product under normal conditions of storage* 32](#_Toc30683323)

[Part III - Third information level: individual products in the meta SPC 3 32](#_Toc30683324)

[1. Trade name(s), authorisation number and specific composition of each individual product 32](#_Toc30683325)

[2.1.3 Packaging of the biocidal product family 33](#_Toc30683326)

[2.1.4 Documentation 33](#_Toc30683327)

[**2.1.4.1** Data submitted in relation to product application 33](#_Toc30683328)

[**2.1.4.2** Access to documentation 35](#_Toc30683329)

[2.2 Assessment of the biocidal family 37](#_Toc30683330)

[2.2.1 Intended use(s) as applied for by the applicant 37](#_Toc30683331)

[**2.2.1.1** **META-SPC 1 – CINQ SUR CINQ FAMILLE** 37](#_Toc30683332)

[**2.2.1.2** **META-SPC 2 – CINQ SUR CINQ ZONES TEMPEREES** 38](#_Toc30683333)

[**2.2.1.3** **META-SPC 3 – CINQ SUR CINQ TROPIC** 40](#_Toc30683334)

[2.2.2 Physical, chemical and technical properties 42](#_Toc30683335)

[**2.2.2.1** **META-SPC 1 – CINQ SUR CINQ FAMILLE** 42](#_Toc30683336)

[**2.2.2.2** **META-SPC 2 – CINQ SUR CINQ ZONES TEMPEREES** 47](#_Toc30683337)

[**2.2.2.3** **META-SPC 3 – CINQ SUR CINQ TROPIC** 53](#_Toc30683338)

[ Post authorisation requirement assessment 60](#_Toc30683339)

[2.2.3 Physical hazards and respective characteristics 62](#_Toc30683340)

[**2.2.3.1** **META-SPC 1 – CINQ SUR CINQ FAMILLE** 62](#_Toc30683341)

[**2.2.3.2** **META-SPC 2 – CINQ SUR CINQ ZONES TEMPEREES** 65](#_Toc30683342)

[**2.2.3.3** **META-SPC 3 – CINQ SUR CINQ TROPIC** 68](#_Toc30683343)

[2.2.4 Methods for detection and identification 71](#_Toc30683344)

[2.2.5 Efficacy against target organisms 76](#_Toc30683345)

[**2.2.5.1** Function and field of use 76](#_Toc30683346)

[**2.2.5.2** Organisms to be controlled and products, organisms or objects to be protected 76](#_Toc30683347)

[**2.2.5.3** Effects on target organisms, including unacceptable suffering 77](#_Toc30683348)

[**2.2.5.4** Mode of action, including time delay 77](#_Toc30683349)

[**2.2.5.5** Efficacy data 77](#_Toc30683350)

[**2.2.5.6** Occurrence of resistance and resistance management 92](#_Toc30683351)

[**2.2.5.7** Known limitations 92](#_Toc30683352)

[**2.2.5.8** Evaluation of the label claims 92](#_Toc30683353)

[**2.2.5.9** Relevant information if the product is intended to be authorised for use with other biocidal product(s) 93](#_Toc30683354)

[2.2.6 Risk assessment for human health 93](#_Toc30683355)

[**2.2.6.1** Assessment of effects on Human Health 93](#_Toc30683356)

[**2.2.6.2** Exposure assessment 101](#_Toc30683357)

[**2.2.6.3** Risk characterisation for human health 124](#_Toc30683358)

[2.2.7 Risk assessment for animal health 137](#_Toc30683359)

[2.2.8 Risk assessment for the environment 138](#_Toc30683360)

[**2.2.8.1** Effects assessment on the environment 138](#_Toc30683361)

[**2.2.8.2** Exposure assessment 139](#_Toc30683362)

[**2.2.8.3** Risk characterisation 148](#_Toc30683363)

[2.2.9 Measures to protect man, animals and the environment 151](#_Toc30683364)

[2.2.10 Assessment of a combination of biocidal products 151](#_Toc30683365)

[2.2.11 Comparative assessment 151](#_Toc30683366)

[*3* Annexes 152](#_Toc30683367)

[3.1 List of studies for the biocidal product (family) 152](#_Toc30683368)

[3.2 Output tables from exposure assessment tools 153](#_Toc30683369)

[3.3 New information on the active substance 154](#_Toc30683370)

[3.4 Residue behaviour 154](#_Toc30683371)

[3.5 Summaries of the efficacy studies (B.5.10.1-xx) 154](#_Toc30683372)

[3.6 Confidential annex 154](#_Toc30683373)

[3.7 Other 154](#_Toc30683374)

**Note to the reader**

This PAR is based on the PAR of the first authorisation and has been updated with the post-authorisation data provided by the applicant and also the minor change application regarding the extension of the shelf life for products of Meta SPC 3 (both are linked, please refer to the overall conclusion).

In this consolidated PAR, the assessments related to the post authorisation data of the product and the minor change are at the end of the concerned section and are highlighted in grey.

**History of the dossier**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Application type** | **refMS** | **Case number in the refMS** | **Decision date** | **Assessment carried out (i.e. first authorisation / amendment /renewal)** |
| NA-APP | *FR* | *BC-KV020758-09* | 23.07.2019 | Initial assessment |
| January 2020 | Post authorisation data assessment |
| NA-MIC | *FR* | *BC-AR056140-44* | 07/07/2020 | Minor change assessment Change in shelf life for Meta-SPC 3 (24 to 36 months) |

# CONCLUSION

* ***Physico-chemical properties***

All products claimed in the biocidal product family CINQ SUR CINQ LOTION are AL formulations. Their technical characteristics are acceptable for AL formulations.

META SPC 1, META SPC 2 and META SPC 3 are covered by the provided data.

Products are flammable H226 cat.3. They have no explosive and no oxidizing properties.

The analytical method is fully validated for the determination of the active substance IR3535 in the products.

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The long term storage stability study for meta-SPC 3 (36 months at ambient temperature in HDPE bottle packaging material (commercial packaging material including discharge and particle size distribution after storage) are on-going and should be provided within one year. The particle size distribution after storage should be provided in post-authorisation within two years for meta SPC 1 and 2, and 1 year for meta SPC 3.

* **Post authorisation requirement assessment**

The following data requested in post-authorisation were provided:

* The particle size distribution after storage for meta-SPC 1, meta-SPC 2 and meta-SPC 3
* The long term storage study for meta-SPC 3

Particle size distribution of 36 months aged product CINQ SUR CINQ 35% (meta SPC 3) was submitted and considered acceptable. It can be read across to other products of meta SPC 1 and meta SPC 2 as the spray devices are identical between meta SPCs.

According to the long term storage study provided the biocidal product of meta SPC 3 is stable after 36 months at ambient temperature. However as no minor change was submitted to request a shelf life change for meta SPC 3, no modification of SPC is performed in the framework of post authorisation application and the 2 years shelf life already authorised is maintained at this time.

* **Minor change 2020**

Long term storage for meta SPC 3 was previously assessed based on the post authorisation data (requested in the initial assessment) and deemed acceptable but not applicable since no minor change was submitted (no modification of the SPC).

Therefore, a minor change application has been formally submitted to claim the shelf life change. Thus, according to the long term storage study provided and already validated, the biocidal products of the meta SPC 3 are considered stable after 36 months at ambient temperature.

* ***Efficacy assessment***

French competent authorities (FR CA) conclude that data presented in the dossier demonstrate that:

- The product from the Meta SPC 1 (one formulation (CINQ SUR CINQ FAMILLE) without any variations) of the BPF “CINQ SUR CINQ LOTION” provides a protection time up to 5 hours against adult mosquitoes (*Culex spp*., *Aedes spp*.) at the application rate of 0.7 mg/cm², up to 3 hours against ticks (*Ixodes ricinus*) at the application rate of 0.95 mg/cm², in temperate climate, and up to 1 hour against *Tabanidae* (*Dasybasis spp.*) at the application rate of 1.95 mg/cm² in tropical conditions.

- For the Meta SPC 2, the two formulations (CINQ SUR CINQ ZONES TEMPEREES AF and CINQ SUR CINQ LOTION NF) tested of the BPF “CINQ SUR CINQ LOTION” provide a protection time up to 5 hours against adult mosquitoes (*Culex spp*., *Aedes spp*.) at the application rate of 0.68 mg/cm², up to 4 hours against ticks (*Ixodes ricinus* at the application rate of 0.93 mg/cm² in temperate climate, and up to 1 hour against *Tabanidae* (*Dasybasis*) at the application rate of 1.48 mg/cm² in tropical conditions.

Although META SPC1&2, tropical conditions[[1]](#footnote-1) for horseflies are more challenging than temperate conditions, the species tested (*Dasybasis spp.)* is not representative of species of horseflies met in Europe. Then FR CA cannot conclude on the efficacy against horseflies in temperate conditions.

It has to be noted, that no claim has been made concerning efficacy in tropical conditions conditions for these both Meta SPC.

- For the Meta SPC 3, the two formulations (CINQ SUR CIND TROPIC AF and CINQ SUR CINQ TROPIC NF) tested of the BPF “CINQ SUR CINQ LOTION” provides a protection up to 5 hours against adult mosquitoes (*Culex spp*., *Aedes spp*.: 6 hours; *Anopheles spp.*: 5 hours) at the application rate of 0.48 mg/cm² in tropical conditions and, up to 1 hour against *Tabanidae* (*Dasybasis spp.*) at the application rate of 1.07 mg/cm² in tropical conditions.

According to the TNsG on PT18 (2012), for a claim against ticks, efficacy of the product on the species *Ixodes ricinus* should be demonstrated and when an efficacy in the tropics is also claimed, an efficacy against *Hyalomma marginatum* should be also demonstrated. No efficacy data was presented to support the efficacy against *Hyalomma maginatum*. Furthermore, the efficacy study submitted in the dossier for these products were performed on *Ixodes ricinus* in temperate conditions. Then the efficacy of the formulations of the Meta SPC 3 against ticks is not validated.

Considering the importance of this active substance in vector control, the authorisation holder has to monitor the resistance phenomenon toward the active substance IR3535. Results of the resistance monitoring must be submitted to the Competent Authorities (CA) or other appointed bodies involved in resistance management every 5 years.

* ***Risk assessment for human health***

***European agreed approach – tier 1 without any specific RMM***

Considering that 55% of area body are exposed (**tier 1**):

* For meta SPC 1:
  + **For application of the product against mosquitoes**:
    - the risk is acceptable for adults and children over 11 years old for one application only. The claimed two applications lead to unacceptable risk.
    - The risk for children between 6 and 11 years is acceptable for one application only. The claimed two applications lead to unacceptable risk.
    - The risk for children between 2 and 6 years is acceptable for one application, as required by applicant.
    - The risk for children from 6 months to 2 years is not acceptable
  + **For application of the product against ticks:** 
    - the risk is acceptable for adults and children over 11 years old for one application, as claimed by the applicant.
    - The risk for children below 11 years is unacceptable.
  + **For application of the product against tabanids**: the risk is unacceptable for adults and children.
* For meta SPC 2:
  + **For application of the product against mosquitoes**:
    - the risk is acceptable for adults and children over 11 years old for one application only. The claimed two applications lead to unacceptable risk.
    - The risk for children between 2 and 11 years is unacceptable.
  + **For application of the product against ticks:** 
    - the risk is acceptable for one application for adults and children over 11 years old, as claimed by the applicant.
    - The risk for children between 2 years and 11 years is unacceptable.
  + **For application of the product against tabanids**: the risk is unacceptable for adults and children.
* For meta SPC 3:
  + **For application of the product against mosquitoes**:
    - the risk is acceptable for adults and children over 11 years old for one application only. The claimed two applications lead to unacceptable risk.
    - The risk for children between 6 and 11 years is acceptable for one application, as required by applicant.
    - The risk for children below 6 years is unacceptable
  + **For application of the product against ticks:** 
    - the risk is acceptable for adults and children over 11 years old for one application, as claimed by the applicant.
    - The risk for children between 2 years and 11 years is unacceptable.
  + **For application of the product against tabanids**: the risk is unacceptable for adults and children.

Applicant proposes the following risk mitigation measure “do not apply on children’ hands”. Considering with RMM may lead to acceptable risk for some categories of users. This RMM has not been agreed at the European level. Hence it is up to each MS to decide whether it can be implemented.

***Conclusions valid for France and not subject to mutual recognition process***

In France, it is considered that repellent are necessary to prevent from mosquitoes and ticks bites and avoid vector-borne diseases. Specific risk mitigation measures can be implemented, one of which being the use of clothes that cover a larger part of the body. The RMM “do not apply on children’ hands” is also considered as appropriate.

For user category for which unacceptable risk are identified with the European scenario, the product can be authorized according to article 19(5), provided that the specific RMMs lead to acceptable risks.

For French approach, it is considered that product is applied on head, hands, ¾ arms and 1/2 legs for adult and head, ¾ arms and 1/2 legs for children since a mitigation measure “do not apply the product on hands of children” is proposed in SPC.

* For meta SPC 1:
  + **For application of the product against mosquitoes**: the risk is acceptable for adults and children over 6 years old for 2 applications, as claimed by applicant.

The risk for children between 6 months and 6 years is acceptable for one application.

* + **For application of the product against ticks:** the risk is acceptable for adults and children above 6 months for one application, as claimed by the applicant.
  + **For application of the product against tabanids**: the risk is unacceptable for adults and children.
* For meta SPC 2:
  + **For application of the product against mosquitoes**:
    - the risk is acceptable for adults and children over 11 years old for 2 applications, as claimed by applicant.
    - The risk for children between 2 and 11 years is acceptable for one application, as claimed by applicant.
  + **For application of the product against ticks:** the risk is acceptable for one application for adults and children from 2 y.o. as claimed by applicant.
  + **For application of the product against tabanids**: the risk is unacceptable for adults and children.
* For meta SPC 3:
  + **For application of the product against mosquitoes**:
    - the risk is acceptable for adults and children over 11 years old for 2 applications, as claimed by applicant.
    - the risk for children between 2 and 11 years old is acceptable for one application, as claimed by applicant.
  + **For application of the product against ticks:** the risk is acceptable for one application for adults and children from 2 y.o. as claimed by applicant
  + **For application of the product against tabanids**: the risk is unacceptable for adults and children.
* ***Risk for consumers via residues***

Regarding the intended use on skin of the family product CINQ SUR CINQ LOTION, a contamination of food cannot be excluded.

An estimation of dietary exposure for toddler, children and adults was performed. These estimations are considered as a worst case using the assumption that all the active substance from the palm hands will be ingested. According to use recommendations and risk mitigation measures, no dietary risk was identified for children and adults considering the directions for use. The following risk mitigation measures should be applied:

* Wash hands before handling food,
* Do not apply on hands of children.
* ***Risk assessment for environment***

The levels of exposure for the non-target organisms of the aquatic compartment (STP, surface water and sediment) following the use of the products from the biocidal product family CINQ SUR CINQ LOTION on human skin are lower than the threshold values for each compartment under the use conditions provided in the SPC.

Considering the profile of the active substance and the uses of the products on human skin, the predicted concentrations in the terrestrial compartment including groundwater are considered negligible under the use conditions provided in the SPC.

* ***General conclusion***

**To conclude, the following uses can be proposed for authorisation in Europe according to Article 19(1):**

* **For the META SPC 1 :** 
  + **treatment against mosquitoes once a day for adults and children over 2 y.o.**
  + **Treatment against ticks once a day for adults and children over 11 y.o.**
* **For the META SPC 2 :** 
  + **treatment against mosquitoes once a day for adults and children over 11 y.o.**
  + **Treatment against ticks once a day for adults and children over 11 y.o.**
* **For the META SPC 3 :** 
  + **treatment against mosquitoes once a day for adults and children over 6 y.o.**

***Other uses can only be authorized according to article 19(5).***

**In France, following uses can be proposed for authorisation:**

* **For the META SPC 1 :** 
  + **treatment against mosquitoes twice a day for adults and children over 6 y.o.**
  + **treatment against mosquitoes once a day for children between 6 months and 6 y.o**
  + **Treatment against ticks once a day for adults and children over 6 months**
* **For the META SPC 2 :** 
  + **treatment against mosquitoes twice a day by adults and children over 11 y.o.**
  + **treatment against mosquitoes once a day for children between 2 and 11 y.o**
  + **Treatment against ticks once a day for adults and children over 2 y.o.**
* **For the META SPC 3 :** 
  + **treatment against mosquitoes twice a day by adults and children over 11 y.o.**
  + **treatment against mosquitoes once a day for children between 2 and 11 y.o**
  + **Treatment against ticks once a day for adults and children over 2 y.o.**

# ASSESSMENT REPORT

## Summary of the product assessment – Minor Change 2020 - application for CINQ SUR CINQ LOTION

# Part I.- First information level

### Administrative information

#### Identifier of the product / product family

| **Identifier** | **Country (if relevant)** |
| --- | --- |
| CINQ SUR CINQ LOTION | France |

#### Authorisation holder

|  |  |  |
| --- | --- | --- |
| **Name and address of the authorisation holder** | **Name** | Laboratoire CHAUVIN |
| **Address** | 416 rue Samuel Morse - CS 99535  34961 Montpellier cedex 2  FRANCE |
| **Authorisation number** | **FR-2019-0092** | |
| **Date of the authorisation** | **23/07/2019** | |
| **Expiry date of the authorisation** | **22/07/2029** | |

#### Manufacturer(s) of the products of the family

|  |  |
| --- | --- |
| **Name of manufacturer** | Laboratoire CHAUVIN |
| **Address of manufacturer** | 416 rue Samuel Morse - CS 99535  34961 Montpellier cedex 2  FRANCE |
| **Location of manufacturing sites** | FABRICATION CHIMIQUE ARDECHOISE  LES ILES FERAYS  07300 Tournon cedex  FRANCE |

#### Manufacturer(s) of the active substance(s)

|  |  |
| --- | --- |
| **Active substance** | Ethyl butylacetylaminopropionate |
| **Name of manufacturer** | Merck KGaA |
| **Address of manufacturer** | Frankfurter Strasse 250  64293 Darmstadt  GERMANY |
| **Location of manufacturing sites** | Merck S.L.U. Poligono Merck  08100 Mollet del Valles  SPAIN |

### Product (family) composition and formulation

NB: the full composition of the product according to Annex III Title 1 should be provided in the confidential annex.

Does the product have the same identity and composition as the product evaluated in connection with the approval for listing of the active substance(s) on the Union list of approved active substances under Regulation No. 528/2012?

Yes

No

#### Identity of the active substance

|  |  |
| --- | --- |
| **Main constituent(s)** | |
| **ISO name** | IR3535, Ethyl butylacetylaminopropionate |
| **IUPAC or EC name** | ethyl 3-[N-acetyl-N-butyl] aminopropionate |
| **EC number** | 257-835-0 |
| **CAS number** | 52304-36-6 |
| **Index number in Annex VI of CLP** |  |
| **Minimum purity / content** | >99% w/w |
| **Structural formula** |  |

#### Candidate(s) for substitution

*Not relevant*

#### Qualitative and quantitative information on the composition of the biocidal product family

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (% technical)** | |
| --- | --- | --- | --- | --- | --- | --- |
| **Min** | **Max** |
| Ethyl butylacetylaminopropionate IR3535 | Ethyl 3-[acetyl(butyl)amino]propanoate | Active substance | 52304-36-6 | 257-835-0 | 20 | 35 |

#### 

#### Information on technical equivalence

*Not relevant*

#### Information on the substance(s) of concern

#### Please see the confidential annex for further details.

#### Assessment of endocrine disruption (ED) properties of the biocidal products of BPF

According to our assessment, none of the co-formulants contained in the products of the CINQ SUR CINQ FAMILY are regulatory identified as endocrine disruptors.

However, some co-formulants are currently being evaluated in the frame of REACH for its potential ED properties.

In addition, based on screening several co-formulants show indications of endocrine activity and this should be further assessed in the frame of REACH Regulation.

Hence, it is not possible to conclude whether these co-formulants should be considered to have ED properties or not before the end of the assessment. In case any co-formulants are finally identified as ED, the biocidal product will be considered as ED and authorisation will have to be revised accordingly.

Please refer to Confidential Annex.

#### Type of formulation

|  |
| --- |
| AL any other liquids, ready to use |

# Part II.- Second information level - meta SPC 1

## 1. Meta SPC 1 administrative information

## 1.1. Meta SPC identifier

| **Identifier** | CINQ SUR CINQ FAMILLE |
| --- | --- |

## 

## 1.2. Suffix to the authorisation number

|  |  |
| --- | --- |
| **Number 1** |  |

## 1.3. Product type(s)

| **Product type(s)** | PT19 |
| --- | --- |

## 2. Meta SPC 1 composition

## 2.1. Qualitative and quantitative information on the composition of the meta SPC 1

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (% technical)** | |
| --- | --- | --- | --- | --- | --- | --- |
| **Min** | **Max** |
| Ethyl butylacetylaminopropionate IR3535 | Ethyl 3-[acetyl(butyl)amino]propanoate | Active substance | 52304-36-6 | 257-835-0 | 20 | 20 |

## 2.2. Type(s) of formulation of the meta SPC 1

| **Formulation** | AL any other liquids, ready to use |
| --- | --- |
|  |  |

## 

## 3. Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 1

| **Classification** | |
| --- | --- |
| Hazard category | Flammable liquid cat 3  Eye Irritant category 2 |
| Hazard statement | H226: Flammable liquid and vapor  H319: Causes serious eye irritation. |
|  | |
| **Labelling** | |
| Signal words | Warning |
| Hazard statements | H226: Flammable liquid and vapor  H319: Causes serious eye irritation. |
| Precautionary statements | P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. – No smoking  P264: Wash … thoroughly after handling.  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. |
|  | |
| Note | EUH 208 “Contains 2-hexyl-3-phenyl-2- propenal (trans & cis), benzyl 2-hydroxybenzoate” May produce an allergic reaction”. |

## 4. Authorised use(s) of the meta SPC 1

**4.1. Use description**

Table 1. Use # 1 – Skin repellent against mosquitoes

|  |  |
| --- | --- |
| **Product Type** | PT 19 |
| **Where relevant, an exact description of the authorised use** | Insect repellents |
| **Target organism(s) (including development stage)** | *Aedes* mosquitoes (*Aedes* *spp*.)  *Culex* mosquitoes (*Culex* *spp*.)  Development stage: adults |
| **Field(s) of use** | Skin application |
| **Application method(s)** | **Method of application:** spraying  **Detailed description of the method:**  Spraying on skin at 10 cm on head, hands (adults only), ¾ arms and 1/2 legs |
| **Application rate(s) and frequency** | **The application rate is** 0.7 mg / cm²of skin  **Protection time:** 5 hours in temperate condition  For European conclusion:  **Number and timing of application:**   * Child to Adult (> 2 years): 1 application per day   For French conclusion:  **Number and timing of application:**   * Child from 6 months up to 6 years: 1 application per day * Child to Adult (> 6 years): 2 applications per day   European conclusion:   |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | | Number of spray | head | neck | per arm | per hand | per leg | per feet | | < 1 year old | 1,7 | 0,8 | 1,2 |  | 2,1 | 0,3 | | 1 to < 2 years old | 2,0 | 0,9 | 1,4 |  | 2,5 | 0,4 | | 2 to < 6 years old | 2,6 | 1,2 | 1,9 |  | 3,6 | 0,5 | | 6 to < 12 years old | 2,6 | 1,2 | 2,5 |  | 5,5 | 0,7 | | adult | 5,4 | 1,1 | 4,7 | 2.0 | 10,7 | 1,4 | |
| **Category(ies) of users** | General public (non-professional) |
| **Pack sizes and packaging material** | * Bottle spray: 100 mL   HDPE for the bottle and PE-LD/PP for the dip tibe inside the bottle and PE-LD for the regulator on the spray and a Copolymer Polypropylene cap. |

## 

## 4.1.1. Use-specific instructions for use

|  |
| --- |
| The product must not be used for tropical species. |

## 

## 4.1.2 Use-specific risk mitigation measures

|  |
| --- |
| For European conclusion: Do not apply the product more than one time per day**.** |

## 

## 4.1.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
| - |

## 

## 4.1.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

|  |
| --- |
| - |

## 4.1.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
| - |

Table 2. Use # 2 – Skin repellent against ticks

|  |  |
| --- | --- |
| **Product Type** | PT 19 |
| **Where relevant, an exact description of the authorised use** | Insect repellents |
| **Target organism(s) (including development stage)** | *Ixodes ricinus*  Development stage: adults and nymphs |
| **Field(s) of use** | Skin application |
| **Application method(s)** | **Method of application:** spraying  **Detailed description of the method:**  Spraying on skin at 10 cm on head, hands (adults only), ¾ arms and 1/2 legs |
| **Application rate(s) and frequency** | **The application rate is** 0.95 mg / cm²of skin  For European conclusion:  **Number and timing of application:**   * Child to Adult (> 11 years): 1 application per day   For French conclusion:  **Number and timing of application:**   * Child to Adult (> 6 months): 1 application per day   **Protection time:** 3 hours in temperate condition  European conclusion:   |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | | Number of spray | head | neck | per arm | per hand | per leg | per feet | | < 1 year old | 2,3 | 1,0 | 1,6 |  | 2,9 | 0,4 | | 1 to < 2 years old | 2,7 | 1,2 | 1,9 |  | 3,4 | 0,5 | | 2 to < 6 years old | 3,5 | 1,6 | 2,6 |  | 4,9 | 0,7 | | 6 to < 12 years old | 3,5 | 1,7 | 3,5 |  | 7,5 | 1,0 | | adult | 7,4 | 1,5 | 6,4 | 2,7 | 14,6 | 1,9 | |
| **Category(ies) of users** | General public (non-professional) |
| **Pack sizes and packaging material** | * Bottle spray: 100 mL   HDPE for the bottle and PE-LD/PP for the dip tibe inside the bottle and PE-LD for the regulator on the spray and a Copolymer Polypropylene cap. |

## 4.2.1. Use-specific instructions for use

|  |
| --- |
| The product must not be used for tropical species. |

## 4.2.2 Use-specific risk mitigation measures

|  |
| --- |
| For European conclusion: Do not apply the product on children under 6 years. |

## 4.2.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
| - |

## 4.2.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

|  |
| --- |
| - |

## 4.2.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
| - |

## 5. General directions for use of the meta SPC 1

## *5.1. Instructions for use*

|  |
| --- |
| * Always read the label or leaflet before use and follow all the instructions provided. * Respect the recommended application doses. * Retreat after water exposure without exceeding the maximal recommended application number. * The user should inform the registration holder if the treatment is ineffective * The use of the product with other repellent products is not recommended. * In case of a concomitant use of the product with sunscreen, first apply the sunscreen and wait 20 minutes before the application of the product. * The protection time is only indicative. Environmental factors (e.g. high temperature, wind velocity) can lower it. |

## *5.2. Risk mitigation measures*

|  |
| --- |
| * Do not spray directly on the face, spray the product in the hand and then spread it onto the face. * For children, the product must be applied by an adult. * Do not apply on hands of children. * Apply the product on skin and spread it uniformly with hands on following areas:   + Adults et children (> 11 years old): apply on head, neck, hands (palms and backs), lower arms, lower legs, feet and 70% of upper arms and thighs   + Children from 6 months to 11 years old: apply on head, neck, lower arms, lower legs, feet and 70% of upper arms and thighs. * Wash hands before handling food. * Keep out of reach of children. * Avoid breathing vapours/spray. * Use only outdoors or in a well-ventilated area. |

## *5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

|  |
| --- |
| Eye contact: Immediately flush with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses if easy to do. Continue to rinse with tepid water for at least 10 minutes. Get medical attention if irritation or vision impairment occurs.  Skin contact: In case of skin lesions, redness or persistent pain after application, consult a doctor.  Inhalation of large quantities: keep at rest in a half-sitting position. Seek medical advice immediately if symptoms occur.  Mouth contact: Wash out mouth with water. Contact poison treatment specialist immediately if symptoms occur and/or in case of mouth contact with large quantities.  Do not give fluids or induce vomiting in case of impaired consciousness; place in recovery position and seek medical advice immediately.  Keep the container or label available. |

## 

## *5.4. Instructions for safe disposal of the product and its packaging*

|  |
| --- |
| * Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets…) nor down the drains * Dispose of unused product, its packaging and all other waste in accordance with local regulations. * The packaging must not be reused. |

## 

## *5.5. Conditions of storage and shelf-life of the product under normal conditions of storage*

|  |
| --- |
| Do not store the product more than 3 years. |

**6. Other information**

|  |
| --- |
| * Number of pump sprays indicated on the label should be in accordance with the application rate. |

# Part III - Third information level: individual products in the meta SPC 1

## 1. Trade name(s), authorisation number and specific composition of each individual product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)** | **CINQ SUR CINQ FAMILLE** | | | | |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (% technical)** |
| Ethyl butylacetylaminopropionate IR3535 | Ethyl 3-[acetyl(butyl)amino]propanoate | Active substance | 52304-36-6 | 257-835-0 | 20 |

# Part II.- Second information level - meta SPC 2

## 1.1. Meta SPC identifier

| **Identifier** | CINQ SUR CINQ ZONES TEMPEREES |
| --- | --- |

## 1.2. Suffix to the authorisation number

|  |  |
| --- | --- |
| **Number 2** |  |

## 1.3. Product type(s)

| **Product type(s)** | PT19 |
| --- | --- |

## 2. Meta SPC 2 composition

## 2.1. Qualitative and quantitative information on the composition of the meta SPC 2

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (% technical)** | |
| --- | --- | --- | --- | --- | --- | --- |
| **Min** | **Max** |
| Ethyl butylacetylaminopropionate IR3535 | Ethyl 3-[acetyl(butyl)amino]propanoate | Active substance | 52304-36-6 | 257-835-0 | 25 | 25 |

## 2.2. Type(s) of formulation of the meta SPC 2

| **Formulation** | AL any other liquids, ready to use |
| --- | --- |
|  |  |

**3. Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 2**

| **Classification** | |
| --- | --- |
| Hazard category | Flammable liquid cat 3  Eye Irritant category 2 |
| Hazard statement | H226: Flammable liquid and vapor  H319: Causes serious eye irritation. |
|  | |
| **Labelling** | |
| Signal words | Warning |
| Hazard statements | H226: Flammable liquid and vapor  H319: Causes serious eye irritation. |
| Precautionary statements | P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. – No smoking  P264: Wash … thoroughly after handling.  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. |
|  | |
| Note | EUH 208 “Contains 2-hexyl-3-phenyl-2- propenal (trans & cis), benzyl 2- hydroxybenzoate, (R)-p-mentha-1,8-diène, 3,7-dimethyl-6-octen-1- ol (citronellol)”. May produce an allergic reaction”. |

**4. Authorised use(s) of the meta SPC 2**

**4.1. Use description**

Table 3. Use # 1 – Skin repellent against mosquitoes

|  |  |
| --- | --- |
| **Product Type** | PT 19 |
| **Where relevant, an exact description of the authorised use** | Insect repellents |
| **Target organism(s) (including development stage)** | *Aedes* mosquitoes (*Aedes* *spp*.)  *Culex* mosquitoes (*Culex* *spp*.)  Development stage: adults |
| **Field(s) of use** | Skin application |
| **Application method(s)** | **Method of application:** spraying  **Detailed description of the method:**  Spraying on skin at 10 cm on head, hands (adults only), ¾ arms and 1/2 legs |
| **Application rate(s) and frequency** | **The application rate is** 0.68 mg / cm²of skin  **Protection time:** 5 hours in temperate condition  For European conclusion:  **Number and timing of application:**   * Child to Adult (> 11 years): 1 application per day   For French conclusion:  **Number and timing of application:**   * Child from 2 years up to 11 years: 1 application per day * Child to Adult (> 11 years): 2 applications per day   European conclusion:   |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | | Number of spray | head | neck | per arm | per hand | per leg | per feet | | < 1 year old | 1,7 | 0,7 | 1,1 |  | 2,1 | 0,3 | | 1 to < 2 years old | 1,9 | 0,9 | 1,3 |  | 2,4 | 0,3 | | 2 to < 6 years old | 2,5 | 1,2 | 1,9 |  | 3,6 | 0,5 | | 6 to < 12 years old | 2,5 | 1,2 | 2,5 |  | 5,4 | 0,7 | | adult | 5,3 | 1,1 | 4,6 | 2,0 | 10,5 | 1,4 | |
| **Category(ies) of users** | General public (non-professional) |
| **Pack sizes and packaging material** | * Bottle spray: 75 mL   HDPE for the bottle and PE-LD/PP for the dip tibe inside the bottle and PE-LD for the regulator on the spray and a Copolymer Polypropylene cap.   * Bottle spray: 100 mL   HDPE for the bottle and PE-LD/PP for the dip tibe inside the bottle and PE-LD for the regulator on the spray and a Copolymer Polypropylene cap. |

## 4.1.1. Use-specific instructions for use

|  |
| --- |
| The product must not be used for tropical species. |

## 4.1.2 Use-specific risk mitigation measures

|  |
| --- |
| For European conclusion: Do not apply the product more than one time per day. |

## 4.1.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
| - |

## 4.1.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

|  |
| --- |
| - |

## 4.1.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
| - |

Table 4. Use # 2 – Skin repellent against ticks

|  |  |
| --- | --- |
| **Product Type** | PT 19 |
| **Where relevant, an exact description of the authorised use** | Insect repellents |
| **Target organism(s) (including development stage)** | *Ixodes ricinus*  Development stage: adults and nymphs |
| **Field(s) of use** | Skin application |
| **Application method(s)** | **Method of application:** spraying  **Detailed description of the method:**  Spraying on skin at 10 cm on head, hands (adults only), ¾ arms and 1/2 legs |
| **Application rate(s) and frequency** | **The application rate is** 0.93 mg / cm²of skin  **Protection time:** 4 hours in temperate condition  For European conclusion:  **Number and timing of application:**   * Child to Adult (> 11 years): 1 application per day   For French conclusion:  **Number and timing of application:**   * Child from 2 years up to 11 years: 1 application per day * Child to Adult (> 11 years): 1 application per day   European conclusion:   |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | | Number of spray | head | neck | per arm | per hand | per leg | per feet | | < 1 year old | 2,3 | 1,0 | 1,6 |  | 2,8 | 0,4 | | 1 to < 2 years old | 2,6 | 1,2 | 1,8 |  | 3,3 | 0,5 | | 2 to < 6 years old | 3,4 | 1,6 | 2,5 |  | 4,9 | 0,7 | | 6 to < 12 years old | 3,5 | 1,6 | 3,4 |  | 7,4 | 1,0 | | adult | 7,3 | 1,5 | 6,3 | 2,7 | 14,3 | 1,9 | |
| **Category(ies) of users** | General public (non-professional) |
| **Pack sizes and packaging material** | * Bottle spray: 75 mL   HDPE for the bottle and PE-LD/PP for the dip tibe inside the bottle and PE-LD for the regulator on the spray and a Copolymer Polypropylene cap.   * Bottle spray: 100 mL   HDPE for the bottle and PE-LD/PP for the dip tibe inside the bottle and PE-LD for the regulator on the spray and a Copolymer Polypropylene cap. |

## 4.1.1. Use-specific instructions for use

|  |
| --- |
| The product must not be used for tropical species. |

## 4.1.2 Use-specific risk mitigation measures

|  |
| --- |
| For European conclusion: Do not apply the product on children under 11 years. |

## 4.1.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
| - |

## 4.1.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

|  |
| --- |
| - |

## 4.1.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

|  |
| --- |
| - |

## 5. General directions for use of the meta SPC 2

## *5.1. Instructions for use*

|  |
| --- |
| * Always read the label or leaflet before use and follow all the instructions provided. * Respect the recommended application doses. * The user should inform the registration holder if the treatment is ineffective * The use of the product with other repellent products is not recommended. * In case of a concomitant use of the product with sunscreen, first apply the sunscreen and wait 20 minutes before the application of the product. * The protection time is only indicative. Environmental factors (e.g. high temperature, wind velocity) can lower it. * Retreat after water exposure without exceeding the maximal recommended application number. |

## *5.2. Risk mitigation measures*

|  |
| --- |
| * Do not spray directly on the face, spray the product in the hand and then spread it onto the face. * For children, the product must be applied by an adult. * Do not apply on hands of children. * Apply the product on skin and spread it uniformly with hands on following areas:   + Adults et children (> 11 years old): apply on head, neck, hands (palms and backs), lower arms, lower legs, feet and 70% of upper arms and thighs   + Children from 2 years to 11 years old: apply on head, neck, lower arms, lower legs, feet and 70% of upper arms and thighs. * Wash hands before handling food. * Keep out of reach of children. * Avoid breathing vapours/spray. * Use only outdoors or in a well-ventilated area. |

## *5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

|  |
| --- |
| Eye contact: Immediately flush with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses if easy to do. Continue to rinse with tepid water for at least 10 minutes. Get medical attention if irritation or vision impairment occurs.  Skin contact: In case of skin lesions, redness or persistent pain after application, consult a doctor.  Inhalation of large quantities: keep at rest in a half-sitting position. Seek medical advice immediately if symptoms occur.  Mouth contact: Wash out mouth with water. Contact poison treatment specialist immediately if symptoms occur and/or in case of mouth contact with large quantities.  Do not give fluids or induce vomiting in case of impaired consciousness; place in recovery position and seek medical advice immediately.  Keep the container or label available. |

## *5.4. Instructions for safe disposal of the product and its packaging*

|  |
| --- |
| * Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets…) nor down the drains * Dispose of unused product, its packaging and all other waste in accordance with local regulations. * The packaging must not be reused. |

## *5.5. Conditions of storage and shelf-life of the product under normal conditions of storage*

|  |
| --- |
| Do not store the product more than 3 years. |

## 6. Other information

|  |
| --- |
| * Number of pump sprays indicated on the label should be in accordance with the application rate. |

# Part III - Third information level: individual products in the meta SPC 2

## 1. Trade name(s), authorisation number and specific composition of each individual product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)** | **CINQ SUR CINQ ZONES TEMPEREES** | | | | |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (% technical)** |
| Ethyl butylacetylaminopropionate IR3535 | Ethyl 3-[acetyl(butyl)amino]propanoate | Active substance | 52304-36-6 | 257-835-0 | 25 |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Trade name(s) | CINQ SUR CINQ ZONES TEMPEREES NOUVELLE FORMULE | | | | |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (% technical)** |
| Ethyl butylacetylaminopropionate IR3535 | Ethyl 3-[acetyl(butyl)amino]propanoate | Active substance | 52304-36-6 | 257-835-0 | 25 |

# Part II.- Second information level - meta SPC 3

## 1.1. Meta SPC identifier

| **Identifier** | CINQ SUR CINQ TROPIC |
| --- | --- |

## 1.2. Suffix to the authorisation number

|  |  |
| --- | --- |
| **Number 3** |  |

## 1.3. Product type(s)

| **Product type(s)** | PT19 |
| --- | --- |

## 2. Meta SPC 3 composition

## 2.1. Qualitative and quantitative information on the composition of the meta SPC 3

| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (% technical)** | |
| --- | --- | --- | --- | --- | --- | --- |
| **Min** | **Max** |
| Ethyl butylacetylaminopropionate IR3535 | Ethyl 3-[acetyl(butyl)amino]propanoate | Active substance | 52304-36-6 | 257-835-0 | 35 | 35 |

## 2.2. Type(s) of formulation of the meta SPC 3

| **Formulation** | AL any other liquids, ready to use |
| --- | --- |
|  |  |

## 3. Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 3

| **Classification** | |
| --- | --- |
| Hazard category | Flammable liquid cat 3  Eye Irritant category 2 |
| Hazard statement | H226: Flammable liquid and vapor  H319: Causes serious eye irritation. |
|  | |
| **Labelling** | |
| Signal words | Warning |
| Hazard statements | H226: Flammable liquid and vapor  H319: Causes serious eye irritation. |
| Precautionary statements | P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. – No smoking  P264: Wash … thoroughly after handling.  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. |
|  | |
| Note | EUH 208 ”Contains 2-hexyl-3-phenyl-2- propenal (trans & cis), benzyl 2- hydroxybenzoate, (R)-p-mentha-1,8-diène, 3,7-dimethyl-6-octen-1- ol (citronellol)”. May produce an allergic reaction”. |

## 4. Authorised use(s) of the meta SPC 3

**4.1. Use description**

Table 5. Use # 1 – Skin repellent against mosquitoes

|  |  |
| --- | --- |
| **Product Type** | PT 19 |
| **Where relevant, an exact description of the authorised use** | Insect repellents |
| **Target organism(s) (including development stage)** | *Aedes* mosquitoes (*Aedes* *spp*.)  *Culex* mosquitoes (*Culex* *spp*.)  *Anopheles* mosquitoes (*Anopheles spp*.)  Development stage: adults |
| **Field(s) of use** | Skin application |
| **Application method(s)** | **Method of application:** spraying  **Detailed description of the method:**  Spraying on skin at 10 cm on head, hands (adults only), ¾ arms and 1/2 legs |
| **Application rate(s) and frequency** | **The application rate is** 0.48 mg / cm²of skin  **Protection time:** 5 hours in tropical conditions  *(Aedes spp.* and *Culex spp.*: 6 hours, *Anopheles spp.*: 5 hours)  For European conclusion:  **Number and timing of application:**   * Child to Adult (> 6 years): 1 application per day   For French conclusion:  **Number and timing of application:**   * Child from 2 years up to 11 years: 1 application per day * Child to Adult (> 11 years): 2 applications per day   European conclusion:   |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | | Number of spray | head | neck | per arm | per hand | per leg | per feet | | < 1 year old | 1,2 | 0,5 | 0,8 |  | 1,5 | 0,2 | | 1 to < 2 years old | 1,4 | 0,6 | 0,9 |  | 1,7 | 0,2 | | 2 to < 6 years old | 1,8 | 0,8 | 1,3 |  | 2,5 | 0,4 | | 6 to < 12 years old | 1,8 | 0,8 | 1,8 |  | 3,8 | 0,5 | | adult | 3,8 | 0,8 | 3,3 | 1.4 | 7,4 | 1,0 | |
| **Category(ies) of users** | General public (non-professional) |
| **Pack sizes and packaging material** | * Bottle spray: 75 mL   HDPE for the bottle and PE-LD/PP for the dip tibe inside the bottle and PE-LD for the regulator on the spray and a Copolymer Polypropylene cap.   * Bottle spray: 100 mL   HDPE for the bottle and PE-LD/PP for the dip tibe inside the bottle and PE-LD for the regulator on the spray and a Copolymer Polypropylene cap. |

## 4.1.1. Use-specific instructions for use

|  |
| --- |
| - |

## 4.1.2 Use-specific risk mitigation measures

|  |
| --- |
| For European conclusion: Do not apply the product more than one time per day |

## 4.1.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

|  |
| --- |
| - |

## 4.1.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

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| - |

## 4.1.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

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| --- |
| - |

## 5. General directions for use of the meta SPC 3

## *5.1. Instructions for use*

|  |
| --- |
| * Always read the label or leaflet before use and follow all the instructions provided. * Respect the recommended application doses. * The user should inform the registration holder if the treatment is ineffective * The use of the product with other repellent products is not recommended. * In case of a concomitant use of the product with sunscreen, first apply the sunscreen and wait 20 minutes before the application of the product. * The protection time is only indicative. Environmental factors (e.g. high temperature, wind velocity) can modify it. * Retreat after water exposure without exceeding the maximal recommended application number. |

## *5.2. Risk mitigation measures*

|  |
| --- |
| * Do not spray directly on the face, spray the product in the hand and then spread it onto the face. * For children, the product must be applied by an adult. * Do not apply on hands of children. * Apply the product on skin and spread it uniformly with hands on following areas:   + Adults et children (> 11 years old): apply on head, neck, hands (palms and backs), lower arms, lower legs, feet and 70% of upper arms and thighs   + Children from 2 years to 11 years old: apply on head, neck, lower arms, lower legs, feet and 70% of upper arms and thighs * Wash hands before handling food. * Keep out of reach of children. * Avoid breathing vapours/spray. * Use only outdoors or in a well-ventilated area. |

## *5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

|  |
| --- |
| Eye contact: Immediately flush with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses if easy to do. Continue to rinse with tepid water for at least 10 minutes. Get medical attention if irritation or vision impairment occurs.  Skin contact: In case of skin lesions, redness or persistent pain after application, consult a doctor.  Inhalation of large quantities: keep at rest in a half-sitting position. Seek medical advice immediately if symptoms occur.  Mouth contact: Wash out mouth with water. Contact poison treatment specialist immediately if symptoms occur and/or in case of mouth contact with large quantities.  Do not give fluids or induce vomiting in case of impaired consciousness; place in recovery position and seek medical advice immediately.  Keep the container or label available. |

## *5.4. Instructions for safe disposal of the product and its packaging*

|  |
| --- |
| * Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets…) nor down the drains * Dispose of unused product, its packaging and all other waste in accordance with local regulations. * The packaging must not be reused. |

## *5.5. Conditions of storage and shelf-life of the product under normal conditions of storage*

|  |
| --- |
| * Shelf life: 36 months |

**6. Other information**

|  |
| --- |
| * Number of pump sprays indicated on the label should be in accordance with the application rate. |

# Part III - Third information level: individual products in the meta SPC 3

## 1. Trade name(s), authorisation number and specific composition of each individual product

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)** | **CINQ SUR CINQ TROPIC** | | | | |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (% technical)** |
| Ethyl butylacetylaminopropionate IR3535 | Ethyl 3-[acetyl(butyl)amino]propanoate | Active substance | 52304-36-6 | 257-835-0 | 35 |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Trade name(s)** | **CINQ SUR CINQ TROPIC NOUVELLE FORMULE** | | | | |
| **Authorisation number** |  | | | | |
| **Common name** | **IUPAC name** | **Function** | **CAS number** | **EC number** | **Content (% technical)** |
| Ethyl butylacetylaminopropionate IR3535 | Ethyl 3-[acetyl(butyl)amino]propanoate | Active substance | 52304-36-6 | 257-835-0 | 35 |

### Packaging of the biocidal product family

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Type of packaging** | **Size/volume of the packaging** | **Material of the packaging** | **Type and material of closure(s)** | **Intended user (e.g. professional, non-professional)** | **Compatibility of the product with the proposed packaging materials (Yes/No)** |
| Bottle spray | 75 mL | HDPE for the bottle and PE-LD/PP for the dip tibe inside the bottle and PE-LD for the regulator on the spray and a Copolymer Polypropylene cap. | - | Non-professional | Yes |
| Bottle spray | 100 mL | HDPE for the bottle and PE-LD/PP for the dip tibe inside the bottle and PE-LD for the regulator on the spray and a Copolymer Polypropylene cap. | - | Non-professional | Yes |

### Documentation

#### Data submitted in relation to product application

**Identity, physico-chemical and analytical method data**

Physico-chemical properties studies and analytical methods on the biocidal product CINQ SUR CINQ LOTION were provided by Laboratoire Chauvin.

* **Post authorisation / Minor change assessment 2020**

Additional studies were provided by the applicant in answer to the post authorisation data requested in the initial assessment (please refer to 3.1. Annexe).

**Efficacy data**

For each meta SPC, two data sets were submitted. The first data set was performed with a higher application rate which was not in accordance with the application rate used in the risk assessment.

A second data set, with a lower application rates for some targets, that includes five new efficacy studies were submitted.

* **META-SPC 1**

**First data set**

* An arm-in-cage study conducted with ten human volunteers with the product “cinq sur cinq famille 20 %” reference FC 005 (20% w/w IR3535) applied on skin against three mosquito species *(Aedes aegypti, Aedes albopictus and Culex pipiens).*
* A laboratory study conducted with ten mice with the product “cinq sur cinq famille 20%” reference FC 005 (20% w/w IR3535) applied on skin mouse against ticks (*Ixodes ricinus*).
* A field trial conducted with ten volunteers with the product “cinq sur cinq famille 20%” reference FC 001 (20% w/w IR3535) applied on skin against horse flies (*Dasybasis spp.*) in tropical condition.

**Second data set**

* A laboratory study conducted with ten mice with the product “cinq sur cinq famille” reference FC 029 (20% w/w IR3535) applied on skin mouse against ticks (*Ixodes ricinus*)
* **META-SPC 2**

**First data set**

* An arm-in-cage study conducted with ten human volunteers with the product “cinq sur cinq zones tempérées 25 % AF” reference FC 029 (25% w/w IR3535) applied on skin against three mosquito species *(Aedes aegypti, Aedes albopictus and Culex pipiens).*
* A laboratory study conducted with ten mice with the product cinq sur cinq zones tempérées 25% AF” reference FC 029 (25% w/w IR3535) applied on skin mouse against ticks (*Ixodes ricinus*)
* A field trial conducted with ten volunteers with the product “cinq sur cinq zones tempérées 25 % AF” reference FC 029 (25% w/w IR3535) applied on skin against horse flies (*Dasybasis spp.*) in tropical condition.
* An arm-in-cage study conducted with ten human volunteers with the product “cinq sur cinq zones tempérées 25 % NF” reference FC 001 (25% w/w IR3535) applied on skin against three mosquito species *(Aedes aegypti, Aedes albopictus and Culex pipiens).*
* A laboratory study conducted with ten mice with the product cinq sur cinq zones tempérées 25 % NF” reference FC 001 (25% w/w IR3535) applied on skin mouse against ticks (*Ixodes ricinus*)
* A field trial conducted with ten volunteers with the product “cinq sur cinq zones tempérées 25 % NF” reference FC 001 (25% w/w IR3535) applied on skin against horse flies (*Dasybasis spp.*) in tropical condition.

**Second data set**

* An arm-in-cage study conducted with ten human volunteers with the product “cinq sur cinq zones tempérées AF” (25% w/w IR3535) applied on skin against three mosquito species *(Aedes aegypti, Aedes albopictus and Culex quinquefasciatus).*
* A laboratory study conducted with ten mice with the product “cinq sur cinq zones tempérées AF” (25% w/w IR3535) applied on skin mouse against ticks (*Ixodes ricinus*)
* **META-SPC 3**

**First data set**

* An arm-in-cage study conducted with ten human volunteers with the product “cinq sur cinq tropic 35% AF” reference FC 119 (35% w/w IR3535) applied on skin against three mosquito species *(Aedes aegypti, Aedes albopictus, Culex pipiens and Anopheles gambiae)* in tropical condition.
* A laboratory study conducted with ten mice with the product “cinq sur cinq tropic 35% AF” reference FC 119 (35% w/w IR3535) applied on skin mouse against ticks (*Ixodes ricinus*) in temperate condition.
* A field trial conducted with ten volunteers with the product “cinq sur cinq tropic 35% AF” reference FC 112 (35% w/w IR3535) applied on skin against horse flies (*Dasybasis spp.*) in tropical condition.
* An arm-in-cage study conducted with ten human volunteers with the product “cinq sur cinq tropic 35% NF” reference FC 001 (35% w/w IR3535) applied on skin against three mosquito species *(Aedes aegypti, Aedes albopictus, Culex pipiens and Anopheles gambiae)* in tropical condition*.*
* A laboratory study conducted with ten mice with the product “cinq sur cinq tropic 35% NF” reference FC 001 (35% w/w IR3535) applied on skin mouse against ticks (*Ixodes ricinus*) in temperate condition.
* A field trial conducted with ten volunteers with the product “cinq sur cinq tropic 35% NF” reference FC 112 (35% w/w IR3535) applied on skin against horse flies (*Dasybasis spp.*) in tropical condition.

**Second data set**

- An arm-in-cage study conducted with ten human volunteers with the product “cinq sur cinq tropic” (25% w/w IR3535) applied on skin against three mosquito species (*Aedes aegypti*, *Aedes albopictus*, *Culex quinquefasciatus* and *Anopheles gambiae*).

- A laboratory study conducted with ten mice with the product “cinq sur cinq tropic” (35% w/w IR3535) applied on skin mouse against ticks (*Ixodes ricinus*)

#### Access to documentation

**Identity, physico-chemical and analytical method data**

Laboratoire Chauvin has access to data on the active substance IR3535 with a Letter of Access of Merck, one applicant of the active substance IR3535.

## Assessment of the biocidal family

The biocidal product is not the same as the one assessed for the inclusion of the active substances in annex 1 of directive 98/8/EC. The composition of the product is confidential and is presented in a confidential annex. The product contains 20 to 35% of technical active substance IR3535 and 19.94-34.90% of pure active substance IR3535 (purity 99.7%).

The product does not contain PT6 preservative.

The end-use concentrations of the product are: 20-35% ready-to-use

Formulation type: AL Any other Liquid

Hydrocarbon and H304 co-formulant content: 0%.

### Intended use(s) as applied for by the applicant – MIC 2020

#### **META-SPC 1 – CINQ SUR CINQ FAMILLE**

. Use # 1 – Skin repellent against mosquitoes

|  |  |
| --- | --- |
| **Product Type** | PT 19 |
| **Where relevant, an exact description of the authorised use** | Insect repellents |
| **Target organism(s) (including development stage)** | *Aedes* mosquitoes (*Aedes* *spp*.)  *Culex* mosquitoes (*Culex* *spp*.)  Development stage: adults |
| **Field(s) of use** | Skin application |
| **Application method(s)** | **Method of application:** spraying  **Detailed description of the method:**  Spraying on skin at 10 cm |
| **Application rate(s) and frequency** | **The application rate is** 0.7 mg / cm²  **Number and timing of application:**   * Child from 6 months up to 6 years: 1 application per day * Child to Adult (> 6 years): 2 applications per day |
| **Category(ies) of users** | General public (non-professional) |
| **Pack sizes and packaging material** | * Bottle spray: 100 mL   HDPE for the bottle |

Use # 2 – Skin repellent against ticks

|  |  |
| --- | --- |
| **Product Type** | PT 19 |
| **Where relevant, an exact description of the authorised use** | Insect repellents |
| **Target organism(s) (including development stage)** | Ticks (*Ixodes ricinus*)  Development stages: nymphs and adults. |
| **Field(s) of use** | Skin application |
| **Application method(s)** | **Method of application:** spraying  **Detailed description of the method:**  Spraying on skin at 10 cm |
| **Application rate(s) and frequency** | **The application rate is** ca. 0.95 mg / cm²  **Number and timing of application:**   * 1 application per day |
| **Category(ies) of users** | General public (non-professional) |
| **Pack sizes and packaging material** | * Bottle spray: 100 mL   HDPE for the bottle |

Use # 3 – Skin repellent against horse-flies

|  |  |
| --- | --- |
| **Product Type** | PT 19 |
| **Where relevant, an exact description of the authorised use** | Insect repellents |
| **Target organism(s) (including development stage)** | *Tabanidae* – Horse flies (*Dasybasis spp.*)  Development stage: adults |
| **Field(s) of use** | Skin application |
| **Application method(s)** | **Method of application:** spraying  **Detailed description of the method:**  Spraying on skin at 10 cm |
| **Application rate(s) and frequency** | **The application rate is** 1.95 mg / cm²  **Number and timing of application:**   * 1 application per day |
| **Category(ies) of users** | General public (non-professional) |
| **Pack sizes and packaging material** | * Bottle spray: 100 mL   HDPE for the bottle |

#### **META-SPC 2 – CINQ SUR CINQ ZONES TEMPEREES**

Use # 1 – Skin repellent against mosquitoes

|  |  |
| --- | --- |
| **Product Type** | PT 19 |
| **Where relevant, an exact description of the authorised use** | Insect repellents |
| **Target organism(s) (including development stage)** | *Aedes* mosquitoes (*Aedes* *spp*.)  *Culex* mosquitoes (*Culex* *spp*.)  Development stage: adults |
| **Field(s) of use** | Skin application |
| **Application method(s)** | **Method of application:** spraying  **Detailed description of the method:**  Spraying on skin at 10 cm |
| **Application rate(s) and frequency** | **The application rate is** 0.68 mg / cm²  **Number and timing of application:**   * Child from 6 months up to 6 years: 1 application per day * Child to Adult (> 6 years): 2 applications per day |
| **Category(ies) of users** | General public (non-professional) |
| **Pack sizes and packaging material** | * Bottle spray: 75 and 100 mL   HDPE for the bottle |

Use # 2 – Skin repellent against ticks

|  |  |
| --- | --- |
| **Product Type** | PT 19 |
| **Where relevant, an exact description of the authorised use** | Insect repellents |
| **Target organism(s) (including development stage)** | Ticks (*Ixodes ricinus*)  Development stages: nymphs and adults. |
| **Field(s) of use** | Skin application |
| **Application method(s)** | **Method of application:** spraying  **Detailed description of the method:**  Spraying on skin at 10 cm |
| **Application rate(s) and frequency** | **The application rate is** ca. 0.93 mg / cm²  **Number and timing of application:**   * 1 application per day |
| **Category(ies) of users** | General public (non-professional) |
| **Pack sizes and packaging material** | * Bottle spray: 75 and 100 mL   HDPE for the bottle |

Use # 3 – Skin repellent against horse-flies

|  |  |
| --- | --- |
| **Product Type** | PT 19 |
| **Where relevant, an exact description of the authorised use** | Insect repellents |
| **Target organism(s) (including development stage)** | *Tabanidae* – Horse flies (*Dasybasis spp.*)  Development stage: adults |
| **Field(s) of use** | Skin application |
| **Application method(s)** | **Method of application:** spraying  **Detailed description of the method:**  Spraying on skin at 10 cm |
| **Application rate(s) and frequency** | **The application rate is** 1.48 mg / cm²  **Number and timing of application:**   * 1 application per day |
| **Category(ies) of users** | General public (non-professional) |
| **Pack sizes and packaging material** | * Bottle spray: 75 and 100 mL   HDPE for the bottle |

#### **META-SPC 3 – CINQ SUR CINQ TROPIC**

Use # 1 – Skin repellent against mosquitoes

|  |  |
| --- | --- |
| **Product Type** | PT 19 |
| **Where relevant, an exact description of the authorised use** | Insect repellents |
| **Target organism(s) (including development stage)** | *Aedes* mosquitoes (*Aedes* *spp*.)  *Culex* mosquitoes (*Culex* *spp*.)  *Anopheles mosquitoes (Anopheles spp.)*  Development stage: adults |
| **Field(s) of use** | Skin application |
| **Application method(s)** | **Method of application:** spraying  **Detailed description of the method:**  Spraying on skin at 10 cm |
| **Application rate(s) and frequency** | **The application rate is** 0.48 mg / cm²  **Number and timing of application:**   * Child from 6 months up to 6 years: 1 application per day * Child to Adult (> 6 years): 2 applications per day |
| **Category(ies) of users** | General public (non-professional) |
| **Pack sizes and packaging material** | * Bottle spray: 75 and 100 mL   HDPE for the bottle |

Use # 2 – Skin repellent against ticks

|  |  |
| --- | --- |
| **Product Type** | PT 19 |
| **Where relevant, an exact description of the authorised use** | Insect repellents |
| **Target organism(s) (including development stage)** | Ticks (*Ixodes ricinus*)  Development stages: nymphs and adults. |
| **Field(s) of use** | Skin application |
| **Application method(s)** | **Method of application:** spraying  **Detailed description of the method:**  Spraying on skin at 10 cm |
| **Application rate(s) and frequency** | **The application rate is** 0.66 mg / cm²  **Number and timing of application:**   * 1 application per day |
| **Category(ies) of users** | General public (non-professional) |
| **Pack sizes and packaging material** | * Bottle spray: 75 and 100 mL   HDPE for the bottle |

Use # 3 – Skin repellent against horse-flies

|  |  |
| --- | --- |
| **Product Type** | PT 19 |
| **Where relevant, an exact description of the authorised use** | Insect repellents |
| **Target organism(s) (including development stage)** | *Tabanidae* – Horse flies (*Dasybasis spp.*)  Development stage: adults |
| **Field(s) of use** | Skin application |
| **Application method(s)** | **Method of application:** spraying  **Detailed description of the method:**  Spraying on skin at 10 cm |
| **Application rate(s) and frequency** | **The application rate is** 1.07 mg / cm²  **Number and timing of application:**   * 1 application per day |
| **Category(ies) of users** | General public (non-professional) |
| **Pack sizes and packaging material** | * Bottle spray: 100 mL   HDPE for the bottle |

### Physical, chemical and technical properties

#### **META-SPC 1 – CINQ SUR CINQ FAMILLE**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **FR Evaluation** | **Reference** |
| Physical state, colour, odour at 20 °C and 101.3 kPa | ECHA Guidance | CINQ SUR CINQ FAMILLE 20%  Batch: FC001  Bottle 100 mL HDPE | Homogeneous liquid colourless with an odour of lightly citrus | Acceptable | Dall’Acqua (2015), study n° 15.024236.0001 |
| Acidity / alkalinity | CIPAC MT 75.3 | CINQ SUR CINQ FAMILLE 20%  Batch: FC001  Bottle 100 mL HDPE | pH at 20°C: 6.46 | Acceptable | Dall’Acqua (2015), study n° 15.024236.0001 |
| Relative density / bulk density | EC method A.3 | CINQ SUR CINQ FAMILLE 20%  Batch: FC001  Bottle 100 mL HDPE | Relative density: 0.951 | Acceptable | Dall’Acqua (2015), study n° 15.024236.0001 |
| Storage stability test – **accelerated storage** | CIPAC MT 46.3  CIPAC MT 75.3  ECHA Guidance  Validated method of quantification of IR3535 (15.024236.0002) | CINQ SUR CINQ FAMILLE 20% NF  Batch: FC001  Bottle 100 mL HDPE commercial packaging | |  |  |  | | --- | --- | --- | |  | T0 | T4 weeks at 50°C | | AS content | 19.9 | 19.4 | | % variation | - | -2.52 | | pH at 20°C | 6.42 | 6.12 | | Physical state | Homogeneous liquid lightly citrus | No change | | Weight (g) | 123.02 | 119.33 | | Microbial assay  TAMC  TYMC | < 10 CFU/g  < 10 CFU/g | < 10 CFU/g  < 10 CFU/g | | Acceptable  The preparation is stable 4 weeks at 50°C. | Dall’Acqua (2015), study n° 15.024236.0004 |
| Storage stability test – **long term storage at ambient temperature** | Method BAUS-006R0 validated in the section analytical method. | CINQ SUR CINQ FAMILLE 20% NF  Batch: FC001  Bottle 100 mL HDPE commercial packaging | |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | |  | T0 | T3 months | T6 months | T12months | T24 months | T36 months | | AS content | 20.2 | 20.6 | 20.6 | 19.8 | 20.3 | 19.82 | | % variation | - | 1.98 | 1.98 | -1.98 | 0.39 | -1.89 | | pH at 20°C | 6.5 | 6.4 | 6.2 | 6.0 | 5.8 | 5.4 | | Physical state | Homogeneous liquid lightly citrus | No change | No change | No change | No change | No change | | Weight (g) | 123.3 | 123.3 | 123 | 121.4 | 120.2 | 118.6 | | Spray diameter (cm) | / | / | / | 11 | 10 | 10 | | Spray pattern | Homogeneous | / | / | Homogeneous | Homogeneous | Homogeneous | | quantity of delivered liquid by spray mL (discharge) | / | / | / | 0.15 | 0.15 | 0.16 | | Nozzle blockage | No residues | No residues | No residues | No residues | No residues | No residues | | Microbial assay  TAMC  TYMC | < 10 CFU/g  < 10 CFU/g | < 10 CFU/g  < 10 CFU/g | < 10 CFU/g  < 10 CFU/g | < 10 CFU/g  < 10 CFU/g | < 10 CFU/g  < 10 CFU/g | < 10 CFU/g  < 10 CFU/g | | The product is stable 36 months at ambient temperature but the particle size distribution after storage should be provided in post-authorisation.  Post authorisation data: Particle size distribution of 36 months aged product CINQ SUR CINQ 35% was submitted and considered acceptable. | Laboratoire Merieux (2018)  Report number SS\_020\_2015 |
| Storage stability test – **low temperature stability test for liquids** | Validated method of quantification of IR3535 (15.024236.0002) (GA-1308-698)  CIPAC MT 75.3 | CINQ SUR CINQ FAMILLE 20% NF  Batch: FC001  Bottle 100 mL HDPE commercial packaging | |  |  |  | | --- | --- | --- | |  | T0 | T7d | | Appearance | Homogeneous liquid lightly citrus | No change | | AS content | 20.0 | 20.0 | | pH at 20°C | 6.42 | 6.43 | | Weight | 123.02 | 123.01 | | Microbial assay  TAMC  TYMC | < 10 CFU/g  < 10 CFU/g | < 10 CFU/g  < 10 CFU/g | | Acceptable  The preparation is stable 7 days at 0°C. | Dall’Acqua (2015), study n° 15.024236.0005 |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** | Statement | - | According to the European risk assessment report of IR3535, it is considered photolytically stable.  The packaging of the CINQ SUR CINQ(R) LOTION products are in opaque PEHD.  The light is considered to have no influence on the stability of the products.  Consequently, no test was performed to study this parameter. | Acceptable | IUCLID |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** | - | - | - | Data on temperature have been provided in the accelerated storage stability study and in the low temperature stability study. | *-* |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | - | - | - | Data on reactivity towards container material have been provided in the accelerated storage stability study and in the low temperature stability study. | *-* |
| Wettability | - | - | - | Not relevant for an AL formulation | - |
| Suspensibility, spontaneity and dispersion stability | - | - | - | Not relevant for an AL formulation | - |
| Wet sieve analysis and dry sieve test | - | - | - | Not relevant for an AL formulation | - |
| Emulsifiability, re-emulsifiability and emulsion stability | - | - | - | Not relevant for an AL formulation | - |
| Disintegration time | - | - | - | Not relevant for an AL formulation | - |
| Particle size distribution, content of dust/fines, attrition, friability | - | - | - | Not relevant for an AL formulation | - |
| Persistent foaming | - | - | - | Not relevant for an AL formulation | - |
| Flowability/Pourability/Dustability | - | - | - | Not relevant for an AL formulation | - |
| Burning rate — smoke generators | - | - | - | Not relevant for an AL formulation | - |
| Burning completeness — smoke generators | - | - | - | Not relevant for an AL formulation | - |
| Composition of smoke — smoke generators | - | - | - | Not relevant for an AL formulation | - |
| Spraying pattern — aerosols | - | - | - | Not relevant for an AL formulation | - |
| Physical compatibility | - | - | - | - | - |
| Chemical compatibility | - | - | - | - | - |
| Degree of dissolution and dilution stability | - | - | - | Not relevant for an AL formulation | - |
| Surface tension | ASTM D1331/89 (2001) | CINQ SUR CINQ FAMILLE 20%  Batch: FC001  Bottle 100 mL HDPE | Test substance, 29.18 mN/m at 25°C. | Acceptable  The preparation is active in surface. | Dall’Acqua (2015), study n° 15.024236.0001 |
| Viscosity | ECD Test Guideline 114 | CINQ SUR CINQ FAMILLE 20%  Batch: FC001  Bottle 100 mL HDPE | Kinematic viscosity at 20°C: 6.14 mm²/s  Kinematic viscosity at 40°C: 3.24 mm²/s  Dynamic viscosity at 20°C: 5.83 mPa s | Acceptable | Dall’Acqua (2015), study n° 15.024236.0001 |
| Discharge | - | CINQ SUR CINQ FAMILLE 20%  Batch: FC001 | Deliverered volume by spray was calculated with a density = 0.940  Delivered volume= 0.1493 mL  Number of spray: 658 | Acceptable  The density is not the same as the one found in the study n° 15.024236.0001 | 031 ETU BAU 15 |
| Particle size distribution | CIPAC MT187 | CINQ SUR CINQ FAMILLE 20%  Batch: FC001  100 mL PE bottle | |  |  |  |  | | --- | --- | --- | --- | | Test item | Dv (10%) µm | Dv (50%) µm | Dv (90%) µm | | 2 | 40.12 | 92.32 | 171.73 | | 3 | 40.94 | 96.63 | 175.32 | | 4 | 40.28 | 107.24 | 187.21 | | mean | 40 | 99 | 178 | | Acceptable | Rodriguez (2015)  Mo5311 |

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| **Conclusion on the physical, chemical and technical properties of the product** |
| The product CINQ SUR CINQ FAMILLE is an AL formulation. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable.  The appearance of the product is a homogeneous liquid lightly citrus odour. There is no effect of high temperature on the stability of the formulation, since after 4 weeks at 50°C and after 36 months at ambient temperature in HDPE bottle packaging material (commercial packaging material), neither the active ingredient content nor the technical properties were changed.  However, the particle size distribution after long term storage is missing and should be provided within two years (Post authorisation data was submitted in January 2020, please refer to the section: **Post authorisation requirement assessment**).  After 7 days at 0°C, the appearance and technical characteristic have not significantly changed. The product is stable at 0°C.  Its technical characteristics are acceptable for an AL formulation.  The wall META SPC 1 is covered by provided data. |

#### **META-SPC 2 – CINQ SUR CINQ ZONES TEMPEREES**

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| --- | --- | --- | --- | --- | --- |
| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **FR Evaluation** | **Reference** |
| Physical state, colour, odour at 20 °C and 101.3 kPa | ECHA Guidance | CINQ SUR CINQ ZONES TEMEPREES  Batch: FC021  Bottle 75 mL HDPE | Homogeneous liquid colourless with an odour of strong citrus | Acceptable | Dall’Acqua (2015), study n° 37101 |
| Acidity / alkalinity | CIPAC MT 75.3 | CINQ SUR CINQ ZONES TEMEPREES  Batch: FC021  Bottle 75 mL HDPE | pH at 20°C: 6.55 | Acceptable  Provided data cover the wall META SPC 2. | Dall’Acqua (2015), study n° 15.024236.0001 |
| Relative density / bulk density | EC method A.3 | CINQ SUR CINQ ZONES TEMEPREES  Batch: FC021  Bottle 75 mL HDPE | Relative density: 0.9462 | Acceptable  Provided data cover the wall META SPC 2. | Dall’Acqua (2015), study n° 15.024236.0001 |
| Storage stability test – **accelerated storage** | CIPAC MT 46.3  CIPAC MT 75.3  ECHA Guidance  Validated method of quantification of IR3535 (37093) | CINQ SUR CINQ ZONES TEMEPREES  Batch: FC021  Bottle 75 mL HDPE  CINQ SUR CINQ ZONES TEMEPREES  Batch: FC001  Bottle 75 mL HDPE (commercial packaging) | Old formulation:  New formulation:   |  |  |  | | --- | --- | --- | |  | T0 | T4 weeks at 50°C | | AS content | 25.6 | 25.61 | | % variation | - | -2.52 | | pH at 20°C | 6.56 | 6.38 | | Physical state | Homogeneous liquid lightly citrus | No change | | Weight (g) | 95.45 | 95.44 |  |  |  |  | | --- | --- | --- | |  | T0 | T4 weeks at 50°C | | AS content | 24.9 | 25.0 | | % variation | - | 0.4 | | pH at 20°C | 6.86 | 6.53 | | Physical state | Homogeneous liquid lightly citrus | No change | | Weight (g) | 96.21 | 92.46 | | Microbial assay  TAMC  TYMC | < 10 CFU/g  < 10 CFU/g | < 10 CFU/g  < 10 CFU/g | | Acceptable  The preparation is stable 4 weeks at 50°C. | Dall’Acqua (2015), study n° 37101  Dall’Acqua (2015), study n°15.024892.0004 |
| Storage stability test – **long term storage at ambient temperature** | Validated method of quantification of IR3535 (37093) | CINQ SUR CINQ ZONES TEMEPREES  Batch: FC021  Bottle 75 mL HDPE (commercial packaging) | |  |  |  |  |  | | --- | --- | --- | --- | --- | |  | T0 | T3 months at RT | T6 months at RT | T9 months at RT | | AS content | 25.6 | 25.7 | 23.6 | 25.3 | | % variation | - | 0.3 | -7.9 | -1.2 | | pH at 20°C | 6.56 | 6.5 | 6.3 | 6.1 | | Physical state | Homogeneous liquid lightly citrus | No change | No change | No change | | Weight (g) | 95.45 | 95.38 | 95.34 | 95.28 | | µbial assay  TAMC  TYMC | < 10 CFU/g  < 10 CFU/g | < 10 CFU/g  < 10 CFU/g | < 10 CFU/g  < 10 CFU/g | < 10 CFU/g  < 10 CFU/g | | The study of long term storage in commercial packaging should be provided within two years. | Laboratoire Merieux (2015)  Test report 200040703  200043295  200046436 |
|  | Method BAUS-006R0 validated in the section analytical method. | Bottle 75 mL HDPE  CINQ SUR CINQ ZONES TEMEPREES  Batch: FC001  Bottle 75 mL HDPE (commercial packaging) | |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | |  | T0 | T3 months | T6 months | T12months | T24 months | T36 months | | AS content | 25.3 | 25.2 | 25.4 | 25.5 | 25.2 | 24.4 | | % variation | - | -0.4 | 0.4 | 0.8 | -0.4 | -3.6 | | pH at 20°C | 6.6 | 6.5 | 6.4 | 6.0 | 5.9 | 5.5 | | Physical state | Homogeneous liquid lightly citrus | No change | No change | No change | No change | No change | | Weight (g) | 96.1 | 96 | 95.9 | 95.9 | 95.7 | 95.6 | | Spray diameter (cm) | / | / | / | 10 | 10 | 10 | | Spray pattern | Homogeneous | / | / | Homogeneous | Homogeneous | Homogeneous | | quantity of delivered liquid by spray mL (discharge) | / | / | / | 0.15 | 0.15 | 0.16 | | Nozzle blockage | No residues | No residues | No residues | No residues | No residues | No residues | | Microbial assay  TAMC  TYMC | < 10 CFU/g  < 10 CFU/g | < 10 CFU/g  < 10 CFU/g | < 10 CFU/g  < 10 CFU/g | < 10 CFU/g  < 10 CFU/g | < 10 CFU/g  < 10 CFU/g | < 10 CFU/g  < 10 CFU/g | | The product is stable 36 months at ambient temperature but the particle size distribution after storage should be provided in post-authorisation  Post authorisation: Particle size distribution of 36 months aged product CINQ SUR CINQ 35% was submitted and considered acceptable. | Laboratoire Merieux (2018)  Report Number SS\_020\_2015 |
| Storage stability test – **low temperature stability test for liquids** | Validated method of quantification of IR3535 (37093)  CIPAC MT 75.3 | CINQ SUR CINQ ZONES TEMEPREES  Batch: FC021  Bottle 75 mL HDPE (commercial packaging) | |  |  |  | | --- | --- | --- | |  | T0 | T7d at 0°C | | Appearance | Homogeneous liquid pale yellow lightly citrus | No change | | AS content | 25.6 | 25.6 | | pH at 20°C | 6.57 | 6.48 | | Weight | 95.36 | 95.31 | | Microbial assay  TAMC  TYMC | < 10 CFU/g  < 10 CFU/g | < 10 CFU/g  < 10 CFU/g | | Acceptable  The preparation is stable 7 days at 0°C. Provided data cover the wall META SPC 2. | Dall’Acqua (2015), study n° 15.024236.0005 |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** | Statement | - | According to the European risk assessment report of IR3535, it is considered photolytically stable.  The packaging of the CINQ SUR CINQ(R) LOTION products are in opaque PEHD.  The light is considered to have no influence on the stability of the products.  Consequently, no test was performed to study this parameter. | Acceptable | IUCLID |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** | - | - | - | Data on temperature have been provided in the accelerated storage stability study and in the low temperature stability study. | *-* |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | - | - | - | Data on reactivity towards container material have been provided in the accelerated storage stability study and in the low temperature stability study. | *-* |
| Wettability | - | - | - | Not relevant for an AL formulation | - |
| Suspensibility, spontaneity and dispersion stability | - | - | - | Not relevant for an AL formulation | - |
| Wet sieve analysis and dry sieve test | - | - | - | Not relevant for an AL formulation | - |
| Emulsifiability, re-emulsifiability and emulsion stability | - | - | - | Not relevant for an AL formulation | - |
| Disintegration time | - | - | - | Not relevant for an AL formulation | - |
| Particle size distribution, content of dust/fines, attrition, friability | - | - | - | Not relevant for an AL formulation | - |
| Persistent foaming | - | - | - | Not relevant for an AL formulation | - |
| Flowability/Pourability/Dustability | - | - | - | Not relevant for an AL formulation | - |
| Burning rate — smoke generators | - | - | - | Not relevant for an AL formulation | - |
| Burning completeness — smoke generators | - | - | - | Not relevant for an AL formulation | - |
| Composition of smoke — smoke generators | - | - | - | Not relevant for an AL formulation | - |
| Spraying pattern — aerosols | - | - | - | Not relevant for an AL formulation | - |
| Physical compatibility | - | - | - | - | - |
| Chemical compatibility | - | - | - | - | - |
| Degree of dissolution and dilution stability | - | - | - | Not relevant for an AL formulation | - |
| Surface tension | ASTM D1331/89 (2001) | CINQ SUR CINQ ZONES TEMEPREES  Batch: FC021  Bottle 75 mL HDPE | Test substance, 28.96 mN/m at 25°C. | Acceptable  The preparation is active surface. Provided data cover the wall META SPC 2. | Dall’Acqua (2015), study n° 15.024236.0001 |
| Viscosity | ECD Test Guideline 114 | CINQ SUR CINQ ZONES TEMEPREES  Batch: FC021  Bottle 75 mL HDPE | Kinematic viscosity at 20°C: 6.16 mm²/s  Kinematic viscosity at 40°C: 3.39 mm²/s  Dynamic viscosity at 20°C: 5.81 mPa s | Acceptable  Provided data cover the wall META SPC 2. | Dall’Acqua (2015), study n° 37105 |
| Discharge | - | CINQ SUR CINQ ZONES TROPIC 25%  Batch: FC001 | Deliverered volume by spray was calculated with a density = 0.950.  Delivered volume= 0.1392 mL  Number of spray: 509 | Acceptable  Provided data cover the wall META SPC 2. | 031 ETU BAU 15 |
| Particle size distribution | CIPAC MT187 | CINQ SUR CINQ ZONES TEMPEREES 25% NF  Batch: FC001  75 mL PE bottle | |  |  |  |  | | --- | --- | --- | --- | | Test item | Dv (10%) µm | Dv (50%) µm | Dv (90%) µm | | 2 | 38.83 | 98.26 | 185.63 | | 3 | 41.79 | 102.33 | 182.37 | | 4 | 43.03 | 93.89 | 165.46 | | mean | 41 | 98 | 178 | | Acceptable  Provided data cover the wall META SPC 2. | Rodriguez (2015)  Mo5304 |

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| **Conclusion on the physical, chemical and technical properties of the product** |
| The two products CINQ SUR CINQ ZONES TEMPEREES (old and new formulation) are an AL formulation. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable The appearance of the product is a homogeneous liquid lightly citrus odour.  There is no effect of high temperature on the stability of the formulation, since after 4 weeks at 50°C and after 36 months at ambient temperature in HDPE bottle packaging material (commercial packaging material), neither the active ingredient content nor the technical properties were changed.  However, the particle size distribution after long term storage is missing and should be provided within two years (Post authorisation data was submitted in January 2020, please refer to the section: **Post authorisation requirement assessment**).  After 7 days at 0°C, the appearance and technical characteristic have not significantly changed. The product is stable at 0°C.  Its technical characteristics are acceptable for an AL formulation.  The wall META SPC 2 is covered, due to the similar compositions, by provided data. |

#### **META-SPC 3 – CINQ SUR CINQ TROPIC**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **FR Evaluation** | **Reference** |
| Physical state, colour, odour at 20 °C and 101.3 kPa | ECHA Guidance | CINQ SUR CINQ TROPIC 35% NF  Batch: FC001  Bottle 75 mL HDPE | Homogeneous liquid pale yellow with an odour of strong citrus | Acceptable | Dall’Acqua (2015), study n° 15.024891.0001 |
| Acidity / alkalinity | CIPAC MT 75.3 | CINQ SUR CINQ TROPIC 35% NF  Batch: FC001  Bottle 75 mL HDPE | pH at 20°C: 7.15 | Acceptable | Dall’Acqua (2015), study n° 15.024891.0001 |
| Relative density / bulk density | EC method A.3 | CINQ SUR CINQ TROPIC 35% NF  Batch: FC001  Bottle 75 mL HDPE | Relative density: 0.9435 | Acceptable  Provided data cover the wall META SPC 3. | Dall’Acqua (2015), study n° 15.024891.0001 |
| Storage stability test – **accelerated storage** | CIPAC MT 46.3  CIPAC MT 75.3  ECHA Guidance  Validated method of quantification of IR3535 (37093) | CINQ SUR CINQ TROPIC 35% AF  Batch: FC112  Bottle 75 mL HDPE  CINQ SUR CINQ TROPIC 35% NF  Batch: FC001  Bottle 75 mL HDPE | Old formulation:  New formulation:   |  |  |  | | --- | --- | --- | |  | T0 | T4 weeks at 50°C | | AS content | 35.63 | 35.55 | | % variation | - | -0.3 | | pH at 20°C | 7.07 | 6.86 | | Physical state | Homogeneous liquid strong citrus | No change | | Weight (g) | 95.54 | 95.52 | | Microbial assay  TAMC  TYMC | < 10 CFU/g  < 10 CFU/g | < 10 CFU/g  < 10 CFU/g |  |  |  |  | | --- | --- | --- | |  | T0 | T4 weeks at 50°C | | AS content | 34.7 | 33.8 | | % variation | - | -2.6 | | pH at 20°C | 7.18 | 7.17 | | Physical state | Homogeneous pale yallow liquid strong citrus | No change | | Weight (g) | 96.43 | 92.57 | | Microbial assay  TAMC  TYMC | < 10 CFU/g  < 10 CFU/g | < 10 CFU/g  < 10 CFU/g | | Acceptable  The preparation is stable 4 weeks at 50°C.  Provided data cover the wall META SPC 3. | Dall’Acqua (2015), study n° 37100  Dall’Acqua (2015), study n°15.024892.0004 |
| Storage stability test – **long term storage at ambient temperature** | Method BAUS-006R0 validated in the section analytical method. | CINQ SUR CINQ TROPIC 35% NF  Batch: FC001  Bottle 100 mL HDPE | |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | |  | T0 | T6 months | T12months | T18months | T24 months | | AS content | 36.71 | 35.82 | 36.13 | 34.54 | 35.34 | | % variation | - | -2.5 | -1.6 | -6 | -3.8 | | pH at 20°C | 6.7 | 6.5 | 6.5 | 6.5 | 6.0 | | Physical state | Homogeneous liquid lightly citrus | No change | No change | No change | No change | | Weight (g) | 126.6 | 123.2 | 123.1 | 123.8 | 122.9 | | Spray diameter (cm) | 10 | 10 | 10 | 10 | 10 | | Spray pattern | Homogeneous | Homogeneous | Homogeneous | Homogeneous | Homogeneous | | quantity of delivered liquid by spray mL (discharge) | 0.15 | 0.17 | 0.17 | 0.17 | 0.16 | | Nozzle blockage | No residues | No residues | No residues | No residues | No residues | | The final study of long term storage in commercial packaging be provided within two years. | Laboratoire Merieux (2018) |
| Storage stability test – **low temperature stability test for liquids** | Validated method of quantification of IR3535 (37093)  CIPAC MT 75.3 | CINQ SUR CINQ TROPIC 35% NF  Batch: FC001  Bottle 75 mL HDPE | |  |  |  | | --- | --- | --- | |  | T0 | T7d | | Appearance | Homogeneous liquid pale yellow strong citrus | No change | | AS content | 34.4 | 34.2 | | % variation | - | -0.6 | | pH at 20°C | 7.18 | 7.17 | | Weight | 96.62 | 96.56 | | Microbial assay  TAMC  TYMC | < 10 CFU/g  < 10 CFU/g | < 10 CFU/g  < 10 CFU/g | | Acceptable  The preparation is stable 7 days at 0°C.  Provided data cover the wall META SPC 3. | Dall’Acqua (2015), study n° 15.024236.0005 |
| Effects on content of the active substance and technical characteristics of the biocidal product - **light** | Statement | - | According to the European risk assessment report of IR3535, it is considered photolytically stable.  The packaging of the CINQ SUR CINQ(R) LOTION products are in opaque PEHD.  The light is considered to have no influence on the stability of the products.  Consequently, no test was performed to study this parameter. | Acceptable | IUCLID |
| Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity** | - | - | - | Data on temperature have been provided in the accelerated storage stability study and in the low temperature stability study. | *-* |
| Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material** | - | - | - | Data on reactivity towards container material have been provided in the accelerated storage stability study and in the low temperature stability study. | *-* |
| Wettability | - | - | - | Not relevant for an AL formulation | - |
| Suspensibility, spontaneity and dispersion stability | - | - | - | Not relevant for an AL formulation | - |
| Wet sieve analysis and dry sieve test | - | - | - | Not relevant for an AL formulation | - |
| Emulsifiability, re-emulsifiability and emulsion stability | - | - | - | Not relevant for an AL formulation | - |
| Disintegration time | - | - | - | Not relevant for an AL formulation | - |
| Particle size distribution, content of dust/fines, attrition, friability | - | - | - | Not relevant for an AL formulation | - |
| Persistent foaming | - | - | - | Not relevant for an AL formulation | - |
| Flowability/Pourability/Dustability | - | - | - | Not relevant for an AL formulation | - |
| Burning rate — smoke generators | - | - | - | Not relevant for an AL formulation | - |
| Burning completeness — smoke generators | - | - | - | Not relevant for an AL formulation | - |
| Composition of smoke — smoke generators | - | - | - | Not relevant for an AL formulation | - |
| Spraying pattern — aerosols | - | - | - | Not relevant for an AL formulation | - |
| Physical compatibility | - | - | - | - | - |
| Chemical compatibility | - | - | - | - | - |
| Degree of dissolution and dilution stability | - | - | - | Not relevant for an AL formulation | - |
| Surface tension | ASTM D1331/89 (2001) | CINQ SUR CINQ TROPIC 35% AF  Batch: FC112  Bottle 75 mL HDPE | Test substance, 28.75 mN/m at 25°C. | Acceptable  The preparation is active in surface.  Provided data cover the wall META SPC 3. | Dall’Acqua (2015), study n° 37104 |
| Viscosity | ECD Test Guideline 114 | CINQ SUR CINQ TROPIC 35% AF  Batch: FC112  Bottle 75 mL HDPE | Kinematic viscosity at 20°C: 6.24 mm²/s  Kinematic viscosity at 40°C: 3.45 mm²/s  Dynamic viscosity at 20°C: 5.88 mPa s | Acceptable  Provided data cover the wall META SPC 3. | Dall’Acqua (2015), study n° 37104 |
| Discharge | - | CINQ SUR CINQ TROPIC 35% NF  Batch: FC001  Batch: FC001 | Deliverered volume by spray was calculated with a density = 0.940.  Delivered volume= 0.1383 mL  Number of spray: 515 | Acceptable  Provided data cover the wall META SPC 3. | 031 ETU BAU 15 |
| Particle size distribution | CIPAC MT187 | CINQ SUR CINQ TROPIC 35% NF  Batch: FC001  75 mL PE bottle | |  |  |  |  | | --- | --- | --- | --- | | Test item | Dv (10%) µm | Dv (50%) µm | Dv (90%) µm | | 2 | 40.27 | 93.10 | 176.16 | | 3 | 43.37 | 105.08 | 185.94 | | 4 | 41.71 | 97.95 | 178.95 | | mean | 42 | 99 | 180 | | Acceptable  Provided data cover the wall META SPC 3. | Rodriguez (2015)  Mo5304 |

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| **Conclusion on the physical, chemical and technical properties of the product** |
| The products of META SPC 3 CINQ SUR CINQ TROPIC (old and new formulation) are an AL formulation. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is a homogeneous liquid lightly citrus odour. There is no effect of high temperature on the stability of the formulation, since after 4 weeks at 50°C, neither the active ingredient content nor the technical properties were changed.  The long term storage stability study (36 months at ambient temperature in HDPE bottle packaging material (commercial packaging material)) should be provided within one year (Post authorisation data was submitted in January 2020, please refer to the section: **Post authorisation requirement assessment**).  Please refer to section **Minor change 2020.**  After 7 days at 0°C, the appearance and technical characteristic have not significantly changed. The product is stable at 0°C. |

* Post authorisation requirement assessment

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Storage stability test – **long term storage at ambient temperature** | Method BAUS-006R0 validated in the section analytical method. | CINQ SUR CINQ 35% new formulation  Batch: FC001  Bottle 100 mL HDPE commercial packaging | |  |  |  |  |  | | --- | --- | --- | --- | --- | |  | T0 | T12months | T24 months | T36 months | | AS content | 36.7 | 36.13 | 35.34 | 35.73 | | pH at 20°C | 6.7 | 6.5 | 6.0 | 6.3 | | Physical state | Homogeneous liquid lightly citrus | | | | | Spray diameter (cm) | / | 10 | 10 | 10 | | Spray pattern | Homogeneous | Homogeneous | Homogeneous | Homogeneous | | quantity delivered by spray (discharge) | / | 0.16 mL | 0.17 mL | 0.15 mL | | Nozzle blockage | No residues | No residues | No residues | No residues | | The product is stable 36 months at ambient temperature | Laboratoire Merieux (2019)  Report number SS\_022\_2016 |
| |  | | --- | | **Particle size distribution** | | CIPAC MT187 | CINQ SUR CINQ 35% new formulation | Particle size distribution of 36 month old sample:  Dv (10%) 37 µm  Dv (50%) 92 µm  Dv (90%) 205 µm | acceptable | L. Mack 2019  Study number Mo6582 |

The following data requested in post-authorisation were provided:

* The particle size distribution after storage for meta-SPC 1, meta-SPC 2 and meta-SPC3
* The long term storage study for meta-SPC3

Particle size distribution of 36 months aged product CINQ SUR CINQ 35% (meta SPC3) was submitted and considered acceptable. It can be read across to other products of meta SPC1 and meta SPC2 as the spray devices are identical between meta SPCs.

According to the long term storage study provided, the biocidal product of meta SPC 3 is stable after 36 months at ambient temperature. However as no minor change was submitted to request a change of shelf life for meta SPC3, no modification of SPC is performed in the framework of post authorisation application and the 2 years shelf life already authorised is maintained at this time.

* **Minor change 2020:**

Based on the evaluation and validation of the long term storage study provided as post authorisation data (please refer to “Post authorisation requirement assessment” above), shelf life for products of the meta SPC 3 is set to 36 months at ambient temperature instead of 24 months.

### Physical hazards and respective characteristics

#### **META-SPC 1 – CINQ SUR CINQ FAMILLE**

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **FR evaluation** | **Reference** |
| --- | --- | --- | --- | --- | --- |
| Explosives | Statement | - | CINQ SUR CINQ LOTION's products have no explosives properties. | Acceptable | IUCLID |
| Flammable gases | - | - | - | Not relevant as the product is a liquid | - |
| Flammable aerosols | - | - | - | Not relevant as the product is a liquid | - |
| Oxidising gases | - | - | - | Not relevant as the product is a liquid | - |
| Gases under pressure | - | - | - | Not relevant as the product is not a gas under pressure | - |
| Flammable liquids | EC test A9 | CINQ SUR CINQ FAMILLE 20%  Batch: FC001  Bottle 100 mL HDPE | Flash point: 26.5°C | Acceptable  The preparation is classified H226 cat.3 | DEKRA (2015), Report GLP114118/B/R1V1/2015 |
| Boiling temperature | EC A2 | CINQ SUR CINQ FAMILLE 20%  Batch: FC001  Bottle 100 mL HDPE | 92.9°C |  | DEKRA (2015), Report GLP114118/B/R1V1/2015 |
| Flammable solids | - | - | - | Not relevant as the product is a liquid | - |
| Self-reactive substances and mixtures | - | - | No data provided. |  |  |
| Pyrophoric liquids | - | - | No data provided. | - | - |
| Pyrophoric solids | - | - | - | Not relevant as the product is a liquid | - |
| Self-heating substances and mixtures | - | - | No data provided. | - | - |
| Substances and mixtures which in contact with water emit flammable gases | - | - | No data provided. | - | - |
| Oxidising liquids | Statement | - | CINQ SUR CINQ LOTION products have not oxidising properties. | Acceptable | IUCLID |
| Oxidising solids | - | - | - | Not relevant as the product is a liquid | - |
| Organic peroxides | - | - | No data provided. | - | - |
| Corrosive to metals | - | - | No data provided. | - | - |
| Auto-ignition temperatures of products (liquids and gases) | EC test A15 | CINQ SUR CINQ FAMILLE 20%  Batch: FC001  Bottle 100 mL HDPE | 392°C | Acceptable  The product is not auto-flammable. | DEKRA (2015), Report GLP114118/B/R1V1/2015 |
| Relative self-ignition temperature for solids | - | - | - | Not relevant as the product is a liquid | - |
| Dust explosion hazard | - | - | - | Not relevant as the product is a liquid | - |

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| **Conclusion on the physical hazards and respective characteristics of the product** |
| The product of META SPC 1 is flammable H226 cat.3. It has no explosive and no oxidizing properties.  Implication concerning labelling:  flammable liquid- category 3 – H226 |

#### **META-SPC 2 – CINQ SUR CINQ ZONES TEMPEREES**

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **FR evaluation** | **Reference** |
| --- | --- | --- | --- | --- | --- |
| Explosives | Statement | - | CINQ SUR CINQ LOTION's products have no explosives properties. | Acceptable | IUCLID |
| Flammable gases | - | - | - | Not relevant as the product is a liquid | - |
| Flammable aerosols | - | - | - | Not relevant as the product is a liquid | - |
| Oxidising gases | - | - | - | Not relevant as the product is a liquid | - |
| Gases under pressure | - | - | - | Not relevant as the product is not a gas under pressure | - |
| Flammable liquids | EC test A9 | CINQ SUR CINQ ZONES TEMPEREES 25%  Batch: FC001  Bottle 100 mL HDPE | Flash point: 27°C | Acceptable  The preparation is classified H226 cat.3  Provided data cover the wall META SPC 2. | DEKRA (2015), Report GLP113300AR1V1/2015 |
| Boiling temperature | EC A2 | CINQ SUR CINQ ZONES TEMPEREES 25%  Batch: FC001  Bottle 100 mL HDPE | 89-93°C | Acceptable  Provided data cover the wall META SPC 2. | DEKRA (2015), Report GLP113300AR1V1/2015 |
| Flammable solids | - | - | - | Not relevant as the product is a liquid | - |
| Self-reactive substances and mixtures | - | - | No data provided. |  |  |
| Pyrophoric liquids | - | - | No data provided. | - | - |
| Pyrophoric solids | - | - | - | Not relevant as the product is a liquid | - |
| Self-heating substances and mixtures | - | - | No data provided. | - | - |
| Substances and mixtures which in contact with water emit flammable gases | - | - | No data provided. | - | - |
| Oxidising liquids | Statement | - | CINQ SUR CINQ LOTION products have not oxidising properties. | Acceptable | IUCLID |
| Oxidising solids | - | - | - | Not relevant as the product is a liquid | - |
| Organic peroxides | - | - | No data provided. | - | - |
| Corrosive to metals | - | - | No data provided. | - | - |
| Auto-ignition temperatures of products (liquids and gases) | EC test A15 | CINQ SUR CINQ ZONES TEMPEREES 25%  Batch: FC001  Bottle 100 mL HDPE | 395°C | Acceptable  Provided data cover the wall META SPC 2. | DEKRA (2015), Report GLP113300AR1V1/2015 |
| Relative self-ignition temperature for solids | - | - | - | Not relevant as the product is a liquid | - |
| Dust explosion hazard | - | - | - | Not relevant as the product is a liquid | - |

|  |
| --- |
| **Conclusion on the physical hazards and respective characteristics of the product** |
| The products of META SPC 2 are flammable H226 cat.3. they have no explosive and no oxidizing properties.  Implication concerning labelling:  flammable liquid- category 3 – H226 |

#### **META-SPC 3 – CINQ SUR CINQ TROPIC**

| **Property** | **Guideline and Method** | **Purity of the test substance (% (w/w)** | **Results** | **FR evaluation** | **Reference** |
| --- | --- | --- | --- | --- | --- |
| Explosives | Statement | - | CINQ SUR CINQ LOTION's products have no explosives properties. | Acceptable  Provided data cover the wall META SPC 3. | IUCLID |
| Flammable gases | - | - | - | Not relevant as the product is a liquid | - |
| Flammable aerosols | - | - | - | Not relevant as the product is a liquid | - |
| Oxidising gases | - | - | - | Not relevant as the product is a liquid | - |
| Gases under pressure | - | - | - | Not relevant as the product is not a gas under pressure | - |
| Flammable liquids | EC test A9 | CINQ SUR CINQ ZONE TEMPEREE 25%  Batch: FC001  Bottle 100 mL HDPE | Flash point: 25.5°C | Acceptable  The preparation is classified H226 cat.3  Provided data cover the wall META SPC 3. | DEKRA (2015), Report GLP114118/A/R1V1/2015 |
| Boiling temperature | EC A2 | CINQ SUR CINQ ZONE TEMPEREE 25%  Batch: FC001  Bottle 100 mL HDPE | 86.6°C | Acceptable  Provided data cover the wall META SPC 3. | DEKRA (2015), Report GLP113300AR1V1/2015 |
| Flammable solids | - | - | - | Not relevant as the product is a liquid | - |
| Self-reactive substances and mixtures | - | - | No data provided. |  |  |
| Pyrophoric liquids | - | - | No data provided. | - | - |
| Pyrophoric solids | - | - | - | Not relevant as the product is a liquid | - |
| Self-heating substances and mixtures | - | - | No data provided. | - | - |
| Substances and mixtures which in contact with water emit flammable gases | - | - | No data provided. | - | - |
| Oxidising liquids | Statement | - | CINQ SUR CINQ LOTION products have not oxidising properties. | Acceptable  Provided data cover the wall META SPC 3. | IUCLID |
| Oxidising solids | - | - | - | Not relevant as the product is a liquid | - |
| Organic peroxides | - | - | No data provided. | - | - |
| Corrosive to metals | - | - | No data provided. | - | - |
| Auto-ignition temperatures of products (liquids and gases) | EC test A15 | CINQ SUR CINQ ZONE TEMPEREE 25%  Batch: FC001  Bottle 100 mL HDPE | 377°C | Acceptable  Provided data cover the wall META SPC 3. | DEKRA (2015), Report GLP113300AR1V1/2015 |
| Relative self-ignition temperature for solids | - | - | - | Not relevant as the product is a liquid | - |
| Dust explosion hazard | - | - | - | Not relevant as the product is a liquid | - |

|  |
| --- |
| **Conclusion on the physical hazards and respective characteristics of the product** |
| The products of META SPC 3 are flammable H226 cat.3. they have no explosive and no oxidizing properties.  Implication concerning labelling:  flammable liquid- category 3 – H226 |

### Methods for detection and identification

**1/ Analytical method for CINQ SUR CINQ FAMILLE**

Report: Dall’Acqua 2015

Report no 15.024236.0002

Test facility:

CHELAB S . r.l

Via fratta, 25

31023 Resana (TV)

ITALY

**Principle of the method:**

Validation method BAUS-006 rev.0. The preparation is analysed by HPLC-DAD at ƛ=220 nm CINQ SUR CINQ FAMILLE 20%.

**Validation data:**

|  |  |  |
| --- | --- | --- |
| Specificity | To demonstrate the specificity of the method, several solution are analyzed:   * Solvent blank (EtOH) * Formulation blank * Reference solution of the active substance IR3535 * Test solution of the product   No interference was found: no peak appears in the chromatograms in the solvent blank and in the formulation blank, one peak is observed at the same retention time for the reference item and test item.  The DAD spectrum of reference solution and test solution have been provided. | |
| Linearity | Linearity was studied by carrying out five concentrations between 80% and 140% of the reference item.  Calibration curve has been provided with a R2 higher than 0.997. | |
| Compound | Linearity % |
| Active substance:IR3535 | 80% to 140%  Y = 5.385.103 X  n=5 |
| Precision | Repeatability was evaluated by analyzing five (n=1) test item solutions. | |
| Compound | Repeatability (RSD) |
| Active substance: IR3535 | RSD = 0.69% |
| Accuracy | Accuracy was determined by analysis of 3 different test solutions at 3 level of concentration (80; 100; 120%). The accuracy results are expressed as the recovery rate.   |  |  |  |  |  | | --- | --- | --- | --- | --- | | Fortification level | Recovery rate | Mean recovery rate | RSD (%) | n | | 80% (15.9% w/w) | 99; 99; 101 | 100 | 1.2 | 3 | | 100% (19.9% w/w) | 101; 100; 101 | 101 | 0.7 | 3 | | 120% (23.9 %w/w) | 100; 98; 98 | 99 | 1.0 | 3 | | |

The analytical method is fully validated for the determination of the active substance IR3535 in the product CINQ SUR CINQ FAMILLE.

**2/ Analytical method for CINQ SUR CINQ ZONES TEMPEREES**

Report: Dall’Acqua 2015

Report no 37093

Test facility:

CHELAB S . r.l

Via fratta, 25

31023 Resana (TV)

ITALY

**Principle of the method:**

Validation method BAUS-006 rev.0. The preparation is analysed by HPLC-DAD at ƛ=220 nm.

CINQ SUR CINQ ZONE TEMPEREES.

Batch FC112

**Validation data:**

|  |  |  |
| --- | --- | --- |
| Specificity | To demonstrate the specificity of the method, several solution are analyzed:   * Solvent blank (EtOH) * Formulation blank * Reference solution of the active substance IR3535 * Test solution of the product   No interference was found: no peak appears in the chromatograms in the solvent blank and in the formulation blank, one peak is observed at the same retention time for the reference item and test item.  The DAD spectrum of reference solution and test solution have been provided. | |
| Linearity | Linearity was studied by carrying out five concentrations between 80% and 140% of the reference item.  Calibration curve has been provided with a R2 higher than 0.999. | |
| Compound | Linearity % |
| Active substance:IR3535 | 80% to 140%  Y = 5.306.103 X  n=5 |
| Precision | Repeatability was evaluated by analyzing five (n=1) test item solutions. | |
| Compound | Repeatability (RSD) |
| Active substance: IR3535 | RSD = 1.58% |
| Accuracy | Accuracy was determined by analysis of 3 different test solutions at 3 level of concentration (80; 100; 120%). The accuracy results are expressed as the recovery rate.   |  |  |  |  |  | | --- | --- | --- | --- | --- | | Fortification level | Recovery rate | Mean recovery rate | RSD (%) | n | | 80% (20% w/w) | 101.6; 101.1; 101.4 | 101.4 | 0.2 | 3 | | 100% (25% w/w) | 98.4; 98.4; 98.5 | 98.4 | 0.1 | 3 | | 120% (30 %w/w) | 100; 100.1; 100.2 | 100.1 | 0.1 | 3 | | |

The analytical method is fully validated for the determination of the active substance IR3535 in the product CINQ SUR CINQ ZONE TEMPEREES. The wall META SPC 2 is covered, due to the similar compositions, by provided data.

**1/ Analytical method for CINQ SUR CINQ TROPIC**

Report: Dall’Acqua 2015

Report no 15.024891.0002

Test facility:

CHELAB S . r.l

Via fratta, 25

31023 Resana (TV)

ITALY

**Principle of the method:**

Validation method BAUS-006 rev.0. The preparation is analysed by HPLC-DAD at ƛ=220 nm.

CINQ SUR CINQ TROPIC 35% NF

Batch FC001

**Validation data:**

|  |  |  |
| --- | --- | --- |
| Specificity | To demonstrate the specificity of the method, several solution are analyzed:   * Solvent blank (EtOH) * Formulation blank * Reference solution of the active substance IR3535 * Test solution of the product   No interference was found: no peak appears in the chromatograms in the solvent blank and in the formulation blank, one peak is observed at the same retention time for the reference item and test item.  The DAD spectrum of reference solution and test solution have been provided. | |
| Linearity | Linearity was studied by carrying out five concentrations between 80% and 140% of the reference item.  Calibration curve has been provided with a R2= 1.000. | |
| Compound | Linearity % |
| Active substance:IR3535 | 80% to 140%  Y = 5.334.103 X  n=5 |
| Precision | Repeatability was evaluated by analyzing five (n=1) test item solutions. | |
| Compound | Repeatability (RSD) |
| Active substance: IR3535 | RSD = 0.54% |
| Accuracy | Accuracy was determined by analysis of 3 different test solutions at 3 level of concentration (80; 100; 120%). The accuracy results are expressed as the recovery rate.   |  |  |  |  |  | | --- | --- | --- | --- | --- | | Fortification level | Recovery rate | Mean recovery rate | RSD (%) | n | | 80% (28.5% w/w) | 100; 100; 100 | 100 | 0.01 | 3 | | 100% (35% w/w) | 98; 98; 98 | 98 | 0.05 | 3 | | 120% (42.5 %w/w) | 99; 99; 99 | 99 | 0.08 | 3 | | |

The analytical method is fully validated for the determination of the active substance IR3535 in the product CINQ SUR CINQ TROPIC 35% NF. The wall META SPC 3 is covered, due to the similar compositions, by provided data.

Analytical methods for IR3535 residues in soil, air, water (drinking water) and sediment are available in Assessment Report of IR3535 Product-type 19, 13.03.2014. The applicant Laboratoire CHAUVIN has a Letter of Access from Merck to these data.

**Analytical methods for the active substance**

|  |  |
| --- | --- |
| Technical active substance (principle of method) | Gas-chromatography with flame ionisation detection |
| Impurities in technical active substance (principle of method) | Gas-chromatography with flame ionisation detection |

**Analytical methods for residues**

|  |  |
| --- | --- |
| Soil (principle of method and LOQ) | Not required: significant residues of IR3535® in soil can be excluded. |
| Air (principle of method and LOQ) | Not required: IR3535® -based insect repellents spray applications involve large droplets which are not respirable. |
| Water (principle of method and LOQ) | Solid phase extraction (SPE) and UPLC-MS/MS detection (LOQ = 0.1 µg/L) |
| Body fluids and tissues (principle of method and LOQ) | Not required: IR3535® is not classified as toxic. |
| Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes) | Not required: IR3535®-based insect repellent products are not used in a manner which may cause contact with such materials. |
| Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes) ( | Not required: IR3535®-based insect repellent products are not used in a manner which may cause contact with such materials. |

* **Method for determination of IR3535 in water:**

**Buttler O. (2012),** Study n° CRA14171, Doc n°435-001.

Principle:

Solid phase extraction (SPE) on Chromabond C18ec cartridges (conditioned with 5 mL methanol, after that 5 mL HPLC water + 0.1 % formic acid). The cartridges were washed with 2 mL HPLC water. After drying, the cartridges were eluted with 5 mL methanol. The eluates were sampled in a measuring flask (10 mL) and filled up to the mark. 0.5 mL of the eluate were diluted with 0.5 mL HPLC water in a vial. This procedure results in an enrichment factor of 10. Then there is UPLC-MS/MS with ESI+:

IR3535 m/z=216-86

m/z=216-128

IR 3535 free-acid m/z=216-86

m/z=216-128

The method is validated for determination of IR3535 and IR 3535 free-acid in surface water with a LOQ = 0.1µg/L.

Based on the intended uses of the product, no contamination of the environment is foreseen. Analytical methods for IR3535 residues in soil, air and sediment are unnecessary.

As the active substance IR3535 is not classified Toxic or Very Toxic, an analytical method for the determination of IR3535 residue in human body fluids and tissues is unnecessary.

As the products of the BPF CINQ SUR CINQ LOTION is not intended to be used with surface in contact with food/feed of plant and animal origin, analytical method for the determination of IR3535 residue in food/feed of plant and animal origin is unnecessary.

|  |
| --- |
| **Conclusion on the methods for detection and identification of the product** |
| The analytical method is fully validated for the determination of the active substance IR3535 in the product.  Analytical methods were provided at EU level for the determination of IR3535 residue in water with respectively LOQ = 0.1 µg/L.  IR3535 is not toxic (T) or very toxic (T+) active substance. Therefore, an analytical method in biological matrices is not required.  The product is not intended to be used on surface in contact with food/feed of plant and animal origin consequently analytical method for the determination of IR3535 in food/feed of plant and animal origin is not required. |

### Efficacy against target organisms

#### Function and field of use

Main Group 03: Pest Control

Product Type 19: Repellents and attractants

The products of the Biocidal Product Family (BPF) are presented as ready-to-use sprays to be applied on human skin. The product is sprayed directly on the exposed area of the skin (*i.e.* face, neck, arms, hands and legs).

#### Organisms to be controlled and products, organisms or objects to be protected

According to the uses claimed by the applicant, the products of the BPF CINQ SUR CINQ LOTION are intended to be used to repel arthropods. The target organisms to be controlled are:

- *Aedes* mosquitoes (*Aedes spp.*), development stage: adults;

- *Anopheles* mosquitoes (*Anopheles spp.*), development stage: adults (Meta SPC 3 only);

- *Culex* mosquitoes (*Culex spp.*), development stage: adults;

- Horse flies ( *Dasybasis spp.*), development stage: adults;

- Ticks (*Ixodes ricinus*), development stage: nymphs and adults.

The purpose of the biocidal products is to protect humans from insect bites.

The application rates recommended by the applicant are the following:

Meta SPC 1:

* 0.7 mg/cm² when used against mosquitoes.
* 0.95 mg/cm² when used against ticks
* 1.95 mg/cm² when used against horse-flies

Meta SPC 2:

* 0.68 mg/cm² when used against mosquitoes.
* 0.93 mg/cm² when used against ticks
* 1.48 mg/cm² when used against horse-flies

Meta SPC 3:

* 0.48 mg/cm² when used against mosquitoes.
* 0.66 mg/cm² when used against ticks
* 1.07 mg/cm² when used against horse-flies

#### Effects on target organisms, including unacceptable suffering

The active substance modifies the behaviour of the target organisms. It repels them from the normal feeding behaviour leading to feed from blood. No unacceptable suffering of the target organisms is expected.

#### Mode of action, including time delay

The mode of action of IR3535 is an active repellent effect as insects avoid entering regions with IR3535 vapours. The exact biochemical mode of action of IR3535 on insects is not well known yet, but it is assumed that IR3535 has an olfactory-based effect.

No delay is observed between the treatment and the occurrence of the biocidal effect.

#### Efficacy data

Two data sets were submitted. The first data set was performed with a higher application rate, which was not in accordance with the application rate used in the risk assessment. Then a second data set with five new efficacy studies, with a lower application rates for some targets, was submitted.

The second data set concerns the following uses:

* Meta SPC 1: Use against ticks
* Meta SPC 2: use against mosquitoes and ticks.
* Meta SPC3: use against mosquitoes and ticks.
* **META-SPC 1**

The applicant has submitted following efficacy studies for the Meta SPC 1:

*(This META-SPC includes one formulation)*

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Experimental data on the efficacy of the biocidal product against target organism(s) – META SPC1** | | | | | | | |
| **Function** | **Field of use envisaged** | **Test substance** | **Test organism(s)** | **Test method** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| *Repellent* | Skin application | ***Cinq sur cinq famille 20%***  *référence FC 005* | *Aedes aegypti*  *Aedes albopictus*  *Culex quinquefasciatus*  200 adult females / cages of 64000 cm3 | WHO/HTM/NTD/WHOPES/2009.4 | Arm in cage  **0.42 g per 600 cm² => 0.7 mg/cm²**  **0.55 g per 600 cm² => 0.92 mg/cm²**  5 minutes repeated every hour until the first landing and then every 30 minutes until proven inefficacy of the product.  10 volunteers  Normal conditions :  27°C 65% RH | Test item has proved a complete protection over a period of:  - 5H at 0.7 mg/cm² and 6H at 0.92 mg/cm² against *Ae. aegypti*, *Ae. albopictus*, *Cx. quinquefasciatus*;  Temperate conditions | Serrano, 2017a  RI = 1  2128-CSCF20%-mosq/0816 |
| *Repellent* | Skin application | ***Cinq sur cinq famille 20%***  *référence FC 005* | *Ixodes ricinus*  5 adults and 5 nymphs per mouse  10 mice | Derivated from OPPTS 810.3700 (2010) | Ticks placed on an untreated zone 3 cm away from the treated mouse  **Application rate: 78.5 mg / 44 cm² => 1.783 mg/cm²**  Records of the number of ticks crossing the separating line between the untreated area and the treated skin part. | Test item has proven a protection over a period of 5 hours against the adults (5.1 h) and nymphs (5.2 h) of the tick *Ixodes ricinus*.  Temperate conditions | Serrano, 2015b  RI = 1  2228-CSCF20%-ticks/0816 |
| *Repellent* | Skin application | ***Cinq sur cinq famille 20%*** | *Ixodes ricinus*  5 adults and 5 nymphs per mouse  10 mice | Derivated from OPPTS 810.3700 (2010) | Ticks placed on an untreated zone 3 cm away from the treated mouse  **Application rate: 41,8 mg / 44 cm² => 0.95 mg/cm²**  Records of the number of ticks crossing the separating line between the untreated area and the treated skin part. | Test item has proven a protection over a period of 3.5 hours against the adults (3.8 h) and nymphs (3.9 h) of the tick *Ixodes ricinus*.  Temperate conditions | Serrano, 2017\*  RI = 1  2257-CSCF-ticks/0917 |
| *Repellent* | Skin application | ***Cinq sur cinq famille 20%***  *Référence FC 001* | *Dasybasis spp.* | Modified WHO/HTM/NTD/WHOPES/2009.4 | Field test on human / 1.17 g per 600 cm² (1.95 mg / cm²) / 5 minutes repeated every hour until proven inefficacy of the product  Temperature > 30 °C | According to the report, a Complete Protection Time would be 1.80 ± 1.32 hours. Taking into account the criteria ” the time elapsed from the product’s application and the first probing confirmed by another probing in the next exposure, Test item has proven a complete protection over a period of 1 hour against adults of the horse flies *Dasybasis spp.*  Tropical conditions | Drago,  2017  RI=2  CHLFAM270715-05b |

* **META-SPC 2**

This META-SPC 2 includes 2 formulations (CINQ SUR CINQ ZONES TEMPEREES AF and CINQ SUR CINQ ZONES TEMPEREES NF) that have been tested in the first data set.

Variations of UV filters and fragrances have been declared and are considered without or with limited impact on efficacy. This is confirmed in the efficacy studies on mosquitoes and ticks where similar protection time between CINQ SUR CINQ ZONE TEMPÉRÉES 25% AF and CINQ SUR CINQ ZONE TEMPÉRÉES 25% NF where observed.

In the second data set, where the application rate was decreased only one formulation CINQ SUR CINQ ZONE TEMPÉRÉES 25% AF was tested. Nevertheless, results with higher application rate (first data set), confirm that a read across can be done between products “AF” and “NF”. Therefore, it can be expected that the efficacy demonstrated with the new application rate for products “AF” is applicable to the products “NF”.

The applicant has submitted following efficacy studies for the Meta SPC 2 carried out with the products **CINQ SUR CINQ ZONE TEMPÉRÉES 25% AFandCINQ SUR CINQ ZONE TEMPÉRÉES 25% NF**:

| **Experimental data on the efficacy of the biocidal product against target organism(s) – META SPC2** | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Function** | **Field of use envisaged** | **Test substance** | **Test organism(s)** | **Test method** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| *Repellent* | Skin application | ***Cinq sur cinq zone tempérées 25% AF***  ***référence FC 029*** | *Aedes aegypti*  *Aedes albopictus*  *Culex quinquefasciatus*  200 adult females / cages of 64000 cm3 | WHO/HTM/NTD/WHOPES/2009.4 | Arm in cage  **0.44 g per 600 cm² => 0.73 mg/cm²**  **0.6 g per 600 cm² => 1 mg/cm²**  5 minutes repeated every hour until the first landing and then every 30 minutes until proven inefficacy of the product.  10 volunteers  Normal conditions :  27°C 65% RH | Test item has proved a complete protection over a period of:  - 5 H at 0.73 mg/cm² and 6H at 1 mg/cm² against *Ae. aegypti*, *Ae. albopictus*, *Cx. quinquefasciatus*;  Temperate conditions | Serrano, 2017b  RI = 1  2128-CSCZT25%AF-mosq/0816 |
| *Repellent* | Skin application | ***Cinq sur cinq zone tempérées 25% AF***  ***référence FC 029*** | *Ixodes ricinus*  5 adults and 5 nymphs per mouse  10 mice | Derivated from OPPTS 810.3700 (2010) | Ticks placed on an untreated zone 3 cm away from the treated mouse  **Application rate: 60.9 mg / 44 cm² => 1.383 mg/cm²**  Records of the number of ticks crossing the separating line between the untreated area and the treated skin part. | Test item has proven a protection over a period of 5 hours against the adults (5.2 h) and nymphs (5.4 h) of the tick *Ixodes ricinus*.  Temperate conditions | Serrano, 2016b  RI = 1  2228-CSCZT25%AF-ticks/0816 |
| *Repellent* | Skin application | ***Cinq sur cinq zone tempérées 25% AF***  *Référence FC 021* | *Dasybasis spp.* | Modified WHO/HTM/NTD/WHOPES/2009.4 | Field test on human / 0.89 g per 600 cm² (1.48 mg / cm²) / 5 minutes repeated every hour until proven inefficacy of the product  Temperature > 30 °C | According to the report, a Complete Protection Time would be 2.6 ± 1.32 hours. Taking into account the criteria “the time elapsed from the product’s application and the first probing confirmed by another probing in the next exposure, Test item has proven a complete protection over a period of 1 hour against adults of the horse flies *Dasybasis spp.*  Tropical conditions | Drago,  2017  RI=2  CHLZOT270715-05b |
| *Repellent* | Skin application | ***Cinq sur cinq zone tempérées 25% NF***  ***référence FC 001*** | *Aedes aegypti*  *Aedes albopictus*  *Culex quinquefasciatus*  200 adult females / cages of 64000 cm3 | WHO/HTM/NTD/WHOPES/2009.4 | Arm in cage  **0.44 g per 600 cm² => 0.73 mg/cm²**  **0.6 g per 600 cm² => 1 mg/cm²**  5 minutes repeated every hour until the first landing and then every 30 minutes until proven inefficacy of the product.  10 volunteers  Normal conditions :  27°C 65 %RH | Test item has proved a complete protection over a period of:  - 5 H at 0.73 mg/cm² and 6 H at 1 mg/cm² against *Ae. aegypti*, *Ae. albopictus*, *Cx. quinquefasciatus*;  Temperate conditions | Serrano, 2017c  RI = 1  2128-CSCZT25%NF-mosq/0816 |
| *Repellent* | Skin application | ***Cinq sur cinq zone tempérées 25% NF***  ***référence FC 001*** | *Ixodes ricinus*  5 adults and 5 nymphs per mouse  10 mice | Derivated from OPPTS 810.3700 (2010) | Ticks placed on an untreated zone 3 cm away from the treated mouse  **Application rate: 60.9 mg / 44 cm² => 1.383 mg/cm²**  Records of the number of ticks crossing the separating line between the untreated area and the treated skin part. | Test item has proven a protection over a period of 5 hours against the adults (5.2h) and nymphs (5.2h) of the tick *Ixodes ricinus*.  Temperate conditions | Serrano, 2016c  RI = 1  2228-CSCZT25%NF-ticks/0816 |
| *Repellent* | Skin application | ***Cinq sur cinq zone tempérées 25% NF***  *Référence FC 001* | *Dasybasis spp.* | Modified WHO/HTM/NTD/WHOPES/2009.4 | Field test on human / 0.89 g per 600 cm² (1.48 mg / cm²) / 5 minutes repeated every hour until proven inefficacy of the product  Temperature > 30 °C | According to the report, a Complete Protection Time would be 4.4 ± 0.84 hours. Taking into account the criteria ” the time elapsed from the product’s application and the first probing confirmed by another probing in the next exposure, Test item has proven a complete protection over a period of 1 hour against adults (2h) of the horse flies *Dasybasis spp.*  Tropical conditions | Drago,  2017  RI=2  CHL25N270715-05b |
| *Repellent* | Skin application | ***Cinq sur cinq zone tempérées***  ***25% AF*** | *Aedes aegypti*  *Aedes albopictus*  *Culex quinquefasciatus*  200 adult females / cages of 64000 cm3 | WHO/HTM/NTD/WHOPES/2009.4 | Arm in cage  **0.408 g per 600 cm² => 0.68 mg/cm²**  5 minutes repeated every hour until the first landing and then every 30 minutes until proven inefficacy of the product.  10 volunteers  Normal conditions :  27°C 65% RH | Test item has proved a complete protection period of 5 H against *Ae. aegypti*, *Ae. albopictus* and *Cx. quinquefasciatus*;  Temperate conditions | Serrano, 2017\*  RI = 1  2257-CSCZT-mosq/0917 |
| *Repellent* | Skin application | ***Cinq sur cinq zone tempérées25% AF*** | *Ixodes ricinus*  5 adults and 5 nymphs per mouse  10 mice | Derivated from OPPTS 810.3700 (2010) | Ticks placed on an untreated zone 3 cm away from the treated mouse  **Application rate: 40.92 mg / 44 cm² => 0.93 mg/cm²**  Records of the number of ticks crossing the separating line between the untreated area and the treated skin part. | Test item has proved a protection period of 4.3 hours against the adults and 4.1 hours against nymphs of the tick *Ixodes ricinus*.  Temperate conditions | Serrano, 2017\*  RI = 1  2257-CSCZT-ticks/0917 |

* **META-SPC 3**

This META-SPC 3 includes 2 formulations (CINQ SUR CINQ ZONES TROPIC 35% AF and CINQ SUR CINQ ZONES TROPIC 35% NF) that have been tested in the first data set.

Variations of UV filters and fragrances have been declared and are considered without or with limited impact on efficacy.

This is confirmed in the efficacy studies on mosquitoes and ticks where similar protection time between CINQ SUR CINQ ZONE TROPIC 35% AF and CINQ SUR CINQ ZONE TROPIC 35% NF where observed.

In the second data set, where the application rate was decreased only one formulation CINQ SUR CINQ ZONE TROPIC 35% AF was tested. Nevertheless, results with higher application rate (first data set), confirm that a read across can be done between products “AF” and “NF”. Therefore, it can be expected that the efficacy demonstrated with the new application rate for products “AF” is applicable to the products “NF”.

The applicant has submitted following efficacy studies for the Meta SPC 3, carried out with the products **CINQ SUR CINQ ZONE TROPIC 35% AF *and* CINQ SUR CINQ ZONE TROPIC 35% NF**:

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Experimental data on the efficacy of the biocidal product against target organism(s) – META SPC3** | | | | | | | |
| **Function** | **Field of use envisaged** | **Test substance** | **Test organism(s)** | **Test method** | **Test system / concentrations applied / exposure time** | **Test results: effects** | **Reference** |
| *Repellent* | Skin application | ***Cinq sur cinq zone tropic 35% AF***  ***référence FC 119*** | *Aedes aegypti*  *Aedes albopictus*  *An.gambiae*  *Culex quinquefasciatus*  200 adult females / cages of 64000 cm3 | WHO/HTM/NTD/WHOPES/2009.4 | Arm in cage  **0.31g per 600 cm² => 0.52 mg/cm²**  5 minutes repeated every hour until the first landing and then every 30 minutes until proven inefficacy of the product.  10 volunteers  Tropical conditions :  32°C 70% RH | Test item has proved a complete protection over a period of:  - 6H at 0.52 mg/cm² against *Ae. aegypti*, *Ae. albopictus*, *Cx. quinquefasciatus, A. gambiae*;  **Tropical conditions** | Serrano, 2017d  RI = 1  2128-CSCT35%AF-mosq/0816 |
| *Repellent* | Skin application | ***Cinq sur cinq zone tropic 35% AF***  ***référence FC 119*** | *Ixodes ricinus*  5 adults and 5 nymphs per mouse  10 mice | Derivated from OPPTS 810.3700 (2010) | Ticks placed on an untreated zone 3 cm away from the treated mouse  **Application rate: 43.3 mg / 44 cm² => 0.98 mg/cm²**  Records of the number of ticks crossing the separating line between the untreated area and the treated skin part. | Test item has proven a protection over a period of 6 hours against the adults (6.4h) and nymphs (6.3h) of the tick *Ixodes ricinus*.  Temperate conditions | Serrano, 2017e  RI = 1  2128-CSCT35%AF-ticks/0816 |
| *Repellent* | Skin application | ***Cinq sur cinq zone tropic 35% AF***  *Référence FC 112* | *Dasybasis spp.* | Modified WHO/HTM/NTD/WHOPES/2009.4 | Field test on human / 0.64 g per 600 cm² (1.07 mg / cm²) / 5 minutes repeated every hour until proven inefficacy of the product  Temperature > 30 °C | According to the report, a Complete Protection Time would be 3 ± 2.0 hours. Taking into account the criteria ” the time elapsed from the product’s application and the first probing confirmed by another probing in the next exposure, Test item has proven a complete protection over a period of 1 hour against adults (1h) of the horse flies *Dasybasis spp.*  Tropical conditions | Drago,  2017  RI=1  CHLTRO270715-05b |
| *Repellent* | Skin application | ***Cinq sur cinq zone tropic 35% NF***  ***référence FC 001*** | *Aedes aegypti*  *Aedes albopictus*  *Culex quinquefasciatus*  *An.gambiae*  200 adult females / cages of 64000 cm3 | WHO/HTM/NTD/WHOPES/2009.4 | Arm in cage  **0.31 g per 600 cm² => 0.52 mg/cm²**  5 minutes repeated every hour until the first landing and then every 30 minutes until proven inefficacy of the product.  10 volunteers  Tropical conditions :  32°C 70% RH | Test item has proved a complete protection over a period of:  - 6H at 0.52 mg/cm² against *Ae. aegypti*, *Ae. albopictus*, *Cx. quinquefasciatus*; *A. gambiae*;  **Tropical conditions** | Serrano, 2017  RI = 1  2128-CSCT35%NF-mosq/0816 |
| *Repellent* | Skin application | ***Cinq sur cinq zone tropic 35% NF***  ***référence FC 001*** | *Ixodes ricinus*  5 adults and 5 nymphs per mouse  10 mice | Derivated from OPPTS 810.3700 (2010) | Ticks placed on an untreated zone 3 cm away from the treated mouse  **Application rate: 43.3 mg / 44 cm² => 0.98 mg/cm²**  Records of the number of ticks crossing the separating line between the untreated area and the treated skin part.  In temperate condition | Test item has proven a protection over a period of 6 hours against the adults (6.1h) and nymphs (6.2h) of the tick *Ixodes ricinus*.  Temperate conditions | Serrano, 2016c  RI = 2  2228-CSCT35%NF-ticks/0816 |
| *Repellent* | Skin application | ***Cinq sur cinq zone tempérées 35% NF***  *Référence FC 001* | *Dasybasis spp.* | Modified WHO/HTM/NTD/WHOPES/2009.4 | Field test on human / 0.64 g per 600 cm² (1.07 mg / cm²) / 5 minutes repeated every hour until proven inefficacy of the product  Temperature > 30 °C | According to the report, a Complete Protection Time would be 2.2 ± 1.48 hours. Taking into account the criteria ” the time elapsed from the product’s application and the first probing confirmed by another probing in the next exposure, Test item has proven a compete protection over a period of 1 hour agaisnt adults (1h) of the horse flies *Dasybasis spp.*  Tropical conditions | Drago,  2017  RI=1  CHL35N270715-05b |
| *Repellent* | Skin application | ***Cinq sur cinq tropic***  ***35% AF*** | *Aedes aegypti*  *Aedes albopictus*  *Culex quinquefasciatus*  *Anopheles gambiae*  200 adult females / cages of 64000 cm3 | WHO/HTM/NTD/WHOPES/2009.4 | Arm in cage  **0.288 g per 600 cm² => 0.48 mg/cm²**  5 minutes repeated every hour until the first landing and then every 30 minutes until proven inefficacy of the product.  10 volunteers  Normal conditions :  32°C 70% RH | Test item has proved a complete protection period over of 6 H against *Ae. aegypti* (6.1 h), *Ae. albopictus* (6 h) and *Cx. Quinquefasciatus* (6.7 h);  For *Anopheles gambiae*, the test item has proved a complete protection of 5.6  Tropical conditions | Serrano, 2017\*  RI = 1  2257-CSCT-mosq  /0917 |
|  | Skin application | ***Cinq sur cinq tropic***  ***35% AF*** | *Ixodes ricinus*  5 adults and 5 nymphs per mouse  [[2]](#footnote-2)10 mice | Derivated from OPPTS 810.3700 (2010) | Ticks placed on an untreated zone 3 cm away from the treated mouse  **Application rate: 29.04 mg / 44 cm² => 0.66 mg/cm²**  Records of the number of ticks crossing the separating line between the untreated area and the treated skin part. | Test item has proven a protection period over of 5 hours against the adults (5.2 h) and nymphs (5.1 h) of the tick *Ixodes ricinus*.  Temperate conditions | Serrano, 2017\*  RI = 2  2257-CSC-ticks/0917 |

|  |
| --- |
| **Conclusion on the efficacy of the product** |
| In conclusion, in accordance with the requirement of the TNsG on PT18/19 (2012), French competent authorities (FR CA) considers that the elements presented in the dossier are sufficient to demonstrate that:   * The product related to the Meta SPC 1 (one formulation without any variations) of the BPF “CINQ SUR CINQ LOTION” provides   + a protection time up to 5 hours against adult mosquitoes (*Culex spp*., *Aedes spp*.) at the application rate of 0.7 mg/cm²,   + up to 3 hours against ticks (*Ixodes ricinus*) at the application rate of 0.95 mg/cm², in temperate climate, and   + up to 1 hour against *Tabanidae* (*Dasybasis spp.*) at the application rate of 1.95 mg/cm² in tropical conditions. * The products related to the Meta SPC 2 (two formulations with variations on the UV filters and fragrances) of the BPF “CINQ SUR CINQ LOTION” provide   + a protection time up to 5 hours against adult mosquitoes (*Culex spp*., *Aedes spp*.) at the application rate of 0.68 mg/cm²,   + up to 4 hours against ticks (*Ixodes ricinus* at the application rate of 0.93 mg/cm² in temperate climate, and   + up to 1 hour against *Tabanidae* (*Dasybasis*) at the application rate of 1.48 mg/cm² in tropical conditions.   For Meta SPC 1 & 2, no claim was made concerning efficacy in tropical conditions. Consequently, the efficacy in these conditions is not validated.  For META SPC1&2, tropical conditions[[3]](#footnote-3) for horseflies are more challenging than temperate conditions, but the species tested (*Dasybasis spp.)* is not representative of species of horseflies met in Europe. Then FR CA cannot conclude on the efficacy against horseflies in temperate conditions.  It has to be noted, that no claim has been made concerning efficacy in tropical conditions conditions for these both Meta SPC.   * The products related to the Meta SPC 3 (two formulations with variations on the UV filters and fragrances) of the BPF “CINQ SUR CINQ LOTION” provide   + a protection up to 6 hours against adult mosquitoes (*Culex spp*., *Aedes spp*.,), and 5 hours against *Anopheles spp.* at the application rate of 0.48 mg/cm² in tropical conditions and,   As the product is intended for non-professional users, which are not able to distinguish the different species of mosquitoes, the validated protection time is 5 hours.   * + up to 1 hour against *Tabanidae* (*Dasybasis spp.*) at the application rate of 1.07 mg/cm² in tropical conditions.   According to the TNsG on PT18 (2012), for a specific claimed use against ticks in the tropics, an efficacy against *Hyalomma marginatum* should be also demonstrated. No efficacy data was presented in the dossier to support the efficacy against *Hyalomma maginatum*. The efficacy studies submitted in the dossier for these products were performed on *Ixodes ricinus* in temperate conditions. Then the efficacy of the formulations of the Meta SPC 3 against ticks in tropical conditions is not validated.  Efficacy tests with lower application rates performed with CINQ SUR CINQ ZONE TEMPÉRÉES 25% AF, and CINQ SUR CINQ ZONE TROPIC 35% AF for Meta SPCs 2 and 3 respectively, showed a slight decrease of the protection time for ticks (Meta SPC2) and mosquitoes for *Anopheles* (Meta SPC3). Considering the previous efficacy studies against mosquitoes and ticks, results revealed similar protection time between CINQ SUR CINQ ZONE TEMPÉRÉES 25% AF and CINQ SUR CINQ ZONE TEMPÉRÉES 25% NF (Meta SPC 2), and between CINQ SUR CINQ ZONE TROPIC 25% AF and CINQ SUR CINQ ZONE TROPIC 25% NF (Meta SPC 3) . Then, results with higher application rate, confirm that a read across can be done between products “AF” and “NF” of Meta SPC 2 and 3. Therefore, it can be expected that the efficacy demonstrated with the new application rate for products “AF” of Meta SPC 2 and 3 is applicable to the products “NF” of Meta SPC 2 and 3.  Meta SPC 2 : Considering the efficacy studies against mosquitoes and ticks at a high application rate, results revealed similar protection times between the two products of META SPC 2 (CINQ SUR CINQ ZONE TEMPÉRÉES 25% AF and CINQ SUR CINQ ZONE TEMPÉRÉES 25% NF). This confirms that a read across can be done between products “AF” and “NF” of Meta SPC 2. Therefore, it is expected that the efficacy demonstrated at a lower application rate for products “AF” is applicable to the products “NF” of Meta SPC 2.  Similarly for meta SPC 3 : the efficacy studies against mosquitoes and ticks at a high application rate revealed similar protection time between the two products of meta SPC 3. The efficacy demonstrated with the lower application rate for products “AF” of Meta SPC 3 is applicable to the products “NF” of Meta SPC 3. |

#### Occurrence of resistance and resistance management

Resistance to IR3535 is not reported up to date in the scientific literature.

To ensure a satisfactory level of efficacy and avoid the development of resistance in susceptible insect populations, the following recommendations have to be implemented:

* Always read the label or leaflet before use and follow all the instructions provided.
* Respect the recommended application doses.
* The users should inform the registration holder if the treatment is ineffective.
* The authorization holder should report any observed resistance incidents to the Competent Authorities (CA) or other appointed bodies involved in resistance management.

Considering the importance of this active substance in vector control, the authorisation holder has to implement a monitoring of scientific literature toward the active substance IR3535. Results of this assessment must be submitted to the Competent Authorities (CA) or other appointed bodies involved in resistance management every 5 years.

#### Known limitations

*None*

#### Evaluation of the label claims

French competent authorities (FR CA) concludes that data presented in the dossier demonstrate that:

* The product of the The Meta SPC 1 (one formulation without any variations) of the BPF “CINQ SUR CINQ LOTION” provides a protection time up to 5 hours against adult mosquitoes (*Culex spp*., *Aedes spp*.), against ticks (*Ixodes ricinus)* up to 3 hours, and up to 1 hour against *Tabanidae* (*Dasybasis spp.*). The efficacy of the product in tropical conditions is not validated.
* The products of the Meta SPC 2 (two formulations with variations on the UV filters and fragrances) of the BPF “CINQ SUR CINQ LOTION” provides a protection time up to 5 hours against adult mosquitoes (*Culex spp*., *Aedes spp*.), up to 4 hours against ticks (*Ixodes ricinus*), and up to 1 hour against *Tabanidae* (*Dasybasis spp.*). The efficacy of the product in tropical conditions is not validated.

Although META SPC1&2, tropical conditions[[4]](#footnote-4) for horseflies are more challenging than temperate conditions, the species tested (*Dasybasis spp.)* is not representative of species of horseflies met in Europe. Then FR CA cannot conclude on the efficacy against horseflies in temperate conditions.

It has to be noted, that no claim has been made concerning efficacy in tropical conditions conditions for these both Meta SPC.

* The products from Meta SPC 3 (two formulations with variations on the UV filters and fragrances) of the BPF “CINQ SUR CINQ LOTION” provides a protection up to 5 hours against adult mosquitoes (*Culex spp*., *Aedes spp*.:6 hours; *Anopheles spp.*: 5 hours), and, up to 1 hour against *Tabanidae* (*Dasybasis spp.*) in tropical conditions at the application rate of 1.07 mg/cm².

According to the TNsG on PT18 (2012), for a claim against ticks, efficacy of the product on the species *Ixodes ricinus* should be demonstrated and when an efficacy in the tropics is also claimed, an efficacy against *Hyalomma marginatum* should be also demonstrated. No efficacy data was presented to support the efficacy against *Hyalomma maginatum*. Furthermore, the efficacy study submitted in the dossier for these products were performed on *Ixodes ricinus* in temperate conditions. Then the efficacy of the formulations of the Meta SPC 3 against ticks is not validated.

The application rate validated are the following:

Meta SPC 1:

* 0.7 mg/cm² when used against mosquitoes (*Aedes spp., Culex spp.*)
* 0.95 mg/cm² when used against ticks (*Ixodes ricinus)*
* 1.95 mg/cm² when used against horse-flies (*Dasybasis spp.)*

Meta SPC 2:

* 0.68 mg/cm² when used against mosquitoes. (*Aedes spp., Culex spp.*)
* 1.93 mg/cm² when used against ticks (*Ixodes ricinus*)
* 1.48 mg/cm² when used against horse-flies(*Dasybasis spp.)*

Meta SPC 3:

* 0.48 mg/cm² when used against mosquitoes. (*Aedes spp., Culex spp., Anopheles spp.*)
* 1.07 mg/cm² when used against horse-flies (*Dasybasis spp.)*

To ensure a satisfactory level of efficacy and avoid the development of resistance, the recommendations proposed in the SPC have to be implemented

#### Relevant information if the product is intended to be authorised for use with other biocidal product(s)

The biocidal products are not intended to be used with other biocidal products.

### Risk assessment for human health

#### Assessment of effects on Human Health

***Skin corrosion and irritation***

No *in vitro* study is available but an *in vivo* study was provided for one of the biocidal products considered as representative of the product family.

*In vivo study:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Summary table of animal studies on skin corrosion /irritation** | | | | | |
| **Method, Guideline,**  **GLP status, Reliability** | **Species, Strain, Sex, No/group** | **Test substance, Vehicle, Dose levels,  Duration of exposure** | **Results**  *Average score**(24, 48, 72h)/*  *observations and time point of onset, reversibility; other adverse local / systemic effects, histopathological*  *findings* | **Remarks** *(e.g. major deviations)* | **Reference** |
| OECD 404, GLP, Klimisch code 1 | 3 rabbits (males) NewZealand | CINQ SUR CINQ TROPIC 35%  Exposure during 4h, observation time 72h | Mean 24-72h, 3 rabbits:  Erythema: 0-0.3 Oedema: 0  Full recovery within 48h. | No deviation  No clinical effect reported. | Gomong P (2006a)  08.01.01\_Skin irritation/corrosion\_5/5 LOTION TROPIC\_EVIC\_2006 |

Human data on skin corrosion/irritation: No human data is available.

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Skin corrosion and irritation** | |
| Value/conclusion | Based on the available data, the products formulated within the ranges of the composition of the biocidal product family are considered as neither corrosive nor irritant to the skin. |
| Justification for the value/conclusion | This conclusion is supported by the available test on product (CINQ SUR CINQ TROPIC) with the highest concentration of active substance and by the calculation using the conventional method as detailed in the CLP Annex I, noting that none of the ingredients are at concentration contributing to hazard. |
| Classification of the product according to CLP | Not classified for skin corrosion/irritation according to CLP criteria. |

***Eye irritation***

No *in vitro* study is available but an *in vivo* study was provided for one of the biocidal products considered as representative of the product family.

*In vivo study:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Summary table of animal studies on serious eye damage and eye irritation** | | | | | |
| **Method, Guideline,**  **GLP status, Reliability** | **Species, Strain, Sex, No/group** | **Test substance,Dose levels, Duration of exposure** | **Results**  *Average score (24, 48, 72h)/*  *observations and time point of onset, reversibility* | **Remarks** *(e.g. major deviations)* | **Reference** |
| OECD 405 (2002),  GLP, Klimisch code 1 | 3 rabbits (males) NewZealand | CINQ SUR CINQ TROPIC 35%  Exposure during 4h, observation time 9 days | Mean 24-72h, 3 rabbits:  Chemosis: 2.0 – 1 -2.0  Redness: 2.7 – 2 - 2.7  Iris:0.3 - 0 - 0.3  Cornea: 2.0- 1.3 - 2.0 Reversibility: 9 days | No deviation  No clinical effect reported. | Gomond P (2006b)  08.02.01\_Eye irritation\_5/5 LOTION TROPIC\_EVIC\_2006 |

Human data on skin corrosion/irritation: No human data is available.

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Eye irritation** | |
| Value/conclusion | Based on the available data, the products formulated within the ranges of the composition of the biocidal product family are considered as irritant to the eye. |
| Justification for the value/conclusion | This conclusion is supported by the available test on product (CINQ SUR CINQ TROPIC) with the highest concentration of active substance and by the calculation using the conventional method as detailed in the CLP Annex I. |
| Classification of the product according to CLP | Classified for eye irritation according to CLP criteria, Eye Irrit. 2, H319. |

***Respiratory tract irritation***

There is currently no testing requirement for respiratory irritation under the BPR (Reg (EU) No 528/2012)). According to the CLP regulation (Reg (EC) No 1272/2008)), this parameter should be based primarily on human data.

Based on the available information, the products of the Biocidal Product Family should not be considered as respiratory tract irritant, because no potential respiratory effects are reported for the main constituents (IR3535, ethanol, water…).

***Skin sensitization***

No *in vitro* study is available but an *in vivo* study was provided for one of the biocidal products considered as representative of the product family.

*In vivo study:*

| **Summary table of animal studies on skin sensitisation** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Method, Guideline, GLP status, . Reliability** | **Species, Strain, Sex, No/group** | **Test substance, Vehicle,**  **Dose levels,  duration of exposure Route of exposure** *(topical/intradermal, if relevant)* | **Results**  *(EC3-value or amount of sensitised animals at induction dose); evidence for local or systemic toxicity (time course of onset)* | **Remarks**  *(e.g. major deviations)* | **Reference** |
| OECD 405 (2002),  GLP, Klimisch code 1 | Guinea Pigs (males, 5 control, 10 per treated groups) | CINQ SUR CINQ TROPIC 35%, vehicule: water.  Induction: intrademal: 1.25%, topical: 100% during 48h.  Challenge: 50% and 100% during 24h. | No skin reaction up to 72h observation time. | No deviation. No systemic findings reported | Gomond P (2006c)  08.03.01\_Skin sensitisation\_5/5 LOTION TROPIC\_EVIC\_2006 |

No information is available on the potenty of the Biocidal Products to induce skin sensitising effects in human.

|  |  |
| --- | --- |
| **Conclusion used in Risk Assessment – Skin sensitisation** | |
| Value/conclusion | Not suspected to be a skin sensitizer |
| Justification for the value/conclusion | None of the components are classified as skin sensitizers, except the perfumes (0.8%). This concentration is below the classification threshold sets in the Annex I of the CLP regulation (1%). In addition, the major sensitizing components in the perfume formulation is at a maximum concentration of 20%, that is not more than 0.16 % in the final product.  In this context, the products are not classified for skin sensitisation. However, the mention EUH 208 has to be added. |
| Classification of the product according to CLP | Not classified.  For meta SPC 1:  EUH 208 ” Contains 2-hexyl-3-phenyl-2- propenal (trans & cis), benzyl 2-hydroxybenzoate” May produce an allergic reaction  For meta SPC 2 and 3:  EUH 208 ”Contains 2-hexyl-3-phenyl-2- propenal (trans & cis), benzyl 2- hydroxybenzoate, (R)-p-mentha-1,8-diène, 3,7-dimethyl-6-octen-1- ol (citronellol)”. May produce an allergic reaction. |

***Respiratory sensitization (ADS)***

No data is available for respiratory sensitisation.

|  |  |
| --- | --- |
| **Conclusion** **used in Risk Assessment – Respiratory sensitisation** | |
| Value/conclusion | Not suspected to be a respiratory sensitizer |
| Justification for the value/conclusion | None of the ingredients are known to exhibit respiratory sensitisation potency nor respiratory irritation potency, according to the CLP regulation. |
| Classification of the product according to CLP | Not classified |

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Respiratory sensitisation |
| Justification | According to Column 3 of the BPR regulation (Reg (EU) No 528/2012) Annex III, valid information is available on each component of the Biocidal Product Family allowing to apply the CLP criteria for classification (Section 3.4.3. CLP regulation (Reg (EC) No 1272/2008) Annex I). |

***Acute toxicity***

*Acute toxicity by oral route*

| **Summary table of animal studies on acute oral toxicity** | | | | | | |
| --- | --- | --- | --- | --- | --- | --- |
| **Method Guideline**  **GLP status, Reliability** | **Species, Strain, Sex, No/group** | **Test substance**  **Dose levels Type of administration** *(gavage, in diet, other)* | **Signs of toxicity** *(nature, onset, duration, severity, reversibility)* | **Value LD50** | **Remarks** *(e.g. major deviations)* | **Reference** |
| OECD 423, GLP, Klimisch code 1 | 6 rabbits (females) Sprague-Dawley) | CINQ SUR CINQ TROPIC 35%, gavage | Slight clinical effects (piloerection) observed during the 1st day post dosing.  No mortality. | ≥ 5000 mg/kg bw (see annex 2d of OECD 423) | No deviation. | Gomond P (2006d)  08.05.01.01\_Acute toxicity: oral\_5/5 LOTION TROPIC\_EVIC\_2006 |

No human data is available.

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute oral toxicity** | |
| Value | LD50 ≥ 5000 mg/kg bw |
| Justification for the selected value | The composition of the biocidal products from the CINQ SUR CINQ LOTION varies significantly in the concentration of the active substance (IR3535) and water. When the active substance concentration increases from 20% (CINQ SUR CINQ FAMILLE) to 35% (CINQ SUR CINQ TROPIC), the water content drops from 28.26% to 16.86%, respectively.  Therefore, by testing the biocidal product with the highest concentration in active substance and classified co-formulants, it is considered as a worst case.  In other word, the available results are considered as valid for the whole range of the biocidal products included in this Biocidal Product Family.  This rational is consolidated by the application of the classification criteria as described in the Annex I of the CLP regulation. |
| Classification of the product according to CLP | Not classified according to the CLP Regulation (Reg (EC) No 1272/2008). |

*Acute toxicity by inhalation*

No study (*in vitro*, *in vivo*) is available for neither of the biocidal products representative of the product family. No human data are available either.

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute inhalation toxicity** | |
| Value | Not acutely toxic by inhalation. |
| Justification for the selected value | None of the ingredients are known to have this toxicological property.  According to the CLP regulation, the Biocidal Products is considered as not acutely toxic by inhalation.. |
| Classification of the product according to CLP | Not classified |

|  |  |
| --- | --- |
| **Data waiving** | |
| Information requirement | Acute toxicity by inhalation. |
| Justification | According to Column 3 of the BPR regulation (Reg (EU) No 528/2012) Annex III, valid information is available on each component of the Biocidal Product Family allowing to apply the CLP criteria for classification (Section 3.1.3. CLP regulation (Reg (EC) No 1272/2008) Annex I). |

*Acute toxicity by dermal route*

No *in vitro* study is available but an *in vivo* study was provided for one of the biocidal products considered as representative of the product family.

*In vivo study:*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Summary table of animal studies on acute dermal toxicity** | | | | | | |
| **Method, Guideline,**  **GLP status,**  **Reliability** | **Species, strain, Sex, No/group** | **Test substance, Vehicle, Dose levels, Surface area** | **Signs of toxicity** *(nature, onset, duration, severity, reversibility)* | **LD50** | **Remarks** *(e.g. major deviations)* | **Reference, IUCLID** |
| OECD 402, GLP, Klimisch code 1 | Rats, SD, males and females, 5 per group | Test item at 2000 mg/kg bw. | No mortality. Porphyrine around muzzle for all animals was recorded the first day of observation. | > 2000 mg/kg bw. | No deviation. | Gomond P (2006e)  08.05.03.01\_Acute toxicity: dermal\_5/5 LOTION TROPIC\_EVIC\_2006 |

No human data are available.

|  |  |
| --- | --- |
| **Value used in the Risk Assessment – Acute dermal toxicity** | |
| Value | Not acutely toxic by dermal route. |
| Justification for the selected value | The composition of the biocidal products family from the CINQ SUR CINQ LOTION varies significantly in the concentration of the active substance (IR3535) and water. When the active substance concentration increases from 20% (CINQ SUR CINQ FAMILLE) to 35% (CINQ SUR CINQ TROPIC), the water content drops from 28.26% to 16.86%, respectively.  Therefore, testing the biocidal product with the highest concentration in active and classified co-formulants is considered as a worst case.  The available results are considered as valid for the whole range of the biocidal products included in this Biocidal Product Family.  According to the CLP regulation, the Biocidal Products included in the Biocidal Product Family are considered as not acutely toxic by dermal route. |
| Classification of the product according to CLP | Not classified |

***Information on dermal absorption***

No study (*in vitro*, *in vivo*) is available on one member of the biocidal product family.

A read across with the dermal absorption value proposed in the study of Broschard *et al.*, 2013 (14%) was proposed by the applicant for the products family. The study of Broschard is summarised in the following table:

| **Summary table of on dermal absorption in human (in vivo)** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Method, Guideline,**  **GLP status, Reliability** | **Species, Number of skin samples tested per dose, Other relevant information about the study** | **Test substance, Doses** | **Absorption data for each compartment and final absorption value** | **Remarks** *(e.g. major deviations)* | **Reference** |
| No guideline followed, not under GLP, Klimisch code 2 | Human (5 males, 5 females), exposed to 3g of a formulation (20% IR3535)  Blood and urine samples were taken up to 24h after application (blood) and 48h (urine)  Analyses of IR3535 and its only metabolite (IR3535-free acid) were done by HPLC | The test item is a formulation of IR3535 (20%) characteristic of commercial products. | Based on the urine level (major route of excretion), the dermal absorption is 13.3%. | see below | Broschard *et al.*, 2013  8.6 (a) Dermal absorption\_Broschard et al 2013 |

It should be noted that this study probably underestimates dermal absorption because:

* a recovery rate is not proposed,
* the samples are performed only on the urine and blood (for example faeces samples are not performed),
* the distribution of the active substance in the skin and the amount remaining in the skin is not determined.

However, the formulations of the products of the Biocidal Products Family CINQ SUR CINQ LOTION are close to the one described in the CAR. In this context, a read across with the product presented in the CAR of the a.s is proposed and a value of 14% is used for risk assessment.

***Available toxicological data relating to non-active substance(s) (i.e. substance(s) of concern)***

No substance of concern is identified.

***Available toxicological data relating to a mixture***

No data

***Other***

*No data*

#### Exposure assessment

**Summary of assessed uses**

**Identification of main paths of human exposure towards active substance(s) and substances of concern from its use in biocidal product**

| **Summary table: relevant paths of human exposure** | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Exposure path** | **Primary (direct) exposure** | | | **Secondary (indirect) exposure** | | | |
| **Industrial use** | **Professional use** | **Non-professional use** | **Industrial use** | **Professional use** | **General public** | **Via food** |
| Inhalation | No | No | Yes | No | No | No | No |
| Dermal | No | No | Yes | No | No | Yes | Yes |
| Oral | No | No | No | No | No | Yes | Yes |

***List of scenarios***

The biocidal products claimed in the CINQ SUR CINQ LOTION are ready to use products containing IR 3535 as active substance. No dilution or other preparation are necessary.

They are applied directly to human skin of adults and children to repel mosquitoes, tabanids and ticks. Application of the biocidal product must be done by adults only. It is considered that the exposure of the person spraying the product is covered by the exposure during the application on the skin.

Three meta SPC, including each 3 intended uses (different doses and number of applications) are proposed by applicant.

|  |  |  |  |
| --- | --- | --- | --- |
|  | **CINQ SUR CINQ FAMILLE (meta SPC 1) 20%** | **CINQ SUR CINQ ZONES TEMPEREES (meta SPC 2) 25%** | **CINQ SUR CINQ TROPIC (meta SPC 3)**  **35%** |
| Mosquitoes | 0.42g/600 cm2 = 0.7 mg/cm2  child > 6 years old and adult : 2 applications/d  child≥ 6 months old – 6 years : 1 application /d) | 0.408g/600 cm2= 0.68 mg/cm2  (child ≥ 11 years old and adult : 2 applications/d  child between 2 years old and -11 years old: 1 application / d) | 0.288g/600 cm2= 0.48 mg/cm2  (child ≥ 11 years old and adult: 2 applications/d  child between 2 years old and -11 years old: 1 application / d) |
| ticks | 41.8 mg/44 cm2 = 0.95 mg/cm2  (child ≥ 6 months old and adult: 1application/d) | 40.92 mg/44 cm2= 0.93 mg/cm2  (child ≥ 2 years old and adult : 1application/d) | 29.04 mg/44 cm2= 0.66 mg/cm2  (child ≥ 2 years old and adult  : 1application/d) |
| tabanids | 1.17g/600 cm2= 1.95 mg/cm2  (child ≥ 6 months old and adult: 1application/d) | 0.89g/600 cm2= 1.48 mg/cm2  (child ≥ 2 years old and adult  : 1application/d) | 0.64g/600 cm2= 1.07 mg/cm2  (child ≥ 2 years old and adult : 1application/d) |

According to consumer spraying model 2 for trigger spray, the user will be exposed to 35.9 mg of product /m3 during few minutes whereas he will be exposed to several grams (10.5 g) of product on skin with a dermal absorption of 20 %. Therefore, the inhalation is assumed to be negligible. Moreover, the product is applied outdoor or in a well aerated room. Therefore, the *primary exposure* is limited to the dermal route.

In order to determine the dermal exposure, the recommendation N°11 of the BPC Ad hoc WG on human exposure[[5]](#footnote-5) is applied. Therefore, it is considered that the person will be exposed to the efficacy dose and wear a short-sleeved shirt (T-shirt) and a short.

The exposed body surface corresponds to 55% of the total body surface: head, neck, hands (palms and backs), lower arms, lower legs, feet and 70% of upper arms and thighs according to Pest Control Products Fact Sheet of Consexpo. These estimations will be named scenario tier 1 (worst-case). This scenario is the one validated at European level following recommendation n°11 of the BPC Ad hoc Working Group on Human Exposure[[6]](#footnote-6).

The estimation of exposure is also performed considering that wearing T-shirt and short leads to an exposure of head, hand, ¾ arm and ½ legs. These simulations will be named scenario tier 2 (”French approach”). This scenario is not subject to mutual recognition process. In this scenario, the exposed body surface corresponds to 36% to 38 % of the total body surface (depending on the age class)[[7]](#footnote-7)

The secondary exposure is limited to hand-to-mouth transfer. It is not expected to be a significant route of exposure.

Hand-to-mouth transfer behaviour is more frequent in small children and is observed mainly in infants until 2-3 years. However, children from 3 years of age and adults may be accidentally exposed orally to the product. In this context, a reverse scenario calculation was included to estimate the percentage of the surface of the hands which can be put in the mouth to reach the AEL.

| **Summary table: scenarios** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Scenario number** | **Scenario**  (e.g. mixing/ loading) | | **Primary or secondary exposure**  **Description of scenario** | | **Exposed group**  (e.g. professionals, non-professionals, bystanders) |
| **Meta SPC 1** | | | | | |
| 1a – Tier 1 | Application on the skin of Mosquitoes repellent | | The biocidal products are applied directly on the skin at the dose of 0.7 mg/cm2:  The *primary exposure* is limited to the dermal route.  Body surface exposed: 55% | | General public.  Adult and child ≥ 6 months. |
| 1b - Tier 2 | Application on the skin of Mosquitoes repellent | | The biocidal products are applied directly on the skin at the dose of 0.7 mg/cm2:  The *primary exposure* is limited to the dermal route.  Body surface exposed:  head, hand, ¾ arm and ½ legs. | | General public.  Adult and child ≥ 6 months. |
| 2a – Tier 1 | Application on the skin of ticks repellent | | The biocidal products are applied directly on the skin at the dose of 0.95 mg/cm2:  The *primary exposure* is limited to the dermal route.  Body surface exposed: 55%  . | | General public.  Adult and child ≥ 6 months. |
| 2b - Tier 2 | Application on the skin of ticks repellent | | The biocidal products are applied directly on the skin at the dose of 0.95 mg/cm2:  The *primary exposure* is limited to the dermal route.  Body surface exposed:  head, hand, ¾ arm and ½ legs. | | General public.  Adult and child ≥ 6 months. |
| 3a – Tier 1 | Application on the skin of tabanids repellent | | The biocidal products are applied directly on the skin at the dose of 1.95 mg/cm2:  The *primary exposure* is limited to the dermal route.  Body surface exposed: 55% | | General public.  Adult and child ≥ 6 months. |
| 3b - Tier 2 | Application on the skin of tabanids repellent | | The biocidal products are applied directly on the skin at the dose of 1.95 mg/cm2:  The *primary exposure* is limited to the dermal route.  Body surface exposed:  head, hand, ¾ arm and ½ legs. | | General public.  Adult and child ≥ 6 months. |
| **Meta SPC 2** | | | | | |
| 4a – Tier 1 | Application on the skin of Mosquitoes repellent | | The biocidal products are applied directly on the skin at the dose of 0.68 mg/cm2:  The *primary exposure* is limited to the dermal route.  Body surface exposed: 55% | | General public.  Adult and child ≥ 2 years. |
| 4b - Tier 2 | Application on the skin of Mosquitoes repellent | | The biocidal products are applied directly on the skin at the dose of 0.68 mg/cm2:  The *primary exposure* is limited to the dermal route.  Body surface exposed:  head, hand, ¾ arm and ½ legs. | | General public.  Adult and child ≥ 2 years. |
| 5a – Tier 1 | Application on the skin of ticks repellent | | The biocidal products are applied directly on the skin at the dose of 0.93 mg/cm2:  The *primary exposure* is limited to the dermal route.  Body surface exposed: 55% | | General public.  Adult and child ≥ 2 years. |
| 5b - Tier 2 | Application on the skin of ticks repellent | | The biocidal products are applied directly on the skin at the dose of 0.93 mg/cm2:  The *primary exposure* is limited to the dermal route.  Body surface exposed:  head, hand, ¾ arm and ½ legs. | | General public.  Adult and child ≥ 2 years. |
| 6a – Tier 1 | Application on the skin of tabanids repellent | | The biocidal products are applied directly on the skin at the dose of 1.48mg/cm2:  The *primary exposure* is limited to the dermal route.  Body surface exposed: 55% | | General public.  Adult and child ≥ 2 years. |
| 6b - Tier 2 | Application on the skin of tabanids repellent | | The biocidal products are applied directly on the skin at the dose of 1.48 mg/cm2:  The *primary exposure* is limited to the dermal route.  Body surface exposed:  head, hand, ¾ arm and ½ legs. | | General public.  Adult and child ≥ 2 years. |
| **Meta SPC 3** | | | | | |
| 7a – Tier 1 | | Application on the skin of Mosquitoes repellent | | The biocidal products are applied directly on the skin at the dose of 0.48 mg/cm2:  The *primary exposure* is limited to the dermal route.  Body surface exposed: 55% | General public.  Adult and child ≥ 2 years.. |
| 7b - Tier 2 | | Application on the skin of Mosquitoes repellent | | The biocidal products are applied directly on the skin at the dose of 0.48 mg/cm2:  The *primary exposure* is limited to the dermal route.  Body surface exposed:  head, hand, ¾ arm and ½ legs. | General public.  Adult and child ≥ 2 years.. |
| 8a – Tier 1 | | Application on the skin of ticks repellent | | The biocidal products are applied directly on the skin at the dose of 0.66 mg/cm2:  The *primary exposure* is limited to the dermal route.  Body surface exposed: 55% | General public.  Adult and child ≥ 2 years. |
| 8b - Tier 2 | | Application on the skin of ticks repellent | | The biocidal products are applied directly on the skin at the dose of 0.66mg/cm2:  The *primary exposure* is limited to the dermal route.  Body surface exposed:  head, hand, ¾ arm and ½ legs. | General public.  Adult and child ≥ 2 years. |
| 9a – Tier 1 | | Application on the skin of tabanids repellent | | The biocidal products are applied directly on the skin at the dose of 1.07 mg/cm2:  The *primary exposure* is limited to the dermal route.  Body surface exposed: 55% | General public.  Adult and child ≥ 2 years. |
| 9b - Tier 2 | | Application on the skin of tabanids repellent | | The biocidal products are applied directly on the skin at the dose of 1.07 mg/cm2:  The *primary exposure* is limited to the dermal route.  Body surface exposed:  head, hand, ¾ arm and ½ legs. | General public.  Adult and child ≥ 2 years. |
| 10 | | Exposure by hand to mouth transfer | | Secondary exposure:  A reverse scenario was performed to estimate the percentage of the surface of the hands which can be put in the mouth to reach the AEL. | General public.  Adult and child. |

***Industrial exposure***

Not relevant

***Professional exposure***

Not relevant

***Non-professional exposure***

*Scenario [1-9]*

Scenario 1- 9 are scenarios of application of the product on the skin. The differences between all these scenarios are the intended uses (application rate, number of application) and the active substance concentration in the product.

| **Description of Scenario [1-9]** | | | |  |
| --- | --- | --- | --- | --- |
| Application on the skin of repellent.  The exposure by dermal route can be calculated according to the following equation:  where:  ID Internal dose (mg/kg b.w./day)  ARp Average dose of product applied on skin (mg/cm²)  CIR3535 Average concentration of substance in product (%)  BS Body surface exposed to the product (cm²)  DA Dermal absorption (%)  BW Body weight (kg)  This equation can be applied to adults and to children. | | | | |
|  | | Parameters | Value | Reference |
| **Common parameters between all scenarios (1-9)** | | | |  |
| Tier 1 (a) | | Body surface exposed to the product for **adult** considering exposure 55% of area body (cm2) | 9130 | Heeg opinion 17 |
| Body surface exposed to the product for **child (6-11 years)** considering exposure to 55% of area body (cm2) | 5060 | Heeg opinion 17 |
| Body surface exposed to the product for **child (2-6 years)** considering exposure to 55% of area body (cm2) | 3740 | Heeg opinion 17 |
| Body surface exposed to the product for **child (1-2 years)** considering exposure to 55% of area body (cm2) | 2640 | Heeg opinion 17 |
| Body surface exposed to the product for **child (6-12 months)** considering exposure to 55% of area body (cm2) | 2255 | Heeg opinion 17 |
| Tier 2(b) | | Body surface exposed to the product for **adult** considering exposure to head, hand, ¾ arm and ½ legs (cm2) | 6298 | Heeg opinion 17 |
| Body surface exposed to the product for **child (6-11 years)** considering exposure to head, hand, ¾ arm and ½ legs (cm2) | 3282 | Heeg opinion 17 |
| Body surface exposed to the product for **child (2-6 years)** considering exposure to head, hand, ¾ arm and ½ legs (cm2) | 2462 | Heeg opinion 17 |
| Body surface exposed to the product for **child (1-2 years)** considering exposure to head, hand, ¾ arm and ½ legs (cm2) | 1754 | Heeg opinion 17 |
| Body surface exposed to the product for **child (6-12 months)** considering exposure to head, hand, ¾ arm and ½ legs (cm2) | 1499 | Heeg opinion 17 |
| Tier 1-2 | | Body weight of an **adult** (kg) | 60 | Heeg opinion 17 |
| Body weight of **child (6-11 years)** (kg) | 23.9 | Heeg opinion 17 |
| Body weight of **child (2-6 years)** (kg) | 16 | Heeg opinion 17 |
| Body weight of **child (1-2 years)** (kg) | 10 | Heeg opinion 17 |
| Body weight of **child (6-12 months)** (kg) | 8 | Heeg opinion 17 |
| **Specific parameters** | | | | |
| Scenario 1  (SPC1) | Average dose of product applied on skin (mg/cm2) | | 0.7 | Applicant data |
| Average concentration of substance in product (%) | | 20 | Applicant data |
| Dermal absorption (%) | | 14 | CAR value |
| Scenario 2  (SPC1) | Average dose of product applied on skin (mg/cm2) | | 0.95 | Applicant data |
| Average concentration of substance in product (%) | | 20 | Applicant data |
| Dermal absorption (%) | | 14 | CAR value |
| Scenario 3  (SPC1) | Average dose of product applied on skin (mg/cm2) | | 1.95 | Applicant data |
| Average concentration of substance in product (%) | | 20 | Applicant data |
| Dermal absorption (%) | | 14 | CAR value |
| Scenario 4  (SPC2) | Average dose of product applied on skin (mg/cm2) | | 0.68 | Applicant data |
| Average concentration of substance in product (%) | | 25 | Applicant data |
| Dermal absorption (%) | | 14 | CAR value |
| Scenario 5  (SPC2) | Average dose of product applied on skin (mg/cm2) | | 0.93 | Applicant data |
| Average concentration of substance in product (%) | | 25 | Applicant data |
| Dermal absorption (%) | | 14 | CAR value |
| Scenario 6  (SPC2) | Average dose of product applied on skin (mg/cm2) | | 1.48 | Applicant data |
| Average concentration of substance in product (%) | | 25 | Applicant data |
| Dermal absorption (%) | | 14 | CAR value |
| Scenario 7  (SPC3) | Average dose of product applied on skin (mg/cm2) | | 0.48 | Applicant data |
| Average concentration of substance in product (%) | | 35 | Applicant data |
| Dermal absorption (%) | | 14 | CAR value |
| Scenario 8  (SPC3) | Average dose of product applied on skin (mg/cm2) | | 0.66 | Applicant data |
| Average concentration of substance in product (%) | | 35 | Applicant data |
| Dermal absorption (%) | | 14 | CAR value |
| Scenario 9  (SPC3) | Average dose of product applied on skin (mg/cm2) | | 1.07 | Applicant data |
| Average concentration of substance in product (%) | | 35 | Applicant data |
| Dermal absorption (%) | | 14 | CAR value |

**Calculations for Scenario [1-9]**

| **Summary table: systemic exposure from non-professional uses** | | | | | |
| --- | --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Estimated inhalation uptake** | **Estimated dermal uptake**  **mg/kg/d** | **Estimated oral uptake** | **Estimated total uptake**  **mg/kg/d** |
| Scenario [1a]  adult | Tier 1 | NR | 2.91 | NR | 2.91 |
| Scenario [1a]  child 6-11 years | Tier 1 | NR | 4.05 | NR | 4.05 |
| Scenario [1a]  child 2-6 years | Tier 1 | NR | 4.58 | NR | 4.58 |
| Scenario [1a]  child 1-2 years | Tier 1 | NR | 5.05 | NR | 5.05 |
| Scenario [1a]  child 6-12 months | Tier 1 | NR | 5.39 | NR | 5.39 |
| Scenario [1b]  adult | Tier 2 | NR | 2.01 | NR | 2.01 |
| Scenario [1b]  child 6-11 years | Tier 2 | NR | 2.62 | NR | 2.62 |
| Scenario [1b]  child 2-6 years | Tier 2 | NR | 3.02 | NR | 3.02 |
| Scenario [1b]  child 1-2 years | Tier 2 | NR | 3.35 | NR | 3.35 |
| Scenario [1b]  child 6-12 months | Tier 2 | NR | 3.58 | NR | 3.58 |
| Scenario [2a]  adult | Tier 1 | NR | 3.95 | NR | 3.95 |
| Scenario [2a]  child 6-11 years | Tier 1 | NR | 5.49 | NR | 5.49 |
| Scenario [2a]  child 2-6 years | Tier 1 | NR | 6.22 | NR | 6.22 |
| Scenario [2a]  child 1-2 years | Tier 1 | NR | 6.85 | NR | 6.85 |
| Scenario [2a]  child 6-12 months | Tier 1 | NR | 7.31 | NR | 7.31 |
| Scenario [2b]  adult | Tier 2 | NR | 2.72 | NR | 2.72 |
| Scenario [2b]  child 6-11 years | Tier 2 | NR | 3.56 | NR | 3.56 |
| Scenario [2b]  child 2-6 years | Tier 2 | NR | 4.09 | NR | 4.09 |
| Scenario [2b]  child 1-2 years | Tier 2 | NR | 4.55 | NR | 4.55 |
| Scenario [2b]  child 6-12 months | Tier 2 | NR | 4.86 | NR | 4.86 |
| Scenario [3a]  adult | Tier 1 | NR | 8.10 | NR | 8.10 |
| Scenario [3a]  child 6-11 years | Tier 1 | NR | 11.27 | NR | 11.27 |
| Scenario [3a]  child 2-6 years | Tier 1 | NR | 12.76 | NR | 12.76 |
| Scenario [3a]  child 1-2 years | Tier 1 | NR | 14.05 | NR | 14.05 |
| Scenario [3a]  child 6-12 months | Tier 1 | NR | 15.01 | NR | 15.01 |
| Scenario [3b]  adult | Tier 2 | NR | 5.59 | NR | 5.59 |
| Scenario [3b]  child 6-11 years | Tier 2 | NR | 7.31 | NR | 7.31 |
| Scenario [3b]  child 2-6 years | Tier 2 | NR | 8.40 | NR | 8.40 |
| Scenario [3b]  child 1-2 years | Tier 2 | NR | 9.34 | NR | 9.34 |
| Scenario [3b]  child 6-12 months | Tier 2 | NR | 9.97 | NR | 9.97 |
| Scenario [4a]  adult | Tier 1 | NR | 3.62 | NR | 3.62 |
| Scenario [4a]  child 6-11 years | Tier 1 | NR | 5.04 | NR | 5.04 |
| Scenario [4a]  child 2-6 years | Tier 1 | NR | 5.71 | NR | 5.71 |
| Scenario [4b]  adult | Tier 2 | NR | 2.50 | NR | 2.50 |
| Scenario [4b]  child 6-11 years | Tier 2 | NR | 3.27 | NR | 3.27 |
| Scenario [4b]  child 2-6 years | Tier 2 | NR | 3.76 | NR | 3.76 |
| Scenario [5a]  adult | Tier 1 | NR | 4.95 | NR | 4.95 |
| Scenario [5a]  child 6-11 years | Tier 1 | NR | 6.89 | NR | 6.89 |
| Scenario [5a]  child 2-6 years | Tier 1 | NR | 7.80 | NR | 7.80 |
| Scenario [5b]  adult | Tier 2 | NR | 3.42 | NR | 3.42 |
| Scenario [5b]  child 6-11 years | Tier 2 | NR | 4.47 | NR | 4.47 |
| Scenario [5b]  child 2-6 years | Tier 2 | NR | 5.14 | NR | 5.14 |
| Scenario [6a]  adult | Tier 1 | NR | 7.88 | NR | 7.88 |
| Scenario [6a]  child 6-11 years | Tier 1 | NR | 10.97 | NR | 10.97 |
| Scenario [6a]  child 2-6 years | Tier 1 | NR | 12.42 | NR | 12.42 |
| Scenario [6b]  adult | Tier 2 | NR | 5.44 | NR | 5.44 |
| Scenario [6b]  child 6-11 years | Tier 2 | NR | 7.11 | NR | 7.11 |
| Scenario [6b]  child 2-6 years | Tier 2 | NR | 8.18 | NR | 8.18 |
| Scenario [7a]  adult | Tier 1 | NR | 3.58 | NR | 3.58 |
| Scenario [7a]  child 6-11 years | Tier 1 | NR | 4.98 | NR | 4.98 |
| Scenario [7a]  child 2-6 years | Tier 1 | NR | 5.64 | NR | 5.64 |
| Scenario [7b]  adult | Tier 2 | NR | 2.47 | NR | 2.47 |
| Scenario [7b]  child 6-11 years | Tier 2 | NR | 3.23 | NR | 3.23 |
| Scenario [7b]  child 2-6 years | Tier 2 | NR | 3.71 | NR | 3.71 |
| Scenario [8a]  adult | Tier 1 | NR | 4.92 | NR | 4.92 |
| Scenario [8a]  child 6-11 years | Tier 1 | NR | 6.85 | NR | 6.85 |
| Scenario [8a]  child 2-6 years | Tier 1 | NR | 7.75 | NR | 7.75 |
| Scenario [8b]  adult | Tier 2 | NR | 3.39 | NR | 3.39 |
| Scenario [8b]  child 6-11 years | Tier 2 | NR | 4.44 | NR | 4.44 |
| Scenario [8b]  child 2-6 years | Tier 2 | NR | 5.10 | NR | 5.10 |
| Scenario [9a]  adult | Tier 1 | NR | 7.98 | NR | 7.98 |
| Scenario [9a]  child 6-11 years | Tier 1 | NR | 11.10 | NR | 11.10 |
| Scenario [9a]  child 2-6 years | Tier 1 | NR | 12.57 | NR | 12.57 |
| Scenario [9b]  adult | Tier 2 | NR | 5.50 | NR | 5.50 |
| Scenario [9b]  child 6-11 years | Tier 2 | NR | 7.20 | NR | 7.20 |
| Scenario [9b]  child 2-6 years | Tier 2 | NR | 8.28 | NR | 8.28 |

*Combined scenarios*

Not relevant

***Exposure of the general public***

*Scenario [10]*

| **Description of Scenario [10]** | | | | |
| --- | --- | --- | --- | --- |
| A reverse scenario is performed to determine the percentage of the hand’s surface which can be put into mouth to reach the AEL. A transfer coefficient of 100% is considered. | | | | |
|  | | Parameters1 | Value | Reference |
| **Common to all population** | | | |  |
| Tier 1 | AEL (mg/kg/d) | | 5 | CAR |
| Oral absorption (%) | | 100 | CAR |
| **Common parameters for all uses** | | | |  |
| Tier 1 | Body weight of an **adult** (kg) | | 60 | Heeg opinion 17 |
| Body weight of **child (6-11 years)** (kg) | | 23.9 | Heeg opinion 17 |
| Body weight of **child (2-6 years)** (kg) | | 16 | Heeg opinion 17 |
| Body weight of **child (1-2 years)** (kg) | | 10 | Heeg opinion 17 |
| Body weight of **child (6-12 months)** (kg) | | 8 | Heeg opinion 17 |
| Surface of one hand of an **adult** (cm2) | | 410 | Heeg opinion 17 |
| Surface of one hand of a **child (6-11 years)** (cm2) | | 214 | Heeg opinion 17 |
| Surface of one hand of a **child (2-6 years)** (cm2) | | 165 | Heeg opinion 17 |
| Surface of one hand of a **child (1-2 years)** (cm2) | | 115 | Heeg opinion 17 |
| Surface of one hand of a **child (6-12 months)** (cm2) | | 98 | Heeg opinion 17 |
| **Specific parameters** | | | | |
| Meta SPC 1  (worst case) | Average dose of product applied on skin (mg/cm2) | | 1.95 | Applicant data |
| Average concentration of substance in product (%) | | 20 | Applicant data |
| Meta SPC 2 (worst case) | Average dose of product applied on skin (mg/cm2) | | 1.48 | Applicant data |
| Average concentration of substance in product (%) | | 25 | Applicant data |
| Meta SPC 3 (worst case) | Average dose of product applied on skin (mg/cm2) | | 1.07 | Applicant data |
| Average concentration of substance in product (%) | | 35 | Applicant data |

**Calculations for Scenario [10]**

| **Summary table: systemic exposure from non-professional uses** | | | | |
| --- | --- | --- | --- | --- |
| **Exposure scenario** | **Tier/PPE** | **Amount of product which can be ingested to reach AEL**  **mg** | **Skin surface which can be put in mouth**  **(cm2)** | **Percentage of the surface of the hand which can be put in mouth** |
| Meta SPC 1 | | | | |
| Scenario [10] Adult | - | 300.0 | 769.2 | 187.6% |
| Scenario [10] child 6-11 years | - | 119.5 | 306.4 | 143.2% |
| Scenario [10] child 2-6 years | - | 78.0 | 200.0 | 120.9% |
| Scenario [10] child 1-2 years | - | 50 | 128.2 | 111.3% |
| Scenario [10] child 6-12 months | - | 40.0 | 102.6 | 104.2% |
| Meta SPC 2 | | | | |
| Scenario [10] Adult | - | 300.0 | 810.8 | 197.8% |
| Scenario [10] child 6-11 years | - | 119.5 | 323.0 | 151.0% |
| Scenario [10] child 2-6 years | - | 78.0 | 210.8 | 127.4% |
| Meta SPC 3 | | | | |
| Scenario [10] Adult | - | 300.0 | 801.1 | 195.4% |
| Scenario [10] child 6-11 years | - | 119.5 | 319.1 | 149.2% |
| Scenario [10] child 2-6 years | - | 78.0 | 208.3 | 125.9% |

***Dietary exposure***

As regards to the intended use of the family products CINQ SUR CINQ LOTION on human skin a contamination of food cannot be excluded. As a consequence, a dietary risk assessment is proposed in framework of this dossier.

Residue definitions

IR3535 is the only active substance considered for the biocidal products CINQ SUR CINQ LOTION. IR3535 (ethyl butylacetylaminopropionate**)** was the only compound considered relevant regarding the dietary exposure.

*List of* scenarios

| **Summary table of main representative dietary exposure scenarios** | | | |
| --- | --- | --- | --- |
| **Scenario number** | **Type of use1** | **Description of scenario** | **Subject of exposure2** |
| 1. | General public | Contamination of food with contact with palm of treated hands | All kind of food |

1 e.g. animal husbandry, food industry, professional use, residential use.

2 e.g. chicken, milk, beer

*Information of non-biocidal use of the active substance*

IR3535 is not known to be used in other areas.

*Estimating Livestock Exposure to Active Substances used in Biocidal Products*

Regarding the intended use of the family product CINQ SUR CINQ LOTION, no livestock exposure to IR3535 is expected.

*Estimating transfer of biocidal active substances into foods as a result of professional and/or industrial application(s)*

The family product CINQ SUR CINQ LOTION is only intended for non-professional use.

*Estimating transfer of biocidal active substances into foods as a result of non-professional use*

**Scenario 1**

Scenario 1 was performed for toddler, children and adult considering reference values mentioned in HEEG opinion 17[[8]](#footnote-8).

The scenario is not considered relevant for infant (<1 year), as the diet of infant consists mainly of milk and puree food, the contamination from hand to food is very limited.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | toddler  1 - 2 years | Child  2-3 years | Child  3-6 years | Child  6-11 years | Adult |
| body weight (kg) | 10 | 12 | 16 | 23.9 | 60 |
| hands (palms and back of both hands) (cm2) | 230.4 | 297 | 415 | 427.8 | 820 |

Considering the intended uses of CINQ SUR CINQ LOTION, its concentration of IR3535, and the default values mentioned above, the exposure for each of the biocidal product of the family (Meta SPC 1: ”FAMILLE”, Meta SPC 2: ”ZONES TEMPEREES”, Meta SPC 3: ”TROPIC”) was estimated as:

* Use 1 : skin repellent against mosquitoes (1-2 applications)
* Use 2 : skin repellent against ticks (1 application)
* Use 3 : skin repellent against horse-flies (1 application)

These biocidal products are intended :

* for children > 6 months for Meta SPC 1 “FAMILLE”,
* or for children > 2 years for Meta SPC 2 “ZONES TEMPEREES” and Meta SPC 3 “TROPIC”
* and for adults for the 3 Meta SPC.

So, the exposure of children, adults, and also for toddlers for Meta SPC 1: “FAMILLE”, is estimated in framework of this dossier.

To estimate dietary exposure, the following assumptions and default values were used:

|  |  |
| --- | --- |
| Ratio surface factor of the palm compared to whole hand | 0.5 |
| transfer factor (hand to food) in % | 100% |
| transfer factor (food to mouth) in % | 100% |
| handwash after use (i.e rinsing factor)[[9]](#footnote-9) | For use 1: 1 (considering that no recommendation to wash hands is proposed)  For uses 2 and 3: 3 (considering that this recommendation could not be applicable and regarding the practical use, this factor is considered not relevant for children) |

* ***Use # 1 – skin repellent against mosquitoes***

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Data and Results for  MetaSPC1 / MetaSPC2 / MetaSPC3 | | | | |
| Product application rate (mg product/cm²) (effective) | 0.70 / 0.68 / 0.48 | | | | |
| Concentration (a.s in % w/w in the product) | 20 / 25 / 35 | | | | |
| Applied active substance (mg a.s/cm²) (effective) | 0.140 / 0.170 / 0.168 | | | | |
| age | Toddler  1-2 years | Child  2-3 years | Child  3-6 years | Child  6-11 years | adult |
| hands (palms and back of both hands) (cm2) | 230 | 297 | 415 | 428 | 820 |
| Intended number of application  (evaluated) | 1/0/0 | 1/1/1 | 1/1/1 | 2/1/1 | 2/2/2 |
| Ratio surface factor of the palm compared to whole hand | 0.5 | 0.5 | 0.5 | 0.5 | 0.5 |
| Food exposure per application (a.s in mg) | 16/20/19 | 21/25/25 | 29/35/35 | 30/36/36 | 57/70/69 |
| transfer factor (hand to food) in % | 100 | 100 | 100 | 100 | 100 |
| transfer factor (food to mouth) in % | 100 | 100 | 100 | 100 | 100 |
| ingested a.s in mg and per application | 16/20/19 | 21/25/25 | 29/35/35 | 30/36/36 | 57/70/69 |
| **total ingested a.s in mg** | **16/0/0** | **21/25/25** | **29/35/35** | **60/36/36** | **115/139/138** |
| Body weight in kg | 10 | 12 | 16 | 23.9 | 60 |
| Exposure per application in mg a.s/kg b.w./day | 1.6/2.0/1.9 | 1.7/2.1/2.1 | 1.8/2.2/2.2 | 1.3/1.5/1.5 | 1/1.2/1.1 |
| **Total exposure in mg a.s/kg b.w./day** | **1.6/0/0** | **1.7/2.1/2.1** | **1.8/2.2/2.2** | **2.5/1.5/1.5** | **1.9/2.3/2.3** |

in bold : results related to intended uses

* ***Use # 2– skin repellent against ticks***

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Data and Results for  MetaSPC1 / MetaSPC2 / MetaSPC3 | | | | |
| Product application rate (mg product/cm²) (effective) | 0.95 / 0.93 / 0.66 | | | | |
| Concentration (a.s in % w/w in the product) | 20 / 25 / 35 | | | | |
| Applied active substance (mg a.s/cm²) (effective) | 0.190 / 0.233 / 0.231 | | | | |
| age | Toddler  1-2 years | Child  2-3 years | Child  3-6 years | Child  6-11 years | adult |
| hands (palms and back of both hands) (cm2) | 230 | 297 | 415 | 428 | 820 |
| Intended number of application  (evaluated) | 1/0/0 | 1/1/1 | 1/1/1 | 1/1/1 | 1/1/1 |
| Ratio surface factor of the palm compared to whole hand | 0.5 | 0.5 | 0.5 | 0.5 | 0.5 |
| Food exposure per application (a.s in mg) | 22/27/27 | 28/35/34 | 39/48/48 | 41/50/49 | 78/95/95 |
| transfer factor (hand to food) in % | 100 | 100 | 100 | 100 | 100 |
| transfer factor (food to mouth) in % | 100 | 100 | 100 | 100 | 100 |
| ingested a.s in mg and per application | 22/27/27 | 28/35/34 | 39/48/48 | 41/50/49 | 78/95/95 |
| **total ingested a.s in mg** | **22/0/0** | **28/35/34** | **39/48/48** | **41/50/49** | **78/95/95** |
| Body weight in kg | 10 | 12 | 16 | 23.9 | 60 |
| Exposure per application in mg a.s/kg b.w./day | 2.2/2.7/2.7 | 2.4/2.9/2.9 | 2.5/3.0/3.0 | 1.7/2.1/2.1 | 1.3/1.6/1.6 |
| **Total exposure in mg a.s/kg b.w./day** | **2.2/0/0** | **2.4/2.9/2.9** | **2.5/3.0/3.0** | **1.7/2.1/2.1** | **1.3/1.6/1.6** |
| Label proposals:  handwash after use (rincing factor)  RMM | n.r.  ”do not treat hands of children | n.r.  ”do not treat hands of children | n.r.  ”do not treat hands of children | n.r.  ”do not treat hands of children | 3  n.r |
| Total exposure in mg a.s/kg b.w./day including precautionary proposition | - | - | - | - | 0.43/0.53/0.53 |

in bold : results related to intended uses

* ***Use # 3 – skin repellent against horse-flies***

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Data and Results for  MetaSPC1 / MetaSPC2 / MetaSPC3 | | | | |
| Product application rate (mg product/cm²) (effective) | 1.95 / 1.48 / 1.07 | | | | |
| Concentration (a.s in % w/w in the product) | 20 / 25 / 35 | | | | |
| Applied active substance (mg a.s/cm²) (effective) | 0.390 / 0.370 / 0.375 | | | | |
| age | Toddler  1-2 years | Child  2-3 years | Child  3-6 years | Child  6-11 years | adult |
| hands (palms and back of both hands) (cm2) | 230 | 297 | 415 | 428 | 820 |
| Intended number of application  (evaluated) | 1/0/0 | 1/1/1 | 1/1/1 | 1/1/1 | 1/1/1 |
| Ratio surface factor of the palm compared to whole hand | 0.5 | 0.5 | 0.5 | 0.5 | 0.5 |
| Food exposure per application (a.s in mg) | 45/43/43 | 58/55/56 | 81/77/78 | 83/79/80 | 160/152/154 |
| transfer factor (hand to food) in % | 100 | 100 | 100 | 100 | 100 |
| transfer factor (food to mouth) in % | 100 | 100 | 100 | 100 | 100 |
| **ingested a.s in mg and per application** | 45/43/43 | 58/55/56 | 81/77/78 | 83/79/80 | 160/152/154 |
| total ingested a.s in mg | **45/0/0** | **58/55/56** | **81/77/78** | **83/79/80** | **160/152/154** |
| Body weight in kg | 10 | 12 | 16 | 23.9 | 60 |
| Exposure per application in mg a.s/kg b.w./day | 4.5/4.3/4.3 | 4.8/4.6/4.6 | 5.1/4.8/4.9 | 3.5/3.3/3.4 | 2.7/2.5/2.6 |
| **Total exposure in mg a.s/kg b.w./day** | **4.5/0/0** | **4.8/4.6/4.6** | **5.1/4.8/4.9** | **3.5/3.3/3.4** | **2.7/2.5/2.6** |
| Label proposals:  handwash after use (rincing factor)  RMM | n.r.  ”do not treat hands of children | n.r.  ”do not treat hands of children | n.r.  ”do not treat hands of children | n.r.  ”do not treat hands of children | 3  n.r |
| Total exposure in mg a.s/kg b.w./day including precautionary proposition | - | - | - | - | 0.89/0.84/0.85 |

in bold : results related to intended uses

**Conclusion**

As regards to the intended uses of the products claimed in the biocidal product family CINQ SUR CINQ LOTION on human skin, and based on the assumptions and the reference values used, an estimation of dietary exposure for toddler, children and adults was performed. These estimations are considered as a worst case using the assumption that all the active substance from the palm hands will be ingested. The exposures via food range from 1.3 to 5.1 mg/kg bw/d for children (1-11 years old) and from 1.3 to 2.7 mg/kg bw/d for adults.

***Exposure associated with production, formulation and disposal of the biocidal product***

*Not relevant*

***Aggregated exposure***

*Not relevant*

***Summary of exposure assessment***

| **Scenarios and values to be used in risk assessment** | | | |
| --- | --- | --- | --- |
| **Scenario number** | **Exposed group**  **(e.g. professionals, non-professionals, bystanders)** | **Tier/PPE** | **Estimated total uptake** |
| **Meta SPC 1** | | | |
| Scenario [1a]  adult | Non professional | Tier 1 | 2.91 |
| Scenario [1a]  child 6-11 years old | Non professional | Tier 1 | 4.05 |
| Scenario [1a]  child 2-6 years old | Non professional | Tier 1 | 4.58 |
| Scenario [1a]  child 1-2 years old | Non professional | Tier 1 | 5.05 |
| Scenario [1a]  child 6-12 months old | Non professional | Tier 1 | 5.39 |
| Scenario [1b]  adult | Non professional | Tier 2 | 2.01 |
| Scenario [1b]  child 6-11 years old | Non professional | Tier 2 | 2.62 |
| Scenario [1b]  child 2-6 years old | Non professional | Tier 2 | 3.02 |
| Scenario [1b]  child 1-2 years old | Non professional | Tier 2 | 3.35 |
| Scenario [1b]  child 6-12 months old | Non professional | Tier 2 | 3.58 |
| Scenario [2a]  adult | Non professional | Tier 1 | 3.95 |
| Scenario [2a]  child 6-11 years old | Non professional | Tier 1 | 5.49 |
| Scenario [2a]  child 2-6 years old | Non professional | Tier 1 | 6.22 |
| Scenario [2a]  child 1-2 years | Non professional | Tier 1 | 6.85 |
| Scenario [2a]  child 6-12 months years | Non professional | Tier 1 | 7.31 |
| Scenario [2b]  adult | Non professional | Tier 2 | 2.72 |
| Scenario [2b]  child 6-11 years | Non professional | Tier 2 | 3.56 |
| Scenario [2b]  child 2-6 years | Non professional | Tier 2 | 4.09 |
| Scenario [2b]  child 1-2 years | Non professional | Tier 2 | 4.55 |
| Scenario [2b]  child 6-12 months | Non professional | Tier 2 | 4.86 |
| Scenario [3a]  adult | Non professional | Tier 1 | 8.10 |
| Scenario [3a]  child 6-11 years | Non professional | Tier 1 | 11.27 |
| Scenario [3a]  child 2-6 years | Non professional | Tier 1 | 12.76 |
| Scenario [3a]  child 1-2 years | Non professional | Tier 1 | 14.05 |
| Scenario [3a]  child 6-12 months years | Non professional | Tier 1 | 15.01 |
| Scenario [3b]  adult | Non professional | Tier 2 | 5.59 |
| Scenario [3b]  child 6-11 years | Non professional | Tier 2 | 7.31 |
| Scenario [3b]  child 2-6 years | Non professional | Tier 2 | 8.40 |
| Scenario [3b]  child 1-2 years | Non professional | Tier 2 | 9.34 |
| Scenario [3b]  child 6-12 months | Non professional | Tier 2 | 9.97 |
| **Meta SPC 2** | | | |
| Scenario [4a]  adult | Non professional | Tier 1 | 3.62 |
| Scenario [4a]  child 6-11 years | Non professional | Tier 1 | 5.04 |
| Scenario [4a]  child 2-6 years | Non professional | Tier 1 | 5.71 |
| Scenario [4b]  adult | Non professional | Tier 2 | 2.50 |
| Scenario [4b]  child 6-11 years | Non professional | Tier 2 | 3.27 |
| Scenario [4b]  child 2-6 years | Non professional | Tier 2 | 3.76 |
| Scenario [5a]  adult | Non professional | Tier 1 | 4.95 |
| Scenario [5a]  child 6-11 years | Non professional | Tier 1 | 6.89 |
| Scenario [5a]  child 2-6 years | Non professional | Tier 1 | 7.80 |
| Scenario [5b]  adult | Non professional | Tier 2 | 3.42 |
| Scenario [5b]  child 6-11 years | Non professional | Tier 2 | 4.47 |
| Scenario [5b]  child 2-6 years | Non professional | Tier 2 | 5.14 |
| Scenario [6a]  adult | Non professional | Tier 1 | 7.88 |
| Scenario [6a]  child 6-11 years | Non professional | Tier 1 | 10.97 |
| Scenario [6a]  child 2-6 years | Non professional | Tier 1 | 12.42 |
| Scenario [6b]  adult | Non professional | Tier 2 | 5.44 |
| Scenario [6b]  child 6-11 years | Non professional | Tier 2 | 7.11 |
| Scenario [6b]  child 2-6 years | Non professional | Tier 2 | 8.18 |
| **Meta SPC 3** | | | |
| Scenario [7a]  adult | Non professional | Tier 1 | 3.58 |
| Scenario [7a]  child 6-11 years | Non professional | Tier 1 | 4.98 |
| Scenario [7a]  child 2-6 years | Non professional | Tier 1 | 5.64 |
| Scenario [7b]  adult | Non professional | Tier 2 | 2.47 |
| Scenario [7b]  child 6-11 years | Non professional | Tier 2 | 3.23 |
| Scenario [7b]  child 2-6 years | Non professional | Tier 2 | 3.71 |
| Scenario [8a]  adult | Non professional | Tier 1 | 4.92 |
| Scenario [8a]  child 6-11 years | Non professional | Tier 1 | 6.85 |
| Scenario [8a]  child 2-6 years | Non professional | Tier 1 | 7.75 |
| Scenario [8b]  adult | Non professional | Tier 2 | 3.39 |
| Scenario [8b]  child 6-11 years | Non professional | Tier 2 | 4.44 |
| Scenario [8b]  child 2-6 years | Non professional | Tier 2 | 5.10 |
| Scenario [9a]  adult | Non professional | Tier 1 | 7.98 |
| Scenario [9a]  child 6-11 years | Non professional | Tier 1 | 11.10 |
| Scenario [9a]  child 2-6 years | Non professional | Tier 1 | 12.57 |
| Scenario [9b]  adult | Non professional | Tier 2 | 5.50 |
| Scenario [9b]  child 6-11 years | Non professional | Tier 2 | 7.20 |
| Scenario [9b]  child 2-6 years | Non professional | Tier 2 | 8.28 |

#### Risk characterisation for human health

**Reference values to be used in Risk Characterisation**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Reference** | **Study** | **NOAEL (LOAEL)** | **AF** | **Correction for oral absorption** | **Value**  **(mg/kg bw/d)** |
| AELshort-term | Rabbit, oral, 28-days toxicity study. | 500 mg/kg/d | 100 | 100 | 5 |
| AELmedium-term | Rabbit, oral, 28-days toxicity study. | 500 mg/kg/d | 100 | 100 | 5 |
| AELlong-term | Rabbit, oral, 28-days toxicity study. | 500 mg/kg/d | 100 | 100 | 5 |
| ARfD | Not applicable | | | | |
| ADI | Not applicable | | | | |

**Maximum residue limits or equivalent**

Residue definitions

Residue definition is established as IR3535.

|  |  |  |  |
| --- | --- | --- | --- |
| **MRLs or other relevant reference values** | **Reference** | **Relevant commodities** | **Value** |
| ARfD | No value was proposed in the CAR. However, in framework of this dossier the value of the AELacute (Rabbit, overall, developmental study/28-d study: NOAEL of 500 mg/kg/day divided by a standard assessment factor of 100) is used | food | 5 mg/kg/day |
| ADI | Not considered necessary regarding the intended uses |  |  |

***Risk for industrial users***

Not relevant

***Risk for professional users***

Not relevant

***Risk for non-professional users***

**Systemic effects**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **AEL**  **mg/kg bw/d** | **Estimated uptake**  **mg/kg bw/d** | **Estimated uptake/ AEL**  **(%)** | **Number of application claimed by applicant** | **Number of application acceptable** | **Acceptable**  **(yes/no) compared to applicant requirement** |
| **Meta SPC 1** | | | | | | | |
| Scenario [1a]  adult | 1 | 5 | 2.91 | 58.2 | 2 | 1 | **Acceptable only one application** |
| Scenario [1a]  child 6-11 years | 1 | 5 | 4.05 | 80.9 | 2 | 1 | **Acceptable only one application\*** |
| Scenario [1a]  child 2-6 years | 1 | 5 | 4.58 | 91.6 | 1 | 1 | Acceptable |
| Scenario [1a]  child 1-2 years | 1 | 5 | 5.05 | 100.9 | 1 | 0 | Unacceptable\*(see conclusion without hand) |
| Scenario [1a]  child 6-12 months | 1 | 5 | 5.39 | 107.7 | 1 | 0 | Unacceptable\*(see conclusion without hand) |
| **Scenario [1b]**  **adult** | **2** | **5** | 2.01 | **40.1** | **2** | **2** | **Acceptable** |
| **Scenario [1b]**  **child 6-11 years** | **2** | **5** | 2.62 | **52.5** | **2** | **1** | **Acceptable only one application\***  (see conclusion without hand) |
| **Scenario [1b]**  **child 2-6 years** | **2** | **5** | 3.02 | **60.3** | **1** | **1** | **Acceptable** |
| **Scenario [1b]**  **child 1-2 years** | **2** | **5** | 3.35 | **67.1** | **1** | **1** | **Acceptable** |
| **Scenario [1b]**  **child 6-12 months** | **2** | **5** | 3.58 | **71.6** | **1** | **1** | **Acceptable** |
| Scenario [2a]  adult | 1 | 5 | 3.95 | 78.9 | 1 | 1 | Acceptable |
| Scenario [2a]  child 6-11 years | 1 | 5 | 5.49 | 109.8 | 1 | 0 | Unacceptable\*  (see conclusion without hand) |
| Scenario [2a]  child 2-6 years | 1 | 5 | 6.22 | 124.7 | 1 | 0 | Unacceptable\* |
| Scenario [2a]  child 1-2 years | 1 | 5 | 6.85 | 136.9 | 1 | 0 | Unacceptable\* |
| Scenario [2a]  child 6-12 months | 1 | 5 | 7.31 | 146.2 | 1 | 0 | Unacceptable\* |
| **Scenario [2b]**  **adult** | **2** | **5** | 2.72 | **54.4** | **1** | **1** | **Acceptable** |
| **Scenario [2b]**  **child 6-11 years** | **2** | **5** | 3.56 | **71.2** | **1** | **1** | **Acceptable** |
| **Scenario [2b]**  **child 2-6 years** | **2** | **5** | 4.09 | **81.9** | **1** | **1** | **Acceptable** |
| **Scenario [2b]**  **child 1-2 years** | **2** | **5** | 4.55 | **91.0** | **1** | **1** | **Acceptable** |
| **Scenario [2b]**  **child 6-12 months** | **2** | **5** | 4.86 | **97.2** | **1** | **1** | **Acceptable** |
| Scenario [3a]  adult | 1 | 5 | 8.10 | 162.0 | 1 | 0 | Unacceptable |
| Scenario [3a]  child 6-11 years | 1 | 5 | 11.27 | 225.4 | 1 | 0 | Unacceptable\* |
| Scenario [3a]  child 2-6 years | 1 | 5 | 12.76 | 255.3 | 1 | 0 | Unacceptable\* |
| Scenario [3a]  child 1-2 years | 1 | 5 | 14.05 | 281.1 | 1 | 0 | Unacceptable\* |
| Scenario [3a]  child 6-12 months | 1 | 5 | 15.01 | 300.1 | 1 | 0 | Unacceptable\* |
| **Scenario [3b]**  **adult** | **2** | **5** | 5.59 | **111.7** | **1** | **0** | **Unacceptable** |
| **Scenario [3b]**  **child 6-11 years** | **2** | **5** | 7.31 | **146.2** | **1** | **0** | **Unacceptable\*** |
| **Scenario [3b]**  **child 2-6 years** | **2** | **5** | 8.40 | **168** | **1** | **0** | **Unacceptable\*** |
| **Scenario [3b]**  **child 1-2 years** | **2** | **5** | 9.34 | **186.8** | **1** | **0** | **Unacceptable\*** |
| **Scenario [3b]**  **child 6-12 months** | **2** | **5** | 9.97 | **199.4** | **1** | **0** | **Unacceptable\*** |
| **Meta SPC 2** | | | | | | | |
| Scenario [4a]  adult | 1 | 5 | 3.62 | 72.4 | 2 | 1 | Acceptable only one application |
| Scenario [4a]  child 6-11 years | 1 | 5 | 5.04 | 100.8 | 1 | 0 | Unacceptable\*  (see conclusion without hand) |
| Scenario [4a]  child 2-6 years | 1 | 5 | 5.71 | 114.1 | 1 | 0 | Unacceptable\*  (see conclusion without hand) |
| **Scenario [4b]**  **adult** | **2** | **5** | 2.50 | **50.0** | **2** | **2** | **Acceptable** |
| **Scenario [4b]**  **child 6-11 years** | **2** | **5** | 3.27 | **65.4** | **1** | **1** | **Acceptable** |
| **Scenario [4b]**  **child 2-6 years** | **2** | **5** | 3.76 | **75.1** | **1** | **1** | **Acceptable** |
| Scenario [5a]  adult | 1 | 5 | 4.95 | 99.1 | 1 | 1 | Acceptable |
| Scenario [5a]  child 6-11 years | 1 | 5 | 6.89 | 137.8 | 1 | 0 | Unacceptable\* |
| Scenario [5a]  child 2-6 years | 1 | 5 | 7.80 | 156.1 | 1 | 0 | Unacceptable\* |
| **Scenario [5b]**  **adult** | **2** | **5** | 3.42 | **68.3** | **1** | **1** | **Acceptable** |
| **Scenario [5b]**  **child 6-11 years** | **2** | **5** | 4.47 | **89.4** | **1** | **1** | **Acceptable** |
| **Scenario [5b]**  **child 2-6 years** | **2** | **5** | 5.14 | **102.7** | **1** | **0** | **Unacceptable\*** (see conclusion without hand) |
| Scenario [6a]  adult | 1 | 5 | 7.88 | 157.6 | 1 | 0 | Unacceptable |
| Scenario [6a]  child 6-11 years | 1 | 5 | 10.97 | 219.3 | 1 | 0 | Unacceptable\* |
| Scenario [6a]  child 2-6 years | 1 | 5 | 12.42 | 248.4 | 1 | 0 | Unacceptable\* |
| **Scenario [6b]**  **adult** | **2** | **5** | 5.44 | **108.7** | **1** | **0** | **Unacceptable** |
| **Scenario [6b]**  **child 6-11 years** | **2** | **5** | 7.11 | **142.3** | **1** | **0** | **Unacceptable\*** |
| **Scenario [6b]**  **child 2-6 years** | **2** | **5** | 8.18 | **163.5** | **1** | **0** | **Unacceptable\*** |
| **Meta SPC 3** | | | | | | | |
| Scenario [7a]  adult | 1 | 5 | 3.58 | 71.6 | 2 | 1 | Acceptable only one application |
| Scenario [7a]  child 6-11 years | 1 | 5 | 4.98 | 99.6 | 1 | 1 | Acceptable |
| Scenario [7a]  child 2-6 years | 1 | 5 | 5.64 | 112.8 | 1 | 0 | Unacceptable\*  (see conclusion without hand) |
| **Scenario [7b]**  **adult** | **2** | **5** | 2.47 | **49.4** | **2** | **2** | **Acceptable** |
| **Scenario [7b]**  **child 6-11 years** | **2** | **5** | 3.23 | **64.6** | **1** | **1** | **Acceptable** |
| **Scenario [7b]**  **child 2-6 years** | **2** | **5** | 3.71 | **74.2** | **1** | **1** | **Acceptable** |
| Scenario [8a]  adult | 1 | 5 | 4.92 | 98.4 | 1 | 1 | Acceptable |
| Scenario [8a]  child 6-11 years | 1 | 5 | 6.85 | 136.9 | 1 | 0 | Unacceptable\* |
| Scenario [8a]  child 2-6 years | 1 | 5 | 7.75 | 155.1 | 1 | 0 | Unacceptable\* |
| **Scenario [8b]**  **adult** | **2** | **5** | 3.39 | **67.9** | **1** | **1** | **Acceptable** |
| **Scenario [8b]**  **child 6-11 years** | **2** | **5** | 4.44 | **88.8** | **1** | **1** | **Acceptable** |
| **Scenario [8b]**  **child 2-6 years** | **2** | **5** | 5.10 | **102.1** | **1** | **0** | **Unacceptable\*** (see conclusion without hand) |
| Scenario [9a]  adult | 1 | 5 | 7.98 | 159.6 | 1 | 0 | Unacceptable |
| Scenario [9a]  child 6-11 years | 1 | 5 | 11.10 | 222.0 | 1 | 0 | Unacceptable\* |
| Scenario [9a]  child 2-6 years | 1 | 5 | 12.57 | 251.4 | 1 | 0 | Unacceptable\* |
| **Scenario [9b]**  **adult** | **2** | **5** | 5.50 | **110.1** | **1** | **0** | **Unacceptable** |
| **Scenario [9b]**  **child 6-11 years** | **2** | **5** | 7.20 | **144** | **1** | **0** | **Unacceptable\*** |
| **Scenario [9b]**  **child 2-6 years** | **2** | **5** | 8.28 | **165.5** | **1** | **0** | **Unacceptable\*** |

\*Since the applicant recommends to not apply the product on child’s hand and that the product has to be applied by an adult, a refinement of the risk assessment was performed excluding the application on the hands of the child. The hands represent 13% of the treated body surface. This refinement was performed when a mitigation measure (reduction of number of application) could be applied or an unacceptable risk is observed.

***Risk assessment for children (up to 11 y.o.) for which unacceptable risks were identified, considering the RMM “do not apply on childrens’ hands”***

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Task/**  **Scenario** | **Tier** | **AEL**  **mg/kg bw/d** | **Estimated uptake**  **mg/kg bw/d** | **Estimated uptake/ AEL**  **(%)** | **Number of application claimed by applicant** | **Number of application acceptable** | **Acceptable**  **(yes/no) compared to applicant requirement** |
| **Meta SPC 1** | | | | | | | |
| Scenario [1a]  child 6-11 years | **1** | **5** | **3.49** | **69.8** | **2** | **1** | **Acceptable only one application** |
| Scenario [1a]  child 1-2 years | **1** | **5** | **4.40** | **88** | **2** | **1** | **Acceptable only one application** |
| **Scenario [1b]**  **child 6-11 years** | **2** | **5** | **2.28** | **45.6** | **2** | **2** | Acceptable |
| Scenario [1a]  child 6-12 months | **1** | **5** | **4.70** | **93.9** | **1** | **1** | Acceptable |
| Scenario [2a]  child 6-11 years | 1 | 5 | **4.74** | **94.8** | **1** | **1** | Acceptable |
| Scenario [2a]  child 2-6 years | 1 | 5 | **5.38** | **107.5** | **1** | **0** | Unacceptable |
| Scenario [2a]  child 1-2 years | 1 | 5 | **5.97** | **119.4** | **1** | **0** | Unacceptable |
| Scenario [2a]  child 6-12 months | 1 | 5 | **6.37** | **127.5** | **1** | **0** | Unacceptable |
| Scenario [3a]  child 6-11 years | 1 | 5 | **9.73** | **194.5** | **1** | **0** | Unacceptable |
| Scenario [3a]  child 2-6 years | 1 | 5 | **11.04** | **220.7** | **1** | **0** | Unacceptable |
| Scenario [3a]  child 1-2 years | 1 | 5 | **12.26** | **245.1** | **1** | **0** | Unacceptable |
| Scenario [3a]  child 6-12 months | 1 | 5 | **13.08** | **261.7** | **1** | **0** | Unacceptable |
| **Scenario [3b]**  **child 6-11 years** | **2** | **5** | **6.36** | **127.2** | **1** | **0** | Unacceptable |
| **Scenario [3b]**  **child 2-6 years** | **2** | **5** | **7.27** | **145.5** | **1** | **0** | Unacceptable |
| **Scenario [3b]**  **child 1-2 years** | **2** | **5** | **8.11** | **162.3** | **1** | **0** | Unacceptable |
| **Scenario [3b]**  **child 6-12 months** | **2** | **5** | **8.66** | **173.2** | **1** | **0** | Unacceptable |
| **Meta SPC 2** | | | | | | | |
| Scenario [4a]  child 6-11 years | **1** | **5** | **4.35** | **87** | **1** | **1** | **Acceptable** |
| Scenario [4a]  child 2-6 years | **1** | **5** | **4.93** | **98.7** | **1** | **1** | **Acceptable** |
| Scenario [5a]  child 6-11 years | **1** | **5** | **5.95** | **118.9** | **1** | **0** | **Unacceptable** |
| Scenario [5a]  child 2-6 years | **1** | **5** | **6.75** | **135.0** | **1** | **0** | **Unacceptable** |
| **Scenario [5b]**  **child 2-6 years** | **2** | **5** | **4.45** | **88.9** | **1** | **1** | **Acceptable** |
| Scenario [6a]  child 6-11 years | 1 | 5 | **9.46** | **189.3** | **1** | **0** | **Unacceptable** |
| Scenario [6a]  child 2-6 years | 1 | 5 | **10.74** | **214.8** | **1** | **0** | **Unacceptable** |
| **Scenario [6b]**  **child 6-11 years** | **2** | **5** | **6.19** | **123.7** | **1** | **0** | **Unacceptable** |
| **Scenario [6b]**  **child 2-6 years** | **2** | **5** | **7.08** | **141.5** | **1** | **0** | **Unacceptable** |
| **Meta SPC 3** | | | | | | | |
| Scenario [7a]  child 2-6 years | **1** | **5** | **4.88** | **97.5** | **1** | **1** | **Acceptable** |
| Scenario [8a]  child 6-11 years | **1** | **5** | **5.91** | **118.2** | **1** | **0** | **Unacceptable** |
| Scenario [8a]  child 2-6 years | **1** | **5** | **6.70** | **134.1** | **1** | **0** | **Unacceptable** |
| **Scenario [8b]**  **child 2-6 years** | **2** | **5** | **4.42** | **88.4** | **1** | **1** | **Acceptable** |
| Scenario [9a]  child 6-11 years | **1** | **5** | **9.58** | **191.6** | **1** | **0** | **Unacceptable** |
| Scenario [9a]  child 2-6 years | **1** | **5** | **10.87** | **217.4** | **1** | **0** | **Unacceptable** |
| **Scenario [9b]**  **child 6-11 years** | **2** | **5** | **6.26** | **125.2** | **1** | **0** | **Unacceptable** |
| **Scenario [9b]**  **child 2-6 years** | **2** | **5** | **7.16** | **143.3** | **1** | **0** | **Unacceptable** |

**Conclusion**

***European agreed approach – tier 1 without any specific RMM***

Considering that 55% of area body are exposed (**tier 1**):

* For meta SPC 1:
  + **For application of the product against mosquitoes**:
    - the risk is acceptable for adults and children over 11 years old for one application only. The claimed two applications lead to unacceptable risk.
    - The risk for children between 6 and 11 years is acceptable for one application only. The claimed two applications lead to unacceptable risk.
    - The risk for children between 2 and 6 years is acceptable for one application, as required by applicant.
    - The risk for children from 6 months to 2 years is not acceptable
  + **For application of the product against ticks:** 
    - the risk is acceptable for adults and children over 11 years old for one application, as claimed by the applicant.
    - The risk for children below 11 years is unacceptable.
  + **For application of the product against tabanids**: the risk is unacceptable for adults and children.
* For meta SPC 2:
  + **For application of the product against mosquitoes**:
    - the risk is acceptable for adults and children over 11 years old for one application only. The claimed two applications lead to unacceptable risk.
    - The risk for children between 2 and 11 years is unacceptable.
  + **For application of the product against ticks:** 
    - the risk is acceptable for one application for adults and children over 11 years old, as claimed by the applicant.
    - The risk for children between 2 years and 11 years is unacceptable.
  + **For application of the product against tabanids**: the risk is unacceptable for adults and children.
* For meta SPC 3:
  + **For application of the product against mosquitoes**:
    - the risk is acceptable for adults and children over 11 years old for one application only. The claimed two applications lead to unacceptable risk.
    - The risk for children between 6 and 11 years is acceptable for one application, as required by applicant.
    - The risk for children below 6 years is unacceptable
  + **For application of the product against ticks:** 
    - the risk is acceptable for adults and children over 11 years old for one application, as claimed by the applicant.
    - The risk for children between 2 years and 11 years is unacceptable.
  + **For application of the product against tabanids**: the risk is unacceptable for adults and children.

Applicant proposes the following risk mitigation measure “do not apply on children’ hands”. Considering with RMM may lead to acceptable risk for some categories of users. This RMM has not been agreed at the European level. Hence it is up to each MS to decide whether it can be implemented.

***Conclusions valid for France and not subject to mutual recognition process***

In France, it is considered that repellent are necessary to prevent from mosquitoes and ticks bites and avoid vector-borne diseases. Specific risk mitigation measures can be implemented, one of which being the use of clothes that cover a larger part of the body. The RMM “do not apply on children’ hands” is also considered as appropriate.

For user category for which unacceptable risk are identified with the European scenario, the product can be authorized according to article 19(5), provided that the specific RMM lead to acceptable risks.

For French approach, it is considered that product is applied on head, hands, ¾ arms and 1/2 legs for adult and head, ¾ arms and 1/2 legs for children since a mitigation measure “do not apply the product on hands of children” is proposed in SPC.

* For meta SPC 1:
  + **For application of the product against mosquitoes**: the risk is acceptable for adults and children over 6 years old for 2 applications, as claimed by applicant.

The risk for children between 6 months and 6 years is acceptable for one application

* + **For application of the product against ticks:** the risk is acceptable for adults and children above 6 months for one application, as claimed by the applicant.
  + **For application of the product against tabanids**: the risk is unacceptable for adults and children.
* For meta SPC 2:
  + **For application of the product against mosquitoes**:
    - the risk is acceptable for adults and children over 11 years old for 2 applications, as claimed by applicant.
    - The risk for children between 2 and 11 years is acceptable for one application, as claimed by applicant.
  + **For application of the product against ticks:** the risk is acceptable for one application for adults and children from 2 y.o. as claimed by applicant.
  + **For application of the product against tabanids**: the risk is unacceptable for adults and children.
* For meta SPC 3:
  + **For application of the product against mosquitoes**:
    - the risk is acceptable for adults and children over 11 years old for 2 applications, as claimed by applicant.

The risk for children between 2 and 11 years old is acceptable for one application, as claimed by applicant.

* + **For application of the product against ticks:** the risk is acceptable for one application for adults and children from 2 y.o. as claimed by applicant
  + **For application of the product against tabanids**: the risk is unacceptable for adults and children.

***Risk for the general public***

A reverse scenario is performed to determine the percentage of the surface of the hand which can be put into mouth to reach the AEL (cf exposure part).

More than 100% of the hand can be put in the hand for adult and children. Therefore, the risk is considered acceptable.

***Risk for consumers via residues in food***

As regards to the intended uses of the family product of CINQ SUR CINQ LOTION on skin and the ARfD (based on AEL) proposed for IR3535, the following dietary risk assessments were performed:

* ***Use # 1 – skin repellent against mosquitoes***

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| age | Toddler  1-2 years | Child  2-3 years | Child  3-6 years | Child  6-11 years | adult |
| Exposure per application in mg a.s/kg b.w./day | 1.6/2.0/1.9 | 1.7/2.1/2.1 | 1.8/2.2/2.2 | 1.3/1.5/1.5 | 1/1.2/1.1 |
| **Total exposure in mg a.s/kg b.w./day** | **1.6/0/0** | **1.7/2.1/2.1** | **1.8/2.2/2.2** | **2.5/1.5/1.5** | **1.9/2.3/2.3** |
| ARfD (mg a.s/kg b.w./day ) | 5 | 5 | 5 | 5 | 5 |
| % of ARfD (per application) | 32/39/39 | 35/42/42 | 36/44/44 | 25/30/30 | 19/23/23 |
| % of ARfD (in total) | **32/0/0** | **35/42/42** | **36/44/44** | **50/30/30** | **38/46/46** |

in bold : results related to intended uses

As regards to the intended use 1 and based on the assumption and the reference values used, no dietary risk for adults and children is expected.

For this use, the applicant proposes the following recommendations:

* *Do not apply on child's hand.*
* ***Use # 2– skin repellent against ticks***

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| age | Toddler  1-2 years | Child  2-3 years | Child  3-6 years | Child  6-11 years | adult |
| Exposure per application in mg a.s/kg b.w./day | 2.2/2.7/2.7 | 2.4/2.9/2.9 | 2.5/3.0/3.0 | 1.7/2.1/2.1 | 1.3/1.6/1.6 |
| **Total exposure in mg a.s/kg b.w./day** | **2.2/0/0** | **2.4/2.9/2.9** | **2.5/3.0/3.0** | **1.7/2.1/2.1** | **1.3/1.6/1.6** |
| Total exposure in mg a.s/kg b.w./day including hand washing | nr | nr | nr | nr | 0.43/0.53/0.53 |
| ARfD (mg a.s/kg b.w./day ) | 5 | 5 | 5 | 5 | 5 |
| % of ARfD (per application) | 44/54/53 | 47/58/58 | 49/60/60 | 34/42/41 | 26/32/32 |
| % of ARfD (in total) | **44/0/0** | **47/58/58** | **49/60/60** | **34/42/41** | **26/32/32** |
| % of ARfD including hand washing | nr | nr | nr | nr | **9/11/11** |

in bold : results related to intended uses

nr: not relevant

As regards the intended use 2 and based on the assumption and the reference values used, no dietary risk for adults and children is expected.

For this use, the applicant proposes the following recommendations:

* *Do not apply on child's hand.*
* *Carefully wash your hands after using this product.*
* ***Use # 3 – skin repellent against horse-flies***

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| age | Toddler  1-2 years | Child  2-3 years | Child  3-6 years | Child  6-11 years | adult |
| Exposure per application in mg a.s/kg b.w./day | 4.5/4.3/4.3 | 4.8/4.6/4.6 | 5.1/4.8/4.9 | 3.5/3.3/3.4 | 2.7/2.5/2.6 |
| **Total exposure in mg a.s/kg b.w./day** | **4.5/0/0** | **4.8/4.6/4.6** | **5.1/4.8/4.9** | **3.5/3.3/3.4** | **2.7/2.5/2.6** |
| Total exposure in mg a.s/kg b.w./day including hand washing | nr | nr | nr | nr | 0.89/0.84/0.85 |
| ARfD (mg a.s/kg b.w./day ) | 5 | 5 | 5 | 5 | 5 |
| % of ARfD (per application) | 90/85/86 | 97/92/93 | 101/96/97 | 70/66/67 | 53/51/51 |
| % of ARfD (in total) | **90/0/0** | **97/92/93** | **101/96/97** | **70/66/67** | **53/51/51** |
| % of ARfD including hand washing | nr | nr | nr | nr | **17/17/17** |

in bold : results related to intended uses

nr: not relevant

As regards the intended use 3 and based on the assumption and the reference values used, the exposure could exceed the toxicological threshold for children 3-6 years with application of BP MetaSPC1”Family”.

For this use, the applicant proposes the following recommendations:

* *Do not apply on child's hand.*
* *Carefully wash your hands after using this product.*

As a consequence. the following recommendation is considered necessary regarding dietary risk assessment:

* *Do not apply on child's hand.*

**Conclusion**

As regards to the intended uses of the family product CINQ SUR CINQ LOTION on human skin and based on the assumption and the reference values used, no dietary risk for adults and children is expected.

The applicant proposes the following use recommendations:

* *Do not sum up the different use modalities.*
* *Do not apply on child's hand.*
* *Do not use on infant below 6 months for the Products “FAMILLE” or Do not use on infant below 24 months for the Products “ZONES TEMPÉRÉES” and “TROPIC”.*
* *Do not spray on food-stuff or in a room where food-stuffs are stored.*
* *Keep away from food drink and animal feedingstuffs.*

Considering the Biocidal Product use, the following RMM are considered necessary regarding dietary risk assessment:

* “Do not apply on children’s hands”.

And the following can be mentioned as use recommendations:

* “Wash hands before handling food”.

***Risk characterisation from combined exposure to several active substances or substances of concern within a biocidal product***

*Not relevant*

### Risk assessment for animal health

*Not relevant*

### Risk assessment for the environment

|  |
| --- |
| Please notice that the environmental risk assessment is reported as provided by the applicant. The FR CA position is presented in **green evaluation boxes at the end of each part of the environmental section.** |

From the composition of the different products constituting the familly, none of the classified substances, other than the IR3535®, is in concentration sufficiently high to classify the products, neither individually, nor by additivity. Consequently, no substance of concern, other than the active substance, is present in the biocidal products covered by the familly.

Furthermore, no synergistic interactions are likely to occur between the product components: none of the components of the product family are known or intended synergists, or enhance the uptake, the excretion/clearance of other components, or have structural similarities with known synergists...

**No new studies have been submitted on the biocidal products**. As a consequence, the environmental risk assessment of the active substance has been performed based on the environmental fate, behaviour, and ecotoxicity data from its Assessment Report by the Belgium Competent Autority for PT19 uses (AR-PT19, 2014).

The environmental risk assessment has been performed according to the new Emission Scenario Document dedicated to PT19 (ESD-PT19, 2015).

|  |
| --- |
| **Infobox 1** – No other substance than the active is considered as of concern in the products of the family CINQ SUR CINQ LOTION. |

#### Effects assessment on the environment

Information relating to the ecotoxicity of the biocidal active substance (excerpt from AR-PT19):

No toxic effects where observed during the acute toxicity studies on fish (*Danio rerio*), *Daphnia magna* and algae (*Desmodesmus subspicatus*) (LC50 >100 mg/L). Therefore IR3535® is considered as not toxic for the aquatic environment.

The effect on aerobic biological sewage treatment processes was assessed by determining inhibition of respiration of the micro-organisms present in activated sludge following 3 hours contact. No inhibitory effect on aquatic microbial activity was registered for IR3535® (EC50 > 1000 mg/L).

Long term aquatic tests were not required because no acute toxicity was observed for the aquatic environment and the substance is primarily emitted to the STP before reaching the aquatic environment. Besides the Sewage Treatment Plant (STP) simulation test showed an elimination of 99 % in the STP.

No marine species were tested based on the presence of studies performed on freshwater species, all suggesting low toxicity and because no major emissions to the marine environment are expected.

In the absence of any long-term toxicity endpoints and marine data, the TGD on Risk Assessment prescribes an assessment factor of 1000 for the freshwater environment and 10000 for the marine environment.

For the sediment compartment, there are also no toxicity data available. The PNECsediment was calculated based on equilibrium partitioning method and PNECwater.

No terrestrial toxicity tests were performed for IR3535®. Due to the method of application directly on the skin only limited and very local emissions to the soil are expected. IR3535® is not likely to become accumulated in the soil in large amounts. PNECsoil has been calculated based on the equilibrium partitioning method.

The physicochemical properties of IR3535® do not suggest that this substance will pose a risk to the atmospheric environment.

The low BCF values suggest that IR3535® has a low bioaccumulation potential. Therefore the risk of secondary poisoning *via* ingestion of contaminated food (eg. earthworms or fish) by birds or mammals is also low and no avian dietary tests were required.

PNEC determination (not originally present in the AR-PT19 (2014)) used for the environmental risk assessment:

|  |  |  |
| --- | --- | --- |
|  | Rationale | Value |
| PNECaqua (mg/L) | 100 (the highest tested concentration inducing no toxicological effect) /1000 (default assessment factor when only short term data is available) | 0.1 |
| PNECsediment (mg/kgwwt) | By equilibrium partition method  PNEC sed = (Ksusp-water/RHOsusp)\*PNECaqua\*1000  and KOC=475.25 L/kg | 1.11 |
| PNECsoil (mg/kgwwt) | By equilibrium partition method  PNEC soil = (Ksoil-water/RHOsoil)\*PNECaqua\*1000  and VP=0.15Pa and WS=70 000 mg/L | 0.85 |
| PNECSTP (mg/L) | 1000 (EC50 OCDE 209) / 100 | 10 |

|  |
| --- |
| **Infobox 2** – We agree with the PNEC values presented by the applicant.  Regarding the PNEC STP, the CAR of IR3535 stated on a PNEC value equals to 100 mg/L applying an AF of 10 to the NOEC value (1000 mg/L). Nevertheless, as no effect was observed in the respiration inhibition test (OECD 209), both EC50 and NOEC are above the highest tested concentration of 1000 mg/L. In this specific case, FR CA agrees to use the lowest PNEC value (10 mg/L) as proposed by the applicant. It should also be noted, that there is no consequence on the risk characterisation ratios. |

***Foreseeable routes of entry into the environment on the basis of the use envisaged***

Considering the intended uses described in section 2.2.1, and according to the corresponding scenario described in the ESD-PT19 (2015), the foreseeable route of entry into the environment of the biocidal products is the aquatic environment, through wastewater treatment plant *via* bathing and showering of treated people (Scenario 1: Skin repellent, human skin application, release to wastewater via bathing and showering of treated people), and to surface water bodies *via* swimming of treated people (Scenario 2: Skin repellent, human skin application, direct release to surface water bodies via swimming of treated people).

#### Exposure assessment

**General information**

|  |  |
| --- | --- |
| Assessed PT | PT 19: Insect repellent |
| Assessed scenarios | **Scenario 1**: Skin repellent, human skin application, release to wastewater *via* bathing and showering of treated people.  **Scenario 2**: Skin repellent, human skin application, direct release to surface water bodies *via* swimming of treated people. |
| ESD(s) used | ESD-PT19 (2015) |
| Approach | Consumption based approach only. According to the ESD-PT19 (2015), the tonnage based approach is only appropriate for emission assessments at the stage of inclusion of an active substance into the Union list. |
| Distribution in the environment | Calculated based on equations from the BPR-guidance vol.IV–part.B (2015). |
| Groundwater simulation | No simulation for leaching to groundwater was performed. |
| Confidential Annexes | NO |
| Life cycle steps assessed | Production: No  Formulation No  Use: Yes  Service life: No |
| Remarks | A “worst-case use” was applied for the environmental risk assessment, which covers all intended uses described in section 2.2.1 (more details below)*.*  Evaluation done taking into account WGV2018 agreement on treated skin surface:  TAB ENV v2.0 entry **ENV 172** - Refinement of risk assessment PT19: reduction of treated skin surface area and taking into account dermal adsorption  The WG agreed to apply the new value of the HEAdoc recommendation of January 2018 for the treated skin area, i.e. 55% of 16600 cm2 (= 9130 cm²), since this could be considered as a mean value taking into account the different skin areas for women, men and children. |

|  |
| --- |
| **Infobox 3** – We agree with the proposed scenarios. |

***Emission estimation***

The worst case use was determined based on the total quantity of active substance applied on skin in one day for each intended uses described in section 2.2.1, with the assumption that the surface of treated area of human skin is the same for all, as described below.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Target species |  | CINQ SUR CINQ FAMILLE | CINQ SUR CINQ ZONES TEMPEREES | CINQ SUR CINQ TROPIC | REFERENCE |
| META SPC-1 | META SPC-2 | META SPC-3 |
| Mosquitoes | Quantity of product applied per application [mg/cm²] | 0.70 | 0.73 | 0.52 | *c.f.* section 2.2.1 |
| a.s. content [% w/w] | 20% | 25% | 35% | *c.f.* section 2.1.2.3. |
| Number of application per day [day-1] | 2 | 2 | 2 | *c.f.* section 2.2.1 |
| Total quantity of active substance applied in one day [mg a.s./cm²/day] | 0.28 | 0.37 | 0.36 | - |
| Ticks | Quantity of product applied per application [mg/cm²] | 1.78 | 1.38 | 0.98 | *c.f.* section 2.2.1 |
| a.s. content [% w/w] | 20% | 25% | 35% | *c.f.* section 2.1.2.3. |
| Number of application per day [day-1] | 1 | 1 | 1 | *c.f.* section 2.2.1 |
| Total quantity of active substance applied in one day [mg a.s./cm²/day] | 0.36 | 0.35 | 0.34 | - |
| Horseflies | Quantity of product applied per application [mg/cm²] | 1.95 | 1.48 | 1.07 | *c.f.* section 2.2.1 |
| a.s. content [% w/w] | 20% | 25% | 35% | *c.f.* section 2.1.2.3. |
| Number of application per day [day-1] | 1 | 1 | 1 | *c.f.* section 2.2.1 |
| Total quantity of active substance applied in one day [mg a.s./cm²/day] | **0.39** | 0.37 | 0.37 | - |

As a result, the use of the product CINQ SUR CINQ FAMILLE (META-SPC1) against house flies was considered as the worst case use for the environmental risk assessment of the product family.

**Scenario [1] Skin repellent, human skin application, release to wastewater via bathing and showering of treated people (according to ESD-PT19 (2015), and BPR-guidance vol.IV–part.B (2015)).**

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters for calculating the local emission** | | | |
| **Input** | **Value** | **Unit** | **Remarks** |
| Scenario:Skin repellent, human skin application, release to wastewater via bathing and showering of treated people | | | |
| Nlocal : number of inhabitants feeding one sewage treatment plant | 10000 | [cap] | D – ESD-PT19 (2015) |
| Cform: active substance in the product | 200 | [g.kg-1] | S - *c.f.* section 2.1.2.3. |
| Qformappl : consumption per application | 1.95 | [mg.cm-2] | S - Worst case use |
| Nappl : number of applications per day | 1 | [d-1] | S - Worst case use |
| AREAskin : treated area of human skin | 16600 | [cm²] | P - table 3-3 of ESD\_PT19 (2015) – Worst case use: total surface area for a standard adult |
| Fair : fraction released to air | 0 | [-] | D – ESD-PT19 (2015) |
| Fskin : fraction dermally absorbed | 0 | [-] | D – ESD-PT19 (2015) |
| Fwater : Fraction released to waste water | 1 | [-] | D – ESD-PT19 (2015) |
| Finh : Fraction of inhabitants using a repellent product | 0.2 | [-] | P - table 3-5 of ESD\_PT19 (2015) |
| Fpenetr : market share of repellent | 0.5 | [-] | D – ESD-PT19 (2015) |
| RHOform : specific density of the product | 1000 | [kg.m-3] | D – ESD-PT19 (2015) |

Calculations for Scenario 1 : Skin repellent, human skin application, release to wastewater via bathing and showering of treated people

| **Resulting local emission to relevant environmental compartments and PECs** | | |
| --- | --- | --- |
| **Compartment** | **Results** | **Remarks** |
| **Elocalwater** | **6.47E+00 kg.d-1** | O - Eq. 5 of BPR-guidance vol.IV–part.B (2015) |
| Clocal,inf | 3.24E+00 mg.L-1 | O - Eq. 32 of BPR-guidance vol.IV–part.B (2015) |
| Fstpwater | 1.00E-02 | S - Estimation by EUSES/simple treat |
| **Clocal,eff = PECSTP** | **3.24E-02 mg.L-1** | O - Eq. 33 of BPR-guidance vol.IV–part.B (2015) |
| Kpsusp | 4.75E+01 L.kg-1 | O - Eq. 23 of BPR-guidance vol.IV–part.B (2015) |
| **PEClocal,water** | **3.23E-03 mg.L-1** | O - Eq. 48 of BPR-guidance vol.IV–part.B (2015) |
| Ksusp-water | 1.28E+01 m3.m-3 | O - Eq. 24 of BPR-guidance vol.IV–part.B (2015) |
| **PEClocal,sed** | **3.60E-02 mg.kg-1wwt** | O - Eq. 50 of BPR-guidance vol.IV–part.B (2015) |
| **PEClocal,soil** | **0.00E+00 mg.kg-1wwt** | O - Negligeable in the present situation (99% elimination in STP simulation test. 1% goes in water effluent). |

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| **Infobox 4 –**  **For scenario 1 (indirect release after skin application)**, we agree with the evaluation proposed by the applicant. It is a worst case covering all the products of the family, considering an application rate of 1.95 mg product/cm2 for the product containing 200 g/kg.  It is worth noting that the value for AREAskin has been revised recently (WGI2017) to a harmonized value of 10660 cm2, corresponding to 64% of the total body surface. As the higher surface area (16600 cm2) proposed by the applicant does not change the conclusions, it was kept for the assessment.  At the end of the risk assessment, a harmonized value of 55% of the total body surface area (to be consistent with toxicological section) has been agreed in European discussions. As the first assessment has been realized with a value of 64% (therefore worst case), the conclusions will remains unchanged. |

**Scenario [2] Skin repellent, human skin application, release to surface water bodies via swimming of treated people(according to ESD-PT19(2015), and BPR-guidance vol.IV–part.B (2015)).**

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters for calculating the local emission** | | | |
| **Input** | **Value** | **Unit** | **Remarks** |
| Scenario 2: Skin repellent, human skin application, release to surface water bodies via swimming of treated people. | | | |
| Nswimmer : daily number of swimmers | 1500 | [-] | D – ESD-PT19 (2015) |
| Cformweight: active substance in the product | 200 | [g.kg-1] | S - worst case use |
| Qformappl : consumption per application | 1.95 | [mg.cm-2] | S - worst case use |
| Nappl : number of applications per day | 1 | [d-1] | D - ESD\_PT19 (2015) |
| AREAskin : treated area of human skin | 16600 | [cm²] | P - table 3-3 of ESD\_PT19 (2015) – Worst case use: total surface area for a standard adult |
| Fswim : fraction of swimmers using the repellent product | 0.1 | [-] | D for product autorisation - ESD\_PT19 (2015) |
| Fwaterbody : Fraction released to surface water body | 1 | [-] | D – ESD-PT19 (2015) |
| RHOform : specific density of the product | 1000 | [kg.m-3] | D – ESD-PT19 (2015) |
| Vwaterbody : volume of water body | 435000 | [m3] | D - ESD\_PT19 (2015) |
| Temission,1d  Temission,91d : number of emission days | 1  91 | [d] | D - ESD\_PT19 (2015) |
| Nemission,91d : number of emission events | 91 | [-] | D - ESD\_PT19 (2015) |

Calculations for Scenario 2: Skin repellent, human skin application, release to surface water bodies via swimming of treated people.

| **Resulting local emission to relevant environmental compartments and PECs** | | |
| --- | --- | --- |
| **Compartment** | **Results** | **Remarks** |
| **Elocalwater** | **0.97 kg.d-1** | O - eq. 3.12- ESD\_PT19 (2015) |
| Kdegwater | 4.45E-02 d-1 | S - calculated considering a DT50(12°C) = 15.59 days |
| Clocalwater,1d | 2.23E-03 mg.L-1 | O - eq. 3.13 of ESD\_PT19 (2015) |
| Clocalwater,91d | 2.03E-01 mg.L-1 | O - eq. 3.14 of ESD\_PT19 (2015) |
| Clocalwater,91d-ref | 5.04E-02 mg.L-1 | O - eq. 3.15 of ESD\_PT19 (2015) |
| **PEClocal,water** | **5.04E-02 mg.L-1** | Eq. 48 of BPR-guidance vol.IV–part.B (2015) |
| Kpsusp | 47.525 L.kg-1 | Eq. 23 of BPR-guidance vol.IV–part.B (2015) |
| Ksusp-water | 12.78125 m3.m-3 | Eq. 24 of BPR-guidance vol.IV–part.B (2015) |
| **PEClocal,sed** | **5.61E-01 mg.kg-1wwt** | Eq. 50 of BPR-guidance vol.IV–part.B (2015) |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Infobox 5 –**  **For scenario 2 (direct release via swimming after skin application)**,  We do not agree with the DT50 considered by the applicant as the proposed value (15.59 d at 12°C) corresponds to the transformation of IR3535 to its free acid. Free acid have a higher half-life. Thus, we propose the value of 299.64 days at 12°C for the degradation of free acid in total system.  We propose to evaluate an application rate of 1.95 mg product/cm² for the product containing 200g of ai/kg, which corresponds to a worst case covering all the products of family for horseflies and ticks target species. We also propose to evaluate an application rate of 0.73 mg product/cm² for the product containing 250g of ai/kg, which corresponds to a worst case covering all the products of family for Mosquitoes target.  The treated area of human skin has been refined to 10660 cm2 (64% of the total body surface) considering the recent European agreements.  At the end of the risk assessment, a harmonized value of 55% of the total body surface area (to be consistent with toxicological section) has been agreed in European discussions. As the first assessment has been realized with a value of 64% (therefore worst case), the conclusions will remains unchanged.  Finally, two assessments have been conducted separately: for low infested areas and for high infested areas. The exposure assessment has been conducted for the highest and the lowest infested areas, considering respectively a fraction of swimmers using the repellent product of 0.1 that is a worst case and 0.02.   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Input parameters for calculating the local emission** | | | | | | **Input** | **Value Ticks/**  **Horseflies** | **Value**  **Mosquitoes** | **Unit** | **Remarks** | | Scenario 2: Skin repellent, human skin application, release to surface water bodies via swimming of treated people. | | | | | | DT50 total – IR3535 free acid \* | 299.64 | 299.64 | [d] |  | | Nswimmer : daily number of swimmers | 1500 | 1500 | [-] | D – ESD-PT19 (2015) | | Cformweight: active substance in the product | 200 | 250 | [g.kg-1] | S - worst case use | | Qformappl : consumption per application | 1.95 | 0.73 | [mg.cm-2] | S - worst case use | | Nappl : number of applications per day | 1 | 1 | [d-1] | D - ESD\_PT19 (2015) | | AREAskin : treated area of human skin | 10660 | 10660 | [cm²] | P - table 3-3 of ESD\_PT19 (2015) – Worst case use: total surface area for a standard adult | | Fswim : fraction of swimmers using the repellent product | 0.1/0.02\*\* | 0.1/0.02\*\* | [-] | D - ESD\_PT19 (2015) | | Fwaterbody : Fraction released to surface water body | 1 | 1 | [-] | D – ESD-PT19 (2015) | | RHOform : specific density of the product | 1000 | 1000 | [kg.m-3] | D – ESD-PT19 (2015) | | Vwaterbody : volume of water body | 435000 | 435000 | [m3] | D - ESD\_PT19 (2015) | | Temission,1d  Temission,91d : number of emission days | 1  91 | 1  91 | [d] | D - ESD\_PT19 (2015) | | Nemission,91d : number of emission events | 91 | 91 | [-] | D - ESD\_PT19 (2015) |   \* The DT50 total corresponds to the degradation of the IR3535 acid free in the total system. It is the worst case value from two available studies  \*\* A value of 0.1 for Fswin should be used to cover areas with higher insect infestation. Whereas a value of 0.02 should be used to cover areas with lower insect infestation.  Calculations for Scenario 2: Skin repellent, human skin application, release to surface water bodies via swimming of treated people.   | **Resulting local emission to relevant environmental compartments and PECs for uses against Horseflies and Ticks** | | | | | --- | --- | --- | --- | | **Compartment** | **Results** | | **Remarks** | | **Lower insect infestation**  **(Fswim : 0.02)** | **Higher insect infestation**  **(Fswim : 0.1)** | | **Elocalwater** | **0.12 kg.d-1** | **0.62 kg.d-1** | eq. 3.12- ESD\_PT19 (2015) | | **PEClocal,water** | **2.36E-02 mg.L-1** | **1.18E-01 mg.L-1** | eq. 3.15 of ESD\_PT19 (2015) | | **PEClocal,sed** | **2.62E-01 mg.kg-1wwt** | **1.31 mg.kg-1wwt** | Eq. 50 of BPR-guidance vol.IV–part.B (2015) |  | **Resulting local emission to relevant environmental compartments and PECs for uses against Mosquitoes** | | | | | --- | --- | --- | --- | | **Compartment** | **Results** | | **Remarks** | | **Lower insect infestation**  **(Fswim : 0.02)** | **Higher insect infestation**  **(Fswim : 0.1)** | | **Elocalwater** | **0.06 kg.d-1** | **0.29 kg.d-1** | eq. 3.12- ESD\_PT19 (2015) | | **PEClocal,water** | **1.10E-02 mg.L-1** | **5.51E-02 mg.L-1** | eq. 3.15 of ESD\_PT19 (2015) | | **PEClocal,sed** | **1.23E-01 mg.kg-1wwt** | **6.13E-01 mg.kg-1wwt** | Eq. 50 of BPR-guidance vol.IV–part.B (2015) | |

***Fate and distribution in exposed environmental compartments***

| **Identification of relevant receiving compartments based on the exposure pathway** | | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Fresh-water | Freshwater sediment | Sea-water | Seawater sediment | STP | Air | Soil | Ground-water | Other |
| Scenario 1 | Yes | Yes | NR | NR | Yes | NR | Yes | Yes |  |
| Scenario 2 | Yes | Yes | NR\* | NR\* | NR | NR | NR | NR |  |

*NR: not relevant*

*NR\*: To represent a realistic worst-case scenario, the release of repellents from the skin of treated humans into ponds, lakes or reservoirs during swimming was evaluated. Due to dilution effects, neither coastal areas nor rivers were considered in the context of the PT19 ESD.*

|  |
| --- |
| **Infobox 6 –**  **For scenario 1,** we agree for the identification of relevant receiving compartments proposed by the applicant; however it should be noted that the seawater and seawater sediment compartments are covered by the risk assessment in the freshwater and freshwater sediment compartments. There is no consequence on the risk characterisation ratio. |

|  |  |  |  |
| --- | --- | --- | --- |
| **Input parameters (only set values) for calculating the fate and distribution in the environment** | | | |
| Input | Value | Unit | Remarks |
| Molecular weight | 215.29 |  |  |
| Vapour pressure (at 20°C) | 0.15 | Pa |  |
| Water solubility (at 20°C) | 70000 | mg/l |  |
| Log Octanol/water partition coefficient | 1.7 | Log 10 |  |
| Organic carbon/water partition coefficient (Koc) | 475.325 | l/kg |  |
| Henry’s Law Constant (at 25°C) | 6.08E-4 | Pa/m3/mol |  |
| Biodegradability | Not ready biodegradable |  |  |
| Biodegradability | 99% elimination |  |  |
| DT50 in surface water | 15.59 | d (at 12ºC) |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **Calculated fate and distribution in the STP *[if STP is a relevant compartment]*** | | | |
| Compartment | Percentage [%] | | Remarks |
| Scenario 1 | Scenario 2 |
| Air |  |  |  |
| Water | 1 | NR |  |
| Sludge |  |  |  |
| Degraded in STP | 99 | NR | From STP simulation test |

*NR: not relevant*

|  |
| --- |
| **Infobox 7 –**  We agree with the proposed values.  Concerning the distribution in the STP, the proposed values were accepted for the approval of the substance as a Tier 2 approach based on a STP simulation test, leading to no exposure of the terrestrial compartment (including groundwater).  We do not agree with the DT50 value. IR3535 is transformed in its free acid which has a higher half-life. Thus, we propose the value of 299.64 days at 12° C for the degradation of free acid in total system. |

***Calculated PEC values***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Summary table on calculated PEC values** | | | | |
|  | **PECSTP** | **PECwater** | **PECsed** | **PECsoil** |
| [mg/L] | [mg/l] | [mg/kgwwt] | [mg/m3] |
| Scenario 1 | 3.24E-02 | 3.23E-03 | 3.60E-02 | 0 |
| Scenario 2 | NR | 5.04E-02 | 5.61E-01 | NR |

*NR: not relevant*

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Infobox 8 – FR:**  We agree with the PEC values for scenarios 1 (indirect release after skin application) but not for the scenario 2 (direct release via swimming after skin application).   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Summary table on calculated PEC values only for Mosquitoes** | | | | | | Scenario 2 (mosquitoes) | **PECSTP** | **PECwater** | **PECsed** | **PECsoil** | | [mg/m3] | [mg/L] | [mg/kgwwt] | [mg/m3] | | Low insect infestation (Fswim : 0.02) | NR | 1.10E-02 | 1.23E-01 | NR | | High insect infestation (Fswim : 0.1) | NR | 5.51E-02 | 6.13E-01 | NR |  |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Summary table on calculated PEC values only for Horseflies/Ticks** | | | | | | Scenario 2 (horseflies/ticks) | **PECSTP** | **PECwater** | **PECsed** | **PECsoil** | | [mg/m3] | [mg/L] | [mg/kgwwt] | [mg/m3] | | Low insect infestation (Fswim : 0.02) | NR | 2.36E-02 | 2.62E-01 | NR | | High insect infestation (Fswim : 0.1) | NR | 1.18E-01 | 1.31 | NR | |

***Primary and secondary poisoning***

The IR3535® is unlike to bioaccumulate in aquatic or terrestrial environment according to the TGD. It has a low log Kow (1.7) and it is not highly adsorptive. For these reasons, primary and secondary poisoning assessment have been waived.

|  |
| --- |
| **Infobox 9 –**  We agree with this waiving. |

#### Risk characterisation

***Atmosphere***

Conclusion:IR3535® has a low potential for volatilisation. Consequently, exposure assessment and risk characterisation were not conducted for the atmosphere.

***Sewage treatment plant (STP)***

|  |  |
| --- | --- |
| **Summary table on calculated PEC/PNEC values** | |
|  | **PEC/PNECSTP** |
| Scenario 1 | 3.24E-03 |
| Scenario 2 | Not relevant |

Conclusion: No risk is identified for the sewage treatment plant.

***Aquatic compartment***

|  |  |  |
| --- | --- | --- |
| **Summary table on calculated PEC/PNEC values** | | |
|  | **PEC/PNECwater** | **PEC/PNECsed** |
| Scenario 1 | 3.23E-02 | 3.24E-02 |
| Scenario 2 | 5.04E-01 | 5.05E-01 |

Conclusion: No risk is identified fort the aquatic compartment.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Infobox 10 –**  We agree with the ratios proposed by the applicant for scenario 1.  We do not agree with the scenario 2 :   |  |  |  | | --- | --- | --- | | **Summary table on calculated PEC/PNEC values** | | | | Scenario 2 **(mosquitoes)** | **PEC/PNECwater** | **PEC/PNECsed** | | Low insect infestation (Fswim : 0.02) | 1.10E-01 | 1.10E-01 | | High insect infestation (Fswim : 0.1) | 5.51E-01 | 5.51E-01 |  |  |  |  | | --- | --- | --- | | **Summary table on calculated PEC/PNEC values** | | | | Scenario 2 **(horseflies/ticks)** | **PEC/PNECwater** | **PEC/PNECsed** | | Low insect infestation (Fswim : 0.02) | 2.36E-01 | 2.36E-01 | | High insect infestation (Fswim : 0.1) | **1.18** | **1.18** |   The risk is not acceptable for the Scenario 2 (direct release via swimming after skin application) for horseflies/ticks target and considering a high insect infestation.  Risks are acceptable for applications against mosquitoes.  The treated area of human skin has been refined to 8710 cm2 (area for head, arms and legs) considering the claimed uses by the applicant for horseflies and ticks (only neck, arms and legs). This refined value of 8710 cm² covers the value proposed by the toxicological section corresponding to 38% of total body surface.  Thus, the new ratios for the high insect infestation are presented below :   |  |  |  | | --- | --- | --- | | **Summary table on calculated PEC/PNEC values** | | | | Scenario 2 **(horseflies/ticks)** | **PEC/PNECwater** | **PEC/PNECsed** | | High insect infestation (Fswim : 0.1) | 9.62E-01 | 9.62E-01 |   The risk is acceptable with the refined human skin area. |

***Terrestrial compartment***

|  |  |
| --- | --- |
| **Calculated PEC/PNEC values** | |
|  | **PEC/PNECsoil** |
| Scenario 1 | 0 |
| Scenario 2 | Not relevant |

Conclusion: No risk is identified fort the terrestrial compartment.

***Groundwater***

No simulation for leaching to groundwater was performed and consequently no risk characterisation was conducted for this compartment.

***Primary and secondary poisoning***

Primary poisoning

The IR3535® is unlike to bioaccumulate in aquatic or terrestrial environment according to the TGD. It has a low log Kow (1.7) and it is not highly adsorptive. For these reasons, primary and secondary poisoning assessment have been waived.

***Mixture toxicity***

Mixture toxicity is not relevant.

***Aggregated exposure (combined for relevant emmission sources)***

The scenario 1 and scenario 2 described above could be aggregated as a worst case.

|  |  |  |  |
| --- | --- | --- | --- |
| **Summary table on calculated ΣPEC/PNEC values** | | | |
| **ΣPEC/PNECSTP** | **ΣPEC/PNECwater** | **ΣPEC/PNECsed** | **ΣPEC/PNECsoil** |
| 3.24E-03 | 5.37E-01 | 5.37E-01 | 0 |

Conclusion: bases on aggregated exposure, there is no risk for any of the environmental compartments.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Infobox 11 –**  Considering the new PECs values, the scenario 1 and scenario 2 described above could be aggregated as a worst case (taking into account the high infested area for the direct releases).   |  |  |  |  |  | | --- | --- | --- | --- | --- | |  | **Summary table on calculated ΣPEC/PNEC values** | | | | |  | **ΣPEC/PNECSTP** | **ΣPEC/PNECwater** | **ΣPEC/PNECsed** | **ΣPEC/PNECsoil** | | Mosquitoes | 3.24E-03 | 5.83E-01 | 5.83E-01 | 0 | | Horseflies/Ticks | 3.24E-03 | 9.94E-01 | 9.94E-01 | 0 |   Conclusion: Based on aggregated exposure, there is no risk for any of the environmental compartments. |

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| **Overall conclusion on the risk assessment for the environment of the product** |
| The use of the biocidal products does not induce risk for any of the environmental compartments. |
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| **Infobox 12 –**  We agree with the applicant conclusions considering the strict practical uses claimed by the applicant. |

### Measures to protect man, animals and the environment

*Please refer to summary of the product assessment and to the relevant sections of the assessment report.*

### Assessment of a combination of biocidal products

*Not relevant*

### Comparative assessment

*Not relevant*

# Annexes

## List of studies for the biocidal product (family)

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Author(s)** | **Year** | **Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published** | **Data Protection Claimed (Yes/No)** | **Owner (PUB / ORG)** | **Date of first submission** |
| L. Mack | 2019 | Particle size distribution CIPAC MT187 | YES | Laboratoire CHAUVIN |  |
| Laboratoire  Merieux | 2019 | Storage stability test – long term storage at ambient temperature  Batch: FC001  Bottle 100 mL HDPE commercial packaging | YES | Laboratoire CHAUVIN |  |
| Serrano, B. | 2017a | Laboratory assessment of a personal skin repellent against mosquitoes  Trial against Aedes aegypti, Aedes albopictus, Culex quinquefasciatus | YES | Laboratoire CHAUVIN |  |
| Serrano, B. | 2016a | Laboratory assessment of a personal skin repellent against ticks | Yes | Laboratoire CHAUVIN |  |
| Serrano, B. | 2017b | Laboratory assessment of a personal skin repellent against mosquitoes  Aedes aegypti, Aedes albopictus, Culex quinquefasciatus | Yes | Laboratoire CHAUVIN |  |
| Serrano, B. | 2017c | Laboratory assessment of a personal skin repellent against mosquitoes  Aedes aegypti, Aedes albopictus, Culex quinquefasciatus | Yes | Laboratoire CHAUVIN |  |
| Serrano, B. | 2016b | Laboratory assessment of a personal skin repellent against ticks | Yes | Laboratoire CHAUVIN |  |
| Serrano, B. | 2016c | Laboratory assessment of a personal skin repellent against ticks | Yes | Laboratoire CHAUVIN |  |
| Serrano, B. | 2017d | Laboratory assessment of a personal skin repellent against mosquitoes  Trial against Aedes aegypti, Aedes albopictus, Culex quinquefasciatus, *Anopheles gambiae* | Yes | Laboratoire CHAUVIN |  |
| Serrano, B. | 2017e | Laboratory assessment of a personal skin repellent against mosquitoes  Trial against Aedes aegypti, Aedes albopictus, Culex quinquefasciatus, *Anopheles gambiae* | Yes | Laboratoire CHAUVIN |  |
| Serrano, B. | 2016 | Laboratory assessment of a personal skin repellent against ticks | Yes | Laboratoire CHAUVIN |  |
| Serrano, B. | 2017 | Laboratory assessment of a personal skin repellent against ticks | Yes | Laboratoire CHAUVIN |  |
| Drago, A | 2017 | Efficacy test of the topical repellent “cinq sur cinq famille” against Horse flies in filed. | Yes | Laboratoire CHAUVIN |  |
| Drago, A | 2017 | Efficacy test of the topical repellent “cinq sur cinq zones tempérées” against horse flies in field | Yes | Laboratoire CHAUVIN |  |
| Drago, A | 2017 | Efficacy test of the topical repellent “cinq sur cinq tropic” against horse flies in field | Yes | Laboratoire CHAUVIN |  |
| Drago, A | 2017 | Efficacy test of the topical repellent “cinq sur cinq zones tempérées nouvelle formule” against horse flies in field | Yes | Laboratoire CHAUVIN |  |
| Drago, A | 2017 | Efficacy test of the topical repellent « cinq sur cinq tropic nouvelle” against horse flies in field | Yes | Laboratoire CHAUVIN |  |
| Serrano, B. | 2017 | Laboratory assessment of a personal skin repellent against ticks  Report N°2257-CSCF-ticks/0917 | Yes | Laboratoire CHAUVIN |  |
| Serrano, B. | 2017 | Laboratory assessment of a personal skin repellent against mosquitoes  Trial against Aedes aegypti, Aedes albopictus, Culex quinquefasciatus,  Report N° 2257-CSCZT mosq/0917 | Yes | Laboratoire CHAUVIN |  |
| Serrano, B. | 2017 | Laboratory assessment of a personal skin repellent against ticks  Report N° 2257-CSCZT ticks/0917 | Yes | Laboratoire CHAUVIN |  |
| Serrano, B. | 2017 | Laboratory assessment of a personal skin repellent against mosquitoes  Trial against Aedes aegypti, Aedes albopictus, Culex quinquefasciatus, *Anopheles gambiae*  Report N° 2257-CSCT-mosq  /0917 | Yes | Laboratoire CHAUVIN |  |
| Serrano, B. | 2017 | Laboratory assessment of a personal skin repellent against ticks  Report N° 2257-CSC-ticks/0917 | Yes | Laboratoire CHAUVIN |  |

## Output tables from exposure assessment tools

See excel data sheet

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## New information on the active substance

*Not relevant*

## Residue behaviour

*Not relevant*

## Summaries of the efficacy studies (B.5.10.1-xx)

*See IUCLID files*

## Confidential annex

*See the relevant document in annex*

## Other

*Not relevant*

1. Herczeg et al. (2015). The effect of weather variables on the flight activity of horseflies (Diptera: *Tabanidae*) in the continental climate of Hungary. Parasitol Res (2015) 114:1087–1097.

   Baldacchino et al. (2014). Biting behaviour of *Tabanidae* on cattle in mountainous summer pastures, Pyrenees, France, and effects of weather variables. Bulletin of Entomological Research (2014) 104, 471–479. [↑](#footnote-ref-1)
2. (\*): second data set [↑](#footnote-ref-2)
3. Herczeg et al. (2015). The effect of weather variables on the flight activity of horseflies (Diptera: *Tabanidae*) in the continental climate of Hungary. Parasitol Res (2015) 114:1087–1097.

   Baldacchino et al. (2014). Biting behaviour of *Tabanidae* on cattle in mountainous summer pastures, Pyrenees, France, and effects of weather variables. Bulletin of Entomological Research (2014) 104, 471–479. [↑](#footnote-ref-3)
4. Herczeg et al. (2015). The effect of weather variables on the flight activity of horseflies (Diptera: *Tabanidae*) in the continental climate of Hungary. Parasitol Res (2015) 114:1087–1097.

   Baldacchino et al. (2014). Biting behaviour of *Tabanidae* on cattle in mountainous summer pastures, Pyrenees, France, and effects of weather variables. Bulletin of Entomological Research (2014) 104, 471–479. [↑](#footnote-ref-4)
5. Proposal for harmonising the assessment of human exposure to repellents (PT19) Agreed at the HH WH III 2016 [↑](#footnote-ref-5)
6. Recommendation 11 of the BPC Ad hoc Working Group on Human Exposure : Proposal for harmonising the assessment of human exposure to repellents (PT19). [↑](#footnote-ref-6)
7. Please note that, as the risk mitigation measure “do not apply on children’s hand” is proposed to limit dietary and hand-to-mouth uptake, the risk assessment has also been performed for children without exposure to hands. These exposures assessment is not detailed but the calculations of risk ratio are given here below [↑](#footnote-ref-7)
8. HEEG opinion 17: US EPA Exposure Factors Handbook (2011 Issue), which are derived from US EPA Analysis of NHANES 1999-2006 [↑](#footnote-ref-8)
9. Dilution factor from ConsExpo 4.0, Consumer Exposure and Uptake Models. Program Manuel. Bilthoven, The Netherlands: National Institute for Public Health and the Environment (RIVM). Report no. 320104004. & RIVM report 320104001/2006 : Cosmetics Fact Sheet To assess the risks for the consumer (Updated version for ConsExpo 4) H.J. Bremmer, L.C.H. Prud’homme de Lodder, J.G.M. van Engelen [p34 : "Weight fraction dilution Wf / 3" " Estimate dilution factor 3 (wetting hands)] [↑](#footnote-ref-9)