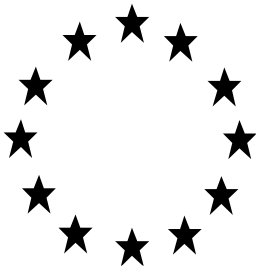
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

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
Case Number (NA-MIC) in R4BP: BC-DQ067817-15
Case Number (NA-MIC) in R4BP: BC-BS082261-33

Evaluating Competent Authority: France

Date: June 2019
Revised: July 2024

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NOTE TO THE READER

This PAR is based on the PAR of the first authorisation, that has been updated with the post-authorisation data provided by the applicant and the first minor change application (2020) regarding the extension of the shelf life for products of Meta SPC 3 (both are linked, please refer to the overall conclusion).

This PAR has also been updated with the second minor change application (2021) further extending the shelf life for the products of Meta SPC 3.

Finally, this PAR has been updated with the third minor change application (2023) concerning the addition or replacement of a co-formulant for the three Meta-SPCs and the update of the protection times against target organisms considering the new efficacy studies performed according to the new version of the guidance documents. The implementation of these changes to the three Meta SPCs of the CINQ SUR CINQ LOTION family made it necessary to reorganise them into six new Meta SPCs as follows, in order to maintain their regulatory compliance:

- Former Meta SPC 1 → Split into new Meta SPC 1 and 4
- Former Meta SPC 2 → Split into new Meta SPC 2 and 5
- Former Meta SPC 3 → Split into new Meta SPC 3 and 6

In this consolidated PAR, the assessments related to the minor change application (2023) 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)
NA-ADC	*FR*	*BC-KR063277-16*	09/02/2021	Administrative change: addition of 2 new trade names.for the meta SPC2
NA-MIC	*FR*	*BC-DQ067817-15*	17/12/2021	Minor change assessment: Change in shelf life for Meta-SPC 3 (36 to 48 months)
NA-MIC	*FR*	*BC-BS082261-33*	11/07/2024	Minor change assessment: Addition or replacement of one co-formulant and update of the protection time against target organisms considering the new efficacy studies performed according to the new version of the guidance documents.

1 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.

➢ **Minor change 2021**

A minor change application has been submitted to claim an increase of the shelf life for meta SPC 3. Thus, according to the long term storage study provided, the biocidal products of the meta SPC 3 are considered stable after 48 months at ambient temperature in commercial packagings.

➢ **Minor change 2023**

The minor change consists in the addition or the replacement of one of the co-formulants initially used in the formulation of the CINQ SUR CINQ LOTION products with a similar co-formulant at the same content. The change has no impact on the physico-chemical properties of the CINQ SUR CINQ LOTION products. The change of composition is acceptable. No further data is required.

- ***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] 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 CINQ 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.

[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.

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.

- **Minor change 2023**

The elements presented in the dossier are sufficient to demonstrate that:

- The products related to the new Meta SPC 1 and 4 of the BPF "CINQ SUR CINQ LOTION" provide:
  - a complete protection time up to 5 hours against adult mosquitoes (*Culex spp*., *Aedes spp*.) at the application rate of 0.7 mg/cm², in temperate conditions.
  - a complete protection time up to 5 hours against ticks (*Ixodes ricinus*) at the application rate of 0.95 mg/cm², in temperate conditions.

- The products related to the new Meta SPC 2 and 5 of the BPF "CINQ SUR CINQ LOTION" provide:
  - a complete protection time up to 8 hours against adult mosquitoes (*Culex spp*., *Aedes spp*.) at the application rate of 0.68 mg/cm² (protection time up to 7 hours claimed),
  - a complete protection time up to 5.5 hours against ticks (*Ixodes ricinus)* at the application rate of 0.93 mg/cm² in temperate climate (protection time up to 5 hours claimed).

- The products related to the new Meta SPC 3 and 6 of the BPF "CINQ SUR CINQ LOTION" provide:
  - a protection up to 7.5 hours against adult mosquitoes (*Culex spp*., *Aedes spp*., and *Anopheles spp.*), at the application rate of 0.48 mg/cm² in tropical conditions (protection time up to 7 hours claimed).

- ***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.

➢ **Minor change 2023**

The minor change has no impact on classification and risk assessment. However, it has an impact on EUH 208 labelling and leads to a reorganisation of the Meta SPCs so that, within the same Meta SPC, all products have the same EUH 208 conclusion.
The Meta SPCs are thus reorganised as follows:

- Former Meta SPC 1 → Split into new Meta SPC 1 and 4
- Former Meta SPC 2 → Split into new Meta SPC 2 and 5
- Former Meta SPC 3 → Split into new Meta SPC 3 and 6

- ***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.

➢ **Minor change 2023**

The minor changes have no impact on classification of the biocidal product family, nor on the analysis of the substances of concern nor on the environmental risk assessment. The initial conclusion remains unchanged.

- ***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.**

- **Minor change 2023**

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

- **For the META SPC 1 & 4 :**
  - **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 & 5 :**
  - **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 & 6 :**
  - **treatment against mosquitoes once a day for adults and children over 6 y.o.**

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

In France, following uses can be proposed for authorisation:

- **For the META SPC 1 & 4 :**
  - **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 & 5 :**
  - **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 & 6 :**
  - **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**

2 ASSESSMENT REPORT

2.1 Summary of the product assessment – Minor Change application 2023 for CINQ SUR CINQ LOTION

PART I.- FIRST INFORMATION LEVEL

2.1.1 Administrative information

2.1.1.1 Identifier of the product / product family

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

2.1.1.2 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**	

2.1.1.3 Manufacturer(s) of the products of the family

Name of manufacturer	FABRICATION CHIMIQUE ARDECHOISE
Address of manufacturer	LES ILES FERAYS 07300 TOURNON CEDEX FRANCE
Location of manufacturing sites	LES ILES FERAYS 07300 TOURNON CEDEX FRANCE

2.1.1.4 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

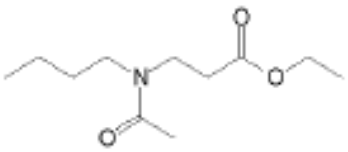
2.1.2 Product (family) composition and formulation

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 ☒

2.1.2.1 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	

2.1.2.2 Candidate(s) for substitution

Not relevant

2.1.2.3 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

2.1.2.4 Information on technical equivalence

Not relevant

2.1.2.5 Information on the substance(s) of concern

Please see the confidential annex for further details.

2.1.2.6 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.

2.1.2.7 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 vapour H319: Causes serious eye irritation
Labelling	
Signal words	Warning
Hazard statements	H226: Flammable liquid and vapour 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 hands 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.
Note	EUH 208 "Contains 2-hexyl-3-phenyl-2-propenal (trans & cis), benzyl 2-hydroxybenzoate and linalyl acetate" 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 product / cm² of skin **Protection time:** 5 hours in temperate condition <u>For European conclusion:</u> **Number and timing of application:** ▪ Child to Adult (> 2 years): 1 application per day <u>For French conclusion:</u> **Number and timing of application:**

<table>
<tr><td></td><td>

Child from 6 months up to 6 years: 1 application per day
Child to Adult (> 6 years): 2 applications per day

European conclusion:
<table>
<tr><th>Number of spray</th><th>head</th><th>neck</th><th>per arm</th><th>per hand</th><th>per leg</th><th>per feet</th></tr>
<tr><td>< 1 year old</td><td>1,7</td><td>0,8</td><td>1,2</td><td></td><td>2,1</td><td>0,3</td></tr>
<tr><td>1 to < 2 years old</td><td>2,0</td><td>0,9</td><td>1,4</td><td></td><td>2,5</td><td>0,4</td></tr>
<tr><td>2 to < 6 years old</td><td>2,6</td><td>1,2</td><td>1,9</td><td></td><td>3,6</td><td>0,5</td></tr>
<tr><td>6 to < 12 years old</td><td>2,6</td><td>1,2</td><td>2,5</td><td></td><td>5,5</td><td>0,7</td></tr>
<tr><td>adult</td><td>5,4</td><td>1,1</td><td>4,7</td><td>2.0</td><td>10,7</td><td>1,4</td></tr>
</table>
</td></tr>
<tr><td>Category(ies) of users</td><td>General public (non-professional)</td></tr>
<tr><td>Pack sizes and packaging material</td><td>

Bottle spray: 100 mL
HDPE for the bottle and PE-LD/PP for the dip tube inside the bottle and PE-LD for the regulator on the spray and a Copolymer Polypropylene cap.

</td></tr>
</table>

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

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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

-

4.2. Use description

Table 2. Use # 2 – Skin repellent against ticks

<table>
<tr><td>Product Type</td><td>PT 19</td></tr>
<tr><td>Where relevant, an exact description of the authorised use</td><td>Insect repellents</td></tr>
<tr><td>Target organism(s) (including development stage)</td><td>Ixodes ricinus

Development stages: adults and nymphs</td></tr>
<tr><td>Field(s) of use</td><td>Skin application</td></tr>
<tr><td>Application method(s)</td><td>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</td></tr>
<tr><td>Application rate(s) and frequency</td><td>The application rate is 0.95 mg product / cm² of skin

<u>For European conclusion:</u>
Number and timing of application:
▪ Child to Adult (> 11 years): 1 application per day

<u>For French conclusion:</u>
Number and timing of application:
▪ Child to Adult (> 6 months): 1 application per day

Protection time: 5 hours in temperate condition

European conclusion:
<table>
<tr><th>Number of spray</th><th>head</th><th>neck</th><th>per arm</th><th>per hand</th><th>per leg</th><th>per feet</th></tr>
<tr><td>< 1 year old</td><td>2,3</td><td>1,0</td><td>1,6</td><td></td><td>2,9</td><td>0,4</td></tr>
<tr><td>1 to < 2 years old</td><td>2,7</td><td>1,2</td><td>1,9</td><td></td><td>3,4</td><td>0,5</td></tr>
<tr><td>2 to < 6 years old</td><td>3,5</td><td>1,6</td><td>2,6</td><td></td><td>4,9</td><td>0,7</td></tr>
<tr><td>6 to < 12 years old</td><td>3,5</td><td>1,7</td><td>3,5</td><td></td><td>7,5</td><td>1,0</td></tr>
<tr><td>adult</td><td>7,4</td><td>1,5</td><td>6,4</td><td>2,7</td><td>14,6</td><td>1,9</td></tr>
</table></td></tr>
<tr><td>Category(ies) of users</td><td>General public (non-professional)</td></tr>
<tr><td>Pack sizes and packaging material</td><td>▪ Bottle spray: 100 mL
HDPE for the bottle and PE-LD/PP for the dip tube inside the bottle and PE-LD for the regulator on the spray and a Copolymer Polypropylene cap.</td></tr>
</table>

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, exposure to water, etc.) 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 and 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	**FR-2019-0092-01-01**				
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 vapour H319: Causes serious eye irritation
Labelling	
Signal words	Warning
Hazard statements	H226: Flammable liquid and vapour 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 hands 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.
Note	EUH 208 "Contains benzyl 2-hydroxybenzoate and linalyl acetate" 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 product / cm² of skin **Protection time:** 7 hours in temperate condition <u>For European conclusion:</u> **Number and timing of application:** ▪ Child to Adult (> 11 years): 1 application per day <u>For French conclusion:</u>

<table>
<tr><td></td><td>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:
<table>
<tr><td>Number of spray</td><td>head</td><td>neck</td><td>per arm</td><td>per hand</td><td>per leg</td><td>per feet</td></tr>
<tr><td>< 1 year old</td><td>1,7</td><td>0,7</td><td>1,1</td><td></td><td>2,1</td><td>0,3</td></tr>
<tr><td>1 to < 2 years old</td><td>1,9</td><td>0,9</td><td>1,3</td><td></td><td>2,4</td><td>0,3</td></tr>
<tr><td>2 to < 6 years old</td><td>2,5</td><td>1,2</td><td>1,9</td><td></td><td>3,6</td><td>0,5</td></tr>
<tr><td>6 to < 12 years old</td><td>2,5</td><td>1,2</td><td>2,5</td><td></td><td>5,4</td><td>0,7</td></tr>
<tr><td>adult</td><td>5,3</td><td>1,1</td><td>4,6</td><td>2,0</td><td>10,5</td><td>1,4</td></tr>
</table></td></tr>
<tr><td>Category(ies) of users</td><td>General public (non-professional)</td></tr>
<tr><td>Pack sizes and packaging material</td><td>▪ Bottle spray: 75 mL
HDPE for the bottle and PE-LD/PP for the dip tube 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 tube inside the bottle and PE-LD for the regulator on the spray and a Copolymer Polypropylene cap.</td></tr>
</table>

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

-

4.2. Use description

Table 4. Use # 2 – Skin repellent against ticks

<table>
<tr><td>Product Type</td><td>PT 19</td></tr>
<tr><td>Where relevant, an exact description of the authorised use</td><td>Insect repellents</td></tr>
<tr><td>Target organism(s) (including development stage)</td><td>Ixodes ricinus

Development stages: adults and nymphs</td></tr>
<tr><td>Field(s) of use</td><td>Skin application</td></tr>
<tr><td>Application method(s)</td><td>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</td></tr>
<tr><td>Application rate(s) and frequency</td><td>The application rate is 0.93 mg product / cm² of skin

Protection time: 5 hours in temperate condition

<u>For European conclusion:</u>
Number and timing of application:
▪ Child to Adult (> 11 years): 1 application per day

<u>For French conclusion:</u>
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:
<table>
<tr><td>Number of spray</td><td>head</td><td>neck</td><td>per arm</td><td>per hand</td><td>per leg</td><td>per feet</td></tr>
<tr><td>< 1 year old</td><td>2,3</td><td>1,0</td><td>1,6</td><td></td><td>2,8</td><td>0,4</td></tr>
<tr><td>1 to < 2 years old</td><td>2,6</td><td>1,2</td><td>1,8</td><td></td><td>3,3</td><td>0,5</td></tr>
<tr><td>2 to < 6 years old</td><td>3,4</td><td>1,6</td><td>2,5</td><td></td><td>4,9</td><td>0,7</td></tr>
<tr><td>6 to < 12 years old</td><td>3,5</td><td>1,6</td><td>3,4</td><td></td><td>7,4</td><td>1,0</td></tr>
<tr><td>adult</td><td>7,3</td><td>1,5</td><td>6,3</td><td>2,7</td><td>14,3</td><td>1,9</td></tr>
</table></td></tr>
<tr><td>Category(ies) of users</td><td>General public (non-professional)</td></tr>
<tr><td>Pack sizes and packaging material</td><td>▪ Bottle spray: 75 mL
HDPE for the bottle and PE-LD/PP for the dip tube 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 tube inside the bottle and PE-LD for the regulator on the spray and a Copolymer Polypropylene cap.</td></tr>
</table>

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 11 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 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, exposure to water, etc.) 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 and 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 CINQ SUR CINQ ZONES TEMPEREES FRANCE – EUROPE**				
Authorisation number	**FR-2019-0092-02-01**				
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 vapour H319: Causes serious eye irritation
Labelling	
Signal words	Warning
Hazard statements	H226: Flammable liquid and vapour 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 hands 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.
Note	EUH 208 "Contains benzyl 2-hydroxybenzoate and linalyl acetate" 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 product / cm² of skin **Protection time:** 7 hours in tropical conditions <u>For European conclusion:</u> **Number and timing of application:** ▪ Child to Adult (> 6 years): 1 application per day <u>For French conclusion:</u> **Number and timing of application:**

<table>
<tr><td></td><td>
▪ Child from 2 years up to 11 years: 1 application per day
▪ Child to Adult (> 11 years): 2 applications per day

European conclusion:
<table>
<tr><th>Number of spray</th><th>head</th><th>neck</th><th>per arm</th><th>per hand</th><th>per leg</th><th>per feet</th></tr>
<tr><td>< 1 year old</td><td>1,2</td><td>0,5</td><td>0,8</td><td></td><td>1,5</td><td>0,2</td></tr>
<tr><td>1 to < 2 years old</td><td>1,4</td><td>0,6</td><td>0,9</td><td></td><td>1,7</td><td>0,2</td></tr>
<tr><td>2 to < 6 years old</td><td>1,8</td><td>0,8</td><td>1,3</td><td></td><td>2,5</td><td>0,4</td></tr>
<tr><td>6 to < 12 years old</td><td>1,8</td><td>0,8</td><td>1,8</td><td></td><td>3,8</td><td>0,5</td></tr>
<tr><td>adult</td><td>3,8</td><td>0,8</td><td>3,3</td><td>1.4</td><td>7,4</td><td>1,0</td></tr>
</table>
</td></tr>
<tr><td>Category(ies) of users</td><td>General public (non-professional)</td></tr>
<tr><td>Pack sizes and packaging material</td><td>
▪ Bottle spray: 75 mL
HDPE for the bottle and PE-LD/PP for the dip tube 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 tube inside the bottle and PE-LD for the regulator on the spray and a Copolymer Polypropylene cap.
</td></tr>
</table>

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

-

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 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, exposure to water, etc.) 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 and 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: 48 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	**FR-2019-0092-03-01**				
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

PART II.- SECOND INFORMATION LEVEL - META SPC 4

1. Meta SPC 4 administrative information

1.1. Meta SPC identifier

Identifier	CINQ SUR CINQ FAMILLE NOUVELLE FORMULE

1.2. Suffix to the authorisation number

Number 4	

1.3. Product type(s)

Product type(s)	PT19

2. Meta SPC 4 composition

2.1. Qualitative and quantitative information on the composition of the meta SPC 4

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 4

Formulation	AL any other liquids, ready to use

3. Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 4

Classification	
Hazard category	Flammable liquid cat 3 Eye Irritant category 2
Hazard statement	H226: Flammable liquid and vapour H319: Causes serious eye irritation
Labelling	
Signal words	Warning
Hazard statements	H226: Flammable liquid and vapour 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 hands 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.
Note	EUH 208 "Contains benzyl 2-hydroxybenzoate and linalyl acetate" May produce an allergic reaction.

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

4.1. Use description

Table 6. Use # 1 – Skin repellent against mosquitoes

Product Type	PT 19
Where relevant, an exact description of the authorised use	Insect repellents

<table>
<tr><td>Target organism(s) (including development stage)</td><td>Aedes mosquitoes (Aedes spp.)
Culex mosquitoes (Culex spp.)

Development stage: adults</td></tr>
<tr><td>Field(s) of use</td><td>Skin application</td></tr>
<tr><td>Application method(s)</td><td>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</td></tr>
<tr><td>Application rate(s) and frequency</td><td>The application rate is 0.7 mg product / cm² of skin

Protection time: 5 hours in temperate condition

<u>For European conclusion:</u>
Number and timing of application:
▪ Child to Adult (> 2 years): 1 application per day

<u>For French conclusion:</u>
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:
<table>
<tr><th>Number of spray</th><th>head</th><th>neck</th><th>per arm</th><th>per hand</th><th>per leg</th><th>per feet</th></tr>
<tr><td>< 1 year old</td><td>1,7</td><td>0,8</td><td>1,2</td><td></td><td>2,1</td><td>0,3</td></tr>
<tr><td>1 to < 2 years old</td><td>2,0</td><td>0,9</td><td>1,4</td><td></td><td>2,5</td><td>0,4</td></tr>
<tr><td>2 to < 6 years old</td><td>2,6</td><td>1,2</td><td>1,9</td><td></td><td>3,6</td><td>0,5</td></tr>
<tr><td>6 to < 12 years old</td><td>2,6</td><td>1,2</td><td>2,5</td><td></td><td>5,5</td><td>0,7</td></tr>
<tr><td>adult</td><td>5,4</td><td>1,1</td><td>4,7</td><td>2.0</td><td>10,7</td><td>1,4</td></tr>
</table></td></tr>
<tr><td>Category(ies) of users</td><td>General public (non-professional)</td></tr>
<tr><td>Pack sizes and packaging material</td><td>▪ Bottle spray: 100 mL
HDPE for the bottle and PE-LD/PP for the dip tube inside the bottle and PE-LD for the regulator on the spray and a Copolymer Polypropylene cap.</td></tr>
</table>

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

-

4.2. Use description

Table 7. Use # 2 – Skin repellent against ticks

<table>
<tr><td>Product Type</td><td>PT 19</td></tr>
<tr><td>Where relevant, an exact description of the authorised use</td><td>Insect repellents</td></tr>
<tr><td>Target organism(s) (including development stage)</td><td>Ixodes ricinus

Development stages: adults and nymphs</td></tr>
<tr><td>Field(s) of use</td><td>Skin application</td></tr>
<tr><td>Application method(s)</td><td>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</td></tr>
<tr><td>Application rate(s) and frequency</td><td>The application rate is 0.95 mg product / cm² of skin

<u>For European conclusion:</u>
Number and timing of application:
▪ Child to Adult (> 11 years): 1 application per day

<u>For French conclusion:</u>
Number and timing of application:
▪ Child to Adult (> 6 months): 1 application per day

Protection time: 5 hours in temperate condition

European conclusion:
<table>
<tr><td>Number of spray</td><td>head</td><td>neck</td><td>per arm</td><td>per hand</td><td>per leg</td><td>per feet</td></tr>
<tr><td>< 1 year old</td><td>2,3</td><td>1,0</td><td>1,6</td><td></td><td>2,9</td><td>0,4</td></tr>
<tr><td>1 to < 2 years old</td><td>2,7</td><td>1,2</td><td>1,9</td><td></td><td>3,4</td><td>0,5</td></tr>
</table>
</td></tr>
</table>

	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 tube 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 4

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, exposure to water, etc.) 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 and 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 4

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

Trade name(s)	CINQ SUR CINQ FAMILLES				
Authorisation number	**FR-2019-0092-04-01**				
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 5

1.1. Meta SPC identifier

Identifier	CINQ SUR CINQ ZONES TEMPEREES NOUVELLE FORMULE

1.2. Suffix to the authorisation number

Number 5	

1.3. Product type(s)

Product type(s)	PT19

2. Meta SPC 5 composition

2.1. Qualitative and quantitative information on the composition of the meta SPC 5

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 5

Formulation	AL any other liquids, ready to use

3. Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 5

Classification	
Hazard category	Flammable liquid cat 3 Eye Irritant category 2
Hazard statement	H226: Flammable liquid and vapour H319: Causes serious eye irritation
Labelling	
Signal words	Warning
Hazard statements	H226: Flammable liquid and vapour 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 hands 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.
Note	EUH 208 "Contains 2-hexyl-3-phenyl-2- propenal (trans & cis), benzyl 2-hydroxybenzoate and linalyl acetate" May produce an allergic reaction.

4. Authorised use(s) of the meta SPC 5

4.1. Use description

Table 8. 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 product / cm² of skin **Protection time:** 7 hours in temperate condition <u>For European conclusion:</u> **Number and timing of application:** ▪ Child to Adult (> 11 years): 1 application per day

<table>
<tr><td></td><td>
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:
<table>
<tr><th>Number of spray</th><th>head</th><th>neck</th><th>per arm</th><th>per hand</th><th>per leg</th><th>per feet</th></tr>
<tr><td>< 1 year old</td><td>1,7</td><td>0,7</td><td>1,1</td><td></td><td>2,1</td><td>0,3</td></tr>
<tr><td>1 to < 2 years old</td><td>1,9</td><td>0,9</td><td>1,3</td><td></td><td>2,4</td><td>0,3</td></tr>
<tr><td>2 to < 6 years old</td><td>2,5</td><td>1,2</td><td>1,9</td><td></td><td>3,6</td><td>0,5</td></tr>
<tr><td>6 to < 12 years old</td><td>2,5</td><td>1,2</td><td>2,5</td><td></td><td>5,4</td><td>0,7</td></tr>
<tr><td>adult</td><td>5,3</td><td>1,1</td><td>4,6</td><td>2,0</td><td>10,5</td><td>1,4</td></tr>
</table>
</td></tr>
<tr><td>Category(ies) of users</td><td>General public (non-professional)</td></tr>
<tr><td>Pack sizes and packaging material</td><td>▪ Bottle spray: 75 mL
HDPE for the bottle and PE-LD/PP for the dip tube 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 tube inside the bottle and PE-LD for the regulator on the spray and a Copolymer Polypropylene cap.</td></tr>
</table>

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

-

4.2. Use description

Table 9. Use # 2 – Skin repellent against ticks

<table>
<tr><td>Product Type</td><td>PT 19</td></tr>
<tr><td>Where relevant, an exact description of the authorised use</td><td>Insect repellents</td></tr>
<tr><td>Target organism(s) (including development stage)</td><td>Ixodes ricinus

Development stages: adults and nymphs</td></tr>
<tr><td>Field(s) of use</td><td>Skin application</td></tr>
<tr><td>Application method(s)</td><td>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</td></tr>
<tr><td>Application rate(s) and frequency</td><td>The application rate is 0.93 mg product / cm² of skin

Protection time: 5 hours in temperate condition

<u>For European conclusion:</u>
Number and timing of application:
▪ Child to Adult (> 11 years): 1 application per day

<u>For French conclusion:</u>
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:
<table>
<tr><td>Number of spray</td><td>head</td><td>neck</td><td>per arm</td><td>per hand</td><td>per leg</td><td>per feet</td></tr>
<tr><td>< 1 year old</td><td>2,3</td><td>1,0</td><td>1,6</td><td></td><td>2,8</td><td>0,4</td></tr>
<tr><td>1 to < 2 years old</td><td>2,6</td><td>1,2</td><td>1,8</td><td></td><td>3,3</td><td>0,5</td></tr>
<tr><td>2 to < 6 years old</td><td>3,4</td><td>1,6</td><td>2,5</td><td></td><td>4,9</td><td>0,7</td></tr>
<tr><td>6 to < 12 years old</td><td>3,5</td><td>1,6</td><td>3,4</td><td></td><td>7,4</td><td>1,0</td></tr>
<tr><td>adult</td><td>7,3</td><td>1,5</td><td>6,3</td><td>2,7</td><td>14,3</td><td>1,9</td></tr>
</table></td></tr>
<tr><td>Category(ies) of users</td><td>General public (non-professional)</td></tr>
<tr><td>Pack sizes and packaging material</td><td>▪ Bottle spray: 75 mL
HDPE for the bottle and PE-LD/PP for the dip tube 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 tube inside the bottle and PE-LD for the regulator on the spray and a Copolymer Polypropylene cap.</td></tr>
</table>

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 11 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 5

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, exposure to water, etc.) 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 and 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 5

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

Trade name(s)	**CINQ SUR CINQ ZONES TEMPEREES NOUVELLE FORMULE CINQ SUR CINQ ZONES TEMPEREES NOUVELLE FORMULE FRANCE – EUROPE**				
Authorisation number	**FR-2019-0092-05-01**				
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 6

1.1. Meta SPC identifier

Identifier	CINQ SUR CINQ TROPIC NOUVELLE FORMULE

1.2. Suffix to the authorisation number

Number 6	

1.3. Product type(s)

Product type(s)	PT19

2. Meta SPC 6 composition

2.1. Qualitative and quantitative information on the composition of the meta SPC 6

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 6

Formulation	AL any other liquids, ready to use

3. Hazard and precautionary statements according to Regulation (EC) 1272/2008 of the meta SPC 6

Classification	
Hazard category	Flammable liquid cat 3 Eye Irritant category 2
Hazard statement	H226: Flammable liquid and vapour H319: Causes serious eye irritation
Labelling	
Signal words	Warning
Hazard statements	H226: Flammable liquid and vapour 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 and linalyl acetate" May produce an allergic reaction.

4. Authorised use(s) of the meta SPC 6

4.1. Use description

Table 10. 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 product / cm² of skin **Protection time:** 7 hours in tropical conditions <u>For European conclusion:</u> **Number and timing of application:** ▪ Child to Adult (> 6 years): 1 application per day

<table>
<tr><td></td><td>
<u>For French conclusion:</u>
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:
<table>
<tr><th>Number of spray</th><th>head</th><th>neck</th><th>per arm</th><th>per hand</th><th>per leg</th><th>per feet</th></tr>
<tr><td>< 1 year old</td><td>1,2</td><td>0,5</td><td>0,8</td><td></td><td>1,5</td><td>0,2</td></tr>
<tr><td>1 to < 2 years old</td><td>1,4</td><td>0,6</td><td>0,9</td><td></td><td>1,7</td><td>0,2</td></tr>
<tr><td>2 to < 6 years old</td><td>1,8</td><td>0,8</td><td>1,3</td><td></td><td>2,5</td><td>0,4</td></tr>
<tr><td>6 to < 12 years old</td><td>1,8</td><td>0,8</td><td>1,8</td><td></td><td>3,8</td><td>0,5</td></tr>
<tr><td>adult</td><td>3,8</td><td>0,8</td><td>3,3</td><td>1.4</td><td>7,4</td><td>1,0</td></tr>
</table>
</td></tr>
<tr><td>Category(ies) of users</td><td>General public (non-professional)</td></tr>
<tr><td>Pack sizes and packaging material</td><td>▪ Bottle spray: 75 mL
HDPE for the bottle and PE-LD/PP for the dip tube 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 tube inside the bottle and PE-LD for the regulator on the spray and a Copolymer Polypropylene cap.</td></tr>
</table>

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

-

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 6

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, exposure to water, etc.) 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 and 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: 48 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 6

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

Trade name(s)	**CINQ SUR CINQ TROPIC NOUVELLE FORMULE**				
Authorisation number	**FR-2019-0092-06-01**				
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

2.1.3 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

2.1.4 Documentation

2.1.4.1 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).

- **Minor change assessment 2021**

Additional studies were provided by the applicant, the biocidal products of the meta SPC 3 are considered stable after 48 months at ambient temperature.

- **Minor change assessment 2023**

No new study has been submitted for the Physico-chemical section.

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*)

- **Minor change assessment 2023 (for the new Meta SPC 1 and 4)**

- An arm-in-cage study conducted with ten human volunteers with the product "cinq sur cinq famille 20 %" reference FC 051 (20% w/w IR3535) applied on skin against three mosquito species *(Aedes aegypti, Culex pipiens and Anopheles gambiae).*
- A laboratory study conducted with ten mice with the product "cinq sur cinq famille 20%" reference FC 051 (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*)

- **Minor change assessment 2023 (for the new Meta SPC 2 and 5)**

- An arm-in-cage study conducted with ten human volunteers with the product "cinq sur cinq zones tempérées 25 %" reference FC 054 (25% w/w IR3535) applied on skin against three mosquito species (*Aedes albopictus, Culex quinquefasciatus* and *Anopheles gambiae*).
- A laboratory study conducted with ten mice with the product "cinq sur cinq zones tempérées" reference FC 054 (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*)

- **Minor change assessment 2023 (for the new Meta SPC 3 and 6)**

- An arm-in-cage study conducted with ten human volunteers with the product "cinq sur cinq tropic" (25% w/w IR3535) reference FC 302 applied on skin against three mosquito species (Aedes albopictus, Culex quinquefasciatus and Anopheles gambiae).

2.1.4.2 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.

2.2 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%.

2.2.1 Intended use(s) as applied for by the applicant

2.2.1.1 META-SPC 1 – CINQ SUR CINQ FAMILLE (Initial application, MIC 2020, MIC 2021)

. 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

2.2.1.2 META-SPC 2 – CINQ SUR CINQ ZONES TEMPEREES (Initial application, MIC 2020, MIC 2021)

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

2.2.1.3 META-SPC 3 – CINQ SUR CINQ TROPIC (Initial application, MIC 2020, MIC 2021)

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

2.2.1.4 META-SPC 1 – CINQ SUR CINQ FAMILLE (MIC 2023)

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 / cm² of 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
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.

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 on head, hands (adults only), ¾ arms and 1/2 legs
Application rate(s) and frequency	**The application rate is** ca. 0.95 mg / cm² of 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 to Adult (> 6 months): 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 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.

2.2.1.5 META-SPC 2 – CINQ SUR CINQ FAMILLE (MIC 2023)

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 / cm² of skin Protection time: 7 hours in temperate condition <u>For European conclusion:</u> **Number and timing of application:** - Child to Adult (> 11 years): 1 application per day <u>For French conclusion:</u> **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
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.

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 on head, hands (adults only), ¾ arms and 1/2 legs

Application rate(s) and frequency	**The application rate is** ca. 0.93 mg / cm² of skin Protection time: 5 hours in temperate condition <u>For European conclusion:</u> **Number and timing of application:** - Child to Adult (> 11 years): 1 application per day <u>For French conclusion:</u> **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
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.

2.2.1.6 META-SPC 3 – CINQ SUR CINQ FAMILLE (MIC 2023)

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 / cm² of skin Protection time: 7 hours in tropical conditions (Aedes spp. and Culex spp.: 8 hours Anopheles spp.: 7 hours) <u>For European conclusion:</u> **Number and timing of application:** - Child to Adult (> 6 years): 1 application per day <u>For French conclusion:</u>

	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
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.

2.2.1.7 META-SPC 4 – CINQ SUR CINQ FAMILLE (MIC 2023)

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 / cm² of skin **Protection time:** 5 hours in temperate condition <u>For European conclusion</u>: **Number and timing of application:** - Child to Adult (> 2 years): 1 application per day <u>For French conclusion</u>: **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 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.

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 on head, hands (adults only), ¾ arms and 1/2 legs
Application rate(s) and frequency	**The application rate is** ca. 0.95 mg / cm² of skin Protection time: 5 hours in temperate condition <u>For European conclusion:</u> **Number and timing of application:** - Child to Adult (> 11 years): 1 application per day <u>For French conclusion:</u> **Number and timing of application:** - Child to Adult (> 6 months): 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 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.

2.2.1.8 META-SPC 5 – CINQ SUR CINQ FAMILLE (MIC 2023)

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 / cm² of skin Protection time: 7 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
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.

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 on head, hands (adults only), ¾ arms and 1/2 legs
Application rate(s) and frequency	**The application rate is** ca. 0.93 mg / cm² of 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): 1 application per day
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.

2.2.1.9 META-SPC 6 – CINQ SUR CINQ FAMILLE (MIC 2023)

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 / cm² of skin Protection time: 7 hours in tropical conditions (Aedes spp. and Culex spp.: 8 hours Anopheles spp.: 7 hours) <u>For European conclusion:</u> **Number and timing of application:** - Child to Adult (> 6 years): 1 application per day <u>For French conclusion:</u> **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
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.

2.2.2 Physical, chemical and technical properties

2.2.2.1 META-SPC 1 (new META SPC 1 and 4)

The new Meta SPC 1 and 4 are similar. They can be considered covered by the product of former Meta SPC 1.

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

<table>
<tr>
<td>Storage stability test – accelerated storage</td>
<td>CIPAC MT 46.3
CIPAC MT 75.3
ECHA Guidance
Validated method of quantification of IR3535 (15.024236.0002)</td>
<td>CINQ SUR CINQ FAMILLE 20% NF

Batch: FC001

Bottle 100 mL HDPE commercial packaging</td>
<td>
<table>
<tr><td></td><td>T0</td><td>T4 weeks at 50°C</td></tr>
<tr><td>AS content</td><td>19.9</td><td>19.4</td></tr>
<tr><td>% variation</td><td>-</td><td>-2.52</td></tr>
<tr><td>pH at 20°C</td><td>6.42</td><td>6.12</td></tr>
<tr><td>Physical state</td><td>Homogeneous liquid lightly citrus</td><td>No change</td></tr>
<tr><td>Weight (g)</td><td>123.02</td><td>119.33</td></tr>
<tr><td>Microbial assay
TAMC
TYMC</td><td>
< 10 CFU/g
< 10 CFU/g</td><td>
< 10 CFU/g
< 10 CFU/g</td></tr>
</table>
</td>
<td>Acceptable
The preparation is stable 4 weeks at 50°C.</td>
<td>Dall’Acqua (2015), study n° 15.024236.0004</td>
</tr>
<tr>
<td>Storage stability test – long term storage at ambient temperature</td>
<td>Method BAUS-006R0 validated in the section analytical method.</td>
<td>CINQ SUR CINQ FAMILLE 20% NF

Batch: FC001

Bottle 100 mL HDPE commercial packaging</td>
<td>
<table>
<tr><td></td><td>T0</td><td>T3 months</td><td>T6 months</td><td>T12months</td><td>T24 months</td><td>T36 months</td></tr>
<tr><td>AS content</td><td>20.2</td><td>20.6</td><td>20.6</td><td>19.8</td><td>20.3</td><td>19.82</td></tr>
<tr><td>% variation</td><td>-</td><td>1.98</td><td>1.98</td><td>-1.98</td><td>0.39</td><td>-1.89</td></tr>
<tr><td>pH at 20°C</td><td>6.5</td><td>6.4</td><td>6.2</td><td>6.0</td><td>5.8</td><td>5.4</td></tr>
<tr><td>Physical state</td><td>Homogeneous liquid lightly citrus</td><td>No change</td><td>No change</td><td>No change</td><td>No change</td><td>No change</td></tr>
<tr><td>Weight (g)</td><td>123.3</td><td>123.3</td><td>123</td><td>121.4</td><td>120.2</td><td>118.6</td></tr>
<tr><td>Spray diameter (cm)</td><td>/</td><td>/</td><td>/</td><td>11</td><td>10</td><td>10</td></tr>
</table>
</td>
<td>The product is stable 36 months at ambient temperature but the particle size distribution after storage should be provided in post-authorisation.

<u>Post authorisation data:</u> Particle size distribution of 36 months aged product CINQ SUR CINQ 35% was submitted and considered acceptable.</td>
<td>Laboratoire Merieux (2018) Report number SS_020_2015</td>
</tr>
</table>

			<table><tr><td>Spray pattern</td><td>Homogeneous</td><td>/</td><td>/</td><td>Homogeneous</td><td>Homogeneous</td><td>Homogeneous</td></tr><tr><td>quantity of delivered liquid by spray mL (discharge)</td><td>/</td><td>/</td><td>/</td><td>0.15</td><td>0.15</td><td>0.16</td></tr><tr><td>Nozzle blockage</td><td>No residues</td><td>No residues</td><td>No residues</td><td>No residues</td><td>No residues</td><td>No residues</td></tr><tr><td>Microbial assay TAMC TYMC</td><td>< 10 CFU/g < 10 CFU/g</td><td>< 10 CFU/g < 10 CFU/g</td><td>< 10 CFU/g < 10 CFU/g</td><td>< 10 CFU/g < 10 CFU/g</td><td>< 10 CFU/g < 10 CFU/g</td><td>< 10 CFU/g < 10 CFU/g</td></tr></table>		
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	<table><tr><td></td><td>T0</td><td>T7d</td></tr><tr><td>Appearance</td><td>Homogeneous liquid lightly citrus</td><td>No change</td></tr><tr><td>AS content</td><td>20.0</td><td>20.0</td></tr><tr><td>pH at 20°C</td><td>6.42</td><td>6.43</td></tr><tr><td>Weight</td><td>123.02</td><td>123.01</td></tr><tr><td>Microbial assay TAMC TYMC</td><td> < 10 CFU/g < 10 CFU/g</td><td> < 10 CFU/g < 10 CFU/g</td></tr></table>	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.	Acceptable	IUCLID

			The light is considered to have no influence on the stability of the products. Consequently, no test was performed to study this parameter.		
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	-

<table>
<tr><td>Burning completeness — smoke generators</td><td>-</td><td>-</td><td>-</td><td>Not relevant for an AL formulation</td><td>-</td></tr>
<tr><td>Composition of smoke — smoke generators</td><td>-</td><td>-</td><td>-</td><td>Not relevant for an AL formulation</td><td>-</td></tr>
<tr><td>Spraying pattern — aerosols</td><td>-</td><td>-</td><td>-</td><td>Not relevant for an AL formulation</td><td>-</td></tr>
<tr><td>Physical compatibility</td><td>-</td><td>-</td><td>-</td><td>-</td><td>-</td></tr>
<tr><td>Chemical compatibility</td><td>-</td><td>-</td><td>-</td><td>-</td><td>-</td></tr>
<tr><td>Degree of dissolution and dilution stability</td><td>-</td><td>-</td><td>-</td><td>Not relevant for an AL formulation</td><td>-</td></tr>
<tr><td>Surface tension</td><td>ASTM D1331/89 (2001)</td><td>CINQ SUR CINQ FAMILLE 20%

Batch: FC001

Bottle 100 mL HDPE</td><td>Test substance, 29.18 mN/m at 25°C.</td><td>Acceptable
The preparation is active in surface.</td><td>Dall’Acqua (2015), study n° 15.024236.0001</td></tr>
<tr><td>Viscosity</td><td>ECD Test Guideline 114</td><td>CINQ SUR CINQ FAMILLE 20%

Batch: FC001

Bottle 100 mL HDPE</td><td>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</td><td>Acceptable</td><td>Dall’Acqua (2015), study n° 15.024236.0001</td></tr>
<tr><td>Discharge</td><td>-</td><td>CINQ SUR CINQ FAMILLE 20%

Batch: FC001</td><td>Deliverered volume by spray was calculated with a density = 0.940
Delivered volume= 0.1493 mL
Number of spray: 658</td><td>Acceptable
The density is not the same as the one found in the study n° 15.024236.0001</td><td>031 ETU BAU 15</td></tr>
<tr><td>Particle size distribution</td><td>CIPAC MT187</td><td>CINQ SUR CINQ FAMILLE 20%

Batch: FC001
100 mL PE bottle</td><td><table><tr><th>Test item</th><th>Dv (10%) µm</th><th>Dv (50%) µm</th><th>Dv (90%) µm</th></tr><tr><td>2</td><td>40.12</td><td>92.32</td><td>171.73</td></tr><tr><td>3</td><td>40.94</td><td>96.63</td><td>175.32</td></tr><tr><td>4</td><td>40.28</td><td>107.24</td><td>187.21</td></tr><tr><td>mean</td><td>40</td><td>99</td><td>178</td></tr></table></td><td>Acceptable</td><td>Rodriguez (2015) Mo5311</td></tr>
</table>

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.

- **Minor change assessment 2023**

No new physico-chemical properties are provided in the dossier.
This minor change consists of the addition of one co-formulant. This minor change requires a split of previous meta SPCs for toxicological reasons and in order to maintain their regulatory compliance. The new Meta SPC 1 and 4 are derived from previous Meta SPC 1.
The new Meta SPC 1 and 4 are similar and can be considered as covered by the product of former Meta SPC 1.

The addition of the new co-formulant in the composition of the product family has no impact on the physico-chemical properties of the products in both new Meta SPC 1 and 4.

2.2.2.2 META-SPC 2 (new META SPC 2 and 5)

New Meta SPC 2 and 5 are similar. They can be considered covered by the product of former Meta SPC 2.

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

<table>
<tr>
<td>Storage stability test – accelerated storage</td>
<td>CIPAC MT 46.3
CIPAC MT 75.3
ECHA Guidance
Validated method of quantification of IR3535 (37093)</td>
<td>CINQ SUR CINQ ZONES TEMEPREES

Batch: FC021

Bottle 75 mL HDPE

CINQ SUR CINQ ZONES TEMEPREES

Batch: FC001

Bottle 75 mL HDPE (commercial packaging)</td>
<td>Old formulation:
<table>
<tr><td></td><td>T0</td><td>T4 weeks at 50°C</td></tr>
<tr><td>AS content</td><td>25.6</td><td>25.61</td></tr>
<tr><td>% variation</td><td>-</td><td>-2.52</td></tr>
<tr><td>pH at 20°C</td><td>6.56</td><td>6.38</td></tr>
<tr><td>Physical state</td><td>Homogeneous liquid lightly citrus</td><td>No change</td></tr>
<tr><td>Weight (g)</td><td>95.45</td><td>95.44</td></tr>
</table>
<table>
<tr><td></td><td>T0</td><td>T4 weeks at 50°C</td></tr>
<tr><td>AS content</td><td>24.9</td><td>25.0</td></tr>
<tr><td>% variation</td><td>-</td><td>0.4</td></tr>
<tr><td>pH at 20°C</td><td>6.86</td><td>6.53</td></tr>
<tr><td>Physical state</td><td>Homogeneous liquid lightly citrus</td><td>No change</td></tr>
<tr><td>Weight (g)</td><td>96.21</td><td>92.46</td></tr>
<tr><td>Microbial assay
TAMC
TYMC</td><td>
< 10 CFU/g
< 10 CFU/g</td><td>
< 10 CFU/g
< 10 CFU/g</td></tr>
</table>
New formulation:</td>
<td>Acceptable
The preparation is stable 4 weeks at 50°C.</td>
<td>Dall’Acqua (2015), study n° 37101
Dall’Acqua (2015), study n°15.024892.0004</td>
</tr>
</table>

<table>
<tr>
<td>Storage stability test – long term storage at ambient temperature</td>
<td>Validated method of quantification of IR3535 (37093)</td>
<td>CINQ SUR CINQ ZONES TEMEPREES

Batch: FC021

Bottle 75 mL HDPE (commercial packaging)</td>
<td>
<table>
<tr><td></td><td>T0</td><td>T3 months at RT</td><td>T6 months at RT</td><td>T9 months at RT</td></tr>
<tr><td>AS content</td><td>25.6</td><td>25.7</td><td>23.6</td><td>25.3</td></tr>
<tr><td>% variation</td><td>-</td><td>0.3</td><td>-7.9</td><td>-1.2</td></tr>
<tr><td>pH at 20°C</td><td>6.56</td><td>6.5</td><td>6.3</td><td>6.1</td></tr>
<tr><td>Physical state</td><td>Homogeneous liquid lightly citrus</td><td>No change</td><td>No change</td><td>No change</td></tr>
<tr><td>Weight (g)</td><td>95.45</td><td>95.38</td><td>95.34</td><td>95.28</td></tr>
<tr><td>µbial assay
TAMC
TYMC</td><td>
< 10 CFU/g
< 10 CFU/g</td><td>
< 10 CFU/g
< 10 CFU/g</td><td>
< 10 CFU/g
< 10 CFU/g</td><td>
< 10 CFU/g
< 10 CFU/g</td></tr>
</table>
</td>
<td>The study of long term storage in commercial packaging should be provided within two years.</td>
<td>Laboratoire Merieux (2015) Test report 200040703 200043295 200046436</td>
</tr>
<tr>
<td></td>
<td>Method BAUS-006R0 validated in the section analytical method.</td>
<td>Bottle 75 mL HDPE

CINQ SUR CINQ ZONES TEMEPREES

Batch: FC001

Bottle 75 mL HDPE (commercial packaging)</td>
<td>
<table>
<tr><td></td><td>T0</td><td>T3 months</td><td>T6 months</td><td>T12months</td><td>T24 months</td><td>T36 months</td></tr>
<tr><td>AS content</td><td>25.3</td><td>25.2</td><td>25.4</td><td>25.5</td><td>25.2</td><td>24.4</td></tr>
<tr><td>% variation</td><td>-</td><td>-0.4</td><td>0.4</td><td>0.8</td><td>-0.4</td><td>-3.6</td></tr>
<tr><td>pH at 20°C</td><td>6.6</td><td>6.5</td><td>6.4</td><td>6.0</td><td>5.9</td><td>5.5</td></tr>
<tr><td>Physical state</td><td>Homogeneous liquid lightly citrus</td><td>No change</td><td>No change</td><td>No change</td><td>No change</td><td>No change</td></tr>
<tr><td>Weight (g)</td><td>96.1</td><td>96</td><td>95.9</td><td>95.9</td><td>95.7</td><td>95.6</td></tr>
</table>
</td>
<td>The product is stable 36 months at ambient temperature but the particle size distribution after storage should be provided in post-authorisation

<u>Post authorisation:</u>
Particle size distribution of 36 months aged product CINQ SUR CINQ 35% was submitted and considered acceptable.</td>
<td>Laboratoire Merieux (2018) Report Number SS_020_2015</td>
</tr>
</table>

			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		
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						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
			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							
Effects on content of the active substance and technical characteristics of the	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.								Acceptable	IUCLID

biocidal product - **light**			The light is considered to have no influence on the stability of the products. Consequently, no test was performed to study this parameter.		
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	<table><tr><th>Test item</th><th>Dv (10%) µm</th><th>Dv (50%) µm</th><th>Dv (90%) µm</th></tr><tr><td>2</td><td>38.83</td><td>98.26</td><td>185.63</td></tr><tr><td>3</td><td>41.79</td><td>102.33</td><td>182.37</td></tr></table>	Acceptable Provided data cover the wall META SPC 2.	Rodriguez (2015) Mo5304

		Batch: FC001 75 mL PE bottle	4	43.03	93.89	165.46			
			mean	41	98	178			

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.

- **Minor change assessment 2023**

No new physico-chemical properties are provided in the dossier.
This minor change consists of the addition of one co-formulant. This minor change requires a split of previous meta SPC for toxicological reasons and in order to maintain their regulatory compliance. The new Meta SPC 2 and 5 are derived from previous Meta SPC 2.
The new Meta SPC 2 and 5 are similar and can be considered as covered by the product of former Meta SPC 2.

The addition of the new co-formulant in the composition of the product family has no impact on the physico-chemical properties of the products in both new Meta SPC 2 and 5.

2.2.2.3 META-SPC 3 (new META SPC 3 and 6)

New Meta SPC 3 and 6 are similar. They can be considered covered by the product of former Meta SPC 3.

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

<table>
<tr>
<td>Storage stability test – accelerated storage</td>
<td>CIPAC MT 46.3
CIPAC MT 75.3
ECHA Guidance
Validated method of quantification of IR3535 (37093)</td>
<td>CINQ SUR CINQ TROPIC 35% AF

Batch: FC112

Bottle 75 mL HDPE

CINQ SUR CINQ TROPIC 35% NF

Batch: FC001

Bottle 75 mL HDPE</td>
<td>Old formulation:
<table>
<tr><td></td><td>T0</td><td>T4 week</td></tr>
<tr><td>AS content</td><td>35.63</td><td>35.55</td></tr>
<tr><td>% variation</td><td>-</td><td>-0.3</td></tr>
<tr><td>pH at 20°C</td><td>7.07</td><td>6.86</td></tr>
<tr><td>Physical state</td><td>Homogeneous liquid strong citrus</td><td>No chan</td></tr>
<tr><td>Weight (g)</td><td>95.54</td><td>95.52</td></tr>
<tr><td>Microbial assay
TAMC
TYMC</td><td>
< 10 CFU/g
< 10 CFU/g</td><td>
< 10 CF
< 10 CF</td></tr>
</table>
<table>
<tr><td></td><td>T0</td><td>T4 weeks at 50°C</td></tr>
<tr><td>AS content</td><td>34.7</td><td>33.8</td></tr>
<tr><td>% variation</td><td>-</td><td>-2.6</td></tr>
<tr><td>pH at 20°C</td><td>7.18</td><td>7.17</td></tr>
<tr><td>Physical state</td><td>Homogeneous pale yallow liquid strong citrus</td><td>No change</td></tr>
<tr><td>Weight (g)</td><td>96.43</td><td>92.57</td></tr>
<tr><td>Microbial assay
TAMC
TYMC</td><td>
< 10 CFU/g
< 10 CFU/g</td><td>
< 10 CFU/g
< 10 CFU/g</td></tr>
</table>
New formulation:</td>
<td>Acceptable
The preparation is stable 4 weeks at 50°C.
Provided data cover the wall META SPC 3.</td>
<td>Dall’Acqua (2015), study n° 37100
Dall’Acqua (2015), study n°15.024892.0004</td>
</tr>
</table>

<table>
<tr>
<td>Storage stability test – long term storage at ambient temperature</td>
<td>Method BAUS-006R0 validated in the section analytical method.</td>
<td>CINQ SUR CINQ TROPIC 35% NF

Batch: FC001

Bottle 100 mL HDPE</td>
<td>
<table>
<tr><td></td><td>T0</td><td>T6 months</td><td>T12months</td><td>T18months</td><td>T24 months</td></tr>
<tr><td>AS content</td><td>36.71</td><td>35.82</td><td>36.13</td><td>34.54</td><td>35.34</td></tr>
<tr><td>% variation</td><td>-</td><td>-2.5</td><td>-1.6</td><td>-6</td><td>-3.8</td></tr>
<tr><td>pH at 20°C</td><td>6.7</td><td>6.5</td><td>6.5</td><td>6.5</td><td>6.0</td></tr>
<tr><td>Physical state</td><td>Homogeneous liquid lightly citrus</td><td>No change</td><td>No change</td><td>No change</td><td>No change</td></tr>
<tr><td>Weight (g)</td><td>126.6</td><td>123.2</td><td>123.1</td><td>123.8</td><td>122.9</td></tr>
<tr><td>Spray diameter (cm)</td><td>10</td><td>10</td><td>10</td><td>10</td><td>10</td></tr>
<tr><td>Spray pattern</td><td>Homogeneous</td><td>Homogeneous</td><td>Homogeneous</td><td>Homogeneous</td><td>Homogeneous</td></tr>
<tr><td>quantity of delivered liquid by spray mL (discharge)</td><td>0.15</td><td>0.17</td><td>0.17</td><td>0.17</td><td>0.16</td></tr>
<tr><td>Nozzle blockage</td><td>No residues</td><td>No residues</td><td>No residues</td><td>No residues</td><td>No residues</td></tr>
</table>
</td>
<td>The final study of long term storage in commercial packaging be provided within two years.</td>
<td>Laboratoire Merieux (2018)</td>
</tr>
<tr>
<td>Storage stability test – low temperature stability test for liquids</td>
<td>Validated method of quantification of IR3535 (37093)
CIPAC MT 75.3</td>
<td>CINQ SUR CINQ TROPIC 35% NF

Batch: FC001</td>
<td>
<table>
<tr><td></td><td>T0</td><td>T7d</td></tr>
</table>
</td>
<td>Acceptable
The preparation is stable 7 days at 0°C.</td>
<td>Dall’Acqua (2015), study n° 15.024236.0005</td>
</tr>
</table>

		Bottle 75 mL HDPE	Appearance	Homogeneous liquid pale yellow strong citrus	No change	Provided data cover the wall META SPC 3.	
			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		
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 -	-	-	-			Data on reactivity towards container material have been	-

reactivity towards container material				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	<table><tr><th>Test item</th><th>Dv (10%) µm</th><th>Dv (50%) µm</th><th>Dv (90%) µm</th></tr><tr><td>2</td><td>40.27</td><td>93.10</td><td>176.16</td></tr></table>	Acceptable Provided data cover the wall META SPC 3.	Rodriguez (2015) Mo5304

			3	43.37	105.08	185.94			
			4	41.71	97.95	178.95			
			mean	42	99	180			

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 (48 months at ambient temperature in HDPE bottle packaging material (commercial packaging material)) has been provided and the product is stable 48 months at ambient temperature in commercial packaging (Post authorisation data was submitted in January 2020, please refer to the section: **Post authorisation requirement assessment** and data were provided in September 2021, please refer to the section: **Minor change 2021**).

Please refer to section **Minor change 2020** and **Minor change 2021.**

After 7 days at 0°C, the appearance and technical characteristic have not significantly changed. The product is stable at 0°C.

- **Minor change assessment 2023**

No new physico-chemical properties are provided in the dossier.

This minor change consists of the addition of one co-formulant. This minor change requires a split of previous Meta SPCs for toxicological reasons and in order to maintain their regulatory compliance. The new Meta SPC 3 and 6 are derived from previous Meta SPC 3.

The new Meta SPC 3 and 6 are similar and can be considered as covered by the product of former meta SPC 3.

The addition of the new co-formulant in the composition of the product family has no impact on the physico-chemical properties of the products in both new Meta SPC 3 and 6.

- **Post authorisation requirement assessment**

<table>
<tr>
<td>Storage stability test – long term storage at ambient temperature</td>
<td>Method BAUS-006R0 validated in the section analytical method.</td>
<td>CINQ SUR CINQ 35% new formulation

Batch: FC001

Bottle 100 mL HDPE commercial packaging</td>
<td>
<table>
<tr><td></td><td>T0</td><td>T12months</td><td>T24 months</td><td>T36 months</td></tr>
<tr><td>AS content</td><td>36.7</td><td>36.13</td><td>35.34</td><td>35.73</td></tr>
<tr><td>pH at 20°C</td><td>6.7</td><td>6.5</td><td>6.0</td><td>6.3</td></tr>
<tr><td>Physical state</td><td colspan="4">Homogeneous liquid lightly citrus</td></tr>
<tr><td>Spray diameter (cm)</td><td>/</td><td>10</td><td>10</td><td>10</td></tr>
<tr><td>Spray pattern</td><td>Homogeneous</td><td>Homogeneous</td><td>Homogeneous</td><td>Homogeneous</td></tr>
<tr><td>quantity delivered by spray (discharge)</td><td>/</td><td>0.16 mL</td><td>0.17 mL</td><td>0.15 mL</td></tr>
<tr><td>Nozzle blockage</td><td>No residues</td><td>No residues</td><td>No residues</td><td>No residues</td></tr>
</table>
</td>
<td>The product is stable 36 months at ambient temperature</td>
<td>Laboratoire Merieux (2019) Report number SS_022_2016</td>
</tr>
<tr>
<td>Particle size distribution</td>
<td>CIPAC MT187</td>
<td>CINQ SUR CINQ 35% new formulation</td>
<td>Particle size distribution of 36 month old sample:

Dv (10%) 37 µm
Dv (50%) 92 µm
Dv (90%) 205 µm</td>
<td>acceptable</td>
<td>L. Mack 2019 Study number Mo6582</td>
</tr>
</table>

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.

- **Minor change 2021:**

<table>
<tr>
<td>Storage stability test – long term storage at ambient temperature</td>
<td>Method BAUS-006R0 validated in the section analytical method.</td>
<td>CINQ SUR CINQ 35% old formulation

Batch: FC163

Bottle 75 mL HDPE commercial packaging</td>
<td>
<table>
<tr><td></td><td>T0</td><td>T12 months</td><td>T24 months</td><td>T36 months</td><td>T42 months</td><td>T48 months</td></tr>
<tr><td>AS content</td><td>36.7</td><td>36.0</td><td>35.9</td><td>36.6</td><td>36.2</td><td>35.3</td></tr>
<tr><td>pH at 20°C</td><td>7.0</td><td>6.5</td><td>6.3</td><td>6.3</td><td>6.0</td><td>6.1</td></tr>
<tr><td>Physical state</td><td colspan="6">Liquid free from extraneous materials, colourless, strong citrus odour. No phase separation. No sedimentation.</td></tr>
<tr><td>Spray diameter (cm)</td><td>10</td><td>10</td><td>10</td><td>10</td><td>10</td><td>10</td></tr>
<tr><td>Spray pattern</td><td>Homogeneous</td><td>Homogeneous</td><td>Homogeneous</td><td>Homogeneous</td><td>Homogeneous</td><td>Homogeneous</td></tr>
<tr><td>quantity delivered by spray (discharge)</td><td>0.16 mL</td><td>0.17 mL</td><td>0.17 mL</td><td>0.16 mL</td><td>0.16 mL</td><td>0.15 mL</td></tr>
</table>
</td>
<td>The product is stable 48 months at ambient temperature. This study is applicable to the new formulation.</td>
<td>Laboratoire Merieux (2019) Report number SS_022_2016</td>
</tr>
</table>

			Nozzle blockage	No residues	No residues	No residues	No residues	No residues	No residues		
Particle size distribution	CIPAC MT187	CINQ SUR CINQ 35% n old formulation	Particle size distribution of 48 month old sample: Dv (10%) 30 µm Dv (50%) 79 µm Dv (90%) 195 µm							acceptable	M. Mullewitz 2020 Study number Mo6839

Based on the evaluation and validation of the long term storage study provided, the shelf life for products of the meta SPC 3 is set to 48 months at ambient temperature instead of 36 months.

- **Minor change assessment 2023**

No new physico-chemical properties are provided in the dossier.
The addition of/replacement with the new co-formulant in the composition of the products has no impact on the physico-chemical properties.

2.2.3 Physical hazards and respective characteristics

2.2.3.1 META-SPC 1 (new META SPC 1 and 4)

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	-

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

- **Minor change assessment 2023**

The composition of the new and the old co-formulants are similar (see confidential part). The content of the co-formulant did not change in the new product. In consequence, the change should not impact the hazard properties of the products of the BPF.

2.2.3.2 META-SPC 2 (new META SPC 2 and 5)

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

- **Minor change assessment 2023**

The composition of the new and the old co-formulants are similar (see confidential part). The content of the co-formulant did not change in the new product. In consequence, the change should not impact the hazard properties of the products of the BPF.

2.2.3.3 META-SPC 3 (new META SPC 3 and 6)

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

- **Minor change assessment 2023**

The composition of the new and the old co-formulants are similar (see confidential part). The content of the co-formulant did not change in the new product. In consequence, the change should not impact the hazard properties of the products of the BPF.

2.2.4 Methods for detection and identification

1/ Analytical method for former META SPC 1 (new META SPC 1 and 4)

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 R^2 higher than 0.997.	
	Compound	Linearity %
	Active substance:IR3535	80% to 140% $Y = 5.385.10^3 X$ n=5
Precision	Repeatability was evaluated by analyzing five (n=1) test item solutions.	
	Compound	Repeatability (RSD)
	Active substance: IR3535	RSD = 0.69%

<table>
<tr><td>Accuracy</td><td>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.
<table>
<tr><th>Fortification level</th><th>Recovery rate</th><th>Mean recovery rate</th><th>RSD (%)</th><th>n</th></tr>
<tr><td>80% (15.9% w/w)</td><td>99; 99; 101</td><td>100</td><td>1.2</td><td>3</td></tr>
<tr><td>100% (19.9% w/w)</td><td>101; 100; 101</td><td>101</td><td>0.7</td><td>3</td></tr>
<tr><td>120% (23.9 %w/w)</td><td>100; 98; 98</td><td>99</td><td>1.0</td><td>3</td></tr>
</table>
</td></tr>
</table>

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 former META SPC 2 (new META SPC 2 and 5)

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:

<table>
<tr><td>Specificity</td><td>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.</td></tr>
<tr><td>Linearity</td><td>Linearity was studied by carrying out five concentrations between 80% and 140% of the reference item.
Calibration curve has been provided with a R^2 higher than 0.999.
<table>
<tr><td>Compound</td><td>Linearity %</td></tr>
</table>
</td></tr>
</table>

<table>
<tr><td></td><td>Active substance:IR3535</td><td>80% to 140%
Y = 5.306.10^3 X
n=5</td></tr>
<tr><td rowspan="3">Precision</td><td colspan="2">Repeatability was evaluated by analyzing five (n=1) test item solutions.</td></tr>
<tr><td>Compound</td><td>Repeatability (RSD)</td></tr>
<tr><td>Active substance: IR3535</td><td>RSD = 1.58%</td></tr>
<tr><td>Accuracy</td><td colspan="2">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.
<table>
<tr><th>Fortification level</th><th>Recovery rate</th><th>Mean recovery rate</th><th>RSD (%)</th><th>n</th></tr>
<tr><td>80% (20% w/w)</td><td>101.6; 101.1; 101.4</td><td>101.4</td><td>0.2</td><td>3</td></tr>
<tr><td>100% (25% w/w)</td><td>98.4; 98.4; 98.5</td><td>98.4</td><td>0.1</td><td>3</td></tr>
<tr><td>120% (30 %w/w)</td><td>100; 100.1; 100.2</td><td>100.1</td><td>0.1</td><td>3</td></tr>
</table></td></tr>
</table>

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.

3/ Analytical method for former META SPC 3 (new META SPC 3 and 6)

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:

<table>
<tr><td>Specificity</td><td>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.</td></tr>
<tr><td>Linearity</td><td>Linearity was studied by carrying out five concentrations between 80% and 140% of the reference item.
Calibration curve has been provided with a R^2= 1.000.
<table>
<tr><td>Compound</td><td>Linearity %</td></tr>
<tr><td>Active substance:IR3535</td><td>80% to 140%
Y = $5.334.10^3$ X
n=5</td></tr>
</table></td></tr>
<tr><td>Precision</td><td>Repeatability was evaluated by analyzing five (n=1) test item solutions.
<table>
<tr><td>Compound</td><td>Repeatability (RSD)</td></tr>
<tr><td>Active substance: IR3535</td><td>RSD = 0.54%</td></tr>
</table></td></tr>
<tr><td>Accuracy</td><td>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.
<table>
<tr><th>Fortification level</th><th>Recovery rate</th><th>Mean recovery rate</th><th>RSD (%)</th><th>n</th></tr>
<tr><td>80% (28.5% w/w)</td><td>100; 100; 100</td><td>100</td><td>0.01</td><td>3</td></tr>
<tr><td>100% (35% w/w)</td><td>98; 98; 98</td><td>98</td><td>0.05</td><td>3</td></tr>
<tr><td>120% (42.5 %w/w)</td><td>99; 99; 99</td><td>99</td><td>0.08</td><td>3</td></tr>
</table></td></tr>
</table>

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.

- **Minor change assessment 2023**

The change should not have any impact on the methods for detection and identification of BPF.

2.2.5 Efficacy against target organisms

2.2.5.1 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).

2.2.5.2 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.

<u>The application rates recommended by the applicant are the following:</u>

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

➢ **Minor change assessment 2023**

Several changes are intended in this dossier:
- Addition or replacement of a co-formulant for the three former Meta SPCs.
  Following this change, for toxicological reasons and in order to maintain their regulatory compliance, the former 3 Meta SPCs have been split as follows:
  - Former Meta SPC 1 → Split into new Meta SPC 1 and 4
  - Former Meta SPC 2 → Split into new Meta SPC 2 and 5
  - Former Meta SPC 3 → Split into new Meta SPC 3 and 6

- Extension of the CPT against mosquitoes in all six new META SPCs and against ticks in the new META SPC 1, 2, 4, 5.

2.2.5.3 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.

2.2.5.4 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.

2.2.5.5 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.

➢ **Minor change assessment 2023**

To extend the protection time against mosquitoes and ticks, additional efficacy studies were provided considering the new version of the efficacy guidance vol II parts B&C on PT19 (2021).
This data concerns the following uses:

- New Meta SPC 1 and 4: use against mosquitoes and ticks
- New Meta SPC 2 and 5: use against mosquitoes and ticks
- New Meta SPC 3 and 6: use against mosquitoes

- **META-SPC 1 (First application) – New META SPC 1 and 4 (Minor change 2023)**

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 (First application)							
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 cm^3	WHO/HTM/NTD/WHOPES/ 2009.4	Arm in cage **0.42 g per 600 cm^2 => 0.7 mg/cm^2** **0.55 g per 600 cm^2 => 0.92 mg/cm^2** 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/cm^2 and 6H at 0.92 mg/cm^2 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 cm^2 => 1.783 mg/cm^2** 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 cm^2 => 0.95 mg/cm^2** Records of the number of ticks crossing the separating line between	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*.	Serrano, 2017* RI = 1 2257-CSCF-ticks/0917

					the untreated area and the treated skin part.	Temperate conditions	
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

- **Minor change assessment 2023**

In the frame of this minor change:

- the composition of the products of the new META SPC 1 and 4 have been slightly modified in order to let the possibility of formulating products with an alternative perfume than the one already present in the composition.
- in order to extend the complete protection time against mosquitoes and ticks, taking into account the new version of the efficacy guidance Vol II parts B&C on PT19 (2021) on these targets, the following efficacy studies with the product CINQ SUR CINQ FAMILLE (FC051) on mosquitoes and ticks were provided:

Experimental data on the efficacy of the biocidal product against target organism(s) – META SPC1 & 4 (Minor change)							
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*** *reference FC051 20% IR3535*	*Aedes albopictus* *Culex quinquefasciatus* *Anopheles gambiae* 100 adult females / cages of 64000 cm^3	WHO/HTM/NTD/WHOPES/ 2009.4 Vol II (Parts B&C) – Version 4.0 - December 2021	Arm in cage **0.7 mg product/cm² (0.42 g per 600 cm)** 3 minutes repeated every hour until the first landing and then every 30 minutes until proven inefficacy of the product. 10 volunteers Test conditions: 27°C ± 2 °C 80%±10 RH In the control: *Aedes spp*. 20 landings/minute *Culex spp*. 5 landings/minute *Anopheles spp*. 5 landings/minute Mortality: <0.3%	Test item provided a complete protection over a period of: - 5.1H against *Ae albopictus* - 5.8H against *C. quinquefasciatus*	Serrano, 2022 RI = 1 2761a/0222 6.7-01a A. gambiae not considered in the context of this minor change.
Repellent	Skin application	***Cinq sur cinq famille*** *Reference FC051 20% IR3535*	*Ixodes ricinus* 5 adults and 5 nymphs per mouse 10 mice	Derivated from OPPTS 810.3700 (2010) Vol II (Parts B&C) – Version 4.0 - December 2021	Choice test: Ticks placed on an untreated zone 3 cm away from the treated mouse. **Application rate: 41,8 mg / 44 cm² => 0.95 mg product/cm²** Records of the number of ticks crossing the	Test item has proven a complete protection over a period of 5 hours against the adults (5.3 h) and nymphs (5.1 h) of the tick *Ixodes ricinus*. Temperate conditions	Serrano, 2022 RI = 1 2761d/0222 6.7-01d

					separating line between the untreated area and the treated part. Test conditions in the room: 27°C ± 2 65%±5 %RH Light air extraction: 30 m^3 / h		

- **META-SPC 2 (First application) – new META SPC 2 and 5 (Minor change 2023)**

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% AF and CINQ SUR CINQ ZONE TEMPÉRÉES 25% NF**:

Experimental data on the efficacy of the biocidal product against target organism(s) – META SPC2 (First application)							
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 cm^3	WHO/HTM/NTD/WHOPES/ 2009.4	Arm in cage **0.44 g per 600 cm^2 => 0.73 mg/cm^2** **0.6 g per 600 cm^2 => 1 mg/cm^2** 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/cm^2 and 6H at 1 mg/cm^2 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 cm^2 => 1.383 mg/cm^2** 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 cm^2 (1.48 mg / cm^2) / 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	Drago, 2017 RI=2 CHLZOT270715-05b

Experimental data on the efficacy of the biocidal product against target organism(s) – META SPC2 (First application)							
						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	
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 cm^3	WHO/HTM/NTD/WHOPES/ 2009.4	Arm in cage **0.44 g per 600 cm^2 => 0.73 mg/cm^2** **0.6 g per 600 cm^2 => 1 mg/cm^2** 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/cm^2 and 6 H at 1 mg/cm^2 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 cm^2 => 1.383 mg/cm^2** Records of the number of ticks crossing the	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*.	Serrano, 2016c RI = 1 2228-CSCZT25%NF-ticks/0816

Experimental data on the efficacy of the biocidal product against target organism(s) – META SPC2 (First application)							
					separating line between the untreated area and the treated skin part.	Temperate conditions	
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 CHL25N27071 5-05b
Repellent	Skin application	***Cinq sur cinq zone tempérées 25% AF***	*Aedes aegypti Aedes albopictus Culex quinquefasciatus* 200 adult females /	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 :	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

Experimental data on the efficacy of the biocidal product against target organism(s) – META SPC2 (First application)							
			cages of 64000 cm^3		27°C 65% RH		
Repellent	Skin application	***Cinq sur cinq zone tempérées 25% 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

➢ **Minor change assessment 2023**

In the frame of this minor change:

- The composition of the products of the new META SPC 2 and 5 have been modified to replace one perfume by another one with a better toxicological profile, at the same content.
- To extend the complete protection time against mosquitoes and ticks, taking into account the new version of the efficacy guidance Vol II parts B&C on PT19 (2021) on these targets, the following efficacy studies with the product CINQ SUR CINQ ZONE TEMPÉRÉES (FC054 – new composition) on mosquitoes and ticks were provided:

Experimental data on the efficacy of the biocidal product against target organism(s) – META SPC2 & 5 (Minor change)							
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*** ***Reference FC054***	*Aedes albopictus* *Culex quinquefasciatus*	WHO/HTM/NTD/WHOPES/2009.4 Vol II (Parts B&C) – Version 4.0 - December 2021	Arm in cage **0.68 mg product/cm²** 3 minutes repeated every hour until the first landing and then every 30 minutes until proven inefficacy of the product.	Test item provided a complete protection over a period of: - 8.1H against *Ae albopictus*	Serrano, 2022 RI = 1 **Report 2761b/0222**

Experimental data on the efficacy of the biocidal product against target organism(s) – META SPC2 & 5 (Minor change)							
			100 adult females / cages of 64000 cm^3		10 volunteers Normal conditions : 27 ± 2 °C 80 ± 10% RH In the control: *Aedes spp*. 20 landings/minute *Culex spp*. 5 landings/minute *Anopheles spp*. 5 landings/minute Mortality: <0.3%	- 8.2H against *C. quinquefasciatus* - 7.5H against *A. gambiae*	6.7-02a The target A. gambia is not considered in the context of this Minor change
Repellent	Skin application	***Cinq sur cinq zone tempérées*** ***Reference FC054***	*Ixodes ricinus* 5 adults and 5 nymphs per mouse 10 mice	Derivated from OPPTS 810.3700 (2010) Vol II (Parts B&C) – Version 4.0 - December 2021	Choice test: Ticks placed on an untreated zone 3 cm away from the treated mouse. **Application rate: 40,92 mg / 44 cm^2 => 0.93 mg product/cm^2** Records of the number of ticks crossing the separating line between the untreated area and the treated part. Test conditions in the room: 27°C ± 2 °C 65% ± 5 %RH Light air extraction: 30 m^3 / h	Test item has proven a complete protection over a period of 5.5 hours against the adults (5.6 h) and nymphs (5.3 h) of the tick *Ixodes ricinus*. Temperate conditions	Serrano, 2022 RI = 1 2761e/0222 6.7-2e

- **META-SPC 3 (First application) – new META SPC 3 and 6 (Minor change 2023)**

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 (First application)							
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 cm^3	WHO/HTM/NTD/WHOPES/ 2009.4	Arm in cage **0.31g per 600 cm^2 => 0.52 mg/cm^2** 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/cm^2 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 cm^2 => 0.98 mg/cm^2** 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 cm^2 (1.07 mg / cm^2) / 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	Drago, 2017 RI=1 CHLTRO270715-05b

						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	
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 cm^3	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 cm^3	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]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

- **Minor change assessment 2023**

In the frame of this minor change:

- The composition of the products of the META SPC 3 and 6 have been modified to replace one perfume by another one with a better toxicological profile, at the same content. This change is considered to have no significant impact on the efficacy already demonstrated in the first authorisation. Nevertheless, the applicant requested an extension of the protection time against mosquitoes. Taking into account the new version of the efficacy guidance vol II parts B&C on PT19 (2021), the following efficacy study with the product CINQ SUR CINQ ZONE TROPIC (FC302 – new composition) was provided:

Experimental data on the efficacy of the biocidal product against target organism(s) – META SPC3 & 6 (Minor change)							
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 tropic*** ***Reference FC302***	*Aedes albopictus* *Culex quinquefasciatus* *Anopheles gambiae*	WHO/HTM/NTD/WHOPES/ 2009.4 Vol II (Parts B&C) – Version 4.0 - December 2021	Arm in cage **0.48 mg product/cm²** 3 minutes repeated every hour until the first landing and then every 30 minutes until	Test item provided a complete protection over a period of: - 8.2 H against *Ae albopictus* - 8.1 H against *C. quinquefasciatus*	Serrano, 2022 RI = 1 **Report 2761c/0222v2** 6.7-03b

(*): second data set

			100 adult females / cages of 64000 cm^3		proven inefficacy of the product. 10 volunteers Normal conditions : 27°C ± 2 °C 80 % ± 10 % RH In the control: *Aedes spp*. 20 landings/minute *Culex spp*. 5 landings/minute *Anopheles spp*. 5 landings/minute Mortality: <0.3%	- 7.4 H against *A. gambiae*	

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] 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.

[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.

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.

- **Minor change assessment 2023**

The elements presented in the dossier are sufficient to demonstrate that:

- The products related to the new Meta SPC 1 and 4 of the BPF "CINQ SUR CINQ LOTION" provide:
  - a complete protection time up to 5 hours against adult mosquitoes (*Culex spp*., *Aedes spp*.) at the application rate of 0.7 mg/cm², in temperate conditions.
  - a complete protection time up to 5 hours against ticks (*Ixodes ricinus*) at the application rate of 0.95 mg/cm², in temperate conditions.

- The products related to the new Meta SPC 2 and 5 of the BPF "CINQ SUR CINQ LOTION" provide:
  - a complete protection time up to 8 hours against adult mosquitoes (*Culex spp*., *Aedes spp*.) at the application rate of 0.68 mg/cm² (protection time up to 7 hours claimed),
  - a complete protection time up to 5.5 hours against ticks (*Ixodes ricinus)* at the application rate of 0.93 mg/cm² in temperate climate (protection time up to 5 hours claimed).

- The products related to the new Meta SPC 3 and 6 of the BPF "CINQ SUR CINQ LOTION" provide:
  - a protection up to 7.5 hours against adult mosquitoes (*Culex spp*., *Aedes spp*., and *Anopheles spp.*), at the application rate of 0.48 mg/cm² in tropical conditions (protection time up to 7 hours claimed).

2.2.5.6 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.

2.2.5.7 Known limitations

None

2.2.5.8 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] 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.

[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.

- 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

➢ **Minor change assessment 2023**

Please refer to the SPC.

2.2.5.9 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.

2.2.6 Risk assessment for human health

2.2.6.1 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.

- **Minor change assessment 2023**

The minor change does not affect the conclusion for skin corrosion and irritation. Please see the confidential PAR.

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.

- **Minor change assessment 2023**

The minor change does not affect the conclusion for eye irritation. Please see the confidential PAR.

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…).

- **Minor change assessment 2023**

The minor change does not affect the conclusion for respiratory tract irritation. Please see the confidential PAR.

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. <u>For meta SPC 1:</u> 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. **Minor change 2023:** Please see the confidential PAR for reorganisation and justification. Due to the addition or replacement of the new co-formulant and in order to maintain their regulatory compliance: • Former Meta SPC 1 → Split into new Meta SPC 1 and 4 • Former Meta SPC 2 → Split into new Meta SPC 2 and 5 • Former Meta SPC 3 → Split into new Meta SPC 3 and 6 **For new Meta SPC 1, 5 and 6:** EUH 208 "Contains 2-hexyl-3-phenyl-2- propenal (trans & cis), benzyl 2-hydroxybenzoate and linalyl acetate" May produce an allergic reaction. **For new Meta SPC 2, 3 and 4:** EUH 208 "Contains benzyl 2- hydroxybenzoate and linalyl acetate". May produce an allergic reaction.

- **Minor change assessment 2023**

Please see confidential PAR.
The minor change consists of the addition or replacement of a co-formulant by a new one in all three former Meta SPCs. In order to maintain their regulatory compliance:
• Former Meta SPC 1 → Split into new Meta SPC 1 and 4
• Former Meta SPC 2 → Split into new Meta SPC 2 and 5
• Former Meta SPC 3 → Split into new Meta SPC 3 and 6

For the new Meta SPC 1, 5 and 6, the EUH 208 mention is "Contains 2-hexyl-3-phenyl-2-propenal (trans & cis), benzyl 2-hydroxybenzoate and linalyl acetate. May produce an allergic reaction."
For the new Meta SPC 2, 3 and 4, the EUH 208 mention is "Contains benzyl 2-hydroxybenzoate and linalyl acetate. 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).

- **Minor change assessment 2023**

The minor change does not affect the conclusion for respiratory sensitisation. Please see the confidential PAR.

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

- **Minor change assessment 2023**

The minor change does not affect the conclusion for acute dermal, oral and inhalation toxicity. Please see the confidential PAR.

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_ XXXX et al XXXX

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.

- **Minor change assessment 2023**

The minor change does not affect the dermal absorption.

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

2.2.6.2 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	40.92 mg/44 cm2= 0.93 mg/cm2	29.04 mg/44 cm2= 0.66 mg/cm2

	(child ≥ 6 months old and adult: 1application/d)	(child ≥ 2 years old and adult : 1application/d)	(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 /m^3 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] 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].

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]

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.

[5] Proposal for harmonising the assessment of human exposure to repellents (PT19) Agreed at the HH WH III 2016

[6] Recommendation 11 of the BPC Ad hoc Working Group on Human Exposure : Proposal for harmonising the assessment of human exposure to repellents (PT19).

[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

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/cm^2: 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/cm^2: 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/cm^2: 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/cm^2: 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/cm^2: 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/cm^2: 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/cm^2: 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/cm^2: 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/cm^2: 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/cm^2: 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/cm^2: 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/cm^2: 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/cm^2: 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/cm^2: 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/cm^2: 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/cm^2: 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/cm^2: 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/cm^2: 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.

- **Minor change assessment 2023**

This minor change has no impact on the exposure assessment considering that the original META SPC 1 covers the new META SPC 1 and 4, the original META SPC 2 covers the new META SPC 2 and 5 and the original META SPC 3 covers the new META SPC 3 and 6.

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:

$$ID = \frac{ARp \times CIR3535 \times BS \times DA}{100 \times 100 \times BW}$$

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 (cm^2)	9130	Heeg opinion 17
	Body surface exposed to the product for **child (6-11 years)** considering exposure to 55% of area body (cm^2)	5060	Heeg opinion 17
	Body surface exposed to the product for **child (2-6 years)** considering exposure to 55% of area body (cm^2)	3740	Heeg opinion 17
	Body surface exposed to the product for **child (1-2 years)** considering exposure to 55% of area body (cm^2)	2640	Heeg opinion 17
	Body surface exposed to the product for **child (6-12 months)** considering exposure to 55% of area body (cm^2)	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 (cm^2)	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 (cm^2)	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 (cm^2)	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 (cm^2)	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 (cm^2)	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/cm^2)	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/cm^2)	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/cm^2)	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/cm^2)	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/cm^2)	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/cm^2)	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/cm^2)	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/cm^2)	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/cm^2)	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

- **Minor change assessment 2023**

This minor change has no impact on the exposure assessment for the non-professional users considering that the original META SPC 1 covers the new META SPC 1 and 4, the original META SPC 2 covers the new META SPC 2 and 5 and the original META SPC 3 covers the new META SPC 3 and 6.

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.			
	Parameters[1]	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)** (cm^2)	214	Heeg opinion 17
	Surface of one hand of a **child (2-6 years)** (cm^2)	165	Heeg opinion 17
	Surface of one hand of a **child (1-2 years)** (cm^2)	115	Heeg opinion 17
	Surface of one hand of a **child (6-12 months)** (cm^2)	98	Heeg opinion 17
Specific parameters			
Meta SPC 1 (worst case)	Average dose of product applied on skin (mg/cm^2)	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/cm^2)	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/cm^2)	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%

- **Minor change assessment 2023**

This minor change has no impact on the exposure assessment for the general public considering that the original META SPC 1 covers the new META SPC 1 and 4, the original META SPC 2 covers the new META SPC 2 and 5 and the original META SPC 3 covers the new META SPC 3 and 6.

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 use[1]**	**Description of scenario**	**Subject of exposure[2]**
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].
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) (cm^2)	230.4	297	415	427.8	820

[8] HEEG opinion 17: US EPA Exposure Factors Handbook (2011 Issue), which are derived from US EPA Analysis of NHANES 1999-2006

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]	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)

[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)]

- ***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) (cm^2)	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) (cm^2)	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) (cm^2)	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

2.2.6.3 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 AEL_{acute} (Rabbit, overall, developmental study/28-d study: NOAEL of 500	food	5 mg/kg/day

	mg/kg/day divided by a standard assessment factor of 100) is used		
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]	1	5	12.57	251.4	1	0	Unacceptable*

child 2-6 years							
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]	1	5	**5.38**	**107.5**	**1**	**0**	Unacceptable

child 2-6 years							
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]	**1**	**5**	**5.95**	**118.9**	**1**	**0**	**Unacceptable**

child 6-11 years							
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]	**2**	**5**	**6.26**	**125.2**	**1**	**0**	**Unacceptable**

child 6-11 years							
Scenario [9b] child 2-6 years	**2**	**5**	**7.16**	**143.3**	**1**	**0**	**Unacceptable**

- **Minor change assessment 2023**

This minor change has no impact on the risk characterisation for human health considering that the original META SPC 1 covers the new META SPC 1 and 4, the original META SPC 2 covers the new META SPC 2 and 5 and the original META SPC 3 covers the new META SPC 3 and 6.

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.

- **Minor change assessment 2023**

This minor change has no impact on the conclusion considering that the original META SPC 1 covers the new META SPC 1 and 4, the original META SPC 2 covers the new META SPC 2 and 5 and the original META SPC 3 covers the new META SPC 3 and 6.

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.

➢ **Minor change assessment 2023**

This minor change has no impact on the conclusion considering that the original META SPC 1 covers the new META SPC 1 and 4, the original META SPC 2 covers the new META SPC 2 and 5 and the original META SPC 3 covers the new META SPC 3 and 6.

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.

➢ **Minor change assessment 2023**

This minor change has no impact on the risk characterisation for the general public considering that the original META SPC 1 covers the new META SPC 1 and 4, the original META SPC 2 covers the new META SPC 2 and 5 and the original META SPC 3 covers the new META SPC 3 and 6.

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

2.2.7 Risk assessment for animal health

Not relevant

2.2.8 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 family, 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 family.
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.

2.2.8.1 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
$PNEC_{aqua}$ (mg/L)	100 (the highest tested concentration inducing no toxicological effect) /1000 (default assessment factor when only short term data is available)	0.1
$PNEC_{sediment}$ (mg/kg_{wwt})	By equilibrium partition method PNEC sed = $(K_{susp\text{-}water}/RHO_{susp})*PNEC_{aqua}*1000$ and K_{OC}=475.25 L/kg	1.11
$PNEC_{soil}$ (mg/kg_{wwt})	By equilibrium partition method PNEC soil = $(K_{soil\text{-}water}/RHO_{soil})*PNEC_{aqua}*1000$ and VP=0.15Pa and WS=70 000 mg/L	0.85
$PNEC_{STP}$ (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).

2.2.8.2 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 cm^2 (= 9130 cm^2), 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			

N_{local} : 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.
$Qform_{appl}$: consumption per application	1.95	[$mg.cm^{-2}$]	S - Worst case use
N_{appl} : number of applications per day	1	[d^{-1}]	S - Worst case use
$AREA_{skin}$: 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
F_{air} : fraction released to air	0	[-]	D – ESD-PT19 (2015)
F_{skin} : fraction dermally absorbed	0	[-]	D – ESD-PT19 (2015)
F_{water} : Fraction released to waste water	1	[-]	D – ESD-PT19 (2015)
F_{inh} : Fraction of inhabitants using a repellent product	0.2	[-]	P - table 3-5 of ESD_PT19 (2015)
F_{penetr} : 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**
$Elocal_{water}$	**6.47E+00 $kg.d^{-1}$**	O - Eq. 5 of BPR-guidance vol.IV–part.B (2015)
$C_{local,inf}$	3.24E+00 $mg.L^{-1}$	O - Eq. 32 of BPR-guidance vol.IV–part.B (2015)
$Fstp_{water}$	1.00E-02	S - Estimation by EUSES/simple treat
$C_{local,eff}$ = PEC_{STP}	**3.24E-02 $mg.L^{-1}$**	O - Eq. 33 of BPR-guidance vol.IV–part.B (2015)
Kp_{susp}	4.75E+01 $L.kg^{-1}$	O - Eq. 23 of BPR-guidance vol.IV–part.B (2015)
$PEC_{local,water}$	**3.23E-03 $mg.L^{-1}$**	O - Eq. 48 of BPR-guidance vol.IV–part.B (2015)
$K_{susp-water}$	1.28E+01 $m^3.m^{-3}$	O - Eq. 24 of BPR-guidance vol.IV–part.B (2015)
$PEC_{local,sed}$	**3.60E-02 $mg.kg^{-1}_{wwt}$**	O - Eq. 50 of BPR-guidance vol.IV–part.B (2015)
$PEC_{local,soil}$	**0.00E+00 $mg.kg^{-1}_{wwt}$**	O - Negligeable in the present situation (99% elimination in STP simulation test. 1% goes in water effluent).

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/cm^2 for the product containing 200 g/kg.

It is worth noting that the value for $AREA_{skin}$ has been revised recently (WGI2017) to a harmonized value of 10660 cm^2, corresponding to 64% of the total body surface. As the higher surface area (16600 cm^2) 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.			
$N_{swimmer}$: daily number of swimmers	1500	[-]	D – ESD-PT19 (2015)
$Cform_{weight}$: active substance in the product	200	[$g.kg^{-1}$]	S - worst case use
$Qform_{appl}$: consumption per application	1.95	[$mg.cm^{-2}$]	S - worst case use
N_{appl} : number of applications per day	1	[d^{-1}]	D - ESD_PT19 (2015)
$AREA_{skin}$: 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
F_{swim} : fraction of swimmers using the repellent product	0.1	[-]	D for product autorisation - ESD_PT19 (2015)
$F_{waterbody}$: 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)
$V_{waterbody}$: volume of water body	435000	[m^3]	D - ESD_PT19 (2015)
$T_{emission,1d}$ $T_{emission,91d}$: number of emission days	1 91	[d]	D - ESD_PT19 (2015)
$N_{emission,91d}$: 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**
$Elocal_{water}$	**0.97 $kg.d^{-1}$**	O - eq. 3.12- ESD_PT19 (2015)
$Kdeg_{water}$	4.45E-02 d^{-1}	S - calculated considering a DT50(12°C) = 15.59 days
$Clocal_{water,1d}$	2.23E-03 $mg.L^{-1}$	O - eq. 3.13 of ESD_PT19 (2015)
$Clocal_{water,91d}$	2.03E-01 $mg.L^{-1}$	O - eq. 3.14 of ESD_PT19 (2015)
$Clocal_{water,91d-ref}$	5.04E-02 $mg.L^{-1}$	O - eq. 3.15 of ESD_PT19 (2015)
$PEC_{local,water}$	**5.04E-02 $mg.L^{-1}$**	Eq. 48 of BPR-guidance vol.IV–part.B (2015)
Kp_{susp}	47.525 $L.kg^{-1}$	Eq. 23 of BPR-guidance vol.IV–part.B (2015)
$K_{susp-water}$	12.78125 $m^3.m^{-3}$	Eq. 24 of BPR-guidance vol.IV–part.B (2015)
$PEC_{local,sed}$	**5.61E-01 $mg.kg^{-1}_{wwt}$**	Eq. 50 of BPR-guidance vol.IV–part.B (2015)

Infobox 5 –

For scenario 2 (direct release via swimming after skin application),

We do not agree with the DT_{50} 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 cm^2 (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.				
DT_{50} total – IR3535 free acid *	299.64	299.64	[d]	
$N_{swimmer}$: daily number of swimmers	1500	1500	[-]	D – ESD-PT19 (2015)
$Cform_{weight}$: active substance in the product	200	250	[$g.kg^{-1}$]	S - worst case use
$Qform_{appl}$: consumption per application	1.95	0.73	[$mg.cm^{-2}$]	S - worst case use
N_{appl} : number of applications per day	1	1	[d^{-1}]	D - ESD_PT19 (2015)
$AREA_{skin}$: 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
F_{swim} : fraction of swimmers using the repellent product	0.1/0.02**	0.1/0.02**	[-]	D - ESD_PT19 (2015)
$F_{waterbody}$: 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)
$V_{waterbody}$: volume of water body	435000	435000	[m^3]	D - ESD_PT19 (2015)
$T_{emission,1d}$ $T_{emission,91d}$: number of emission days	1 91	1 91	[d]	D - ESD_PT19 (2015)
$N_{emission,91d}$: number of emission events	91	91	[-]	D - ESD_PT19 (2015)

* The DT_{50} 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 F_{swin} 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 (F_{swim} : 0.02)	**Higher insect infestation (F_{swim} : 0.1)**	
$Elocal_{water}$	**0.12 kg.d^{-1}**	**0.62 kg.d^{-1}**	eq. 3.12- ESD_PT19 (2015)
$PEC_{local,water}$	**2.36E-02 mg.L^{-1}**	**1.18E-01 mg.L^{-1}**	eq. 3.15 of ESD_PT19 (2015)
$PEC_{local,sed}$	**2.62E-01 mg.kg^{-1}_{wwt}**	**1.31 mg.kg^{-1}_{wwt}**	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 (F_{swim} : 0.02)	**Higher insect infestation (F_{swim} : 0.1)**	
$Elocal_{water}$	**0.06 kg.d^{-1}**	**0.29 kg.d^{-1}**	eq. 3.12- ESD_PT19 (2015)
$PEC_{local,water}$	**1.10E-02 mg.L^{-1}**	**5.51E-02 mg.L^{-1}**	eq. 3.15 of ESD_PT19 (2015)
$PEC_{local,sed}$	**1.23E-01 mg.kg^{-1}_{wwt}**	**6.13E-01 mg.kg^{-1}_{wwt}**	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		
DT_{50} 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 DT_{50} 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				
	PEC_{STP}	**PEC_{water}**	**PEC_{sed}**	**PEC_{soil}**
	[mg/L]	[mg/l]	[mg/kg_{wwt}]	[mg/m^3]
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)	**PEC_{STP}**	**PEC_{water}**	**PEC_{sed}**	**PEC_{soil}**
	[mg/m^3]	[mg/L]	[mg/kg_{wwt}]	[mg/m^3]
Low insect infestation (F_{swim} : 0.02)	NR	1.10E-02	1.23E-01	NR
High insect infestation (F_{swim} : 0.1)	NR	5.51E-02	6.13E-01	NR

Summary table on calculated PEC values only for Horseflies/Ticks				
Scenario 2 (horseflies/ticks)	**PEC_{STP}**	**PEC_{water}**	**PEC_{sed}**	**PEC_{soil}**
	[mg/m^3]	[mg/L]	[mg/kg_{wwt}]	[mg/m^3]
Low insect infestation (F_{swim} : 0.02)	NR	2.36E-02	2.62E-01	NR
High insect infestation (F_{swim} : 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.

2.2.8.3 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	
	$PEC/PNEC_{STP}$
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		
	$PEC/PNEC_{water}$	**$PEC/PNEC_{sed}$**
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)**	**$PEC/PNEC_{water}$**	**$PEC/PNEC_{sed}$**
Low insect infestation (F_{swim} : 0.02)	1.10E-01	1.10E-01
High insect infestation (F_{swim} : 0.1)	5.51E-01	5.51E-01

Summary table on calculated PEC/PNEC values		
Scenario 2 **(horseflies/ticks)**	**$PEC/PNEC_{water}$**	**$PEC/PNEC_{sed}$**
Low insect infestation (F_{swim} : 0.02)	2.36E-01	2.36E-01
High insect infestation (F_{swim} : 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 cm^2 (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 cm^2 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/PNEC$_{water}$**	**PEC/PNEC$_{sed}$**
High insect infestation (F_{swim} : 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/PNEC$_{soil}$
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/PNEC$_{STP}$	**ΣPEC/PNEC$_{water}$**	**ΣPEC/PNEC$_{sed}$**	**ΣPEC/PNEC$_{soil}$**
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/PNEC$_{STP}$	**ΣPEC/PNEC$_{water}$**	**ΣPEC/PNEC$_{sed}$**	**ΣPEC/PNEC$_{soil}$**
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.

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.

Infobox 12 –

We agree with the applicant conclusions considering the strict practical uses claimed by the applicant.

- **Minor change assessment 2023**

The minor changes (replacement of a co-formulant and modification of the protection time against mosquitoes and ticks) have no impact on the classification of the biocidal product, nor on the analysis of the substances of concern nor on the environmental risk assessment (see more details in the confidential PAR). The initial conclusion remains unchanged.

2.2.9 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.

2.2.10 Assessment of a combination of biocidal products

Not relevant

2.2.11 Comparative assessment

Not relevant

3 ANNEXES

3.1 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	

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
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	

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
Serrano, B.	2022	Simulated-use trial of a skin mosquito repellent product Trial against Aedes albopictus, Culex quinquefasciatus and Anopheles gambiae Report No. 2761a/0222	YES	Laboratoire CHAUVIN	
Serrano, B.	2022	Laboratory trial of a skin tick repellent product Trial against Ixodes ricinus Report No. 2761d/0222	YES	Laboratoire CHAUVIN	
Serrano, B.	2022	Simulated-use trial of a skin mosquito repellent product Trial against Aedes albopictus, Culex quinquefasciatus and Anopheles gambiae Report No. 2761b/0222	YES	Laboratoire CHAUVIN	
Serrano, B.	2022	Laboratory trial of a skin tick repellent product Trial against Ixodes ricinus Report No. 2761e/0222	YES	Laboratoire CHAUVIN	
Serrano, B.	2022	Simulated-use trial of a skin mosquito repellent product Trial against Aedes albopictus, Culex quinquefasciatus and Anopheles gambiae Report No. 2761c/0222	YES	Laboratoire CHAUVIN	

3.2 Output tables from exposure assessment tools

See excel data sheet

expo - post CG.xlsx

3.3 New information on the active substance

Not relevant

3.4 Residue behaviour

Not relevant

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

See IUCLID files

3.6 Confidential annex

See the relevant document in annex

3.7 Other

Not relevant