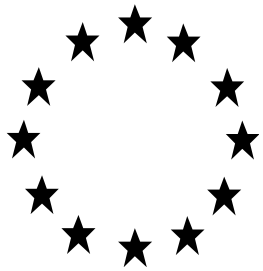
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS

(submitted by the evaluating Competent Authority)



[CYPERNET]

Product type(s) [18]

[Cypermethrin]

Case Number in R4BP: [BC-KK059722-31]

Evaluating Competent Authority: [ANSES – FR CA]

Date: [01/2023]

In this template:

- **Explanatory notes are marked as follows:**

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Explanatory note for the use of this template:

The PAR (i.e. "DRAFT RISK ASSESSMENT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS (submitted by the applicant)") together with the IUCLID file and the SPC replaces the formerly valid formats of Document I, II and III which were in use under Directive 98/8/EC according the former Guidance document "TNsG on Preparation of Dossiers and Study Evaluation".

The PAR template should allow for a certain flexibility. Free text may be added, where necessary, and the content of the section may be adapted to the specific needs required for the different product types. Also tables can be added or deleted, when needed.

The PAR template is suitable for both a single biocidal product and a biocidal product. The content of the template can be adapted accordingly.

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1 CONCLUSION

The product CYPERNET is a net TP18 with the active substance cypermethrin and intended to be used by professionals as a barrier between two spaces or as a protection for materials and goods against numerous different flying and crawling insects.

Conclusion on APCP

CYPERNET is an LN (Long lasting insecticidal net). All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable.
A 2 years shelf-life is proposed, awaiting the final results of the long term stability study. All packaging can be considered as acceptable.
Its technical characteristics are acceptable for an LN formulation.
Final long-term storage study is required in post-authorization. The product is not classified for physical hazard aspect.

Analytical method for the determination of cypermethrin in the product CYPERNET was provided and validated. Monitoring methods for the determination of cypermethrin (soil, water, air, foodstuffs of plant and animal origin) are addressed by active substance data in the CAR.

Conclusion on efficacy

According to the requirements of Efficacy guidance Vol II part B/C, the product CYPERNET (28 months-stored product) is efficient for the protection of commodities, premises and livestock building (except for flies):
- against mosquitoes (*Culex sp, Aedes sp, Anopheles sp*), biting midge (*Culicoides sp*) and flies (*M.domestica, S.calcitrans*) as a separation between areas,
- against clothes moths (*Tineola bisselliella*) as a protective barrier to seal pallets/Stored items.

Efficacy is not demonstrated for stored goods-attacking insects (grain weevil *(Sitophilus granaries)*, rice weevil *(Sitophilus oryzae*), lesser grain borer *(Rhizopertha dominica*), saw-tooth beetle *(Oryzaephilus surinamensis*), mites (cacao moth (*Ephestia elutella),* indian meal moth (*Plodia interpunctella),* mediterranean flour moth (*Ephestia kuehniella),* tobacco beetle *(Lasioderma serricorne)),* black garden ants (*Lasius niger), and* bed bugs (*Cimex lectularius*), since no field test has been submitted.

According to lab studies, efficacy is validated up to 18 months after nets openings.

Conclusion for human health:

The risk is acceptable for professional and general public in the condition claimed in the SPC.

Conclusion relating to indirect exposure via food

Considering the intended use, poultry exposure via consumption of dead insects contaminated with the product cannot be excluded. Poultry exposure and human exposure via consumption of poultry products were estimated. No risk for consumers via residues in food is expected. Nevertheless, based on a worst case exposure scenario, exceedance of current EU MRL in poultry tissues and eggs (set under regulation (EC) No 396/2005) arising from biocidal use intended in this dossier cannot be excluded. Refinement of residue estimation is not possible in absence of robust quantative data. Consequently, the product cannot be used in poultry buildings.

Conclusion on Environment:

According to the claimed uses of the biocidal product CYPERNET, a qualitative approach has been taken for the environmental risk assessment. It is intended for professional indoor use only. There is no potential exposure to rainfall and the wet cleaning whilst the product is in situ is not intended. Therefore no emission to the environment are expected and risks are acceptable for the biocidal product if the following instructions of use are applied:

- *Apply indoor only.*
- *Use only in areas kept away from water (not subject to washing / sluicing / weathering).*
- *This biocidal net MUST NOT be washed, due to risk to the environment.*
- *Use the biocidal net as indicated in the instructions for use. Do not use for other purposes.*
- *Remove all pieces of biocidal nets pre-cleaning and/or disinfectant events.*

Overall conclusion.

Target organisms	Doses	Condition of use	Conclusions
Insecticide efficacy against crawling insects (*Sitophilus granarius* (grain weevil - adults), *Sitophilus oryzae* (rice weevil -adults), *Rhizopertha dominica* (lesser grain borer -adults), *Oryzaephilus surinamensis* (saw-tooth beetle -adults), *Lasius niger* (common black ant -adults), *Cimex lectularius* (bed bug -adults), *Lasioderma serricorne* (tobacco beetle -adults)) and flying insects (*Ephestia elutella* (cacao moth –adults & nymphs), *Tineola bisselliella* (clothe moth – adults & nymphs), *Plodia interpunctella* (Indian meal moth –adults & nymphs), *Ephestia kuehniella* (Mediterranean flour moth – adults & nymphs), *Stomoxys calcitrans* (stable fly -adults), *Musca domestica* (common house fly -adults), *Culicoides imicola* (biting midge - adults), *Aedes albopictus* (Tiger mosquito -adults), other mosquito (*Culex pipiens* and *Anopheles gambiae*)	0.5% of cypermethrin	Manual application, indoor. Install the net : - as a 'curtain' (to ensure zone separation) within a structure/premises (e.g. custom unit, warehousing) or to seal windows or unused opening/portals - As a protective barrier: to seal pallets/stored items (e.g. packaged stored foodstuffs, wood, paper, fabrics, carpets, textiles, cloth), or by the placement of swatches in areas of pest harborage (under mattresses, behind headboards) or where specific stored items are susceptible to pest damage (e.g. museum display units).	**Not acceptable:** Efficacy not demonstrated.
Biting midge (adults) *Culicoides sp* Mosquito (adults) *Aedes sp* *Culex sp* *Anopheles sp* Flies (adults) *M.domestica* *S.calcitrans*	0.5% of cypermethrin	Manual application, indoor for the protection of commodities, premises and livestock building (except flies and in poultry building) . Install the net as a 'curtain' (to ensure zone separation) within a structure/premises (e.g. custom unit, warehousing) or to seal windows or unused opening/portals	**Acceptable**
Tineola bisselliella (clothe moth –adults & nymphs)	0.5% of cypermethrin	Manual application, indoor for the protection of commodities, premises and livestock building (except in poultry building). Protective barrier to seal pallets/stored items	**Acceptable**

2 2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product

Identifier[1]	**Country (if relevant)**
CYPERNET I.N.S Insect Net Solution	France, Germany, Italy, Belgium, Spain, Switzerland Belgium

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	Edialux France
	Address	Z.A. Macon EST 01750 Replonges France
Authorisation number		
Date of the authorisation		
Expiry date of the authorisation		

2.1.1.3 Manufacturer(s) of the products

Name of manufacturer	Shanghai Siang May Ltd.
Address of manufacturer	Room No.11A66, 2299 Yan'An West Road 200336 Shanghai City China
Location of manufacturing sites	Room No.11A66, 2299 Yan'An West Road 200336 Shanghai City China

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

Active substance	Cypermethrin
Name of manufacturer	Arysta Lifesciences Benelux Sprl.
Address of manufacturer	Rue de Rénory 26/1 BE-4102 Ougrée Belgium
Location of manufacturing sites	Lote Parshuram Tal. Khed Dist. Ratnagiri 415 722 Maharashtra, India

Active substance	Cypermethrin
Name of manufacturer	LIMARU NV (Acting for Tagros Chemicals India Private Limited)
Address of manufacturer	LIMARU NV

1 Please fill in here the identifying product name from R4BP.

	Business Center Mezzo Paalsesteenweg 170 Bus 7 3583 Beringen
Location of manufacturing sites	Tagros Chemicals India Private Ltd A-4/1 & 2, SIPCOT Industrial Complex 607005 Pachayankuppam Cuddalore Tamilnadu India

2.1.2 Product composition and formulation

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

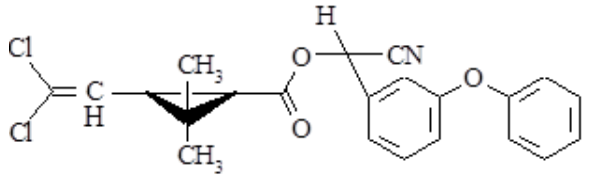
Does the product have the same identity and composition as the product evaluated in connection with the approval for listing of the active substance(s) on the Union list of approved active substances under Regulation No. 528/2012?

Yes ☐
No ☒

2.1.2.1 Identity of the active substance

Main constituent(s)	
ISO name	Cypermethrin, Cypermethrin cis:trans/40:60
IUPAC or EC name	(RS)-α-cyano-3 phenoxybenzyl-(1RS)-cis, trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropane carboxylate
EC number	257-842-9
CAS number	52315-07-8
Index number in Annex VI of CLP	607-421-00-4
Minimum purity / content	Minimum purity: 92% Cypermethrin cis:trans/40(±5):60(±5)

Cis I	23.3%
Cis II	16.8%
Total Cis Isomers	40.1%
Trans I	35.8%
Trans II	24.1%
Total Trans Isomers	59.9%

Structural formula	

2.1.2.2 Candidate(s) for substitution

Cypermethrin is not a candidate for substitution in accordance with Article 10 of the BPR.

2.1.2.3 Qualitative and quantitative information on the composition of the biocidal product

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Cypermethrin	(RS)-α-cyano-3 phenoxybenzyl-(1RS)-cis, trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropane carboxylate	Active substance	52315-07-8	257-842-9	0.5 – including carrier)

The product consists of 100% technical cypermethrin on a HDPE carrier.

2.1.2.4 Information on technical equivalence

The active substance (cypermethrin) contained in the product 'CYPERNET' is from the same source as the active substance (cypermethrin) listed in the Union list of approved active substances under Regulation No. 528/2012. Arysta Lifesciences Benelux Sprl and LIMARU NV (Acting for Tagros Chemical India Private Limited) (TE: TAP-D-1477453-13-00/F) are the active substance suppliers for the product 'CYPERNET'.

2.1.2.5 Information on the substance(s) of concern

There is no substance of concern in the product.

2.1.2.6 Assessment of endocrine disruption (ED) properties of the biocidal product

The BPF does not contain any active substances having endocrine-disrupting properties.

2.1.2.7 Type of formulation

LN- Long lasting insecticidal net

2.1.3 Hazard and precautionary statements[2]

Classification and labelling of the products according to the Regulation (EC) 1272/2008

[It should also be stated if some P statements triggered by the criteria in CLP has been excluded due to the risk assessment.]

2 For micro-organisms based products: indication on the need for the biocidal product to carry the biohazard sign specified in Annex II to Directive 2000/54/EC (Biological Agents at Work).

Classification	
Hazard category	Acute Tox. 4 (Oral) Acute Tox. 4 (Inhalation) STOT SE 3 STOT RE 2 Aquatic Acute 1 Aquatic Chronic 1
Hazard statement	H302: Harmful if swallowed H332: Harmful if inhaled H335: May cause respiratory irritation H373: May cause damage to organs (nervous system) through prolonged or repeated exposure H400: Very toxic to aquatic life H410: Very toxic to aquatic life with long lasting effects
Labelling	
Signal words	Warning
Hazard statements	H302+H332: Harmful if swallowed or inhaled H335: May cause respiratory irritation H373: May cause damage to organs (nervous system) through prolonged or repeated exposure H410: very toxic to aquatic life with long lasting effects
Precautionary statements	~~P260: Do not breathe dust/fume/gas/mist/vapours/spray.~~ ~~P261: Avoid breathing dust/fume/gas/mist/vapours/spray.~~ P264: Wash hands thoroughly after handling. P270: Do not eat, drink or smoke when using this product. ~~P271: Use only outdoors or in a well-ventilated area.~~ P301: IF SWALLOWED: P312: Call a POISON CENTER/doctor if you feel unwell. P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing. P330: Rinse mouth. P314: Get medical advice/attention if you feel unwell. P403 + P233: Store in a well-ventilated place. Keep container tightly closed. P405: Store locked up. P273: Avoid release to the environment. P501: Dispose of contents/containers in accordance with local regulations.
Note	Considering that the very low Pvapor of cypermethrin (10^{-7}Pa) and the lack of formation of dust/fume/gas/mist and spray, the exposure via inhalation could not occur, P260, P261 and P271 are deleted.

2.1.4 Authorised use(s)

2.1.4.1 Use description[3]

Table 1. Use # 1 – **Insecticide net – zone separation**

Product Type	**18**
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	Mosquitoes (*Culex sp, Aedes sp, Anopheles sp*), adults Biting midge (*Culicoides sp*), adults Flies (*M.domestica*, *S.calcitrans*), adults
Field of use	The product may be applied/used indoors (commodities, premises and livestock buildings (except for flies and in poultry buildings) as follows: • As a 'curtain' (to ensure zone separation) within a structure/premises (e.g. custom unit, warehousing) or to seal windows or unused opening/portals Indoor Use Only
Application method(s)	Long lasting net
Application rate(s) and frequency	Ready to use
Category(ies) of users	Professionals
Pack sizes and packaging material	Opaque HDPE bag covering roll of net Size: 2.4m x 50m 2.4m x 25m 2.4m x 10m 0.15m x 50m 0.30m x 50m 2.4m x 2.4m 2m X 2.4m

2.1.4.2 Use-specific instructions for use[4]

- Do not use against flies in livestock buildings.

3 Copy this section as many times as necessary (one table per use, together with any instructions for use, risk mitigation measures and other directions for use that are use-specific. It has to be noted that in accordance with Document CA-May14-Doc.5.6 – Final, the SPC of a biocidal product presents the authorised uses as a number of pre-defined uses to which the product label shall have full correspondence.

4 Describe the necessary instructions for use like for example: period of time needed for the biocidal effect; the interval to be observed between applications of the biocidal product or between application and the next use of the product treated, or the next access by humans or animals to the area where the biocidal product has been used, including particulars concerning decontamination means and measures and duration of necessary ventilation of treated areas; particulars for adequate cleaning of equipment; particulars concerning precautionary measures during transport; precautions to be taken to avoid the development of resistance.

2.1.4.3 Use-specific risk mitigation measures

-

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

-

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

-

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

-

2.1.4.7 Use description[5]

Table 2. Use # 2 – **Insecticide net – protective barrier of pallets/stored items**

Product Type	**18**
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	*Tineola bisselliella* (clothes moth –larvae)
Field of use	The product may be applied/used indoors (commodities, premises and livestock buildings except poultry building) as follows: • As a protective barrier: to seal pallets/stored items Indoor Use Only
Application method(s)	Long lasting net
Application rate(s) and frequency	Ready to use
Category(ies) of users	Professionals
Pack sizes and packaging material	Opaque HDPE bag covering roll of net Size: 2.4m x 50m 2.4m x 25m

5 Copy this section as many times as necessary (one table per use, together with any instructions for use, risk mitigation measures and other directions for use that are use-specific. It has to be noted that in accordance with Document CA-May14-Doc.5.6 – Final, the SPC of a biocidal product presents the authorised uses as a number of pre-defined uses to which the product label shall have full correspondence.

	2.4m x 10m 0.15m x 50m 0.30m x 50m 2.4m x 2.4m 2m X 2.4m

2.1.4.8 Use-specific instructions for use[6]

-

2.1.4.9 Use-specific risk mitigation measures

-

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

-

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

-

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

-

6 Describe the necessary instructions for use like for example: period of time needed for the biocidal effect; the interval to be observed between applications of the biocidal product or between application and the next use of the product treated, or the next access by humans or animals to the area where the biocidal product has been used, including particulars concerning decontamination means and measures and duration of necessary ventilation of treated areas; particulars for adequate cleaning of equipment; particulars concerning precautionary measures during transport; precautions to be taken to avoid the development of resistance.

2.1.5 General directions for use

2.1.5.1 Instructions for use[7]

- Comply with the instructions for use.
- Alternate products containing active substances with a different mode of action (to remove resistant individuals from the population).
- Adopt integrated pest management methods such as the combination of chemical, physical control methods and other public health measures, taking into account local specificities (climatic conditions, target species, conditions of use, etc).
- Inform the registration holder if the treatment is ineffective.
- Replace the net if damaged (e.g. holes).
- Replace the nets in place after 18 months.
- Apply indoor only.
- Use only in areas kept away from water (not subject to washing / sluicing / weathering).
- This biocidal net MUST NOT be washed, due to risk to the environment.
- Use the biocidal net as indicated in the instructions for use. Do not use for other purposes.
- Do not use the product in poultry buildings.
- Remove all pieces of biocidal nets pre-cleaning and/or disinfectant events.

2.1.5.2 Risk mitigation measures

- The product has to be applied in area, where contact with animals and general public is avoided.
- Place the product out of reach of livestock.
- Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) during handling of the net.
- Avoid contact with skin.
- Do not use the product on food or feed.
- Keep cats away from treated net. Due to their particular sensitivity to pyrethroid the product can cause severe adverse reactions in cats.

2.1.5.3 Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

Pyrethroids may cause paresthesia (burning and prickling of the skin without irritation).
If symptoms persist: Get medical advice.

IF ON SKIN: Wash skin with water. If symptoms occur call a POISON CENTRE or a doctor.
IF SWALLOWED: Rinse mouth.
If symptoms: Call 112/ambulance for medical assistance.
If no symptoms: Call a POISON CENTRE or a doctor.

[7] Describe the necessary instructions for use like for example: period of time needed for the biocidal effect; the interval to be observed between applications of the biocidal product or between application and the next use of the product treated, or the next access by humans or animals to the area where the biocidal product has been used, including particulars concerning decontamination means and measures and duration of necessary ventilation of treated areas; particulars for adequate cleaning of equipment; particulars concerning precautionary measures during transport; precautions to be taken to avoid the development of resistance.

IF IN EYES: If symptoms occur rinse with water. Remove contact lenses, if present and easy to do. Call a POISON CENTRE or a doctor.
IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing.
If symptoms: Call 112/ambulance for medical assistance.
If no symptoms: Call a POISON CENTRE or a doctor.

2.1.5.4 Instructions for safe disposal of the product and its packaging

- Do not discharge unused product, residues or pieces of product on the ground or into water courses.
- Dispose of unused product, its packaging and all other waste in accordance with local regulations.
- At the end of treatment, the net must be considered as hazardous waste.

2.1.5.5 Conditions of storage and shelf-life of the product under normal conditions of storage

- Shelf-life: 2 years

2.1.6 Other information

- Instructions and RMMs must be fixed to the net.

2.1.7 Packaging of the biocidal product

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)
Bag covering roll of net	2.4m x 50m	HDPE	Opaque bag	professional	Yes
	2.4m x 25m	HDPE	Opaque bag	professional	Yes
	2.4m x 10m	HDPE	Opaque bag	professional	Yes
	0.15m x 50m	HDPE	Opaque bag	professional	Yes
	0.30m x 50m	HDPE	Opaque bag	professional	Yes
	2.4m x 2.4m	HDPE	Opaque bag	professional	Yes
	2m X 2.4m	HDPE	Opaque bag	professional	Yes

** The HDPE net consists of 2x1 inlay mesh nets.*
Yarn diameter: 0,21mm,

Mesh size: 2.2 – 2.0 mm
Weight: 120gms
Number of meshes per cm^2: 16

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

No new data is submitted in support of the product authorisation on the active substance.

Efficacy data: New data have been submitted in the purpose of product authorisation. All documents are available in IUCLID and are listed in annex.

2.1.8.2 Access to documentation

A letter of Access is submitted for the complete active substance dossier for cypermethrin from the active substance supplier Arysta Lifesciences Benelux Sprl.

2.2 Assessment of the biocidal product

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

Table 2. Intended use # 1 – **Insecticide net - indoor**

Product Type(s)	18
Where relevant, an exact description of the authorised use	
Target organism (including development stage)	Insecticide efficacy against crawling insects (*Sitophilus granarius* (grain weevil -adults), *Sitophilus oryzae* (rice weevil -adults), *Rhizopertha dominica* (lesser grain borer -adults), *Oryzaephilus surinamensis* (saw-tooth beetle -adults), *Lasius niger* (common black ant -adults), *Cimex lectularius* (bed bug -adults), *Lasioderma serricorne* (tobacco beetle -adults)) and flying insects (*Ephestia elutella* (cacao moth –adults & nymphs), *Tineola bisselliella* (clothe moth –adults & nymphs), *Plodia interpunctella* (Indian meal moth –adults & nymphs), *Ephestia kuehniella* (Mediterranean flour moth –adults & nymphs), *Stomoxys calcitrans* (stable fly -adults), *Musca domestica* (common house fly -adults), *Culicoides imicola* (biting midge -adults), *Aedes albopictus* (Tiger mosquito -adults), *Culex pipiens* and *Anopheles gambiae*)
Field of use	The product 'CYPERNET' is used for the protection of commodities, premises and livestock buildings from crawling and/or flying pests. The product may be applied/used indoors as follows: • As a 'curtain' (to ensure zone separation) within a structure/premises (e.g. custom unit, warehousing). • As a protective barrier to seal pallets/stored items (e.g. packaged stored foodstuffs, wood, paper, fabrics, carpets, textiles, cloth). • As a protective barrier to seal windows or unused opening/portals. • By the placement of swatches in areas of pest harborage (under mattresses, behind headboards) or where specific stored items are susceptible to pest damage (e.g. museum display units). Indoor Use Only
Application method(s)	Manual application Installation of netting as physical barrier and/or discreet placement of netting swatches in areas of pest harbourage.
Application rate(s) and frequency	Net is effective for 24 months
Category(ies) of user(s)	Professional use (only)

Pack sizes and packaging material	The net is available in various sizes packaged in an opaque HDPE bag. Please see the relevant section for details

2.2.2 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Comments
Explosives	n/a	n/a	WAIVER – A study does not need to be conducted because there are no chemical groups present in components of the product associated with explosive properties. Cypermethrin also has a harmonised classification that does not include explosivity.	n/a	Acceptable Viewing the composition of the product (see confidential annex), the product is not expected to have explosive properties according to CLP regulation.
Flammable gases	n/a	n/a	WAIVER – The product is not a gas.	n/a	
Flammable aerosols	n/a	n/a	WAIVER – The product is not an aerosol.	n/a	
Oxidising gases	n/a	n/a	WAIVER – The product is not a gas.	n/a	
Gases under pressure	n/a	n/a	WAIVER – The product is not a gas.	n/a	
Flammable liquids	n/a	n/a	WAIVER – The product is not a liquid.	n/a	
Flammable solids	n/a	n/a	WAIVER – The product is an extruded net and cypermethrin has a harmonised classification that does not include flammability. The other components of the product are also not classified as flammable.	n/a	Acceptable Viewing the composition of the product (see confidential annex), the product is not expected to have flammable properties according to CLP regulation.
Self-reactive substances and mixtures	n/a	n/a	WAIVER – The product is an extruded net. Cypermethin has a harmonised classification that does not include explosivity or self-reactivity. The other components of the product are also not classified as self-reactive.	n/a	Acceptable Viewing the composition of the product (see confidential annex), the product is not expected to have self-reactive

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Comments
					properties according to CLP regulation.
Pyrophoric liquids	n/a	n/a	WAIVER – The product is not a liquid.	n/a	
Pyrophoric solids	n/a	n/a	WAIVER – The product is an extruded net that is known to be stable in air.	n/a	
Self-heating substances and mixtures	n/a	n/a	WAIVER – The product is an extruded net. Polyethylene, that makes up > 90 % of the product, has a melting point below 160 °C. According to the ECHA Guidance on the Application of the CLP criteria substances or mixtures with a low melting point (≤160 °C) should not be considered for classification as self-heating. Cypermethrin has a harmonised classification that does not include self-heating.	n/a	Acceptable Viewing the composition of the product (see confidential annex), the product is not expected to have self-heating properties according to CLP regulation.
Substances and mixtures which in contact with water emit flammable gases	n/a	n/a	WAIVER – The product is an extruded net. The chemical stuctures of the components do not contains metals or metalloids.	n/a	Acceptable, not classified
Oxidising liquids	n/a	n/a	WAIVER – The product is not a liquid.	n/a	
Oxidising solids	n/a	n/a	WAIVER – The components of the product contain oxygen or halogen atoms which are chemically bonded only to carbon or hydrogen.	n/a	Acceptable Viewing the composition of the product (see confidential annex), the product is not expected to have oxidising properties according to CLP regulation.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Comments
Organic peroxides	n/a	n/a	WAIVER – The components of the product do not fall under the definition of organic peroxides according to GHS and the relevant UN Manual of tests and criteria.	n/a	Acceptable, not classified
Corrosive to metals	n/a	n/a	WAIVER – The product is an extruded net. There is no established suitable test method for solid substances.	n/a	Acceptable, the product is solid. Viewing the composition of the product (see confidential annex), the product is not expected to corrosive to metals properties according to CLP regulation.
Auto-ignition temperatures of products (liquids and gases)	n/a	n/a	WAIVER – The product is neither a liquid nor gas.	n/a	See CAR of active substance The auto-ignition temperature of the active substance is 400°C.
Relative self-ignition temperature for solids	n/a	n/a	WAIVER – The product is an extruded net. Polyethylene, that makes up > 90 % of the product, has a melting point below 160 °C. According to the ECHA Guidance on the Application of the CLP criteria, a study does not need to be conducted for substances or mixtures with a low melting point (≤160 °C). Cypermethrin also has a harmonised classification that does not include self-heating or self-ignition.	n/a	Acceptable Viewing the composition of the product (see confidential annex), the product is not expecting to have self-ignition properties according to CLP regulation.
Dust explosion hazard	n/a	n/a	WAIVER – The product is an extruded net that does not generate any dust.	n/a	

Conclusion on the physical hazards and respective characteristics of the product
The product is not explosive nor self-reactive and has no oxidising properties. The product is not flammable or has no self-ignition properties.

The product is an extruded net that is not classified for any physical hazard, in accordance with the CLP Regulation (Reg. (EC) No 1272/2008).

2.2.3 Physical, chemical and technical properties

The product does not contain hydrocarbons or H304 co-formulant content higher than 10%.
Packaging: HDPE
The product is ready-to-use.

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Comment
Physical state at 20 °C and 101.3 kPa	Not stated	<1% w/w cypermethrin	Product: Solid Cypermethrin: viscous liquid	SDS, 21/09/2018 (Version: 1.2) RRCo-000740_01 RRCo-000741_01	Acceptable
Colour at 20 °C and 101.3 kPa	Not stated	<1% w/w cypermethrin	Product: white Cypermethrin: Faint yellow	SDS, 21/09/2018 (Version: 1.2) RRCo-000740_01 RRCo-000741_01	
Odour at 20 °C and 101.3 kPa	Not stated	<1% w/w cypermethrin	Characteristic	SDS, 21/09/2018 (Version: 1.2)	
Acidity / alkalinity	-	-	pH (1% dilution) = 6.9 (22.0°C) pH being between 4 and 10, neither acidity nor alkalinity test has been carried out.	[redacted] RRCo-000739_01	Acceptable
Relative density / bulk density	n/a	n/a	WAIVER – The product is 100% active substance applies on HDPE support.	n/a	Not relevant

<table>
<tr><th>Property</th><th>Guideline and Method</th><th>Purity of the test substance (% (w/w)</th><th>Results</th><th>Reference</th><th>Comment</th></tr>
<tr><td rowspan="2">Storage stability test – accelerated storage</td><td>CIPAC MT 46.4
Method HPLC/DAD validated in RRCo-000741_01 validated</td><td>CYPERNET cypermethrin: 5 g/kg</td><td>Pieces of net in their packaging were stored in a glass bottle for 14 days at 54°C ± 2°C.

<u>Cypermethrin content</u> Before storage: 3.64 g/kg
After storage: 3.62 g/kg.

This is not considered a significant change.

pH (1%) before storage: 6.9 (22.0°C)
Afetr storage: 6.7 (21.7°C)

Appearance of the test item and of the packaging did not changed after storage</td><td>[redacted]
RRCo-000739_01</td><td>Acceptable, CYPERNET is stable after accelerated storage (14 days at 54 °C) when stored in its packaging in glass bottle.</td></tr>
<tr><td>CIPAC MT 46.4
Method HPLC/DAD validated in RRCo-000741_01 validated</td><td>CYPERNET (black), cypermethrin: 5 g/kg</td><td>Pieces of net were stored in a glass bottle for 14 days at 54°C ± 2°C.

<u>Cypermethrin content</u> Before storage: 5.67 g/kg
After storage: 5.62 g/kg (-0.9% vs. T0).

This is not considered a significant change.</td><td>[redacted]
Report RE/20/U10/25111</td><td>A similar product is stable after accelerated storage (14 days at 54 °C) when stored in glass bottle.</td></tr>
<tr><td>Storage stability test – long term storage at ambient temperature</td><td>-
RRCo-000740_01

Method HPLC/DAD validated in RRCo-</td><td>CYPERNET cypermethrin: 5 g/kg</td><td>
<table>
<tr><th></th><th>Initial</th><th>After 6m at ambient T°</th><th>After 12mat ambient T°</th></tr>
<tr><td>Appearance</td><td>Color = White</td><td colspan="2">No crack, no swelling, no colour change.
Color = White</td></tr>
<tr><td>Packaging stability</td><td>Color: black (outer) and white (inner)</td><td colspan="2">No crack, no swelling, no colour change
Color: black (outer) and white (inner)</td></tr>
</table>
</td><td>RRCo-000740_01</td><td>Interim results show the product is stable for at least 1 year when stroed at ambient temperature in its commercial packaging.</td></tr>
</table>

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Comment
	000741_01 validated		Content a.s. (% w/w): 0.36 / 0.40 / 0.39 pH (1%): 6.9 / 7.2 / 7.5		The final study will be required in post-authorization.
Storage stability test – **low temperature stability test for liquids**	n/a	n/a	WAIVER – The product is an extruded net, not a liquid.	n/a	Acceptable Not relevant
Effects on content of the active substance and technical characteristics of the biocidal product - **light**	n/a	n/a	WAIVER – The packaging is opaque.	n/a	The substance is not light sensitive; therefore, no other data is required.
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	-	-	PLACEHOLDER – Storage stability studies are ongoing that will address this endpoint.	-	See above

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Comment
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	-	-	PLACEHOLDER – Storage stability studies are ongoing that will address this endpoint.	-	See storage stability study
Wettability	n/a	n/a	WAIVER – Not applicable to the formulation type (extruded net, RTU)	n/a	
Suspensibility, spontaneity and dispersion stability	n/a	n/a	WAIVER – Not applicable to the formulation type (extruded net, RTU)	n/a	
Wet sieve analysis and dry sieve test	n/a	n/a	WAIVER – Not applicable to the formulation type (extruded net, RTU)	n/a	
Emulsifiability, re-emulsifiability and emulsion stability	n/a	n/a	WAIVER – Not applicable to the formulation type (extruded net, RTU)	n/a	
Disintegration time	n/a	n/a	WAIVER – Not applicable to the formulation type (extruded net, RTU)	n/a	
Particle size distribution, content of dust/fines, attrition, friability	n/a	n/a	WAIVER – Not applicable to the formulation type (extruded net, RTU)	n/a	
Persistent foaming	n/a	n/a	WAIVER – Not applicable to the formulation type (extruded net, RTU)	n/a	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference	Comment
Flowability/Pourability/Dustability	n/a	n/a	WAIVER – Not applicable to the formulation type (extruded net, RTU)	n/a	
Burning rate — smoke generators	n/a	n/a	WAIVER – Not applicable to the formulation type (extruded net, RTU)	n/a	
Burning completeness — smoke generators	n/a	n/a	WAIVER – Not applicable to the formulation type (extruded net, RTU)	n/a	
Composition of smoke — smoke generators	n/a	n/a	WAIVER – Not applicable to the formulation type (extruded net, RTU)	n/a	
Spraying pattern — aerosols	n/a	n/a	WAIVER – Not applicable to the formulation type (extruded net, RTU)	n/a	
Physical compatibility	n/a	n/a	WAIVER – The product is not intended to be used with other products.	n/a	
Chemical compatibility	n/a	n/a	WAIVER – The product is not intended to be used with other products.	n/a	
Degree of dissolution and dilution stability	n/a	n/a	WAIVER – Not applicable to the formulation type (extruded net, RTU)	n/a	
Surface tension	n/a	n/a	WAIVER – The product is an extruded net, not a liquid. Not applicable as solubility of active substance is <1mg/L (OECD 115)	n/a	See CAR of active substance
Viscosity	n/a	n/a	WAIVER – The product is an extruded net, not a liquid. Cypermethrin: >40000mPa.s at 20°C and 1700 mPa.s at 40°C (OECD 114)	n/a	See CAR of active substance

Conclusion on the physical, chemical and technical properties of the product

CYPERNET is an LN (Long lasting insecticidal net). 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 colourless solid, with a characteristic odour. There is no effect of high temperature on the stability of the formulation, since after 14 days at 54 °C, the active ingredient content was not changed. The stability data indicate a shelf life of at least 2 year at ambient temperature when stored in HDPE, to be confirmed by the final long term stability study.. As the formulation is LN, all packaging can be considered as acceptable. Its technical characteristics are acceptable for an LN formulation.

Final long-term storage study will be required in post-authorization.

2.2.4 Methods for detection and identification

Principle of the method: The product Cypernet and fortified sample of Cypernet were prepared with cypermethrin reference item (when necessary) and extracted by heptane and analysed by HPLC/DAD (278nm).

Analytical methods for the analysis of the product as such including the active substance, impurities and residues									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Active substance - Cypermethrin	HPLC/DAD	0.4% 0.6%	r^2=0.999 n=5 (in double) from 50 to 400mg/L	No interference >3%	92 – 97 98 - 104	95 100	2.42 2.18 Horrat <1	0.4%	[redacted] RRCo-000741_01
Analytical method for the determination of cypermethrin was provided and validated. Moreover, as the composition of product is 100% active substance on a HDPE carrier, the heptane solvent will extract only the substance and not the carrier. Therefore, the analytical method provided in the CAR of active substance is applicable 'Bates, 2002, Covance report no 40/029-D2149 CYP/C66).									
WAIVER – Validated methods to determine relevant impurities or substances of concern in the product are waived as the technical active does not contain any relevant impurities or substances of concern.									

Analytical methods for soil									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
WAIVER – addressed by active substance data.									

Analytical methods for air								
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
WAIVER – addressed by active substance data.									

Analytical methods for water								
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
WAIVER – addressed by active substance data.									

Analytical methods for animal and human body fluids and tisues								
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
WAIVER – Cypermethrin is not classified as toxic or very toxic (that is, without classification under Acute toxicity (cat. 1-3), CMR (cat. 1) or STOT (cat. 1)). Methods in body fluids and tissues are not therefore required in accordance with the Guidance on the BPR.									

Analytical methods for monitoring of active substances and residues in food and feeding stuff								
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
WAIVER – addressed by active substance data.									

Conclusion on the methods for detection and identificationof the product
Analytical method for the determination of cypermethrin was provided and validated. Moreover, as the composition of product is 100% active substance on a HDPE carrier, the solvent will extract only the substance and not the carrier. Therefore, the analytical method provided in the CAR of active substance is applicable. Validated methods to determine relevant impurities or substances of concern in the product are waived as the technical active does not contain any relevant impurities.

Monitoring methods (soil, water, air, foodstuffs of plant and animal origin) are addressed by active substance data.
Monitoring methods in body fluids and tissues can be waived, on the basis that cypermethin is not classified as toxic or very toxic (that is, without classification under Acute toxicity (cat. 1-3), CMR (cat. 1) or STOT (cat. 1)).

2.2.5 Efficacy against target organisms

2.2.5.1 Function and field of use

MG 03: Pest Control
Product Type 18: Insecticides, acaricides and products to control other arthropods.

The product 'CYPERNET' is a ready to use polyethylene net impregnated with the active substance cypermethrin at 0.5% w/w. 'CYPERNET' comes in a range of sizes and can be used for protection in the food industry for manufacturing and storage places, and livestock buildings. It can be used to protect goods, property, areas, animals and people from a wide range of crawling and flying insect species. The product 'CYPERNET' is intended to be used for the protection of commodities, premises and livestock buildings from some crawling and/or flying pests. According to the applicant, the product may be applied/used indoors by professionals as follows:

- As a 'curtain' (to ensure zone separation) within a structure/premises (e.g. custom unit, warehousing).
- As a protective barrier to seal pallets/stored items (e.g. packaged stored foodstuffs, wood, paper, fabrics, carpets, textiles, cloth).
- As a protective barrier to seal windows or unused opening/portals.
- By the placement of swatches in areas of pest harborage (under mattresses, behind headboards) or where specific stored items are susceptible to pest damage (e.g. museum display units).

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

Target organisms intended to be controlled are:
- Stored goods-attacking insects*:* grain weevil *(Sitophilus granaries)*, rice weevil *(Sitophilus oryzae*), lesser grain borer *(Rhizopertha dominica*), saw-tooth beetle *(Oryzaephilus surinamensis*), mites (cacao moth (*Ephestia elutella),* indian meal moth (*Plodia interpunctella),* mediterranean flour moth (*Ephestia kuehniella),* tobacco beetle *(Lasioderma serricorne);*
- Black garden ants (*Lasius niger)*;
- Bed bugs (*Cimex lectularius*);
- Clothes moth *(Tineola bisselliella);*
- Flies: stable fly *(Stomoxys calcitrans*), house fly (*Musca domestica*),
- Biting midges *(Culicoides imicola*),
- Mosquitoes: *Aedes* spp, *Anopholes* spp*, Culex spp*

2.2.5.3 Effects on target organisms, including unacceptable suffering

The product 'CYPERNET' acts on contact resulting in rapid 'knockdown' followed by death.

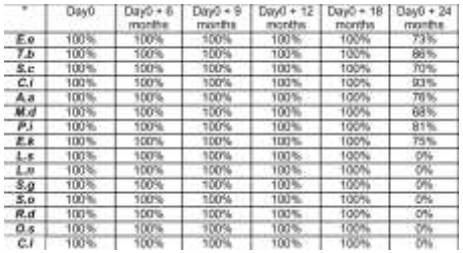
2.2.5.4 Mode of action, including time delay

CYPERMETHRIN cis:trans/40:60 is a synthetic pyrethroid with contact and stomach action. It acts by preventing the transmission of impulses along the nervous system of the insect. It is thought that this is achieved by blocking the sodium channels in nerve membranes, thus preventing action potentials passing down the nerve axon. Typically, this intoxication results in a rapid "knockdown". The affected insect shows uncoordinated movements and finally dies (Cypermethrin Assessment Report, 2019).

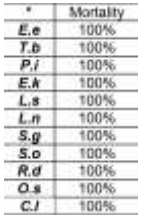
2.2.5.5 Efficacy data

The applicant submitted several studies according to Vol II part B/C efficacy guidance. These studies were conducted with the product SIANG MAY CYP Net or the product I.N.S Insect Net Solution, both identical to the product Cypernet.

Experimental data on the efficacy of the biocidal product against target organism(s)

Function	Field of use envisaged	Test substance	Test organism(s)	Test method	Test system / concentrations applied / exposure time	Test results: effects	Reference
PT18 Insecticide	Protective barrier and zone separation	Cypernet ("SIANG MAY CYP Net") containing cypermethrin at 0.5% w/w. Stored-aged product outside of its original packaging: 6/9/12/18/24 months (nets were kept flat at a temperature of 25°C+/- 2°C and relative humidity of 70+/- 10%, with no ventilation, Photoperiod: 16 hours light and 8 hours dark	*Sitophilus granarius* (adult) *Sitophilus oryzae* (adult) *Rhizopertha dominica (adult)* *Oryzaephilus surinamensis* adult) *Lasius niger* (adult worker) *Cimex lectularius (adult)* *Lasioderma serricorne* (adult) *Ephestia elutella* (nymph) *Tineola bisselliella* (larvae) *Stomoxys calcitrans* (adult) *Musca domestica* (adult) *Plodia interpunctella nymph)* *Ephestia kuehniella* (nymph) *Culicoides imicola* (adult)	Laboratory trial (direct contact) CEB 135 method adapted	Room volume: 50m3 Temperature: 22.1 to 22.5°C Relative humidity: 63 to 71% Light: 1200 lux Exposure time: 1hour Net parts: 15 cm X 15 cm 4 replicates with batches of 25 insects ±1 Untreated control KT100 after 1H exposure and mortality 24H after exposure	Mortality of the untreated control: <5 % KT100 results  Mortality at 24H:  Until 18 months, 100% mortality is obtained within 24H for the insects tested. After a storage of 24 months, from 2 to 7 days, are needed to kill the pests.	6.7-01 6.7-02 [redacted] 1708a RI=1

			Aedes albopictus (adult)				
PT18 Insecticide	Protective barrier and zone separation	Cypernet ("SIANG MAY CYP Net") containing cypermethrin at 0.5% w/w. Fresh product	*Culex pipiens (adult)*	Laboratory trial (direct contact) CEB 135 method adapted	Room volume: 50m3 Temperature: 22.2 to 22.6°C Relative humidity: 63 to 71% Light: 1200 lux Exposure time: 1hour Net parts: 15 cm X 15 cm 4 replicates with batches of 25 insects ±1 Untreated control KT100 after 1H exposure and mortality 24H after exposure	Mortality of the untreated control: 2 % KT100 results (fresh product) Day0 1 hour Mortality at 24H (fresh product) Test product 100%	6.7-06 [redacted] 2586a RI=1
PT18 Insecticide	Protective barrier	Cypernet containing cypermethrin at 0.5 % w/w. Fresh product	*Sitophilus granarius* (adult) *Sitophilus oryzae* (adult) *Rhizopertha dominica (adult)* *Oryzaephilus surinamensis* adult) *Lasius niger* (adult worker) *Cimex lectularius (adult)* *Lasioderma serricorne* (adult) *Ephestia elutella* (nymph)	SU test (choice test)	Test chamber:12m3 Temperature: 22°C (+/- 1°C) Relative humidity: 60+/- 5% Photoperiod: 8 hours light Few cardboards (harborages), water and food sources are placed half in the floor AND half in harborages under the net => to check if the insects are dying by contact with the net trying to reach the food/water placed under.	Mortality of the untreated control: <2 % Mortality after 24 H exposure (fresh product) * / Mortality E.e 100% T.b 100% S.c 100% C.i 100% A.a 100% C.p 100% M.d 100% P.i 100% E.k 100% L.s 100% L.n 100% S.g 100% S.o 100% R.d 100% O.s 100% C.l 100%	6.7-03 [redacted] 2586b/0720 RI=2

			Tineola bisselliella (larvae) *Stomoxys calcitrans* (adult) *Musca domestica* (adult) *Plodia interpunctella nymph)* *Ephestia kuehniella* (nymph) *Culicoides imicola* (adult) *Aedes albopictus* (adult)		Net parts: 15 cm X 15 cm 5 replicates with batches of 25 insects ±1 Untreated control Mortality 24H after exposure		
PT18 Insecticide	Protective barrier	Cypernet ("I.N.S Insect Net Solution ") containing cypermethrin at 0.5% w/w. Stored- aged product in its original packaging: 28 months kept in ambient temperature	*Sitophilus granarius* (adult) *Sitophilus oryzae* (adult) *Rhizopertha dominica (adult)* *Oryzaephilus surinamensis* adult) *Lasius niger* (adult worker) *Cimex lectularius (adult)* *Lasioderma serricorne* (adult) *Ephestia elutella* (nymph) *Tineola bisselliella* (larvae) *Plodia interpunctella nymph)* *Ephestia kuehniella* (nymph)	SU test (non choice test)	Test chamber:12m3 Temperature: 22°C (+/- 1°C) Relative humidity: 60+/- 5% Photoperiod: 8 hours light Few cardboards (harborages), food sources placed in harborages under the net => No other food source was available in order to force insects to reach the food in presence Net parts: 15 cm X 15 cm 5 replicates with batches of 25 insects ±1 Untreated control Mortality 24H after exposure	Mortality of the untreated control: <1 % Mortality after 24 H exposure (28 months-aged product)  => 100% mortality obtained. Moreover no eggs were laid, no insects found under the net (alive or dad) and no loss of the food under the net. The net provided an effective lethal barrier to the insects. Food sources are not appropriate for bedbugs (blood)	6.7-04 [redacted] 2586-SIM/0720 RI=2

	Mortality
E.e	100%
T.b	100%
P.i	100%
E.k	100%
L.s	100%
L.n	100%
S.g	100%
S.o	100%
R.d	100%
O.s	100%
C.l	100%

PT18 Insecticide	Zone separation	Cypernet ("I.N.S Insect Net Solution ") containing cypermethrin at 0.5% w/w. Stored-aged product in its original packaging: 28 months kept in ambient temperature	*Culicoides imicola* (adult) *Aedes albopictus* (adult) *Culex pipiens (adult)* *Anopheles gambiae (adult)* *Stomoxys calcitrans* (adult) *Musca domestica* (adult)	SU test	Test chamber: 60m3. A panel is separating this room in two volumes of 30m3 with an opening between them. Room1 (dark): insects released free-flying Room2: attractant (cage of mouse with enough smell to attract the insects) Temperature: 25°C (+/- 1°C) Relative humidity: 65+/- 5% Light 1500 lux The product set as a curtain between the two volumes (90cm X 1m) 5 replicates with batches of 50 insects Untreated control KD: 1 and 4 hours Mortality 24H after exposure	Mortality of the untreated control: <1 % Results: * / % of Knockdown-ed insects after 1 hour / % of Knockdown-ed insects after 4 hours / % of Mortality of the insects after 24 hours A.s 100% 100% 100% A.al 100% 100% 100% C.p 100% 100% 100% A.g 100% 100% 100% C.l 100% 100% 100% M.d 44% 100% 100% S.c 100% 100% 100% => 100% mortality obtained. Moreover no insects were found on the other side (alive or dead). The net provided an effective lethal barrier to the insects.	6.7-05 [redacted] 2586-SIM2/0720 RI=2

The uses claimed are assimilated to a surface treatment (the product CYPERNET is applied over the surfaces. i.e on stored items to be protected, or can be considered as a treated surface when used as a separation) and has been assessed as such:

- For stored goods-attacking insects and mites, the product CYPERNET falls into the category "products other than gases for storerooms with or without stored products". Only field tests are required for professional users.
- For ants, the product CYPERNET falls into the category "products intended for use as a general surface treatment for professionals". Lab test, simulated-use test and field trial are required.
- For bedbugs, the product CYPERNET falls into the category "products intended for use as a general surface treatment for professionals". Lab test and field trial are required (simulated-use test can be waived if robust field trial).
- For flies, the product CYPERNET falls into the category "products intended for use as general surface treatment". Simulated-use test is mainly required but for stables, field test is requested.
- For textile-attacking insects, no specific category of product is mentioned. Mainly simulated-use tests are required.
- For mosquitoes, the product CYPERNET falls into the category 'products intended for use as a general surface treatment". Lab test and simulated-use test are required.
- For culicoïdes, not specifically addressed in the guidance, the requirements can be extrapolated from those of mosquitoes.

Efficacy should be demonstrated according to the general requirements of a surface treatment in order to prove that food/stored items are protected from insect attacks or that insects are prevented for entering a room when the net is used as a curtain.

Laboratory tests have been conducted according to CEB 135 method adapted, demonstrating 100 % mortality within 24H, until 18 months stored product outside of the packaging, for all the insects tested. For a 24 months-stored product outside of the packaging, 100% mortality is obtained within 2-7 days with regard to the insects.
Simulated-use tests have been carried out with fresh product or 28 month-stored product inside the packaging. The designs of the tests simulate the use of the net either as a protective barrier of items from some crawling and flying insects (choice or non-choice test), either as a separation between two areas (specifically for flying insects claimed). Results showed 100% mortality after 24H for all the insects tested.

No field test has been submitted. However, according to the efficacy guidance Vol II part B/C, for general surface treatment for professional users, field studies have to be provided for ants, bedbugs, stored goods-attacking insects, and flies (only for use in livestock buildings). Moreover, it has to be noted that no residual efficacy has been demonstrated.

During the commenting period, the applicant argued difficulties about performing field tests: the owner of the facility (warehouse or other store area) would allow a control (unprotected stored goods) to be destroyed either by insects that are artificially introduced or where an infestation already exists. This would have two negative impacts. Firstly, the financial loss of the goods but also secondly an increase in infestation as the insects feed and multiply. It would most likely be difficult to eradicate the pests after the study.
Nevertheless eCA has the opinion that the guidance expect some layouts for the design of the field tests (e.g for stored goods-attacking insects, only data on two major representative insects, monitoring prior the treatment to avoid untreated site...). Moreover, generally in the field, lots of factors might be expected to influence product performance (risk of invasion from adjacent areas, general levels of sanitation, treatment history, attractiveness of the items protected, degradation of the product due to external conditions etc ...). Products

already assessed as surface treatment in Europe against stored-goods attacking insects, flies (in livestock buildings), ants and bedbugs, have been tested in the frame of field studies to fulfil the requirements of the guidance.

Conclusion on the efficacy of the product
According to the requirements of Efficacy guidance Vol II part B/C, the product CYPERNET (28 months-stored product) is efficient for the protection of commodities, premises and livestock building (except for flies): - against mosquitoes (*Culex sp*, *Aedes sp*, *Anopheles sp*), biting midge (*Culicoides sp*) and flies (*M.domestica, S.calcitrans*) as a separation between two areas. - against clothes moths (*Tineola bisselliella*) as a protective barrier to seal pallets/stored items. Efficacy is not demonstrated for stored goods-attacking insects (grain weevil *(Sitophilus granaries)*, rice weevil *(Sitophilus oryzae*), lesser grain borer *(Rhizopertha dominica*), saw-tooth beetle *(Oryzaephilus surinamensis*), mites (cacao moth (*Ephestia elutella),* indian meal moth (*Plodia interpunctella),* mediterranean flour moth (*Ephestia kuehniella),* tobacco beetle *(Lasioderma serricorne)),* black garden ants (*Lasius niger), and* bed bugs (*Cimex lectularius*), since no field test has been submitted. According to lab studies, efficacy is validated up to 18 months after nets openings.

5.1.1.1 Occurrence of resistance and resistance management

According to the Assessment Report of Cypermethrin cis/trans 40/60 (February 2017), resistance to pyrethroid insecticides has been reported for a number of pests both in agriculture and public health.

The authorization holder should report any observed incidents related to the efficacy to the Competent Authorities (CA) or other appointed bodies involved in resistance management.

5.1.1.2 Known limitations

None.

5.1.1.3 Evaluation of the label claims

Please refer to conclusion on efficacy regarding the accordance of the label claimed with the submitted efficacy data and uses claimed.

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

The product CYPERNET is not intended to be used with another biocidal product

5.1.2 Risk assessment for human health

5.1.2.1 Assessment of effects on Human Health

Skin corrosion and irritation

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	Not irritating
Justification for the value/conclusion	The classification is determined according to the method by calculation described in the CLP regulation. No component is classified for skin irritation.
Classification of the product according to CLP	Not required

Data waiving	
Information requirement	No study is performed
Justification	According to the Note for guidance "Handling "carriers" in the authorisation of biocidal products", nets are considered as "functional Biocidal product" (case B). Therefore, the classification is based on the composition of the final product without carrier. The classification is determined according to the method by calculation described in the CLP regulation.

Eye irritation

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	Not irritating
Justification for the value/conclusion	The classification is determined according to the method by calculation described in the CLP regulation. No component is classified for eye irritation
Classification of the product according to CLP	Not required

Data waiving	
Information requirement	No study is performed

Justification	According to the Note for guidance "Handling "carriers" in the authorisation of biocidal products", nets are considered as "functional Biocidal product" (case B). Therefore, the classification is based on the composition of the final product without carrier. The classification is determined according to the method by calculation described in the CLP regulation.

Respiratory tract irritation

Conclusion used in the Risk Assessment – Respiratory tract irritation	
Justification for the conclusion	Considering the concentration of the active substance, a classification for respiratory tract irritation is needed.
Classification of the product according to CLP	According to the method by calculation proposed in the CLP Regulation, the product is classified STOT SE 3 H335: May cause respiratory irritation.

Data waiving	
Information requirement	No study is performed
Justification	According to the Note for guidance "Handling "carriers" in the authorisation of biocidal products", nets are considered as "functional Biocidal product" (case B). Therefore, the classification is based on the composition of the final product without carrier. The classification is determined according to the method by calculation described in the CLP regulation.

Skin sensitization

Conclusion used in Risk Assessment – Skin sensitisation	
Value/conclusion	Not sensitising
Justification for the value/conclusion	The classification is determined according to the method by calculation described in the CLP regulation. No component is classified for skin sensitisation
Classification of the product according to CLP	Not required

Data waiving	
Information requirement	No study is performed
Justification	According to the Note for guidance "Handling "carriers" in the authorisation of biocidal products", nets are considered as "functional Biocidal product" (case B). Therefore, the classification is based on the composition of the final product without carrier.

	The classification is determined according to the method by calculation described in the CLP regulation.

Respiratory sensitization

Conclusion used in Risk Assessment – Respiratory sensitisation	
Value/conclusion	Not sensitising
Justification for the value/conclusion	No component is classified for respiratory sensitisation
Classification of the product according to CLP	Not required

Data waiving	
Information requirement	No study is performed
Justification	According to the Note for guidance "Handling "carriers" in the authorisation of biocidal products", nets are considered as "functional Biocidal product" (case B). Therefore, the classification is based on the composition of the final product without carrier.

Acute toxicity

Acute toxicity by oral route

Value used in the Risk Assessment – Acute oral toxicity	
Value	H302: Harmful if swallowed
Justification for the selected value	The classification is determined according to the method by calculation described in the CLP regulation. Considering the concentration of the active substance, a classification for acute toxicity by oral route is needed.
Classification of the product according to CLP	Acute Tox. 4 (Oral) H302: Harmful if swallowed

Data waiving	
Information requirement	No study is performed
Justification	According to the Note for guidance "Handling "carriers" in the authorisation of biocidal products", nets are considered as "functional Biocidal product" (case B). Therefore, the classification is based on the composition of the final product without carrier. The classification is determined according to the method by calculation described in the CLP regulation.

Acute toxicity by inhalation

Value used in the Risk Assessment – Acute inhalation toxicity	
Value	H332: Harmful if inhaled
Justification for the selected value	The classification is determined according to the method by calculation described in the CLP regulation. Considering the concentration of the active substance, a classification for acute toxicity by inhalation route is needed.
Classification of the product according to CLP	Acute Tox. 4 (inhalation) H332: Harmful if inhaled

Data waiving	
Information requirement	No study is performed
Justification	According to the Note for guidance "Handling "carriers" in the authorisation of biocidal products", nets are considered as "functional Biocidal product" (case B). Therefore, the classification is based on the composition of the final product without carrier. The classification is determined according to the method by calculation described in the CLP regulation.

Acute toxicity by dermal route

Value used in the Risk Assessment – Acute dermal toxicity	
Value	Not acute toxic by dermal route
Justification for the selected value	The classification is determined according to the method by calculation described in the CLP regulation. No component is classified for acute dermal toxicity
Classification of the product according to CLP	Not required

Data waiving	
Information requirement	No study is performed
Justification	According to the Note for guidance "Handling "carriers" in the authorisation of biocidal products", nets are considered as "functional Biocidal product" (case B). Therefore, the classification is based on the composition of the final product without carrier. The classification is determined according to the method by calculation described in the CLP regulation.

Information on dermal absorption

No new *in vitro, in vivo* or human data regarding dermal absorption are submitted in support of the Product.

Value(s) used in the Risk Assessment – Dermal absorption	
Substance	Cypermethrin
Value(s)*	50%
Justification for the selected value(s)	No dermal absorption study is available to determine the dermal absorption. Exposure to dried residue of cypermethrin can occur after contact with the net. This residue could be diluted at the surface of the body in the sweat. Therefore, according to the previous European discussion on absorption of dried residue, the default dermal absorption value of 50% (proposed in the EFSA guidance on dermal absorption (2017)) is used.

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

Not relevant.

Available toxicological data relating to a mixture

Not relevant.

Other

The product is classified STOT RE 2 H373: May cause damage to organs (nervous system) through prolonged or repeated exposure considering the classification of the active substance.

5.1.3 Exposure assessment and risk characterisation for human health

The product 'CYPERNET' is a net incorporating cypermethrin at a rate of 0.5% w/w. The product is for professional use (only) and is used indoors for the protection of commercial premises, domestic premises and livestock buildings from crawling and/or flying pests.
The net can be used as a mosquito net if it is not in contact with the skin.

The placement of product will be undertaken by professionals (only) to avoid unintended secondary contact to the general public.

The product 'CYPERNET' has a nominal weight of 132 g/m^2 and contains 0.5% w/w of the active ingredient cypermethrin, providing a target concentration of 0.066 mg cypermethrin/cm^2 of netting.

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	na	No	na	na	na	No	Not relevant
Dermal	na	Yes	na	na	na	Yes	
Oral	na	No	na	na	na	Yes	Yes

List of scenarios

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)
1.	Installation of impregnated netting in an indoor area.	**Primary exposure:** A professional user (adult) installs and/or places the impregnated netting 'CYPERNET' in commercial, domestic or livestock structures.	Professional
2.	Contact with impregnated netting following the installation of 'CYPERNET' in domestic/commercial premises	**Secondary exposure:** An person in contact with impregnated netting following the installation of the product 'CYPERNET' in domestic and/or commercial premises.	General public
3	Exposure to volatilised cypermethrin	**Secondary exposure:** Exposure to volatilised cypermethrin after application	General public

Table 5.1 Reference values to be used in risk characterisation

Reference	**Study**	**NOAEL (LOAEL) or NOAEC (LOAEC)**	**AF**	**Correction for absorption**	**Value**
AELshort-term	Rat, acute delayed neurotoxicity, oral	20	100	44%	0.088 mg/kg bw/d
AELmedium-term	Dog, 90-days, oral	12.5	100	44%	0.055 mg/kg bw/d
AELlong-term	Rat; 2-years, oral	5	100	44%	0.022 mg/kg bw/d
ARfD	Values agreed at WG-IV-2016, based on derivation made for Plant Protection Products regulation				0.2 mg/kg bw/d
ADI					0.05 mg/kg bw/d

Industrial user

Not relevant

Professional user

Scenario [1]

Description of Scenario [1]

The exposure of the professional can occur during the installation/handling of the net.
Considering the low vapour pressure of the active substance ($6*10^{-7}$ Pa), exposure via inhalation is considered negligible. No exposure via oral route is expected. Therefore, exposure is essentially via dermal route.

No model is available to determine this exposure. In this context, a reverse scenario is performed to determine the surface which can be touched per day by a professional.
This surface is determined from the AEL long term of 0.022 mg/kg/d and using the adult body weight and surface area values listed in the HEAdhoc Recommendation 14[8].

The following formula are applied:

Maximum external dose (mg/day) = (AEL * bodyweight) / (Dermal absorption * PPE penetration factor)

Available concentration of as on the tissue (mg/cm2)= target concentration on the tissue * translodgeable fraction

Maximum area of tissue which could be touched (cm2):
Maximum external dose / Available concentration of as on the tissue

	Parameters[1]	Value
Common parameters	Body weight	60 kg (HEAdhoc Recommendation 14)
	Dermal absorption	50%
	Target concentration on the tissue	0.066 mg as/cm2
	Translodgeable fraction	6% (Standard operating procedures for residential pesticide exposure assessment - USEPA report 2012)
Tier 1	PPE penetration factor	100%
Tier 2[2]	PPE penetration factor	10% (HEEG opinion 9)

Outcome of systemic exposure and risk characterisation

[8] ECHA (2017) (2013) Recommendation 14 of the BPC Ad hoc Working Group on Human Exposure: Default human factor values for use in exposure assessments for biocidal products

Table 5.2 Summary table: estimated systemic exposure and risk characterisation for professional users

Exposure scenario	**Tier/PPE**	**Area of tissue which could be touched per day (cm2)**	**Proportion of the total body surface which could be in contact with net**	**Acceptable (Yes/No)**
Scenario [1]	1/no PPE	667	4%	No
	2/PPE	6667	40%	Yes

A professional can touch 667 cm2 of net without PPE to reach the AEL.
This surface is low.
When PPE are worn, 6667 cm2 of net can be touched, representing 40% of the total body surface of an adult.
Considering that contact will occur essentially on the hands (representing 5% of the total body surface), the risk for professional is acceptable when gloves are worn. Moreover, a RMM to avoid the contact with skin is also added.

Considering the risk for local effect:

Exposure information					Risk		
Hazard category	**Effects in terms of C&L**	**Tasks, uses, processes**	**Potential exposure routes**	**Potential degree of exposure**	**Relevant RMMs & PPE**	**Conclusion on risk**	**Uncertainties attached to conclusion that may increase (↑) or decrease (↓) risk or both (↑↓**
Low	STOT SE 3, H335 (may cause respiratory irritation)	Installation of impregnated netting in an indoor area	Inhalation	Considering the low vapor pressure of cypermethrin and lack of formation of aerosol, no inhalation exposure is expected.	Not necessary	**Acceptable**	(↓) low vapor pressure lack of formation of aerosol

Non-professional exposure

Not relevant

Exposure of the general public

The intended uses claimed by the applicant are varied:
- As a 'curtain' (to ensure zone separation) within a structure/premises (e.g. custom unit, warehousing).
- As a protective barrier to seal pallets/stored items (e.g. packaged stored foodstuffs, wood, paper, fabrics, carpets, textiles, cloth).
- As a protective barrier to seal windows or unused opening/portals.
- By the placement of swatches in areas of pest harborage (under mattresses, behind -headboards) or where specific stored items are susceptible to pest damage (e.g. museum display units).
- The net can be used as a mosquito net if it is not in contact with the skin.

As the product is applied in area, where contact with general public is avoided, two scenario for general public are assessed:
- Occasional contact with impregnated netting following the installation of 'CYPERNET' in domestic/commercial premises
- Exposure to volatilised cypermethrin

Scenario [2]

Description of Scenario [2]			
After installation of the net, occasional contact with the general public can occur. The scenario of an infant touching with hands the net is considered. Dermal and oral exposure can occur.			
	Parameters[1]	Value	Reference and justification[3]
Dermal route: contact with net			
	Palm area of the hands in contact with the net	98.4 cm2	Recommendation 14 of the ad hoc WG on human exposure.
	Target concentration on the tissue	0.066 mg as/cm2	Applicant data
	Dermal absorption	50%	
	Translodgeable fraction	6%	Standard operating procedures for residential pesticide exposure assessment - USEPA report 2012
	Body weight	8 kg	Recommendation 14 of the ad hoc WG on human exposure.

Description of Scenario [2]			
Oral route: hand to mouth contact, considering that 100% of the hand is mouthed			
	Salivary extraction factor	57%	Standard operating procedures for residential pesticide exposure assessment - USEPA report 2012
	Oral absorption	57%	CAR

Outcome of systemic exposure and risk characterisation

Summary table: estimated systemic exposure and risk characterisation for non-professional users

Exposure scenario	**Tier/PPE**	**Estimated dermal uptake [mg/kg bw/day]**	**Estimated oral via hand to mouth contact [mg/kg bw/day]**	**Estimated total uptake [mg/kg bw/day]**	**Estimated uptake/ AEL (%)** AEL = 0.088 mg/kg bw/d	**Acceptable (Yes/No)**
Infant		2,44E-02	1.60E-02	4.02E-02	46%	Yes

The exposure is inferior to AEL. Therefore, the risk is acceptable. Moreover, this scenario is conservative as it is considered that 100% of the substance is available for the contact and 100% of the exposed hands are mouthed.

Scenario [3]

Description of Scenario [3]
After installation of the net, contact with volatilised residue can occur. HEEG opinion 13 is applied to determine the relevance of this exposure. Considering: - Molecular weight (mw): 416.3 g/mol - Vapour pressure (vp): 6*10^-7 Pa - AEL long term: 0.022 mg/kg/d, the result of 0.328 * (mw*vp)/AEL long term is < 1. Therefore, the screening test demonstrates that inhalation exposure to vapour is negligible.

Monitoring data

No data

Dietary exposure

Regarding the intended use as a protective barrier to seal pallets/stored items (e.g. packaged foodstuffs), no food contamination is expected. Indeed, as cypermethrin is incorporated into the net and packaging materials are present between the net and foodstuffs, transfer of residues from the net to the food is expected to be negligible. Nevertheless, the following risk mitigation measures is added to prevent any food contamination:

- -
- Do not use the product on food or feed.

Regarding the intended use in livestock buildings, exposure of poultry through consumption of dead insects contaminated with the product has to be considered. Indeed, poultry seek out dead insect intentionally.

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.	Animal husbandry	Dietary exposure to poultry contaminated through ingestion of dead flies contaminated with the product	Poultry and consumers

[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

Summary table of other (non-biocidal) uses			
	Sector of use[1]	**Intended use**	**Reference value(s) [2]**
1.	Plant protection products	Insecticide for use on crops	**Residue definition:** Cypermethrin (cypermethrin including other mixtures of constituent isomers (sum of isomers)) MRL from 0.05 mg/kg to 3 mg/kg (Reg. (EU) 2017/626).
2.	Veterinary medicinal products	Antiparasitic agents/Agents against ectoparasites	**Residue definition:** Cypermethrin (sum of isomers) MRL (all ruminants)* : 20 µg/kg in muscle, liver, kidney 200 µg/kg in fat MRL (*Salmonidae*)* : 50 µg/kg in muscle and skin

* Reg. (EU) 37/2010

Estimating Livestock Exposure to Active Substances used in Biocidal Products

Description of Scenario [1]			
Consumption of dead flies contaminated with the product is the only way livestock can be exposed to cypermethrin since the product is intended to be used out of reach of animals and has a low vapour pressure (6 x 10^{-7} Pa at 25°C). This oral exposure is only relevant for poultry according to ECHA guidance on the BPR (volume III Human Health) as it is the only livestock specie that seeks out dead insects intentionally.			
	Parameters[1]		Value
Tier 1	Concentration of cypermethrin in BP		0.5 % w/w
	Biocidal product consumption by flies (default value : guidance on BPR, vol. III, parts B+C, section 6)		3.5 mg/fly/day
	Maximum amount of cypermethrin per fly		0.0175 mg/fly/d
	Fly consumption per animal (default value : guidance on BPR, vol. III, parts B+C, section 6)		10 flies/day
	Oral absorption		100%
	Body weights (default values : guidance on BPR, vol. III, parts B+C, section 6)	Broilers	1.7 kg
		Laying hen	1.9 kg
		Turkey	7 kg

Calculations for estimating livestock exposure for Scenario [1]

Internal dose received by the animal and WCCE*				
Guidance on the Biocidal Products Regulation -Volume III Human Health - Assessment & Evaluation (Parts B+C) -6. Guidance on Estimating Livestock Exposure to Active Substances used in Biocidal Products. BfR calculator The internal dose received by poultry is equal to the estimated oral exposure since a value of 100 % is considered for oral absorption. For the WCCE calculation, the worst case for meat (broiler) and the worst case for eggs (laying hen) are used.				
	Animal	Oral exposure (Total exposure) in mg a.s./kg bw/d	Trigger value of 0.004 mg/kg bw/d exceeded?	WCCE* (mg a.s/kg bw/d)
Scenario [1]	Broiler	0.1029	Yes	0.001
	Laying hen	0.0921	Yes	
	Turkey	0.0250	Yes	

**Worst case consumer exposure: combined estimate of the internal dose with the standard food basket (300 g muscle, 100 g liver, 50 g fat, 50 g kidney plus 1500 g milk, 100 g eggs and 20 g honey); A default body weight of 60 kg for an adult is used.*

It should be noted that the estimated concentrations of cypermethrin in poultry tissues and eggs exceed the MRLs of 0.05* mg/kg in poultry liver, kidney and eggs and 0.1 mg/kg in poultry muscle and fat set under regulation (EC) No 396/2005. According to the EU Commission note regarding biocidal MRL[9], biocidal uses should respect MRLs already established under PPP regulation or MRLs should be revised for taking into account biocidal uses of the active substance. Nevertheless, poultry exposure may likely be overestimated since calculations are based on conservative assumptions representing a worst case scenario. However, in the absence of data allowing to refine poultry exposure and/or residue levels in poultry commodities, and since revising in force MRL is not possible in the short term without data, the product should not be used in poultry buildings.

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

Not relevant.

[9] CA-March17-Doc.7.6.c-final. Note for agreement with Competent Authorities for Biocidal Products. An interim approach for the establishment of maximum residue limits for residues of active substances contained in biocidal products for food and feed and specific migration limits in food contact materials.

5.1.3.1 Risk characterisation for human health

Maximum residue limits or equivalent

No specific biocide MRLs are established for this active substance. Nevertheless, MRLs are established in Regulation (EU) 1107/2009 and Regulation (EU) 37/2010 (See paragraph above "Information of non-biocidal use of the active substance").

Risk for consumers via residues in food

WCCE (mg a.s/kg bw/d)	ADI (mg/kg bw/d)	% ADI
0.001	0.05	**2.02**

Calculated WCCE is below 30% ADI of cypermethrin. As a result, no risk for consumers via residues in food is expected from intended uses of CYPERNET in livestock buildings.

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

[Please, refer to Guidance for Human Health Risk Assessement, Volume III, Part B - to characterise the risk in case of exposure to several active substances or substances of concern within a product]

5.1.4 Risk assessment for animal health

The following RMM is proposed:

- The product has to be applied in area, where contact with animals and general public is avoided.

Furthermore, as cats are sensitivity to pyrethroid, the following agreed phrase is added:

- Keep cats away from treated net. Due to their particular sensitivity to pyrethroid the product can cause severe adverse reactions in cats.

Therefore, no risk for animal is expected.

5.1.5 Risk assessment for the environment

The product CYPERNET is an impregnated polyethylene net (RTU) treated with cypermethrin at 0.5% w/w (with the carrier), intended for professional indoor use only as a PT 18 insecticide against a diverse number of target pests. Indoor uses include applying the net over pallets and other items that require storage, as zone separations (curtains), placing strips of nets behind skirting boards or carpets, under beds (or under box springs) or behind furniture (against bed bugs), and inside stables to obstruct openings not exposed to the rain while letting air enter but not insects.

At the end of product application, the net is considered as hazardous waste, and empty packaging that has been in contact with the net as well as unused pieces of net must be disposed of as hazardous waste. The product label states that any residue or pieces of

product should not be thrown into drains and waterways. For the indoor use, exposure to wet cleaning while the product is *in situ* is unlikely to occur. Consequently, a qualitative approach is considered appropriate for the environmental risk assessment.

Cypermethrin has been reviewed under the EU Review programme and details of the evaluation are included in the Assessment Report for PT 18 (2017).

5.1.5.1 Effects assessment on the environment

Information relating to the ecotoxicity of the biocidal product which is sufficient to enable a decision to be made concerning the classification of the product is required

The product does not contain any other co-formulants that are classified for an environmental hazard. Product classification is therefore driven by the active substance, cypermethrin. The harmonised classification of cypermethrin (ATP 17 Regulation) is Aquatic Acute 1, H400 (with an M-factor of 100000) and Aquatic Chronic 1, H410 (with an M-factor of 100000).

The product contains 100% w/w cypermethrin (without the carrier) and is therefore classified as Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410) under the CLP Regulation rules.

It should be noted that with or without carrier the classification of the product remains the same.

Further Ecotoxicological studies

Data waiving	
Information requirement	Not relevant
Justification	Sufficient data are available for the active substance cypermethrin. Beyond the active substance, the product does not contain any other components which are likely to alter the ecotoxicity profile of the active substance in the environment. Ecotoxicology data available for the active substance may therefore be extrapolated to the product. Additional studies with the impregnated product are therefore not justified on scientific grounds.

Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk (ADS)

Data waiving	
Information requirement	Not relevant
Justification	Sufficient data are available for the active substance cypermethrin. Beyond the active substance, the product does not contain any other components which are likely to alter the ecotoxicity profile of the active substance in the environment. Ecotoxicology data

	available for the active substance may therefore be extrapolated to the product. Additional studies with the impregnated product are therefore not justified on scientific grounds.

Supervised trials to assess risks to non-target organisms under field conditions

Data waiving	
Information requirement	Not relevant
Justification	Sufficient data are available for the active substance cypermethrin. Beyond the active substance, the product does not contain any other components which are likely to alter the ecotoxicity profile of the active substance in the environment. Ecotoxicology data available for the active substance may therefore be extrapolated to the product. Additional studies with the impregnated product are therefore not justified on scientific grounds.

Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk

Data waiving	
Information requirement	Not relevant
Justification	The biocidal product does not occur in the form of baits or granules, thus ingestion by non-target organisms will not occur and further testing is not relevant.

Secondary ecological effect e.g. when a large proportion of a specific habitat type is treated (ADS)

Not relevant.

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

According to the applicant, the product is a cypermethrin impregnated RTU polyethylene net intended for professional indoor use only as a PT18 insecticide against a diverse number of target pests. An exposure to wet cleaning while the product is *in situ* is unlikely to occur. At the end of its service life the product will be removed and considered as hazardous waste and destroyed as such. Therefore, no intended releases (direct or indirect) to the environment are expected.

Nevertheless, some risk mitigation measures will be proposed in order to ensure that exposure to environment remains unlikely for this product.

Further studies on fate and behaviour in the environment (ADS)

Data waiving

Information requirement	Not relevant
Justification	The product is intended for professional indoor use only as an insecticide against a diverse number of target pests under PT 18 and is applied as a cypermethrin impregnated RTU polyethylene net. The product contains a single active substance and does not contain any environmentally relevant substances of concern or co-formulants which are likely to alter the environmental fate and behaviour (degradation or mobility) of the active substance, cypermethrin. The environmental fate and behaviour of the products may therefore be extrapolated from information available on the active substance.

Leaching behaviour (ADS)

Data waiving	
Information requirement	Not relevant
Justification	The product is intended for professional indoor use only as an insecticide against a diverse number of target pests under PT 18 and is applied as a cypermethrin impregnated RTU polyethylene net. Given that the product is only intended for indoor use, leaching will not occur and therefore testing on leaching behaviour is not relevant.

Testing for distribution and dissipation in soil (ADS)

Data waiving	
Information requirement	Not relevant
Justification	The product contains a single active substance and does not contain any environmentally relevant substances of concern or co-formulants which are likely to alter the environmental fate and behaviour (degradation or mobility) of the active substance in soil. The environmental fate and behaviour of the product may therefore be based on the active substance, of which sufficient information is already available, therefore additional testing is not considered necessary. Cypermethrin has a high adsorption coefficient (Koc), indicating strong adsorption potential and therefore low mobility in soil. Aerobic and anaerobic soil degradation data shows that cypermethrin is degradable in soil.

Testing for distribution and dissipation in water and sediment (ADS)

Data waiving

Information requirement	Not relevant
Justification	The product contains a single active substance and does not contain any environmentally relevant substances of concern or co-formulants which are likely to alter the environmental fate and behaviour (degradation or mobility) of the active substance in water and sediment. The environmental fate and behaviour of the product may therefore be based on the active substance, of which sufficient information is already available, therefore additional testing is not considered necessary. Cypermethrin has a low water solubility and a high adsorption coefficient (Koc), indicating strong adsorption capacity to sediment. Degradation data shows that cypermethrin is degradable in water-sediment systems, however resulting metabolites are persistent. It is therefore anticipated that following release to the aquatic environment, cypermethrin will primarily occur in the sediment compartment.

Testing for distribution and dissipation in air (ADS)

Data waiving	
Information requirement	Not relevant
Justification	The product contains a single active substance and does not contain any environmentally relevant substances of concern or co-formulants which are likely to alter the environmental fate and behaviour (degradation or mobility) of the active substance. The environmental fate and behaviour of the product may therefore be based on the active substance, of which sufficient information is already available, therefore additional testing is not considered necessary. Cypermethrin has a low vapour pressure (6×10^{-7} Pa at 25°C) and Henry's law constant and a half-life of 0.749 days for photolysis in air (OH), indicating that atmospheric concentrations will be negligible.

If the biocidal product is to be sprayed near to surface waters then an overspray study may be required to assess risks to aquatic organisms or plants under field conditions (ADS)

Not relevant.

If the biocidal product is to be sprayed outside or if potential for large scale formation of dust is given then data on overspray behaviour may be required to assess risks to bees and non-target arthropods under field conditions (ADS)

Not relevant.

5.1.5.2 Exposure assessment

General information

Assessed PT	PT 18
Assessed scenarios	A **qualitative approach** is considered appropriate for addressing the environmental risk assessment and a quantitative assessment has not been performed. More detail in next paragraph *Emission estimation* below the table.
ESD(s) used	-
Approach	Qualitative approach
Distribution in the environment	Guidance on the BPR: Volume IV Environment, Assessment & Evaluation (Parts B+C)
Groundwater simulation	No
Confidential Annexes	No
Life cycle steps assessed	Production: No Formulation No Use: Yes (qualitative) Service life: Yes (qualitative)
Remarks	-

Emission estimation

According to the applicant:

The biocidal product is an impregnated polyethylene net (RTU) treated with cypermethrin at 0.5% w/w (with the carrier), intended for professional indoor use only. Intended applications of the product include applying the net over pallets and other items that require storage, as zone separations (curtains), placing strips of nets behind skirting boards or carpets, under beds (or under box springs) or behind furniture to provide treatment against bed bugs, and placing net inside stables to obstruct openings to prevent insects from entering. It should be noted that during uses in stables, the placement of the net will mean that there will be no potential for exposure to rainfall (and subsequently no risk of leaching) and no exposure of livestock. Wet cleaning whilst the product is *in situ* is highly unlikely to occur given the intended uses of the product (this includes the intended use of the product against bed bugs, of which the PT 18 ESD typically assumes wet cleaning will occur for formulations), thus emissions to wastewater (and subsequent indirect emissions to the environment) are not anticipated. Given that the product is intended for indoor use only, there is no potential risk of active substance leaching from the product since there will be no exposure to rainfall. Consequently, no emissions (direct or indirect) of the active substance (cypermethrin) into the environment are anticipated during the intended uses of the product.

The product label states that at the end of its service life, the product is removed and destroyed, along with any empty packaging that has been in contact with the net as well as unused pieces of net, and that these are all considered as hazardous waste that must be disposed of as such. The product label also states that any residue or pieces of product should not be thrown into drains and waterways.

Given that the product is intended for professional use only, it is anticipated that product disposal will be highly controlled and covered by national legislation, with no releases (direct or indirect) to the environment following normal intended product use and disposal. A qualitative approach is therefore considered appropriate and estimation of emissions into the environment have therefore not been conducted.

Therefore in order to ensure no exposure to the environment, the following instructions of use are necessary:

- *Apply indoor only.*
- *Use only in areas kept away from water (not subject to washing / sluicing / weathering)*
- *This biocidal net MUST NOT be washed, due to risk to the environment.*
- *Use the biocidal net as indicated in the instructions for use. Do not use for other purposes.*
- *Remove all pieces of biocidal nets pre-cleaning and/or disinfectant events.*

Fate and distribution in exposed environmental compartments

A qualitative approach has been taken for the environmental risk assessment on the basis that emissions to the environment (both direct and indirect) will not occur as a result of the

intended uses and disposal of the biocidal product. As such, fate and distribution data in exposed environmental compartments are not necessary.

Calculated PEC values

Calculation of PEC values is not applicable, given that a qualitative approach has been taken for the environmental risk assessment on the basis that emissions to the environment (both direct and indirect) will not occur as a result of the intended use and disposal of the biocidal product.

Primary and secondary poisoning

The biocidal product occurs in the form of an impregnated polyethylene net (RTU) treated with cypermethrin and is intended for professional indoor use only, with no potential for emissions into the environment. Consequently, there is no risk of primary or secondary poisoning.

5.1.5.3 Risk characterisation

Atmosphere

Conclusion: The biocidal product is in the form of an impregnated polyethylene net (RTU) treated with cypermethrin and is intended for professional indoor use only. Cypermethrin has a low vapour pressure (6 x 10^{-7} Pa at 25°C) and Henry's law constant and a half-life of 0.749 days for photolysis in air (OH), indicating that atmospheric concentrations will be negligible. Exposure to air is therefore not considered. There are no indications that cypermethrin contributes to depletion of the ozone layer as it is not listed as 'controlled substance' in Annex I of Regulation (EC) No 1005/2009 of the European Parliament. Acceptable risk is therefore considered for the air compartment.

Sewage treatment plant (STP), Aquatic compartment, Terrestrial compartment and Groundwater

Conclusion: A qualitative approach has been taken for the environmental risk assessment on the basis that emissions to the environment (both direct and indirect) will not occur as a result of the intended uses and disposal of the biocidal product.

Acceptable risks to STP microorganisms, the aquatic compartment, the terrestrial compartment and groundwater is therefore concluded.

Primary and secondary poisoning

Conclusion: According to the information detailed in the section 2.2.8.2, no unacceptable risk of primary or secondary poisoning is anticipated of cypermethrin in aquatic or terrestrial environments.

Mixture toxicity

Conclusion: A mixture assessment is not necessary since the product only contains one active substance and no environmentally relevant substances of concern.

Aggregated exposure (combined for relevant emission sources)

Not relevant.

Overall conclusion on the risk assessment for the environment of the product
The product CYPERNET is an impregnated polyethylene net (RTU) treated with the active substance, cypermethrin, at 0.5% w/w (with the carrier). According to the claimed uses of the biocidal product, a qualitative approach has been taken for the environmental risk assessment of the biocidal product. It is intended for professional indoor use only. There is no risk for potential exposure to rainfall and the wet cleaning whilst the product is in situ is highly unlikely so no emissions into the environment are expected. Therefore, the risks are acceptable for the biocidal product considering the following instructions of use: - *Apply indoor only.* - *Use only in areas kept away from water (not subject to washing / sluicing / weathering).* - *This biocidal net MUST NOT be washed, due to risk to the environment.* - *Use the biocidal net as indicated in the instructions for use. Do not use for other purposes.* - *Remove all pieces of biocidal nets pre-cleaning and/or disinfectant events.*

5.1.6 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.]

5.1.7 Assessment of a combination of biocidal products

For biocidal products that are intended to be authorised for the use with other biocidal products.

[Please, refer to Guidance for Human Health Risk Assessement, Volume III, Part B - to characterise the risk in case of exposure to several products]

6 ANNEXES[10]

6.1 List of studies for the biocidal product

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)
No author provided	Year: 2018	Title: CYP Shading/Windbreak/Protection Net Safety Data Sheet Report no. 21/09/2018 (Version: 1.2)	No	[redacted]
[redacted]	Year: 2020	Title: Test Report Report no. RE / 20 / U10 / 25111	No	[redacted]
[redacted]	Year: 2018	Title: Test Report Report no. FCM1814192(EN)(R1)	No	[redacted]
[redacted]	Year: 2015	Title: ASSESSMENT OF THE INSECTICIDE EFFICACY OF AN IMPREGNATED NET Report no. 1708a/1113	No	[redacted]
[redacted]	Year: 2015	Title: ASSESSMENT OF THE INSECTICIDE EFFICACY OF AN IMPREGNATED NET 24 months Report no. 1708a/113	No	[redacted]

6.2 Output tables from exposure assessment tools

6.3 New information on the active substance

6.4 Residue behaviour

10 When an annex in not relevant, please do not delete the title, but indicate the reason why the annex should not be included.

6.5 Summaries of the efficacy studies (B.5.10.1-xx)[11]

See iuclid files

6.6 Confidential annex

6.7 Other

11 If an IUCLID file is not available, please indicate here the summaries of the efficacy studies.