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ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

PARANIX ENVIRONNEMENT

Product type(s)

PT18: Insecticides, acaricides and products to control other arthropods

Authorisation number: FR-2017-0088

R4BP asset number: FR-0013362-0000

1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	PARANIX ENVIRONNEMENT PARANIX ANTI POUX SPECIAL ENVIRONNEMENT PARANIX EXTRA FORT ENVIRONNEMENT PARANIX EXTRA FORT SPECIAL ENVIRONNEMENT PARANIX EXTRA FORT ANTI POUX SPECIAL ENVIRONNEMENT DUO LP PRO ANTI-POUX SPECIAL ENVIRONNEMENT DUO LP PRO SPECIAL ENVIRONNEMENT ANTI- POUX DUO LP PRO SPECIAL ENVIRONNEMENT DUO LP PRO ANTI-POUX ENVIRONNEMENT DUO LP PRO ENVIRONNEMENT ANTI-POUX DUO LP PRO ENVIRONNEMENT PARANIX EXPRESS
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1.2. Authorisation holder

Name and address of the authorisation holder	Name	Omega Pharma International n.v.
	Address	Venecoweg, 26 9810 nazareth Belgium
Authorisation number		FR-2017-0088
<i>R4BP asset number</i>		FR-0013362-0000
Date of the authorisation		27/10/2017
Expiry date of the authorisation		27/10/2027

1.3. Manufacturer(s) of the product

Name of manufacturer	LABORATOIRE ARDEPHARM
Address of manufacturer	LES ILES FERAYS 07300 TOURNON-SUR- RHONE France
Location of manufacturing sites	LABORATOIRE ARDEPHARM site 1 LES ILES FERAYS 07300 TOURNON-SUR-RHONE France

1.4. Manufacturer(s) of the active substance(s)

Active substance	1R-trans phenothrin
Name of manufacturer	Sumitomo Chemical (UK) Plc
Address of manufacturer	Hyte house W 7NL Londres United Kingdom of Great Britain and Northern Ireland (the)
Location of manufacturing sites	Sumitomo Chemical (UK) Plc site 1 Aza-sabishirotai 033-0022 Aomori Japan

Active substance	pyriproxyfen
Name of manufacturer	SUMITOMO CHEMICAL (UK) PLC

Address of manufacturer	HYTE HOUSE W 7NL LONDRES United Kingdom of Great Britain and Northern Ireland (the)
Location of manufacturing sites	Sumitomo Chemical (UK) Plc site 1 Aza-sabishirotai 033-0022 Aomori Japan

2. PRODUCT COMPOSITION AND FORMULATION

2.1. Qualitative and quantitative information on the composition of the product

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
1R-trans phenothrin	3-phenoxybenzyl (1R,3R)-2,2-dimethyl- 3-(2-methylprop-1-enyl)cyclopropanecarboxylate	active substance	26046-85-5	247-431-2	0,28
pyriproxyfen	4-phenoxyphenyl (RS)-2-(2-pyridyloxy)propyl ether	active substance	95737-68-1	429-800-1	0,0146
isododecane	Hydrocarbons, C4, 1,3-butadiene-free, polymd., triisobutylene fraction, hydrogenated	Non-active substance	93685-81-5	297-629-8	99,667

2.2. Type(s) of formulation

AE Aerosol dispenser

3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	H222 : Extremely flammable aerosol, H229 : Pressurised container: May burst if heated H229: Pressurised container: May burst if heated H410: Very toxic to aquatic life with long lasting effects. EUH066: Repeated exposure may cause skin dryness or cracking.
Precautionary statements	P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P211: Do not spray on an open flame or other ignition source. P251: Do not pierce or burn, even after use. P410+P412: Protect from sunlight. Do no expose to temperatures exceeding 50°C/ 122°F. P273: Avoid release to the environment. P391: Collect spillage. P501: Dispose of {0:....:contents container} to {1:....}.

4. AUTHORISED USE(S)

4.1. Use description

Table 1. Spray Application by general public

Product type	PT18: Insecticides, acaricides and products to control other arthropods
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Scientific name: <i>Pediculus humanus capitis</i> Common name: Head lice Development stage: larvae Scientific name: <i>Pediculus humanus capitis</i> Common name: Head lice Development stage: adults
Field(s) of use	indoor use Indoor use
Application method(s)	Method: spraying Detailed description: Curative treatment on porous and non porous surfaces infested by lice.
Application rate(s) and frequency	Application rate: 26.7 g/m ² Dilution (%): 0 Number and timing of application: 26.7 g/m ² Contact time 10 minutes The product has not residual efficacy Application can be renewed upon reappearance of the lice
Category(ies) of users	general public (non-professional)
Pack sizes and packaging material	Can in aluminium with internal epoxyphenolic varnish of 270, 335 and 520 mL

4.1.1. Use-specific instructions

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4.1.2. Use-specific risk mitigation measures

4.1.3. Use-specific risk mitigation measures

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

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

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

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5. GENERAL DIRECTIONS FOR USE¹

5.1. Instructions for use

- Always read the label or leaflet before use and respect follow all the instructions provided
- The users should inform if the treatment is ineffective and report straightforward to the registration holder
- Shake well before use
- Spray directly onto objects likely to have been in contact with lice by holding the aerosol at 30/40 cm of the objects to be treated
- Proceed with short pressures without prolonged spraying
- Spray 27 g / m², Contact time of 10 minutes and then suck the dead lice
- In case of re-infestation, renew the application
- Integrate other control measures against lice (high temperature washing, wet combing, use of anti-lice products applied on the hair (medical device)...))

5.2. Risk mitigation measures

- During application indoor open the windows.
- After application open the windows and leave the room and wait 2 hours before re-entry .
- Do not apply on mattress of children younger than 2 years old.
- Avoid any direct and indirect contact with food and feed.
- Do not apply to washable surfaces or textiles.
- During application protect the adjacent surface with a non-washable plastic sheet.
- Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets...) nor down the drains.

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

- Inhalation: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Seek medical advice immediately if symptoms occur and/or large quantities have been inhaled.
- Do not give fluids or induce vomiting in case of impaired consciousness; place in recovery position and seek medical advice immediately.
- Ingestion: Wash out mouth with water. Do not drink or induce vomiting. Contact poison treatment specialist. Seek medical advice immediately if symptoms occur and/or large quantities have been ingested.
- Skin contact: Remove contaminated clothing and shoes. Wash contaminated skin with soap and water. Contact poison treatment specialist if symptoms occur.
- Eye contact: Immediately flush with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses if easy to do. Continue to rinse with warm water for at least 10 minutes. Get medical attention if irritation or vision impairment occurs.
- Keep the container or label available.

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

- Completely empty the container. Keep the label on the container.
- Dispose of this material and its container at hazardous or special waste collection point in accordance with local/national regulations.
- The disposal of this packaging in the environment will be banned.
- Do not empty into drains and streams.

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

- Shelf-life: 2 years
- Do not store at the temperature higher than 40°C

¹Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses.

6. OTHER INFORMATION

If the processing is not effective, the person responsible for placing the product on the market must inform the competent authority.

The number of sprays indicated on the label should be adjusted to the permitted dose.