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ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

Zenitrin EC

Product type(s)

PT18: Insecticides, acaricides and products to control other arthropods

Authorisation number: ES/APP(NA)-2024-18-00942

R4BP asset number: ES-0024643-0000

1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	Zenitrin EC Alfabiol EC Alfaplus EC Alfasect EC Alfasure EC Alphakill EC Shalfa EC
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1.2. Authorisation holder

Name and address of the authorisation holder	Name	Sharda Cropchem España S.L.
	Address	Edificio Atalayas Business Center Carril Condomina N°3 Planta 12 30006 Murcia Spain
Authorisation number	ES/APP(NA)-2024-18-00942	
<i>R4BP asset number</i>	ES-0024643-0000	
Date of the authorisation	10/06/2024	
Expiry date of the authorisation	10/06/2034	

1.3. Manufacturer(s) of the product

Name of manufacturer	Sharda Cropchem España S.L.
Address of manufacturer	Edificio Atalayas Business Center, Carril Condomina 3, 12th floor 30006 Murcia Spain
Location of manufacturing sites	Sharda Cropchem España S.L. site 1 DTS-OABE, S.L. Pol. Ind. Zabale, Parcela 3 48410 Orozco, Vizcaya Spain Sharda Cropchem España S.L. site 2 LABORATORIOS ZOTAL en Ctra. Nacional 630, Km 809 41900 Camas, Sevilla Spain Sharda Cropchem España S.L. site 3 Asplant Skotniczy Spółka Jawna ul. Chopina 78A, 43-600 Jaworzno Poland Sharda Cropchem España S.L. site 4 Productos Flower S.A. Pol. Ind. la Canaleta, s/n, 25300 Tàrrega Lleida Spain Sharda Cropchem España S.L. site 5 I.R.C.A. Service SpA Strada Statale Cremasca 591, 10 24040 Fornovo San Giovanni (Bg) Italy Sharda Cropchem España S.L. site 6 FERBI Srl Srl Viale 1° Maggio – C.da Ripoli, 64023 Mosciano S. Angelo (Te) Italy Sharda Cropchem España S.L. site 7 Vebi Istituto Biochimico s.r.l. Via Desman, 43 35010 Borgoricco (PD) Italy Sharda Cropchem España S.L. site 8 Lérida Union Química, SA (LUQSA). Afores, s/n, 25173 Sudanell, Lérida Spain Sharda Cropchem España S.L. site 9 Van Moer SRL Streer Ithaca N200, Bolintin Deal, 087015 Judet Giurgiu Romania

	Sharda Cropchem España S.L. site 10 Ellagret S.A Thesis Xiropigada, 196 00 Manda Attikis Greece Sharda Cropchem España S.L. site 11 Lérida Unión Química S.A. (LUQSA) Afores S/N, - Sudanel, 25173 Lleida Spain Sharda Cropchem España S.L. site 12 REA S.r.l. Zona Ind. ASI NORD Aggl. S. Marco - Via L. Einaudi S.S. 87 – KM 20.700, 81025 Marcianise Italy Sharda Cropchem España S.L. site 13 GMB Internacional SA Avenida del Mas de l'Oli, 144, Manises 46940 Valencia Spain
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1.4. Manufacturer(s) of the active substance(s)

Active substance	[1.alpha.(S*),3.alpha.]-(.alpha.)-cyano-(3-phenoxyphenyl)methyl3-(2,2-dichlor-oethenyl)-2,2-dichlorovinyl)-2,2-dimethyl-cyclopropanecarboxylate (alpha-Cypermethrin)
Name of manufacturer	Sharda Europe B.V.B.A (acting for Sharda Cropchem Limited (India))
Address of manufacturer	Heedstraat 58, 1730 Asse Belgium
Location of manufacturing sites	Sharda Europe B.V.B.A (acting for Sharda Cropchem Limited (India)) site 1 Heranba Industries Limited. UNIT II, PLOT NO: A2-2214/15, III PHASE, GIDC, VAPI DIST VALSAD 396195 Gujarat India

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 (%)
[1.alpha. (S*),3.alpha.]- (.alpha.)- cyano-(3- phenoxyphenyl)methyl3- (2,2-dichlor- oethenyl)-2,2- dichlorovinyl)-2,2- dimethyl- cyclopropanecarboxylate (alpha- Cypermethrin)		Active substance	67375-30-8		6 % (w/w)

2.2. Type(s) of formulation

EC Emulsifiable concentrate

3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	H302: Harmful if swallowed. H304: May be fatal if swallowed and enters airways. H318: Causes serious eye damage. H335: May cause respiratory irritation. H336: May cause drowsiness or dizziness. H410: Very toxic to aquatic life with long lasting effects. EUH066: Repeated exposure may cause skin dryness or cracking.
Precautionary statements	P261: Avoid breathing spray. P261: Avoid breathing fume. P261: Avoid breathing gas. P261: Avoid breathing mist. P261: Avoid breathing vapours. P261: Avoid breathing 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. P273: Avoid release to the environment. P280: Wear eye protection/face protection. P301+P310: IF SWALLOWED: Immediately call a protective gloves/ protective clothing/eye. P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing. P330: Rinse mouth. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310: Immediately call a. P391: Collect spillage. P405: Store locked up. P501: Dispose of contents to in accordance with current regulations..

4. AUTHORISED USE(S)

4.1. Use description

Table 1.

Use # 1 – Surface treatment by spraying including cracks and crevices against crawling insects, indoor in household and commercial environments by professional users

Product type	PT18: Insecticides, acaricides and products to control other arthropods
Where relevant, an exact description of the authorised use	Insecticide against crawling and flying insects
Target organism(s) (including development stage)	Scientific name: Blattellidae: Blattellidae: Common name: cockroaches Development stage: adults Scientific name: Formicinae: Formicinae: Common name: ants Development stage: adults Scientific name: Tenebrionidae: Common name: Litter beetle (<i>Alphitobius diaperinus</i>)- Development stage: adults Scientific name: Dermanyssidae: Common name: Poultry red mites (<i>Dermanyssus gallinae</i>)- Development stage: adults
Field(s) of use	indoor use Indoor use in private, commercial, and public buildings. Spraying on insect paths or places where insects may hide, rest, lay or settle with low-pressure sprayer in private houses or commercial and public use buildings.
Application method(s)	Method: spraying Detailed description: Spraying on insect paths or places where insects may hide, rest, lay or settle with low-pressure sprayer in private houses or commercial and public use buildings
Application rate(s) and frequency	Application Rate: 25 ml of product in 5L of water. 1 l of in-use solution to treat 20 m ² surface 0.5 Number and timing of application: Maximum 2 applications/year
Category(ies) of users	professional
Pack sizes and packaging material	Plastic bottle (COEX): 100, 250, 500, 750, 1000, 2000 y 5000 ml. Screw cap.

4.1.1. Use-specific instructions for use

Dilute 25ml product in 5 litres of water and apply 1 litre diluted product per 20m² surface.
 Spray on insect paths or places where insects may hide, rest, lay or settle with low pressure sprayer in private houses or commercial and public use buildings.
 Do not apply in surfaces likely to be subjected to wet cleaning.
 Do not use the product more than 2 times per year.

4.1.2. Use-specific risk mitigation measures

Only for treat maximum 5.9 and 27 m² of surface in household and commercial building.
 The product has to be applied only on restricted areas on surfaces not regularly cleaned, for example behind or under the fridge, under the oven or the water heater, in all cracks and crevices that can be a harbourage for crawling insects.

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

See section General directions for use

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

See section General directions for use

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

See section General directions for use

4.2. Use description

Table 2.

Use # 2 – Surface treatment by spraying including crack and crevices against crawling insects, indoor in livestock and breeding premises by professional users.

Product type	PT18: Insecticides, acaricides and products to control other arthropods
Where relevant, an exact description of the authorised use	Insecticide against crawling insects
Target organism(s) (including development stage)	Scientific name: Blattellidae: Blattellidae; Common name: cockroaches - (Blattella germanica, Blatta orientalis)- Development stage: adults Scientific name: Formicinae: Formicinae; Common name: ants - (Lasius niger)- Development stage: adults

	Scientific name: Tenebrionidae: Tenebrionidae: Common name: - Litter beetle (<i>Alphitobius diaperinus</i>)- Development stage: adults Scientific name: Dermanyssidae: Dermanyssidae: Common name: poultry red mite - (<i>Dermanyssus gallinae</i>)- Development stage: adults
Field(s) of use	indoor use Indoor use in livestock and breeding premises
Application method(s)	Method: spraying Detailed description: Apply at the normal rate after clean out and before the animals enter the house. Spray the entire surfaces of cages, or spots in boxes, percheres, joists, window ledges, pipes and floors where appropriate. Pay particular attention to corners, cracks and crevices which may harbour insects or where insects may lay. The product can be applied in all the following animal house categories: Dairy Cattle Beef Cattle & Veal Calves Pigs Chicken (free range or battery cages) Non chicken poultry (turkeys, ducks and geese)
Application rate(s) and frequency	Application Rate: Dilute 25 ml product in 5 litres of water, then apply 1 litre diluted product per 20 m2 surface. 0.5 Number and timing of application: Maximum 4 applications/year
Category(ies) of users	professional
Pack sizes and packaging material	Bottle, Plastic(COEX): 100, 250, 500, 750, 1000, 2000 and 5000 ml Bottles are provided with a dosing cup and screw cap

4.2.1. Use-specific instructions for use

Dilute 25 ml of product in 5 l of water, then apply 1 l of diluted product per 20 m2 surface

Apply at the normal rate after clean out and before the animals enter the house. Spray the entire surfaces of cages, or spots in boxes, percheres, joists, window ledges, pipes and floors where appropriate. Pay particular attention to corners, cracks and crevices which may harbour insects

Do not apply in surfaces likely to be subjected to wet cleaning.

4.2.2. Use-specific risk mitigation measures

Avoid product application in presence of animals. When possible, remove animals from the treated premises before treatment or cover animal cages with a plastic.

Avoid as much as possible contact of animals with treated surfaces.

Cover water tanks, feed, troughs and other surfaces or equipment that may enter in contact with animal feed/foodstuffs before treatment to avoid any contamination.

Do not use in animal housings where exposure to a STP and/ or direct emission to surface water cannot be prevented.

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

See section General directions for use

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

See section General directions for use

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

See section General directions for use

4.3. Use description

Table 3.

Use # 3 – Surface treatment by spraying against stable flies, wasps and mosquitoes, indoor in livestock and breeding premises by professional users.

Product type	PT18: Insecticides, acaricides and products to control other arthropods
Where relevant, an exact description of the authorised use	Insecticide against stable flies, wasps and mosquitoes.
Target organism(s) (including development stage)	Scientific name: Hymenoptera: Vespinae: Common name: wasps - <i>Vespula velutina</i> Development stage: adults Scientific name: Culicidae: Common name: mosquitoes - <i>Culex quinquefasciatus</i> Development stage: adults Scientific name: Muscidae: Common name: stable flies - <i>Stomoxys calcitrans</i> Development stage: adults
Field(s) of use	indoor use Indoor use in livestock and breeding premises.
Application method(s)	Method: spraying Detailed description: Apply at the normal rate after clean out and before the animals enter the house. Spray the entire surfaces of cages, or spots in boxes, percheries, joists, window ledges, pipes and floors where appropriate. Pay particular attention to corners, cracks and crevices, which may harbour insects or where insects may lay. The product can be applied in all the following animal house categories:

	Dairy Cattle Beef Cattle & Veal Calves Pigs Chicken (free range or battery cages) Non chicken poultry (turkeys, ducks and geese)
Application rate(s) and frequency	Application Rate: Dilute 25 ml product in 5 litres of water, then apply 1 litre diluted product per 20 m2 surface. - 0.5 % 0.5 Number and timing of application: Maximum 4 applications/year.
Category(ies) of users	trained professional professional
Pack sizes and packaging material	Plastic bottle (COEX): 100, 250, 500, 750, 1000, 2000 y 5000 ml. Screw cap.

4.3.1. Use-specific instructions for use

Dilute 25 mL of product in 5L of water, then apply 1L of diluted product per 20 m2 surface.

Apply at the normal rate after clean out and before the animals enter the house. Spray the entire surfaces of cages, boxes, percheres, joists, window ledges, pipes and floors where appropriate. Pay particular attention to corners, cracks and crevices which may harbour insects.

Do not apply in surfaces likely to be subjected to wet cleaning.

4.3.2. Use-specific risk mitigation measures

Avoid product application in presence of animals. When possible, remove animals from the treated premises before treatment or cover animal cages with a plastic.

Avoid as much as possible contact of animals with treated surfaces.

Cover water tanks, feed, troughs and other surfaces or equipment that may enter in contact with animal feed/ foodstuffs before treatment to avoid any contamination.

Do not use in animal housings where exposure to a STP and/or direct emission to surface water cannot be prevented.

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

See this point in Directions for use

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

See this point in Directions for use

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

See this point in Directions for use

5. GENERAL DIRECTIONS FOR USE¹

5.1. Instructions for use

Always read the label or leaflet before use and respect all the instructions provided.

Dilute 25 mL of product in 5L of water. Apply 1L of in use solution to treat 20m² surface.

The in-use dilution will be applied through a low-pressure sprayer (hand-held or knapsack sprayer). Application must be performed to a band of 0.1 m width on the treated surfaces.

Do not apply in surfaces likely to be subjected to wet cleaning.

5.2. Risk mitigation measures

Wear protective chemical resistant gloves (penetration 10%), clothing (penetration 20%) and face protection during product dilution and application (gloves and clothing materials to be specified by the authorisation holder within the product information).

Avoid contact with skin and eyes.

Avoid breathing vapours/spays.

Do not eat or drink or smoke while using this product.

Use only in a well ventilated area.

Ensure adequate ventilation during and after use.

Wash hands thoroughly after handling.

Keep uninvolved persons, children and pets away from treated surfaces/areas until dried.

Ensure adequate ventilation before re-entry in treated premises.

Remove or cover terrariums, aquariums and animal cages before application. Turn off aquarium air-filter while spraying.

Keep cats away from treated surfaces. Due to their particular sensitivity to (name of the pyrethroid or pyrethrin), the product can cause severe adverse reactions in cats.

Contains α -cypermethrin, may be dangerous/toxic to pets (e.g. cats, bees, fish and other aquatic organisms).

Do not apply in rooms where fish tanks and/or terrariums are present.

Keep out of reach of children and non-target animals/pets.

Do not spray directly on people, animals or bedding.

Do not use directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed and drinks.

Remove all food, feed and drinks prior to treatment.

Take into account the life cycle and characteristics of target insects to adapt treatments. In particular, target the most susceptible stage of the pest, timing of applications and areas to be treated.

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.).

Avoid any unnecessary contact with the product. Misuse can cause damage to one's health and the environment.

Check the efficacy of the product on site: if need be, cause of reduced efficacy must be investigated to ensure that there is no resistance or to identify potential resistance.

Do not use the product in areas where resistance is suspected or established.

Inform the authorisation holder if the treatment is ineffective.

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

IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing. If symptoms:

Immediately call 112/ambulance for medical assistance. If no symptoms: Call a POISON CENTRE or a doctor.

IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow.

Do NOT induce vomiting. Call 112/ambulance for medical assistance.

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

Information to Healthcare personnel/doctor: Initiate life support measures if needed, thereafter call a POISON CENTRE.

IF ON SKIN: Immediately wash skin with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes. Call a POISON CENTRE or a doctor.

IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes. Call 112/ambulance for medical assistance.

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

IF MEDICAL ADVICE IS NEEDED, HAVE PRODUCT CONTAINER OR LABEL AT HAND

Emergency measures to protect the environment:

Precautions: Prevent product from entering the environment (surface and ground water), sewerage, drainage, etc. with the construction of protective barriers and closing drains. Communicate to the competent authorities or tipping leaks into waterways, drains, sewers ...

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

Empty containers, unused product, washing water, containers and other waste generated during application are considered hazardous waste. Deposit packaging waste at the established collection points or deliver it to a registered hazardous waste operator as agreed with the extended producer responsibility system. Deliver the other wastes to a registered establishment or undertaking for hazardous waste, in accordance with current regulations.

Code the waste according to Decision 2014/955 / EU.

Do not release to soil, ground, surface water or any kind of sewer.

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

Keep out of reach of children and non-target animals/pets.

The product should be stored in tightly closed containers in a cool, dry, well-ventilated area.

Avoid high temperatures and direct action of sunlight.

Protect from moisture.

The containers must be placed in such a way as to allow free air circulation.

Do not store with oxidizers, alkalis (caustic solutions), or acids.

Keep away from foodstuffs, beverages and feed.

Check stocks regularly for damage.

Shelf-life: 2 years

6. OTHER INFORMATION

Additional information (only relevant in Spain):

Following the provisions of BPR art. 37(1), the Spanish Competent Authority (ES CA) will modify the conditions of the Authorisation of this b.p. in the Spanish market in order to adapt the User categories to our national legal requirements (i.e. Royal Decree 830/2010).

The conclusions reached in this PAR are regarded as applicable to the Spanish categories of **TRAINED PROFESSIONALS** and **PROFESSIONALS**.

- **TRAINED PROFESSIONALS:** pest control operators, having received specific training in biocidal product uses according to the national legislation in force.
- **PROFESSIONALS:** User applying biocidal products in the workplace. This user has some knowledge and skills in the handling of chemicals, and is able to correctly use personal protective equipment (PPE) if necessary.

In that context, the exposure assessment will be the same for professionals and trained professional users and the difference between the two will depend on the expert judgment following "limiting criteria" below:

1. The hazardousness of the product under evaluation.
2. The use being requested.
3. The frequency of use.
4. Complexity of control measures.