### **ANNEX**

### SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

### STILL HORSE

# **Product type(s)**

PT18: Insecticides, acaricides and products to control other arthropods

**Authorisation number:** BE2021-0004

**R4BP asset number:** BE-0015378-0000

### 1. ADMINISTRATIVE INFORMATION

# 1.1. Trade name(s) of the product

Trade name(s)	STILL HORSE
	DEFEND HORSE
	EQUIZEN
	PERMEKIN

### 1.2. Authorisation holder

Name and address of the authorisation holder	Name	ARMOSA TECH SA
	Address	Rue des Tuiliers, 1 4480 Engis Belgium
Authorisation number		BE2021-0004
R4BP asset number		BE-0015378-0000
Date of the authorisation		31/03/2021
Expiry date of the authorisation		08/03/2031

# 1.3. Manufacturer(s) of the product

Name of manufacturer	ARMOSA SA
Address of manufacturer	Rue des Tuiliers 1 4480 Engis Belgium
Location of manufacturing sites	ARMOSA SA site 1 Rue des Tuiliers 1 4480 Engis Belgium

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

Active substance	Permethrin
Name of manufacturer	Limaru NV ((Acting on behalf of Tagros Chemicals India Limited (India))
Address of manufacturer	Jhaver Centre, Raja Annamalai Building, IVth Floor, 72 Marshall Road, Egmore 600008 Chennai India
Location of manufacturing sites	Limaru NV ((Acting on behalf of Tagros Chemicals India Limited (India)) site 1 Tagros Chemicals India Ltd. A-4/1&2, Sipcot Industrial Complex Pachayankuppam Cuddalore - 607 005 Tamilnadu 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 (%)
Permethrin		active substance	52645-53-1	258-067-9	0,97

# 2.2. Type(s) of formulation

EW Emulsion, oil in water

### 3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	H410: Very toxic to aquatic life with long lasting effects.
	EUH208: Contains Permethrin, Citral and Cineol. May produce an allergic reaction.
Precautionary statements	P101: If medical advice is needed, have product container or label at hand.
	P102: Keep out of reach of children.
	P103: Read carefully and follow all instructions.
	P273: Avoid release to the environment.
	P391: Collect spillage.
	P501: Dispose of contents to in accordance with local/regional/national/international regulation.
	P501: Dispose of container to in accordance with local/regional/national/international regulation.

# 4. AUTHORISED USE(S)

# 4.1. Use description

**Table 1. Sponge application** 

Product type	PT18: Insecticides, acaricides and products to control other arthropods
Where relevant, an exact description of the authorised use	STILL HORSE is a contact insecticide, prevents nuisance of flies and is applied directly on horse's skin.
Target organism(s) (including development stage)	Common name: Autumn House fly Development stage: adults  Scientific name: Muscidae: Stomoxys calcitrans Common name: Stable fly Development stage: adults  Scientific name: Musca domestica Common name: house fly Development stage: adults
	Scientific name: Tabanus bovinus Common name: horse fly Development stage: adults  Scientific name: Hippobosca equina Common name: forest fly Development stage: adults  Scientific name: Muscidae: Muscidae: Common name: Flies
Field(s) of use	Other  To be applied on horses to protect them against flies in an outdoor environment.
Application method(s)	Method: Lotion application using a synthetic sponge.  Detailed description: Method of application: lotion application using a synthetic sponge. The bottle should be shaken before use. The solution should be applied manually using a synthetic sponge. Treat the body parts where the insects tend to gather, ie. around the eyes, on the back, and around their tail
Application rate(s) and frequency	Application rate: 25 mL of product (RTU) per horse (8.3 ml per m² of horse skin to be treated)  Dilution (%): 0  Number and timing of application: The product has a duration of action of up to 4 days. The treatment can be repeated after 4 days (96h) during the 3 months of the summer season (23 days/year).

Category(ies) of users	professional
Pack sizes and packaging material	250 mL, 500mL and 1L plastic bottle with a 25 mL dosing chamber or dosing caps.

#### 4.1.1. Use-specific instructions

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

#### **4.1.2.** Use-specific risk mitigation measures

#### 4.1.3. Use-specific risk mitigation measures

- Regarding sponge application, the user can:
- Treat horses during 150 minutes/day which is equivalent to 5 horses/day (with PPE: gloves and coated coverall) or ride 4 horses.
- Or only treat and ride 3 horses/day

# 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

Please refer to General directions for use

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

Please refer to General directions for use

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

Please refer to General directions for use

### 5. GENERAL DIRECTIONS FOR USE<sup>1</sup>

#### 5.1. **Instructions for use**

Always read the label or leaflet before use and respect all the instructions provided **Dosage for treatment of the whole animal:** 25 ml (8.3 ml per m<sup>2</sup> of horse skin to be treated)

**Duration of action:** up to 4 days (96h).

Frequency of the treatment: Each 4 days (96h) during the summer season. Repeat treatment, depending on weather conditions and the number of flies.

Inform the registration holder if the treatment is ineffective.

The authorization holder should report any observed incidents related to the efficacy to the Competent Authorities (CA).

The product is not intended to be used with other biocidal products.

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.).

Alternate products containing active substances with a different mode of action, (to remove resistant individuals from the population).

Do not use the product in areas where resistance to the active substance contained in this product is suspected or established

#### 5.2. **Risk mitigation measures**

- To protect the soil and surface water wash horses treated with the biocidal product only on paved/sealed ground connected to the waste water system.
- This product is intended to be applied on recreational and/or sport horses only. The use of the product is strictly prohibited on horse destined for consumption/integrating the food chain.
- The frequency of use may not exceed one application each 4 days during the 3 months of the summer season
- The product should be applied to dry skin. It should be avoided to use the product before washing or wet weather to preserve full effectiveness, and enable better protection of the environment.
- Do not use in animals with liver problems, anemia and widely spread skin lesions.
- The Still Horse application on sensitive parts like the abdomen can cause local edema.
- Do not use on pregnant or lactating mare.
- Ensure good ventilation of the work station. Avoid contact with skin and eyes. Avoid breathing vapours.
- Do not rinse the sponge after use
- Keep out of reach of children.
- Keep out of reach of pets, especially cats due to high sensitivity to permethrin toxicity.
- Keep children and pets away during treatment.
- Do not (use/apply) directly on or near food, feed or drinks, or on surfaces or utensils likely to be in direct contact with food, feed, drinks and livestock.
- Keep cats away from treated surfaces due to the high sensitivity to permethrin toxicity
- Do not treat horses below 250kg

<sup>&</sup>lt;sup>1</sup>Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses.

- Wear long trousers and shoes during grooming/cleaning and riding.
- The general public (children > 6y) can groom/clean and ride only 1 treated horse/day.

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

#### First-aid measures:

- After inhalation: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
- After skin contact: Wash with plenty of soap and water. Take off contaminated clothing. If skin irritation or rash occurs: Get medical advice/attention.
- After eye contact: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.
- After ingestion : Call a poison center or a doctor if you feel unwell.
- If medical advice is needed, have product container or label at hand.
- Pyrethroids may cause paresthesia (burning and prickling of the skin without irritation). If symptoms persist: Get medical advice.

#### Hygiene measures

- Do not eat, drink or smoke when using this product. Always wash hands after handling the product.
- Do not store near food, drink and animal feeding stuff.

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

- -Regional legislation (waste): Disposal must be done according to official regulations.
- -Waste treatment methods: Dispose of this material and its container at hazardous or special waste collection point. Dispose in a safe manner in accordance with local/national regulations.
- -Ecology waste materials: Avoid release to the environment.

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

#### **Storage conditions:**

The package should be kept away from direct sunlight and stored in a cool, dark, dry place and protected from heat. The product must not be stored or applied at temperatures  $\leq 0^{\circ}$ C.

#### **Shelf-life of the product:**

24 months

# 6. OTHER INFORMATION

Correct wording of EUH208: Contains Permethrin, Citral and Cineol. May produce an allergic reaction.