Product: IVERMECTINA USO VETERINARIO (EUR. PH.)

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1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product name: IVERMECTINA USO VETERINARIO (EUR. PH.)

Product code: 006233 N° CAS: 70288-86-7 N° EC: 274-536-0

1.2. Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses: Veterinary Active Pharmaceutical Ingredient

1.3. Details of the supplier of the safety data sheet

Company: METAPHARMACEUTICAL INDUSTRIAL SLU

JOSEP PLA 163 2º 5ª 08020 BARCELONA

SPAIN

Phone number: (0034) 933 089 976

Contact e-mail: <u>info@metaph.es</u>

Web page: <u>www.metaph.com</u>

1.4. Emergency telephone number

National Institute of Toxicology of Madrid: (0034) 915 620 420

2. HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

The product is classified as dangerous according to the provisions of Regulation (EC) 1272/2008 (CLP):

Acute Tox. 2, H300 Acute Tox. 3, H311 Aquatic Acute 1, H400

2.2. Label Elements



Signal word (CLP): DANGER

Hazard statements (CLP)

H300: Fatal if swallowed

H311: Toxic in contact with skin H400: Very toxic to aquatic life

Precautionary statements (CLP)

P273: Avoid release to the environment

P280: Wear protective gloves/protective clothing/eye protection/face protection

P301+P310: IF SWALLOWED: Immediately call a POISON CENTRE/doctor/... if you feel unwell

P321: Specific treatment

P330: Rinse mouth

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P391: Collect spillage

P501: Dispose of contents/container to...

2.3. Other hazards

No additional information available.

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances

Product name: IVERMECTINE (HUMAN USE)
Synonyms: IVERMECTINA, IVERMECTIN

IUPAC name: 22,23-dihydroavermectin B1a + 22,23-dihydroavermectin B1b

Nº CAS: 70288-86-7
Nº EC: 274-536-0
Molecular formula: C95H146O28

3.2. Mixtures

Not applicable.

4. FIRST AID MEASURES

4.1. Description of first aid measures

General advises: Consult a doctor. Show the safety data sheet to the doctor on duty.

Inhalation: Take outdoors. If breathing is irregular, call a doctor immediately. Only apply

artificial respiration if breathing stops or under medical supervision.

Skin contact: Wash immediately with plenty of soap and water for at least 15 minutes. Take off

all contaminated clothing immediately. Get medical attention if irritation develops

and persists.

Eye contact: Remove contact lenses and rinse immediately with plenty of water, also under the

eyelids, for at least 15 minutes. Get medical attention.

Ingestion: If conscious, give victim plenty of water to drink. Never give anything by mouth to

an unconscious person. Call a doctor immediately.

4.2. Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described on the label (see section 2.2) and/or in heading 11.

4.3. Indication of any immediate medical attention and special treatment needed

Get medical advice/attention. If possible show this sheet, if not available show packaging or label.

5. FIREFIGHTING MEASURES

5.1. Extinguishing media

Suitable extinguishing methods: Foam, dry powder, carbon dioxide, sand, water mist

Unsuitable extinguishing methods: Direct water jet.

Neighboring fires (containers exposed to fire): Atomized or nebulized water.

5.2. Special hazards arising from the substance or mixture

In the event of fire, fumes that are harmful to health may be produced.

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5.3. Advice for firefighters

General information: Cool containers with water to prevent product decomposition and development of potential

health hazards. Always use full fire protection. Collect the water that should not enter the sewer. Eliminate the contaminated water used to extinguish and the remains of the second

current regulations.

Equipment: Helmet with visor, flame retardant clothing (jacket and trousers with braces around the arms,

legs and waist, EN 469), gloves (fire and dielectric proof, EN 659), a mask with a full-face mask. operator's face or car (protective car) in the case of large amounts of smoke, a self-

contained breathing apparatus (EN 137).

6. ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Refer to section 8 for information on specific handling precautions.

6.2. Environmental precautions

Avoid getting into sewers and water pipes. If the product reaches drains or public water pipes, notify the authorities.

6.3. Methods and material for containment and cleaning up

Collect and prepare for disposal without generating dust. Store in appropriate, closed containers for disposal.

6.4. Reference to other sections

No additional information available.

7. HANDLING AND STORAGE

7.1. Precautions for safe handling

Wash hands and other exposed areas with mild soap and water before eating, drinking, smoking, and leaving work. Provide good ventilation of the processing area to prevent vapor formation.

7.2. Conditions for safe storage, including any incompatibilities

Store in a cool place. Keep the container tightly closed in a dry and well-ventilated place.

7.3. Specific end use(s)

For exposure control and individual protection measures, see section 8.

For waste disposal, follow the recommendations in section 13.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Exposure controls/personal protection

No additional information available.

8.2. Exposure controls

Since the use of appropriate technical measures should always take precedence over personal protective equipment, ensure good ventilation in the workplace by means of effective local suction. When choosing personal protective equipment, ask your chemical suppliers if necessary. Personal protective equipment must bear the CE marking that certifies compliance with the applicable regulations. Arrange an emergency shower with a visco-elastic tray.









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Eye and face protection: Protection masks and safety glasses according to EN 165, EN 166, EN 167, EN 168.

Hands protection: Handle with gloves. The selected protective gloves must comply with the specifications

of the EU Directive 89/686/EEC and the standards EN 374-1, EN 374-2, EN 374-3, EN

420 derived from it.

Respiratory protection: Where risk assessment shows that air purifying respirators are appropriate, use type

N95 (USA) or type P1 (EN 149) dust mask. Use respirators and components tested and approved under the appropriate government standards such as NIOSH (USA) or CEN

(EU).

Skin protection: Choose body protection based on the amount and concentration of the dangerous

substance in the workplace.

Hygiene measures: Handle with adequate industrial hygiene precautions, and respect safety practices.

Wash your hands before breaks and after finishing the workday.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Appearance: Solid, crystalline

Color: White

Odor: Characteristic

Molecular weight ($g \cdot mol^{-1}$): 1736.16

9.2. Other information

No additional information available.

10.STABILITY AND REACTIVITY

10.1. Reactivity

Stable under normal conditions.

10.2. Chemical stability

No additional information available.

10.3. Possibility of hazardous reactions

The product does not present the possibility of dangerous polymerization.

10.4. Conditions to avoid

High temperatures and solar light.

10.5. Incompatible materials

Strong oxidizing agents.

10.6. Hazardous decomposition products

When heated to decomposition, emits carbon oxides (CO_x).



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11.TOXICOLOGICAL INFORMATION

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute oral toxicity (LD50, rat): No additional information available (Lack of data) Skin corrosion/irritation: No additional information available (Lack of data) Serious eye damage/eye irritation: No additional information available (Lack of data) Skin or respiratory sensitization: No additional information available (Lack of data) Germ cell mutagenicity: No additional information available (Lack of data) No additional information available (Lack of data) Carcinogenicity: No additional information available (Lack of data) Reproductive toxicity: No additional information available (Lack of data) STOT - single exposure: STOT - repeated exposure: No additional information available (Lack of data) Aspiration Hazard: No additional information available (Lack of data)

Potential Health Effects

Inhalation:

No additional information available (Lack of data)
Ingestion:

No additional information available (Lack of data)
Skin:

No additional information available (Lack of data)
Eyes:

No additional information available (Lack of data)
Signs and Symptoms of Exposure:

No additional information available (Lack of data)

11.2. Information on other hazards

No additional information available.

12.ECOLOGICAL INFORMATION

Use in accordance with good work practices, avoiding dispersing the product in the environment. Notify the competent authorities if the product has reached water courses or if it has contaminated the soil or vegetation.

12.1. Toxicity

No additional information available.

12.2. Persistence and degradability

No additional information available.

12.3. Bioaccumulative potential

No additional information available.

12.4. Results of PBT and vPvB assessment

No additional information available.

12.5. Endocrine disrupting properties

No additional information available.

12.6. Other adverse effects

No additional information available.

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13.DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Product: Consider all federal, state and local environmental regulations. Contact a licensed

professional waste disposal service to dispose of this material. Dissolve or mix material with a combustible solvent and burn in a chemical incinerator equipped with an

afterburner and scrubber.

Contaminated packaging: Dispose of as unused product.

14.INFORMACIÓN RELATIVA AL TRANSPORTE

The product is classified by the conventions of dangerous substances.

14.1. UN Number

ADR/RID, IMDG, IATA: 2811

14.2. UN proper shipping name

ADR/RID: TOXIC SOLID, ORGANIC, N.E.P. (IVERMECTIN)

IMDG: TOXIC SOLID, ORGANIC, N.O.S. (IVERMECTIN)

IATA: TOXIC SOLID, ORGANIC, N.O.S. (IVERMECTIN)

14.3. Transport hazard class(es)

Class Label Pictog

ADR / RID: 6.1

IMDG: 6.1 6.1

IATA: 6.1

IAIA. 0.1 0..

14.4. Packing group

ADR/RID, IMDG, IATA: I

14.5. Environmental hazards

No additional information available.

14.6. Special precautions for user

No additional information available.

14.7. Maritime transport in bulk according to IMO instruments

No additional information available.



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15.REGULATORY INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

The Safety Data Sheet complies with the requirements of Regulation (EU) 2020/878 of the Commission of June 18, 2020, by which Annex II of Regulation (EC) No. 1907/2006 of the European Parliament and of the Council is modified, relating to the registration, evaluation, authorization and restriction of chemical substances and mixtures (REACH).

15.2. Chemical safety assessment

No additional information available.

16.OTHER INFORMATION

Abbreviations and acronyms:

PBT: Persistent, bioaccumulative and toxic mPmB: Very persistent and very bioaccumulative

REACH: Registration, Evaluation, Authorization and Restriction of Chemicals

Data sources used:

Regulation (CE) No. 1272/2008 of the European Parliament and of the Council, of December 16, 2008, on the classification, labeling and packaging of substances and mixtures, and by which Directives 67/548/CEE and 1999 are modified and repealed /45/CE and modifies Regulation (CE) No. 1907/2006.

Regulation (EU) 2020/878 of the Commission of June 18, 2020, by which Annex II of Regulation (EC) No. 1907/2006 of the European Parliament and of the Council, regarding registration, evaluation, authorization and the restriction of chemical substances and mixtures (REACH)

Safety Data Sheet according to Annex II of REACH Regulation (EU) 2020/878

Department issuing the Safety Data Sheet:

Technical Department

The information in this Product Safety Data Sheet is based on current knowledge and current EC and national laws, as far as the working conditions of users are beyond our knowledge and control. The product must not be used for purposes other than those specified, without first having a written instruction on its handling. It is always the responsibility of the user to take the appropriate measures in order to comply with the requirements established in the legislation.