Product: **DITHRANOL (ANTRALINE – Cignoline) (EUR. PH.)**

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

1.1. Product identifier

Product name: **DITHRANOL (ANTRALINE – Cignoline) (EUR. PH.)**

Product code: 002393 N° CAS: 1143-38-0 N° EC: 214-538-0

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

Relevant identified uses: Active Pharmaceutical Ingredient

1.3. Details of the supplier of the safety data sheet

Company: METAPHARMACEUTICAL INDUSTRIAL SL

JOSEP PLA 163 2º 5ª 08020 BARCELONA

SPAIN

Phone number: (0034) 933 089 976

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

Web page: www.metaph.com

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):

Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335

2.2. Label Elements



Signal word (CLP): WARNING Hazard statements (CLP)

H315: Causes skin irritation.

H319: Causes serious eye damage.H335: May cause respiratory irritation.

Precautionary statements (CLP)

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

P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if

present and easy to do. Continue rising.

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2.3. Other hazards

No additional information available.

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances

Product name: DITHRANOL (ANTRALINE - Cignoline) (EUR. PH.)

Synonyms: ANTRALINE

IUPAC name: 1,8,9-Trihydroxyanthracene, 1,8-dihydroxyanthracen-9(10H)-one

 N° CAS:
 1143-38-0

 N° EC:
 214-538-0

 Molecular formula:
 $C_{14}H_{10}O_3$

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 section11.

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

Carbon oxides and nitrogen oxides (NOx).

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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

Equip cleaning staff with proper protective equipment. Avoid both dust formation and suction. Avoid breathing in fumes, gases, or air condensation. Ventilate the area and evacuate non-essential personnel.

For more information on exposure control and personal protective measures, see section 8.

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

Ensure waste is collected and contained. Clean thoroughly. Wash the non-recoverable remainder with: Sodium hypochlorite solution.

6.4. Reference to other sections

For exposure control and personal protective measures, see section 8.

For waste disposal, follow the recommendations of section 13.

7. HANDLING AND STORAGE

7.1. Precautions for safe handling

Avoid contact with skin and eyes. Avoid the powder formation and aerosols.

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

Keep the container well closed, in a fresh and dry place.

7.3. Specific end use(s)

No additional information available.

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

Physical state: Crystalline powder

Color: Yellow ochre

Smell: Weak Molecular weight $(g \cdot mol^{-1})$: 209.25

Melting Point (°C): 248

9.2. Other information

No additional information available.

10.STABILITY AND REACTIVITY

10.1. Reactivity

No additional information available.

10.2. Chemical stability

Stable under the recommended handling and storage conditions (see section 7).

10.3. Possibility of hazardous reactions

Decomposition by heat could produce toxic fumes as CO, CO_2 and NOx.

10.4. Conditions to avoid

Avoid any wrong manipulation: high pressions and/or temperatures.

10.5. Incompatible materials

Strong oxidizing agents.

10.6. Hazardous decomposition products

Toxic fumes of: carbon monoxide (CO) and carbon dioxide (CO₂).

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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): 3216 mg/Kg

Acute intraperitoneal toxicity (LD50, rat): 3 mg/Kg

Skin corrosion/irritation: No additional information available (Lack of data)

Serious eye damage/eye irritation: It may cause ocular irritation.

Skin or respiratory sensitization: It may cause respiratory irritation.

Germ cell mutagenicity: No additional information available (Lack of data)

Carcinogenicity: No component of this product is identified at levels greater than or

equal to 0.1% as a probable, possible, or confirmed human carcinogen

by the International Agency for Research on Cancer (IARC).

Reproductive toxicity: No additional information available (Lack of data)

STOT – single exposure: No additional information available (Lack of data)

STOT – repeated exposure: Liver and gastrointestinal system.

Aspiration Hazard: No additional information available (Lack of data)

Potential Health Effects

Inhalation: Harmful if inhaled. It can cause irritation in the respiratory tract.

Ingestion: Harmful by ingestion.

Skin: Harmful if absorbed by the skin. It can cause skin irritation.

Eyes: It can cause irritation to the eyes.

Signs and Symptoms of Exposure: Symptoms from exposure may include burning or heartburn,

coughing, gasping, laryngitis, shortness of breath, headache, and

vomiting.

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 should not be considered dangerous according to the applicable regulations on the carriage of dangerous goods by road (ADR), by rail (RID), by sea (IMDG Code) and by air (IATA).

14.1. UN Number

It is not dangerous to transport.

14.2. UN proper shipping name

It is not dangerous to transport.

14.3. Transport hazard class(es)

No additional information available.

14.4. Packing group

No additional information available.

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.

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.

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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.