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

1.1. Product identifier

Product name: HIDROQUINONA USP (GMP EUR)

Product code: 2564

N° CAS: 123-31-9 N° EC: 204-617-8

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: info@metaph.es

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. 4, H302 Skin Sens. 1, H317 Eye Dam. 1, H318 Muta. 2, H341 Carc. 2, H351

Aquatic Acute 1, H400

2.2. Label Elements









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

H302: Harmful if swallowed.

H317: May cause an allergic skin reaction.

H318: Causes serious eye damage.

H341: Suspected of causing genetic defects.

H351: Suspected of causing cancer. H400: Very toxic to aquatic life.

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Precautionary statements (CLP)

P202: Do not handle until all safety precautions have been read and understood.

P261: Avoid breathing dust/fume/gas/mist/vapors/spray.

P273: Avoid release to the environment.

P391: Collect spillage.

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

present and easy to do. Continue rinsing.

P309+P311: IF exposed or concerned: Call a POISON CENTER/doctor/...

2.3. Other hazards

No additional information available.

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances

Product name: HIDROQUINONA USP (GMP EUR)

Synonyms: HYDROQUINONE

IUPAC name: 1,4-dihydroxybenzene

N° CAS: 123-31-9 N° EC: 204-617-8

Molecular formula: C₆H₆O₂

3.2. Mixtures

Not applicable.

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.

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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.

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 cleanup staff with the proper means of protection. Ventilate the area. Evacuate unnecessary personnel.

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

Store away from other materials. If it is on the ground, sweep or collect (shovel or similar) to deposit in appropriate containers. Limit dust production.

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

VLA-ED: 2 mg/m³

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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.









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: Solid

Color: Colorless to white

Smell: Almost odorless

Molecular weight (g·mol⁻¹): 110.11

pH (7%): ~ 3.75

Melting Point (°C): 172

Bolling point (°C): 287

Ignite point (°C):

ignite point (${}^{\circ}$ C): 515

Inflammation point (°C): 165
Relative density (20 °C): 0.503

Relative density (20 °C): 0.503 g/mL Solubility: 70 g/l

Solubility: 70 g/L

Partition coefficient n-octanol/water: Log Pow 0.59

9.2. Other information

No additional information available.

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10.STABILITY AND REACTIVITY

10.1. Reactivity

No special conditions. Stable under recommended handling and storage conditions (see section 7).

10.2. Chemical stability

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

10.3. Possibility of hazardous reactions

Possible dust explosion. In case of strong heating, explosive mixtures with air can be produced. Sublimable. Energy reducer.

10.4. Conditions to avoid

Avoid heating. light sensitive.

10.5. Incompatible materials

Strong oxidants. Alkali hydroxides. Aluminum. Oxygen. Sodium hydroxide.

10.6. Hazardous decomposition products

Information not available.

11.TOXICOLOGICAL INFORMATION

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

Acute oral toxicity (LD50, rat): 302 mg/Kg

Skin corrosion/irritation: Causes skin irritation

Serious eye damage/eye irritation: Causes eye irritation (disorder of the cornea)

Skin or respiratory sensitization: Risk of skin sensitization

Germ cell mutagenicity: Suspected to cause genetic defects in humans

Carcinogenicity: Information not available

Reproductive toxicity: Category 1A: May impair fertility or harm the fetus

STOT – single exposure: Information not available
STOT – repeated exposure: Information not available

Aspiration Hazard: Irritation of the mucous membranes

Potential Health Effects

Inhalation: Harmful if inhaled. It may cause irritation to the respiratory tract.

Ingestion: Harmful if swallowed.

Skin: Harmful if absorbed through the skin. It may cause skin irritation.

Eyes: It may cause eye irritation.

Signs and Symptoms of Exposure: Cough. Difficulty breathing. Pulmonary edema. Corneal disorder.

11.2. Information on other hazards

No additional information available.

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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

EC50 (fish): 0.2 mg/L (Leuciscus idus)

LC50 (fish):

0.044 mg/L/96 hours (P. promelas)

EC50 (crustaceans):

0.29 mg/L/48 hours (Daphnia magna)

EC50 (bacteria): 0.038 mg/L/30 minutes (Photobacterium phosphoreum)

12.2. Persistence and degradability

Average biodegradation.

12.3. Bioaccumulative potential

Bioaccumulation of the product is not expected.

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.

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: 3077

14.2. UN proper shipping name

ADR/RID: ENVIRONMENTALLY HAZARDOUS SOLID, N. O. S. (CONTAINS HYDROQUINONE)

IMDG: ENVIRONMENTALLY HAZARDOUS SOLID, N. O. S. (CONTAINS HYDROQUINONE)

ENVIRONMENTALLY HAZARDOUS SOLID, N. O. S. (CONTAINS HYDROQUINONE)

14.3. Transport hazard class(es)

Class Label Pictogram

ADR / RID: 9



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IMDG: 9 9

IATA: 9 9



14.4. Packing group

ADR/RID, IMDG, IATA: III

14.5. Environmental hazards

ADR / RID: Dangerous for the environment



IMDG: Marine pollutant



IATA: Dangerous for the environment



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.