Product: POLYETHYLENEGLYCOL 4000 Powder (EUR. PH.)

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

1.1. Product identifier

Product name: POLYETHYLENEGLYCOL 4000 Powder (EUR. PH.)

Product code: 1461

N° CAS: 25322-68-3 N° EC: 500-038-2

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

Relevant identified uses: Pharmaceutical excipient

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: <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 not classified as dangerous according to the provisions of Regulation (EC) 1272/2008 (CLP):

2.2. Label Elements

The product is not classified as dangerous according to the provisions of Regulation (EC) 1272/2008 (CLP)

2.3. Other hazards

No additional information available.

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances

Product name: POLYETHYLENEGLYCOL 4000 Powder

Synonyms: POLYETHYLEN GLYCOLE, POLIETILENGLICOL

IUPAC name: Poly(oxy-1,2-ethanediyl), alpha. -hydro-. omega. -hydroxy

 N° CAS:
 25322-68-3

 N° EC:
 500-038-2

 Molecular formula:
 C28H27CIF5NO

3.2. Mixtures

Not applicable.

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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

No acute or delayed effects are known to result from exposure to the product.

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.

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

Avoid any direct contact with the product. Do not breathe dust/fume/gas/mist/vapors/spray. Wear suitable protective clothing, gloves and eye or face protection.

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.

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6.4. Reference to other sections

No additional information available.

7. HANDLING AND STORAGE

7.1. Precautions for safe handling

Avoid dispersion of the product into the environment. Smoking, eating, and drinking must be prohibited in the application area. Comply with occupational safety and hygiene regulations. Store the product in containers made of material identical to the original.

7.2. Conditions for safe storage, including any incompatibilities

The product does not require any special storage measures.

Store containers in a cool, dry place.

Protect from heat and direct sunlight. Prevent freezing.

Storage class (TRGS 510, Germany): 11 (Solid compounds that cannot be assigned to any other storage class).

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.









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 430 derived from it

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.

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9. PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Aspect: Solid, powder

Color: White

Odor: Almost odorless

Melting Point (°C): 50 – 58

Flash point (°C): > 250 (DIN 51376) Ignition temperature (°C): > 320 (DIN 51794)

Decomposition temperature (°C): > 220 Water solubility (20 °C): 500 g/L pH (100 g/L, 20 °C): 4-7

9.2. Other information

No additional information available.

10.STABILITY AND REACTIVITY

10.1. Reactivity

No special conditions. It degrades slowly at high temperature in the presence of air.

10.2. Chemical stability

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

10.3. Possibility of hazardous reactions

Dusts are potentially explosive when mixed with air.

10.4. Conditions to avoid

Avoid dispersion into the environment.

10.5. Incompatible materials

Strong oxidizing agents and inorganic acids.

10.6. Hazardous decomposition products

No additional information available.

11.TOXICOLOGICAL INFORMATION

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

Acute oral toxicity (LD50, rat): > 10000 mg/Kg Skin corrosion/irritation: > 20000 mg/Kg Serious eye damage/eye irritation: > 2,5 mg/L (6h)

Skin or respiratory sensitization:

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

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:

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

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

No additional information available (Lack of data)

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Potential Health Effects

Inhalation:

No additional information available (Lack of data)

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

Slightly toxic to water (class 1).

LC50: > 50000 mg/L (Pimephales promelas, 96 h) (OECD 203)

EC50: > 20000 mg/L (Daphnia magna; 48 h) OECD 202

EC50: > 5000 mg/L (16h)

12.2. Persistence and degradability

Degradability: > 95.0 % (23 days) – rapidly biodegradable.

12.3. Bioaccumulative potential

No additional information available.

12.4. Results of PBT and vPvB assessment

According to available data, the product does not contain any PBT or vPvB substances in concentrations above 0.10%.

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.

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14.INFORMACIÓN RELATIVA AL TRANSPORTE

The product is classified by the conventions of dangerous substances.

14.1. UN Number

Not hazardous to transport.

14.2. UN proper shipping name

Not hazardous to transport.

14.3. Transport hazard class(es)

Not hazardous to transport.

14.4. Packing group

Not hazardous to transport.

14.5. Environmental hazards

Not hazardous to transport.

14.6. Special precautions for user

Not hazardous to transport.

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.