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- MATERIAL SAFETY DATA SHEET -

CEFALEXINE MONOHYDRATE MICRONIZED

Code: F 550513

1. CHEMICAL AND COMPANY IDENTIFICATION

Product Name	CEFALEXINE MONOHYDRATE MICRONIZED
Company Identification	ACS DOBFAR s.p.a Viale Addetta, 6/8/10 20067 Milan Italy (I) tel: +39 - 02 - 90693207 fax: +39 - 02 - 90693279
For emergency in Italy contact:	Niguarda Hospital in Milan: +39 02 6610102
For emergency abroad	Contact the nearest Hospital (Drugs and Poison Department).
Application:	Cephalosporin antibiotic

2. COMPOSITION/INFORMATION ON INGREDIENTS

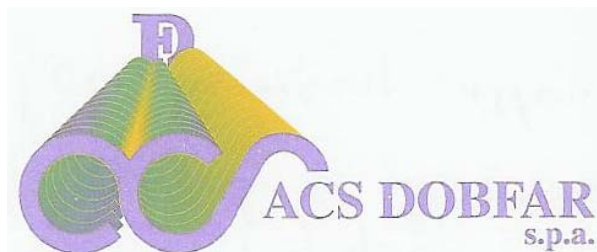
CAS N: 23325-78-2 (monohydrate) 15686-71-2 (base form)	EC N: non listed (monohydrate) 239-773-6(base form)	Annex I: non listed
Molecular Formula	C₁₆H₁₇N₃O₄S · H₂O	
Structural formula		
Molecular weight	365.41	
Chemical name	5-Thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid, 7-[[[(2R)-aminophenylacetyl]amino]-3-methyl-8-oxo-, monohydrate, (6R,7R)-7-(D-alpha-Amino-alpha-phenylacetamido)-3-methyl-3-cephem-4-carboxylic acid monohydrate thia-1-azabicyclo(4.2.0)oct-2-ene-2-carboxylic acid, 5-, 7-(2-amino-2-phenylacetamido)-3-methyl-8-oxo-, monohydrate, d-	
Commercial Names and synonyms	Cefalexine, Cephalaxine, Ceporex, Cefalexina, Cephalaxin, Cephalaxin Monohydrate; Cephalaxin Capsule Mix; Cephalaxin Monohydrate; 066873 Formulation; H69; H71; 4202; 4203; Keflex; Keforal; Branfalexina; Kefalex; Keflex Package; L-Keflex; Orex; Orakef; Kefloridina; Keflex KX; Keferol;	

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3. HAZARD IDENTIFICATION

Classification and Labelling Information

This chemical substance is not classified in the Annex I of Directive 67/548/EEC

The producer classified the substance as Harmful: May cause sensitization by inhalation and skin contact (see section 15).

European Priority Lists Information

This chemical substance is not listed in a priority list (as foreseen under Council Regulation (EEC) No 793/93 on the evaluation and control of the risks of existing substances.).

HPV-LPV (High and Low Production Volume) Information

This chemical substance has not been reported by EU Industry as an HPVC or LPVC.

IUCLID Chemical Data Sheet Information

Not available for this substance.

European Risk Assessment Information:

Not available for this substance.

CAUTION: This chemical substance is intended for human consumption under guidance of physician. Allergic reaction to cefalexine monohydrate have been reported and they may generate rash, nasal congestion, cough, dry throat and eye irritation. Avoid skin contact, eye contact, inhalation and ingestion.

4. FIRST AID MEASURES

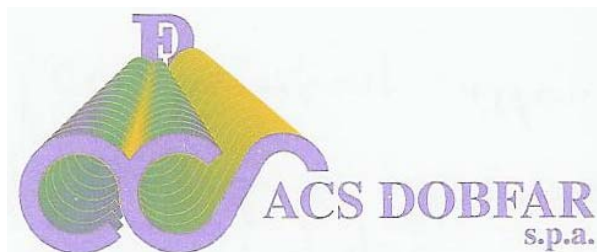
Ingestion	Never attempt to induce vomiting. Do not attempt to give any solid or liquid by mouth if the exposed subject is unconscious or semi-unconscious. Wash mouth out with water and consult the local poison centre and a physician.
Inhalation	Using appropriate personal protective equipment, remove to fresh air and monitor breathing. If breathing becomes difficult or ceases ensure and maintaining ventilation. Give oxygen as appropriate and consult a physician.
Skin contact	Using appropriate personal protective equipment, remove contaminated clothing and shoes and flush exposed area with copious amount of water. Obtain medical attention if skin react occurs.
Eyes contact	Flush immediately with copious amount of water for at least 15 minutes. Assure adequate flushing by separating the eyelids with finger. Obtain medical attention.

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5. FIRE FIGHTING MEASURES

Fire and explosion Hazards	Dust clouds are potentially sensitive to ignition from electrostatic discharge.
Extinguish media	Dry chemical powder, carbon dioxide, water spray, dry chemical, foam or halon. Water is recommended for fires involving packaging.
Special Procedure	Since toxic, corrosive or flammable vapours and gases might be evolved from fires involving this material, self-contained breathing apparatus and full protective equipment are recommended for fire-fighters. Move containers from the fire area if possible without increased personal risk.
Unusual Fire Hazard:	Upon thermal decomposition it may emit toxic or corrosive gases.

6. ACCIDENTAL RELEASE MEASURES

Personal precaution	Activate your facilities emergency response plan and evacuated area. Wear the protective clothing and apparatus to prevent contact and inhalation. Eliminate all source of ignition and ventilated the area and avoid dust generation
Environmental precaution	Prevent entry into waterways, sewer, surface drainage system and poorly ventilated area.
Clean-up method	Collect and place it in a suitable, properly labelled contained for recovery or disposal. Following removal of spillage, Wash spill site and ventilated area after material pickup is complete.
Decontamination procedures	Consider use of water, detergent solution, or other soluble solvent for clean-up and decontamination operation. Avoid decontamination with oxidizing agents such as household bleach which will release hazardous hydrochloric acid vapours.

7. HANDLING AND STORAGE

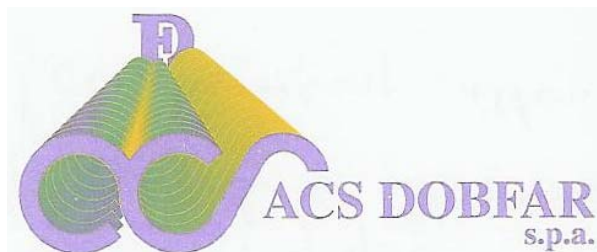
Handling	Avoid prolonged or repeated exposure. Wash thoroughly after handling material. The site should be equipped with a safety shower and an eye wash station.
Storage	Store in a tightly closed container in a cool, dry place away from source of ignition.

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Avoid heat exposure and friction and prolonged storage at elevated temperatures either.

8. EXPOSURE CONTROL

Personal Protective equipment	Wear chemical resistant gloves. Glove selection must take into account any solvent present and potential allergic reactions that can occur with certain material (e.g: Latex ®) Wear chemical safety goggles if eyes contact is possible. If respiratory protective is used, the type of protection will depend upon air concentration present. Follow local regulations for respirator use in the work place. Wear suitable protective clothing to avoid skin contact.
Occupational Exposure limits	TLV-TWA (8 hour) = n.a TLV- STEL (15 min) = n.a Lilly Exposure Guideline =< 100 microgramms/m ³ TWA for 12 hours

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state	Crystalline powder.
Colour	White
Odour	Odourless
Density (relative)	n.a
Boiling Point	n.app
Melting Point	193-200 °C
Solubility	n.a
ph	n.a

10. STABILITY AND REACTIVITY

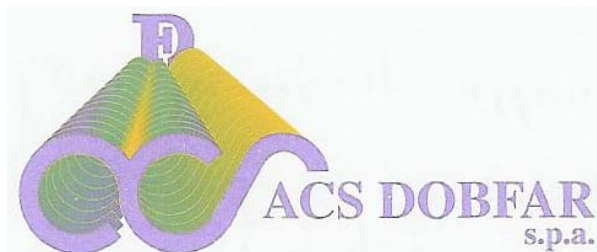
Stability	Stable under normal handling procedures at normal temperature and pressure
Incompatibilities and Conditions to avoid	Avoid direct sunlight it may discolour on exposure to light Avoid contact with strong oxidizing agents, alkali metals. No hazardous polymerization.

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11. TOXICOLOGICLA INFORMATION

Oral toxicity	It may be harmful by inhalation. LD50 (oral rat) > 5000 mg/kg no deaths, increased urine output, weight loss. Monkey, 1000 mg/kg, no deaths, diarrhea
Inhalation Toxicity	Can produce respiratory sensitization. Cephalexin hydrochloride - Rat, 1990 mg/m ³ for 4 hours, no deaths.
Skin effect	Minor irritation might occur following direct contact. Assessment based upon information obtained from literature sources. Cephalexin monohydrate - Rabbit, 153 mg/rabbit, no deaths or toxicity.
Eyes Effects	Irritation might occur following direct contact with eyes. Assessment based upon information obtained from literature sources.
Target Organ Effects	No specific target organ effect effects have been identified in animals studies
Sensitisation	Not applicable information found
Generic Toxicity	Not expected to be genotoxic based on examination of chemical structure and effects of similar materials.
Carcinogenesis	Not carcinogenity data found. Not listed by GSK, IARC, NTP, ACGIH or OSHA
Mutagenesis	Not mutagenic in bacterial cells
Impairment of fertility	n.a
Reproductive effects	Not effects identified in animals studies
Other Effect	Salivation and vomiting

12. ECOLOGICAL INFORMATION

Not applicable ecological information found

13. DISPOSAL

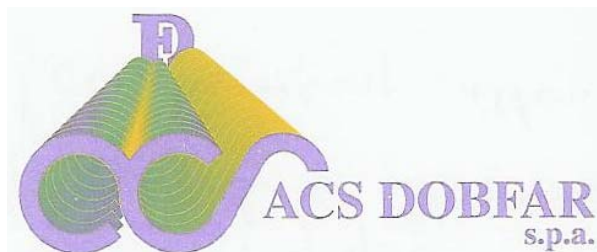
Collect for recycling or recovery if possible. Observe local environmental regulation. Do not wash away into shower or water way.

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14. TRANSPORT INFORMATION

The MSDS should accompany all shipments for reference in the event of spillage or incident release. Transport and shipping of this material is not restricted. It has no known, significant hazards requiring special packaging or labelling for air, maritime, Europe ground transport purpose.

15. GENERAL AND REGULATORY INSTRUCTION

Classification	In accordance with Directive 67/548/EEC -
Labelling	 Xn - Harmful
Risk Phrases	R42/43 - May cause sensitization by inhalation and skin contact.
Safety Phrases	S22 - Do not breathe dust S24 - Avoid contact with skin S25 - Avoid contact with eyes.

16. OTHER INFORMATIONS

References:

1. ACS-DOBFAR (Previous release)
2. ESIS (European chemical Substances Information System)
3. Lilly ®
4. NIOSH

Legend:

n.a.: not available n.e : not established n.app: not applicable

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. It must be noted that this product is an experimental substance whose pharmacological properties are incompletely characterized. It is responsibility of the purchaser to insure that worker who use this product are aware of its experimental nature and take all necessary precautions to prevent contact, inhalation, or any other mode of exposure.

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