

ELI LILLY AND COMPANY  
MATERIAL SAFETY DATA SHEET  
CEPHALEXIN CAPSULES AND TABLETS  
EFFECTIVE DATE: 23-APR-94

SECTION 1 - CHEMICAL PRODUCT AND COMPANY

MANUFACTURER:  
ELI LILLY AND COMPANY  
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COMMON NAME: CEPHALEXIN CAPSULES AND TABLETS

CAS NUMBER(S):  
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)-  
CHEMICAL NAME 2: 7-(D-ALPHA-AMINO-ALPHA-PHENYLACETAMIDO)-3-METHYL-3-CEPHEM-4-CARBOXYLIC ACID MONOHYDRATE  
MOLECULAR WEIGHT:  
SYNONYM(S): CEPHALEXIN; CEPHALEXIN MONOHYDRATE; CEPHALEXIN CAPSULE MIX; CEPHALEXIN MONOHYDRATE CAPSULE MIX; 066873 FORMULATION; H69; H71; 4202; 4203; CEFLEXINA CAPSULES; CEPHALEXIN M. F. BLEND  
TRADENAME(S): KEFLEX; KEFORAL; BRANFALEXINA; KEFALEX; KEFLEX PACKAGE; L-KEFLEX; OREX; ORAKEF; KEFLORIDINA; KEFLEX KX; KEFEROL; FALEX  
LILLY ITEM CODE(S): AH0377; AH0378; MS5062; MS5063; ND0711; ND0720; ND0730; ND0753; ND0762; ND0832; ND0833; ND0834; ND0861; ND0862; ND0868; ND0877; PU0401; PU0402; PU0403; PU3001; PU3069; PU3070; PU3140; PU3141; QA432Z; QA433Y; QA455Z; QA476X; TA1872; TA1894; TA1895; TA1896; TA4053; TA4090; TA4091; TA4202; TA4203; TA4210; TA4211; UC5010; UC5011; UC5346; UC5347; UC5348; UC5349; UC5376; UC5377; UC5930; UC5931; UC5938; UC5939; UC5942; UC5943; UC5944; UC5945; UC5961; UC5962; UC5970; UC5974; UC5975; UC5976; UC5977; UC5978; UC5979; UC8932; UC8933; UC8945; UC8946; UE0001; UE0002; UF0015; UF0016; VF0072; VF0077; VF0079; VF0084; VF0085; VF0090; VF0092; VF0100; VF0101; VF0122; VF0155; VF0159; VF0160; VF0223; VF0224; VF0225; VF0226; VF0227; VF0254; VF0255; VF0256; VF0257; VF0264; VF0265; VF0273; VF0288; VF0289; VF0291; VF0292

SEE ATTACHED GLOSSARY FOR ABBREVIATIONS.

SECTION 2 - COMPOSITION / INFORMATION ON INGREDIENTS

| INGREDIENT             | CAS        | CONCENTRATION |
|------------------------|------------|---------------|
| CEPHALEXIN MONOHYDRATE | 23325-78-2 | 14- 96        |
| EXCIPIENTS             | NA         | 4- 85         |

CONTAINS NO HAZARDOUS COMPONENTS (ONE PERCENT OR GREATER) OR CARCINOGENS (ONE-TENTH PERCENT OR GREATER) NOT LISTED ABOVE.

EXPOSURE GUIDELINES: CEPHALEXIN MONOHYDRATE - LEG <100 MICROGRAMS/M3 TWA FOR 12 HOURS.

SECTION 3 - HAZARDS IDENTIFICATION

APPEARANCE: WHITE OR COLORED POWDER FINISHED AS CAPSULES OR COATED TABLETS  
PHYSICAL STATE: SOLID  
ODOR: ODORLESS  
EMERGENCY OVERVIEW EFFECTIVE DATE: 23-APR-94  
LILLY LABORATORY LABELING CODES:  
HEALTH 1 FIRE 1 REACTIVITY 0

PRIMARY PHYSICAL AND HEALTH HAZARDS: NOT HAZARDOUS IF INTACT. SEVERE ALLERGEN.

CAUTION STATEMENT: INTACT CEPHALEXIN CAPSULES AND TABLETS ARE NOT CONSIDERED TO BE A H

HEALTH HAZARD. CEPHALEXIN CAPSULES AND TABLETS CONTAINS CEPHALEXIN WHICH CAUSES SEVERE ALLERGIC REACTIONS.

ROUTES OF ENTRY: INHALATION AND SKIN CONTACT.

POTENTIAL SIGNS AND SYMPTOMS OF OCCUPATIONAL EXPOSURE: CAPSULES AND TABLETS ARE INTENDED FOR HUMAN CONSUMPTION UNDER GUIDANCE OF A PHYSICIAN. CAPSULES AND TABLETS ARE NOT CONSIDERED HAZARDOUS UNDER NORMAL HANDLING PROCEDURES. ALLERGIC REACTIONS TO CEPHALEXIN MONOHYDRATE HAVE BEEN REPORTED. ALLERGIC REACTIONS TO CONTENTS OF CAPSULES OR TO THE POWDER USED TO MAKE THE TABLETS MAY INCLUDE RASH, NASAL CONGESTION, COUGH, DRY THROAT, AND EYE IRRITATION.

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: PENICILLIN OR CEPHALOSPORIN HYPERSENSITIVITY.

CARCINOGENICITY: CEPHALEXIN MONOHYDRATE - NO CARCINOGENICITY DATA FOUND. NOT LISTED BY IARC, NTP, ACGIH, OR OSHA.

#### SECTION 4 - FIRST AID MEASURES

EYES: FLUSH EYES WITH PLENTY OF WATER. GET MEDICAL ATTENTION.

SKIN: REMOVE CONTAMINATED CLOTHING AND CLEAN BEFORE REUSE. WASH ALL EXPOSED AREAS OF SKIN WITH PLENTY OF SOAP AND WATER. GET MEDICAL ATTENTION IF IRRITATION DEVELOPS.

INHALATION: MOVE INDIVIDUAL TO FRESH AIR. GET MEDICAL ATTENTION IF BREATHING DIFFICULTY OCCURS. IF NOT BREATHING, PROVIDE ARTIFICIAL RESPIRATION ASSISTANCE (MOUTH-TO-MOUTH) AND CALL A PHYSICIAN IMMEDIATELY.

INGESTION: DO NOT INDUCE VOMITING. CALL A PHYSICIAN OR POISON CONTROL CENTER. IF AVAILABLE, ADMINISTER ACTIVATED CHARCOAL (6-8 HEAPING TEASPOONS) WITH TWO TO THREE GLASSES OF WATER. DO NOT GIVE ANYTHING BY MOUTH TO AN UNCONSCIOUS PERSON. IMMEDIATELY TRANSPORT TO A MEDICAL CARE FACILITY AND SEE A PHYSICIAN.

#### SECTION 5 - FIRE FIGHTING MEASURES

FLASH POINT: NOT APPLICABLE

UEL: NO APPLICABLE INFORMATION FOUND

LEL: NO APPLICABLE INFORMATION FOUND

EXTINGUISHING MEDIA: USE WATER, CARBON DIOXIDE, DRY CHEMICAL, FOAM, OR HALON.

UNUSUAL FIRE AND EXPLOSION HAZARDS: AS A FINELY DIVIDED MATERIAL, MAY FORM DUST MIXTURES IN AIR WHICH COULD EXPLODE IF SUBJECTED TO AN IGNITION SOURCE.

HAZARDOUS COMBUSTION PRODUCTS: MAY EMIT TOXIC FUMES WHEN EXPOSED TO HEAT OR FIRE.

#### SECTION 6 - ACCIDENTAL RELEASE MEASURES

SPILLS: CONTAIN DRY MATERIAL BY LIGHTLY MISTING WITH WATER, FOLLOWED BY SWEEPING UP OR VACUUMING. VACUUMING MAY DISPERSE DUST IF APPROPRIATE DUST COLLECTION FILTER IS NOT PART OF THE VACUUM. BE AWARE OF POTENTIAL FOR DUST EXPLOSION WHEN USING ELECTRICAL EQUIPMENT. WEAR PROTECTIVE EQUIPMENT, INCLUDING EYE PROTECTION, TO AVOID EXPOSURE (SEE SECTION 8 FOR SPECIFIC HANDLING PRECAUTIONS).

#### SECTION 7 - HANDLING AND STORAGE

SEE SECTION 8 FOR APPROPRIATE PERSONAL PROTECTIVE EQUIPMENT.

STORAGE CONDITIONS: CONTROLLED ROOM TEMPERATURE: 15 TO 30 C (59 TO 86 F).

#### SECTION 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

SEE SECTION 2 FOR EXPOSURE GUIDELINES.

SEE SECTION 2 FOR EXPOSURE GUIDELINE INFORMATION.

FILLED CAPSULES AND COATED COMPRESSED TABLETS ARE NOT CONSIDERED HAZARDOUS UNDER NORMAL HANDLING PROCEDURES AND PROTECTIVE EQUIPMENT IS NOT REQUIRED. THE FOLLOWING ARE RECOMMENDED FOR MANUFACTURING OR OTHER SITUATIONS WHERE EXPOSURE TO CONTENTS MAY OCCUR.

RESPIRATORY PROTECTION: USE AN APPROVED RESPIRATOR.

EYE PROTECTION: CHEMICAL GOGGLES AND/OR FACE SHIELD.

VENTILATION: LABORATORY FUME HOOD OR LOCAL EXHAUST VENTILATION.

OTHER PROTECTIVE EQUIPMENT: CHEMICAL-RESISTANT GLOVES AND BODY COVERING TO MINIMIZE SKIN CONTACT. IF HANDLED IN A VENTILATED ENCLOSURE, AS IN A LABORATORY SETTING, RESPIRATOR AND GOGGLES OR FACE SHIELD MAY NOT BE REQUIRED. SAFETY GLASSES ARE ALWAYS REQUIRED.

OTHER HANDLING PRECAUTIONS: IN PRODUCTION SETTINGS, AIRLINE-SUPPLIED, HOOD-TYPE RESPIRATORS ARE PREFERRED. SHOWER AND CHANGE CLOTHING IF SKIN CONTACT OCCURS.

#### SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

BOILING POINT: NOT APPLICABLE  
MELTING POINT: NO APPLICABLE INFORMATION FOUND  
SPECIFIC GRAVITY: NO APPLICABLE INFORMATION FOUND  
PH: NO APPLICABLE INFORMATION FOUND  
EVAPORATION RATE: NO APPLICABLE INFORMATION FOUND  
WATER SOLUBILITY: SLIGHTLY SOLUBLE  
VAPOR DENSITY: NO APPLICABLE INFORMATION FOUND  
VAPOR PRESSURE: NO APPLICABLE INFORMATION FOUND

#### SECTION 10 - STABILITY AND REACTIVITY

STABILITY: STABLE AT NORMAL TEMPERATURES AND PRESSURES.

INCOMPATIBILITY: MAY REACT WITH STRONG OXIDIZING AGENTS (E.G., PEROXIDES, PERMANGANATES, NITRIC ACID, ETC.).

HAZARDOUS DECOMPOSITION: MAY EMIT TOXIC FUMES WHEN HEATED TO DECOMPOSITION.

HAZARDOUS POLYMERIZATION: WILL NOT OCCUR.

#### SECTION 11 - TOXICOLOGICAL INFORMATION

ANIMAL TOXICITY DATA SINGLE EXPOSURE NO DATA ARE AVAILABLE FOR CEPHALEXIN CAPSULES AND TABLETS. TOXICITY DATA FOR CEPHALEXIN MONOHYDRATE AND CEPHALEXIN HYDROCHLORIDE ARE PRESENTED.

ORAL: CEPHALEXIN MONOHYDRATE - RAT, 5000 MG/KG, NO DEATHS, INCREASED URINE OUTPUT, WEIGHT LOSS.  
MONKEY, 1000 MG/KG, NO DEATHS, DIARRHEA.

SKIN: CEPHALEXIN MONOHYDRATE - RABBIT, 153 MG/RABBIT, NO DEATHS OR TOXICITY.

INHALATION: CEPHALEXIN HYDROCHLORIDE - RAT, 1990 MG/M3 FOR 4 HOURS, NO DEATHS.

INTRAVENOUS: CEPHALEXIN MONOHYDRATE - RAT, 700 MG/KG, NO DEATHS OR TOXICITY.  
DOG, 100  
MG/KG, NO DEATHS, VOMITING, TARRY STOOLS.

SKIN CONTACT: CEPHALEXIN MONOHYDRATE - RABBIT, NONIRRITANT

EYE CONTACT: CEPHALEXIN MONOHYDRATE - RABBIT, SLIGHT IRRITANT

ANIMAL TOXICITY DATA REPEAT EXPOSURE NO DATA ARE AVAILABLE FOR CEPHALEXIN CAPSULES AND TABLETS. TOXICITY DATA FOR CEPHALEXIN MONOHYDRATE ARE PRESENTED.

TARGET ORGAN EFFECTS: CEPHALEXIN MONOHYDRATE -NO EFFECTS IDENTIFIED IN ANIMAL STUDIES.

OTHER EFFECTS: CEPHALEXIN MONOHYDRATE - SALIVATION AND VOMITING.

REPRODUCTION: CEPHALEXIN MONOHYDRATE -NO EFFECTS IDENTIFIED IN ANIMAL STUDIES.

SENSITIZATION: CEPHALEXIN MONOHYDRATE - NO APPLICABLE INFORMATION FOUND.

MUTAGENICITY: CEPHALEXIN MONOHYDRATE - NOT MUTAGENIC IN BACTERIAL CELLS.

SECTION 12 - ECOLOGICAL INFORMATION

NO APPLICABLE ECOLOGICAL INFORMATION FOUND.

SECTION 13 - DISPOSAL CONSIDERATIONS

WASTE DISPOSAL: DISPOSE OF ANY CLEANUP MATERIALS AND WASTE RESIDUE ACCORDING TO ALL APPLICABLE LAWS AND REGULATIONS.

SECTION 14 - TRANSPORT INFORMATION

REGULATORY ORGANIZATIONS:

IMO: NOT REGULATED

ICAO/IATA: NOT REGULATED

DOT: NOT REGULATED

SECTION 15 - REGULATORY INFORMATION

U.S. REGULATIONS:

CEPHALEXIN MONOHYDRATE

TSCA - NO

CERCLA - NOT ON THIS LIST

SARA 302 - NOT ON THIS LIST

SARA 313 - NOT ON THIS LIST

EC CLASSIFICATION AND RISK AND SAFETY PHRASES:

EC CLASSIFICATION:

CONTAINS CEPHALEXIN MONOHYDRATE (C = 14-96%)

XN (HARMFUL)

XI (IRRITANT)

RISK PHRASES:

R 42/43 - MAY CAUSE SENSITIZATION BY INHALATION AND SKIN CONTACT.

SAFETY PHRASES:

SECTION 16 - OTHER INFORMATION

AS OF THE DATE OF ISSUANCE, WE ARE PROVIDING AVAILABLE INFORMATION RELEVANT TO THE HANDLING OF THIS MATERIAL IN THE WORKPLACE. ALL INFORMATION CONTAINED HEREIN IS OFFERED WITH THE GOOD FAITH BELIEF THAT IT IS ACCURATE. THIS MATERIAL SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). IN THE EVENT OF AN ADVERSE INCIDENT ASSOCIATED WITH THIS MATERIAL, THIS SAFETY DATA SHEET IS NOT INTENDED TO BE A SUBSTITUTE FOR CONSULTATION WITH APPROPRIATELY TRAINED PERSONNEL. NOR IS THIS SAFETY DATA SHEET INTENDED TO BE A SUBSTITUTE FOR PRODUCT LITERATURE WHICH MAY ACCOMPANY THE FINISHED PRODUCT.

FOR ADDITIONAL INFORMATION CONTACT:

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FOR ADDITIONAL COPIES CONTACT:

ELI LILLY AND COMPANY

GLOSSARY:

ACGIH = AMERICAN CONFERENCE OF GOVERNMENTAL INDUSTRIAL HYGIENISTS  
AIHA = AMERICAN INDUSTRIAL HYGIENE ASSOCIATION  
BEI = BIOLOGICAL EXPOSURE INDEX  
CAS NUMBER = CHEMICAL ABSTRACT SERVICE REGISTRY NUMBER  
CERCLA = COMPREHENSIVE ENVIRONMENTAL RESPONSE COMPENSATION AND LIABILITY ACT (OF 1980)  
CHEMTREC = CHEMICAL TRANSPORTATION EMERGENCY CENTER  
DOT = DEPARTMENT OF TRANSPORTATION  
EC = EUROPEAN COMMUNITY  
EINECS = EUROPEAN INVENTORY OF EXISTING CHEMICAL SUBSTANCES  
ELINCS = EUROPEAN LIST OF NEW CHEMICAL SUBSTANCES  
EPA = ENVIRONMENTAL PROTECTION AGENCY  
HEPA = HIGH EFFICIENCY PARTICULATE AIR (FILTER)  
IARC = INTERNATIONAL AGENCY FOR RESEARCH ON CANCER  
ICAO/IATA = INTERNATIONAL CIVIL AVIATION ORGANIZATION/INTERNATIONAL AIR TRANSPORT ASSOCIATION  
IEG = LILLY INTERIM EXPOSURE GUIDELINE  
IMO = INTERNATIONAL MARITIME ORGANIZATION  
KOW = OCTANOL/WATER PARTITION COEFFICIENT  
LEG = LILLY EXPOSURE GUIDELINE  
LEL = LOWER EXPLOSIVE LIMIT  
MSDS = MATERIAL SAFETY DATA SHEET  
MSHA = MINE SAFETY AND HEALTH ADMINISTRATION  
NA = NOT APPLICABLE, EXCEPT IN SECTION 14 WHERE NA = NORTH AMERICA  
NADA = NEW ANIMAL DRUG APPLICATION  
NAIF = NO APPLICABLE INFORMATION FOUND  
NCI = NATIONAL CANCER INSTITUTE  
NIOSH = NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH  
NOS = NOT OTHERWISE SPECIFIED  
NTP = NATIONAL TOXICOLOGY PROGRAM  
OSHA = OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION  
PEL = PERMISSIBLE EXPOSURE LIMIT (OSHA)  
PKA = ACID WATER DISSOCIATION CONSTANT  
RCRA = RESOURCE CONSERVATION AND RECOVERY ACT  
RQ = REPORTABLE QUANTITY  
RTECS = REGISTRY OF TOXIC EFFECTS OF CHEMICAL SUBSTANCES  
SARA = SUPERFUND AMENDMENTS AND REAUTHORIZATION ACT  
STEG = LILLY SHORT TERM EXPOSURE GUIDELINE  
STEL = SHORT TERM EXPOSURE LIMIT  
TLV = THRESHOLD LIMIT VALUE (ACGIH)  
TPQ = THRESHOLD PLANNING QUANTITY  
TSCA = TOXIC SUBSTANCES CONTROL ACT  
TWA = TIME WEIGHTED AVERAGE/8 HOURS UNLESS OTHERWISE NOTED  
UEL = UPPER EXPLOSIVE LIMIT  
UN = UNITED NATIONS