SAFETY DATA SHEET



1. Identification

Product identifier CEFTIN TABLETS

Other means of identification

Not available.

Synonym(s)

CEFTIN TABLETS 125 MG * CEFTIN TABLETS 250 MG * CEFTIN TABLETS 500 MG * CEFTUM TABLETS * CEFUROX TABLETS * CUROCEF TABLETS * ELOBACT TABLETS * ORACEF TABLETS * ZINADOL TABLETS * ZINAT TABLETS * ZINAT TABLETS * ZIPOS TABLETS * ZOREF TABLETS * NDC NO 0173-0387-00 * NDC NO 0173-0394-00 * CEFUROXIME AXETIL,

FORMULATED PRODUCT

Recommended use Medicinal Product

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant

to medicinal use of the product. In this instance patients should consult prescribing

information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate

safety data sheet for each ingredient.

Recommended restrictions No other uses are advised.

Manufacturer/Importer/Supplier/Distributor information

Manufacturer

GlaxoSmithKline US 5 Moore Drive

Research Triangle Park, NC 27709 USA

US General Information (normal business hours): +1-888-825-5249

Email Address: msds@gsk.com Website: www.gsk.com EMERGENCY PHONE NUMBERS -TRANSPORT EMERGENCIES::

US / International toll call +1 703 527 3887

available 24 hrs/7 days; multi-language response

2. Hazard(s) identification

Classified hazards

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Label elements

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Hazard(s) not otherwise classified (HNOC)

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

3. Composition/information on ingredients

Mixtures

Material name: CEFTIN TABLETS SDS US

Chemical name	Common name and synonyms	CAS number	%
CEFUROXIME AXETIL	AXETIL CEFUROXIME ESTER E47 CEFUROXIME 1-ACETOXY ESTER E47 UOP CCI15641 OPI OPIT UOPT 3 (GW ACN) CEFUROXIME AXETIL ESTER 5-THIA-1-AZABICYCLO(4.2.0)OCT-2-ENE-2-ACID, 3-(((AMINOCARBONYL)OXY)METHYL)-7-((2 FURANYL(METHOXY IMINO)ACETYL)AMINO)-8-OXO-, 1-(ACETYLOXY)ETHYL ESTER, (6R-(6ALPHA,7BETA(Z)))- (9CI)	64544-07-6	51.6 - < 54.9
MICROCRYSTALLINE CELLULOSE	AVICEL PH MICROCRYSTALLINE CELLULOSE ABICEL ALPHA-CELLULOSE ARBOCEL ARBOCELL B 600/30 ARBOCELL BC 200 AVICEL PH101 AVICEL PH102 AVICEL PH103 AVICEL PH105 AVICEL PH200 BETA-AMYLOSE CELLEX MX CELLULOSE (8CI9CI) CELLULOSE (8CI9CI) CELLULOSE CRYSTALLINE CELLULOSE, FOOD GRADE CELLUFI CRYSTALLINE CELLULOSE EMOCEL MCC MICROCRYSTALLINE CELLULOSE POWDERED CELLULOSE POWDERED CELLULOSE RTECS FJ5691460 SOLKA FLOC BW200 CELLULOSE (PAPER FIBRES) CELLULOSE, PAPER FIBRES CELLULOSA (FIBRA PAPEL) TSELLULOSA (FIBRA PAPEL)	9004-34-6	10 - < 20
HYDROXYPROPYL METHYL CELLULOSE	METHOCEL K4M GONIOSOL ISOPRO ALKALINE ISOPTO PLAIN ISOPTO TEARS METHOCEL E,F,K METHOCEL HG METHYL CELLULOSE PROPYLENE GLYCOL ETHER HYPROMELLOSE TEARISOL ULTRA TEARS RTECS NF9125000 CELLULOSE, 2-HYDROXYPROPYL METHYL ESTER METHYLHYDROXYPROPYLCELLULOSE PHARMACOAT 603	9004-65-3	10

Chemical name	Common name and synonyms	CAS number	%
DODECYL SODIUM SULFATE	SODIUM DOCECYL SULFATE SODIUM N-DODECYL SULFATE SODIUM DODECYL SULPHATE DODECYL SULFATE, SODIUM SALT SODIUM LAURYL SULPHATE SODIUM MONOLAURYL SULFATE N-DODECYL SULFATE SODIUM LAURYL SODIUM SULFATE LAURYL SULFATE SODIUM LAURYL SULFATE SODIUM SALT MONODODECYL SODIUM SULFATE SODIUM DODECYLSULFATE SULFURIC ACID, MONODODECYL ESTER, SODIUM SALT SODIUM MONODODECYL SULFATE SDS SLS C12H25NaO4S OHS08485 RTECS WT1050000 SULFURIC ACID MONODODECYL ESTER SODIUM SALT (SODIUM LAURYL SULFATE) N-ALKYL(C8-C20)SULFATE, NATRIUMSALZ	151-21-3	<1
SILICON DIOXIDE COLLOIDAL	NATITIONISALZ	7631-86-9	< 0.3
METHYL PARABEN	GR30517X METHYL P-HYDROXYBENZOATE P-HYDROXYBENZOIC ACID, METHYL ESTER 4-HYDROXYBENZOIC ACID, METHYL ESTER METHYL P-OXYBENZOATE METHYL PARAHYDROXYBENZOATE C8H8O3 OHS14677 RTECS DH2450000 NIPOGIN U124	99-76-3	0.1
PROPYL PARABEN	PROPYL P-HYDROXYBENZOATE NIPASOL TEGOSEPT P PROTABEN 4-HYDROXYBENZOIC ACID, PROPYL ESTER P-HYDROXYBENZOIC ACID, PROPYL ESTER PASEPTOL PARASEPT ASEPTOFORM P BETACIDE P BONOMOLD OP PROPYL ASEPTOFORM PROPYL P-OXYBENZOATE PROPYL CHEMOSEPT PRESERVAL P CHEMOCIDE PK SOLBROL P PROPYL PARASEPT C10H12O3 OHS19941 RTECS DH2800000	94-13-3	0.08

Hazardous components Chemical name	Common name and synonyms	CAS number	%
PROPYLENE GLYCOL	1,2-PROPANEDIOL 1,2-DIHYDROXYPROPANE 2-HYDROXYPROPANOL ISOPROPYLENE GLYCOL METHYLETHYLENE GLYCOL MONOPROPYLENE GLYCOL 2,3-PROPANEDIOL ALPHA-PROPYLENE GLYCOL 1,2-PROPYLENE GLYCOL (RS)-1,2-PROPANEDIOL 1,2-(RS)-PROPANEDIOL 1,2-PROPANEDIOL DL-1,2-PROPANEDIOL DL-1,2-PROPANEDIOL DL-1,2-PROPANEDIOL DL-PROPYLENE GLYCOL PROPANE-1,2-DIOL (PROPYLENE GLYCOL) PROPANE-1-2-DIOL PROPANE-1-2-DIOL PROPANEDIOL,1,2-	57-55-6	0.06

Other components below reportable levels

10 - < 20

4. First-aid measures

Inhalation If dust from the material is inhaled, remove the affected person immediately to fresh air. Oxygen or artificial respiration if needed. Do not use mouth-to-mouth method if victim inhaled the substance.

Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. If experiencing respiratory symptoms: Call a POISON CENTER

or doctor/physician.

Skin contact Wash off with soap and plenty of water. If skin irritation or rash occurs: Get medical

advice/attention. For minor skin contact, avoid spreading material on unaffected skin.

Eye contact Rinse with water. Get medical attention if irritation develops and persists.

Ingestion Rinse mouth. Get medical attention if symptoms occur.

Most important

symptoms/effects, acute and

delayed

May cause allergic skin reaction. May cause allergic respiratory reaction.

Indication of immediate medical attention and special

treatment needed

Provide general supportive measures and treat symptomatically. Symptoms may be delayed.

General information Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. Wash contaminated clothing before reuse.

5. Fire-fighting measures

Suitable extinguishing media

Unsuitable extinguishing

media

Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2).

None known.

Specific hazards arising from

the chemical

During fire, gases hazardous to health may be formed.

Special protective equipment and precautions for firefighters

Fire-fighting

equipment/instructions

In the event of fire, cool tanks with water spray.

Specific methods Cool containers exposed to flames with water until well after the fire is out.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Keep unnecessary personnel away. For personal protection, see section 8 of the MSDS.

Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Methods and materials for containment and cleaning up

Stop the flow of material, if this is without risk. Following product recovery, flush area with water.

For waste disposal, see section 13 of the MSDS.

Environmental precautions Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling Avoid prolonged exposure. Observe good industrial hygiene practices.

Material name: CFFTIN TABLETS SDS US

^{*}Designates that a specific chemical identity and/or percentage of composition has been withheld as a trade secret.

Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the MSDS).

8. Exposure controls/personal protection

Occupational exposure limits

GSK Components	Туре	Value	Note
CEFUROXIME AXETIL	15 MIN STEL	100 mcg/m3	
(CAS 64544-07-6)	OHC	3 3	SKIN SENSITISER RESPIRATORY SENSITISER
DODECYL SODIUM SULFATE (CAS 151-21-3)	OHC	2	SENSITISER
HYDROXYPROPYL METHYL CELLULOSE	OHC	1	
(CAS 9004-65-3) MICROCRYSTALLINE CELLULOSE (CAS	OHC	1	
9004-34-6) PROPYL PARABEN (CAS 94-13-3)	8 HR TWA	5000 mcg/m3	
94 -13-3)	ОНС	1	
US. OSHA Table Z-1 Limits Components	for Air Contaminants (29 CFR 1910.1000 Type	0) Value	Form
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	PEL	5 mg/m3	Respirable fraction.
US. OSHA Table Z-3 (29 CF	:P 1010 1000\	15 mg/m3	Total dust.
Components	Type	Value	
SILICON DIOXIDE COLLOIDAL (CAS 7631-86-9)	TWA	0.8 mg/m3	
1001000)			
		20 millions of particle	
US. ACGIH Threshold Limit Components	t Values Type		
		particle	
Components MICROCRYSTALLINE CELLULOSE (CAS	Type TWA	particle Value	Form
Components MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6) US. NIOSH: Pocket Guide t Components MICROCRYSTALLINE CELLULOSE (CAS	Type TWA o Chemical Hazards	particle Value 10 mg/m3	Form Respirable.
Components MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6) US. NIOSH: Pocket Guide t Components MICROCRYSTALLINE	Type TWA o Chemical Hazards Type	particle Value 10 mg/m3 Value	
Components MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6) US. NIOSH: Pocket Guide t Components MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6) SILICON DIOXIDE COLLOIDAL (CAS 7631-86-9)	Type TWA To Chemical Hazards Type REL	value 10 mg/m3 Value 5 mg/m3 10 mg/m3 6 mg/m3	Respirable.
Components MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6) US. NIOSH: Pocket Guide t Components MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6) SILICON DIOXIDE COLLOIDAL (CAS 7631-86-9) US. AIHA Workplace Enviro	Type TWA TWA O Chemical Hazards Type REL TWA TWA Donmental Exposure Level (WEEL) Guides	particle Value 10 mg/m3 Value 5 mg/m3 10 mg/m3 6 mg/m3	Respirable. Total
Components MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6) US. NIOSH: Pocket Guide t Components MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6) SILICON DIOXIDE COLLOIDAL (CAS 7631-86-9) US. AIHA Workplace Enviro Components PROPYLENE GLYCOL	Type TWA TWA TWA Type REL TWA TWA TWA Type Type	particle Value 10 mg/m3 Value 5 mg/m3 10 mg/m3 6 mg/m3 S Value 10 mg/m3	Respirable. Total Form
Components MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6) US. NIOSH: Pocket Guide t Components MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6) SILICON DIOXIDE COLLOIDAL (CAS 7631-86-9) US. AIHA Workplace Environments PROPYLENE GLYCOL (CAS 57-55-6)	Type TWA TWA TWA Type REL TWA TWA TWA TWA TWA	particle Value 10 mg/m3 Value 5 mg/m3 10 mg/m3 6 mg/m3 s Value 10 mg/m3 6 mg/m3	Respirable. Total Form Aerosol.
Components MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6) US. NIOSH: Pocket Guide t Components MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6) SILICON DIOXIDE COLLOIDAL (CAS 7631-86-9) US. AIHA Workplace Envire Components PROPYLENE GLYCOL (CAS 57-55-6) ogical limit values propriate engineering trols	Type TWA TWA TWA Type REL TWA TWA TWA TWA TWA No biological exposure limits noted for the An Exposure Control Approach (ECA) is upon the OEL/Occupational Hazard Cate	particle Value 10 mg/m3 Value 5 mg/m3 10 mg/m3 6 mg/m3 s Value 10 mg/m3 e ingredient(s). e established for operations in egory and the outcome of a second content of the content	Respirable. Total Form Aerosol. nvolving this material base
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6) US. NIOSH: Pocket Guide to Components MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6) SILICON DIOXIDE COLLOIDAL (CAS 7631-86-9) US. AIHA Workplace Environce Components PROPYLENE GLYCOL (CAS 57-55-6) ogical limit values propriate engineering trols vidual protection measures Eye/face protection	Type TWA TWA TWA Type REL TWA TWA TWA TWA TWA No biological exposure limits noted for the An Exposure Control Approach (ECA) is upon the OEL/Occupational Hazard Cat assessment. I, such as personal protective equipment Not normally needed.	particle Value 10 mg/m3 Value 5 mg/m3 10 mg/m3 6 mg/m3 s Value 10 mg/m3 he ingredient(s). It established for operations it egory and the outcome of a setablished to the outcome of a	Respirable. Total Form Aerosol. nvolving this material base site- or operation-specific response.
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6) US. NIOSH: Pocket Guide to Components MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6) SILICON DIOXIDE COLLOIDAL (CAS 7631-86-9) US. AIHA Workplace Environce Components PROPYLENE GLYCOL (CAS 57-55-6) ogical limit values propriate engineering trols vidual protection measures	Type TWA TWA TWA Type REL TWA TWA TWA TWA TWA No biological exposure limits noted for the An Exposure Control Approach (ECA) is upon the OEL/Occupational Hazard Cataassessment. Type TWA Response Control Approach (ECA) is upon the OEL/Occupational Hazard Cataassessment.	particle Value 10 mg/m3 Value 5 mg/m3 10 mg/m3 6 mg/m3 s Value 10 mg/m3 ine ingredient(s). It is established for operations it egory and the outcome of a state of the other. Glove selection of the other other other.	Respirable. Total Form Aerosol. nvolving this material base site- or operation-specific resiterial but also on other qualications.

Material name: CEFTIN TABLETS

SDS US

110539 Version #: 11 Revision date: 09-30-2013 Issue date: 09-30-2013

Respiratory protection No personal respiratory protective equipment normally required. Thermal hazards Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations

An occupational/industrial hygiene monitoring method has been developed for this material. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and

safety professional.

9. Physical and chemical properties

Appearance

Physical state Solid. **Form** Tablet. Color Not available. Odor Not available. Not available. Odor threshold Not available. pН Not available. Melting point/freezing point

Initial boiling point and boiling

range

Not available.

Not available. Flash point Not available. **Evaporation rate** Flammability (solid, gas) Not available. Upper/lower flammability or explosive limits

Flammability limit - lower

Not available.

Flammability limit - upper

(%)

Not available.

Not available. Explosive limit - lower (%) Explosive limit - upper (%) Not available.

Not available. Vapor pressure Vapor density Not available. Not available. Relative density Solubility(ies) Not available. Not available. Partition coefficient

(n-octanol/water)

Auto-ignition temperature Not available. Not available. **Decomposition temperature Viscosity** Not available.

10. Stability and reactivity

Reactivity The product is stable and non-reactive under normal conditions of use, storage and transport.

Chemical stability Material is stable under normal conditions.

Possibility of hazardous

reactions

No dangerous reaction known under conditions of normal use.

Conditions to avoid Contact with incompatible materials. Incompatible materials Strong oxidizing agents. Fluorine.

Hazardous decomposition

products

Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.

11. Toxicological information

Information on likely routes of exposure

Ingestion Not expected to be toxic following ingestion.

Inhalation May cause allergy or asthma symptoms or breathing difficulties if inhaled. Inhalation of dusts may

cause respiratory irritation.

Skin contact May cause an allergic skin reaction. Dust in the eyes will cause irritation. Eye contact

Material name: CFFTIN TABLETS

Symptoms related to the physical, chemical and

Not available.

Information on toxicological effects

CEFUROXIME AXETIL (CAS 64544-07-6)

toxicological characteristics

Acute toxicity May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause allergic skin

reaction.

Components Species Test Results

Acute

Oral

Urai LD50

Rat > 2000 g/kg

DODECYL SODIUM SULFATE (CAS 151-21-3)

Acute

Oral

LD50 Rat 1288 mg/kg

HYDROXYPROPYL METHYL CELLULOSE (CAS 9004-65-3)

Acute

Oral

LD50 Rat > 2000 mg/kg

METHYL PARABEN (CAS 99-76-3)

Acute

Oral

LD50 Mouse > 8 g/kg

MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)

Acute

Dermal

LD50 Rabbit > 2000 mg/kg

Oral

LD50 Rat > 2000 mg/kg

PROPYL PARABEN (CAS 94-13-3)

Acute

Oral

LD50 Rat > 2000 mg/kg

Skin corrosion/irritationBased on available data, the classification criteria are not met.

Corrosivity

CEFUROXIME AXETIL

Read across Result: Mild irritant Species: Human

Serious eye damage/eye

irritation

Dust in the eyes will cause irritation.

Eye CELIDOVIME AVI

CEFUROXIME AXETIL Read across
Result: Mild irritant
Species: Human

Respiratory sensitization May cause allergy or asthma symptoms or breathing difficulties if inhaled.

CEFUROXIME AXETIL Read Across
Result: Positive

Result: Positive Species: Human

Skin sensitization May cause an allergic skin reaction.

Maximisation assay (Magnusson and Kligman)

HYDROXYPROPYL METHYL CELLULOSE Result: Negative

Species: Guinea pig

Sensitization

CEFUROXIME AXETIL Read Across

Result: Positive Species: Human

Germ cell mutagenicity Based on available data, the classification criteria are not met.

Material name: CEFTIN TABLETS

^{*} Estimates for product may be based on additional component data not shown.

CEFUROXIME AXETIL Ames

Result: Negative

Chromosomal Aberration Assay In Vitro

Result: Positive

Mouse Lymphoma Cell Assay

Result: Negative

in vitro micronucleus assay

Result: Negative Species: Rat

Carcinogenicity

This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA. Due to lack of

data the classification is not possible.

IARC Monographs. Overall Evaluation of Carcinogenicity

SILICON DIOXIDE COLLOIDAL (CAS 7631-86-9) 3 Not classifiable as to carcinogenicity to humans.

Reproductive toxicity Based on available data, the classification criteria are not met.

CEFUROXIME AXETIL Embryofetal Development

Result: No known effects

Species: Human

Specific target organ toxicity -

single exposure

Due to lack of data the classification is not possible.

Specific target organ toxicity -

repeated exposure

Due to lack of data the classification is not possible.

Due to lack of data the classification is not possible. **Aspiration hazard**

12. Ecological information

Ecotoxicity No information is available about the potential of this product to produce adverse environmental

effects.

	CIICCIS.		
Components		Species	Test Results
CEFUROXIME AXETIL (CAS 64544-07-6)	
Aquatic			
Acute			
Activated Sludge Respiration	IC50	Residential sludge	> 100 mg/l, 3 hours, OECD 209
Algae	EC50	Green algae (Selenastrum capricornutum)	> 91 mg/l, 72 hours, Static test, OECD 201
	NOEC	Green algae (Selenastrum capricornutum)	91 mg/l, 72 hours, Static test
Crustacea	EC50	Water flea (Daphnia magna)	> 1000 mg/l, 48 hours, Static test, OECD 202
	NOEC	Water flea (Daphnia magna)	> 1000 mg/l, 48 hours, Static test
Fish	EC50	Rainbow trout (Adult Oncorhyncus mykiss)	> 120 mg/l, 96 hours, Static test, OECD 203
	NOEC	Rainbow trout (Adult Oncorhyncus mykiss)	120 mg/l, 96 hours, Static test
Microtox	MIC	Azotobacter beijerinckii	0.2 mg/l
Other	MIC	Aspergillus niger	> 1 mg/l
		Nostoc commune	0.2 mg/l
		Pseudomonas aeruginosa	> 1 mg/l
		Trichoderma harzianum	> 1 mg/l
HYDROXYPROPYL MET	THYL CELLULOS	SE (CAS 9004-65-3)	
Aquatic		,	
Acute			
Fish	EC50	Fish	> 100 mg/L, 96 hours
PROPYLENE GLYCOL (CAS 57-55-6)		
Acute			
	IC50	Activated sludge	> 1000 mg/l, 3 hours
Aquatic			
Acute			
Algae	EC50	Green algae (Selenastrum capricornutum)	19000 mg/l, 14 days

Material name: CEFTIN TABLETS

8 / 11

110539 Version #: 11 Revision date: 09-30-2013 Issue date: 09-30-2013

omponents		Species	Test Results
	NOEC	Green algae (Selenastrum capricornutum)	15000 mg/l, 14 days
Crustacea	EC50	Daphnia	43500 mg/l, 48 hours
	NOEC	Daphnia	28500 mg/l, 48 hours
Fish	EC50	Fathead minnow (Adult Pimephales promelas)	51400 mg/l, 96 hours, Static test
		Rainbow trout (Adult Oncorhyncus mykiss)	51600 mg/l, 96 hours, Static test
	NOEC	Fathead minnow (Adult Pimephales promelas)	41000 mg/l, 96 hours, Static test
		Rainbow trout (Adult Oncorhyncus mykiss)	42000 mg/l, 96 hours, Static test
Microtox	EC50	Microtox	51400 mg/l, 30 minutes
LICON DIOXIDE CO	LLOIDAL (CAS 76	31-86-9)	
Aquatic			
Acute			
Algae	EC50	Green algae (Selenastrum capricornutum)	440 mg/l, 72 hours
	NOEC	Green algae (Selenastrum capricornutum)	60 mg/l, 72 hours
Crustacea	EC50	Water flea (Daphnia magna)	> 10000 mg/l, 24 hours, Static test
		Common corn / luvenile Cyprinus corn	io) > 10000 mg/L 72 hours
Fish	EC50	Common carp (Juvenile Cyprinus carp	10) - 10000 Hig/i, 12 Hours
Fish	EC50	Zebra fish (Adult Brachydanio rerio)	5000 mg/l, 96 hours, Static test

^{*} Estimates for product may be based on additional component data not shown.

Persistence and degradability

_		
ы	nntn	lysis
	11010	19313

Half-life (Photolysis-aqueous)

PROPYLENE GLYCOL 1.3 - 2.3 Years Estimated

Half-life (Photolysis-atmospheric)

PROPYLENE GLYCOL 32 Hours Estimated

UV/visible spectrum wavelength

CEFUROXIME AXETIL 290 nm

Hydrolysis

Half-life (Hydrolysis-acidic)

CEFUROXIME AXETIL 299 Hours

Half-life (Hydrolysis-basic)

CEFUROXIME AXETIL 1.05 Hours

Half-life (Hydrolysis-neutral)

CEFUROXIME AXETIL 30.2 Hours

Biodegradability

Percent degradation (Aerobic biodegradation-soil)

CEFUROXIME AXETIL 42.8 - 80 %, 64 days

Percent degradation (Anaerobic biodegradation)

PROPYLENE GLYCOL 100 %, 9 days

Bioaccumulative potential

Partition coefficient n-octanol / water (log Kow)

PROPYLENE GLYCOL -0.92
-1.35
HYDROXYPROPYL METHYL CELLULOSE -5
CEFUROXIME AXETIL 0.8 - 1.24
DODECYL SODIUM SULFATE 1.6
METHYL PARABEN 1.96
PROPYL PARABEN 3.04

Bioconcentration factor (BCF)

HYDROXYPROPYL METHYL CELLULOSE 3.2 Estimated PROPYLENE GLYCOL < 1 Estimated

Mobility in soil

Adsorption

Soil/sediment sorption - log Koc

CEFUROXIME AXETIL 1.09 - 1.19

Mobility in general

Volatility

Henry's law

CEFUROXIME AXETIL 0 atm m^3/mol, 25 C Estimated HYDROXYPROPYL METHYL CELLULOSE 0 atm m3/mol Estimated PROPYLENE GLYCOL 0 atm m^3/mol Estimated

Distribution

Octanol/water distribution coefficient log DOW

PROPYL PARABEN 3.04

Other adverse effects Not available.

13. Disposal considerations

Disposal instructionsCollect and reclaim or dispose in sealed containers at licensed waste disposal site.

Local disposal regulations Dispose in accordance with all applicable regulations.

Hazardous waste code

The waste code should be assigned in discussion between the user, the producer and the waste

disposal company.

Waste from residues / unused

products

Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see:

Disposal instructions).

Contaminated packaging Empty containers should be taken to an approved waste handling site for recycling or disposal.

Since emptied containers may retain product residue, follow label warnings even after container is

emptied.

14. Transport information

DOT

Not regulated as a dangerous good.

IATA

Not regulated as a dangerous good.

IMDG

Not regulated as a dangerous good.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

MARPOL Annex II applies to liquids used in a ship's operation that pose a threat to the marine

environment. These materials may not be transported in bulk.

15. Regulatory information

US federal regulations

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

SARA 304 Emergency release notification

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - Yes

Delayed Hazard - Yes Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No

SARA 302 Extremely hazardous substance

No

SARA 311/312 Hazardous

No

chemical

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Material name: CEFTIN TABLETS

SDS US

10 1111

Safe Drinking Water Act

(SDWA)

Not regulated.

Food and Drug Not regulated. Administration (FDA)

US state regulations

US. Massachusetts RTK - Substance List

MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6) SILICON DIOXIDE COLLOIDAL (CAS 7631-86-9)

US. New Jersey Worker and Community Right-to-Know Act

Not regulated.

US. Pennsylvania RTK - Hazardous Substances

MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)

PROPYLENE GLYCOL (CAS 57-55-6)

SILICON DIOXIDE COLLOIDAL (CAS 7631-86-9)

US. Rhode Island RTK

Not regulated.

US. California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

Country(s) or region

Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No

^{*}A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s) A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing

Toxic Substances Control Act (TSCA) Inventory

16. Other information, including date of preparation or last revision

Inventory name

Issue date 09-30-2013 **Revision date** 09-30-2013

Version # 11

United States & Puerto Rico

Further information This material has not been assessed for HMIS or NFPA ratings.

References **GSK Hazard Determination**

Disclaimer The information and recommendations in this safety data sheet are, to the best of our knowledge,

> accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and

the suitability of the material or product for any particular purpose.

Product and Company Identification: Business Units **Revision Information**

Composition / Information on Ingredients: Ingredients

Exposure Controls / Personal Protection:

Physical & Chemical Properties:

Transport Information: Agency Name, Packaging Type, and Transport Mode Selection

Regulatory Information: United States

GHS: Classification

Material name: CEFTIN TABLETS SDS US

110539 Version #: 11 Revision date: 09-30-2013 Issue date: 09-30-2013

No

On inventory (yes/no)*