

1. Identification

Product identifier	CEFTIN FOR ORAL SUSPENSION
Other means of identification	Not available.
Synonym(s)	CEFTIN SUSPENSION 125 MG/5 ML * CEFTIN SUSPENSION 250 MG/5 ML * CEFTIN ORAL SUSPENSION * CEFTUM ORAL SUSPENSION 125 MG/5 ML * CEFUROX ORAL SUSPENSION * CEFOCER ORAL SUSPENSION * ELOBACT ORAL SUSPENSION * ELOBACT GRANULES * ELOBACT 125 MG DOSIERBRIEFE * ZINADOL ORAL SUSPENSION * ZINAT SUSPENSION * ZINNAT SUSPENSION SACHET 125 MG * ZINNAT SUSPENSION 25 MG/ML * ZINACEF SUSPENSION * ZIPOS ORAL SUSPENSION * ZOREF ORAL SUSPENSION * NDC NO 0173-0740-00 * NDC NO 0173-0741-00 * NDC NO 0173-0741-10 * 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
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Email Address: msds@gsk.com
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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

Hazardous components			
Chemical name	Common name and synonyms	CAS number	%
SUCROSE	SACCHAROSE SUGAR CANE SUGAR BEET SUGAR CONFECTIONER'S SUGAR BETA-D-FRUCTOFURANOSYL-ALPHA-D-G ALPHA-D-GLUCOPYRANOSIDE, BETA-D-FRUCTOFURANOSYL GRANULATED SUGAR (ALPHA-D-GLYCOSIDO)-BETA-D-FRUCTOF ROCK CANDY ALPHA-D-GLUCOPYRANOSYL BETA-D-FRUCTOFURANOSIDE NCI-C56597 AMERFOND MICROSE MANALOX WHITE SUGAR SUCRALOX D-(+)-SACCHAROSE D-(+)-SUCROSE C12H22O11 OHS22174 RTECS WN6500000 SAHHAROOS	57-50-1	60 - < 70
STEARIC ACID	1-HEPTADECANECARBOXYLIC ACID OCTADECANOIC ACID STEAROPHANIC ACID N-OCTADECANOIC ACID C18H36O2 OHS21873 RTECS WI2800000	57-11-4	20 - < 30
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	3.5 - < 7.5
TUTTI FRUTTI	TUTTI FRUTTI 51880/A TUTTI FRUTTI FLAVOUR	Unassigned	1 - < 3
ACESULFAME K	1,2,3-OXATHIAZIN-4(3H)-ONE, 6-METHYL-, 2,2-DIOXIDE, POTASSIUM SALT (9CI) ACESULFAM ACETOSULFAM HOE 0-95K MS/D 00012 MT 5566 N-(AMINOSULPHONYL)ACETAMIDE POTASSIUM 6-METHYL-1,2,3-OXATHIAZIN-4-ONE-2,2-D POTASSIUM SALT OF 6-METHYL-3,4-DIHYDRO-1,2,3-OXATHIAZIN (SUNETT) RM 389 RMS 727	55589-62-3	< 1

Hazardous components			
Chemical name	Common name and synonyms	CAS number	%
ASPARTAME	L-PHENYLALANINE, N-L-ALPHA-ASPARTYL-1-METHYL ESTER N-L-ALPHA-ASPARTYL-1-METHYL ESTER L-PHENYLALANINE SUCCINAMIC ACID, 3-AMINO-N-(ALPHA-CARBOXYPHENETHYL) N-METHYL ESTER, STEREOISOMER ASPARTYLPHENYLALANINE METHYL ESTER METHYL ASPARTYLPHENYLALANATE NUTRASWEET GR192715X	22839-47-0	< 1
XANTHAN GUM	1266 (GW ACN) ACTIGUM CX 9 B 1459 BIOPOLYMER 9702 BIOPOLYMER XB 23 BIOPOLYMER XB-23 XANTHAN GUM BIOZAN R ENORFLO X FLOCON 1035 FLOCON 4800 GALAXY XB KELFLO KELTROL KELTROL (GUM) KELTROL BT KELTROL F KELTROL T KELTROL TF KELZAN KENTROL POLYSACCHARIDE B 1459 RHODOPOL 23 RM 416 RM 578 U 1573 U 2248 XANFLOOD XANTHOMONAS GUM	11138-66-2	< 0.1
Other components below reportable levels			< 1

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

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	Alcohol resistant foam. Water spray. Water fog. Dry chemical powder.
Unsuitable extinguishing media	Carbon dioxide (CO2).

Specific hazards arising from the chemical	During fire, gases hazardous to health may be formed.
Special protective equipment and precautions for firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
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. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits. Avoid inhalation of dust from the spilled material. For personal protection, see section 8 of the MSDS.
Methods and materials for containment and cleaning up	Minimize dust generation and accumulation. If sweeping of a contaminated area is necessary use a dust suppressant agent which does not react with the product. Sweep up or vacuum up spillage and collect in suitable container for disposal. Collect dust using a vacuum cleaner equipped with HEPA filter. 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	Minimize dust generation and accumulation. Provide appropriate exhaust ventilation at places where dust is formed. Avoid breathing dust. Avoid contact with skin and eyes. Avoid prolonged exposure. In case of insufficient ventilation, wear suitable respiratory equipment. Practice good housekeeping.
Conditions for safe storage, including any incompatibilities	Store in original tightly closed container. Store in a well-ventilated place. Guard against dust accumulation of this material. Store away from incompatible materials (see Section 10 of the MSDS).

8. Exposure controls/personal protection

Occupational exposure limits

GSK

Components	Type	Value	Note
ACESULFAME K (CAS 55589-62-3)	OHC	1	
ASPARTAME (CAS 22839-47-0)	8 HR TWA	5000 mcg/m3	
	OHC	1	
CEFUROXIME AXETIL (CAS 64544-07-6)	15 MIN STEL	100 mcg/m3	
	OHC	3	RESPIRATORY SENSITISER SKIN SENSITISER
		3	
TUTTI FRUTTI (CAS Unassigned)	8 HR TWA	5000 mcg/m3	
	OHC	1	
XANTHAN GUM (CAS 11138-66-2)	OHC	1	

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Components	Type	Value	Form
SUCROSE (CAS 57-50-1)	PEL	5 mg/m3 15 mg/m3	Respirable fraction. Total dust.

US. ACGIH Threshold Limit Values

Components	Type	Value
STEARIC ACID (CAS 57-11-4)	TWA	10 mg/m3
SUCROSE (CAS 57-50-1)	TWA	10 mg/m3

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value	Form
SUCROSE (CAS 57-50-1)	TWA	5 mg/m3 10 mg/m3	Respirable. Total

Biological limit values	No biological exposure limits noted for the ingredient(s).
Appropriate engineering controls	An Exposure Control Approach (ECA) is established for operations involving this material based upon the OEL/Occupational Hazard Category and the outcome of a site- or operation-specific risk assessment.

Individual protection measures, such as personal protective equipment

Eye/face protection	Not normally needed.
Hand protection	The choice of an appropriate glove does not only depend on its material but also on other quality features and is different from one producer to the other. Glove selection must take into account any solvents and other hazards present.
Other	Not normally needed.
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	Powder.
Color	Not available.
Odor	Not available.
Odor threshold	Not available.
pH	Not available.
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not available.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	Not available.
Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	Not available.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
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	Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Contact with incompatible materials.
Incompatible materials	Strong oxidizing agents.
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.
Eye contact	May be irritating to eyes.

Symptoms related to the physical, chemical and toxicological characteristics
Not available.

Information on toxicological effects

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

Components	Species	Test Results
ACESULFAME K (CAS 55589-62-3)		
Acute		
<i>Oral</i>		
LD50	Rat	> 2000 mg/kg
CEFUROXIME AXETIL (CAS 64544-07-6)		
Acute		
<i>Oral</i>		
LD50	Rat	> 2000 g/kg
STEARIC ACID (CAS 57-11-4)		
Acute		
<i>Oral</i>		
LD50	Rat	> 5000 mg/kg
XANTHAN GUM (CAS 11138-66-2)		
Acute		
<i>Inhalation</i>		
LC50	Rat	> 21 mg/l, 1 hour exposure
<i>Oral</i>		
LD50	Rat	> 5000 mg/kg

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

Skin corrosion/irritation
Based 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	
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 Species: Human

Skin sensitization
May cause an allergic skin reaction.

Sensitization	
CEFUROXIME AXETIL	Read Across Result: Positive Species: Human

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

CEFUROXIME AXETIL	Ames Result: Negative Chromosomal Aberration Assay In Vitro Result: Positive
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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.
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.
Aspiration hazard	Due to lack of data the classification is not possible.
Further information	This material is a cephalosporin antibiotic.

12. Ecological information

Ecotoxicity	No information is available about the potential of this product to produce adverse environmental effects.
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Components		Species	Test Results
ACESULFAME K (CAS 55589-62-3)			
Aquatic			
<i>Acute</i>			
Crustacea	NOEC	Water flea (Daphnia magna)	> 1000 mg/l, 24 hours
Fish	EC50	Zebra fish (Adult Brachydanio rerio)	> 1000 mg/l, 96 hours
<i>Chronic</i>			
Other	LC50	Bacteria	> 10000 mg/l
CEFUROXIME AXETIL (CAS 64544-07-6)			
Aquatic			
<i>Acute</i>			
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 Oncorhynchus mykiss)	> 120 mg/l, 96 hours, Static test, OECD 203
	NOEC	Rainbow trout (Adult Oncorhynchus 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
STEARIC ACID (CAS 57-11-4)			
Aquatic			
<i>Acute</i>			
Fish	EC50	Orange-red killfish (Adult Oryzias latipes)	125 mg/l, 96 hours
Microtox	EC50	Microtox	12 mg/l, 15 minutes

Components	Species	Test Results
XANTHAN GUM (CAS 11138-66-2)		
Aquatic		
Acute		
Fish	EC50	Rainbow trout (Adult Oncorhyncus mykiss)
		420 mg/l, 96 hours, Static test
* Estimates for product may be based on additional component data not shown.		
Persistence and degradability		
Photolysis		
Half-life (Photolysis-atmospheric)		
STEARIC ACID		17 Hours Estimated
UV/visible spectrum wavelength		
CEFUROXIME AXETIL		290 nm
STEARIC ACID		210 nm
Hydrolysis		
Half-life (Hydrolysis-acidic)		
CEFUROXIME AXETIL		299 Hours
Half-life (Hydrolysis-basic)		
ASPARTAME		< 1 Days Measured
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
STEARIC ACID		50 %, 13 days
Bioaccumulative potential		
Partition coefficient n-octanol / water (log Kow)		
SUCROSE		-3
CEFUROXIME AXETIL		0.8 - 1.24
STEARIC ACID		8.23
		8.42
Bioconcentration factor (BCF)		
ASPARTAME		1 Estimated
STEARIC ACID		> 9999 Estimated
Mobility in soil		
Adsorption		
Soil/sediment sorption - log Koc		
ASPARTAME		1.78 Estimated
CEFUROXIME AXETIL		1.09 - 1.19
STEARIC ACID		5.86 Estimated
Mobility in general		
Volatility		
Henry's law		
ASPARTAME		< 0 atm m^3/mol Estimated
CEFUROXIME AXETIL		0 atm m^3/mol, 25 C Estimated
STEARIC ACID		0.000051 Estimated
SUCROSE		< 0 atm m^3/mol Estimated
Other adverse effects	Not available.	
13. Disposal considerations		
Disposal instructions	Collect 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 - Yes Pressure Hazard - No Reactivity Hazard - No
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SARA 302 Extremely hazardous substance	No
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SARA 311/312 Hazardous chemical	No
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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.

Safe Drinking Water Act (SDWA)	Not regulated.
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Food and Drug Administration (FDA)	Not regulated.
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US state regulations

US. Massachusetts RTK - Substance List

SUCROSE (CAS 57-50-1)

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

Not regulated.

US. Pennsylvania RTK - Hazardous Substances

SUCROSE (CAS 57-50-1)

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	Inventory name	On inventory (yes/no)*
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

Country(s) or region	Inventory name	On inventory (yes/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
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	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 country(s).

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

Issue date	09-30-2013
Revision date	09-30-2013
Version #	14
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.
Revision Information	Product and Company Identification: Business Units Composition / Information on Ingredients: Ingredients Physical & Chemical Properties: Transport Information: Agency Name, Packaging Type, and Transport Mode Selection Regulatory Information: United States GHS: Classification