SAFETY DATA SHEET

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Trade name or designation of the mixture CEFTIN FOR ORAL SUSPENSION

Registration number -

Synonyms 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 * CEFOCEF 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

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

Identified uses 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.

Uses advised against No other uses are advised.

1.3. Details of the supplier of the safety data sheet

GlaxoSmithKline UK
980 Great West Road
Brentford, Middlesex TW8 9GS UK
UK General Information (normal business hours): +44-20-8047-5000
Email Address: msds@gsk.com
Website: www.gsk.com

1.4. Emergency telephone number

TRANSPORT EMERGENCIES::
UK In-country toll call: +(44)-870-8200418
International toll call: +1 703 527 3887
available 24 hrs/7 days; multi-language response

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

The mixture has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.

Classification according to Directive 67/548/EEC or 1999/45/EC as amended

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

Classification according to Regulation (EC) No 1272/2008 as amended

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

2.2. Label elements

Label according to Regulation (EC) No. 1272/2008 as amended

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

Supplemental label information Not applicable.

2.3. Other hazards Assume that this material is capable of sustaining combustion.
Assume that this material is capable of producing a dust explosion if ignited as a dust cloud.
Assume that this material is capable of being ignited by an electrostatic discharge.
May cause allergy or asthma symptoms or breathing difficulties if inhaled.
May cause an allergic skin reaction.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

General information

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	INDEX No.	Notes
Sucrose	60 - < 70	57-50-1 200-334-9	-	-	
Classification: **DSD:** - **CLP:** -					
Stearic acid	20 - < 30	57-11-4 200-313-4	-	-	
Classification: **DSD:** - **CLP:** -					
CEFUROXIME AXETIL	3.5 - < 7.5	64544-07-6 -	-	-	
Classification: **DSD:** R42/43 **CLP:** Skin Sens. 1;H317, Resp. Sens. 1;H334					
TUTTI FRUTTI	1 - < 3	Unassigned -	-	-	
Classification: **DSD:** - **CLP:** -					
ASPARTAME	< 1	22839-47-0 245-261-3	-	-	
Classification: **DSD:** - **CLP:** -					
XANTHAN GUM	< 0.1	11138-66-2 234-394-2	-	-	
Classification: **DSD:** - **CLP:** -					
Other components below reportable levels	1 - < 3				

CLP: Regulation No. 1272/2008.
DSD: Directive 67/548/EEC.
M: M-factor
vPvB: very persistent and very bioaccumulative substance.
PBT: persistent, bioaccumulative and toxic substance.
#: This substance has been assigned Community workplace exposure limit(s).

Composition comments The full text for all R- and H-phrases is displayed in section 16.

SECTION 4: First aid measures

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

4.1. Description of 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 CENTRE 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 Get medical attention if symptoms occur. Rinse mouth.

4.2. Most important symptoms and effects, both acute and delayed May cause allergic skin reaction. May cause allergic respiratory reaction.

4.3. Indication of any immediate medical attention and special treatment needed Provide general supportive measures and treat symptomatically. Symptoms may be delayed.

SECTION 5: Firefighting measures

General fire hazards Assume that this material is capable of sustaining combustion.

5.1. Extinguishing media

Suitable extinguishing media Alcohol resistant foam. Water spray. Water fog. Dry chemical powder.

Unsuitable extinguishing media Carbon dioxide (CO_2).

5.2. Special hazards arising from the substance or mixture During fire, gases hazardous to health may be formed.

5.3. Advice for firefighters

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

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

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel Keep unnecessary personnel away. Wear a dust mask if dust is generated above exposure limits. Avoid inhalation of dust from the spilled material. For personal protection, see section 8.

For emergency responders Keep unnecessary personnel away. Use personal protection recommended in Section 8 of the MSDS.

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

6.3. Methods and material for containment and cleaning up Minimise 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.

6.4. Reference to other sections For personal protection, see section 8. For waste disposal, see section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling Minimise 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.

7.2. 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).

7.3. Specific end use(s) Medicinal Product

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limits

GSK

Components	Type	Value	Note
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	SKIN SENSITISER
		3	RESPIRATORY SENSITISER
TUTTI FRUTTI (CAS Unassigned)	8 HR TWA	5000 mcg/m3	
	OHC	1	
XANTHAN GUM (CAS 11138-66-2)	OHC	1	

UK. EH40 Workplace Exposure Limits (WELs)

Components	Type	Value
Sucrose (CAS 57-50-1)	STEL	20 mg/m3
	TWA	10 mg/m3

Recommended monitoring procedures Follow standard monitoring procedures.

Derived No Effect Level (DNEL) Not available.

Predicted no effect concentrations (PNECs) Not available.

8.2. Exposure controls

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

General information Personal protection equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment. Follow all local regulations if personal protective equipment (PPE) is used in the workplace.

Eye/face protection Not normally needed.

Skin protection

- 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. Select suitable chemical resistant protective gloves (EN 374) with a protective index 6 (>480min permeation time).

- Other Not normally needed.

Respiratory protection No personal respiratory protective equipment normally required.

Thermal hazards Wear appropriate thermal protective clothing, when necessary.

Hygiene measures 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.

Environmental exposure controls

Hazard guidance and control recommendations Not available.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance

Physical state Solid.

Form Powder.

Colour Not available.

Odour Not available.

Odour 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.

Vapour pressure Not available.

Vapour 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.
Explosive properties	Not available.
Oxidizing properties	Not available.
9.2. Other information	No relevant additional information available.

SECTION 10: Stability and reactivity

10.1. Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
10.2. Chemical stability	Material is stable under normal conditions.
10.3. Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
10.4. Conditions to avoid	Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Contact with incompatible materials.
10.5. Incompatible materials	Strong oxidising agents.
10.6. Hazardous decomposition products	Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.

SECTION 11: Toxicological information

General information Occupational exposure to the substance or mixture may cause adverse effects. This material is an antibiotic, a cephalosporin.

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 Not available.

11.1. 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
CEFUROXIME AXETIL (CAS 64544-07-6)		
Acute		
Oral		
LD50	Rat	> 2000 g/kg
Stearic acid (CAS 57-11-4)		
Acute		
Oral		
LD50	Rat	> 5000 mg/kg
XANTHAN GUM (CAS 11138-66-2)		
Acute		
Inhalation		
LC50	Rat	> 21 mg/l, 1 hour exposure
Oral		
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 sensitisation May cause allergy or asthma symptoms or breathing difficulties if inhaled.

CEFUROXIME AXETIL

Read Across
Result: positive
Species: Human

Skin sensitisation May cause an allergic skin reaction.

Sensitisation

CEFUROXIME AXETIL

Read Across
Result: positive
Species: Human

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

Germ cell mutagenicity

Mutagenicity

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 Due to lack of data the classification is not possible.

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

Reproductive toxicity

Reproductivity

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.

Mixture versus substance information Not available.

Other information This material is a cephalosporin antibiotic.

SECTION 12: Ecological information

12.1. Toxicity No information is available about the potential of this product to produce adverse environmental effects.

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

Components		Species	Test results
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			
Acute			
Fish	EC50	Orange-red killfish (Adult Oryzias latipes)	125 mg/l, 96 hours
Microtox	EC50	Microtox	12 mg/l, 15 minutes
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.

12.2. Persistence and degradability

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-inherent)

CEFUROXIME AXETIL	74 %, < 1 day Modified Zahn-Wellens, primary biodegradation, loss of parent., Activated sludge
Stearic acid	77 %, 28 days BOD
Sucrose	69 % BOD5

Percent degradation (Aerobic biodegradation-ready)

ASPARTAME	60 - 90 %, 5 days
CEFUROXIME AXETIL	28 %, 28 days Modified Sturm test. 42 %, 64 days Modified Sturm test.
Stearic acid	95 %, 22 days Sturm test

Percent degradation (Aerobic biodegradation-soil)

CEFUROXIME AXETIL	42.8 - 80 %, 64 days
Stearic acid	50 %, 13 days

12.3. Bioaccumulative potential

Partition coefficient n-octanol/water (log Kow)

CEFUROXIME AXETIL	0.8 - 1.24
Stearic acid	8.23 8.42
Sucrose	-3

Bioconcentration factor (BCF)

ASPARTAME	1 Estimated
Stearic acid	> 9999 Estimated

12.4. 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

12.5. Results of PBT and vPvB assessment Not available.

12.6. Other adverse effects Not available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Residual waste 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.

EU waste code The Waste code should be assigned in discussion between the user, the producer and the waste disposal company.

Disposal methods/information Collect and reclaim or dispose in sealed containers at licensed waste disposal site.

Special precautions Dispose in accordance with all applicable regulations.

SECTION 14: Transport information

ADR

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

14.7. Transport in bulk according to Annex II of MARPOL73/78 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.

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

EU regulations

Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex I

Not listed.

Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex II

Not listed.

Regulation (EC) No. 850/2004 On persistent organic pollutants, Annex I as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 1 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 2 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 3 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex V as amended

Not listed.

Regulation (EC) No. 166/2006 Annex II Pollutant Release and Transfer Registry

Not listed.

Regulation (EC) No. 1907/2006, REACH Article 59(1) Candidate List as currently published by ECHA

Not listed.

Authorisations

Regulation (EC) No. 1907/2006, REACH Annex XIV Substances subject to authorization, as amended

Not listed.

Restrictions on use

Regulation (EC) No. 1907/2006, REACH Annex XVII Substances subject to restriction on marketing and use as amended

Not listed.

Directive 2004/37/EC: on the protection of workers from the risks related to exposure to carcinogens and mutagens at work

Not listed.

Directive 92/85/EEC: on the safety and health of pregnant workers and workers who have recently given birth or are breastfeeding

Not listed.

Other EU regulations

Directive 96/82/EC (Seveso II) on the control of major-accident hazards involving dangerous substances

Not listed.

Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

Not listed.

Directive 94/33/EC on the protection of young people at work

Not listed.

Other regulations	The product is classified and labelled in accordance with EC directives or respective national laws. This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006.
National regulations	Young people under 18 years old are not allow to work with this product according to the EU Directive 94/33/EC on the protection of young people at work. Follow national regulation for work with chemical agents.
15.2. Chemical safety assessment	No Chemical Safety Assessment has been carried out.

SECTION 16: Other information

List of abbreviations	Not available.
References	GSK Hazard Determination
Information on evaluation method leading to the classification of mixture	The classification for health and environmental hazards is derived by a combination of calculation methods and test data, if available.
Full text of any statements or R-phrases and H-statements under Sections 2 to 15	R42/43 May cause sensitization by inhalation and skin contact. H317 May cause an allergic skin reaction. H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Revision information	Product and Company Identification: Business Units Composition / Information on Ingredients: Ingredients Physical & Chemical Properties: Transport Information: Agency Name and Packaging Type/Transport Mode Selection Regulatory Information: United States GHS: Classification
Training information	Follow training instructions when handling this material.
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.