

Safety Data Sheet (GHS)

according to Regulation (EC) No.1907/2006

Date of issue: 11-MAY-2017

Replaces version of: 31-MAR-2017

Cefdinir B 454983 (AT14)

Section 1: Identification of the substance/preparation and of the company

1.1 Product identifier

Product name Cefdinir B
Chemical Name CEFDINIR
CAS Number 91832-40-5

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

Usage Pharmaceutical active ingredient

1.3 Details of the supplier of the Safety Data Sheet

Company name Novartis Pharma AG
4002 Basel
Switzerland
Tel: +41 61 324 11 11, email: sds.support@novartis.com

1.4 Emergency telephone number

Emergency phone number CHEMTEL (International) +1 813 676 1670 (365/24/7)

Section 2: Hazards identification

2.1 Classification of the substance or mixture

GHS hazard category

Acute Toxicity (oral): not classified

Respiratory sensitizer Cat.1

Skin sensitizer: Cat.1

Germ cell mutation: not classified

Carcinogenicity: not classified

Reproductive toxicity: not classified

Explosives, oxidizing, self-reactive or self-heating, pyrophoric substances, substances which in contact with water emit flammable gases, organic peroxides: not classified

Flammable solid: not classified

2.2 Label elements

GHS-Label Self assessment according REGULATION (EC) No 1272/2008



Danger

Hazard statements

H317: May cause an allergic skin reaction.

H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Precautionary statements

P261: Avoid breathing dust/fume/gas/mist/vapours/spray.

P280: Wear protective gloves/protective clothing/eye protection/face protection.

P302/352: IF ON SKIN: Wash with plenty of water/...

P333/313: If skin irritation or rash occurs: Get medical advice/attention.

P342/311: If experiencing respiratory symptoms: Call a POISON CENTER/doctor/...

2.3 Other hazards

Specific hazards May deflagrate.

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Section 3: Composition / information on ingredients

Chemical characterisation of the substance / preparation:

Type	Substance
Chemical Class	antibiotics
Chemical Name	CEFDINIR
CAS Number	91832-40-5

For TLV values of declared components, see Section 8, Exposure controls / Personal

Full text of H-Phrases see under Section 16

Section 4: First aid measures

4.1 Description of first aid measures

Inhalation	Remove from danger zone. Obtain immediate medical assistance.
Skin Contact	Remove contaminated clothing. Rinse contaminated skin immediately with plenty of water and seek medical advice.
Eye Contact	Immediately rinse eyes thoroughly with running water as long as possible (approx. 15 min). Take injured quickly to factory medical center or call an ambulance (code word: eye accident).
Ingestion	If feeling sick, immediately call for a physician or take patient to factory medical centre (if necessary, call for an ambulance). If swallowed, seek medical advice immediately and show this container or label.

Self-protection of the first aider

For personal protection see Section 8

4.2 Most important symptoms and effects, both acute and delayed

Acute/Chronic Effects and Symptoms Allergy.

4.3 Indication of any immediate medical attention and special treatment needed

Notes to Physician Apply general supportive and symptomatic treatment.

Section 5: Fire fighting measures

5.1. Extinguishing media

Suitable Extinguishing Media Water spray or fog, foam, dry chemical powder, CO2, dry sand

Unsuitable Extinguishing Media No restrictions

5.2 Special hazards arising from the substance or mixture

Dangerous Combustion Products Carbon dioxide
carbon monoxide
nitrogen oxides
sulfur dioxide

5.3. Advice for firefighters

Protective equipment for firefighters Wear self-contained breathing apparatus and fire protective suite.

Section 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

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Personal precautions Avoid contact with skin, eyes and clothing.

6.2 Environmental precautions

Environmental precautions Must not be released into sewers, drains or wells.

6.3 Methods and material for containment and cleaning up

Methods for cleaning Transfer large quantities into a container, rinse the rest with plenty of water.

6.4 Reference to other sections

For personal protection see Section 8, for disposal considerations see Section 13

Section 7: Handling and storage

7.1. Precautions for safe handling

Storage and Handling Precautions Keep container tightly closed. Keep dry. Ensure efficient exhaust ventilation when using this product Store in a cool place and protect from light.

For Industrial Hygiene Measures see Section 8, Exposure controls / Personal protection

7.2 Conditions for safe storage, including any incompatibilities

Preventive Precautions (fire/explosion) Observe the usual precautionary measures required for chemicals with dust explosive properties (Observe national regulations).

7.3 Specific end use(s)

See Subsection 1.2

Section 8: Exposure controls / Personal protection

8.1 Control parameters

List type	Value	Unit	
Occupational Exposure Limit (OEL)	130	µg/m ³	HHA Database

8.2 Exposure controls

Industrial Hygiene The personal protective measure may be adapted appropriately when working in closed systems or under laboratory conditions.
Regular cleaning of equipment, work area and clothing.
Open handling at operator intervention points with local exhaust ventilation (e.g. downflow booths).
Internal working procedures available to personnel covering personal hygiene, standard cleaning, waste disposal and maintenance.
Personnel instructed and trained, regular refresher training established.
Double wardrobe must be available.

Open Handling

Respiration : If the Breathing Zone sampling results exceed the established occupational exposure limit (OEL) or the minimum concentration defined by the occupational hazard band, use respiratory protection with sufficient protection factor to ensure exposure is below the exposure limit. Unless the exposure results indicate the requirement for an air supplied device, use HEPA filters for powders or aerosols and cartridge or canister filters for vapors and gases.

Filter : P3 (EN143)

Eye : Safety glasses (EN166)

Hand : Normal length chemical-mechanical resistant gloves (EN374/EN388)

Glove Material : Nitrile

Breakthrough time: 240 min

Thickness: 0.4 mm

Additional protection : working clothes (EN 340)

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These values are derived from experiments, literature and information from the glove manufacturer.

They can also be derived from similar materials. In daily work please be aware that the using time depends on several factors and can be shorter than the officially tested permeation time.

Section 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	solid
Formulation	powder
Colour	white to faint yellow
Odour	no data available
Odour threshold	no data available
pH	3.2 (Concentration: 0.64 g/l, Temperature: 20 °C)
Melting point/range	170 °C (decomposing)
Boiling Point	no data available
Flash Point	not applicable
Evaporation Rate (Ref: Ether)	not applicable
Combustibility Test	Standard conditions: 3 = local burning or glowing showing very little tendency to spread (Temperature: 20 °C)
Explosion Limits	not applicable
Vapour Pressure [hPa]	not applicable
Vapour Density	not applicable
Density	no data available
Solubility (Aqueous Solvents)	Water: 0.64 g/l (Temperature: 20 °C)
Solubility (Solvents)	no data available
Partition Coefficient	no data available
Autoignition/MIT	Temperature: 400 °C Method: BAM (fluidized dust)
Dynamic Decomposition	no data available
Isoperibolic Decomposition (>8h)	Stable up to: 120 °C Method: Radex isoperibolic (long duration decomposition test open cup 8h)
Flammable Gases over Viscosity	Temperature: 350 °C (Gas volume: 100 l/kg) not applicable
Explosivity/Reactivity	Deflagration: Positive (Temperature: 70 °C) Drop-Weight Test: Negative
Test for self-heating	no data available
Fire-promoting properties	no data available

9.2 Other information

Dust Explosion	Positive Minimum Ignition Energy: 100 - 300 mJ
Specific Resistivity	2.8 - 3.4 * 10E13 Ohm m (humidity: 38 %, Temperature: 21 °C)
pKa	9.7

Section 10: Stability and reactivity

10.1 Reactivity

Reaction products with None known

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water

10.2 Chemical stability

Hydrolysis : no data available

10.3 Possibility of hazardous reactions

Materials to avoid strong acids

strong bases

10.4 Conditions to avoid

Conditions to avoid Stable at normal conditions

10.5 Incompatible materials

For Incompatible materials see Subsection 7.2 Conditions for safe storage, including any incompatibilities

10.6 Hazardous decomposition products

Hazardous Decomposition Products None, when used and handled as intended.

Section 11: Toxicological information

11.1 Information on toxicological effects

Acute Toxicity	LD50: > 5600 mg/kg Route: oral Species: rat LD50: > 5600 mg/kg Route: oral Species: mouse
Irritation, Corrosion	Eyes (Species: rabbit) non irritant Method: Draize test Skin (Species: rabbit) minimal irritant Method: Draize test
Sensitisation	Skin (Species: human) sensitizing
Mutagenicity	Negative with and without metabolic activation (AMES-Test (reverse mutation assay)) in vitro Negative with and without metabolic activation (Mammalian Cell Mutagenicity Test(HGPRT)) in vitroCell: V79 cells (embryonic lung fibroblasts) of the Chinese hamster Negative with and without metabolic activation (Chromosome Aberration Study) in vitroCell: V79 cells (embryonic lung fibroblasts) of the Chinese hamster Negative with and without metabolic activation (Micronucleus Test) in vivo, Species: mouse, Cell: Bone marrow
Chronic Effects	Pathological findings (Repeated Dose Toxicity) NOEL: 100 mg/kg/d Route: oral Species: rat, Organ: Kidneys Dosage: <= 1000 mg/kg/d, Duration: 26 weeks No histopathological changes. (Repeated Dose Toxicity) Route: oral Species: dog, Organ: Gastrointestinal tract Dosage: <= 800 mg/kg/d, Duration: 26 weeks
Reproduction Toxicity	No Teratogenicity (Embryo-Fetal Development) Route: oral Species: rat No Teratogenicity at maternally toxic dose (Embryo-Fetal Development)

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Route: oral
Species: rabbit
Negative (Peri- and Postnatal Development)
Route: oral
Species: rat

Section 12: Ecological information

Ecotoxicity Summary No quantifiable data available.
Avoid release to the environment.

12.1 Toxicity

Fish acute toxicity no data available

Aquatic invertebrate acute toxicity no data available

Algae Toxicity no data available

Bacterial Respiration Inhibition no data available

12.2 Persistence and degradability

Biological Elimination no data available

12.3 Bioaccumulative potential

Partition Coefficient no data available

Biological accumulation no data available

12.4 Mobility in soil

Soil and Sludge Sorption/Desorption no data available

12.5 Results of PBT and vPvB assessment

PBT assessment no data available

12.6 Other adverse effects

Other adverse effects no data available

12.7 Additional information

no data available

Section 13: Disposal considerations

13.1. Waste treatment methods

Disposal Requirements May be incinerated if local official regulations are observed.

Container Disposal For disposal local regulation is binding.

Section 14: Transport information

Regulation	RID/ADR:	IMDG-Code:	ICAO/IATA-DGR:
14.1 UN Number	0	0	0
14.2 UN Proper Shipping Name	-	-	-
14.3 Transport Hazard Class(es)			
Transport Label(s)			
14.4 Packing Group			

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14.5 Environmental

Hazard

Additional Information Limited Quantities: N.A.

14.6 Special Precaution for User

Transport within user's premises: always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

not applicable

Temperature Undefined

Conditions for Transport

Section 15: Regulatory information

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

List type	assessment	Comment	Date
Water Hazard Class (Germany)	3: Severely water-endangering substance	not yet assessed - no data available	2010-OCT-19

Emergency Regulations List type: Emergency Regulations (CH) (2015-AUG-03)

Not a dangerous good according to StFV

List type: Seveso III - Health Hazard

Lower: 5 t (2016-DEC-21)

Upper: 20 t

Default value, evaluation not possible (ACUTE TOXIC Category 1, all exposure routes)

List type: Seveso III - No threshold required

(2017-MAR-24)

Self Classification (Not a reportable chemical according to Seveso III directive)

15.2 Chemical Safety Assessment

Chemical Safety Assessment not required.

Section 16: Other information

Changes since the previous version in Section Section 2: Hazards identification

Pharmacological Action Antibiotic

Abbreviations used

Recipient Sandoz , Inc
Sandoz

Product should be stored, handled and used in accordance with good industrial hygiene practices and in conformity with legal regulations. The information contained herein is based on the present state of our knowledge and is intended to describe our products from the point of view of safety requirements. It should therefore not be construed as guaranteeing specific properties.