Safety Data Sheet for Drug product

Date of issue: 02-JUN-2015
Replaces version of: 31-MAR-2014
ZARXIO 48MIU/0.8ML 1LISY US 44061139 (KUNDL)

1. Identification of the substance/preparation and of the company

Product name	ZARXIO 48MIU/0.8ML 1LISY US
Generic Name	Filgrastim
Usage	Drug product (pharmaceutical bulk, primary packed, finished product, pharmaceutical intermediate)
Company name	Sandoz GmbH Biochemiestrasse 10 6250 Kundl, Tirol, Austria +43 5338 200 0, E-Mail: sds.support@novartis.com
Emergency phone number	CHEMTEL (International) +1 813 676 1670

2. Hazards identification

For side effects, which could also have impact for people working with this substance, please refer to the Patient Information Leaflet.

3. Composition / information on ingredients

For classification of declared components, see section 15, "Regulatory Information"

Chemical Name	Contains:	CAS Number
Filgrastim	< 1 mg/ml	121181-53-1

Remaining components are inert ingredients.

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

4. First aid measures

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).
Skin Contact	Remove contaminated clothing. Rinse contaminated skin immediately with plenty of water and soap and seek medical advice.
Inhalation	Remove the victim from danger zone, avoid further exposure.
Ingestion	If swallowed, seek medical advice immediately and show this container or label.
Notes to Physician	General measures to eliminate the substance and to reduce absorption.

5. Fire fighting measures

Suitable Extinguishing Media	Water spray or fog, foam, dry chemical powder, CO2, dry sand
Unsuitable Extinguishing Media	No restrictions
Protective equipment for firefighters	Wear self-contained breathing apparatus and fire protective suite.

6. Accidental release measures

Personal precautions	Avoid contact with skin, eyes and clothing.
Environmental precautions	Must not be released into sewers, drains or wells.
Methods for cleaning	Transfer large quantities into a container. Clean up the rest with absorbent material and discharge properly.

7. Handling and storage

No special handling requirements for normal use of this material.
Store in a dry and cool place and observe special instructions from supplier.

8. Exposure controls / Personal protection

Occupational Exposure Limit (OEL)

no data available

TLV values of declared components
Contains:
Filgrastim

List type	µg/m3	
Internal exposure limit	32.2	/ /

Personal protection for open handling

Health care personnel		Safety glasses (EN166) Lab coat Disposable gloves (EN374)

9. Physical and chemical properties

Formulation	aqueous solution
Flash Point	not available

10. Stability and reactivity

Under the normal conditions of use, the product is stable.

11. Toxicological information

Acute Toxicity

Data of Filgrastim
LD50: 13 mg/kg
Route: oral
Species: rat, Sex: male

Data of Filgrastim
LD50: 16 mg/kg
Route: oral
Species: rat, Sex: female

Data of Filgrastim
LD50: 6.6 mg/kg
Route: intravenous
Species: rat, Sex: female

Data of Filgrastim
LD50: 5.1 mg/kg
Route: intravenous
Species: rat, Sex: male

Data of Filgrastim
NTEL: 0.138 mg/kg/d

Irritation, Corrosion unknown

Sensitisation Data of Filgrastim
Respiratory system Suspicion

Additional advice Data of Filgrastim
Tests on bacterial or mammalian cell cultures did not show mutagenic effects relevant to man.

	Data of Filgrastim The compound revealed teratogenic effects in studies with animals.
Mutagenicity	unknown
Chronic Effects	Data of Filgrastim NOAEL: 0.5 mg/kg/d Species: rat Duration: 28 days
Reproduction Toxicity	Values of Filgrastim This substance may have unwanted effects on pregnancy and/or unborn/offspring. It is recommended that pregnant women working with or around this substance are informed and their exposure evaluated according to local policies. Data of Filgrastim NOAEL: 0.01 mg/kg/d Route: intravenous Species: rat

12. Ecological information

Biological Elimination	unknown
Fish acute toxicity	unknown
Aquatic invertebrate acute toxicity	unknown
Algae Toxicity	unknown
Bacterial Respiration Inhibition	unknown
Ecotoxicity Summary	Data of Filgrastim Based on the present knowledge, this product is to be classified as non-hazardous for the environment. Data of Filgrastim No quantifiable data available.

13. Disposal considerations

Disposal Requirements Fill into suitable waste receptacles, seal and label them properly. Incineration in an approved, controlled furnace with combustion gas scrubbing and emission gas control. Local regulations should be adhered to.

14. Transport information

Regulation	Class	UN No.	PG	Label	LQ
RID/ADR:	not restricted	0		, T1, T2	N.A.
IMDG-Code:	not restricted	0		, T1, T2	
ICAO/IATA-DGR:	not restricted	0		, T1, T2	

ICAO/IATA-DGR: no dangerous good
Proper shipping name: -

15. Regulatory information

Classifications of components:

Chemical Name	Contains:	CAS Number	Picto	Signal Word	Classification
Filgrastim	< 1 mg/ml	121181-53-1		D	H300

Remaining components are inert ingredients.

16. Other information

Abbreviations used

H300: Fatal if swallowed.

Recipient

RPh Albert Chen
Sandoz Inc., Broomfield Manufact.
Drug Information
Associate III
2555 West Midway Boulevard
80020
Broomfield
CO

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.