Safety Data Sheet for Drug product

Date of issue: 20-JUN-2016
Replaces version of: 20-MAR-2015
ILARI LYVI 150MG (X) AU 722919 (MARS)

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

Product name	ILARI LYVI 150MG (X) AU
Chemical Class	Human monoclonal antibody
Generic Name	Canakinumab
Pharmacological Action	antirheumatic, antiphlogistic, Immunomodulator, Interleukin 1, beta (IL-1#)
Usage	no data available
Company name	Novartis Pharma AG 4002 Basel Switzerland Tel: +41 61 324 11 11, email: sds.support@novartis.com
Emergency phone number	CHEMTEL (International) +1 813 676 1670 (365/24/7)

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
Canakinumab		914613-48-2

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
Dangerous Combustion Products	None, when used and handled as intended.
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:
Canakinumab

List type	Value	Unit	
Internal exposure limit	300	µg/m3	HHA Database

Personal protection for open handling

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

9. Physical and chemical properties

Formulation	vial with dry content
Flash Point	not applicable

10. Stability and reactivity

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

11. Toxicological information

Acute Toxicity	no data available
Irritation, Corrosion	no data available
Sensitisation	no data available
Mutagenicity	no data available
Chronic Effects	Data of Canakinumab No toxic effect (Repeated Dose Toxicity) NOAEL: 42.9 mg/kg/d Route: subcutaneous Species: Marmoset Dosage: <= 42.9 mg/kg/d, Duration: 13 weeks Data of Canakinumab No effects (Repeated Dose Toxicity) NOAEL: 28.6 mg/kg/d Route: intravenous Species: Marmoset, Organ: No target organ of toxicity Dosage: <= 28.6 mg/kg/d, Duration: 4 weeks Data of Canakinumab No effects (Repeated Dose Toxicity) NOAEL: 28.6 mg/kg/d Route: intravenous Species: Marmoset, Organ: No target organ of toxicity

	Dosage: <= 28.6 mg/kg/d, Duration: 26 weeks
Reproduction Toxicity	Data of Canakinumab NO FERTILITY EFFECTS (Fertility and early Embryonic Development) NOAEL: 21.4 mg/kg/d Route: subcutaneous Species: mouse
	Data of Canakinumab Not teratogenic / not embryotoxic (Embryo-Fetal Development) NOAEL: 21.4 mg/kg/d Route: subcutaneous Species: mouse
	Data of Canakinumab Negative (Embryo-Fetal Development) NOAEL: 21.4 mg/kg/d Route: subcutaneous Species: Marmoset
	Data of Canakinumab Negative (Peri- and Postnatal Development) NOAEL: 21.4 mg/kg/d Route: subcutaneous Species: mouse

12. Ecological information

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

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
Canakinumab	914613-48-2

Remaining components are inert ingredients.

16. Other information

Abbreviations used

Recipient

Henry Delima
Delima Associates
1227 Providence Terr
McLean, VA
USA

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.