

Safety Data Sheet for Drug Products (EU)



Date of issue: 10-DEC-2017

Replaces version of: 10-DEC-2017

SIMUL LYVI 10MG (+) FI 707259 (MARS)

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

Product name SIMUL LYVI 10MG (+) FI
Generic Name BASILIXIMAB
Pharmacological Action immunosuppressant
Usage Drug product (pharmaceutical bulk, primary packed, finished product, pharmaceutical intermediate)
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:
BASILIXIMAB	92 %

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.

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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:

BASILIXIMAB

List type	Value	Unit	
Internal exposure limit	12	$\mu\text{g}/\text{m}^3$	HHA Database

Personal protection for open handling

Health care personnel



Safety glasses (EN166) Lab coat Disposable gloves (EN374)

9. Physical and chemical properties

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 Data of BASILIXIMAB
Negative with and without metabolic activation (AMES-Test (reverse mutation assay))
in vitroCell: Strains of salmonella typhimurium.

Data of BASILIXIMAB
Negative with and without metabolic activation (Chromosome Aberration Study)
in vitroCell: V79 cells (embryonic lung fibroblasts) of the Chinese hamster

Chronic Effects Data of BASILIXIMAB
No effects (Repeated Dose Toxicity)
NTEL: 4.5 mg/kg
Route: intravenous
Species: Rhesus Monkey (Macaca mulatta), Organ: No target organ of toxicity
Duration: 4 weeks

Data of BASILIXIMAB
No effects (Repeated Dose Toxicity)
NOEL: 24 mg/kg/w
Route: intravenous
Species: Rhesus Monkey (Macaca mulatta), Organ: No target organ of toxicity
Duration: 39 weeks

Reproduction Toxicity Data of BASILIXIMAB

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Not teratogenic / not embryotoxic (Embryo-Fetal Development)
Route: intravenous
Species: cynomolgus monkey (Macaca fascicularis)

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 BASILIXIMAB
Based on results of similar compounds, good bioelimination can be expected.

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			N.A.
IMDG-Code:	Not restricted	0			
ICAO/IATA-DGR:	Not restricted	0			

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

15. Regulatory information

Classifications of components:

Chemical Name	Contains:	Classification
BASILIXIMAB	92 %	P

Remaining components are inert ingredients.

16. Other information

Abbreviations used

P: Caution: Handle with care - product not fully tested!

Recipient Henry Delima
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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.