

# **Golimumab Formulation**

Version Revision Date: SDS Number: Date of last issue: 29.09.2023 28.09.2024 26441-00025 Date of first issue: 29.10.2014

## **SECTION 1. PRODUCT AND COMPANY IDENTIFICATION**

Product name : Golimumab Formulation

Manufacturer or supplier's details

Company name of supplier : MSD

Address : 126 E. Lincoln Avenue

Rahway, New Jersey U.S.A. 07065

Telephone : 908-740-4000 Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical Restrictions on use : Not applicable

#### **SECTION 2. HAZARDS IDENTIFICATION**

**GHS Classification** 

Respiratory sensitization : Category 1

**GHS** label elements

Hazard pictograms



Signal Word : Danger

Hazard Statements : H334 May cause allergy or asthma symptoms or breathing diffi-

culties if inhaled.

Precautionary Statements : Prevention:

P261 Avoid breathing mist or vapors. P284 Wear respiratory protection.

Response:

P304 + P340 IF INHALED: Remove person to fresh air and

keep comfortable for breathing.

P342 + P311 If experiencing respiratory symptoms: Call a

POISON CENTER or doctor/ physician.

Disposal:

P501 Dispose of contents/ container to an approved waste dis-

posal plant.

Other hazards

None known.

#### **SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**



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Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)	
Golimumab	476181-74-5	>= 10 -< 20	

#### **SECTION 4. FIRST AID MEASURES**

General advice : In the case of accident or if you feel unwell, seek medical

advice immediately.

When symptoms persist or in all cases of doubt seek medical

advice.

If inhaled : If inhaled, remove to fresh air.

If not breathing, give artificial respiration. If breathing is difficult, give oxygen.

Get medical attention.

In case of skin contact : Wash with water and soap as a precaution.

Get medical attention if symptoms occur.

In case of eye contact : Flush eyes with water as a precaution.

Get medical attention if irritation develops and persists.

If swallowed : If swallowed, DO NOT induce vomiting.

Get medical attention if symptoms occur. Rinse mouth thoroughly with water.

Most important symptoms

and effects, both acute and

delayed

May cause allergy or asthma symptoms or breathing

difficulties if inhaled.

Excessive exposure may aggravate preexisting asthma and

other respiratory disorders (e.g. emphysema, bronchitis,

reactive airways dysfunction syndrome).

Protection of first-aiders : First Aid responders should pay attention to self-protection,

and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician : Treat symptomatically and supportively.

#### **SECTION 5. FIRE-FIGHTING MEASURES**

Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

Specific hazards during fire

fighting

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod-

ucts

Carbon oxides Sulfur oxides

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances and the surrounding environment.

Use water spray to cool unopened containers.

Remove undamaged containers from fire area if it is safe to do

so.



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Evacuate area.

Special protective equipment :

for fire-fighters

In the event of fire, wear self-contained breathing apparatus.

Use personal protective equipment.

#### **SECTION 6. ACCIDENTAL RELEASE MEASURES**

Personal precautions, protec- :

tive equipment and emergency procedures

Use personal protective equipment.

Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

Environmental precautions : Avoid release to the environment.

Prevent further leakage or spillage if safe to do so.

Prevent spreading over a wide area (e.g., by containment or

oil barriers).

Retain and dispose of contaminated wash water.

Local authorities should be advised if significant spillages

cannot be contained.

Methods and materials for containment and cleaning up

Soak up with inert absorbent material.

For large spills, provide diking or other appropriate

containment to keep material from spreading. If diked material

can be pumped, store recovered material in appropriate

container.

Clean up remaining materials from spill with suitable

absorbent.

Local or national regulations may apply to releases and disposal of this material, as well as those materials and items

employed in the cleanup of releases. You will need to

determine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

#### **SECTION 7. HANDLING AND STORAGE**

Technical measures : See Engineering measures under EXPOSURE

CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation

Advice on safe handling

Use only with adequate ventilation.

Do not breathe mist or vapors.

Do not swallow.

Avoid contact with eyes.

Avoid prolonged or repeated contact with skin.

Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure

assessment

Keep container tightly closed.

Already sensitized individuals, and those susceptible

to asthma, allergies, chronic or recurrent respiratory disease,

should consult their physician regarding working with

respiratory irritants or sensitizers.

Take care to prevent spills, waste and minimize release to the

environment.



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Hygiene measures : If exposure to chemical is likely during typical use, provide eye

flushing systems and safety showers close to the working

place

When using do not eat, drink or smoke. Wash contaminated clothing before re-use.

Conditions for safe storage : Keep in properly labeled containers.

Keep tightly closed.

Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:

Strong oxidizing agents

Gases

#### **SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

# Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Golimumab	476181-74-5	TWA	70 μg/m3 (OEB 3)	Internal

**Engineering measures** : Ensure adequate ventilation, especially in confined areas.

Minimize workplace exposure concentrations.

Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or

exposure assessment demonstrates exposures outside the

recommended guidelines, use respiratory protection.

Filter type

Hand protection

Particulates type

Material : Chemical-resistant gloves

Remarks : Choose gloves to protect hands against chemicals depending

on the concentration specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before

breaks and at the end of workday.

Eye protection : Wear the following personal protective equipment:

Safety glasses

Skin and body protection : Skin should be washed after contact.

#### **SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance : Aqueous solution

Color : opalescent

Odor : No data available

Odor Threshold : No data available



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pH : 5.5

Melting point/freezing point : No data available

Initial boiling point and boiling

range

No data available

Flash point : No data available

Evaporation rate : No data available

Flammability (solid, gas) : Not applicable

Flammability (liquids) : No data available

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

Vapor pressure : No data available

Relative vapor density : No data available

Relative density : No data available

Solubility(ies)

Water solubility : soluble

Partition coefficient: n-

octanol/water

No data available

Autoignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, kinematic : No data available

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Molecular weight : No data available

Particle characteristics

Particle size : No data available

# **SECTION 10. STABILITY AND REACTIVITY**

Reactivity : Not classified as a reactivity hazard. Chemical stability : Stable under normal conditions.

Possibility of hazardous reac- : Can react with strong oxidizing agents.



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tions

Conditions to avoid : None known.
Incompatible materials : Oxidizing agents

Hazardous decomposition : No hazardous decomposition products are known.

products

## **SECTION 11. TOXICOLOGICAL INFORMATION**

## Information on likely routes of exposure

Inhalation Skin contact Ingestion Eye contact

# **Acute toxicity**

Not classified based on available information.

#### Skin corrosion/irritation

Not classified based on available information.

## Serious eye damage/eye irritation

Not classified based on available information.

## Respiratory or skin sensitization

# Skin sensitization

Not classified based on available information.

## Respiratory sensitization

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

## **Components:**

#### Golimumab:

Routes of exposure : Inhalation

Assessment : May cause sensitization by inhalation.

#### Germ cell mutagenicity

Not classified based on available information.

## Carcinogenicity

Not classified based on available information.

# Reproductive toxicity

Not classified based on available information.

# **Components:**

#### Golimumab:

Effects on fertility : Test Type: Fertility/early embryonic development

Species: Mouse, male

Application Route: Intravenous injection

Fertility: NOAEL Parent: 40 mg/kg body weight

Test Type: Fertility/early embryonic development

Species: Mouse, female



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Application Route: Intravenous injection

Fertility: NOAEL Parent: 40 mg/kg body weight

Effects on fetal development : Test Type: Embryo-fetal development

Species: Monkey

Teratogenicity: NOAEL: 100 mg/kg body weight Embryo-fetal toxicity.: NOAEL: 100 mg/kg body weight

Test Type: Development

Species: Monkey

Developmental Toxicity: NOAEL F1: 50 mg/kg body weight

Test Type: Embryo-fetal development

Species: Mouse

Application Route: Intravenous injection
Teratogenicity: NOAEL: 40 mg/kg body weight
Embryo-fetal toxicity.: NOAEL: 40 mg/kg body weight
Result: negative, No effects on fetal development.

## STOT-single exposure

Not classified based on available information.

## STOT-repeated exposure

Not classified based on available information.

## Repeated dose toxicity

# **Components:**

# Golimumab:

Species : Monkey
NOAEL : 50 mg/kg
Application Route : Intravenous
Exposure time : 6 Months
Number of exposures : Intermittent

Species : Monkey
NOAEL : 25 mg/kg
Application Route : Subcutaneous
Exposure time : 6 Months

Species : Mouse
NOAEL : 40 mg/kg
Application Route : Intravenous

# **Aspiration toxicity**

Not classified based on available information.

# Experience with human exposure

## **Components:**

## Golimumab:

Inhalation : Symptoms: mild infections, upper respiratory tract infection,

viral infections, bronchitis, sinusitis, fungal infections



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#### **SECTION 12. ECOLOGICAL INFORMATION**

## **Ecotoxicity**

#### Components:

#### Golimumab:

# **Ecotoxicology Assessment**

Acute aquatic toxicity : No data available

Chronic aquatic toxicity : No data available

# Persistence and degradability

No data available

# Bioaccumulative potential

No data available

## Mobility in soil

No data available

#### Other adverse effects

No data available

#### **SECTION 13. DISPOSAL CONSIDERATIONS**

# **Disposal methods**

Waste from residues : Do not dispose of waste into sewer.

Dispose of in accordance with local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste

handling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

#### **SECTION 14. TRANSPORT INFORMATION**

#### **International Regulations**

#### **UNRTDG**

Not regulated as a dangerous good

#### **IATA-DGR**

Not regulated as a dangerous good

#### **IMDG-Code**

Not regulated as a dangerous good

## Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

## **Domestic regulation**

#### NOM-002-SCT

Not regulated as a dangerous good



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## Special precautions for user

Not applicable

#### **SECTION 15. REGULATORY INFORMATION**

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

Federal Law for the control of chemical precursors, essential chemical products and machinery for

producing capsules, tablets and pills.

Not applicable

## The ingredients of this product are reported in the following inventories:

AICS : not determined

DSL : not determined

IECSC : not determined

#### **SECTION 16. OTHER INFORMATION**

Revision Date : 28.09.2024 Date format : dd.mm.yyyy

## Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR -Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation: DSL - Domestic Substances List (Canada): ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk, IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Sub-



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stances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

Sources of key data used to compile the Material Safety Data Sheet

Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

cy, http://echa.europa.eu/

The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

MX / Z8