

**Golimumab Formulation**

Version            Revision Date:            SDS Number:            Date of last issue: 2023/02/13  
3.0                2023/02/23                26433-00024            Date of first issue: 2014/10/29

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**1. PRODUCT AND COMPANY IDENTIFICATION**

Product name                                : Golimumab Formulation

**Manufacturer or supplier's details**

Company                                        : MSD

Address                                         : JL Raya Pandaan KM. 48  
Pandaan, Jawa Timur - Indonesia

Telephone                                      : 908-740-4000

Emergency telephone number : 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

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**2. HAZARDS IDENTIFICATION****GHS Classification**

Respiratory sensitisation                  : Category 1

**GHS label elements**

Hazard pictograms                            :



Signal word                                    : Danger

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

Precautionary statements                  :  
**Prevention:**  
P261 Avoid breathing mist or vapours.  
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/ doctor.  
**Disposal:**  
P501 Dispose of contents/ container to an approved waste

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disposal plant.

### Other hazards which do not result in classification

None known.

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

#### Components

| Chemical name | CAS-No.     | Concentration (% w/w) |
|---------------|-------------|-----------------------|
| Golimumab     | 476181-74-5 | >= 10 -< 30           |

### 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 : Excessive exposure may aggravate preexisting asthma and other respiratory disorders (e.g. emphysema, bronchitis, reactive airways dysfunction syndrome).  
 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
- 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.

### 5. FIREFIGHTING MEASURES

- Suitable extinguishing media : Water spray  
 Alcohol-resistant foam  
 Carbon dioxide (CO<sub>2</sub>)  
 Dry chemical
- Unsuitable extinguishing media : None known.
- Specific hazards during fire-fighting : Exposure to combustion products may be a hazard to health.
- Hazardous combustion products : Carbon oxides  
 Sulphur oxides

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Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.  
Use water spray to cool unopened containers.  
Remove undamaged containers from fire area if it is safe to do so.  
Evacuate area.

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.  
Use personal protective equipment.

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### 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective 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 dyking or other appropriate containment to keep material from spreading. If dyked 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.

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### 7. HANDLING AND STORAGE

Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation : Use only with adequate ventilation.

Advice on safe handling : Avoid breathing mist or vapours.  
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 sensitised individuals, and those susceptible to asthma, allergies, chronic or recurrent respiratory disease, should consult their physician regarding working with respiratory irritants or sensitisers.  
Take care to prevent spills, waste and minimize release to the

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environment.  
 Conditions for safe storage : Keep in properly labelled 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

### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Components with workplace control parameters

| Components | CAS-No.     | Value type<br>(Form of exposure) | Control parameters / Permissible concentration | Basis    |
|------------|-------------|----------------------------------|--|----------|
| Golimumab  | 476181-74-5 | TWA                              | 70 µg/m <sup>3</sup> (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 : Particulates type

Hand protection

Material : Chemical-resistant gloves

Remarks : Choose gloves to protect hands against chemicals depending on the concentration and quantity of the hazardous substance and 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.

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.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : Aqueous solution

Colour : opalescent

Odour : No data available

Odour 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  |
| Vapour pressure                                  | : | No data available  |
| Relative vapour density                          | : | No data available  |
| Relative density                                 | : | No data available  |
| Solubility(ies)<br>Water solubility              | : | soluble  |
| Partition coefficient: n-octanol/water           | : | No data available  |
| Auto-ignition temperature                        | : | No data available  |
| Decomposition temperature                        | : | No data available  |
| Viscosity<br>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 size                                    | : | No data available  |

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**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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Conditions to avoid : None known.

Incompatible materials : Oxidizing agents

Hazardous decomposition products : No hazardous decomposition products are known.

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### 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 sensitisation

##### Skin sensitisation

Not classified based on available information.

##### Respiratory sensitisation

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

#### Components:

##### Golimumab:

Exposure routes : Inhalation  
Assessment : May cause sensitisation 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  
Application Route: Intravenous injection  
Fertility: NOAEL Parent: 40 mg/kg body weight

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Effects on foetal development : Test Type: Embryo-foetal development  
 Species: Monkey  
 Teratogenicity: NOAEL: 100 mg/kg body weight  
 Embryo-foetal toxicity: NOAEL: 100 mg/kg body weight

Test Type: Development  
 Species: Monkey  
 Developmental Toxicity: NOAEL F1: 50 mg/kg body weight

Test Type: Embryo-foetal development  
 Species: Mouse  
 Application Route: Intravenous injection  
 Teratogenicity: NOAEL: 40 mg/kg body weight  
 Embryo-foetal toxicity: NOAEL: 40 mg/kg body weight  
 Result: negative, No effects on foetal 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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**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

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**13. DISPOSAL CONSIDERATIONS****Disposal methods**

Waste from residues : Dispose of in accordance with local regulations.

Do not dispose of waste into sewer.

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.

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**14. TRANSPORT INFORMATION****International Regulations****UNRTDG**

UN number : Not applicable

Proper shipping name : Not applicable

Class : Not applicable

Subsidiary risk : Not applicable

Packing group : Not applicable

Labels : Not applicable

**IATA-DGR**

UN/ID No. : Not applicable

Proper shipping name : Not applicable

Class : Not applicable

Subsidiary risk : Not applicable

Packing group : Not applicable

Labels : Not applicable

Packing instruction (cargo) : Not applicable



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aircraft)  
Packing instruction (passenger aircraft) : Not applicable

**IMDG-Code**

UN number : Not applicable  
Proper shipping name : Not applicable  
Class : Not applicable  
Subsidiary risk : Not applicable  
Packing group : Not applicable  
Labels : Not applicable  
EmS Code : Not applicable  
Marine pollutant : Not applicable

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

Not applicable for product as supplied.

**Special precautions for user**

Not applicable

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**15. REGULATORY INFORMATION****Safety, health and environmental regulations/legislation specific for the substance or mixture**

**Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.**

**Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health**

Hazardous substances that must be registered : Not applicable

**Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances**

Hazardous substances approved for use : Not applicable

Prohibited substances : Not applicable

Restricted substances : Not applicable

**Regulation of the Ministry of Trade No. 7 of 2022 on Distribution and Control of Hazardous Materials**

Type of hazardous materials subject to distribution and control, Annex I : Not applicable

Type of hazardous materials subject to distribution and control, Annex II : Not applicable

**The components of this product are reported in the following inventories:**

AICS : not determined

DSL : not determined

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IECSC : not determined

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### 16. OTHER INFORMATION

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#### Further information

Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Date format : yyyy/mm/dd

#### 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 Substances 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

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only

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to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

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