Golimumab Formulation

1. PRODUCT AND COMPANY IDENTIFICATION

   Product name : Golimumab Formulation

   Manufacturer or supplier’s details
   Company : MSD
   Address : 50 Tuas West Drive
   Singapore - Singapore 638408
   Telephone : +1-908-740-4000
   Emergency telephone number : 65 6697 2111 (24/7/365)
   E-mail address : EHSDATASTEWARD@msd.com

   Recommended use of the chemical and restrictions on use
   Recommended use : Pharmaceutical

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 disposal plant.
3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mixture</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Golimumab</td>
<td>476181-74-5</td>
<td>&gt;= 10 -&lt; 20</td>
</tr>
</tbody>
</table>

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.

5. FIREFIGHTING MEASURES

Suitable extinguishing media: Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

Unsuitable extinguishing media: None known.

Specific hazards during firefighting: Exposure to combustion products may be a hazard to health.

Hazardous combustion products: Carbon oxides
Sulphur oxides

Specific extinguishing methods: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
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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.

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.

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 should consult their physician regarding working with respiratory irritants or sensitisers.
Take care to prevent spills, waste and minimize release to the 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

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Golimumab</td>
<td>476181-74-5</td>
<td>TWA</td>
<td>12 µg/m³</td>
<td>Internal</td>
</tr>
</tbody>
</table>

**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:** 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
- **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)
  Water solubility : soluble
Partition coefficient: n-octanol/water : No data available
Auto-ignition 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 size : No data available

10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reactions : Can react with strong oxidizing agents.
Conditions to avoid : None known.
Incompatible materials: Oxidizing agents
Hazardous decomposition products: No hazardous decomposition products are known.

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
- Dose: 40 milligram per kilogram
- Duration of Single Treatment: 11 Weeks
- Frequency of Treatment: 1 days/week
- Fertility: NOAEL Parent: 40 mg/kg body weight

- Test Type: Fertility/early embryonic development
- Species: Mouse, female
- Application Route: Intravenous injection
Dose: 40 milligram per kilogram  
Duration of Single Treatment: 3 Weeks  
Frequency of Treatment: 1 days/week  
Fertility: NOAEL Parent: 40 mg/kg body weight

<table>
<thead>
<tr>
<th>Effects on foetal development</th>
<th>Test Type: Embryo-foetal development</th>
<th>Species: Monkey</th>
<th>Dose: 50 milligram per kilogram</th>
<th>Frequency of Treatment: 2 days/week</th>
<th>Teratogenicity: NOAEL: 100 mg/kg body weight</th>
<th>Embryo-foetal toxicity: NOAEL: 100 mg/kg body weight</th>
</tr>
</thead>
</table>

Test Type: Development  
Species: Monkey  
Dose: 50 milligram per kilogram  
Frequency of Treatment: 2 daily  
Developmental Toxicity: NOAEL F1: 50 mg/kg body weight

<table>
<thead>
<tr>
<th>Test Type: Embryo-foetal development</th>
<th>Species: Mouse</th>
<th>Application Route: Intravenous injection</th>
<th>Dose: 40 milligram per kilogram</th>
<th>Frequency of Treatment: 2 days</th>
<th>Teratogenicity: NOAEL: 40 mg/kg body weight</th>
<th>Embryo-foetal toxicity: NOAEL: 40 mg/kg body weight</th>
<th>Result: negative, No effects on foetal development</th>
</tr>
</thead>
</table>

**STOT - single exposure**  
Not classified based on available information.

**STOT - repeated exposure**  
Not classified based on available information.

**Repeated dose toxicity**

**Components:**

**Golimumab:**

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Number of exposures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monkey</td>
<td>50 mg/kg</td>
<td>Intravenous injection</td>
<td>6 Months</td>
<td>Intermittent</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Monkey</td>
<td>25 mg/kg</td>
<td>Subcutaneous</td>
<td>6 Months</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>Application Route</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mouse</td>
<td>40 mg/kg</td>
<td>Intravenous</td>
</tr>
</tbody>
</table>
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

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

13. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues: 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.

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.

### 15. REGULATORY INFORMATION

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

**Workplace Safety and Health Act and Workplace Safety and Health (General Provisions) Regulations:** This product is subjected to the SDS, labelling, PEL and other requirements in the Act/Regulations.

<table>
<thead>
<tr>
<th>Regulation</th>
<th>Requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Environmental Protection and Management Act and Environmental Protection and Management (Hazardous Substances) Regulations</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Fire Safety (Petroleum and Flammable Materials) Regulations</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Inventory</th>
<th>Determination</th>
</tr>
</thead>
<tbody>
<tr>
<td>AICS</td>
<td>not determined</td>
</tr>
<tr>
<td>DSL</td>
<td>not determined</td>
</tr>
<tr>
<td>IECSC</td>
<td>not determined</td>
</tr>
</tbody>
</table>

### 16. OTHER INFORMATION

**Further information**
Sources of key data used to compile the Safety Data Sheet:

Date format: dd.mm.yyyy

Full text of other abbreviations:

AIC - 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; MARPOL 73/78 - International Convention for the Prevention of Pollution from Ships; PEL - Permissible Exposure Limit; SDS - Safety Data Sheet; OECD - Organisation for Economic Co-operation and Development; OSHA - Occupational Safety and Health Administration; PEL - Permissible Exposure Limit; PPE - Personal Protective Equipment; RIFM - Research Institute for Fragrance Materials; RINEOS - Risk Information Exchange Scheme; USEPA - United States Environmental Protection Agency; UN - United Nations; WorkSafeBC - WorkSafe BC; WSW - Workplace Safety and Health; WTO - World Trade Organization
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 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.