SAFETY DATA SHEET

Golimumab Formulation

Section 1: Identification

Product name: Golimumab Formulation

Manufacturer or supplier’s details
Company: MSD
Address: 33 Whakatiki Street - Private Bag 908
         Upper Hutt - New Zealand
Telephone: 908-740-4000
Emergency telephone number: 1-908-423-6000
E-mail address: EHSDATASTEWARD@msd.com
Telefax: 908-735-1496

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

Section 2: Hazard 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.
P285 In case of inadequate ventilation wear respiratory protection.

Response:
P304 + P341 IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position 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
disposal plant.

Other hazards which do not result in classification
None known.

Section 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; 30</td>
</tr>
</tbody>
</table>

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 products : Carbon oxides
Sulphur oxides
Section 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 dyeing or other appropriate containment to keep material from spreading. If dyed 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:
- 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.

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 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

Section 8: Exposure controls/personal protection

Components with workplace control parameters

<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:
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.

Section 9: Physical and chemical properties

Appearance: Aqueous solution
Colour: Opalescent
Odour: No data available
Odour Threshold: No data available
### Section 10: Stability and reactivity

<table>
<thead>
<tr>
<th>Property</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Reactivity</strong></td>
<td>Not classified as a reactivity hazard.</td>
</tr>
<tr>
<td><strong>Chemical stability</strong></td>
<td>Stable under normal conditions.</td>
</tr>
<tr>
<td><strong>Possibility of hazardous reac-</strong></td>
<td>Can react with strong oxidizing agents.</td>
</tr>
</tbody>
</table>

**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
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Section 11: Toxicological information

Exposure routes:
- 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.

Chronic toxicity

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

Effects on foetal development:

Test Type: Embryo-foetal development
Species: Monkey
Dose: 50 milligram per kilogram
Frequency of Treatment: 2 days/week
Teratogenicity: NOAEL: 100 mg/kg body weight
Embryo-foetal toxicity: NOAEL: 100 mg/kg body weight

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

Test Type: Embryo-foetal development
Species: Mouse
Application Route: Intravenous injection
Dose: 40 milligram per kilogram
Frequency of Treatment: 2 days
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

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 : 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
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Version 3.7  Revision Date: 16.10.2020  SDS Number: 26446-00015  Date of last issue: 13.09.2019

Date of first issue: 29.10.2014

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.

National Regulations
NZS 5433
Not regulated as a dangerous good

Section 15: Regulatory information

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

HSNO Approval Number
HSR100425 Pharmaceutical Active Ingredients Group Standard 2017

HSW Controls
Certified handler certificate not required.
Tracking hazardous substance not required.
Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

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

AICS : not determined

DSL : not determined

IECSC : not determined

Section 16: Other information

Further information

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
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**NZ / EN**