SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Golimumab Formulation

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier
Trade name : Golimumab Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against
Use of the Substance/Mixture : Pharmaceutical

1.3 Details of the supplier of the safety data sheet
Company : MSD
Shotton Lane
NE23 3JU Cramlington NU - Great Britain

Telephone : 44 1 670 59 30 00
Telefax : 908-735-1496
E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number
1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture
Classification (REGULATION (EC) No 1272/2008)
Respiratory sensitisation, Category 1 H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.

2.2 Label elements
Labelling (REGULATION (EC) No 1272/2008)
Hazard pictograms :

Signal word : Danger
Hazard statements : H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Precautionary statements : Response:
P304 + P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P342 + P311 If experiencing respiratory symptoms: Call a
Hazardous components which must be listed on the label:
Golimumab

2.3 Other hazards
None known.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

<table>
<thead>
<tr>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Registration number</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Golimumab</td>
<td>476181-74-5</td>
<td></td>
<td></td>
<td></td>
<td>Resp. Sens.1; H334</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
</tbody>
</table>

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of 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.

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).

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.

4.2 Most important symptoms and effects, both acute and delayed

Risks: 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).

4.3 Indication of any immediate medical attention and special treatment needed

Treatment: Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

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

Unsuitable extinguishing media: None known.

5.2 Special hazards arising from the substance or mixture

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

Hazardous combustion products:
- Carbon oxides
- Sulphur oxides

5.3 Advice for firefighters

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

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.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions:
- Use personal protective equipment.
- Follow safe handling advice and personal protective equipment recommendations.

6.2 Environmental precautions

Environmental precautions:
- Discharge into the environment must be avoided.
- Prevent further leakage or spillage if safe to do so.
- Prevent spreading over a wide area (e.g. by containment or oil barriers).
6.3 Methods and material for containment and cleaning up

Methods for cleaning up: Soak up with inert absorbent material. For large spills, provide dyking 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.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

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

Local/Total ventilation: Use only with adequate ventilation.

Advice on safe handling: Avoid inhalation of vapour or mist. 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.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers: Keep in properly labelled containers. Keep tightly closed. Store in accordance with the particular national regulations.

Advice on common storage: Do not store with the following product types: Strong oxidizing agents

7.3 Specific end use(s)
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according to Regulation (EC) No. 1907/2006

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Specific use(s) : No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</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></td>
</tr>
</tbody>
</table>

8.2 Exposure controls

Engineering measures
Ensure adequate ventilation, especially in confined areas.
Minimize workplace exposure concentrations.

Personal protective equipment

Eye protection : Wear the following personal protective equipment:
Safety glasses
Equipment should conform to NS EN 166

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.

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

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 (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic 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
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.

9.2 Other information
Flammability (liquids): No data available
Molecular weight: No data available
Particle size: No data available

SECTION 10: Stability and reactivity

10.1 Reactivity
Not classified as a reactivity hazard.

10.2 Chemical stability
Stable under normal conditions.
10.3 Possibility of hazardous reactions
   Hazardous reactions: Can react with strong oxidizing agents.

10.4 Conditions to avoid
   Conditions to avoid: None known.

10.5 Incompatible materials
   Materials to avoid: Oxidizing agents

10.6 Hazardous decomposition products
   No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects
   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.
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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
**Golimumab Formulation**

<table>
<thead>
<tr>
<th>Application Route</th>
<th>Exposure time</th>
<th>Number of exposures</th>
<th>Species</th>
<th>NOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Species</th>
<th>NOAEL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intravenous</td>
<td>6 Months</td>
<td>Intermittent</td>
<td>Monkey</td>
<td>25 mg/kg</td>
<td>Subcutaneous</td>
<td>6 Months</td>
<td>Mouse</td>
<td>40 mg/kg</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

**SECTION 12: Ecological information**

**12.1 Toxicity**

**Components:**

**Golimumab:**

**Ecotoxicology Assessment**

Acute aquatic toxicity: No data available

Chronic aquatic toxicity: No data available

**12.2 Persistence and degradability**

No data available

**12.3 Bioaccumulative potential**

No data available

**12.4 Mobility in soil**

No data available

**12.5 Results of PBT and vPvB assessment**

Not relevant

**12.6 Other adverse effects**

No data available
SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product: Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

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

14.1 UN number
Not regulated as a dangerous good

14.2 UN proper shipping name
Not regulated as a dangerous good

14.3 Transport hazard class(es)
Not regulated as a dangerous good

14.4 Packing group
Not regulated as a dangerous good

14.5 Environmental hazards
Not regulated as a dangerous good

14.6 Special precautions for user
Not applicable

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code
Remarks: Not applicable for product as supplied.

SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII): Conditions of restriction for the following entries should be considered: Number on list 3

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59): Not applicable

REACH - List of substances subject to authorisation (Annex XIV): Not applicable

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer: Not applicable

Regulation (EC) No 850/2004 on persistent organic pollutants: Not applicable

Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import: Not applicable
of dangerous chemicals
Not applicable

Other regulations:
Young people under the age of 18 are not allowed to use or be exposed to the product professionally. Young people above the age of 15 are, however, except from this rule if the product is a necessary part of their education.

The components of this product are reported in the following inventories:
AICS : not determined
DSL : not determined
IECSC : not determined

15.2 Chemical safety assessment
A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

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

Full text of H-Statements
H334 : May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Full text of other abbreviations
Resp. Sens. : Respiratory sensitisation

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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 Chemicals 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New
Golimumab Formulation

Version 2.2  Revision Date: 09/13/2019  SDS Number: 26444-00014  Date of last issue: 24.04.2019  Date of first issue: 29.10.2014

Further information

Classification of the mixture: Resp. Sens. 1  Classification procedure: H334  Calculation method

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.

NO / EN