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
   Piercetown
   A86 HD21 Dunboyne, Ireland
   Telephone: 908-740-4000
   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 POISON CENTER/doctor.
**Golimumab Formulation**

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date</th>
<th>SDS Number</th>
<th>Date of last issue</th>
<th>Date of first issue</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.6</td>
<td>27.08.2021</td>
<td>26435-00018</td>
<td>09.04.2021</td>
<td>29.10.2014</td>
</tr>
</tbody>
</table>

**Hazardous components which must be listed on the label:**
Golimumab

**Section 2.3 Other hazards**
This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

**Section 3: Composition/information on ingredients**

### 3.2 Mixtures

#### Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Golimumab</td>
<td>476181-74-5</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:
- 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 (see section 7) and personal protective equipment recommendations (see section 8).

6.2 Environmental precautions
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.

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 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.

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 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

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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.

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)
Specific use(s): No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

<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>Internal</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 I.S. 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 expo-
Filter type: Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical state</td>
<td>Aqueous solution</td>
</tr>
<tr>
<td>Colour</td>
<td>Opalescent</td>
</tr>
<tr>
<td>Odour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>5.5</td>
</tr>
<tr>
<td>Viscosity</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td>Soluble</td>
</tr>
<tr>
<td>Water solubility</td>
<td>Soluble</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>No data available</td>
</tr>
<tr>
<td>Particle characteristics</td>
<td></td>
</tr>
<tr>
<td>Particle size</td>
<td>No data available</td>
</tr>
</tbody>
</table>

9.2 Other information
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Explosives : Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.
Evaporation rate : No data available
Molecular weight : 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 hazard classes as defined in Regulation (EC) No 1272/2008
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.
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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

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.

11.2 Information on other hazards

Endocrine disrupting properties

Product:
Assessment: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

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

Product:
Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Endocrine disrupting properties

Product:
Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 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 or ID 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 Maritime transport in bulk according to IMO instruments
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
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable
Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable
Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable
REACH - List of substances subject to authorisation (Annex XIV) : Not applicable

Other regulations:
Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

The components of this product are reported in the following inventories:
AICS : not determined
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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; AIIC - Australian Inventory of Industrial Chemicals; 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 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative.
Further information

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

IE / EN