1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

Product Identifier

Material Name: INFLECTRA (infliximab-dyyb) for Injection

Trade Name: INFLECTRA
Synonyms: Infliximab-dyyb
Chemical Family: Recombinant chimeric monoclonal antibody

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product

Details of the Supplier of the Safety Data Sheet

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-800-879-3477

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161

Emergency telephone number: CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification Not classified as hazardous

US OSHA Specific - Classification

Physical Hazard: Combustible Dust

Label Elements

Signal Word: Warning
Hazard Statements: May form combustible dust concentrations in air

Other Hazards

An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

Note:

This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Hazardous

PZ03193
3. COMPOSITION / INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
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<tbody>
<tr>
<td>Infliximab</td>
<td>170277-31-3</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>1</td>
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</tbody>
</table>

Water for Injection 7732-18-5 231-791-2 Not Listed *
Polysorbate 80 9005-65-6 Not Listed Not Listed *
Disodium Succinate Hexahydrate 6106-21-4 Not Listed Not Listed *
Succinic acid 110-15-6 203-740-4 Not Listed *
Sucrose 57-50-1 200-334-9 Not Listed *

Additional Information: * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.
In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

4. FIRST AID MEASURES

Description of First Aid Measures

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately. It is considered unlikely that, if swallowed, significant amounts of this material would be absorbed into the blood circulation.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Most Important Symptoms and Effects, Both Acute and Delayed

Symptoms and Effects of Exposure: No data available
Medical Conditions: None known
Aggravated by Exposure: None

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO2, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.
Fire / Explosion Hazards: Dust can form an explosive mixture in air. Fine particles (such as dust and mists) may fuel fires/explosions.
Advice for Fire-Fighters
During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures
Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Environmental Precautions
Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting:
Remove all sources of ignition. Contain the source of the spill if it is safe to do so. Collect spilled material by a method that controls dust generation. Avoid use of a filtered vacuum to clean spills of dry solids. Clean spill area thoroughly.

Additional Consideration for Large Spills:
Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe Handling
Avoid open handling. Ground and bond all bulk transfer equipment. Minimize dust generation. Use appropriate engineering controls to maintain exposures below the B-OEB taking all applicable routes of exposure into consideration. A change area to facilitate ‘good laboratory/manufacturing’ decontamination practices is recommended. Avoid inhalation and contact with skin, eye, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.
Specific end use(s): Pharmaceutical drug product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

Sucrose

<table>
<thead>
<tr>
<th>Source</th>
<th>Threshold Limit Value (TWA)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Australia TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Belgium OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Bulgaria OEL - TWA</td>
<td>10.0 mg/m³</td>
</tr>
<tr>
<td>Estonia OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>France OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Ireland OEL - TWAs</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Latvia OEL - TWA</td>
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</tr>
<tr>
<td>Lithuania OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>OSHA - Final PELS - TWAs:</td>
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</tr>
<tr>
<td>Portugal OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Slovakia OEL - TWA</td>
<td>6 mg/m³</td>
</tr>
<tr>
<td>Spain OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
</tbody>
</table>
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

The Biotherapeutic Occupational Exposure Band (B-OEB) is an acceptable daily intake (ADI) range, based on available hazard data with appropriate safety factors applied. Engineering control measures should be utilized to bring exposures into the relevant B-OEB; supplementary administrative controls and personal protective equipment are to be used to achieve exposure control to the bottom of the band.

**Infliximab**

**Pfizer Occupational Exposure Band (OEB):**

**B-OEB 3 (control exposure to the range of 100 µg/day to <1,000 µg/day)**

**Exposure Controls**

**Engineering Controls:** Engineering controls should be used as the primary means to control exposures. Use process containment, local exhaust ventilation, biosafety cabinet, or other engineering controls to maintain airborne levels within the B-OEB range.

**Personal Protective Equipment:** Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

**Hands:** Wear impervious gloves (e.g. Nitrile, etc.) as minimum protection. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

**Eyes:** Wear safety glasses as minimum protection. (Safety glasses must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

**Skin:** Wear impervious protective clothing when handling this compound. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

**Respiratory protection:** Under normal conditions of use, if the applicable Biotherapeutic Occupational Exposure Band (B-OEB) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the B-OEB (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

9. PHYSICAL AND CHEMICAL PROPERTIES

**Physical State:** Powder

**Odor:** No data available.

**Molecular Formula:** Not applicable

**Color:** White to off-white

**Odor Threshold:** No data available.

**Molecular Weight:** 150 KDa

**Solvent Solubility:** No data available

**Water Solubility:** No data available

**pH:** 5.0 - 7.4

**Melting/Freezing Point (°C):** No data available

**Boiling Point (°C):** No data available.

**Partition Coefficient: (Method, pH, Endpoint, Value)**

**Infliximab**

No data available

**Disodium Succinate Hexahydrate**

No data available

**Sucrose**

No data available

**Succinic acid**

No data available

**Water for Injection**

No data available
9. PHYSICAL AND CHEMICAL PROPERTIES

No data available

**Polysorbate 80**

No data available

- **Decomposition Temperature (°C):** No data available.
- **Evaporation Rate (Gram/s):** No data available
- **Vapor Pressure (kPa):** No data available
- **Vapor Density (g/ml):** No data available
- **Relative Density:** No data available
- **Viscosity:** No data available

**Flammability:**

- **Autoignition Temperature (Solid) (°C):** No data available
- **Flammability (Solids):** No data available
- **Flash Point (Liquid) (°C):** No data available
- **Upper Explosive Limits (Liquid) (% by Vol.):** No data available
- **Lower Explosive Limits (Liquid) (% by Vol.):** No data available

10. STABILITY AND REACTIVITY

- **Reactivity:** No data available
- **Chemical Stability:** Stable under normal conditions of use.
- **Possibility of Hazardous Reactions**
  - **Oxidizing Properties:** No data available
  - **Conditions to Avoid:** Fine particles (such as dust and mists) may fuel fires/explosions. As a precautionary measure, keep away from heat sources and electrostatic discharge.
  - **Incompatible Materials:** As a precautionary measure, keep away from strong oxidizers
  - **Hazardous Decomposition Products:** No data available

11. TOXICOLOGICAL INFORMATION

**Information on Toxicological Effects**

**Short Term:**
As with any protein, the possibility of allergic reactions exists.

**Known Clinical Effects:**
Adverse effects most commonly reported in clinical use include respiratory tract infection, viral illness, hematological effects, skin effects, allergic reaction. Additionally effects on cardiovascular system, gastrointestinal system, musculoskeletal system may occur.

**Acute Toxicity: (Species, Route, End Point, Dose)**

**Infliximab**

- **Rat Intravenous NOAEL 50 mg/kg**

**Sucrose**

- **Rat Oral LD50 29.7 g/kg**

**Polysorbate 80**

- **Rat Oral LD50 25 g/kg**

**Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)**
11. TOXICOLOGICAL INFORMATION

**Infliximab**

<table>
<thead>
<tr>
<th>Duration</th>
<th>Species</th>
<th>Route</th>
<th>Dose</th>
<th>NOAEL</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 Week(s)</td>
<td>Rat</td>
<td>Intravenous</td>
<td>50 mg/kg (3 doses)</td>
<td>NOAEL</td>
<td>None identified</td>
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<tr>
<td>6 Month(s)</td>
<td>Mouse</td>
<td>Intravenous</td>
<td>40 mg/kg/day</td>
<td>NOAEL</td>
<td>None identified</td>
</tr>
</tbody>
</table>

**Genetic Toxicity: (Study Type, Cell Type/Organism, Result)**

**Infliximab**

*In Vivo* Micronucleus Mouse  Negative

Bacterial Mutagenicity (Ames) *Salmonella*  Negative

**Sucrose**

Bacterial Mutagenicity (Ames) *Salmonella*  Negative

**Carcinogen Status:**
None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

12. ECOLOGICAL INFORMATION

**Environmental Overview:**
Environmental properties of the formulation have not been investigated. Releases to the environment should be avoided.

**Toxicity:**
No data available

**Persistence and Degradability:**
No data available

**Bio-accumulative Potential:**
No data available

**Mobility in Soil:**
No data available

13. DISPOSAL CONSIDERATIONS

**Waste Treatment Methods:**
Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transportation as per defining criteria in the international transportation regulations and the shipper's knowledge of the material.
## 15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

### Water for Injection

<table>
<thead>
<tr>
<th>Regulation/Standard</th>
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</tr>
</thead>
<tbody>
<tr>
<td>CERCLA/SARA 313 Emission reporting</td>
<td>Not Listed</td>
</tr>
<tr>
<td>California Proposition 65</td>
<td>Not Listed</td>
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<tr>
<td>Inventory - United States TSCA - Sect. 8(b)</td>
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<tr>
<td>Australia (AICS):</td>
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<tr>
<td>REACH - Annex IV - Exemptions from the obligations of Register:</td>
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<td>EU EINECS/ELINCS List</td>
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### Infliximab

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<tr>
<td>Standard for the Uniform Scheduling for Drugs and Poisons:</td>
<td>Schedule 4</td>
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### Polysorbate 80

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### Disodium Succinate Hexahydrate

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### Succinic acid

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### Sucrose

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</table>
15. REGULATORY INFORMATION

16. OTHER INFORMATION

Data Sources: The data contained in this MSDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.

Reasons for Revision: New data sheet.

Revision date: 24-Oct-2016


Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet