# SAFETY DATA SHEET

## * 1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

**Material** ARZERRA INJECTION

**Synonym(s)** HUMAX-CD20 VIALS 20 MG/ML * GSK1841157A VIALS * OFATUMUMAB, FORMULATED PRODUCT

**Recommended Use** Medicinal Product

**Company Name**

GlaxoSmithKline UK
980 Great West Road
Brentford, Middlesex TW8 9GS UK
UK General Information: +44-20-8047-5000

GlaxoSmithKline US
5 Moore Drive
Research Triangle Park, NC 27709 USA
US General Information: +1-888-825-5249

Email Address: msds@gsk.com
Website: www.gsk.com

EMERGENCY PHONE NUMBERS -
Transport Emergencies (by country / geographic region):

| | |
|---|---|
| Africa (Arab-speaking): | +961-3-487-287 (Lebanon) |
| Africa (English, French, Portuguese-speaking): | +44-208-762-8322 (UK) |
| Asia Pacific (except China): | +65-633-44-177 (Singapore) |
| China: | +86-10-5100-3039 (Beijing) |
| EU: | +44-208-762-8322 (UK) |
| Israel: | +44-208-762-8322 (UK) |
| Middle East (except Israel): | +961-3-487-287 (Lebanon) |
| US: | +1-703-527-3887 (US) |

available 24 hrs/7 days; multi-language response

Medical Emergencies: +1-612-221-3999, Ext 221 (US)
available 24 hrs/7 days; multi-language response

## 2. HAZARDS IDENTIFICATION

**Fire and Explosion Hazards**

This product is classified as non-flammable.

**Health** Handling this product in its final form presents minimal risk from occupational exposure. Health effects information is based on hazards of components.

**Environment** No information is available about the potential of this product to produce adverse environmental effects.

## 3. COMPOSITION / INFORMATION ON INGREDIENTS

| Ingredients | CAS # | Percent | EC-No. |
|---|---|---|---|
| OFATUMUMAB | Unassigned | 2 | |
| Other components below reportable levels | | 98 | |

## * 4. FIRST-AID MEASURES

**Ingestion** Never attempt to induce vomiting. Do not attempt to give any solid or liquid by mouth if the exposed subject is unconscious or semi-conscious. Wash out the mouth with water. If the exposed subject is fully conscious, give plenty of water to drink. Obtain medical attention.

**Inhalation** Physical form suggests that risk of inhalation exposure is negligible.

**Skin contact** Using appropriate personal protective equipment, remove contaminated clothing and flush exposed area with large amounts of water. Obtain medical attention if skin reaction occurs, which may be immediate or delayed.

**Eye contact** Wash immediately with clean and gently flowing water. Continue for at least 15 minutes.

**NOTES TO HEALTH PROFESSIONALS**

**Medical Treatment** Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information centre.

**Medical Conditions Caused or Aggravated by Exposure** None for occupational exposure.

**Antidotes** No specific antidotes are recommended.

## 5. FIRE-FIGHTING MEASURES

**Fire and Explosion Hazards** Not expected for the product, although the packaging is combustible.

**Extinguishing Media** No special requirements needed.

**Special Firefighting Procedures** For single units (packages): No special requirements needed.
For larger amounts (multiple packages/pallets) of product: Since toxic, corrosive or flammable vapours might be evolved from fires involving this product and associated packaging, self contained breathing apparatus and full protective equipment are recommended for firefighters.
If possible, contain and collect firefighting water for later disposal.

**Hazardous Combustion Products** Toxic, corrosive or flammable thermal decomposition products are expected when the product is exposed to fire.

## 6. ACCIDENTAL RELEASE MEASURES

**Personal Precautions** Wear protective clothing and equipment consistent with the degree of hazard.

**Environmental Precautions** For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.

**Clean-up Methods** Collect and place it in a suitable, properly labelled container for recovery or disposal.

**Decontamination Procedures** No specific decontamination or detoxification procedures have been identified for this product.

## * 7. HANDLING AND STORAGE

**HANDLING**

**General Requirements** No special control measures required for the normal handling of this product. Normal room ventilation is expected to be adequate for routine handling of this product.

**STORAGE** Store at 2 to 8 °C (36 to 46 °F). Do not freeze. No storage requirements are considered necessary for the control of fire and explosion hazards.

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**OCCUPATIONAL EXPOSURE LIMITS**

**GSK Occupational Hazard Category** 2

**ENGINEERING CONTROLS**

**Exposure Controls** The API, ofatumumab, has been assigned to GSK Occupational Hazard Category (OHC) 2 with a hygiene guide of >100 - 1000 mcg/m3.
The GSK Exposure Control Matrix recommends controls which are effective only for dusts and solid particulates. Consult your local occupational hygiene specialist, or safety officer for effective controls for liquids, vapours, and gases.

**Other Equipment or Procedures** None required for normal handling. Wash hands and arms thoroughly after handling.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

**Appearance**

**Physical Form** Liquid.

**Packaging** Vial.

## 10. STABILITY AND REACTIVITY

**Stability** This product is expected to be stable.

**Conditions to Avoid** None for normal handling of this product.

## 11. TOXICOLOGY INFORMATION

**Pharmacological Effects** This preparation contains ingredient(s) with the following activity: monoclonal antibody.

**Routes of Exposure**

**Oral Toxicity** Not expected to be toxic following ingestion.

**Skin Effects** Irritation is not expected following direct contact.

**Eye Effects** Irritation is not expected following direct contact with eyes.

**Sensitisation** Sensitisation (allergic skin reaction) is not expected.

**Genetic Toxicity** Not expected to be genotoxic under occupational exposure conditions.

**Carcinogenicity** No components are listed as carcinogens by GSK, IARC, NTP or US OSHA. Not expected to produce cancer in humans under occupational exposure conditions.

**Reproductive Effects** Not expected to produce adverse effects on fertility or development under occupational exposure conditions.

**Other Adverse Effects** None known for occupational exposure.

## 12. ECOLOGICAL INFORMATION

**Summary** No information is available about the potential of this product to produce adverse environmental effects. Local regulations and procedures should be consulted prior to environmental release.

## 13. DISPOSAL CONSIDERATIONS

**Disposal Recommendations** Collect for recycling or recovery if possible. The disposal method for rejected products/returned goods must ensure that they cannot be re-sold or re-used.

**Regulatory Requirements** Observe all local and national regulations when disposing of this product.

## 14. TRANSPORT INFORMATION

The SDS should accompany all shipments for reference in the event of spillage or accidental release. Only authorised persons trained and competent in accordance with appropriate national and international regulatory requirements may prepare dangerous goods for transport.

**UN Classification and Labelling**

**Transport Information** Transportation and shipping of this product is not restricted. It has no known, significant hazards requiring special packaging or labelling for air, maritime, US or European ground transport purposes.

## 15. REGULATORY INFORMATION

The information included below is an overview of the major regulatory requirements. It should not be considered to be an exhaustive summary. Local regulations should be consulted for additional requirements.

**EU Classification and Labelling**

Exempt from requirements of EU Dangerous Preparations directive - product regulated as a medicinal product, cosmetic product or medical device.

**US OSHA Standard (29 CFR Part 1910.1200)**

**Classification** This product is exempt from the requirements of the OSHA Hazard Communication Standard.

**Other US Regulations**

**TSCA Status** Exempt

## 16. OTHER INFORMATION

**References** GSK Hazard Determination

**SDS Version Number** 4

### SDS Sections Updated

| Sections | Subsections |
|---|---|
| FIRST-AID MEASURES | Eye Contact |
| | Medical Treatment |
| HANDLING AND STORAGE | Storage |
| IDENTIFICATION OF SUBSTANCE / PREPARATION AND OF COMPANY | |

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.