



# SAFETY DATA SHEET

## 1. Identification

**Product identifier** ARZERRA INJECTION

**Other means of identification**

**Synonyms** HUMAX-CD20 VIALS 20 MG/ML \* GSK1841157A VIALS \* OFATUMUMAB, FORMULATED PRODUCT

**Recommended use** Medicinal Product.

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.

**Recommended restrictions** No other uses are advised.

### Manufacturer/Importer/Supplier/Distributor information

#### Manufacturer

GlaxoSmithKline US  
5 Moore Drive  
Research Triangle Park, NC 27709 USA  
US General Information (normal business hours): +1-888-825-5249  
Email Address: msds@gsk.com  
Website: www.gsk.com  
EMERGENCY PHONE NUMBERS -  
TRANSPORT EMERGENCIES:  
US / International toll call +1 703 527 3887  
available 24 hrs/7 days; multi-language response

## 2. Hazard(s) identification

### Classified hazards

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

### Label elements

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

### Hazard(s) not otherwise classified (HNOC)

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

## 3. Composition/information on ingredients

### Mixtures

Chemical name	Common name and synonyms	CAS number	%
OFATUMUMAB		Unassigned	1 - < 3
L-(+)-ARGININE	ARGININE, L- * L-ARGININEAMINOVALERIC ACID * ARG * 2-AMINO-5-GUANIDINOVALERIC ACID * (S)-2-AMINO-5-((AMINOIMINOMETHYL)AMINO) PENTANOIC ACID * GUANIDINE AMINOVALERIC ACID * AMINO-4-GUANIDOVALERIC ACID * 2-AMINO-5-GUANIDINOPENTANOIC ACID * ARGININE * L-ARGININE * 1-AMINO-4-GUANIDOVALERIC ACID * L-1-AMINO-4-GUANIDOVALERIC ACID * (S)-(+)-ARGININE * C6H14N4O2 * OHS12379 * RTECS CF1934200 * PROTEINOGENE AMINOSÄUREN UND STEREOISOMERE D-FORMEN UND IHRE SALZE MIT GEGENIONEN DER WGK 1	74-79-3	1

Chemical name	Common name and synonyms	CAS number	%
HYDROCHLORIC ACID	HYDROCHLORIC ACID SOLUTIONS * RTECS MW4025000 * MURIATIC ACID * AQUEOUS HYDROGEN CHLORIDE * CHLOROHYDRIC ACID * HCL	7647-01-0	0.1
ETHYLENEDIAMINETETRAACETIC ACID, DISODIUM SALT, DIHYDRATE	(ETHYLENEDINITRILLO)TETRA-ACETIC ACID, DISODIUM SALT, DIHYDRATE * DISODIUM DIHYDROGEN ETHYLENEDIAMINETETRAACETATE DIHYDRATE * DISODIUM EDTA DIHYDRATE * DISODIUM ETHYLENEDIAMINETETRAACETATE * DISODIUM ETHYLENEDIAMINETETRAACETATE DIHYDRATE * EDETATE DISODIUM * EDTA, DISODIUM DIHYDRATE * ETHYLENEDIAMINE TETRAACETATE ACID DISODIUM SALT, DIHYDRATE * ETHYLENEDIAMINETETRAACETIC ACID DISODIUM SALT DIHYDRATE * RTECS AH4410000	6381-92-6	0.002
Other components below reportable levels			>95.0

\*Designates that a specific chemical identity and/or percentage of composition has been withheld as a trade secret.

#### 4. First-aid measures

<b>Inhalation</b>	Move to fresh air. If breathing is difficult, trained personnel should give oxygen. Call a physician if symptoms develop or persist. Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
<b>Skin contact</b>	Immediately flush skin with plenty of water. Take off contaminated clothing and wash before reuse. Get medical attention if symptoms occur.
<b>Eye contact</b>	Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.
<b>Ingestion</b>	If swallowed, rinse mouth with water (only if the person is conscious). If ingestion of a large amount does occur, call a poison control center immediately. Do not induce vomiting without advice from poison control center.
<b>Most important symptoms/effects, acute and delayed</b>	None known.
<b>Indication of immediate medical attention and special treatment needed</b>	No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information center.
<b>General information</b>	In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

#### 5. Fire-fighting measures

<b>Suitable extinguishing media</b>	Water. Foam. Dry chemical powder. Carbon dioxide (CO2).
<b>Unsuitable extinguishing media</b>	None known.
<b>Specific hazards arising from the chemical</b>	During fire, gases hazardous to health may be formed.
<b>Special protective equipment and precautions for firefighters</b>	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
<b>Fire fighting equipment/instructions</b>	Move containers from fire area if you can do so without risk.
<b>Specific methods</b>	Use standard firefighting procedures and consider the hazards of other involved materials.
<b>General fire hazards</b>	This product is non-flammable.

#### 6. Accidental release measures

<b>Personal precautions, protective equipment and emergency procedures</b>	Keep unnecessary personnel away. For personal protection, see section 8 of the SDS.
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**Methods and materials for containment and cleaning up**

Large Spills: Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. Cover with plastic sheet to prevent spreading. Absorb in vermiculite, dry sand or earth and place into containers. Following product recovery, flush area with water.

Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.

Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS. Avoid discharge into drains, water courses or onto the ground.

**Environmental precautions****7. Handling and storage****Precautions for safe handling**

Avoid prolonged exposure. Observe good industrial hygiene practices.

**Conditions for safe storage, including any incompatibilities**

Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS).

**8. Exposure controls/personal protection****Occupational exposure limits****GSK****Material****Type****Value**

ARZERRA INJECTION

OHC

2

**Components****Type****Value**ETHYLENEDIAMINETETR  
AACETIC ACID, DISODIUM  
SALT, DIHYDRATE (CAS  
6381-92-6)

8 HR TWA

3000 mcg/m3

OHC

1

**US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)****Components****Type****Value**HYDROCHLORIC ACID  
(CAS 7647-01-0)

Ceiling

7 mg/m3

5 ppm

**US. ACGIH Threshold Limit Values****Components****Type****Value**HYDROCHLORIC ACID  
(CAS 7647-01-0)

Ceiling

2 ppm

**US. NIOSH: Pocket Guide to Chemical Hazards****Components****Type****Value**HYDROCHLORIC ACID  
(CAS 7647-01-0)

Ceiling

7 mg/m3

5 ppm

**Biological limit values**

No biological exposure limits noted for the ingredient(s).

**Exposure guidelines****Appropriate engineering controls**

General ventilation normally adequate. An Exposure Control Approach (ECA) is established for operations involving this material based upon the OEL/Occupational Hazard Category and the outcome of a site- or operation-specific risk assessment.

**Individual protection measures, such as personal protective equipment****Eye/face protection**

Not normally needed. If contact is likely, safety glasses with side shields are recommended.

**Skin protection****Hand protection**

Not normally needed. For prolonged or repeated skin contact use suitable protective gloves.

**Other**

Not normally needed. Wear suitable protective clothing as protection against splashing or contamination.

**Respiratory protection**

No personal respiratory protective equipment normally required. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits. When workers are facing concentrations above the exposure limit they must use appropriate certified respirators.

**Thermal hazards**

Wear appropriate thermal protective clothing, when necessary.

**General hygiene considerations**

Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional.

**9. Physical and chemical properties****Appearance**

<b>Physical state</b>	Liquid.
<b>Form</b>	Vial.
<b>Color</b>	Not available.

**Odor** Not available.

**Odor threshold** Not available.

**pH** Not available.

**Melting point/freezing point** Not available.

**Initial boiling point and boiling range** Not available.

**Flash point** Not available.

**Evaporation rate** Not available.

**Flammability (solid, gas)** Not available.

**Upper/lower flammability or explosive limits**

**Flammability limit - lower (%)** Not available.

**Flammability limit - upper (%)** Not available.

**Explosive limit - lower (%)** Not available.

**Explosive limit - upper (%)** Not available.

**Vapor pressure** Not available.

**Vapor density** Not available.

**Relative density** Not available.

**Solubility(ies)**

**Solubility (water)** Not available.

**Partition coefficient (n-octanol/water)** Not available.

**Auto-ignition temperature** Not available.

**Decomposition temperature** Not available.

**Viscosity** Not available.

**10. Stability and reactivity**

**Reactivity** The product is stable and non-reactive under normal conditions of use, storage and transport.

**Chemical stability** Material is stable under normal conditions.

**Possibility of hazardous reactions** No dangerous reaction known under conditions of normal use.

**Conditions to avoid** Contact with incompatible materials.

**Incompatible materials** Strong oxidizing agents.

**Hazardous decomposition products** None known. Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

**11. Toxicological information****Information on likely routes of exposure**

**Inhalation** Under normal conditions of intended use, this material is not expected to be an inhalation hazard.

**Skin contact** Health injuries are not known or expected under normal use.

**Eye contact** Health injuries are not known or expected under normal use. Direct contact with eyes may cause temporary irritation.

**Ingestion**

Health injuries are not known or expected under normal use. May be harmful if swallowed. However, ingestion is not likely to be a primary route of occupational exposure.

**Symptoms related to the physical, chemical and toxicological characteristics**

None known.

**Information on toxicological effects****Acute toxicity**

Expected to be a low hazard for usual industrial or commercial handling by trained personnel.

**Components****Species****Test Results**

## HYDROCHLORIC ACID (CAS 7647-01-0)

**Acute***Inhalation*

LC50

Mouse

1108 ppm, 1 Hours

Rat

3124 ppm, 1 Hours

LCL0

Guinea pig

4416 ppm, 30 minutes

Human

3000 ppb, 5 minutes

1300 ppm, 30 minutes

Rabbit

4416 ppm, 30 minutes

NOEL

Human

<= 1.8 ppm, 45 minutes No effect on respiratory function in asthmatics.

*Oral*

LD50

Rabbit

900 mg/kg

Rat

700 mg/kg

**Chronic***Inhalation*

LOAEL

Rat

10 ppm, 128 weeks

**Subacute***Oral*

LD

Rat

34.1 mg/kg/day, 9 weeks

LOEL

Rat

10.2 mg/kg/day, 9 weeks

**Subchronic***Inhalation*

LOEC

Rat

10 ppm, 3 months Inflammation of lips and nasal cavity.

NOAEC

Rat

20 ppm, 3 months

## L-(+)-ARGININE (CAS 74-79-3)

**Acute***Oral*

Rat

&gt; 5000 mg/kg

\* Estimates for product may be based on additional component data not shown.

**Skin corrosion/irritation**

Health injuries are not known or expected under normal use.

**Corrosivity**

L-(+)-ARGININE

Literature search

Result: Non-irritant

HYDROCHLORIC ACID

OECD 404

Result: Corrosive

Species: Rabbit

Test Duration: 1 Hours

**Serious eye damage/eye irritation**

Health injuries are not known or expected under normal use. Direct contact with eyes may cause temporary irritation.

**Eye**

L-(+)-ARGININE

Literature search

Result: May cause irritation

**Eye**

HYDROCHLORIC ACID

OECD 405

Result: Corrosive effects/irritation

Species: Rabbit

**Respiratory or skin sensitization****Respiratory sensitization** No studies have been conducted.**Skin sensitization** None known. This product is not expected to cause skin sensitization.**Germ cell mutagenicity** No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.**Mutagenicity**

HYDROCHLORIC ACID

&lt;= 10 mmol/L Chromosomal Aberration Assay In Vitro, CHO cells, IUCLID

Result: Positive

Ames, IUCLID

Result: Negative

E coli Pol-A repair assay, IUCLID

Result: Negative

L5178Y mouse lymphoma thymidine kinase locus assay, IUCLID

Result: Negative

Yeast Mutation Assay, IUCLID

Result: Negative

**Carcinogenicity**

Not classifiable as to carcinogenicity to humans. Carcinogenic effects are not expected as a result of occupational exposure.

HYDROCHLORIC ACID

10 ppm Inhalation

Result: Negative

Species: Rat

Observation Period: 128 months

Notes: IUCLID

**IARC Monographs. Overall Evaluation of Carcinogenicity**

HYDROCHLORIC ACID (CAS 7647-01-0)

3 Not classifiable as to carcinogenicity to humans.

**OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)**

Not listed.

**Reproductive toxicity**

Contains no ingredient listed as toxic to reproduction

**Reproductivity**

HYDROCHLORIC ACID

302 ppm Embryo-foetal development, IUCLID

Result: Maternal toxicity, resorptions, foetal malformations.

Species: Rat

**Specific target organ toxicity - single exposure**

Not assigned.

HYDROCHLORIC ACID

Result: Respiratory irritation/corrosion.

**Specific target organ toxicity - repeated exposure**

Not assigned.

**Aspiration hazard**

Not established.

**Further information**

Occupational exposure to the substance or mixture may cause adverse effects.

**12. Ecological information****Ecotoxicity**

Not expected to be harmful to aquatic organisms.

**Components****Species****Test Results**

ETHYLENEDIAMINETETRAACETIC ACID, DISODIUM SALT, DIHYDRATE (CAS 6381-92-6)

**Aquatic***Acute*

Crustacea

EC50

Water flea (Daphnia magna)

21.6 mg/l, 48 hours Static test

NOEC

Water flea (Daphnia magna)

4.1 mg/l, 48 hours Static test

Fish

EC50

Bluegill sunfish (Adult Lepomis macrochirus)

52.5 mg/l, 96 hours Static test

Channel catfish (Adult Ictalurus punctatus)

164 mg/l, 96 hours Static test

Components	Species	Test Results
	Fathead minnow (Adult Pimephales promelas)	75.9 mg/l, 96 hours Static test

\* Estimates for product may be based on additional component data not shown.

**Persistence and degradability** Not available.

**Biodegradability**

**Percent degradation (Aerobic biodegradation-inherent)**

ETHYLENEDIAMINETETRAACETIC ACID, DISODIUM SALT, DIHYDRATE 37 %, 14 days Zahn-Wellens, Activated sludge

**Percent degradation (Aerobic biodegradation-soil)**

ETHYLENEDIAMINETETRAACETIC ACID, DISODIUM SALT, DIHYDRATE 13 - 45 %, 15 weeks

**Bioaccumulative potential** Not available.

**Partition coefficient n-octanol / water (log Kow)**

L-(+)-ARGININE -4.2

**Bioconcentration factor (BCF)**

ETHYLENEDIAMINETETRAACETIC ACID, DISODIUM SALT, DIHYDRATE 0.8 - 1.8 Measured, Lepomis macrochirus, bluegill sunfish

**Mobility in soil** Not available.

**Mobility in general** Not available.

**Other adverse effects** Not available.

**13. Disposal considerations**

**Disposal instructions** Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Do not discharge into drains, water courses or onto the ground. Dispose in accordance with all applicable regulations.

**Local disposal regulations** Dispose in accordance with all applicable regulations.

**Hazardous waste code** The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

**Waste from residues / unused products** Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions). Avoid discharge into water courses or onto the ground.

**Contaminated packaging** Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

**14. Transport information**

**DOT**

Not regulated as a dangerous good.

**IATA**

Not regulated as dangerous goods.

**IMDG**

Not regulated as dangerous goods.

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code** MARPOL Annex II applies to liquids used in a ship's operation that pose a threat to the marine environment. These materials may not be transported in bulk.

**15. Regulatory information**

**US federal regulations**

**TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)**

Not regulated.

**CERCLA Hazardous Substance List (40 CFR 302.4)**

HYDROCHLORIC ACID (CAS 7647-01-0) Listed.

**SARA 304 Emergency release notification**

HYDROCHLORIC ACID (CAS 7647-01-0) 5000 LBS

**OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)**

Not listed.

**Superfund Amendments and Reauthorization Act of 1986 (SARA)**

**Hazard categories**  
 Immediate Hazard - No  
 Delayed Hazard - No  
 Fire Hazard - No  
 Pressure Hazard - No  
 Reactivity Hazard - No

**SARA 302 Extremely hazardous substance**

Chemical name	CAS number	Reportable quantity	Threshold planning quantity	Threshold planning quantity, lower value	Threshold planning quantity, upper value
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HYDROCHLORIC ACID	7647-01-0	5000	500 lbs		
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**SARA 311/312 Hazardous chemical** No

**SARA 313 (TRI reporting)**  
 Not regulated.

**Other federal regulations****Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List**

HYDROCHLORIC ACID (CAS 7647-01-0)

**Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)**

HYDROCHLORIC ACID (CAS 7647-01-0)

**Safe Drinking Water Act (SDWA)** Not regulated.

**Drug Enforcement Administration (DEA). List 2, Essential Chemicals (21 CFR 1310.02(b) and 1310.04(f)(2))**

HYDROCHLORIC ACID (CAS 7647-01-0)

**DEA Essential Chemical Code Number**

HYDROCHLORIC ACID (CAS 7647-01-0) 6545

**Drug Enforcement Administration (DEA). List 1 & 2 Exempt Chemical Mixtures (21 CFR 1310.12(c))**

HYDROCHLORIC ACID (CAS 7647-01-0) 20 %WV

**DEA Exempt Chemical Mixtures Code Number**

HYDROCHLORIC ACID (CAS 7647-01-0) 6545

**US state regulations****US. California Controlled Substances. CA Department of Justice (California Health and Safety Code Section 11100)**

Not listed.

**US. Massachusetts RTK - Substance List**

HYDROCHLORIC ACID (CAS 7647-01-0)

**US. New Jersey Worker and Community Right-to-Know Act**

HYDROCHLORIC ACID (CAS 7647-01-0)

**US. Pennsylvania Worker and Community Right-to-Know Law**

HYDROCHLORIC ACID (CAS 7647-01-0)

**US. Rhode Island RTK**

HYDROCHLORIC ACID (CAS 7647-01-0)

**US. California Proposition 65**

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

**International Inventories**

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No



Country(s) or region	Inventory name	On inventory (yes/no)*
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

\*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

## 16. Other information, including date of preparation or last revision

<b>Issue date</b>	03-09-2015
<b>Revision date</b>	03-09-2015
<b>Version #</b>	06
<b>Further information</b>	HMIS® is a registered trade and service mark of the NPCA.
<b>HMIS® ratings</b>	Health: 1 Flammability: 0 Physical hazard: 0
<b>NFPA ratings</b>	Health: 1 Flammability: 0 Instability: 0
<b>References</b>	GSK Hazard Determination
<b>Disclaimer</b>	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.
<b>Revision Information</b>	Product and Company Identification: Product and Company Identification Composition / Information on Ingredients: Undisclosed Ingredient Statement Physical & Chemical Properties: Transport Information: Regulatory Information: United States