DARZALEX 100mg/5 mL, 400mg/20mL, vial

Version	Revision Date:	SDS Number:	Date of last issue: 2017/06/29
1.53	2017/09/21	100000009101	Date of first issue: 2014/11/21

SECTION 1. IDENTIFICATION

Product name : DARZALEX 100mg/5 mL, 400mg/20mL, vial
Substance name : DARATUMUMAB finished pharmaceutical product
DARATUMUMAB finished pharmaceutical bulk material
DARATUMUMAB final vialed product
Reference number : JNJ-54767414-AAA

Manufacturer or supplier's details

Company name of supplier : Janssen Pharmaceuticals, Inc.

Address : 1125 Trenton-Harbourton Rd
Titusville NJ 08560
US

Telephone : (609) 730-2000
E-mail address Responsible/issuing person : SDSJanssen@its.jnj.com

Emergency telephone number : CHEMTREC US: 1-800-424-9300
CHEMTREC International: +1 703-527-3887

Recommended use of the chemical and restrictions on use

Recommended use : Large Molecule Pharmaceutical intended for medical use
Finished Pharmaceutical Product
This SDS is only intended for occupational use and not for consumer use (see patient packaging insert for consumer use). This SDS is written to provide environmental, health and safety information for personnel that will be handling this finished pharmaceutical product. For health and safety information during manufacturing of this product we refer to the appropriate SDS for each component.
This dosage form is not exempt from the requirements of the OSHA Hazard Communication Standard (US OSHA Standard 29 CFR Part 1910.1200).

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

Not a hazardous substance or mixture.

GHS label elements

Not a hazardous substance or mixture.

Other hazards

This Finished Pharmaceutical Product is non-hazardous based on chemical classification rules. Avoid direct contact and significant aerosol/dust exposure which has the remote possibilities of eliciting an allergic response. May cause sensitization of susceptible personse.
This material is not likely to be significantly absorbed via occupational routes of entry due to its chemical structure and large molecular weight.

Accidental injection may cause effects similar to those seen in clinical use and mentioned in the patient packaging insert.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Chemical nature : Liquid

Hazardous components

Chemical name	CAS-No.	Concentration (%)
DARATUMUMAB monoclonal antibody	945721-28-8	>= 1 - < 5
acetic acid	64-19-7	< 0.02
DARATUMUMAB monoclonal antibody	945721-28-8	>= 1 - < 5
acetic acid	64-19-7	< 0.1

SECTION 4. FIRST AID MEASURES

If inhaled : If breathed in, move person into fresh air.
Consult a physician.

In case of skin contact : Take off contaminated clothing and shoes immediately.
Consult a physician.
Wash off immediately with plenty of water.
Wash contaminated clothing before re-use.

In case of eye contact : Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes.
Remove contact lenses.
Consult a physician.

If swallowed : If swallowed, rinse mouth with water (only if the person is conscious).
Call a physician immediately.
Product is digested in the GI tract and unlikely to be systemically absorbed in significant amounts.

Most important symptoms and effects, both acute and delayed : Consult the patient packaging insert for more information about this Finished Pharmaceutical Product.

Notes to physician : Treat symptomatically.
Consult the patient packaging insert for more information about this Finished Pharmaceutical Product.

SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Specific hazards during fire- : No information available.

fighting

Further information : No information available.

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

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures : In the event of an accidental release the emergency response team must respond based on a risk assessment and use personal protective equipment as appropriate.
Avoid direct contact with broken glass, plastic and other sharps.
Avoid splashes and spray formation.
Evacuate personnel to safe areas.
Avoid direct contact and significant aerosol exposure.

Environmental precautions : Should not be released into the environment.
Do not flush into surface water or sanitary sewer system.

Methods and materials for containment and cleaning up : Small spills: Gently cover the spill with an absorbent towel or pad.
Wet absorbent pad with 10% bleach solution. Allow 30 minutes contact time.
Large spills: Allow the dust/aerosol to settle for 30 minutes or use appropriate respiratory protection.
Dam up.
Soak up with inert absorbent material.
Add bleach (5.25% sodium hypochlorite) solution to a final liquid concentration of 10% (1 part bleach, mixed with 9 parts liquid) to absorbent materials. Allow 30 minute contact time.
Large spills + Small spills: Keep in suitable, closed containers for disposal. Treat recovered material as described in the section "Disposal considerations".
Clean up with a 10% bleach (5.25% sodium hypochlorite) solution, 1 part bleach, mixed with 9 parts water is recommended for cleaning of surfaces and equipment.
Clean spill location and adjacent surfaces thoroughly with ethanol or water with detergent.
Special consideration may need to be evaluated based on specific hazards.

SECTION 7. HANDLING AND STORAGE

Advice on protection against fire and explosion : The product is not flammable.

Advice on safe handling : Do not break, crush or spill this Finished Pharmaceutical Product.
Avoid splashes.
Avoid formation of aerosol.

Do not heat the product.
Avoid inhalation, ingestion and contact with skin and eyes.
Use personal protective equipment as required.

Conditions for safe storage : To maintain product quality, do not store in heat or direct sunlight.
Store in original container.
Keep containers tightly closed in a dry, cool and well-ventilated place.
Keep away from heat.
Keep locked up.
Keep refrigerated.

Recommended storage temperature : 2 - 8 °C

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
DARATUMUMAB monoclonal antibody	945721-28-8	PBOEL-HHC	2	J&J OEL/PBOEL HHC
	Further information: J&J has a hazard banding notation: PBOEL HHC. This substance is classified by J&J as being PBOEL HHC 2. This means that the OEL is estimated to be from 20 to 100 µg/m3			
acetic acid	64-19-7	TWA	10 ppm	ACGIH
		STEL	15 ppm	ACGIH
		TWA	10 ppm	ACGIH
		STEL	15 ppm	ACGIH
		TWA	10 ppm 25 mg/m3	NIOSH REL
		ST	15 ppm 37 mg/m3	NIOSH REL
		TWA	10 ppm 25 mg/m3	OSHA Z-1
		TWA	10 ppm 25 mg/m3	OSHA P0
		PEL	10 ppm 25 mg/m3	CAL PEL
		STEL	15 ppm 37 mg/m3	CAL PEL
		C	40 ppm	CAL PEL

Engineering measures : All personal protective equipment should be based on a risk assessment. Consult a Environment Health Safety expert if necessary.

Personal protective equipment

Respiratory protection	:	Engineering controls should always be the primary method of controlling exposures. There is remote possibility that this product could be aerosolized and inhaled in the workplace. If respiratory protective equipment is needed for certain activities, the type as well as the corresponding protection factor will depend upon the risk assessment and air concentrations, hazards, physical and warning properties of substances present.
Hand protection		
Remarks	:	Disposable gloves
Eye protection	:	Safety glasses
Skin and body protection	:	Lab coat
Protective measures	:	The type of protective equipment must be selected based on the Environmental Health and Safety risk assessment. Consult a Environmental Health and Safety expert if necessary.
Hygiene measures	:	Handle in accordance with good industrial hygiene and safety practice. Remove gloves and wash hands when work with material is completed. Do not reuse gloves. In some cases, wearing two pairs of gloves may be appropriate. Contaminated work clothing should not be allowed out of the workplace.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	Aqueous solution, Liquid bulk pharmaceutical product., Vial
Colour	:	colourless, to, yellow, brown
pH	:	5.5

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	None reasonably foreseeable.
Chemical stability	:	Stable under recommended storage conditions.
Possibility of hazardous reactions	:	No dangerous reaction known under conditions of normal use.
Conditions to avoid	:	To avoid thermal decomposition, do not overheat. Exposure to sunlight.
Incompatible materials	:	None known.

Hazardous decomposition products : None known.

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

Product:

Acute oral toxicity : Remarks: No data available

Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

Acute toxicity (other routes of administration) : Remarks: No data available

Components:

acetic acid
Acute oral toxicity : LD50 (Rat): 3,310 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 44 mg/l
Exposure time: 4 h

acetic acid
Acute oral toxicity : LD50 (Rat): 3,310 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 44 mg/l
Exposure time: 4 h

Skin corrosion/irritation

Product:

Result: No skin irritation
Remarks: Expert judgement

Components:

acetic acid
Result: Causes severe burns.

acetic acid
Result: Causes severe burns.

Serious eye damage/eye irritation

Product:

Result: No eye irritation

Remarks: Expert judgement

Components:

acetic acid
Result: Corrosive to eyes

acetic acid
Result: Corrosive to eyes

Respiratory or skin sensitisation

Product:

Remarks: Large protein biotherapeutics in the dry or reconstituted (solution in buffer) forms are not expected to elicit skin corrosion/irritation, skin sensitization, or cause damage to/irritate the eyes.

Assessment:	Single-dose acute toxicity studies were not performed. This product is a large protein biotherapeutic intended for injection. It is not expected to be absorbed via the oral, dermal, or inhalation routes of exposure.

Germ cell mutagenicity

Product:

Genotoxicity in vitro	:	Remarks: No data available
Genotoxicity in vivo	:	Remarks: No data available
Germ cell mutagenicity - Assessment	:	Routine genotoxicity studies are not applicable to biotherapeutics as large proteins cannot diffuse into cells and interact with DNA or chromosomal material., As systemic exposure from handling is expected to be negligible in the workplace, hazards from worker exposure is considered unlikely.

Components:

acetic acid

Germ cell mutagenicity - Assessment	:	Not mutagenic in Ames Test

acetic acid

Germ cell mutagenicity - Assessment	:	Not mutagenic in Ames Test

Carcinogenicity

Product:

Remarks: No data available

Carcinogenicity - Assessment	:	Carcinogenicity studies are not warranted to support marketing for therapeutics intended to treat patients with

advanced cancer., As systemic exposure from handling is expected to be negligible in the workplace, hazards from worker exposure is considered unlikely.

IARC No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

NTP No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity

Product:

Effects on fertility : Remarks: No data available

Effects on foetal development : Remarks: No data available

Reproductive toxicity - Assessment : As maternal systemic exposure from handling is expected to be negligible and placental transfer of monoclonal antibodies in humans is very low during the period of organogenesis (1st trimester), embryo/fetal harm from worker exposure is considered unlikely.

STOT - single exposure

Product:

Remarks: No data available

STOT - repeated exposure

Product:

Remarks: No data available

Repeated dose toxicity

Product:

Species: Non-human primate, male and female
LOAEL: 5 mg/kg
Application Route: intravenous injection
Exposure time: 6 weeks
Number of exposures: weekly
Subsequent observation period: 56 days
GLP: yes
Target Organs: Blood
Symptoms: Changes in the blood count
Remarks: No significant adverse effects were reported

Species: Non-human primate, male and female
Application Route: intravenous injection
Exposure time: 2 weeks
Number of exposures: weekly
Subsequent observation period: 2 months
GLP: no

Repeated dose toxicity - Assessment : Single-dose acute toxicity studies were not performed. This product is a large protein biotherapeutic intended for injection. It is not expected to be absorbed via the oral, dermal, or inhalation routes of exposure.

Aspiration toxicity

No data available

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Product:

Toxicity to fish : Remarks: No data available

Toxicity to daphnia and other aquatic invertebrates : Remarks: No data available

Toxicity to algae : Remarks: No data available

Components:

acetic acid

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 47 mg/l
Exposure time: 24 h

acetic acid

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 47 mg/l
Exposure time: 24 h

Persistence and degradability

Product:

Biodegradability : Remarks: No data available

Bioaccumulative potential

Product:

Bioaccumulation : Remarks: No data available

Mobility in soil

No data available

Other adverse effects

Product:

Ozone-Depletion Potential	:	Regulation: 40 CFR Protection of Environment; Part 82 Protection of Stratospheric Ozone - CAA Section 602 Class I Substances Remarks: This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).
Additional ecological information	:	Should not be released into the environment.

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues	:	In accordance with National, Federal, State and Local regulations. Decontaminate all waste before disposal (steam sterilization, chemical disinfection and/or incineration).
Contaminated packaging	:	Empty containers should be taken to an approved waste handling site for recycling or disposal.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG
Not regulated as a dangerous good

IATA-DGR
Not regulated as a dangerous good

IMDG-Code
Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

National Regulations

49 CFR
Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION

Clean Air Act

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).
This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).
This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).
This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCMI Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act

The following Hazardous Substances are listed under the U.S. CleanWater Act, Section 311, Table 116.4A:

acetic acid	64-19-7	0.0185 %

The following Hazardous Chemicals are listed under the U.S. CleanWater Act, Section 311, Table 117.3:

acetic acid	64-19-7	0.0185 %

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

US State Regulations

Massachusetts Right To Know

No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know

water	7732-18-5	90 - 100 %
acetic acid	64-19-7	0 - 0.1 %

New Jersey Right To Know

water	7732-18-5	90 - 100 %
D-Mannitol	69-65-8	1 - 5 %
DARATUMUMAB monoclonal antibody	945721-28-8	1 - 5 %

California Prop 65

This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

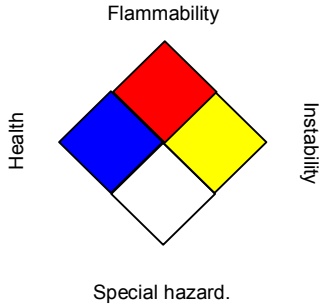
Other regulations : Restricted to professional users.

This product is not subject to TSCA and TSCA 12(b) Export notification because Food, Drugs and cosmetic products are exempt.

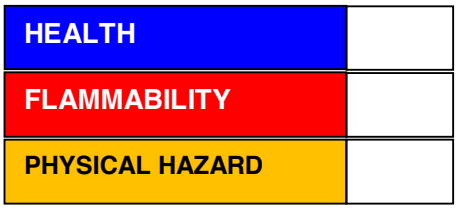
SECTION 16. OTHER INFORMATION

Further information

NFPA:



HMIS III:



0 = not significant, 1 =Slight,
2 = Moderate, 3 = High
4 = Extreme, * = Chronic

For research use only.
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Date and Number Formats

This document uses the following notation for printing dates and numbers:

Date:	Dec 31th, 2012	as	2012/12/31
Numbers:	123456,78	as	123,456.78

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