Version	Revision Date:	SDS Number:	Date of last issue: 2017/02/25
1.96	2017/03/25	100000009885	Date of first issue: 2013/12/23

SECTION 1. IDENTIFICATION

Substance name : CNTO 1959 Pre-filled syringe
CNTO 1959
Guselkumab

Reference number : JNJ-54160366-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
Monoclonal antibody

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

Not a hazardous substance or mixture.

GHS label elements

Not a hazardous substance or mixture.

Other hazards

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

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Chemical nature : Liquid

Hazardous components

Chemical name	CAS-No.	Concentration (%)
CNTO 1959	Not Assigned	>= 5 - < 10
alpha-D-Glucopyranoside, beta-D-	57-50-1	>= 5 - < 10

fructofuranosyl		

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. Wash off immediately with plenty of water. Consult a physician. 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	:	No information available.
Notes to physician	:	Treat symptomatically.

SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media	:	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Specific hazards during firefighting	:	The product is not flammable.
Hazardous combustion products	:	No hazardous combustion products are known
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 : No data available

Advice on safe handling : 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 and sources of ignition.
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
CNTO 1959	Not Assigned	PBOEL-HHC	2	J&J PBOEL-HHC list
	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			
alpha-D-Glucopyranoside, beta-D-fructofuranosyl	57-50-1	TWA	10 mg/m3	ACGIH
		TWA (Respirable)	5 mg/m3	NIOSH REL
		TWA (total)	10 mg/m3	NIOSH REL
		TWA (total dust)	15 mg/m3	OSHA Z-1
		TWA (respirable fraction)	5 mg/m3	OSHA Z-1
		TWA (Total dust)	15 mg/m3	OSHA P0
		TWA (respirable dust fraction)	5 mg/m3	OSHA P0
		PEL (Total dust)	10 mg/m3	CAL PEL
		PEL (respirable dust fraction)	5 mg/m3	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.
No personal respiratory protective equipment normally required.

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, Prefilled syringe
Colour	:	clear, colourless
pH	:	5.8

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 light.
Incompatible materials	:	None known.
Hazardous decomposition products	:	None known.

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

Components:

CNTO 1959

Acute toxicity (other routes of administration)	:	Remarks: This product is not expected to be absorbed via the oral, dermal, or inhalation routes of exposure.

Single-dose acute toxicity studies were not performed.

Skin corrosion/irritation

Components:

CNTO 1959
Result: No skin irritation

Serious eye damage/eye irritation

No data available

Respiratory or skin sensitisation

Components:

CNTO 1959
Result: Not a skin sensitizer.
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

Components:

CNTO 1959
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., Known to induce heritable mutations in germ cells of humans, based on human epidemiological studies.

Carcinogenicity

Components:

CNTO 1959
Carcinogenicity - Assessment : Standard carcinogenicity bioassays are generally inappropriate for biotechnology derived pharmaceuticals.

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 identified as a carcinogen or potential carcinogen by OSHA.

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

Components:

CNTO 1959

Effects on fertility :

Species: Guinea pig
Sex: male
Dose: 25, 100mg/kg
Frequency of Treatment: 2 x week
Application Route: Subcutaneous; injection made in the back or neck of animal
NOAEL: 100 mg/kg,
Remarks: No adverse effects on sexual function and fertility.

Species: Guinea pig
Sex: female
Dose: 0, 25, 100mg/kg
Frequency of Treatment: 2 x week
Application Route: Subcutaneous; injection made in the back or neck of animal
NOAEL: 100 mg/kg,
Remarks: No adverse effects on sexual function and fertility.

Species: Monkey
Sex: female
Dose: 10, 50mg/kg
Frequency of Treatment: 1 x week
Application Route: Subcutaneous; injection made in the back or neck of animal
NOAEL: 50 mg/kg,
Remarks: No effect on fertility endpoints was observed in non-human primates.

STOT - single exposure

Components:

CNTO 1959

Remarks: No data available

STOT - repeated exposure

Components:

CNTO 1959

Exposure routes: Subcutaneous; injection made in the back or neck of animal
Target Organs: No specific target organs noted
Assessment: The substance or mixture is not classified as specific target organ toxicant, repeated exposure.
Remarks: No significant adverse effects were reported

Exposure routes: intravenous injection
Target Organs: No specific target organs noted
Assessment: The substance or mixture is not classified as specific target organ toxicant,

repeated exposure.
Remarks: No significant adverse effects were reported

Repeated dose toxicity

Components:

CNTO 1959
Species: Non-human primate, male and female
NOAEL: 50 mg/kg
Application Route: Subcutaneous; injection made in the back or neck of animal
Exposure time: 5 weeks, 24 weeks
Number of exposures: 1 x week
Dose: 0, 10, 50mg/kg
Subsequent observation period: 3-month recovery
GLP: yes
Remarks: No significant adverse effects were reported

Species: Non-human primate, male and female
NOAEL: 50 mg/kg
Application Route: intravenous injection
Exposure time: 5 weeks
Number of exposures: 1 x week
Dose: 0, 50mg/kg
GLP: yes
Remarks: No significant adverse effects were reported

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

Components:

CNTO 1959
Toxicity to fish : Method: No information available.

Persistence and degradability

No data available

Bioaccumulative potential

Components:

CNTO 1959
Partition coefficient: n-octanol/water : 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).

Components:

CNTO 1959

Additional ecological information : No data available

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).

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

EPCRA - Emergency Planning and Community Right-to-Know Act

SARA 302 : No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

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

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.
This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

US State Regulations

Massachusetts Right To Know

alpha-D-Glucopyranoside, beta-D-fructofuranosyl	57-50-1	5 - 10 %

Pennsylvania Right To Know

water	7732-18-5	70 - 90 %
CNTO 1959	Not Assigned	5 - 10 %
alpha-D-Glucopyranoside, beta-D-fructofuranosyl	57-50-1	5 - 10 %

New Jersey Right To Know

water	7732-18-5	70 - 90 %
CNTO 1959	Not Assigned	5 - 10 %
alpha-D-Glucopyranoside, beta-D-fructofuranosyl	57-50-1	5 - 10 %

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.

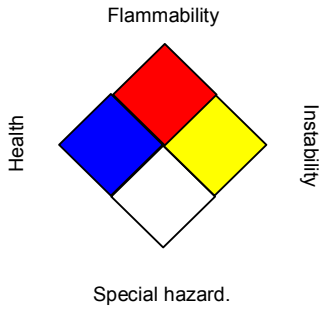
Biosafety Regulations and Guidelines:
World Health Organization, Laboratory biosafety manual. - 3rd

ed., ISBN 92 4 154650 6 (LC/NLM classification: QY 25)
WHO/CDS/CSR/LYO/2004.11.
OSHA Bloodborne Pathogen Standard 29 CFR 1910.1030 and the OSHA Standard Interpretation on Applicability of 1910.1030 to Establish Human Cell Lines;
U.S. Department of Health and Human Services Public Health Services, Biosafety in Microbiological and Biomedical Laboratories (BMBL) - 5th ed., HHS Publication No. (CDC) 21-1112

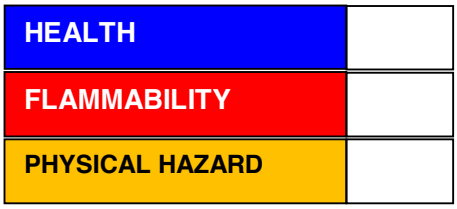
SECTION 16. OTHER INFORMATION

Further information

NFPA:



HMIS III:



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

Revision Date : 2017/03/25

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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