

SAFETY DATA SHEET



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SECTION 1. IDENTIFICATION

Substance name : CNTO 4424 (Drug Product)
RYBREVANT

Reference number : JNJ-61186372-AAA

Manufacturer or supplier's details

Company name of supplier : Janssen Pharmaceuticals, Inc.

Address : 1125 Trenton-Harbourton Rd
Titusville NJ 08560

USA

Telephone : +16097302000

E-mail address of person
responsible for the SDS : SDSJanssen@its.jnj.com

Emergency telephone
number : CHEMTREC US: 1-800-424-9300
CHEMTREC International: +1 703-741-5970

Recommended use of the chemical and restrictions on use

Recommended use : Large Molecule Pharmaceutical intended for medical use.
Bispecific/Multispecific antibody

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Not a hazardous substance or mixture.

GHS label elements

Not a hazardous substance or mixture.

Other hazards

Avoid direct contact and significant aerosol/dust exposure which has the remote possibilities of eliciting an allergic response. May cause sensitization in susceptible persons.

This material is not likely to be significantly absorbed via occupational routes of entry due to its chemical structure and large molecular weight.

May damage the developing embryo/fetus if administered parenterally at therapeutic concentrations.

Maternal systemic exposure from worker handling is expected to be negligible and embryo/fetal harm from worker exposure is considered unlikely.

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SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
alpha-D-Glucopyranoside, beta-D-fructofuranosyl	57-50-1	>= 5 - < 10
JNJ-61186372-AAA	Not Assigned	>= 5 - < 10

Actual concentration is withheld as a trade secret

SECTION 4. FIRST AID MEASURES

General advice : If accidentally injected (needle prick or through broken skin): Stimulate bleeding for approximately 5 minutes. Wash off immediately with soap and plenty of water. Call a physician immediately.

If inhaled : If breathed in, move person into fresh air. Rinse nose and mouth with salt water. Call a physician immediately.

In case of skin contact : Take off contaminated clothing and shoes immediately. Wash off immediately with soap and plenty of water. If skin irritation persists, call a physician. Consult a physician. Process contaminated clothing and PPE's according to hospital procedures in accordance with applicable waste disposal regulations.

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

If swallowed : Do NOT induce vomiting. If swallowed, rinse mouth with water (only if the person is conscious). Drink plenty of water. 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 : musculoskeletal pain
nausea
Fatigue
Oedema
Cough
constipation
Vomiting

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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.

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.

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.

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SECTION 7. HANDLING AND STORAGE

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

Advice on safe handling : Avoid splashes.
Avoid formation of aerosol.
Avoid inhalation, ingestion and contact with skin and eyes.
Avoid any unintended exposure by accidental needle prick/stick.
Do not heat the product.
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 fire, sparks and heated surfaces.
Store in a place accessible by authorized persons only.

Recommended storage temperature : 36 - 46 °F / 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
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
JNJ-61186372-AAA	Not Assigned	PBOEL-HHC	2	J&J OEL/PBOEL HHC
		Further information: J&J has a hazard banding notation: PBOEL		

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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

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. Avoid use of sharps, utilize safe-engineered sharps or non-penetrable gloves, where appropriate.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : solution, Vial

Colour : colourless, to, light yellow

pH : 5.7

Flash point : No data available

Flammability (solid, gas) : The product is not flammable.

SECTION 10. STABILITY AND REACTIVITY

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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	: No data available
Hazardous decomposition products	: None known.

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

No data available

Skin corrosion/irritation

No data available

Serious eye damage/eye irritation

No data available

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:

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.
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Carcinogenicity

Product:

Remarks	: Not applicable
Carcinogenicity -	: Carcinogenicity studies are not warranted to support

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Assessment marketing for therapeutics intended to treat patients with advanced cancer.

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	: Species: Monkey, male and female Dose: 120 milligram per kilogram Remarks: No significant adverse effects were reported No effect on fertility endpoints was observed in non-human primates.
Reproductive toxicity - Assessment	: This product is a bispecific antibody composing cMet. cMet is a receptor tyrosine kinase inhibitor which is known to be teratogenic at therapeutic concentrations., 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., Weight of evidence does not support classification for reproductive toxicity

STOT - single exposure

No data available

STOT - repeated exposure

No data available

Repeated dose toxicity

Product:

Species	: Non-human primate
NOAEL	: 120 mg/kg
Application Route	: intravenous injection
Exposure time	: 13 weeks
Number of exposures	: weekly
Dose	: 20, 60, 120 mg/kg
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.

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Aspiration toxicity

No data available

Experience with human exposure

No data available

Toxicology, Metabolism, Distribution

No data available

Neurological effects

No data available

Further information

No data available

Other health hazards

No data available

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

No data available

Persistence and degradability

No data available

Bioaccumulative potential

No data available

Mobility in soil

No data available

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues	: In accordance with National, Federal, State and Local regulations. Decontaminate all waste (i.e. steam sterilization/autoclaving, chemical disinfection) before disposal or ensure incineration of medical waste as a proper disposal route
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SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG

Not regulated as a dangerous good

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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

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : No SARA Hazards

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.

US State Regulations

Massachusetts Right To Know

alpha-D-Glucopyranoside, beta-D-fructofuranosyl	57-50-1
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Pennsylvania Right To Know

water	7732-18-5
alpha-D-Glucopyranoside, beta-D-fructofuranosyl	57-50-1
JNJ-61186372-AAA	Not Assigned

New York City Hazardous Substances

No components listed on the New York City Hazardous Substances List

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.

California Permissible Exposure Limits for Chemical Contaminants

alpha-D-Glucopyranoside, beta-D-fructofuranosyl	57-50-1
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Other regulations

Restricted to professional users.

Biosafety Regulations and Guidelines:

World Health Organization, Laboratory biosafety manual. - 4 th ed., ISBN 9789240011311, 2020, pp. 124.

OSHA Bloodborne Pathogen Standard 29 CFR 1910.1030 and the OSHA Standard

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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

Full text of other abbreviations

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
J&J OEL/PBOEL HHC	:	J&J OEL/PBOEL HHC
NIOSH REL	:	USA. NIOSH Recommended Exposure Limits
OSHA P0	:	USA. Table Z-1-A Limits for Air Contaminants (1989 vacated values)
OSHA Z-1	:	USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
ACGIH / TWA	:	8-hour, time-weighted average
J&J OEL/PBOEL HHC / PBOEL-HHC	:	PBOEL-HHC
NIOSH REL / TWA	:	Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
OSHA P0 / TWA	:	8-hour time weighted average
OSHA Z-1 / TWA	:	8-hour time weighted average

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-

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Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

For research use only.

Revision Date : 2023/12/24

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

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

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