

SAFETY DATA SHEET



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SECTION 1. IDENTIFICATION

Substance name : TECVAYLI
Teclistamab drug product

Reference number : JNJ-64007957-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

No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required.

Other hazards

No serious adverse effect would be expected for healthy individuals who inadvertently come into contact with the product.

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

This product poses low safety risk during human contacts.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

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Chemical nature : Liquid

Components

Chemical name	CAS-No.	Concentration (% w/w)
JNJ-64007957	Not Assigned	$\geq 5 - < 10$
alpha-D-Glucopyranoside, beta-D-fructofuranosyl	57-50-1	$\geq 5 - < 10$
acetic acid	64-19-7	< 0.1

Actual concentration is withheld as a trade secret

SECTION 4. FIRST AID MEASURES

- General advice : This material is being evaluated for use as a biological agent or in the manufacturing of a biological agent.
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.
- Most important symptoms and effects, both acute and delayed : Immune system effects
injection site reactions
Neurological disorders
- Notes to physician : Treat symptomatically.

SECTION 5. FIREFIGHTING MEASURES

- Suitable extinguishing media : Use extinguishing measures that are appropriate to local

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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.
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 : 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.

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

Recommended storage temperature : 36 - 46 °F / 2 - 8 °C

Further information on storage stability : Keep refrigerated.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
JNJ-64007957	Not Assigned	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.				
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
acetic acid	64-19-7	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

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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 : liquid

Colour : colourless, to, light yellow

Odour : No data available

pH : 5.2

Melting point/ range : No data available

Boiling point/boiling range : No data available

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Flash point	:	No data available
Evaporation rate	:	No data available
Flammability (solid, gas)	:	The product is not flammable.
Self-ignition	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	No data available
Relative vapour density	:	No data available
Relative density	:	No data available
Density	:	No data available
Solubility(ies)		
<u>Water solubility</u>	:	No data available
<u>Solubility in other solvents</u>	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Explosive properties	:	No data available
Oxidizing properties	:	No data available
Conductivity	:	No data available
	:	No data available

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.

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Incompatible materials : No data available

Hazardous decomposition products : None known.

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

Product:

Acute oral toxicity : Remarks: 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.

Acute inhalation toxicity : Remarks: 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.

Acute dermal toxicity : Remarks: 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.

Acute toxicity (other routes of administration) : Remarks: 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.

Components:

acetic acid:

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

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

Skin corrosion/irritation

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.

Components:

acetic acid:

Result : Causes severe burns.

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Serious eye damage/eye irritation

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.

Components:

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.

Germ cell mutagenicity

Product:

Genotoxicity in vitro : Remarks: No data available

Genotoxicity in vivo : Remarks: No data available

Germ cell mutagenicity - Assessment : Genotoxicity studies have not been conducted., In accordance with ICH S6(R1), the administration of large quantities of peptides/proteins may yield uninterpretable results.

It is not expected that these substances would interact directly with DNA or other chromosomal material.

Components:

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.

IARC No component of this product present at levels greater than or equal to 0.1% is

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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 : No reproductive toxicology studies have been conducted.

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.

Teratogenicity - Assessment : Pregnancy risk was considered through a weight-of-evidence assessment and it is concluded that this product is not expected to be teratogenic based on its on-target specificity.

STOT - single exposure

Product:

Remarks : Single-dose toxicity study was evaluated in the Repeated-dose toxicity studies.
No product-related changes in the clinical condition of the animals were observed.
No clear changes in cytokine concentrations in animals were observed.

STOT - repeated exposure

Product:

Remarks : No product-related changes in the clinical condition of the animals were observed.
No clear changes in cytokine concentrations in animals were observed.

Repeated dose toxicity

Product:

Species : Monkey, male
NOEL : 30 mg/kg
Application Route : intravenous injection

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Exposure time : 5 Weeks
Number of exposures : weekly
Dose : 0.1, 1, 10
Method : ICH S6, ICH S9
GLP : yes

Species : Monkey, male and female
NOEL : 30 mg/kg
Application Route : intravenous injection
Exposure time : 5 Weeks
Number of exposures : weekly
Dose : 0.1, 10, 30
Method : ICH S6, ICH S9
GLP : yes

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

Product:

Toxicity to fish :
Remarks: No data available

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

Toxicity to microorganisms : Remarks: No data available

Components:

acetic acid:

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

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Persistence and degradability

Product:

Biodegradability : Remarks: No data available

Bioaccumulative potential

Product:

Bioaccumulation : Remarks: No data available

Mobility in soil

Product:

Distribution among environmental compartments : Remarks: No data available

Other adverse effects

Product:

Results of PBT and vPvB assessment : Remarks: No data available

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 (i.e. steam sterilization/autoclaving, chemical disinfection) before disposal or ensure incineration of medical waste as a proper disposal route

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.

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National Regulations

49 CFR

Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION

US State Regulations

Massachusetts Right To Know

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

Pennsylvania Right To Know

water	7732-18-5
JNJ-64007957	Not Assigned
alpha-D-Glucopyranoside, beta-D-fructofuranosyl	57-50-1
acetic acid	64-19-7

Maine Chemicals of High Concern

Product does not contain any listed chemicals

Vermont Chemicals of High Concern

Product does not contain any listed chemicals

Washington Chemicals of High Concern

Product does not contain any listed chemicals

California Permissible Exposure Limits for Chemical Contaminants

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

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 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

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ACGIH / TWA : 8-hour, time-weighted average
ACGIH / STEL : Short-term exposure limit
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
NIOSH REL / ST : STEL - 15-minute TWA exposure that should not be exceeded at any time during a workday
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-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

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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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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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