

SAFETY DATA SHEET



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SECTION 1. IDENTIFICATION

Substance name : Commercial use BCMA Chimeric Antigen Receptor-T Cells
(Drug Product) - No-DG
CAR-T (cell immunotherapy)
CARVYKTI®
ciltacabtagene autoleucel (Cilta-cel)

Reference number : JNJ-68284528-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 : Biopharmaceutical
Cell therapy drugs.

SECTION 2. HAZARDS IDENTIFICATION

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

Flammable liquids : Category 4

GHS label elements

Signal word : Warning

Hazard statements : H227 Combustible liquid.

Precautionary statements : **Prevention:**
P210 Keep away from heat/ sparks/ open flames/ hot surfaces.
No smoking.
P280 Wear protective gloves/ eye protection/ face protection.

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Response:

P370 + P378 In case of fire: Use dry sand, dry chemical or alcohol-resistant foam to extinguish.

Storage:

P403 + P235 Store in a well-ventilated place. Keep cool.

Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards

Health Hazards, Risk Group 2

Risk Group 2 (RG2) agents are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are often available.

This substance/mixture has no or negligible biosafety risk over and above that of a standard human blood product regarding the transmission of transfusion-related blood borne infectious diseases.

This product consists of genetically modified autologous human T-cells. It is potentially infectious, like all human-derived material such as blood, tissues, and fluids.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Chemical nature : Liquid

Components

Chemical name	CAS-No.	Concentration (% w/w)
DMSO	67-68-5	≥ 5 - < 10

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 : No information available.

In case of skin contact : Take off contaminated clothing and shoes immediately.
Wash off immediately with 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.

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- 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 : Clinical signs
Fever
effects on blood pressure
May produce an allergic reaction.
Brain swelling
Parkinsonism
Peripheral nerve damage
Immunoglobulin deficiency
Inflammatory disorders
Decrease in blood cells
High risk on infections
Consult the patient packaging insert for more information about this Finished Pharmaceutical Product.
- 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 : Special considerations for Biological Risk from any particular (micro-)organism are based on several factors including but not limited to amount of infectious material present, infectious dose, mode of transmission, seriousness of illness, susceptibility of the host and availability of vaccines or drugs.
Avoid direct contact with broken glass, plastic and other sharps.
Avoid splashes and spray formation.

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Avoid direct contact and significant aerosol exposure.
A spill procedure shall be developed and available, based on the local risk assessment prioritizing worker safety.

Environmental precautions : Should not be released into the environment.

Methods and materials for containment and cleaning up : Decontaminate work surfaces and materials with a suitable disinfectant after the completion of procedures, after any spill, and at the end of the work shift if the surface may have become contaminated since the last cleaning.

Suitable disinfectant products for blood-based products shall be labelled (minimally) as intermediate-level disinfectants (defined as being effective against viruses (especially enveloped viruses), mycobacteria, fungi, and vegetative bacteria) and applied according to the label claims. Equivalents to intermediate-level disinfectants can include freshly prepared 0.5% sodium hypochlorite (typically 10% household bleach) for at least 30 minutes, 2.5% Umonium 38 for at least 15 minutes, or equivalent.

In case of spill: Contain or stop spill immediately.
For high energy spills, such as sprays/splashes, and uncontrolled leaks, leave the room immediately and allow the aerosol to settle or clear.
Consideration in the risk assessment shall be given to the number of room air exchanges per hour required before reentering the room. Alternatively, a timeframe of at least 30 minutes is recommended.

Wearing defined personal protective equipment is required upon reentering of the room.

For minimal or small spills, no evacuation is required.
For all spills, gently cover spill with paper towels or equivalent absorbent material to absorb the liquid and avoid further spread.

Apply suitable disinfectant (as determined above), starting at the perimeter and work towards the center. Allow sufficient contact time before cleaning up.

Then reapply the disinfectant and wipe down surfaces and materials.
Perform a final cleaning process at the spill location and adjacent surfaces with a disinfectant, such as 70% ethanol, IPA or equivalent.

Remove and safely dispose of all disinfected absorbent materials as potentially contaminated waste.

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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 : Prevent exposure to aerosols and splashes.
Avoid splashes.
Do not heat the product.
Avoid inhalation, ingestion and contact with skin and eyes.
Use personal protective equipment as required.
Standard good (micro)biological practices and hospital procedures developed in line with national policies/laws must be followed to avoid transmission of (potentially) hazardous (micro)organisms.
- 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 frozen.
- Recommended storage temperature : $\leq -184^{\circ}\text{F}$ / $\leq -120^{\circ}\text{C}$

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
DMSO	67-68-5	TWA	250 ppm	US WEEL
DMSO	67-68-5	TWA	250 ppm	US WEEL

- Engineering measures** : All personal protective equipment should be based on a risk assessment. Consult a Environment Health Safety expert if necessary.
The work area should be installed in accordance with the requirements of Biosafety level 2 (BSL2)
Standard infection control precautions and hospital procedures developed in line with national policies/laws must be followed to prevent the transmission of biological agents and transfusion-related blood borne infectious diseases.
All open manipulations and process (and process related) activities are preferred to be carried out in physical containment device or ventilated enclosure (e.g. Biosafety cabinet).

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Personal protective equipment

Respiratory protection	:	No personal respiratory protective equipment normally required.
Hand protection	:	
Remarks	:	Disposable gloves
Eye protection	:	Safety glasses
Skin and body protection	:	disposable one-piece overall 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 laboratory/(micro)biology practice. Remove gloves and wash hands when work with material is completed. Do not reuse gloves. Contaminated work clothing should not be allowed out of the workplace. Research, development and manufacturing is performed at the level of BSL-2.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	frozen, liquid
Colour	:	No data available
Odour	:	No data available
pH	:	5 - 8
Melting point/ range	:	No data available
Boiling point/boiling range	:	No data available
Flash point	:	No data available
Evaporation rate	:	No data available
Vapour pressure	:	No data available
Relative vapour density	:	No data available

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Relative density	:	No data available
Density	:	No data available
Solubility(ies) <u>Solubility in other solvents</u>	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Viscosity <u>Viscosity, kinematic</u>	:	No data available
Molecular weight	:	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. Exposure to sunlight.
Incompatible materials	:	None known.
Hazardous decomposition products	:	None known.

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

Product:

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

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administration)

Application Route: intravenous injection

GLP: no

Remarks: Dose levels administered (mg/kg): 5 × 106/kg and 40 × 106/kg purified T cells transfected with LCAR-B38M. LCAR-B38M was well tolerated in two male cynomolgus monkeys following a single infusion in one male at 5× 106/kg and another male at 40 × 106/kg. The cynomolgus monkey is not considered a pharmacologically relevant species for the nonclinical assessment of LCAR-B38M because LCAR-B38M (anti-human BCMA) does not bind to the cynomolgus monkey ortholog of human BCMA.

Components:

DMSO:

Acute oral toxicity : LD50 Oral (Rat): 14,500 mg/kg

Acute inhalation toxicity : LC50 (Rat): 40250 ppm
Exposure time: 4 h
Test atmosphere: vapour

Acute dermal toxicity : LD50 Dermal (Rabbit): > 5,000 mg/kg

Skin corrosion/irritation

Product:

Remarks : This product is not expected to elicit skin corrosion/irritation, skin sensitization, or cause damage to irritate the eyes.

Components:

DMSO:

Species : Rabbit
Exposure time : 4 h
Result : No skin irritation

Serious eye damage/eye irritation

Product:

Remarks : This product is not expected to elicit skin corrosion/irritation, skin sensitization, or cause damage to irritate the eyes.

Components:

DMSO:

Species : Rabbit
Result : slight irritation

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Respiratory or skin sensitisation

Product:

Remarks : This product is not expected to elicit skin corrosion/irritation, skin sensitization, or cause damage to irritate the eyes.

Components:

DMSO:

Result : Does not cause skin sensitisation.

Germ cell mutagenicity

Product:

Genotoxicity in vitro : Remarks: Routine genotoxicity studies are generally not conducted for this product.

Genotoxicity in vivo : Remarks: Routine genotoxicity studies are generally not conducted for this product.
This product poses a low risk of genotoxicity.

Carcinogenicity

Product:

Remarks : No data available

Carcinogenicity - Assessment : Standard carcinogenicity bioassays are generally inappropriate for this product.

Reproductive toxicity

Product:

Effects on fertility : Remarks: Not applicable

Effects on foetal development : Remarks: Generally, juvenile toxicology studies are not conducted for this product.

Reproductive toxicity - Assessment : Weight of evidence does not support classification for reproductive toxicity

Teratogenicity - Assessment : Not expected to be teratogenic based on weight-of-evidence risk assessments.

STOT - single exposure

Product:

Remarks : Single dose toxicity studies are generally not conducted for biotherapeutics.

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STOT - repeated exposure

No data available

Repeated dose toxicity

No data available

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 algae/aquatic :
plants Remarks: No data available

Components:

DMSO:

Toxicity to fish : (Pimephales promelas (fathead minnow)): 34,000 mg/l
Exposure time: 96 h
Test Type: LC50

(Oncorhynchus mykiss (rainbow trout)): 35,000 mg/l
Exposure time: 96 h
Test Type: LC50

(Daphnia pulex (Water flea)): 27,500 mg/l
Test Type: EC50

(Lepomis macrochirus (Bluegill sunfish)): > 400,000 mg/l

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Exposure time: 96 h
Test Type: EC50

Persistence and degradability

Product:

Biodegradability : Remarks: No data available

Bioaccumulative potential

Product:

Bioaccumulation : Remarks: No data available

Components:

DMSO:

Partition coefficient: n-octanol/water : log Pow: -2.03

Mobility in soil

No data available

Other adverse effects

Product:

Additional ecological information : There is no data available for this product.
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

Remarks : Not subject to provisions of IATA DGR according to 3.6.2.3.1

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(a)

IMDG-Code

Not regulated as a dangerous good

Remarks : Not subject to provisions of IMDG according to 2.6.3.3.1 (a)

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

Other regulations

For use by laboratories for research.

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

Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified micro-organisms.

SECTION 16. OTHER INFORMATION

Full text of other abbreviations

US WEEL : USA. Workplace Environmental Exposure Levels (WEEL)

US WEEL / TWA : 8-hr TWA

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

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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

For research use only.

Revision Date : 2025/08/06

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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