Version	Revision Date:	SDS Number:	Date of last issue: 2024/09/19
2.0	2025/04/02	100000016452	Date of first issue: 2021/01/22

SECTION 1. IDENTIFICATION

Substance name : IMAAVY TM (nipocalimab) injection (process 3.0), for intravenous use

300 mg/1.62 mL (185 mg/mL) in a single-dose vial
1200 mg/6.5 mL (185 mg/mL) in a single-dose vial

Reference number : JNJ-86507083-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.
Monoclonal 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

This product is not expected to be absorbed via the oral, dermal, or inhalation routes of exposure. Individuals who are at high risk (e.g. HIV-positive individuals, immunocompromised individuals) need to take precautions to minimize exposure.
No serious adverse effect would be expected for healthy individuals who inadvertently come into contact with the product and can be resolved without intervention.

Avoid exposure to women during pregnancy.
Avoid Needle stick and contact of broken skin.
Long term and large scale exposure may lead to reduction of effectiveness of Routine Vaccines.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Chemical nature : Liquid

Components

Chemical name	CAS-No.	Concentration (% w/w)
nipocalimab	3010953-47-3	>= 10 - < 20
alpha-D-Glucopyranoside, beta-D-fructofuranosyl	57-50-1	>= 5 - < 10
POLYSORBATE 80#	9005-65-6	< 0.1

Voluntarily-disclosed non-hazardous substance
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 accidently 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 saline.
Call a physician immediately.

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.

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 : Abdominal pain
Diarrhoea
Nausea
urinary tract infection
insomnia
Dizziness
muscle spasms
increased lipids
oedema peripheral
pyrexia

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.
Water mist
Foam
Carbon dioxide (CO2)
Sand
Aqueous film forming foam (AFFF).

Specific hazards during firefighting : The product is not flammable.

Hazardous combustion products : Carbon oxides
Nitrogen oxides (NOx)
Sulphur oxides

Further information : In the event of fire, cool tanks with water spray.

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

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.
Avoid formation of aerosol.
Avoid direct contact and significant aerosol exposure.
Evacuate personnel to safe areas.

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. Keep refrigerated.
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
nipocalimab	3010953-47-3	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			
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

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	:	clear, liquid
Colour	:	colourless, to, slight, brown
pH	:	6

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	:	Oxidizing agents Peroxides, organic Chlorine-based bleaching agents
Hazardous decomposition products	:	Halogenated compounds

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 toxicity studies designed to evaluate the potential adverse effects of doses causing major (life-threatening) toxicity are not considered appropriate for this product that has inherently low toxicity.

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 toxicity studies designed to evaluate the potential adverse effects of doses causing major (life-threatening) toxicity are not considered appropriate for this product that has inherently low toxicity.

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 studies designed to evaluate the potential adverse effects of doses causing major (life-threatening) toxicity are not considered appropriate for this product that has inherently low toxicity.

Acute toxicity (other routes of administration) :
Remarks: Acute toxicity studies designed to evaluate the potential adverse effects of doses causing major (life-threatening) toxicity are not considered appropriate for this product that has inherently low toxicity.

Components:

POLYSORBATE 80:

Acute toxicity (other routes of administration) : LD50 (Rat): 6,804 mg/kg
Application Route: oral administration

Skin corrosion/irritation

Product:

Remarks : This product is not expected to elicit skin or eye irritation or corrosion.

Serious eye damage/eye irritation

Product:

Remarks : This product is not expected to elicit skin or eye irritation or corrosion.

Respiratory or skin sensitisation

Product:

Remarks : No data available
This product is not expected to elicit skin sensitization.

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.

Carcinogenicity

Product:

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 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
Application Route: intravenous injection
Dose: 1 milligram per kilogram
Duration of Single Treatment: 26 Weeks
Frequency of Treatment: 1 days/week
GLP: yes

Species: Monkey, male and female
Application Route: intravenous injection
Dose: 100 milligram per kilogram
Duration of Single Treatment: 26 Weeks
Frequency of Treatment: 1 days/week
GLP: yes

Species: Monkey, male and female
Application Route: intravenous injection
Dose: 300 milligram per kilogram
Duration of Single Treatment: 26 Weeks
Frequency of Treatment: 1 days/week
General Toxicity - Parent: NOAEL: 300 mg/kg
GLP: yes

Remarks: No adverse effects on sexual function and fertility.

Effects on foetal development : Species: Monkey, female
Application Route: intravenous injection
Embryo-foetal toxicity: NOAEL: 300 mg/kg body weight
GLP: yes

Species: Monkey, female
Application Route: intravenous injection
General Toxicity Maternal: NOAEL: 300 mg/kg body weight
GLP: yes
Remarks: Generally, juvenile toxicology studies are not conducted for this product.

Reproductive toxicity - Assessment : As an IgG1 monoclonal antibody, it may be transferred across the placenta.

Teratogenicity - Assessment : No evidence of adverse effects on sexual function and fertility, or on development, based on animal experiments., Effects on lactation (based on animal studies), Placental infarctions were observed in 4 out of 25 available placentas from the nipocalimab-treated animals.

STOT - single exposure

Product:

Remarks : Not applicable

STOT - repeated exposure

Product:

Remarks : No significant adverse effects were reported

Repeated dose toxicity

Product:

Species	:	Monkey, male and female
NOAEL	:	300 mg/kg
Application Route	:	intravenous injection
Exposure time	:	26 Weeks
GLP	:	yes
Target Organs	:	No specific target organs noted

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

Product:

Remarks : No immunotoxicity effects were observed.
In the GLP 8-week IV immunotoxicity study in male and female cynomolgus monkeys, 300 mg/kg/week (NOAEL) nipocalimab specifically decreased IgG without affecting non-IgG immunoglobulins, immune cell populations, innate or adaptive immune cell functions, or the ability to mount T-cell-dependent antibody responses. (Study 20104942).

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

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:

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

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

US State Regulations

Massachusetts Right To Know

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

Pennsylvania Right To Know

nipocalimab	3010953-47-3
alpha-D-Glucopyranoside, beta-D-fructofuranosyl	57-50-1

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
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-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.

This SDS received a major version update triggered by a change in Section 1.

Revision Date : 2025/04/02

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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