SAFETY DATA SHEET

Version	Revision Date:	SDS Number:	Date of last issue: 2025/09/11
9.3	2025/09/18	100000014880	Date of first issue: 2018/10/01

SECTION 1. IDENTIFICATION

Substance name : ZAVESCA 100 mg capsules
Miglustat (OGT 918)

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 : Finished Pharmaceutical Product
This SDS is only intended for occupational use and not for consumer use (see patient packaging insert for consumer use). This SDS is written to provide environmental, health and safety information for personnel that will be handling this finished pharmaceutical product. For health and safety information during manufacturing of this product we refer to the appropriate SDS for each component.
This dosage form is exempt from the requirements of the OSHA Hazard Communication Standard (US OSHA Standard 29 CFR Part 1910.1200).

SECTION 2. HAZARDS IDENTIFICATION

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

Carcinogenicity : Category 2

Reproductive toxicity : Category 1B

GHS label elements

Hazard pictograms :

Signal word : Danger

Hazard statements : H351 Suspected of causing cancer.
H360FD May damage fertility. May damage the unborn child.

Precautionary statements :

Prevention:

P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

P308 + P313 IF exposed or concerned: Get medical advice/ attention.

Storage:

P405 Store locked up.

Disposal:

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

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Chemical nature : Solid

Components

Chemical name	CAS-No.	Concentration (% w/w)
3,4,5-Piperidinetriol, 1-butyl-2-(hydroxymethyl)-, (2R,3R,4R,5S)-	72599-27-0	>= 50 - < 70
Octadecanoic acid, magnesium salt	557-04-0	>= 0.1 - < 1
titandioxide	13463-67-7	>= 0.1 - < 1

Actual concentration is withheld as a trade secret

SECTION 4. FIRST AID MEASURES

If inhaled : Health injuries are not known or expected under normal use.
Consult a physician.

In case of skin contact	:	Take off contaminated clothing and shoes immediately. Wash off with soap and water. If symptoms persist, call a physician.
In case of eye contact	:	Rinse immediately with plenty of water, also under the eyelids, for at least 5 minutes. Remove contact lenses. If eye irritation persists, consult a specialist.
If swallowed	:	If swallowed, rinse mouth with water (only if the person is conscious). Call a physician immediately.
Most important symptoms and effects, both acute and delayed	:	No information available. Suspected of causing cancer. May damage fertility. May damage the unborn child.
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.
Hazardous combustion products	:	No information available.
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. Evacuate personnel to safe areas.
Environmental precautions	:	Should not be released into the environment.
Methods and materials for containment and cleaning up	:	Large spills: Sweep up or vacuum with HEPA filter or via wet cleaning into suitable containers for disposal. Pick up and arrange without creating dust. Keep in properly labelled containers. Small spills: Moisten a towel, cover the spill, pick up the spill or use HEPA vacuum. Large spills + Small spills: Keep in suitable, closed containers for disposal. Treat recovered material as described in the section "Disposal considerations".

SECTION 7. HANDLING AND STORAGE

Advice on protection against fire and explosion : No data available

Advice on safe handling : Do not break, crush or spill this Finished Pharmaceutical Product.
To avoid thermal decomposition, do not overheat.
Use personal protective equipment as required.
Avoid inhalation, ingestion and contact with skin and eyes.

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

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
3,4,5-Piperidinetriol, 1-butyl-2-(hydroxymethyl)-, (2R,3R,4R,5S)-	72599-27-0	TWA	0.100 mg/m3	J&J OEL/PBOEL HHC
		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., Notation REPRO: has the potential to have adverse effects on reproduction and fetal development			
Octadecanoic acid, magnesium salt	557-04-0	TWA (Inhalable particulate matter)	10 mg/m3	ACGIH
		TWA (Respirable particulate matter)	3 mg/m3	ACGIH
titandioxide	13463-67-7	TWA	2.4 mg/m3	J&J OEL/PBOEL HHC
		TWA	10 mg/m3	ACGIH

Engineering measures : All personal protective equipment should be based on a risk

assessment. Consult a Environment Health Safety expert if necessary.
If this product is processed not in accordance with the prescribed use, contact the Industrial Hygiene / Environment Health Safety Expert to assess the situation.
Validated Industrial Hygiene Analytical methods are developed to monitor and quantify inhalable exposure to the Active Pharmaceutical Ingredient. For more information contact Bureau Veritas Laboratories - Lake Zurich (BV_LZLab@bureauveritas.com) or the Laboratory of Occupational and Environmental Hygiene (lamh.be).

Personal protective equipment

Respiratory protection	:	No personal respiratory protective equipment normally required.
Hand protection Remarks	:	Disposable gloves
Eye protection	:	No special precautions required.
Skin and body protection	:	closed work clothing
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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	solid
Colour	:	No data available
Odour	:	No data available
Odour Threshold	:	No data available
pH	:	No data available
Melting point/ range	:	No data available
Boiling point/boiling range	:	No data available
Flash point	:	No data available

Evaporation rate	:	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)

Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available

Viscosity

Viscosity, dynamic	:	No data available
Viscosity, kinematic	:	No data available
Explosive properties	:	No data available
Oxidizing properties	:	No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	None reasonably foreseeable.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	No dangerous reaction known under conditions of normal use.
Conditions to avoid	:	To avoid thermal decomposition, do not overheat. Heat, flames and sparks.
Incompatible materials	:	None known.
Hazardous decomposition products	:	None known.

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

Product:

Acute oral toxicity : Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

Acute inhalation toxicity : Acute toxicity estimate: 176.29 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: Calculation method

Components:

3,4,5-Piperidinetriol, 1-butyl-2-(hydroxymethyl)-, (2R,3R,4R,5S)-:

Acute oral toxicity : LD50 (Mouse): > 5,000 mg/kg
Assessment: The substance or mixture has no acute oral toxicity

Skin corrosion/irritation

Components:

3,4,5-Piperidinetriol, 1-butyl-2-(hydroxymethyl)-, (2R,3R,4R,5S)-:

Result : Mild skin irritation

Serious eye damage/eye irritation

No data available

Respiratory or skin sensitisation

Components:

3,4,5-Piperidinetriol, 1-butyl-2-(hydroxymethyl)-, (2R,3R,4R,5S)-:

Result : Does not cause skin sensitisation.

Germ cell mutagenicity

Components:

3,4,5-Piperidinetriol, 1-butyl-2-(hydroxymethyl)-, (2R,3R,4R,5S)-:

Germ cell mutagenicity - Assessment : No evidence of mutagenicity based on weight of evidence.

Carcinogenicity

Components:

3,4,5-Piperidinetriol, 1-butyl-2-(hydroxymethyl)-, (2R,3R,4R,5S)-:

Carcinogenicity - : Limited evidence of carcinogenicity in animal studies and/or

Assessment human studies.

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

Components:

3,4,5-Piperidinetriol, 1-butyl-2-(hydroxymethyl)-, (2R,3R,4R,5S)-:

Reproductive toxicity - Assessment : Sufficient evidence of reprotoxicity based on animals.

Teratogenicity - Assessment : Sufficient evidence of adverse effects on development based on animals.

STOT - single exposure

No data available

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

No data available

Persistence and degradability

No data available

Bioaccumulative potential

Components:

3,4,5-Piperidinetriol, 1-butyl-2-(hydroxymethyl)-, (2R,3R,4R,5S)-:

Bioaccumulation	:	Remarks: Due to the distribution coefficient n-octanol/water, accumulation in organisms is not expected.
Partition coefficient: n-octanol/water	:	log Pow: 0.13 pH: 7.4

Octadecanoic acid, magnesium salt:

Partition coefficient: n-octanol/water	:	Remarks: No data available

titandioxide:

Partition coefficient: n-octanol/water	:	Remarks: 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.
Contaminated packaging	:	Empty containers should be taken to an approved waste handling site for recycling or disposal.

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

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 : Carcinogenicity
Reproductive toxicity

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
No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know

3,4,5-Piperidinetriol, 1-butyl-2-(hydroxymethyl)-, (2R,3R,4R,5S)-	72599-27-0
gelatine	9000-70-8
sodium starch glycolate	9063-38-1

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 List of Hazardous Substances

crospovidone	9003-39-8

Other regulations
Restricted to professional users.

Medicinal products in the finished state, intended for the final user, are not subject to GHS

labeling.

This product is not subject to TSCA and TSCA 12(b) Export notification because Food, Drugs and cosmetic products are exempt.

SECTION 16. OTHER INFORMATION

Full text of other abbreviations

ACGIH	:	US. ACGIH Threshold Limit Values
ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
J&J OEL/PBOEL HHC	:	J&J OEL/PBOEL HHC
ACGIH / TWA	:	Time weighted average
ACGIH / TWA	:	8-hour, time-weighted average
J&J OEL/PBOEL HHC / TWA	:	Time weighted average
J&J OEL/PBOEL HHC / PBOEL-HHC	:	PBOEL-HHC

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

Revision Date : 2025/09/18

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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