

# SAFETY DATA SHEET



## Insulin Porcine Formulation

Version  
3.0

Revision Date:  
16.06.2025

SDS Number:  
27380-00024

Date of last issue: 28.09.2024  
Date of first issue: 03.11.2014

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### SECTION 1. IDENTIFICATION

Product name : Insulin Porcine Formulation

Other means of identification : CANINSULIN (A007401)  
CANINSULIN INSULIN FOR DOGS AND CATS (37255)  
CANINSULIN VETPEN INSULIN FOR DOGS AND CATS  
(65973)

#### Manufacturer or supplier's details

Company : MSD

Address : Talcahuano 750, 6th floor, Ciudad Autonoma  
Buenos Aires, Argentina C1013AAP

Telephone : 908-740-4000

Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

#### Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

Restrictions on use : Not applicable

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### SECTION 2. HAZARDS IDENTIFICATION

#### GHS Classification

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 which do not result in classification

None known.

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### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

#### Components

Chemical name	CAS-No.	Concentration (% w/w)
Insulin (ox), 8A-L-threonine-10A-L-isoleucine-	12584-58-6	>= 0,1 -< 1

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### SECTION 4. FIRST AID MEASURES

If inhaled : If inhaled, remove to fresh air.  
Get medical attention if symptoms occur.

# SAFETY DATA SHEET



## Insulin Porcine Formulation

Version 3.0	Revision Date: 16.06.2025	SDS Number: 27380-00024	Date of last issue: 28.09.2024 Date of first issue: 03.11.2014
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In case of skin contact	: Wash with water and soap as a precaution. Get medical attention if symptoms occur.
In case of eye contact	: Flush eyes with water as a precaution. Get medical attention if irritation develops and persists.
If swallowed	: If swallowed, DO NOT induce vomiting. Get medical attention if symptoms occur. Rinse mouth thoroughly with water.
Most important symptoms and effects, both acute and delayed	: None known.
Protection of first-aiders	: No special precautions are necessary for first aid responders.
Notes to physician	: Treat symptomatically and supportively.

## SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media	: Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical
Unsuitable extinguishing media	: None known.
Specific hazards during fire fighting	: Exposure to combustion products may be a hazard to health.
Hazardous combustion products	: No hazardous combustion products are known
Specific extinguishing methods	: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.
Special protective equipment for fire-fighters	: Wear self-contained breathing apparatus for firefighting if necessary. Use personal protective equipment.

## SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	: Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
Environmental precautions	: Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Prevent spreading over a wide area (e.g., by containment or oil barriers). Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.

# SAFETY DATA SHEET



## Insulin Porcine Formulation

Version 3.0 Revision Date: 16.06.2025

SDS Number: 27380-00024

Date of last issue: 28.09.2024  
Date of first issue: 03.11.2014

Methods and materials for containment and cleaning up : Soak up with inert absorbent material. For large spills, provide diking or other appropriate containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absorbent. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

## SECTION 7. HANDLING AND STORAGE

Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation : Use only with adequate ventilation.

Advice on safe handling : Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment  
Take care to prevent spills, waste and minimize release to the environment.

Conditions for safe storage : Keep in properly labeled containers.  
Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:  
Strong oxidizing agents  
Gases

## SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Insulin (ox), 8A-L-threonine-10A-L-isoleucine-	12584-58-6	TWA	3 µg/m <sup>3</sup> (OEB 4)	Internal

Engineering measures : Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections). All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices). Minimize open handling.

# SAFETY DATA SHEET



## Insulin Porcine Formulation

Version 3.0      Revision Date: 16.06.2025      SDS Number: 27380-00024      Date of last issue: 28.09.2024  
Date of first issue: 03.11.2014

---

### Personal protective equipment

Respiratory protection	: No personal respiratory protective equipment normally required.
Hand protection	
Material	: Chemical-resistant gloves
Remarks	: Consider double gloving.
Eye protection	: Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
Skin and body protection	: Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.
Hygiene measures	: If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

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## SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	: suspension
Color	: off-white
Odor	: odorless
Odor Threshold	: No data available
pH	: 7 - 7,8
Melting point/freezing point	: No data available
Initial boiling point and boiling range	: 100 °C
Flash point	: No data available
Evaporation rate	: No data available
Flammability (solid, gas)	: Not applicable
Flammability (liquids)	: No data available

# SAFETY DATA SHEET



## Insulin Porcine Formulation

Version 3.0      Revision Date: 16.06.2025      SDS Number: 27380-00024      Date of last issue: 28.09.2024  
Date of first issue: 03.11.2014

---

Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Vapor pressure : No data available

Relative vapor density : No data available

Relative density : 1,004 - 1,007

Density : No data available

Solubility(ies)

Water solubility : soluble

Partition coefficient: n-octanol/water : Not applicable

Autoignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, kinematic : No data available

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Molecular weight : No data available

Particle characteristics

Particle size : No data available

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## SECTION 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reactions : Can react with strong oxidizing agents.

Conditions to avoid : None known.

Incompatible materials : Oxidizing agents

Hazardous decomposition products : No hazardous decomposition products are known.

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## SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure : Inhalation  
Skin contact  
Ingestion

# SAFETY DATA SHEET



## Insulin Porcine Formulation

Version 3.0 Revision Date: 16.06.2025 SDS Number: 27380-00024 Date of last issue: 28.09.2024 Date of first issue: 03.11.2014

Eye contact

### Acute toxicity

Not classified based on available information.

### Components:

#### Insulin (ox), 8A-L-threonine-10A-L-isoleucine-:

Acute toxicity (other routes of administration) : LD50 (Rat): > 36 mg/kg

### Skin corrosion/irritation

Not classified based on available information.

### Components:

#### Insulin (ox), 8A-L-threonine-10A-L-isoleucine-:

Remarks : No data available

### Serious eye damage/eye irritation

Not classified based on available information.

### Components:

#### Insulin (ox), 8A-L-threonine-10A-L-isoleucine-:

Remarks : No data available

### Respiratory or skin sensitization

#### Skin sensitization

Not classified based on available information.

#### Respiratory sensitization

Not classified based on available information.

#### Germ cell mutagenicity

Not classified based on available information.

### Components:

#### Insulin (ox), 8A-L-threonine-10A-L-isoleucine-:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Test system: *Salmonella typhimurium*  
Method: OECD Test Guideline 471  
Result: negative

Test Type: Chromosome aberration test in vitro  
Test system: Chinese hamster lung cells  
Method: OECD Test Guideline 473  
Result: negative

Genotoxicity in vivo : Test Type: In vivo micronucleus test  
Cell type: Bone marrow  
Method: OECD Test Guideline 475  
Result: negative

# SAFETY DATA SHEET



## Insulin Porcine Formulation

Version 3.0 Revision Date: 16.06.2025 SDS Number: 27380-00024 Date of last issue: 28.09.2024 Date of first issue: 03.11.2014

||| Germ cell mutagenicity - Assessment : Weight of evidence does not support classification as a germ cell mutagen.

### Carcinogenicity

Not classified based on available information.

### Components:

#### Insulin (ox), 8A-L-threonine-10A-L-isoleucine-:

||| Species : Rat  
Application Route : Subcutaneous  
Exposure time : 2 Years  
LOAEL : 180 µg/kg

||| Carcinogenicity - Assessment : Weight of evidence does not support classification as a carcinogen

### Reproductive toxicity

Not classified based on available information.

### Components:

#### Insulin (ox), 8A-L-threonine-10A-L-isoleucine-:

||| Effects on fertility : Test Type: Fertility/early embryonic development  
Species: Rat  
Application Route: Intraperitoneal  
Fertility: NOAEL Mating/Fertility: 360 µg/kg  
Symptoms: No effects on fertility.  
Result: No effects on fertility and early embryonic development were detected.

### STOT-single exposure

Not classified based on available information.

### STOT-repeated exposure

Not classified based on available information.

### Repeated dose toxicity

### Components:

#### Insulin (ox), 8A-L-threonine-10A-L-isoleucine-:

||| Species : Rat  
Application Route : Inhalation  
Exposure time : 6 Months  
Symptoms : Hypoglycemia

||| Species : Monkey  
Application Route : Inhalation  
Exposure time : 6 Months  
Symptoms : Hypoglycemia

||| Species : Rat

# SAFETY DATA SHEET



## Insulin Porcine Formulation

Version 3.0 Revision Date: 16.06.2025 SDS Number: 27380-00024 Date of last issue: 28.09.2024 Date of first issue: 03.11.2014

---

||| NOAEL : 0,085 mg/kg  
||| Application Route : Subcutaneous  
||| Exposure time : 1 Months

||| Species : Dog  
||| NOAEL : 0,07 mg/kg  
||| Application Route : Subcutaneous  
||| Exposure time : 1 Months

### Aspiration toxicity

Not classified based on available information.

### Experience with human exposure

#### Components:

##### Insulin (ox), 8A-L-threonine-10A-L-isoleucine-:

||| Inhalation : Symptoms: Hypoglycemia, Fatigue, Drowsiness, Sweating, Headache, Nausea, Palpitation, tingling, numbness, altered mental status, Breathing difficulties

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## 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

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## SECTION 13. DISPOSAL CONSIDERATIONS

### Disposal methods

Waste from residues : Do not dispose of waste into sewer.  
Dispose of in accordance with local regulations.  
Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.  
If not otherwise specified: Dispose of as unused product.

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## SECTION 14. TRANSPORT INFORMATION

### International Regulations

#### UNRTDG

Not regulated as a dangerous good

#### IATA-DGR

# SAFETY DATA SHEET



## Insulin Porcine Formulation

Version 3.0      Revision Date: 16.06.2025      SDS Number: 27380-00024      Date of last issue: 28.09.2024  
Date of first issue: 03.11.2014

---

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.

### Special precautions for user

Not applicable

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## SECTION 15. REGULATORY INFORMATION

### Safety, health and environmental regulations/legislation specific for the substance or mixture

Argentina. Carcinogenic Substances and Agents Registry. : Not applicable

Control of precursors and essential chemicals for the preparation of drugs. : Not applicable

### The ingredients of this product are reported in the following inventories:

AICS : not determined

DSL : not determined

IECSC : not determined

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## SECTION 16. OTHER INFORMATION

Revision Date : 16.06.2025  
Date format : dd.mm.yyyy

### Further information

Sources of key data used to compile the Material Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

### Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; 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; IARC - International Agency for Research on Cancer; IATA

# SAFETY DATA SHEET



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27380-00024

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- 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; KECL - 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; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; 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; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; 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; WHMIS - Workplace Hazardous Materials Information System

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 is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

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