

# **Insulin Porcine Formulation**

Version Revision Date: SDS Number: Date of last issue: 07.12.2023 2.9 28.09.2024 27388-00024 Date of first issue: 03.11.2014

#### **SECTION 1. IDENTIFICATION**

Product identifier : 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 : Rua Coronel Bento Soares, 530

Cruzeiro - Sao Paulo - Brazil CEP 12730-340

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

### **SECTION 2. HAZARDS IDENTIFICATION**

### GHS Classification in accordance with ABNT NBR 14725 Standard

Not classified as hazardous in accordance with ABNT NBR 14725

### GHS label elements in accordance with ABNT NBR 14725 Standard

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.

### **SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Classification	Concentration (% w/w)
Insulin (ox), 8A-I-threonine-	12584-58-6		0,137
10A-I-isoleucine-			

## **SECTION 4. FIRST AID MEASURES**

If inhaled : If inhaled, remove to fresh air.



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Get medical attention if symptoms occur.

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, DO NOT induce vomiting.

Get medical attention if symptoms occur. Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and

None known.

delayed
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 prod: :

ucts

No hazardous combustion products are known

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances 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

necessarv.

Use personal protective equipment.

**SECTION 6. ACCIDENTAL RELEASE MEASURES** 

Personal precautions, protec- :

tive equipment and emer-

gency 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.



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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.

Handle in accordance with good industrial hygiene and safety Advice on safe handling

practice, based on the results of the workplace exposure

assessment

Take care to prevent spills, waste and minimize release to the

environment.

If exposure to chemical is likely during typical use, provide eye Hygiene measures

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.

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-I-threonine- 10A-I-isoleucine-	12584-58-6	TWA	3 μg/m3 (OEB 4)	Internal

**Engineering measures** Use appropriate engineering controls and manufacturing



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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.

Personal protective equipment

Respiratory protection No personal respiratory protective equipment normally

required.

Hand protection

Material Chemical-resistant gloves

Remarks Consider double gloving.

Wear safety glasses with side shields or goggles. Eye protection

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.

#### **SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Physical state suspension

Color off-white

Odor odorless

Odor Threshold No data available

7 - 7,8 pΗ

Melting point/freezing point No data available

Initial boiling point and boiling

range

100 °C

Flash point No data available

No data available **Evaporation rate** 

Flammability (solid, gas) Not applicable



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Flammability (liquids) : No data available

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

# **SECTION 10. STABILITY AND REACTIVITY**

Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reac- : Can react with strong oxidizing agents.

tions

Conditions to avoid : None known. Incompatible materials : Oxidizing agents

Hazardous decomposition : No hazardous decomposition products are known.

products

### **SECTION 11. TOXICOLOGICAL INFORMATION**

Information on likely routes of :

exposure

Inhalation Skin contact Ingestion



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Eye contact

### **Acute toxicity**

Not classified based on available information.

#### **Components:**

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

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

administration)

#### Skin corrosion/irritation

Not classified based on available information.

#### **Components:**

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

Remarks : No data available

### Serious eye damage/eye irritation

Not classified based on available information.

#### **Components:**

### Insulin (ox), 8A-I-threonine-10A-I-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-I-threonine-10A-I-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



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Germ cell mutagenicity -

: Weight of evidence does not support classification as a germ

Assessment

cell mutagen.

## Carcinogenicity

Not classified based on available information.

### **Components:**

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

Species : Rat

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

Carcinogenicity - Assess-

ment

Weight of evidence does not support classification as a car-

cinogen

### Reproductive toxicity

Not classified based on available information.

### **Components:**

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

Effects on fertility : Test Type: Fertility/early embryonic development

Species: Rat

Application Route: Intraperitoneal

Fertility: NOAEL Mating/Fertility: 360  $\mu$ g/kg

Symptoms: No effects on fertility.

Result: No effects on fertility and early embryonic develop-

ment 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-I-threonine-10A-I-isoleucine-:

Species : Rat

5,8 mg/kg

Application Route : Inhalation
Exposure time : 6 Months
Symptoms : Hypoglycemia

Species : Monkey

0,64 mg/kg

Application Route : Inhalation
Exposure time : 6 Months
Symptoms : Hypoglycemia

Species : Rat



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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-I-threonine-10A-I-isoleucine-:

Inhalation : Symptoms: Hypoglycemia, Fatigue, Drowsiness, Sweating,

Headache, Nausea, Palpitation, tingling, numbness, altered

mental status, Breathing difficulties

### **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

## **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.

### **SECTION 14. TRANSPORT INFORMATION**

## International Regulations

**UNRTDG** 

Not regulated as a dangerous good

IATA-DGR



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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.

**Domestic regulation** 

**ANTT** 

Not regulated as a dangerous good

Special precautions for user

Not applicable

#### **SECTION 15. REGULATORY INFORMATION**

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

National List of Carcinogenic Agents for Humans -

Not applicable

(LINACH)

Brazil. List of chemicals controlled by the Federal

: Not applicable

Police

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

AICS : not determined

DSL : not determined

IECSC : not determined

### **SECTION 16. OTHER INFORMATION**

Revision Date : 28.09.2024 Date format : dd.mm.yyyy

**Further information** 

Sources of key data used to compile the Material Safety

Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

Data Sheet cy, http://echa.europa.eu/

### 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 Sys-



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tem; GLP - Good Laboratory Practice; 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; 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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