

# **Insulin Porcine Formulation**

Version Revision Date: SDS Number: Date of last issue: 2023/12/07 7.0 2024/09/28 27406-00026 Date of first issue: 2014/11/03

#### 1. PRODUCT AND COMPANY IDENTIFICATION

Chemical 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)

Supplier's company name, address and phone number

Company name of supplier : MSD

Address : Kumagaya, Saitama Prefecture , Xicheng 810 MSD Co., Ltd.

Menuma factory

Telephone : 048-588-8411

E-mail address : EHSDATASTEWARD@msd.com

Emergency telephone number: +1-908-423-6000

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product Restrictions on use : Not applicable

#### 2. HAZARDS IDENTIFICATION

#### GHS classification of chemical product

Not a hazardous substance or mixture according to the Globally Harmonised System (GHS).

#### **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.

# 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

## Components

Chemical name	CAS-No.	Concentration (% w/w)	ENCS No.
Insulin (ox), 8A-I-threonine-10A-I-	12584-58-6	0.137	-
isoleucine-			



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4. FIRST AID MEASURES

If inhaled : If inhaled, remove to fresh air.

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 : 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

Protection of first-aiders

Notes to physician

None known.

No special precautions are necessary for first aid responders.

Treat symptomatically and supportively.

5. FIREFIGHTING 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 firefighters

Wear self-contained breathing apparatus for firefighting if nec-

essary.

Use personal protective equipment.

**6. ACCIDENTAL RELEASE MEASURES** 

Personal precautions, protective equipment and emer-

gency procedures

Follow safe handling advice (see section 7) and personal pro-

tective equipment recommendations (see section 8).

Environmental precautions : Avoid release to the environment.



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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.

Methods and materials for containment and cleaning up

Soak up with inert absorbent material.

For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absor-

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 deter-

mine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

## 7. HANDLING AND STORAGE

Handling

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 as-

sessment

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

environment.

Avoidance of contact Hygiene measures

: Oxidizing agents

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.

**Storage** 

Conditions for safe storage : Keep in properly labelled containers.

Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:

Strong oxidizing agents

Packaging material : Unsuitable material: None known.



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#### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

# Threshold limit value and permissible exposure limits for each component in the work environment

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Concentration standard / 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

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 con-

tainment devices).
Minimize open handling.

Personal protective equipment

Respiratory protection : No personal respiratory protective equipment normally re-

quired.

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, dis-

posable suits) to avoid exposed skin surfaces.

Use appropriate degowning techniques to remove potentially

contaminated clothing.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state : suspension

Colour : off-white



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Odour odourless

Odour Threshold No data available

Melting point/freezing point No data available

Boiling point, initial boiling point and boiling range

100 °C

Flammability (solid, gas) Not applicable

Flammability (liquids) No data available

Lower explosion limit and upper explosion limit / flammability limit

Upper explosion limit / Up- : No data available

per flammability limit

Lower explosion limit / Lower flammability limit : No data available

Flash point No data available

Decomposition temperature No data available

7 - 7.8 pΗ

Evaporation rate No data available

Auto-ignition temperature No data available

Viscosity

Viscosity, kinematic No data available

Solubility(ies)

Water solubility soluble

Partition coefficient: n-

octanol/water

Not applicable

Vapour pressure No data available

Density and / or relative density

Relative density 1.004 - 1.007

Density No data available

Relative vapour density No data available

Explosive properties Not explosive

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



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Molecular weight : No data available

Particle characteristics

Particle size No data available

#### 10. STABILITY AND REACTIVITY

Reactivity Not classified as a reactivity hazard. Chemical stability Stable under normal conditions. Can react with strong oxidizing agents.

Possibility of hazardous reac-

tions

None known. Conditions to avoid Incompatible materials Oxidizing agents

Hazardous decomposition No hazardous decomposition products are known.

products

#### 11. TOXICOLOGICAL INFORMATION

Information on likely routes of:

exposure

Inhalation Skin contact Ingestion

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



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#### Respiratory or skin sensitisation

#### Skin sensitisation

Not classified based on available information.

### Respiratory sensitisation

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

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-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



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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 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

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



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#### 12. ECOLOGICAL INFORMATION

## **Ecotoxicity**

No data available

#### Persistence and degradability

No data available

## **Bioaccumulative potential**

No data available

#### Mobility in soil

No data available

## Hazardous to the ozone layer

Not applicable

#### Other adverse effects

No data available

#### 13. DISPOSAL CONSIDERATIONS

#### **Disposal methods**

Waste from residues : Dispose of in accordance with local regulations.

Do not dispose of waste into sewer.

Contaminated packaging : Empty containers should be taken to an approved waste han-

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

#### 14. TRANSPORT INFORMATION

## **International Regulations**

### **UNRTDG**

UN number : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable

Environmentally hazardous : no

IATA-DGR

UN/ID No. : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable
Packing instruction (cargo : Not applicable

aircraft)

Packing instruction (passen- : Not applicable



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ger aircraft)

**IMDG-Code** 

**UN** number Not applicable Not applicable Proper shipping name Class Not applicable Not applicable Subsidiary risk Not applicable Packing group Not applicable Labels **EmS Code** Not applicable Not applicable Marine pollutant

#### Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

## **National Regulations**

Refer to section 15 for specific national regulation.

#### Special precautions for user

Not applicable

## 15. REGULATORY INFORMATION

#### **Related Regulations**

#### Fire Service Law

Not applicable to dangerous materials / designated flammables.

#### **Chemical Substance Control Law**

Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.

#### Industrial Safety and Health Law

#### **Harmful Substances Prohibited from Manufacture**

Not applicable

#### Harmful Substances Required Permission for Manufacture

Not applicable

#### **Substances Prevented From Impairment of Health**

Not applicable

# Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity

Not applicable

# Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity

Not applicable

#### **Substances Subject to be Notified Names**

Not applicable



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#### **Substances Subject to be Indicated Names**

Not applicable

Skin and Eye Damage Substances for PPE Requirements (ISHL MO Art. 594-2)

Not applicable

Carcinogenic Substances (Article 577-2 of the Occupational Health and Safety Regulations)

Not applicable

Ordinance on Prevention of Hazards Due to Specified Chemical Substances

Not applicable

**Ordinance on Prevention of Lead Poisoning** 

Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning

Not applicable

**Ordinance on Prevention of Organic Solvent Poisoning** 

Not applicable

Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)

Not applicable

Poisonous and Deleterious Substances Control Law

Not applicable

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof

Not applicable

**High Pressure Gas Safety Act** 

Not applicable

**Explosive Control Law** 

Not applicable

**Vessel Safety Law** 

Not regulated as a dangerous good

**Aviation Law** 

Not regulated as a dangerous good

Marine Pollution and Sea Disaster Prevention etc Law

Bulk transportation : Not classified as noxious liquid substance

Pack transportation : Not classified as marine pollutant

**Narcotics and Psychotropics Control Act** 

Narcotic or Psychotropic Raw Material (Export / Import Permission)

Not applicable

Specific Narcotic or Psychotropic Raw Material (Export / Import permission)

Not applicable



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#### Waste Disposal and Public Cleansing Law

Industrial waste

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

AICS : not determined

DSL : not determined

IECSC : not determined

#### 16. OTHER INFORMATION

#### **Further information**

Sources of key data used to compile the Safety Data Sheet

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

cy, 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.

Date format : yyyy/mm/dd

#### 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 - 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 - Trans-



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portation 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.

JP / EN