

Insulin Porcine Formulation

Version 3.3 Revision Date: 26.09.2023 SDS Number: 10098251-00007 Date of last issue: 20.03.2023
Date of first issue: 28.10.2021

SECTION 1. IDENTIFICATION

Product name : Insulin Porcine Formulation

Manufacturer or supplier's details

Company : MSD

Address : Calle 127A #53A-45 Torre 3 – Piso 8
Bogotá D.C., Colombia Complejo Empresarial Colpatría

Telephone : (+57) 1 2886012

Emergency telephone : 01 8000 916012

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**

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.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

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

SECTION 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.

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Most important symptoms and effects, both acute and delayed	:	Get medical attention if symptoms occur. Rinse mouth thoroughly with water. 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 (CO ₂) 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.
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

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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-I-threonine-10A-I-isoleucine-	12584-58-6	TWA	3 µg/m ³ (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.

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.

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- 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.

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
- 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

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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 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 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.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure	:	Inhalation Skin contact Ingestion Eye contact
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Acute toxicity

Not classified based on available information.

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

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

Skin corrosion/irritation

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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
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	:	Test Type: Chromosome aberration test in vitro Test system: Chinese hamster lung cells Method: OECD Test Guideline 473 Result: negative
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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 - Assessment	:	Weight of evidence does not support classification as a germ cell mutagen.
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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

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

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 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-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

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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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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

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

Transport in bulk according to IMO instruments

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**

Substances and chemicals controlled by the Ministry of Justice : Not applicable

List of substances included for special control and subject to supervision by the Ministry of Health and Social Protection : Not applicable

Resolution 2715/2014, which establishes the substances subject to registration of retail sales, based on defined classification criteria. : Not applicable

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 : 26.09.2023
Date format : dd.mm.yyyy

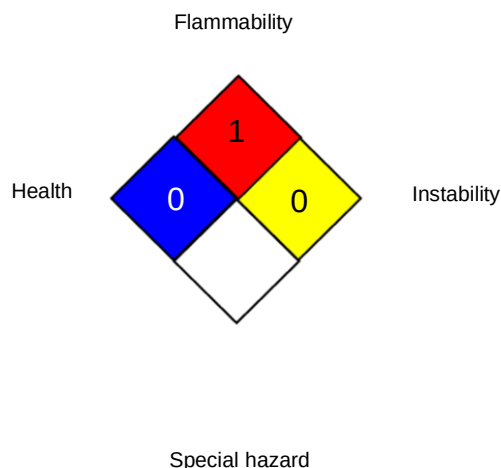
Further information

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/>

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NFPA:



HMIS® IV:

HEALTH	/	0
FLAMMABILITY		1
PHYSICAL HAZARD		0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

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 - Transportation of Dangerous Goods; TECl - 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

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