

## SAFETY DATA SHEETS

**This SDS packet was issued with item:**

078441243

**The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).**

078921509 078947035

**Insulin Porcine Formulation**

Version            Revision Date:            SDS Number:            Date of last issue: 04/27/2022  
6.4                10/01/2022                27417-00022            Date of first issue: 11/03/2014

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**SECTION 1. IDENTIFICATION**

Product name                                : Insulin Porcine Formulation

**Manufacturer or supplier's details**

Company name of supplier                : Merck & Co., Inc  
Address                                        : 126 E. Lincoln Avenue  
    : Rahway, New Jersey U.S.A. 07065  
Telephone                                    : 908-740-4000  
Emergency telephone                      : 1-908-423-6000  
E-mail address                               : EHSDATASTEWARD@merck.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 in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)**

Not a hazardous substance or mixture.

**GHS label elements**

Not a hazardous substance or mixture.

**Other hazards**

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-I-threonine-10A-I- isoleucine-	12584-58-6	0.137

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

Most important symptoms                 : None known.  
and effects, both acute and  
delayed

Protection of first-aiders                 : No special precautions are necessary for first aid responders.

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Notes to physician : Treat symptomatically and supportively.

**SECTION 5. FIRE-FIGHTING MEASURES**

- Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
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 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**

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- 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 <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.

#### 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.

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Hygiene measures : Use appropriate degowning techniques to remove potentially contaminated clothing.  
 : 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	: 212 °F / 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
Relative density	: 1.004 - 1.007
Density	: No data available
Solubility(ies)	
Water solubility	: soluble

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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

**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**

Not classified based on available information.

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

Remarks : No data available

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**Serious eye damage/eye irritation**

Not classified based on available information.

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

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-isooleucine-:**

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-isooleucine-:**

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
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<b>IARC</b>	No ingredient of this product present at levels greater than or equal to 0.1% is
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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 ingredient 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**

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



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**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 : 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 Annex II of MARPOL 73/78 and the IBC Code**

Not applicable for product as supplied.

**Domestic regulation****49 CFR**

Not regulated as a dangerous good

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**Special precautions for user**Not applicable

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**SECTION 15. REGULATORY INFORMATION****CERCLA Reportable Quantity**

Listed substances in the product are at low enough levels to not be expected to exceed the RQ

**SARA 304 Extremely Hazardous Substances Reportable Quantity**

This material does not contain any components with a section 304 EHS RQ.

**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** : No SARA Hazards**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****Pennsylvania Right To Know**

Water

7732-18-5

**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****Further information**

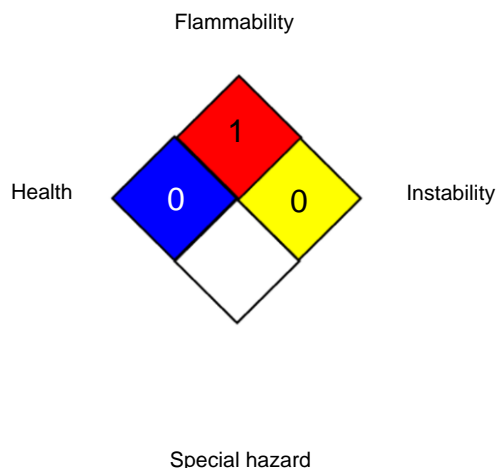
# SAFETY DATA SHEET



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### NFPA 704:



### 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; 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

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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/>

Revision Date : 10/01/2022

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.

US / Z8