

## Insulin Porcine Formulation

Version            Revision Date:            SDS Number:            Date of last issue: 04/24/2019  
5.2                09/13/2019                27417-00014            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                                        : 2000 Galloping Hill Road  
Kenilworth - New Jersey - U.S.A. 07033  
Telephone                                    : 908-740-4000  
Telefax                                        : 908-735-1496  
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

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### SECTION 2. HAZARDS IDENTIFICATION

#### GHS classification in accordance with 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-l-threonine-10A-l- isoleucine-	12584-58-6	>= 0.1 - < 1

Actual concentration is withheld as a trade secret

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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  
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.

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### 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.
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### SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Follow safe handling advice and personal protective equipment recommendations.
- Environmental precautions : Discharge into the environment must be avoided.  
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.
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### SECTION 7. HANDLING AND STORAGE

- Technical measures : See Engineering measures under EXPOSURE

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Local/Total ventilation : CONTROLS/PERSONAL PROTECTION section.  
 : 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

### 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	50 µg/m <sup>3</sup> (OEB 3)	Internal

**Engineering measures** : Ensure adequate ventilation, especially in confined areas.  
 : Minimize workplace exposure concentrations.

#### Personal protective equipment

Respiratory protection : No personal respiratory protective equipment normally required.  
 Hand protection

Remarks : Wash hands before breaks and at the end of workday.  
 Eye protection : Wear the following personal protective equipment:  
 : Safety glasses  
 Skin and body protection : Skin should be washed after contact.  
 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.

### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : suspension  
 Color : off-white  
 Odor : odorless  
 Odor Threshold : No data available  
 pH : 7 - 7.8

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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

Solubility(ies)  
  Water solubility                        : soluble

Partition coefficient: n-octanol/water        : No data available

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

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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                : No hazardous decomposition products are known.

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products

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### 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 : 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

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

**IARC** No ingredient of this product present at levels greater than or equal to 0.1% is 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.

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**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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**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 : 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

### SECTION 15. REGULATORY INFORMATION

#### EPCRA - Emergency Planning and Community Right-to-Know

##### CERCLA Reportable Quantity

Components	CAS-No.	Component RQ (lbs)	Calculated product RQ (lbs)
Zinc chloride	7646-85-7	1000	*

\*: Calculated RQ exceeds reasonably attainable upper limit.

##### 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



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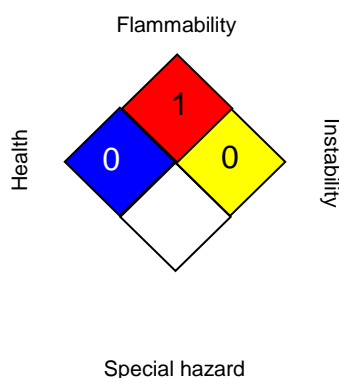
**The ingredients of this product are reported in the following inventories:**

AICS : not determined  
 DSL : not determined  
 IECSC : not determined

### SECTION 16. OTHER INFORMATION

#### Further information

##### NFPA 704:



##### HMIS® IV:

<b>HEALTH</b>	/	0
<b>FLAMMABILITY</b>	1	
<b>PHYSICAL HAZARD</b>	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

AICS - Australian Inventory of Chemical Substances; 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); EC<sub>x</sub> - Concentration associated with x% response; EHS - Extremely Hazardous Substance; EL<sub>x</sub> - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErC<sub>x</sub> - 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; IC<sub>50</sub> - 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; LC<sub>50</sub> - Lethal Concentration to 50 % of a test population; LD<sub>50</sub> - 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

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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; 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

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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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