SAFETY DATA SHEET

Insulin Porcine Formulation

Version 1.11  Revision Date: 13.09.2019  SDS Number: 27416-00012  Date of last issue: 05.06.2018

1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Insulin Porcine Formulation

Manufacturer or supplier’s details

Company: MSD
Address: 50 Tuas West Drive
          Singapore - Singapore  638408
Telephone: 908-740-4000
Emergency telephone number: 65 6697 2111 (24/7/365)
E-mail address: EHSDATASTEWARD@msd.com
Telefax: 908-735-1496

Recommended use of the chemical and restrictions on use

Recommended use: Veterinary product

2. HAZARDS IDENTIFICATION

GHS Classification
Not a hazardous substance or mixture.

GHS label elements
Not a hazardous substance or mixture.

Other hazards which do not result in classification
None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture: Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insulin (ox), 8A-L-threonine-10A-L-isoleucine-</td>
<td>12584-58-6</td>
<td>&gt;= 0.1 - &lt; 1</td>
</tr>
</tbody>
</table>

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.

5. FIREFIGHTING MEASURES

Suitable extinguishing media: Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

Unsuitable extinguishing media: None known.

Specific hazards during firefighting: 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 firefighters: Wear self-contained breathing apparatus for firefighting if necessary.
Use personal protective equipment.

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 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 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
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 labelled containers.
Store in accordance with the particular national regulations.
Materials to avoid: Do not store with the following product types:
Strong oxidizing agents

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insulin (ox), 8A-l-threonine-10A-l-isoleucine-9</td>
<td>12584-58-6</td>
<td>TWA</td>
<td>50 µg/m3 (OEB 3)</td>
<td>Internal</td>
</tr>
</tbody>
</table>

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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: suspension
Colour: off-white
1.1. Odour: odourless

2.1. Odour Threshold: No data available

3.1. pH: 7 - 7.8

4.1. Melting point/freezing point: No data available

5.1. Initial boiling point and boiling range: 100 °C

6.1. Flash point: No data available

7.1. Evaporation rate: No data available

8.1. Flammability (solid, gas): Not applicable

9.1. Flammability (liquids): No data available

10.1. Upper explosion limit / Upper flammability limit: No data available

11.1. Lower explosion limit / Lower flammability limit: No data available

12.1. Vapour pressure: No data available

13.1. Relative vapour density: No data available

14.1. Relative density: 1.004 - 1.007

15.1. Solubility(ies)
   - Water solubility: soluble

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

17.1. Auto-ignition temperature: No data available

18.1. Decomposition temperature: No data available

19.1. Viscosity
   - Viscosity, kinematic: No data available

20.1. Explosive properties: Not explosive

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

22.1. Molecular weight: No data available

23.1. Particle size: No data available

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.

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-l-threonine-10A-l-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-l-threonine-10A-l-isoleucine-:
Remarks: No data available

Serious eye damage/eye irritation
Not classified based on available information.

Components:

Insulin (ox), 8A-l-threonine-10A-l-isoleucine-:
Remarks: No data available

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-l-threonine-10A-l-isoleucine-:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES) Test system: Salmonella typhimurium Method: OECD Test Guideline 471
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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-l-threonine-10A-l-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

Reproductive toxicity
Not classified based on available information.

Components:

Insulin (ox), 8A-l-threonine-10A-l-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-l-threonine-10A-l-isoleucine-
Species: Rat
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<td>05.06.2018</td>
<td>03.11.2014</td>
</tr>
</tbody>
</table>

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

### Species

- **Species**: Monkey
  - **NOAEL**: 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 Month

- **Species**: Dog
  - **NOAEL**: 0.07 mg/kg
  - **Application Route**: Subcutaneous
  - **Exposure time**: 1 Month

### Aspiration toxicity

Not classified based on available information.

### Experience with human exposure

#### Components:

- **Insulin (ox), 8A-l-threonine-10A-l-isoleucine-**

  **Inhalation**
  - Symptoms: Hypoglycemia, Fatigue, Drowsiness, Sweating, Headache, Nausea, Palpitation, tingling, numbness, altered mental status, Breathing difficulties

### 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

### 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 han-
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.

15. REGULATORY INFORMATION

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

Workplace Safety and Health Act and Workplace Safety and Health (General Provisions) Regulations: This product is subjected to the SDS, labelling, PEL and other requirements in the Act/Regulations.

Environmental Protection and Management Act and Environmental Protection and Management (Hazardous Substances) Regulations : Not applicable

Fire Safety (Petroleum and Flammable Materials) Regulations : Not applicable

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


Date format : dd.mm.yyyy
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Date of first issue: 03.11.2014

Full text of other abbreviations

AICS - Australian Inventory of Chemical Substances; 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; 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.

SG / EN