SAFETY DATA SHEET

Insulin Porcine Formulation

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Insulin Porcine Formulation

Manufacturer or supplier’s details
Company : MSD
Address : 91-105 Harpin Street
          Bendigo 3550, Victoria Australia
Telephone : 908-740-4000
Emergency telephone number : 1 800 033 461
E-mail address : EHSDATASTEWARD@msd.com
Telefax : 1 800 817 414

Recommended use of the chemical and restrictions on use
Recommended use : Veterinary product

SECTION 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.

SECTION 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>&lt; 10</td>
</tr>
</tbody>
</table>

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.
**SAFETY DATA SHEET**

**Insulin Porcine Formulation**

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.11</td>
<td>13.09.2019</td>
<td>27383-00012</td>
<td>05.06.2018</td>
<td>03.11.2014</td>
</tr>
</tbody>
</table>

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. |

### SECTION 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.

### 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 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
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.

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.

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

SECTION 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-</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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:
- suspension

Colour:
- off-white
Odour : odourless
Odour 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
Vapour pressure : No data available
Relative vapour density : No data available
Relative density : 1.004 - 1.007
Solubility(ies)
  Water solubility : soluble
Partition coefficient: n-octanol/water : No data available
Auto-ignition 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.
SAFETY DATA SHEET

Insulin Porcine Formulation

SECTION 1. IDENTIFICATION

Identification
Insulin Porcine Formulation

SECTION 2. HAZARD IDENTIFICATION

GHS Classification
None of the components are classified as hazardous according to the GHS system.

SECTION 3. SAFETY PRECAUTIONS FOR USE

Precautions for use
None known.

SECTION 4. FIRST-AID MEASURES

Inhalation
Inhalation of the substance should be avoided.

Skin contact
Skin contact should be avoided.

Ingestion
Ingestion of the substance should be avoided.

Eye contact
Eye contact should be avoided.

SECTION 5. FIRE-FIGHTING MEASURES

Stable under normal conditions.

SECTION 6. ACCIDENTAL RELEASE MEASURES

None known.

SECTION 7. HANDLING AND STORING

Stable under normal conditions.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Stable under normal conditions.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Stable under normal conditions.

SECTION 10. STABILITY AND REACTIVITY

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

Exposure routes
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.

Chronic toxicity

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

- **Species**: Monkey
- **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-l-threonine-10A-l-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.

National Regulations

ADG
Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION

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

Prohibition/Licensing Requirements : There is no applicable prohibition or notification/licensing requirements, including for carcinogens under Commonwealth, State or Territory legislation.

The components of this product are reported in the following inventories:
AICS : not determined
DSL : not determined
IECSC : not determined

SECTION 16. OTHER INFORMATION

Further information
Revision Date : 13.09.2019
Sources of key data used to : Internal technical data, data from raw material SDSs, OECD
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.

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