**SECTION 1. IDENTIFICATION**

Product name: Insulin Porcine (with Metacresol) Formulation

Other means of identification: No data available

**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**

<table>
<thead>
<tr>
<th>Recommended use</th>
<th>Veterinary product</th>
</tr>
</thead>
<tbody>
<tr>
<td>Restrictions on use</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

**SECTION 2. HAZARDS IDENTIFICATION**

GHS classification in accordance with the Hazardous Products Regulations
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**

None known.

**SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Mixture</th>
</tr>
</thead>
</table>

**Components**

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Common Name/Synonym</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>m-Cresol</td>
<td>Phenol, 3-methyl-</td>
<td>108-39-4</td>
<td>0.23</td>
</tr>
<tr>
<td>Insulin (ox), 8A-l-threonine-10A-l-isoleucine-</td>
<td>No data available</td>
<td>12584-58-6</td>
<td>0.15</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.
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. FIRE-FIGHTING MEASURES

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

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

<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>m-Cresol</td>
<td>108-39-4</td>
<td>TWA</td>
<td>5 ppm 22 mg/m³</td>
<td>CA AB OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Inhalable fraction and vapour)</td>
<td>20 mg/m³</td>
<td>CA QC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td>Insulin (ox), 8A-l-threonine-10A-l-isoleucine-</td>
<td>12584-58-6</td>
<td>TWA (Inhalable fraction and vapor)</td>
<td>20 mg/m³</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>

Engineering measures : All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Essentially no open handling permitted. Use closed processing systems or containment technologies. If handled in a laboratory, use a properly designed biosafety cabinet, fume hood, or other containment device if the potential exists for aerosolization. If this potential does not exist, handle over lined trays or benchtops.
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.
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 : white to off-white

Odor : No data available

Odor Threshold : No data available

pH : 6.9 - 7.8

Melting point/freezing point : No data available

Initial boiling point and boiling range : No data available

Flash point : No data available

Evaporation rate : No data available

Flammability (solid, gas) : Not applicable
Insulin Porcine (with Metacresol) Formulation

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 : No data available
Density : 1.003 g/cm³
Solubility(ies)
Water solubility : No data available
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 : Not applicable

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.

Product:
Acute oral toxicity : Acute toxicity estimate: > 2,000 mg/kg
Method: Calculation method

Acute dermal toxicity : Acute toxicity estimate: > 2,000 mg/kg
Method: Calculation method

Components:

m-Cresol:
Acute oral toxicity : LD50 (Rat): 121 mg/kg
Remarks: Based on data from similar materials

Acute inhalation toxicity : Assessment: Corrosive to the respiratory tract.

Acute dermal toxicity : LD50 (Rabbit): 301 mg/kg
Remarks: Based on data from similar materials

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:

m-Cresol:
Species : Rabbit
Result : Corrosive after 3 minutes to 1 hour of exposure

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

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

m-Cresol:
- Species: Rabbit
- Result: Irreversible effects on the eye

Insulin (ox), 8A-l-threonine-10A-l-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:

m-Cresol:
- Genotoxicity in vitro:
  - Test Type: Chromosome aberration test in vitro
    - Method: OECD Test Guideline 473
    - Result: positive
  - Test Type: Bacterial reverse mutation assay (AMES)
    - Method: OECD Test Guideline 471
    - Result: negative

Genotoxicity in vivo:
- Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)
  - Species: Mouse
  - Application Route: Ingestion
  - Method: OECD Test Guideline 475
  - Result: negative

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:

**m-Cresol:**

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species</td>
<td>Mouse, males</td>
</tr>
<tr>
<td>Application Route</td>
<td>Ingestion</td>
</tr>
<tr>
<td>Exposure time</td>
<td>105 weeks</td>
</tr>
<tr>
<td>Result</td>
<td>equivocal</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

### Components:

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species</td>
<td>Mouse, female</td>
</tr>
<tr>
<td>Application Route</td>
<td>Ingestion</td>
</tr>
<tr>
<td>Exposure time</td>
<td>106 - 107 weeks</td>
</tr>
<tr>
<td>Result</td>
<td>positive</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

### Insulin (ox), 8A-l-threonine-10A-l-isoleucine-
- Weight of evidence does not support classification as a carcinogen.

### Reproductive toxicity
- Not classified based on available information.

### Components:

**m-Cresol:**

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Effects on fertility</td>
<td>Test Type: Two-generation reproduction toxicity study</td>
</tr>
<tr>
<td></td>
<td>Species: Rat</td>
</tr>
<tr>
<td></td>
<td>Application Route: Ingestion</td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Effects on fetal development</td>
<td>Test Type: Prenatal development toxicity study (teratogenicity)</td>
</tr>
<tr>
<td></td>
<td>Species: Rat</td>
</tr>
<tr>
<td></td>
<td>Application Route: Ingestion</td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
</tr>
</tbody>
</table>

### Insulin (ox), 8A-l-threonine-10A-l-isoleucine-
- Test Type: Fertility/early embryonic development
Insulin Porcine (with Metacresol) Formulation

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:

m-Cresol:

Species: Rat
NOAEL: 150 mg/kg
Application Route: Ingestion
Exposure time: 13 Weeks
Method: OECD Test Guideline 408

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

**Components:**

**m-Cresol:**

- **Toxicity to fish**
  - LC50 (Onchorhynchus mykiss (rainbow trout)): 8.6 mg/l
  - Exposure time: 96 h
- **Toxicity to daphnia and other aquatic invertebrates**
  - EC50 (Daphnia pulex (Water flea)): > 99.5 mg/l
  - Exposure time: 48 h
- **Toxicity to fish (Chronic toxicity)**
  - NOEC (Pimephales promelas (fathead minnow)): 1.35 mg/l
  - Exposure time: 32 d
  - Remarks: Based on data from similar materials
- **Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)**
  - NOEC (Daphnia magna (Water flea)): 1 mg/l
  - Exposure time: 21 d
  - Remarks: Based on data from similar materials

Persistence and degradability

**Components:**

**m-Cresol:**

- **Biodegradability**
  - Result: Readily biodegradable.
  - Biodegradation: 90 %
  - Exposure time: 28 d
  - Method: OECD Test Guideline 301D

Bioaccumulative potential

**Components:**

**m-Cresol:**

- **Bioaccumulation**
  - Species: Leuciscus idus (Golden orfe)
  - Bioconcentration factor (BCF): 17 - 20
- **Partition coefficient: n-octanol/water**
  - log Pow: 1.96

Mobility in soil

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 Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

Domestic regulation
TDG
Not regulated as a dangerous good

Special precautions for user
Not applicable

SECTION 15. REGULATORY INFORMATION

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

SECTION 16. OTHER INFORMATION

Full text of other abbreviations
ACGIH : USA. ACGIH Threshold Limit Values (TLV)
CA BC OEL : Canada. British Columbia OEL
# Insulin Porcine (with Metacresol) 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>2.0</td>
<td>09/20/2023</td>
<td>11259180-00003</td>
<td>09/14/2023</td>
<td>08/11/2023</td>
</tr>
</tbody>
</table>

- **CA QC OEL**: Québec. Regulation respecting occupational health and safety, Schedule 1, Part 1: Permissible exposure values for airborne contaminants
- **ACGIH / TWA**: 8-hour, time-weighted average
- **CA AB OEL / TWA**: 8-hour Occupational exposure limit
- **CA BC OEL / TWA**: 8-hour time weighted average
- **CA QC OEL / TWAEV**: Time-weighted average exposure value


**Revision Date**: 09/20/2023

**Date format**: mm/dd/yyyy

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

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.

CA / Z8