1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Insulin Glargine Formulation

Manufacturer or supplier’s details
Company: MSD
Address: Briahnager - Off Pune Nagar Road, Wagholi - Pune - India 412 207
Telephone: 908-740-4000
Emergency telephone number: 1-908-423-6000
E-mail address: EHSDATASTEWARD@msd.com
Telefax: 908-735-1496

Recommended use of the chemical and restrictions on use
Recommended use: Pharmaceutical

2. HAZARDS IDENTIFICATION

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989
Classification
Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

GHS Classification
Acute toxicity (Oral): Category 5
Skin corrosion/irritation: Category 2
Serious eye damage/eye irritation: Category 1
Specific target organ toxicity - repeated exposure (Oral): Category 2 (Blood, Nervous system)
Short-term (acute) aquatic hazard: Category 3

GHS label elements
Hazard pictograms:
Signal word: Danger
Hazard statements: H303 May be harmful if swallowed.
H315 Causes skin irritation.
H318 Causes serious eye damage.
H373 May cause damage to organs (Blood, Nervous system) through prolonged or repeated exposure if swallowed.
H402 Harmful to aquatic life.

Precautionary statements:

Prevention:
P260 Do not breathe dust.
P264 Wash skin thoroughly after handling.
P273 Avoid release to the environment.
P280 Wear protective gloves/eye protection/face protection.

Response:
P301 + P312 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.
P302 + P352 IF ON SKIN: Wash with plenty of water.
P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/doctor.
P314 Get medical advice/attention if you feel unwell.
P332 + P313 If skin irritation occurs: Get medical advice/attention.
P362 + P364 Take off contaminated clothing and wash it before reuse.

Disposal:
P501 Dispose of contents/container to an approved waste disposal plant.

Other hazards which do not result in classification
May form explosive dust-air mixture during classification, handling or other means.

3. COMPOSITION/INFORMATION ON INGREDIENTS

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

<table>
<thead>
<tr>
<th>Components</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical name</td>
<td>CAS-No.</td>
</tr>
<tr>
<td>------------------------------</td>
<td>---------</td>
</tr>
<tr>
<td>Insulin Glargine</td>
<td>160337-95-1</td>
</tr>
<tr>
<td>m-Cresol</td>
<td>108-39-4</td>
</tr>
</tbody>
</table>

4. FIRST AID MEASURES

General advice: In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.

If inhaled: If inhaled, remove to fresh air.
Get medical attention if symptoms occur.

In case of skin contact: In case of contact, immediately flush skin with plenty of water for at least 15 minutes while removing contaminated clothing.
In case of eye contact: In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. If easy to do, remove contact lens, if worn. Get medical attention immediately.

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: May be harmful if swallowed. Causes skin irritation. Causes serious eye damage. May cause damage to organs through prolonged or repeated exposure if swallowed.

Protection of first-aiders: First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

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: Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Exposure to combustion products may be a hazard to health.

Hazardous combustion products: Carbon oxides

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: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures: Use personal protective equipment. 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. 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:
- Sweep up or vacuum up spillage and collect in suitable container for disposal.
- Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).
- Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.
- 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.

7. HANDLING AND STORAGE

Technical measures:
- Static electricity may accumulate and ignite suspended dust causing an explosion.
- Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

Local/Total ventilation:
- Use only with adequate ventilation.

Advice on safe handling:
- Do not get on skin or clothing.
- Do not breathe dust.
- Do not swallow.
- Do not get in eyes.
- Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment.
- Keep container tightly closed.
- Minimize dust generation and accumulation.
- Keep container closed when not in use.
- Keep away from heat and sources of ignition.
- Take precautionary measures against static discharges.
- Take care to prevent spills, waste and minimize release to the environment.

Conditions for safe storage:
- Keep in properly labelled containers.
- Keep tightly closed.
- 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 Glargine</td>
<td>160337-95-1</td>
<td>TWA</td>
<td>50 µg/m³</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>50 µg/m³ (OEB 3)</td>
<td>Internal</td>
</tr>
</tbody>
</table>
m-Cresol | 108-39-4 | TWA | 5 ppm 22 mg/m³ | IN OEL
--- | --- | --- | --- | ---
Further information: Potential contribution to the overall exposure by the cutaneous route including mucous membranes and eye.

### Engineering measures
- Ensure adequate ventilation, especially in confined areas.
- Minimize workplace exposure concentrations.
- Apply measures to prevent dust explosions.
- Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment).

### Personal protective equipment

#### Respiratory protection
- If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

#### Filter type
- Combined particulates and organic vapour type

#### Hand protection
- Chemical-resistant gloves

#### Remarks
- Choose gloves to protect hands against chemicals depending on the concentration and quantity of the hazardous substance and specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the end of workday.

#### Eye protection
- Wear the following personal protective equipment:
  - Chemical-resistant goggles must be worn.
  - If splashes are likely to occur, wear a face-shield

#### Skin and body protection
- Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure potential.
- Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc).

#### 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
- Crystalline powder

#### Colour
- white

#### Odour
- No data available
## 10. STABILITY AND REACTIVITY

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
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</thead>
<tbody>
<tr>
<td>Odour Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>May form explosive dust-air mixture during processing, handling or other means.</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td></td>
</tr>
<tr>
<td>Water solubility</td>
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</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>No data available</td>
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<tr>
<td>Auto-ignition temperature</td>
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<tr>
<td>Decomposition temperature</td>
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</tr>
<tr>
<td>Viscosity</td>
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<tr>
<td>Viscosity, kinematic</td>
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<tr>
<td>Explosive properties</td>
<td>Not explosive</td>
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<tr>
<td>Oxidizing properties</td>
<td>The substance or mixture is not classified as oxidizing.</td>
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<tr>
<td>Molecular weight</td>
<td>No data available</td>
</tr>
<tr>
<td>Particle size</td>
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</tr>
</tbody>
</table>

Reactivity: Not classified as a reactivity hazard.
Chemical stability: Stable under normal conditions.
Possibility of hazardous reactions:
May form explosive dust-air mixture during processing, handling or other means.
Can react with strong oxidizing agents.
Conditions to avoid: Heat, flames and sparks.
Avoid dust formation.
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:
May be harmful if swallowed.

Product:
Acute oral toxicity: Acute toxicity estimate: 3,025 mg/kg
Method: Calculation method

Acute dermal toxicity: Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

Components:
Insulin Glargine:
Acute oral toxicity: Remarks: No data available
Acute inhalation toxicity: Remarks: No data available
Acute dermal toxicity: Remarks: No data available

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

Skin corrosion/irritation:
Causes skin irritation.

Components:
Insulin Glargine:
Remarks: No data available
**SAFETY DATA SHEET**

Insulin Glargine 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>
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<tr>
<td>4.2</td>
<td>09/13/2019</td>
<td>45339-00016</td>
<td>24.04.2019</td>
<td>07.01.2015</td>
</tr>
</tbody>
</table>

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

**Serious eye damage/eye irritation**
Causes serious eye damage.

**Components:**

**Insulin Glargine:**
Remarks: No data available

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

**Respiratory or skin sensitisation**

**Skin sensitisation**
Not classified based on available information.

**Respiratory sensitisation**
Not classified based on available information.

**Components:**

**Insulin Glargine:**
Remarks: No data available

**Germ cell mutagenicity**
Not classified based on available information.

**Components:**

**Insulin Glargine:**
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative  
Remarks: Based on data from similar materials

Genotoxicity in vitro: Test Type: In vitro mammalian cell gene mutation test  
Result: negative  
Remarks: Based on data from similar materials

Genotoxicity in vitro: Test Type: Chromosome aberration test in vitro  
Result: negative  
Remarks: Based on data from similar materials

**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)
SAFETY DATA SHEET

Insulin Glargine Formulation

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

Carcinogenicity
Not classified based on available information.

Components:

Insulin Glargine:
Species: Rat
Exposure time: 2 Years
NOAEL: 0.455 mg/kg body weight
Result: negative

Species: Mouse
Exposure time: 2 Years
NOAEL: 0.455 mg/kg body weight
Result: negative

m-Cresol:
Species: Mouse, males
Application Route: Ingestion
Exposure time: 105 weeks
Result: equivocal
Remarks: Based on data from similar materials

Species: Mouse, female
Application Route: Ingestion
Exposure time: 106 - 107 weeks
Result: positive
Remarks: Based on data from similar materials

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

Reproductive toxicity
Not classified based on available information.

Components:

Insulin Glargine:
Effects on fertility: Test Type: Fertility/early embryonic development
Species: Rat
Application Route: Subcutaneous
Fertility: NOAEL: 0.36 mg/kg body weight
SAFETY DATA SHEET

Insulin Glargine Formulation

Result: No effects on fertility

Test Type: Fertility/early embryonic development
Species: Rabbit
Application Route: Subcutaneous
Fertility: NOAEL: 0.072 mg/kg body weight
Result: No effects on fertility

Effects on foetal development:

Species: Rabbit
Application Route: Subcutaneous
Developmental Toxicity: NOAEL: 0.072 mg/kg body weight
Result: No effects on foetal development

Result: No effects on fertility

Test Type: Embryo-foetal development
Species: Rat
Application Route: Subcutaneous
Developmental Toxicity: NOAEL: 0.36 mg/kg body weight
Result: No effects on foetal development

Species: Rabbit
Application Route: Subcutaneous
Developmental Toxicity: LOAEL: 0.072 mg/kg body weight
Result: Fetotoxicity
Remarks: The mechanism or mode of action may not be relevant in humans.

Insulin Glargine:

Exposure routes: Ingestion
Target Organs: Blood, Nervous system
Assessment: May cause damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Insulin Glargine:

Species: Rat
NOAEL: 0.5 mg/kg

m-Cresol:

Effects on fertility:

Test Type: Two-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Result: negative

Effects on foetal development:

Test Type: Prenatal development toxicity study (teratogenicity)
Species: Rat
Application Route: Ingestion
Result: negative

STOT - single exposure
Not classified based on available information.

STOT - repeated exposure
May cause damage to organs (Blood, Nervous system) through prolonged or repeated exposure if swallowed.

Components:

Insulin Glargine:
LOAEL: 1.5 mg/kg
Application Route: Subcutaneous
Exposure time: 30 d
Target Organs: Blood, Nervous system

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

Aspiration toxicity
Not classified based on available information.

Experience with human exposure

Components:
Insulin Glargine:
Inhalation
Target Organs: Blood
Symptoms: Hypoglycemia, Headache, Sweating, Tremors, Nausea

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:
m-Cresol:
Toxicity to fish: LC50 (Oncorhynchus 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: 1.35 mg/l
Exposure time: 32 d
Species: Pimephales promelas (fathead minnow)
Remarks: Based on data from similar materials
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)
NOEC: 1 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)
Remarks: Based on data from similar materials

Persistence and degradability

Components:
m-Cresol:
Biodegradability: Result: Readily biodegradable.
Biodegradation: 90 %
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

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 handling site for recycling or disposal.
If not otherwise specified: Dispose of as unused product.

14. TRANSPORT INFORMATION

International Regulations

UN RTDG
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 IMO instruments
Not applicable for product as supplied.

15. REGULATORY INFORMATION

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

The components of this product are reported in the following inventories:

AICS: not determined
16. OTHER INFORMATION

Further information

Sources of key data used to compile the Safety Data Sheet


Date format

- dd.mm/yyyy

Full text of other abbreviations

ACGIH: USA. ACGIH Threshold Limit Values (TLV)
IN OEL: India. Permissible levels of certain chemical substances in work environment.

ACGIH / TWA: 8-hour, time-weighted average
IN OEL / TWA: Time-Weighted Average Concentration (TWA) (8 hrs.)

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.

IN / EN