SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name: Insulin Glargine Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Substance/Mixture: Pharmaceutical

1.3 Details of the supplier of the safety data sheet

Company: MSD
Innishannon
County Cork - Ireland

Telephone: 353 214329300
Telefax: 908-735-1496
E-mail address of person responsible for the SDS: EHSDATASTEWARD@msd.com

1.4 Emergency telephone number

1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

- Skin irritation, Category 2
  - H315: Causes skin irritation.
- Serious eye damage, Category 1
  - H318: Causes serious eye damage.
- Specific target organ toxicity - repeated exposure, Category 2
  - H373: May cause damage to organs through prolonged or repeated exposure.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

- Hazard pictograms:
- Signal word: Danger
- Hazard statements:
  - H315: Causes skin irritation.
  - H318: Causes serious eye damage.
  - H373: May cause damage to organs through prolonged or repeated exposure.
Precautionary statements:

**Prevention:**
- P260 Do not breathe dust.
- P264 Wash skin thoroughly after handling.
- P280 Wear protective gloves/ eye protection/ face protection.

**Response:**
- 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.

Hazardous components which must be listed on the label:

- Insulin Glargine
- m-Cresol

2.3 Other hazards

- May form explosive dust-air mixture during processing, handling or other means.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insulin Glargine</td>
<td>160337-95-1</td>
<td>STOT RE 2; H373</td>
<td>&gt;= 90 - &lt;= 100</td>
</tr>
<tr>
<td>m-Cresol</td>
<td>108-39-4</td>
<td>Acute Tox. 3; H301</td>
<td>&gt;= 3 - &lt; 5</td>
</tr>
<tr>
<td></td>
<td>203-577-9</td>
<td>Acute Tox. 3; H311</td>
<td></td>
</tr>
<tr>
<td></td>
<td>604-004-00-9</td>
<td>Skin Corr. 1B; H314</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Eye Dam. 1; H318</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Aquatic Chronic 3; H412</td>
<td></td>
</tr>
</tbody>
</table>

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of 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.

**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).
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 and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.

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.

4.2 Most important symptoms and effects, both acute and delayed

Risks
Causes skin irritation.
Causes serious eye damage.
May cause damage to organs through prolonged or repeated exposure.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment
Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

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

Unsuitable extinguishing media
None known.

5.2 Special hazards arising from the substance or mixture

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
Insulin Glargine Formulation

5.3 Advice for firefighters

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

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.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions:
Use personal protective equipment. Follow safe handling advice and personal protective equipment recommendations.

6.2 Environmental precautions

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.

6.3 Methods and material for containment and cleaning up

Methods for 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.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

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.
SAFETY DATA SHEET 
according to Regulation (EC) No. 1907/2006

Insulin Glargine Formulation

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.

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.

7.2 Conditions for safe storage, including any incompatibilities
Requirements for storage areas and containers: Keep in properly labelled containers. Keep tightly closed.
Store in accordance with the particular national regulations.
Advice on common storage: Do not store with the following product types:
Strong oxidizing agents

7.3 Specific end use(s)
Specific use(s): No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</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>m-Cresol</td>
<td>108-39-4</td>
<td>OELV - 8 hrs (TWA)</td>
<td>5 ppm</td>
<td>IE OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>22 mg/m3</td>
<td></td>
</tr>
</tbody>
</table>

Further information: Substances which have the capacity to penetrate intact skin when they come in contact with it, and be absorbed into the body, Where no specific short-term exposure limit is listed, a figure three times the long-term exposure limit value should be used, Indicative Occupational Exposure Limit Value.

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:  

5 / 17
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Insulin Glargine Formulation

Substance name | End Use | Exposure routes | Potential health effects | Value
---|---|---|---|---
m-Cresol | Workers | Inhalation | Long-term systemic effects | 3.5 mg/m³
 | Workers | Inhalation | Acute systemic effects | 343 mg/m³
 | Workers | Skin contact | Long-term systemic effects | 0.5 mg/kg bw/day
 | Workers | Skin contact | Acute systemic effects | 1.47 mg/kg bw/day
 | Consumers | Inhalation | Long-term systemic effects | 0.75 mg/m³
 | Consumers | Inhalation | Acute systemic effects | 222 mg/m³
 | Consumers | Skin contact | Long-term systemic effects | 0.25 mg/kg bw/day
 | Consumers | Skin contact | Acute systemic effects | 0.74 mg/kg bw/day
 | Consumers | Ingestion | Long-term systemic effects | 0.25 mg/kg bw/day
 | Consumers | Ingestion | Acute systemic effects | 0.74 mg/kg bw/day

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

<table>
<thead>
<tr>
<th>Substance name</th>
<th>Environmental Compartment</th>
<th>Value</th>
</tr>
</thead>
</table>
m-Cresol | Fresh water | 0.1 mg/l |
 | Marine water | 0.01 mg/l |
 | Intermittent use/release | 0.076 mg/l |
 | Sewage treatment plant | 1.14 mg/l |
 | Fresh water sediment | 0.71 mg/kg |
 | Marine sediment | 0.071 mg/kg |
 | Soil | 0.0831 mg/kg |

8.2 Exposure controls

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

Eye protection
Wear the following personal protective equipment:
Chemical resistant goggles must be worn.
If splashes are likely to occur, wear:
Face-shield
Equipment should conform to I.S. EN 166

Hand protection

Material
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.

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).

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 (A-P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>Crystalline powder</td>
</tr>
<tr>
<td>Colour</td>
<td>white</td>
</tr>
<tr>
<td>Odour</td>
<td>No data available</td>
</tr>
<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>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>No data available</td>
</tr>
<tr>
<td>Water solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition coefficient: n-</td>
<td>No data available</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET
generated according to Regulation (EC) No. 1907/2006

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>
</thead>
<tbody>
<tr>
<td>3.2</td>
<td>09/13/2019</td>
<td>45338-00016</td>
<td>24.04.2019</td>
<td>07.01.2015</td>
</tr>
</tbody>
</table>

- octanol/water
  - 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.

9.2 Other information
- Flammability (liquids): No data available
- Molecular weight: No data available
- Particle size: No data available

SECTION 10: Stability and reactivity

10.1 Reactivity
- Not classified as a reactivity hazard.

10.2 Chemical stability
- Stable under normal conditions.

10.3 Possibility of hazardous reactions
- Hazardous reactions: May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.

10.4 Conditions to avoid
- Conditions to avoid: Heat, flames and sparks. Avoid dust formation.

10.5 Incompatible materials
- Materials to avoid: Oxidizing agents

10.6 Hazardous decomposition products
- No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects
- 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:**

**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

**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

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

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)
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
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: 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
### 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>
</thead>
<tbody>
<tr>
<td>3.2</td>
<td>09/13/2019</td>
<td>45338-00016</td>
<td>24.04.2019</td>
<td>07.01.2015</td>
</tr>
</tbody>
</table>

- **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.

#### m-Cresol:

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

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

#### STOT - single exposure

Not classified based on available information.

#### STOT - repeated exposure

May cause damage to organs through prolonged or repeated exposure.

### Components:

#### Insulin Glargine:

| Exposure routes | Ingestion  
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Target Organs</td>
<td>Blood, Nervous system</td>
</tr>
<tr>
<td>Assessment</td>
<td>May cause damage to organs through prolonged or repeated exposure.</td>
</tr>
</tbody>
</table>

#### Repeated dose toxicity

### Components:

#### Insulin Glargine:

| Species | Rat  
|---------|------|
| NOAEL   | 0.5 mg/kg  
| 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

SECTION 12: Ecological information

12.1 Toxicity

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

12.2 Persistence and degradability

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

12.3 Bioaccumulative potential

Components:
m-Cresol:
Bioaccumulation : Species: Leuciscus idus (Golden orfe)
Bioconcentration factor (BCF): 17 - 20

Partition coefficient: n- : log Pow: 1.96
Insulin Glargine Formulation

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product: Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

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

14.1 UN number
Not regulated as a dangerous good

14.2 UN proper shipping name
Not regulated as a dangerous good

14.3 Transport hazard class(es)
Not regulated as a dangerous good

14.4 Packing group
Not regulated as a dangerous good

14.5 Environmental hazards
Not regulated as a dangerous good

14.6 Special precautions for user
Not applicable

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code
Remarks: Not applicable for product as supplied.

SECTION 15: Regulatory information

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

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59): Not applicable
REACH - List of substances subject to authorisation (Annex XIV): Not applicable
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer: Not applicable
Regulation (EC) No 850/2004 on persistent organic pollutants: Not applicable
Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals: Not applicable
REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII): Not applicable

Other regulations:
Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

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

15.2 Chemical safety assessment
A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

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

Full text of H-Statements
H301: Toxic if swallowed.
H311: Toxic in contact with skin.
H314: Causes severe skin burns and eye damage.
H318: Causes serious eye damage.
H373: May cause damage to organs through prolonged or repeated exposure if swallowed.
H412: Harmful to aquatic life with long lasting effects.

Full text of other abbreviations
Acute Tox.: Acute toxicity
Aquatic Chronic: Long-term (chronic) aquatic hazard
Eye Dam.: Serious eye damage
Skin Corr.: Skin corrosion
STOT RE: Specific target organ toxicity - repeated exposure
IE OEL: Ireland. List of Chemical Agents and Occupational Exposure Limit Values - Schedule 1
IE OEL / OELV - 8 hrs (TWA): Occupational exposure limit value (8-hour reference period)
Insulin Glargine Formulation

Classification of the mixture:

<table>
<thead>
<tr>
<th>Classification</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin Irrit. 2</td>
<td>H315</td>
</tr>
<tr>
<td>Eye Dam. 1</td>
<td>H318</td>
</tr>
<tr>
<td>STOT RE 2</td>
<td>H373</td>
</tr>
</tbody>
</table>

Further information:

Sources of key data used to compile the Safety Data Sheet:

Classification procedure:
- Calculation method

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.
<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue: 24.04.2019</th>
<th>Date of first issue: 07.01.2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.2</td>
<td>09/13/2019</td>
<td>45338-00016</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

IE / EN