

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Insulin Glargine Formulation

Version 5.0      Revision Date: 14.04.2025      SDS Number: 9371564-00011      Date of last issue: 28.09.2024  
Date of first issue: 27.08.2021

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### 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

Recommended restrictions on use : Not applicable

#### 1.3 Details of the supplier of the safety data sheet

Company : MSD  
120 Moorgate  
EC2M 6UR London, United Kingdom

Telephone : +44 (0) 2081548000

E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

#### 1.4 Emergency telephone number

+1-908-423-6000

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### SECTION 2: Hazards identification

#### 2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)

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) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)

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|                          |   |  |
|--------------------------|---|--|
| Hazard pictograms        | : |  |
| Signal word              | : | Danger   |
| Hazard statements        | : | H315 Causes skin irritation.<br>H318 Causes serious eye damage.<br>H373 May cause damage to organs through prolonged or repeated exposure.   |
| Precautionary statements | : | <b>Prevention:</b><br>P260 Do not breathe dust.<br>P264 Wash skin thoroughly after handling.<br>P280 Wear protective gloves/ eye protection/ face protection.<br><br><b>Response:</b><br>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.<br>P314 Get medical advice/ attention if you feel unwell.<br>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

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

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

## SECTION 3: Composition/information on ingredients

### 3.2 Mixtures

#### Components

| Chemical name    | CAS-No.<br>EC-No.<br>Index-No.<br>Registration number | Classification                             | Concentration<br>(% w/w) |
|------------------|---|--|--------------------------|
| Insulin Glargine | 160337-95-1   | STOT RE 2; H373<br>(Blood, Nervous system) | >= 90 - <= 100           |
| m-Cresol         | 108-39-4<br>203-577-9                                 | Acute Tox. 3; H301<br>Acute Tox. 3; H311   | >= 3 - < 5               |

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|  |              |   |  |
|--|--------------|---|--|
|  | 604-004-00-9 | Skin Corr. 1 B;<br>H314<br>Eye Dam. 1; H318<br>Aquatic Chronic 3;<br>H412 |  |
|--|--------------|---|--|

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.

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## SECTION 5: Firefighting measures

### 5.1 Extinguishing media

Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical

Unsuitable extinguishing media : None known.

### 5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-fighting : 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

### 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.

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## SECTION 6: Accidental release measures

### 6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.  
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

### 6.2 Environmental precautions

Environmental precautions : Avoid release to the environment.  
Prevent further leakage or spillage if safe to do so.  
Retain and dispose of contaminated wash water.  
If spillage enters rivers or watercourses, inform the Environment Agency (emergency telephone number 0800 807060).

### 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.

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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.<br>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.<br>Do not breathe dust.<br>Do not swallow.<br>Do not get in eyes.<br>Wash skin thoroughly after handling.<br>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment<br>Keep container tightly closed.<br>Minimize dust generation and accumulation.<br>Keep container closed when not in use.<br>Keep away from heat and sources of ignition.<br>Take precautionary measures against static discharges.<br>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.<br>Store in accordance with the particular national regulations. |
| Advice on common storage                      | : Do not store with the following product types:<br>Strong oxidizing agents   |

### 7.3 Specific end use(s)

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Specific use(s) : No data available

### SECTION 8: Exposure controls/personal protection

#### 8.1 Control parameters

##### Occupational Exposure Limits

dust of any kind

10 mg/m<sup>3</sup>

Value type (Form of exposure): TWA (Inhalable)

Basis: GB EH40

4 mg/m<sup>3</sup>

Value type (Form of exposure): TWA (Respirable fraction)

Basis: GB EH40

| Components       | CAS-No.     | Value type (Form of exposure) | Control parameters          | Basis    |
|------------------|-------------|-------------------------------|-----------------------------|----------|
| Insulin Glargine | 160337-95-1 | TWA                           | 3 µg/m <sup>3</sup> (OEB 4) | Internal |

##### Derived No Effect Level (DNEL)

| Substance name | End Use   | Exposure routes | Potential health effects   | Value                  |
|----------------|-----------|-----------------|----------------------------|------------------------|
| m-Cresol       | Workers   | Inhalation      | Long-term systemic effects | 3.5 mg/m <sup>3</sup>  |
|                | Workers   | Inhalation      | Acute systemic effects     | 343 mg/m <sup>3</sup>  |
|                | 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/m <sup>3</sup> |
|                | Consumers | Inhalation      | Acute systemic effects     | 222 mg/m <sup>3</sup>  |
|                | 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)

| Substance name | Environmental Compartment | Value      |
|----------------|---------------------------|------------|
| 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  |

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|  |                      |              |
|--|----------------------|--------------|
|  | 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/face protection      | : Wear the following personal protective equipment:<br>Chemical resistant goggles must be worn.<br>If splashes are likely to occur, wear:<br>Face-shield<br>Equipment should conform to BS 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.<br>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.<br>Filter should conform to BS EN 14387  |
| 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

|                 |                      |
|-----------------|----------------------|
| Appearance      | : Crystalline powder |
| Colour          | : white              |
| Odour           | : No data available  |
| Odour Threshold | : No data available  |
| pH              | : No data available  |

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|  |   |   |
|--|---|---|
| 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)                        | : | May form explosive dust-air mixture during processing, handling or other means. |
| 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   |
| Density  | : | No data available   |
| Solubility(ies)                                  |   |   |
| Water solubility                                 | : | No data available   |
| 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.                        |

### 9.2 Other information

|                  |   |                   |
|------------------|---|-------------------|
| Molecular weight | : | No data available |
| Particle size    | : | No data available |

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## SECTION 10: Stability and reactivity

### 10.1 Reactivity

Not classified as a reactivity hazard.

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### 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.

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## 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.



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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

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|                              |  |
|------------------------------|--|
| 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<br>Species: Rat<br>Application Route: Subcutaneous<br>Fertility: NOAEL: 0.36 mg/kg body weight<br>Result: No effects on fertility                              |
|                               | : Test Type: Fertility/early embryonic development<br>Species: Rabbit<br>Application Route: Subcutaneous<br>Fertility: NOAEL: 0.072 mg/kg body weight<br>Result: No effects on fertility                          |
| Effects on foetal development | : Test Type: Embryo-foetal development<br>Species: Rat<br>Application Route: Subcutaneous<br>Developmental Toxicity: NOAEL: 0.36 mg/kg body weight<br>Result: No effects on foetal development                    |
|                               | : Species: Rabbit<br>Application Route: Subcutaneous<br>Developmental Toxicity: LOAEL: 0.072 mg/kg body weight<br>Result: Fetotoxicity<br>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<br>Species: Rat<br>Application Route: Ingestion<br>Result: negative           |
| Effects on foetal development | : Test Type: Prenatal development toxicity study (teratogenicity)<br>Species: Rat<br>Application Route: Ingestion<br>Result: negative |

### STOT - single exposure

Not classified based on available information.

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### STOT - repeated exposure

May cause damage to organs through prolonged or repeated exposure.

#### Components:

##### **Insulin Glargine:**

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

### 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<br>Symptoms: Hypoglycemia, Headache, Sweating, Tremors, Nausea |
|------------|---|---|

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## SECTION 12: Ecological information

### 12.1 Toxicity

#### Components:

##### **m-Cresol:**

|                  |   |   |
|------------------|---|---|
| Toxicity to fish | : | LC50 (Oncorhynchus mykiss (rainbow trout)): 8.6 mg/l<br>Exposure time: 96 h |
|------------------|---|---|

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|  |   |  |
|--|---|--|
| Toxicity to daphnia and other aquatic invertebrates                    | : | EC50 (Daphnia pulex (Water flea)): > 99.5 mg/l<br>Exposure time: 48 h  |
| Toxicity to fish (Chronic toxicity)                                    | : | NOEC: 1.35 mg/l<br>Exposure time: 32 d<br>Species: Pimephales promelas (fathead minnow)<br>Remarks: Based on data from similar materials |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : | NOEC: 1 mg/l<br>Exposure time: 21 d<br>Species: Daphnia magna (Water flea)<br>Remarks: Based on data from similar materials              |

### 12.2 Persistence and degradability

#### Components:

##### **m-Cresol:**

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

### 12.3 Bioaccumulative potential

#### Components:

##### **m-Cresol:**

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

### 12.4 Mobility in soil

No data available

### 12.5 Results of PBT and vPvB assessment

#### Product:

|            |   |  |
|------------|---|--|
| Assessment | : | This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher. |
|------------|---|--|

### 12.6 Other adverse effects

#### Product:

|                                |   |  |
|--------------------------------|---|--|
| Endocrine disrupting potential | : | This substance/mixture does not contain components considered to have endocrine disrupting properties for environment according to UK REACH Article 57(f). |
|--------------------------------|---|--|

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## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

|                        |  |
|------------------------|--|
| Product                | : Dispose of in accordance with local regulations.<br>According to the European Waste Catalogue, Waste Codes are not product specific, but application specific.<br>Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.<br>Do not dispose of waste into sewer. |
| Contaminated packaging | : Empty containers should be taken to an approved waste handling site for recycling or disposal.<br>If not otherwise specified: Dispose of as unused product.  |

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## SECTION 14: Transport information

### 14.1 UN number

|      |                                     |
|------|-------------------------------------|
| ADN  | : Not regulated as a dangerous good |
| ADR  | : Not regulated as a dangerous good |
| RID  | : Not regulated as a dangerous good |
| IMDG | : Not regulated as a dangerous good |
| IATA | : Not regulated as a dangerous good |

### 14.2 UN proper shipping name

|      |                                     |
|------|-------------------------------------|
| ADN  | : Not regulated as a dangerous good |
| ADR  | : Not regulated as a dangerous good |
| RID  | : Not regulated as a dangerous good |
| IMDG | : Not regulated as a dangerous good |
| IATA | : Not regulated as a dangerous good |

### 14.3 Transport hazard class(es)

|      |                                     |
|------|-------------------------------------|
| ADN  | : Not regulated as a dangerous good |
| ADR  | : Not regulated as a dangerous good |
| RID  | : Not regulated as a dangerous good |
| IMDG | : Not regulated as a dangerous good |
| IATA | : Not regulated as a dangerous good |

### 14.4 Packing group

|      |                                     |
|------|-------------------------------------|
| ADN  | : Not regulated as a dangerous good |
| ADR  | : Not regulated as a dangerous good |
| RID  | : Not regulated as a dangerous good |
| IMDG | : Not regulated as a dangerous good |

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Insulin Glargine Formulation

|                |                              |                              |   |
|----------------|------------------------------|------------------------------|---|
| Version<br>5.0 | Revision Date:<br>14.04.2025 | SDS Number:<br>9371564-00011 | Date of last issue: 28.09.2024<br>Date of first issue: 27.08.2021 |
|----------------|------------------------------|------------------------------|---|

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**IATA (Cargo)** : Not regulated as a dangerous good

**IATA (Passenger)** : 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.

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## SECTION 15: Regulatory information

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

Relevant EU provisions transposed through retained EU law

UK REACH List of restrictions (Annex 17) : Not applicable

UK REACH Candidate list of substances of very high concern (SVHC) for Authorisation : Not applicable

The Persistent Organic Pollutants Regulations (retained Regulation (EU) 2019/1021 as amended for Great Britain)

Regulation (EU) No 2024/590 on substances that deplete the ozone layer : Not applicable

UK REACH List of substances subject to authorisation (Annex XIV) : Not applicable

GB Export and import of hazardous chemicals - Prior Informed Consent (PIC) Regulation : Not applicable

Control of Major Accident Hazards Regulations 2015 (COMAH)  
Not applicable

#### Other regulations:

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to protection of young people at work contained in Regulation 19) and of Directive 94/33/EC on the protection of young people at work.

#### 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.

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## SECTION 16: Other information

# SAFETY DATA SHEET

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## Insulin Glargine Formulation

|                |                              |                              |   |
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|----------------|------------------------------|------------------------------|---|

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     |
| GB EH40         | : UK. EH40 WEL - Workplace Exposure Limits               |
| GB EH40 / TWA   | : Long-term exposure limit (8-hour TWA reference period) |

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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; KECL - 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN

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## Insulin Glargine Formulation

Version  
5.0

Revision Date:  
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- United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

### Further information

Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

### Classification of the mixture:

|               |      |
|---------------|------|
| Skin Irrit. 2 | H315 |
| Eye Dam. 1    | H318 |
| STOT RE 2     | H373 |

### Classification procedure:

|                    |
|--------------------|
| Calculation method |
| Calculation method |
| Calculation method |

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.

GB / EN