# SAFETY DATA SHEET

# Insulin Glargine Formulation

| Version | Revision Date: | SDS Number: | Date of last issue: 04.04.2023 |
|---|---|---|---|
| 5.1 | 30.09.2023 | 45327-00026 | Date of first issue: 07.01.2015 |

## SECTION 1. IDENTIFICATION

Product name : Insulin Glargine Formulation

**Manufacturer or supplier's details**

Company : MSD

Address : 855 Leandro N. Alem St., 8 Floor
Buenos Aires, Argentina C1001AFB

Telephone : 908-740-4000

Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

**Recommended use of the chemical and restrictions on use**

Recommended use : Pharmaceutical
Restrictions on use : Not applicable

## SECTION 2. HAZARDS IDENTIFICATION

**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:**

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.
P312 Call a POISON CENTER/ doctor 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 processing, handling or other means.

## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

**Components**

| Chemical name | CAS-No. | Concentration (% w/w) |
|---|---|---|
| Insulin Glargine | 160337-95-1 | >= 90 -<= 100 |
| m-Cresol | 108-39-4 | >= 3 -< 5 |

## SECTION 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 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.<br>If easy to do, remove contact lens, if worn.<br>Get medical attention immediately. |
| If swallowed | : | If swallowed, DO NOT induce vomiting.<br>Get medical attention if symptoms occur.<br>Rinse mouth thoroughly with water. |
| Most important symptoms and effects, both acute and delayed | : | May be harmful if swallowed.<br>Causes skin irritation.<br>Causes serious eye damage.<br>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. |

## SECTION 5. FIRE-FIGHTING MEASURES

| | | |
|---|---|---|
| Suitable extinguishing media | : | Water spray<br>Alcohol-resistant foam<br>Carbon dioxide (CO2)<br>Dry chemical |
| Unsuitable extinguishing media | : | None known. |
| 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.<br>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.<br>Use water spray to cool unopened containers.<br>Remove undamaged containers from fire area if it is safe to do so.<br>Evacuate area. |
| Special protective equipment for fire-fighters | : | In the event of fire, wear self-contained breathing apparatus.<br>Use personal protective equipment. |

## SECTION 6. ACCIDENTAL RELEASE MEASURES

| | | |
|---|---|---|
| Personal precautions, protective equipment and emergency procedures | : | Use personal protective equipment.<br>Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8). |
| Environmental precautions | : | Avoid release to the environment.<br>Prevent further leakage or spillage if safe to do so.<br>Retain and dispose of contaminated wash water.<br>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.

## SECTION 7. HANDLING AND STORAGE

| | | |
|---|---|---|
| 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. |
| Conditions for safe storage | : | Keep in properly labeled containers.<br>Keep tightly closed.<br>Store in accordance with the particular national regulations. |
| Materials to avoid | : | Do not store with the following product types:<br>Strong oxidizing agents |

## SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

**Ingredients with workplace control parameters**

| Components | CAS-No. | Value type (Form of exposure) | Control parame-ters / Permissible concentration | Basis |
|---|---|---|---|---|
| Insulin Glargine | 160337-95-1 | TWA | 3 µg/m3 (OEB 4) | Internal |
| m-Cresol | 108-39-4 | CMP | 5 ppm | AR OEL |
| | Further information: Skin | | | |
| | | TWA (Inhalable fraction and | 20 mg/m³ | ACGIH |

| | | | | |
|---|---|---|---|---|
| | | vapor) | | |

**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 vapor type

Hand protection

Material : Chemical-resistant gloves

Remarks : Choose gloves to protect hands against chemicals depending on the concentration 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:
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.

## SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : Crystalline powder

Color : white

Odor : No data available

Odor Threshold : No data available

pH : No data available

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 |
| Vapor pressure | : | No data available |
| Relative vapor density | : | No data available |
| Density | : | No data available |
| Solubility(ies) | | |
| Water solubility | : | No data available |
| Partition coefficient: n-octanol/water | : | No data available |
| 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 | : | No data available |

## SECTION 10. STABILITY AND REACTIVITY

| | | |
|---|---|---|
| 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.<br>Can react with strong oxidizing agents. |

| | | |
|---|---|---|
| Conditions to avoid | : | Heat, flames and sparks.<br>Avoid dust formation. |
| Incompatible materials | : | Oxidizing agents |
| Hazardous decomposition products | : | No hazardous decomposition products are known. |

## SECTION 11. TOXICOLOGICAL INFORMATION

| | | |
|---|---|---|
| Information on likely routes of exposure | : | Inhalation<br>Skin contact<br>Ingestion<br>Eye contact |

**Acute toxicity**

May be harmful if swallowed.

**Product:**

| | | |
|---|---|---|
| Acute oral toxicity | : | Acute toxicity estimate: 3.025 mg/kg<br>Method: Calculation method |
| Acute dermal toxicity | : | Acute toxicity estimate: > 5.000 mg/kg<br>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<br>Remarks: Based on data from similar materials |
| Acute inhalation toxicity | : | Assessment: Corrosive to the respiratory tract. |
| Acute dermal toxicity | : | LD50 (Rabbit): 301 mg/kg<br>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 sensitization**

**Skin sensitization**

Not classified based on available information.

**Respiratory sensitization**

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 fetal development | : | Test Type: Embryo-fetal development<br>Species: Rat<br>Application Route: Subcutaneous<br>Developmental Toxicity: NOAEL: 0,36 mg/kg body weight<br>Result: No effects on fetal development.<br><br>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 fetal 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.

**STOT-repeated exposure**

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

**Components:**

**Insulin Glargine:**

| | | |
|---|---|---|
| Routes of exposure | : | 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 |

## SECTION 12. ECOLOGICAL INFORMATION

**Ecotoxicity**

**Components:**

**m-Cresol:**

| | | |
|---|---|---|
| Toxicity to fish | : | LC50 (Oncorhynchus mykiss (rainbow trout)): 8,6 mg/l<br>Exposure time: 96 h |
| 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 (Pimephales promelas (fathead minnow)): 1,35 mg/l<br>Exposure time: 32 d<br>Remarks: Based on data from similar materials |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : | NOEC (Daphnia magna (Water flea)): 1 mg/l<br>Exposure time: 21 d<br>Remarks: Based on data from similar materials |

**Persistence and degradability**

**Components:**

**m-Cresol:**

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

**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 |

**Mobility in soil**

No data available

**Other adverse effects**

No data available

## SECTION 13. DISPOSAL CONSIDERATIONS

**Disposal methods**

| | | |
|---|---|---|
| Waste from residues | : | Do not dispose of waste into sewer.<br>Dispose of in accordance with local regulations. |
| 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. |

## 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.

**Special precautions for user**

Not applicable

## SECTION 15. REGULATORY INFORMATION

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

| | | |
|---|---|---|
| Argentina. Carcinogenic Substances and Agents Registry. | : | Not applicable |
| Control of precursors and essential chemicals for the preparation of drugs. | : | Not applicable |

**The ingredients of this product are reported in the following inventories:**

| | | |
|---|---|---|
| AICS | : | not determined |
| DSL | : | not determined |

IECSC : not determined

## SECTION 16. OTHER INFORMATION

Revision Date : 30.09.2023
Date format : dd.mm.yyyy

**Further information**

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

**Full text of other abbreviations**

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
AR OEL : Argentina. Occupational Exposure Limits

ACGIH / TWA : 8-hour, time-weighted average
AR OEL / CMP : TLV (Threshold Limit Value)

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); 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; ERG - Emergency Response Guide; 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; KECI - 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; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; 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; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a

guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

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