

Insulin Glargine Formulation

Version **Revision Date:** SDS Number: Date of last issue: 30.09.2023 28.09.2024 42875-00026 Date of first issue: 07.01.2015 6.0

SECTION 1. IDENTIFICATION

Product identifier : Insulin Glargine Formulation

Manufacturer or supplier's details

Company : MSD

Address : Avenue Comendador Antônio Loureiro Ramos,

nº 1500 - Distrito Industrial

Montes Claros - MG, Brazil 39404-620

Telephone : +55 (38) 3229 7000

Emergency telephone : +55 (38) 3201 5670

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 in accordance with ABNT NBR 14725 Standard

Acute toxicity (Oral) Category 5

Skin irritation Category 2

Serious eye damage : Category 1

repeated exposure (Oral)

Specific target organ toxicity - : Category 2 (Blood, Nervous system)

Short-term (acute) aquatic

hazard

: Category 3

GHS label elements in accordance with ABNT NBR 14725 Standard

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)



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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/ doc-

tor 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/ atten-

tion.

P362 + P364 Take off contaminated clothing and wash it before

reuse.

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.	Classification	Concentration (% w/w)
Insulin Glargine	160337-95-1	STOT RE, (Oral)(Blood, Nervous system), 2	>= 90 -<= 100
m-Cresol	108-39-4	Flam. Liq., 4 Acute Tox. (Oral), 3 Acute Tox. (Dermal), 3 Skin Corr., 1B Eye Dam., 1 Aquatic Acute, 2 Aquatic Chronic, 3	>= 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.



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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.

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.

First Aid responders should pay attention to self-protection, Protection of first-aiders

> 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

> Alcohol-resistant foam Carbon dioxide (CO2)

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.

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod-

Carbon oxides

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances and the surrounding environment.

Use water spray to cool unopened containers.

Remove undamaged containers from fire area if it is safe to do

SO.

Evacuate area.

Special protective equipment:

for fire-fighters

In the event of fire, wear self-contained breathing apparatus.

Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protec- : Use personal protective equipment.



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tive equipment and emergency procedures

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

Environmental precautions

Avoid release to the environment.

Prevent further leakage or spillage if safe to do so. 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.

SECTION 7. HANDLING AND STORAGE

Static electricity may accumulate and ignite suspended dust Technical measures

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.

Wash skin thoroughly after handling.

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.

If exposure to chemical is likely during typical use, provide eye Hygiene measures

flushing systems and safety showers close to the working

When using do not eat, drink or smoke. Wash contaminated clothing before re-use.

Keep in properly labeled containers. Conditions for safe storage

Keep tightly closed.

Store in accordance with the particular national regulations.



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Materials to avoid : Do not store with the following product types:

Strong oxidizing agents

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Insulin Glargine	160337-95-1	TWA	3 μg/m3 (OEB 4)	Internal
m-Cresol	108-39-4	TWA (Inhalable fraction and vapor)	20 mg/m³	ACGIH

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. Combined particulates and organic vapor type

Filter 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).

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state : Crystalline powder



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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 characteristics

Particle size : No data available



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SECTION 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard. Chemical stability : Stable under normal conditions.

Possibility of hazardous reac-

tions

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. Oxidizing agents

Incompatible materials

Hazardous decomposition

products

No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of:

exposure

Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

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.



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Components:

Insulin Glargine:

Remarks No data available

m-Cresol:

Rabbit

Species 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



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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 - Assess-

ment

Weight of evidence does not support classification as a car-

cinogen

Reproductive toxicity

Not classified based on available information.

Components:

Insulin Glargine:



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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

Species: Rat

Application Route: Subcutaneous

Developmental Toxicity: NOAEL: 0,36 mg/kg body weight

Result: No effects on fetal 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 rele-

vant in humans.

m-Cresol:

Effects on fertility : Test Type: Two-generation reproduction toxicity study

Species: Rat

Application Route: Ingestion

Result: negative

Effects on fetal 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:

Routes of exposure : Ingestion

Target Organs : Blood, Nervous system

Assessment : May cause damage to organs through prolonged or repeated

exposure.



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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

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 tox-

icity)

NOEC (Pimephales promelas (fathead minnow)): 1,35 mg/l

Exposure time: 32 d

Remarks: Based on data from similar materials

Toxicity to daphnia and other:

aquatic invertebrates (Chron-

ic toxicity)

NOEC (Daphnia magna (Water flea)): 1 mg/l

Exposure time: 21 d

Remarks: Based on data from similar materials



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Persistence and degradability

Components:

m-Cresol:

Biodegradability : Result: Readily biodegradable.

Biodegradation: 90 % Exposure time: 28 d

Method: OECD Test Guideline 301D

Bioaccumulative potential

Components:

m-Cresol:

Bioaccumulation : Species: Leuciscus idus (Golden orfe)

Bioconcentration factor (BCF): 17 - 20

Partition coefficient: n-

octanol/water

: log Pow: 1,96

Mobility in soil

No data available

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Do not dispose of waste into sewer.

Dispose of in accordance with local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste

handling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG

Not regulated as a dangerous good

IATA-DGR

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

Domestic regulation

ANTT

Not regulated as a dangerous good



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Special precautions for user

Not applicable

SECTION 15. REGULATORY INFORMATION

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

National List of Carcinogenic Agents for Humans -Not applicable

(LINACH)

Brazil. List of chemicals controlled by the Federal Not applicable

Police

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 28.09.2024 Date format dd.mm.yyyy

Further information

Sources of key data used to compile the Material Safety

Data Sheet cy, http://echa.europa.eu/

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

Internal technical data, data from raw material SDSs, OECD

eChem Portal search results and European Chemicals Agen-

Full text of other abbreviations

ACGIH USA. ACGIH Threshold Limit Values (TLV)

ACGIH / TWA 8-hour, time-weighted average

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 Or-



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ganisation 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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