according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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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 Sub- : Pharmaceutical

stance/Mixture

Recommended restrictions

on use

Not applicable

1.3 Details of the supplier of the safety data sheet

Company : MSD

Piercetown

A86 HD21 Dunboyne, Ireland

Telephone : 908-740-4000

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 H373: May cause damage to organs through pro-

exposure, Category 2 longed or repeated exposure.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :

Signal word : Danger

Hazard statements : H315 Causes skin irritation.

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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 pro-

tection.

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

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.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 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. EC-No.	Classification	Concentration (% w/w)
	Index-No. Registration number		
Insulin Glargine	160337-95-1	STOT RE 2; H373 (Blood, Nervous system)	>= 90 - <= 100
m-Cresol	108-39-4 203-577-9	Acute Tox. 3; H301 Acute Tox. 3; H311	>= 3 - < 5

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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		604-004-00-9	Skin Corr. 1B; H314 Eye Dam. 1; H318 Aquatic Chronic 3; H412 EUH071	
			Acute toxicity estimate	
			Acute oral toxicity: 121 mg/kg Acute dermal toxicity:	

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 ad-

vice 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, 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

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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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 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: :

ucts

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 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.

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 pro-

tective 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.

Local authorities should be advised if significant spillages

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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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 con-

tainer 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 deter-

mine 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.

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 as-

sessment

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 contami-

nated 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.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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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

dusts non-specific 4 mg/m3

Value type (Form of exposure): OELV - 8 hrs (TWA) (Respirable

dust)

Basis: IE OEL

10 mg/m3

Value type (Form of exposure): OELV - 8 hrs (TWA) (inhalable

dust)

Basis: IE OEL

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
		or exposure)		
Insulin Glargine	160337-95-	TWA	3 μg/m3 (OEB 4)	Internal
	1			
m-Cresol	108-39-4	OELV - 8 hrs	5 ppm	IE OEL
		(TWA)	22 mg/m3	
	Further information: Substances which have the capacity to penetrate intact skin when they come in contact with it, and be absorbed into the body			

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

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 ef-	0.74 mg/kg

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		fects	bw/day
Consumers	Ingestion	Long-term systemic	0.25 mg/kg
		effects	bw/day
Consumers	Ingestion	Acute systemic ef-	0.74 mg/kg
		fects	bw/day

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

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
	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:

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 expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection. Equipment should conform to I.S. EN 14387

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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

Physical state : Crystalline powder

Colour : white

Odour : No data available

Odour Threshold : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling

range

No data available

Flammability (solid, gas) : May form explosive dust-air mixture during processing, han-

dling 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

Flash point : No data available

Auto-ignition temperature : No data available

Decomposition temperature : No data available

pH : No data available

Viscosity

Viscosity, kinematic : No data available

Solubility(ies)

Water solubility : No data available

Partition coefficient: n-

octanol/water

: No data available

Vapour pressure : No data available

Density : No data available

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Relative vapour density : No data available

Particle characteristics

Particle size : No data available

9.2 Other information

Explosives : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Evaporation rate : No data available

Molecular weight : 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, han-

dling 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 hazard classes as defined in Regulation (EC) No 1272/2008

Information on likely routes of : Inhalation

exposure Skin contact Ingestion

Eye contact

Acute toxicity

Not classified based on available information.

Product:

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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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

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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.

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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:

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 develop-

ment

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

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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 foetal develop-

ment

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 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

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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Aspiration toxicity

Not classified based on available information.

11.2 Information on other hazards

Endocrine disrupting properties

Product:

Assessment : The substance/mixture does not contain components consid-

ered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at

levels of 0.1% or higher.

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 tox-

icity)

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 (Chron-

NOEC: 1 mg/l

Exposure time: 21 d

ic toxicity) Species: Daphnia magna (Water flea)

Remarks: Based on data from similar materials

12.2 Persistence and degradability

Components:

m-Cresol:

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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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-

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 Endocrine disrupting properties

Product:

Assessment : The substance/mixture does not contain components consid-

ered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at

levels of 0.1% or higher.

12.7 Other adverse effects

No data available

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.

Do not dispose of waste into sewer.

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

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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SECTION 14: Transport information

14.1 UN number or ID 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
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 Maritime transport in bulk according to IMO instruments

Remarks : Not applicable for product as supplied.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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SECTION 15: Regulatory information

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

Not applicable

: Not applicable

Not applicable

Not applicable

Not applicable

: Not applicable

REACH - Restrictions on the manufacture, placing on

the market and use of certain dangerous substances,

mixtures and articles (Annex XVII)

REACH - Candidate List of Substances of Very High

Concern for Authorisation (Article 59).

Regulation (EC) on substances that deplete the ozone

laver

Regulation (EU) 2019/1021 on persistent organic pollu-

tants (recast)

Regulation (EU) No 649/2012 of the European Parliament and the Council concerning the export and import

of dangerous chemicals

REACH - List of substances subject to authorisation

(Annex XIV)

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

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.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Insulin Glargine Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 4.3 28.09.2024 45338-00029 Date of first issue: 07.01.2015

EUH071 : Corrosive to the respiratory tract.

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 Carcinogens with Occu-

pational Exposure Limit Values - Code of Practice, Schedule 1

and 2

IE OEL / OELV - 8 hrs (TWA) : Occupational exposure limit value (8-hour 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; 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; 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; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

Further information

Sources of key data used to compile the Safety Data

Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

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

Classification of the mixture:

Classification procedure:

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



Insulin Glargine Formulation

Version 4.3	Revision Date: 28.09.2024	SDS Number: 45338-00029	Date of last issue: 06.04.2024 Date of first issue: 07.01.2015	
Skin l	Irrit. 2	H315	Calculation method	
Eye [Dam. 1	H318	Calculation method	
STOT	ΓRE 2	H373	Calculation method	

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IE / EN