

Insulin Porcine (with Metacresol) Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 28.09.2024 11259071-00005 Date of first issue: 11.08.2023

Section 1: Identification

Product name : Insulin Porcine (with Metacresol) Formulation

Manufacturer or supplier's details

Company : MSD

Address : 33 Whakatiki Street - Private Bag 908

Upper Hutt - New Zealand

Telephone : 0800 800 543

Emergency telephone number : 0800 764 766 (0800 POISON) 0800 243 622 (0800

CHEMCALL)

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product Restrictions on use : Not applicable

Section 2: Hazard identification

GHS Classification

Not a hazardous substance or mixture.

GHS label elements

No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required.

Other hazards which do not result in classification

None known.

Section 3: Composition/information on ingredients

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
m-Cresol	108-39-4	>= 0.1 -< 0.25
Insulin (ox), 8A-I-threonine-10A-I-isoleucine-	12584-58-6	>= 0.1 -< 1

Section 4: First-aid measures

If inhaled : If inhaled, remove to fresh air.



Insulin Porcine (with Metacresol) Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 28.09.2024 11259071-00005 Date of first issue: 11.08.2023

Get medical attention if symptoms occur.

In case of skin contact : Wash with water and soap as a precaution.

Get medical attention if symptoms occur.

In case of eye contact : Flush eyes with water as a precaution.

Get medical attention if irritation develops and persists.

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

Protection of first-aiders Notes to physician : None known.

No special precautions are necessary for first aid responders.

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

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod-

ucts

No hazardous combustion products are known

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 firefighters

Wear self-contained breathing apparatus for firefighting if nec-

essarv

Use personal protective equipment.

Section 6: Accidental release measures

Personal precautions, protective equipment and emer-

gency procedures

Follow safe handling advice (see section 7) and personal pro-

tective equipment recommendations (see section 8).

Environmental precautions : Avoid release to the environment.

Prevent further leakage or spillage if safe to do so.

Prevent spreading over a wide area (e.g. by containment or oil

barriers).

Retain and dispose of contaminated wash water.



Insulin Porcine (with Metacresol) Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 2.2 28.09.2024 11259071-00005 Date of first issue: 11.08.2023

> Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up Soak up with inert absorbent material.

For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absorbent.

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 See Engineering measures under EXPOSURE

CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation

Use only with adequate ventilation. Advice on safe handling

Handle in accordance with good industrial hygiene and safety

practice, based on the results of the workplace exposure as-

sessment

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.

The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the

use of administrative controls.

Conditions for safe storage Keep in properly labelled containers.

Store in accordance with the particular national regulations.

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

Strong oxidizing agents

Section 8: Exposure controls/personal protection

Components with workplace control parameters

Components	CAS-No.	Value type	Control parame-	Basis
		(Form of	ters / Permissible	
		exposure)	concentration	
m-Cresol	108-39-4	WES-TWA	1 ppm	NZ OEL
		(Inhalable	4.5 mg/m3	



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Version Revision Date: SDS Number: Date of last issue: 06.04.2024 28.09.2024 11259071-00005 Date of first issue: 11.08.2023

		Fraction and Vapour)				
	Further information: Skin absorption					
		TWA (Inhalable fraction and vapor)	20 mg/m3	ACGIH		
Insulin (ox), 8A-I-threonine- 10A-I-isoleucine-	12584-58-6	TWA	3 μg/m3 (OEB 4)	Internal		

Engineering measures : All engineering controls should be implemented by facility

design and operated in accordance with GMP principles to

protect products, workers, and the environment.

Essentially no open handling permitted.

Use closed processing systems or containment technologies. If handled in a laboratory, use a properly designed biosafety cabinet, fume hood, or other containment device if the potential exists for aerosolization. If this potential does not exist,

handle over lined trays or benchtops.

Personal protective equipment

Respiratory protection : No personal respiratory protective equipment normally re-

quired.

Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

Eye protection : Wear safety glasses with side shields or goggles.

If the work environment or activity involves dusty conditions,

mists or aerosols, wear the appropriate goggles.

Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or

aerosols.

Skin and body protection : Work uniform or laboratory coat.

Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, dis-

posable suits) to avoid exposed skin surfaces.

Use appropriate degowning techniques to remove potentially

contaminated clothing.

Section 9: Physical and chemical properties

Appearance : suspension

Colour : white to off-white

Odour : No data available

Odour Threshold : No data available

pH : 6.9 - 7.8



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Version Revision Date: SDS Number: Date of last issue: 06.04.2024 2.2 28.09.2024 11259071-00005 Date of first issue: 11.08.2023

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) : Not applicable

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

Relative density : No data available

Density : 1.003 g/cm³

Solubility(ies)

Water solubility : No data available

Partition coefficient: n-

octanol/water

Not applicable

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.

Molecular weight : No data available

Particle characteristics

Particle size : Not applicable

Section 10: Stability and reactivity

Reactivity : Not classified as a reactivity hazard.



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Version Date of last issue: 06.04.2024 Revision Date: SDS Number: 2.2 28.09.2024 11259071-00005 Date of first issue: 11.08.2023

Chemical stability : Stable under normal conditions. Possibility of hazardous reac- : Can react with strong oxidizing agents.

tions

Conditions to avoid : None known. Incompatible materials Oxidizing agents

Hazardous decomposition No hazardous decomposition products are known.

products

Section 11: Toxicological information

Exposure routes Inhalation

Skin contact Ingestion Eye contact

Acute toxicity

Not classified based on available information.

Product:

: Acute toxicity estimate: > 2,000 mg/kg Acute oral toxicity

Method: Calculation method

Acute inhalation toxicity : Acute toxicity estimate: > 20 mg/l

> Exposure time: 4 h Test atmosphere: vapour Method: Calculation method

Acute toxicity estimate: > 2,000 mg/kg Acute dermal toxicity

Method: Calculation method

Components:

m-Cresol:

Acute oral toxicity LD50 (Rat): 121 mg/kg

Remarks: Based on data from similar materials

Acute inhalation toxicity : Acute toxicity estimate: 0.5001 mg/l

Exposure time: 4 h Test atmosphere: vapour Method: Expert judgement

Remarks: Based on national or regional regulation.

Acute dermal toxicity LD50 (Rabbit): 301 mg/kg

Remarks: Based on data from similar materials

Insulin (ox), 8A-I-threonine-10A-I-isoleucine-:

Acute toxicity (other routes of : LD50 (Rat): > 36 mg/kg

administration)

Skin corrosion/irritation

Not classified based on available information.



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Version Revision Date: SDS Number: Date of last issue: 06.04.2024 2.2 28.09.2024 11259071-00005 Date of first issue: 11.08.2023

Components:

m-Cresol:

Species : Rabbit

Result : Corrosive after 3 minutes to 1 hour of exposure

Insulin (ox), 8A-I-threonine-10A-I-isoleucine-:
Remarks : No data available

Serious eye damage/eye irritation

Not classified based on available information.

Components:

m-Cresol:

Species : Rabbit

Result : Irreversible effects on the eye

Insulin (ox), 8A-I-threonine-10A-I-isoleucine-:

Remarks : No data available

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Chronic toxicity

Germ cell mutagenicity

Not classified based on available information.

Components:

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



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Version Revision Date: SDS Number: Date of last issue: 06.04.2024 2.2 28.09.2024 11259071-00005 Date of first issue: 11.08.2023

Result: negative

Insulin (ox), 8A-I-threonine-10A-I-isoleucine-:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

Test system: Salmonella typhimurium Method: OECD Test Guideline 471

Result: negative

Test Type: Chromosome aberration test in vitro Test system: Chinese hamster lung cells Method: OECD Test Guideline 473

Result: negative

Genotoxicity in vivo : Test Type: In vivo micronucleus test

Cell type: Bone marrow

Method: OECD Test Guideline 475

Result: negative

Germ cell mutagenicity -

Assessment

Weight of evidence does not support classification as a germ

cell mutagen.

Carcinogenicity

Not classified based on available information.

Components:

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

Insulin (ox), 8A-I-threonine-10A-I-isoleucine-:

Species : Rat

Application Route : Subcutaneous Exposure time : 2 Years LOAEL : 180 µg/kg

Carcinogenicity - Assess-

ment

Weight of evidence does not support classification as a car-

cinogen



Insulin Porcine (with Metacresol) Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 28.09.2024 11259071-00005 Date of first issue: 11.08.2023

Reproductive toxicity

Not classified based on available information.

Components:

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

Insulin (ox), 8A-I-threonine-10A-I-isoleucine-:

Effects on fertility : Test Type: Fertility/early embryonic development

Species: Rat

Application Route: Intraperitoneal

Fertility: NOAEL Mating/Fertility: 360 µg/kg

Symptoms: No effects on fertility

Result: No effects on fertility and early embryonic develop-

ment were detected.

STOT - single exposure

Not classified based on available information.

Components:

m-Cresol:

Assessment : May cause respiratory irritation.

Remarks : Based on national or regional regulation.

STOT - repeated exposure

Not classified based on available information.

Repeated dose toxicity

Components:

m-Cresol:

Species : Rat

NOAEL : 150 mg/kg Application Route : Ingestion Exposure time : 13 Weeks

Method : OECD Test Guideline 408

Insulin (ox), 8A-I-threonine-10A-I-isoleucine-:

Species : Rat

5.8 mg/kg



Insulin Porcine (with Metacresol) Formulation

Version Date of last issue: 06.04.2024 **Revision Date:** SDS Number: 2.2 28.09.2024 11259071-00005 Date of first issue: 11.08.2023

Application Route : Inhalation Exposure time 6 Months **Symptoms** Hypoglycemia

Species Monkey

0.64 mg/kg

Application Route Inhalation Exposure time 6 Months **Symptoms** Hypoglycemia

Species Rat

0.085 mg/kg NOAEL Application Route Subcutaneous Exposure time 1 Months

Species Dog **NOAEL** 0.07 mg/kg Subcutaneous Application Route Exposure time 1 Months

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Insulin (ox), 8A-I-threonine-10A-I-isoleucine-:

Inhalation Symptoms: Hypoglycemia, Fatigue, Drowsiness, Sweating,

Headache, Nausea, Palpitation, tingling, numbness, altered

mental status, Breathing difficulties

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



Insulin Porcine (with Metacresol) Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 28.09.2024 11259071-00005 Date of first issue: 11.08.2023

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 han-

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

Section 14: Transport information

International Regulations

UNRTDG

UN number : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable

Environmentally hazardous

IATA-DGR

UN/ID No. : Not applicable



Insulin Porcine (with Metacresol) Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 28.09.2024 11259071-00005 Date of first issue: 11.08.2023

Proper shipping name : Not applicable Class : Not applicable Subsidiary risk : Not applicable Packing group : Not applicable Labels : Not applicable Packing instruction (cargo : Not applicable

aircraft)

Packing instruction (passen- : Not applicable

ger aircraft)

IMDG-Code

UN number Not applicable Proper shipping name Not applicable Class Not applicable : Not applicable Subsidiary risk Packing group : Not applicable Labels Not applicable EmS Code Not applicable Not applicable Marine pollutant

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

Not applicable for product as supplied.

National Regulations

NZS 5433

UN number : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable
Hazchem Code : Not applicable

Special precautions for user

Not applicable

Section 15: Regulatory information

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

HSNO Approval Number

Not applicable

Tolerable Exposure Limits (TEL)

Not applicable

Environmental Exposure Limits (EEL)

Not applicable

HSW Controls

Certified handler certificate not required. Tracking hazardous substance not required.



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Version Revision Date: SDS Number: Date of last issue: 06.04.2024 28.09.2024 11259071-00005 Date of first issue: 11.08.2023

Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

The components 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

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 Agen-

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

Date format : dd.mm.yyyy

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

NZ OEL : New Zealand. Workplace Exposure Standards for Atmospher-

ic Contaminants

ACGIH / TWA : 8-hour, time-weighted average

NZ OEL / WES-TWA : Workplace Exposure Standard - 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 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



Insulin Porcine (with Metacresol) Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 28.09.2024 11259071-00005 Date of first issue: 11.08.2023

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.

NZ / EN