

Insulin Porcine (with Metacresol) Formulation

Version 4.0 Revision Date: 14.04.2025 SDS Number: 11259173-00006 Date of last issue: 04.12.2024
Date of first issue: 11.08.2023

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Insulin Porcine (with Metacresol) Formulation

Manufacturer or supplier's details

Company name of supplier : MSD
Address : 126 E. Lincoln Avenue
Rahway, New Jersey U.S.A. 07065
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 : Veterinary product
Restrictions on use : Not applicable

SECTION 2. HAZARDS 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

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 -< 1
Insulin (ox), 8A-l-threonine-10A-l-isoleucine-	12584-58-6	≥ 0.1 -< 1

SECTION 4. FIRST AID MEASURES

If inhaled : If inhaled, remove to fresh air.
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 : 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 : None known.

Protection of first-aiders : No special precautions are necessary for first aid responders.

Notes to physician : Treat symptomatically and supportively.

Insulin Porcine (with Metacresol) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.12.2024
4.0	14.04.2025	11259173-00006	Date of first issue: 11.08.2023

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 products : No hazardous combustion products are known
- Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Use water spray to cool unopened containers.
Remove undamaged containers from fire area if it is safe to do so.
Evacuate area.
- Special protective equipment for fire-fighters : Wear self-contained breathing apparatus for firefighting if necessary.
Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective 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.
Prevent spreading over a wide area (e.g., by containment or oil barriers).
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 : Soak up with inert absorbent material.
For large spills, provide diking or other appropriate containment to keep material from spreading. If diked 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

Insulin Porcine (with Metacresol) Formulation

Version 4.0 Revision Date: 14.04.2025 SDS Number: 11259173-00006 Date of last issue: 04.12.2024
Date of first issue: 11.08.2023

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 assessment
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 labeled containers.
Store in accordance with the particular national regulations.
- Materials to avoid : Do not store with the following product types:
Strong oxidizing agents
Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**Ingredients with workplace control parameters**

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
m-Cresol	108-39-4	VLE-PPT (Inhalable fraction and vapour)	20 mg/m ³	NOM-010-STPS-2014
		TWA (Inhalable fraction and vapor)	20 mg/m ³	ACGIH
Insulin (ox), 8A-I-threonine-10A-I-isoleucine-	12584-58-6	TWA	3 µg/m ³ (OEB 4)	Internal

- Engineering measures** : The information below is intended for larger pilot/commercial-scale operations and manufacturing. For smaller scale, clinical, or pharmacy settings, site-specific internal risk assessment practices should be conducted to determine appropriate exposure control measures. The health hazard risks of handling this material are dependent on multiple factors, including but not limited to physical form and quantity

Insulin Porcine (with Metacresol) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.12.2024
4.0	14.04.2025	11259173-00006	Date of first issue: 11.08.2023

handled. If applicable, use process enclosures, local exhaust ventilation (e.g., Biosafety Cabinet, Ventilated Balance Enclosures), or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels as low as reasonably achievable.

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 required.

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, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : suspension

Color : white to off-white

Odor : No data available

Odor Threshold : No data available

pH : 6.9 - 7.8

Melting point/freezing point : No data available

Initial boiling point and boiling range : No data available

Flash point : No data available

Insulin Porcine (with Metacresol) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.12.2024
4.0	14.04.2025	11259173-00006	Date of first issue: 11.08.2023

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
Vapor pressure	:	No data available
Relative vapor density	:	No data available
Relative density	:	No data available
Density	:	1.003 g/cm ³
Solubility(ies)	:	
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
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	:	Not applicable

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	Can react with strong oxidizing agents.
Conditions to avoid	:	None known.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

Insulin Porcine (with Metacresol) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.12.2024
4.0	14.04.2025	11259173-00006	Date of first issue: 11.08.2023

SECTION 11. TOXICOLOGICAL INFORMATION**Information on likely routes of exposure**

Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity : Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

Acute dermal toxicity : Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

Components:**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

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

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

Skin corrosion/irritation

Not classified based on available information.

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

Insulin Porcine (with Metacresol) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.12.2024
4.0	14.04.2025	11259173-00006	Date of first issue: 11.08.2023

||Result : Irreversible effects on the eye

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

||Remarks : No data available

Respiratory or skin sensitization**Skin sensitization**

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

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
		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.

Insulin Porcine (with Metacresol) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.12.2024
4.0	14.04.2025	11259173-00006	Date of first issue: 11.08.2023

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 - Assessment	: Weight of evidence does not support classification as a carcinogen
------------------------------	--

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

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

Carcinogenicity - Assessment	: Weight of evidence does not support classification as a carcinogen
------------------------------	--

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 fetal development	: 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
----------------------	---

Insulin Porcine (with Metacresol) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.12.2024
4.0	14.04.2025	11259173-00006	Date of first issue: 11.08.2023

development were detected.

STOT-single exposure

Not classified based on available information.

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

Species	: Dog
NOAEL	: 0.07 mg/kg
Application Route	: Subcutaneous
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
------------	---

Insulin Porcine (with Metacresol) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.12.2024
4.0	14.04.2025	11259173-00006	Date of first issue: 11.08.2023

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 toxicity)	:	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 (Chronic toxicity)	:	NOEC (Daphnia magna (Water flea)): 1 mg/l Exposure time: 21 d Remarks: Based on data from similar materials

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.
---------------------	---	---

Insulin Porcine (with Metacresol) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.12.2024
4.0	14.04.2025	11259173-00006	Date of first issue: 11.08.2023

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**NOM-002-SCT**

Not regulated as a dangerous good

Special precautions for user

Not applicable

SECTION 15. REGULATORY INFORMATION**Safety, health and environmental regulations/legislation specific for the substance or mixture**

Federal Law for the control of chemical precursors, : Hydrochloric acid
essential chemical products and machinery for
producing capsules, tablets and pills.

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 : 14.04.2025
Date format : dd.mm.yyyy

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
NOM-010-STPS-2014 : Mexico. Norm NOM-010-STPS-2014 on Chemicals Polluting
the Work Environment - Identification, Assessment and Control - Appendix 1 Occupational Exposure Limits
ACGIH / TWA : 8-hour, time-weighted average

Insulin Porcine (with Metacresol) Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.12.2024
4.0	14.04.2025	11259173-00006	Date of first issue: 11.08.2023

NOM-010-STPS-2014 / VLE- : Time weighted average limit value
PPT

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

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/>

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

The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

MX / Z8