

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
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SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier Trade name	:	Insulin Porcine (with Metacresol) Formulation
1.2 Relevant identified uses of	the s	substance or mixture and uses advised against
Use of the Sub- stance/Mixture		Veterinary product
Recommended restrictions on use	:	Not applicable
1.3 Details of the supplier of the	e saf	ety data sheet
Company	:	MSD Kilsheelan Clonmel Tipperary, IE
Telephone	:	353-51-601000
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)

Not a hazardous substance or mixture.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

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

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.



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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.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Insulin (ox), 8A-I-threonine-10A-I- isoleucine-	12584-58-6 235-703-3		>= 0,1 - < 1

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

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

4.2 Most important symptoms and effects, both acute and delayed None known.

4.3 Indication of any immediate medical attention and special treatment needed Treatment : Treat symptomatically and supportively.



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SECTION 5: Firefighting measures

5.1 Extinguishing media

	5 5		
	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	e substance or mixture
	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
5.3	Advice for firefighters		
	Special protective equipment for firefighters	:	Wear self-contained breathing apparatus for firefighting if nec- essary. 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, protec	tive	e equipment and emergency procedures
Personal precautions	:	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. 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.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up	:	Soak up with inert absorbent material.
		For large spills, provide dyking or other appropriate contain-
		ment to keep material from spreading. If dyked material can



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		Clean up remain bent. Local or national posal of this mat employed in the mine which regu Sections 13 and	e recovered material in appropriate container. ing materials from spill with suitable absor- regulations may apply to releases and dis- erial, as well as those materials and items cleanup of releases. You will need to deter- lations are applicable. 15 of this SDS provide information regarding ational 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	:	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 contami- nated 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.		
7.2 Conditions for safe storage,	inc	luding any incompatibilities		
Requirements for storage areas and containers	:	Keep in properly labelled containers. Store in accordance with the particular national regulations.		
Advice on common storage	:	Do not store with the following product types: Strong oxidizing agents Gases		
7.3 Specific end use(s) Specific use(s)	:	No data available		

7.1 Precautions for safe handling

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits



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Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Insulin (ox), 8A-I- threonine-10A-I- isoleucine-	12584-58-6	TWA	3 μg/m3 (OEB 4)	Internal

8.2 Exposure controls

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

Eye/face 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.
Material	:	Chemical-resistant gloves
Remarks Skin and body protection	:	Consider double gloving. 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.
Respiratory protection	:	No personal respiratory protective equipment normally re- quired.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties



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	range				
	Flamma	ability (solid, gas)	:	Not applicable	
	Flamma	ability (liquids)	:	No data available	9
		explosion limit / Upper bility limit	:	No data available	
		explosion limit / Lower bility limit	:	No data available	
	Flash p	oint	:	No data available	
	Auto-ig	nition temperature	:	No data available)
	Decom	position temperature	:	No data available)
	рН		:	6,9 - 7,8	
	Viscosi Visc	ty sosity, kinematic	:	No data available	•
	Solubili Wat	ty(ies) er solubility	:	No data available	
	Partition octanol	n coefficient: n- /water	:	Not applicable	
	Vapour	pressure	:	No data available	
	Relative	e density	:	No data available	
	Density	,	:	1,003 g/cm ³	
	Relative	e vapour density	:	No data available	
		characteristics icle size	:	Not applicable	
9.2 (Other in Explosi	formation ves	:	Not explosive	
	Oxidizir	ng properties	:	The substance o	r mixture is not classified as oxidizing.
	Evapor	ation rate	:	No data available)
	Molecu	lar weight	:	No data available	9



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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 : Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : None known.

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 exposure	:	Inhalation Skin contact
		Ingestion Eye contact

Acute toxicity

Not classified based on available information.

Product:

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 (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.

Components:

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



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	Remarks		: No data available			
		s eye damage/eye irr ssified based on availa				
	Compo	onents:				
	Insulin (ox), 8A-I-threonine-10A-I-isoleucine-: Remarks : No data available					
	Respir	atory or skin sensitis	tion			
		ensitisation ssified based on availa	le information.			
	Respiratory sensitisation Not classified based on available information.					
	Germ cell mutagenicity Not classified based on available information.					
	Components:					
	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			
	Genoto	oxicity in vivo	 Test Type: In vivo micronucleus test Cell type: Bone marrow Method: OECD Test Guideline 475 Result: negative 			
	Germ o sessme	ell mutagenicity- As- ent	: Weight of evidence does not support classification as cell mutagen.	a germ		
		ogenicity ssified based on availa	le information.			
	Compo	onents:				

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

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



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Carcinogenicity - Assess- ment		: Weight of evide cinogen	ence does not support classification as a car-
Not cla	Reproductive toxicity Not classified based on available <u>Components:</u>		
Insulin (ox), 8A-I-threonine		-10A-I-isoleucine-:	
Effects on fertility		Species: Rat Application Ro Fertility: NOAE Symptoms: No	tility/early embryonic development ute: Intraperitoneal L Mating/Fertility: 360 μg/kg effects on fertility ects on fertility and early embryonic develop- ected.

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

Repeated dose toxicity

Components:

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

Species Application Route Exposure time Symptoms	: : : :	Rat 5,8 mg/kg Inhalation 6 Months Hypoglycemia
Species	:	Monkey 0,64 mg/kg
Application Route Exposure time Symptoms	:	
Species NOAEL Application Route Exposure time	::	Rat 0,085 mg/kg Subcutaneous 1 Months
Species NOAEL Application Route Exposure time	::	Dog 0,07 mg/kg Subcutaneous 1 Months

Aspiration toxicity

Not classified based on available information.



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11.2 Information on other hazards

Endocrine disrupting properties

Product:

Assessment

: 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.

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

12.1 Toxicity

No data available

12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

No data available

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.



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12.7 Other adverse effects

No data available

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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. 		

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
ΙΑΤΑ	:	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
ΙΑΤΑ	:	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
ΙΑΤΑ	:	Not regulated as a dangerous good
14.4 Packing group		
ADN	:	Not regulated as a dangerous good
ADR	:	Not regulated as a dangerous good



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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.

SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII)	:	Not applicable
REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59).	:	Not applicable
REACH - List of substances subject to authorisation (Annex XIV)	:	Not applicable
Regulation (EC) on substances that deplete the ozone layer	:	Not applicable
Regulation (EU) 2019/1021 on persistent organic pollu- tants (recast)	:	Not applicable
Regulation (EU) No 649/2012 of the European Parlia- ment and the Council concerning the export and import of dangerous chemicals	:	Not applicable
Seveso III: Directive 2012/18/EU of the European Parliar major-accident hazards involving dangerous substances. Not applicable		t and of the Council on the control of

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



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are highlighted in the body of this document by two vertical lines.

Full text of other abbreviations

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; 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

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

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



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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.

NO / EN