SAFETY DATA SHEET



Insulin Porcine Formulation

Version 3.4	Revision Date: 2024/09/28		S Number: 100-00023	Date of last issue: 2023/12/07 Date of first issue: 2014/11/03
1. PROE	DUCT AND COMPANY ID	ENT	IFICATION	
Pro	duct name	:	Insulin Porcine F	ormulation
Oth	er means of identification	:		007401) SULIN FOR DOGS AND CATS (37255) ETPEN INSULIN FOR DOGS AND CATS
Mai	nufacturer or supplier's d	letai	ls	
Cor	mpany	:	MSD	
Ado	dress	:	126 E. Lincoln A Rahway, New Je	venue ersey U.S.A. 07065
Tele	ephone	:	908-740-4000	
Em	ergency telephone number	· :	1-908-423-6000	
E-m	nail address	:	EHSDATASTEW	/ARD@msd.com
Red	commended use of the ch	nem	ical and restriction	ons on use
	commended use strictions on use	:	Veterinary produ Not applicable	ct

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 which do not result in classification None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Insulin (ox), 8A-I-threonine-10A-I-isoleucine-	12584-58-6	0.137



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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.
Most important symptoms and effects, both acute and delayed	:	Rinse mouth thoroughly with water. None known.
Protection of first-aiders Notes to physician	:	No special precautions are necessary for first aid responders Treat symptomatically and supportively.
FIREFIGHTING 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 a so. Evacuate area.
Special protective equipment for firefighters	:	Wear self-contained breathing apparatus for firefighting if ne essary.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protec- tive 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.





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		Prevent spread barriers). Retain and disp	e leakage or spillage if safe to do so. ding over a wide area (e.g. by containment or oil pose of contaminated wash water. es should be advised if significant spillages ained.
Methods and materials for containment and cleaning up		For large spills ment to keep n be pumped, sto Clean up rema bent. Local or nation posal of this ma employed in th mine which reg Sections 13 an	hert absorbent material. , provide dyking or other appropriate contain- naterial from spreading. If dyked material can bre recovered material in appropriate container. ining materials from spill with suitable absor- al regulations may apply to releases and dis- aterial, as well as those materials and items e cleanup of releases. You will need to deter- gulations are applicable. Id 15 of this SDS provide information regarding national requirements.

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.
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

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

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

Engineering measures : Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., dripless quick connections). All engineering controls should be implemented by facility



Odour Threshold

pН



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			protect products, Containment tech are required to co	
Pers	onal protective equip	ment		
Resp	piratory protection	:	No personal resp quired.	piratory protective equipment normally re-
Hand	d protection		•	
Μ	laterial	:	Chemical-resista	nt gloves
	emarks protection	:	If the work enviro mists or aerosols Wear a faceshiel	gloving. ses with side shields or goggles. onment or activity involves dusty conditions, s, wear the appropriate goggles. d or other full face protection if there is a ct contact to the face with dusts, mists, or
Skin	and body protection	:	Work uniform or Additional body of task being perfor posable suits) to	garments should be used based upon the med (e.g., sleevelets, apron, gauntlets, dis- avoid exposed skin surfaces. degowning techniques to remove potentially
Hygi	ene measures	:	If exposure to ch eye flushing syst ing place. When using do n Wash contamina The effective ope engineering cont appropriate dego	emical is likely during typical use, provide ems and safety showers close to the work- tot eat, drink or smoke. ted clothing before re-use. eration of a facility should include review of rols, proper personal protective equipment, owning and decontamination procedures, e monitoring, medical surveillance and the
9. PHYSI	CAL AND CHEMICAL	PROF	PERTIES	
Арре	earance	:	suspension	
Colo	ur	:	off-white	
Odou	ur	:	odourless	

: No data available

: 7-7.8

Melting point/freezing point : No data available

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Initial boiling point and boiling is range : 100 °C Flash point : No data available Evaporation rate : No data available Flammability (solid, gas) : No data available Flammability (solid, gas) : No data available Upper explosion limit / Upper rationability limit : No data available Lower explosion limit / Lower rationability limit : No data available Vapour pressure : No data available Relative vapour density : No data available Relative vapour density : No data available Solubility(ies) : No data available Solubility(ies) : No data available Partition coefficient: n-		Revision Date: 2024/09/28		S Number: 00-00023	Date of last issue: 2023/12/07 Date of first issue: 2014/11/03
rangeIVFlash pointINo data availableEvaporation rateINo data availableFlammability (solid, gas)INo tapplicableFlammability (liquids)INo data availableUpper explosion limit / UpperINo data availableUpper explosion limit / LowerINo data availableLower explosion limit / LowerINo data availableVapour pressureINo data availableRelative vapour densityINo data availableRelative densityINo data availableSolubility(ies)INo data availablePartition coefficient n- octanol/waterNo data availableAuto-ignition temperatureINo data availableDecomposition temperatureINo data availableViscosity Viscosity, kinematicINo data availableExplosive propertiesINo data availableOxidizing propertiesINo data availableParticle characteristics Particle sizeINo data availableParticle characteristics Particle sizeINo data availableParticle sizeINo data availableParticle characteristics Particle sizeINo data availableParticle sizeINo data available					
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Molecular weight : No data available Particle characteristics : No data available Particle size : No data available STABILITY AND REACTIVITY : Not classified as a reactivity hazard.	Explosive	e properties	:	Not explosive	
Particle characteristics Particle size : No data available STABILITY AND REACTIVITY Reactivity : Not classified as a reactivity hazard.	Oxidizing	g properties	:	The substance or	mixture is not classified as oxidizing.
Particle size : No data available STABILITY AND REACTIVITY : Not classified as a reactivity hazard.	Molecula	r weight	:	No data available)
Reactivity : Not classified as a reactivity hazard.			:	No data available	9
	STABILIT	Y AND REACTIVITY	,		
			:		





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Possi	bility of hazardous reac	- : Can react wi	th strong oxidizing agents.
tions Cond Incom	itions to avoid npatible materials rdous decomposition	: None known : Oxidizing ago	
1. TOXIC	OLOGICAL INFORMA	TION	
Inforn expos	nation on likely routes of sure	f : Inhalation Skin contact Ingestion Eye contact	
	e toxicity		
	lassified based on availa	able information.	
<u>Com</u>	oonents:		
Acute	in (ox), 8A-I-threonine- toxicity (other routes of histration)		
-	corrosion/irritation lassified based on availa	able information.	
<u>Com</u>	ponents:		
Insul	in (ox), 8A-I-threonine-	10A-I-isoleucine-:	
Rema	arks	: No data availa	able
	us eye damage/eye irr lassified based on availa		
	oonents:		
Insul	in (ox), 8A-I-threonine-	-10A-I-isoleucine-:	
Rema		: No data availa	
Resp	iratory or skin sensitis	sation	
Skin	sensitisation lassified based on availa		
-	iratory sensitisation lassified based on availa	able information.	
	a cell mutagenicity assified based on availa	able information.	
<u>Com</u>	oonents:		
Insul	in (ox), 8A-I-threonine-	-10A-I-isoleucine-:	
Geno	toxicity in vitro	: Test Type: Ba	acterial reverse mutation assay (AMES)



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			n: Salmonella typhimurium ECD Test Guideline 471 ative
		Test system	Chromosome aberration test in vitro n: Chinese hamster lung cells ECD Test Guideline 473 ative
Geno	toxicity in vivo	Cell type: B	In vivo micronucleus test one marrow ECD Test Guideline 475 ative
	cell mutagenicity -	: Weight of e cell mutage	vidence does not support classification as a germ n.
Not c	nogenicity lassified based on avai ponents:	lable information.	
Insul	in (ox), 8A-I-threonine	e-10A-I-isoleucin	9 -:

Species
Application Route
Exposure time
LOAEL:Rat
Subcutaneous
:Carcinogenicity - Assess-
ment:Weight of evidence does not support classification as a car-
cinogen

Reproductive toxicity

Not classified based on available information.

Components:

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.

STOT - repeated exposure

Not classified based on available information.



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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
Application Route Exposure time Symptoms	:	0.64 mg/kg Inhalation 6 Months Hypoglycemia
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.

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

12. ECOLOGICAL INFORMATION

Ecotoxicity

No data available **Persistence and degradability** No data available **Bioaccumulative potential** No data available **Mobility in soil** No data available



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Othe	r adverse effects					
No da	ata available					
13. DISPO	OSAL CONSIDERATIO	NS				
Disp	osal methods					
Waste from residues		•	Do not dispose of waste into sewer. Dispose of in accordance with local regulations.			
Cont	aminated packaging					
14. TRAN	SPORT INFORMATIO	N				
Inter	national Regulations					
UNR	TDG					
	umber	: Not applicable				
Prop	er shipping name	: Not applicable : Not applicable	Not applicable			
	idiary risk	: Not applicable				
Pack	ing group	: Not applicable	Not applicable			
Labe Envir	ls onmentally hazardous	: Not applicable : no				
	-DGR	.				
UN/II	JINO.	: Not applicable				

IATA-DGR		
UN/ID No.	:	Not applicable
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)		
IMDC Code		
IMDG-Code		
UN number		Not applicable

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

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

Not applicable for product as supplied.

Special precautions for user

Not applicable



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15. REGULATORY INFORMATION

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

Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.

Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances
Hazardous to Health

Hazardous substances that must be registered	:	Not applicable
----------------------------------------------	---	----------------

Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances

Hazardous substances approved for use	:	Not applicable
Prohibited substances	:	Not applicable
Restricted substances	:	Not applicable

Regulation of the Ministry of Trade No. 7 of 2022 on Distribution and Control of Hazardous Materials

Type of hazardous materials subject to distribution and : Not applicable control, Annex I

Type of hazardous materials subject to distribution and : Not applicable control, Annex II

The components of this product are reported in the following inventories:

AICS	:	not determined
DSL	:	not determined
IECSC	:	not determined

16. OTHER INFORMATION

Revision Date	:	2024/09/28
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/
Date format	:	yyyy/mm/dd

Full text of other abbreviations



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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

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.

ID / EN