

according to the Hazardous Products Regulations

## **Insulin Porcine Formulation**

Version 2.9	Revision Date: 09/28/2024		DS Number: 389-00026	Date of last issue: 12/07/2023 Date of first issue: 11/03/2014	
SECTION	1. IDENTIFICATION				
Product name Other means of identification		-	Insulin Porcine Formulation CANINSULIN (A007401) CANINSULIN INSULIN FOR DOGS AND CATS (37255) CANINSULIN VETPEN INSULIN FOR DOGS AND CATS (65973)		
Manufacturer or supplier's details					
Comp Addre	any name of supplier ss		Merck & Co., Inc 126 E. Lincoln Av Rahway, New Jer	renue rsey U.S.A. 07065	
Telepł	none	:	908-740-4000		
	ency telephone		1-908-423-6000		
E-mail	address	:	EHSDATASTEW	ARD@merck.com	
Recor	nmended use of the c	hen	nical and restriction	ons on use	
	nmended use	:	Veterinary produc	ct	
Restrie	ctions on use	:	Not applicable		

### **SECTION 2. HAZARDS IDENTIFICATION**

#### GHS classification in accordance with the Hazardous Products Regulations

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

Common Name/Synonym	CAS-No.	Concentration (% w/w)
No data availa- ble	12584-58-6	0.137

#### **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.



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Most important symptoms and effects, both acute and delayed		:	Get medical atten Rinse mouth thoro None known.	tion if symptoms occur. oughly with water.	
_	Protec	tion of first-aiders to physician	:		itions are necessary for first aid responders. cally and supportively.
SEC	TION 5	5. FIRE-FIGHTING ME	ASL	IRES	
	Suitabl	e extinguishing media	:	Water spray Alcohol-resistant Carbon dioxide (C Dry chemical	
	Unsuitable extinguishing media		:	None known.	
	Specifi fighting	c hazards during fire )	:	Exposure to com	oustion products may be a hazard to health.
	Hazaro ucts	lous combustion prod-	:	No hazardous cor	nbustion products are known
	Specifi ods	c extinguishing meth-	:	cumstances and t Use water spray t	measures that are appropriate to local cir- he surrounding environment. o cool unopened containers. ged containers from fire area if it is safe to do
		l protective equipment fighters	:	necessary.	ed breathing apparatus for firefighting if rective equipment.

### SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protec- tive equipment and emer- gency 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



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		container. Clean up rema absorbent. Local or nation disposal of this employed in th determine whic Sections 13 an	d, store recovered material in appropriate ining materials from spill with suitable al regulations may apply to releases and a material, as well as those materials and items e cleanup of releases. You will need to ch regulations are applicable. In 15 of this SDS provide information regarding in 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.
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 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).

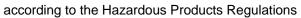
 All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

 Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).

 Minimize open handling.

### Personal protective equipment

Respiratory protection : No personal respiratory protective equipment normally required.



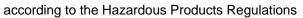


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Hand p	protection					
Ma	terial	: Chemical-resist	ant gloves			
Remarks Eye protection		If the work envir mists or aeroso Wear a faceshie	e gloving. sses with side shields or goggles. ronment or activity involves dusty conditions, ls, wear the appropriate goggles. eld or other full face protection if there is a ect contact to the face with dusts, mists, or			
Skin and body protection		Additional body task being perfo disposable suits Use appropriate	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.			
Hygiene measures :		: If exposure to cl eye flushing sys working place. When using do Wash contamin The effective op engineering cor appropriate deg	hemical is likely during typical use, provide stems and safety showers close to the not eat, drink or smoke. ated clothing before re-use. beration of a facility should include review of ntrols, proper personal protective equipment, owning and decontamination procedures, ne monitoring, medical surveillance and the			

#### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	suspension
Color	:	off-white
Odor	:	odorless
Odor Threshold	:	No data available
рН	:	7 - 7.8
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	100 °C
Flash point	:	No data available
Evaporation rate	:	No data available
Flammability (solid, gas)	:	Not applicable
Flammability (liquids)	:	No data available
Upper explosion limit / Upper	:	No data available





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	flamma	ability limit			
		explosion limit / Lower ability limit	:	No data available	
	Vapor	oressure	:	No data available	)
	Relativ	e vapor density	:	No data available	)
	Relativ	e density	:	1.004 - 1.007	
	Density	/	:	No data available	2
	Solubili Wat	ity(ies) ter solubility	:	soluble	
	Partitio octanol	n coefficient: n-	:	Not applicable	
		nition temperature	:	No data available	)
	Decom	position temperature	:	No data available	)
	Viscosi Visc	ty cosity, kinematic	:	No data available	
	Explosi	ive properties	:	Not explosive	
	Oxidizi	ng properties	:	The substance o	r mixture is not classified as oxidizing.
	Molecu	llar weight	:	No data available	9
	Particle Particle	e characteristics e size	:	No data available	9

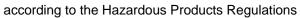
### SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
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 products	:	No hazardous decomposition products are known.

### SECTION 11. TOXICOLOGICAL INFORMATION

### Information on likely routes of exposure

Inhalation Skin contact





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Inges Eye o	stion contact					
	e toxicity lassified based on avail	able	information			
	ponents:					
Acute	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.					
Com	ponents:					
Insul	lin (ox), 8A-I-threonine	-10/	A-I-isoleucine-:			
Rema	arks	:	No data available			
	ous eye damage/eye ir classified based on avail					
<u>Com</u>	ponents:					
	in (ox), 8A-I-threonine	-104				
Rema	arks	:	No data available			
Resp	piratory or skin sensiti	zatio	on			
•	sensitization	ablo	information			
	Not classified based on available information. Respiratory sensitization					
-	Not classified based on available information.					
	Germ cell mutagenicity Not classified based on available information.					
<u>Com</u>	ponents:					
Insul	in (ox), 8A-I-threonine	-104	A-I-isoleucine-:			
Genc	otoxicity in vitro	:		rial reverse mutation assay (AMES) nonella typhimurium est Guideline 471		
				nosome aberration test in vitro nese hamster lung cells est Guideline 473		
Geno	otoxicity in vivo	:	Test Type: In vivo Cell type: Bone m Method: OECD T			



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		Result: nega	tive		
	cell mutagenicity -	: Weight of ev cell mutager	idence does not support classification as a germ		
Not c	<b>Carcinogenicity</b> Not classified based on available information. <u>Components:</u>				
	in (ox), 8A-I-threonine	e-10A-I-isoleucine			
Speci Applio	es cation Route sure time	: Rat : Subcutaneou : 2 Years : 180 µg/kg			
Carci ment	nogenicity - Assess-	: Weight of ev cinogen	idence does not support classification as a car-		
-	<b>Reproductive toxicity</b> 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 development were detected.
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#### STOT-single exposure

Not classified based on available information.

#### STOT-repeated exposure

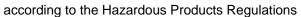
Not classified based on available information.

### Repeated dose toxicity

#### **Components:**

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

Species	:	Rat
Application Route Exposure time Symptoms	: :	5.8 mg/kg Inhalation 6 Months Hypoglycemia
Species	:	Monkey 0.64 mg/kg
Application Route	:	Inhalation





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Expo	sure time	: 6 Months	
Symp	toms	: Hypoglycemia	
••		: Rat : 0.085 mg/kg : Subcutaneous : 1 Months	
		: 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

#### **SECTION 12. ECOLOGICAL INFORMATION**

<b>Ecotoxicity</b> No data available
Persistence and degradability
No data available
Bioaccumulative potential
No data available
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	
Contaminated packaging	Empty containers should be taken to handling site for recycling or dispose If not otherwise specified: Dispose o	al.



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#### **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

#### TDG

Not regulated as a dangerous good

#### Special precautions for user

Not applicable

#### SECTION 15. REGULATORY INFORMATION

#### The ingredients of this product are reported in the following inventories:

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

#### **SECTION 16. OTHER INFORMATION**

#### Full text of other abbreviations

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



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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 Agen- cy, http://echa.europa.eu/
Revision Date Date format	:	09/28/2024 mm/dd/yyyy

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.

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