



SECTION 1: IDENTIFICATION	
1.1 Product identifier	
Product name:	CosACTHen 0.25 mg/ml Solution for Injection for Dogs
Synonyms:	None
Proper Shipping name:	Not applicable
Other means of identification:	None
1.2 Relevant identified uses of the substances or mixture and uses advised against	
Recommended uses:	For the evaluation of adrenal function in dogs
Uses advised against:	Not for human use.
1.3 Details of the supplier of the substance or mixture	
Registered company name (EU):	Dechra Regulatory B.V.
Address:	Handelsweg 25 5531 AE Bladel The Netherlands
Telephone:	+31 (0) 497 544 300
Website:	www.dechra.com
Fax:	+31 (0)497 544 302
Website:	www.dechra.com
Email:	Not Available
Distributor name (Canada):	Dechra Veterinary Products
Address:	1 Holiday Ave, East Tower, Suite 345 Pointe-Claire, QC H9R 5N3 Canada
Telephone:	+1 (855) 332-9334
Website:	www.dechra.ca
Email:	Not Available
1.4 Emergency Telephone Numbers	
Dechra (CA):	+1 (855) 332-9334
Dechra (EU):	+31 (0)497 544 300



SECTION 2: HAZARDS IDENTIFICATION	
2.1 Classification of the substance or mixture	
<p>Not considered a hazardous mixture according to Reg. (EC) No 1272/2008 and their amendments. Not classified as Dangerous Goods for transport purposes (EU).</p> <p>Not considered a Hazardous Substance by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200). Not classified as Dangerous Goods for transport purposes (US).</p>	
Classification according to regulation (EC) No 1272/2008 [CLP] (EU)¹:	Not applicable
Classification (US):	Not applicable
2.2 Label Elements	
GHS Label Elements:	None
Signal Word:	Not applicable
Hazard statement(s):	
None	
Supplementary Statement(s) EU:	
	Not applicable
Precautionary Statement(s) Prevention:	
	Not applicable
Precautionary Statement(s) Response:	
	Not applicable
Precautionary Statement(s) Storage:	
P405	Store locked up.
Precautionary Statement(s) Disposal:	
P501	Dispose of contents/container in accordance with local regulations.
2.3 Other Hazard Information	
REACH (EU) Article 57-59: The mixture does not contain Substances of Very High Concern (SVHC) at the SDS print date.	



SECTION 3: INFORMATION ON THE INGREDIENTS			
3.1 Substances			
See section below for composition of mixtures			
3.2 Mixtures			
1.CAS No 2.EC Number 3.Index Number 4.REACH Number	% Weight	Name	Classification according to regulations (EC) No 1272/2008 [CLP] (EU)
1.7647-14-5 2.231-598-3 3.Not Available 4.01-2119485491-33-XXXX	<1	Sodium chloride	Skin Corrosion/Irritation Category 2, Eye Irritation Category 2, Specific target organ toxicity - single exposure Category 3 (respiratory tract irritation); H315, H319, H335 [1]
1.64-19-7 2.200-580-7 3.607-002-00-6 4.01-2119475328-30-XXXX	<1	Acetic acid	Flammable Liquid Category 3, Skin Corrosion/Irritation Category 1A; H226, H314 [2]
1.6131-90-4 2.204-823-8 3.Not Available 4.01-2119485123-42-XXXX	<0.1	Sodium acetate	Skin Corrosion/Irritation Category 2, Eye Irritation Category 2, Specific target organ toxicity - single exposure Category 3 (respiratory tract irritation); H315, H319, H335 [1]
1.16960-16-0 2.241-031-1 3.Not Available 4.Not Available	<0.1	Tetracosactin	Not applicable
	Balance	Ingredients determined not to be hazardous	
Legend:	1. Classified by Chemwatch; 2 Classification drawn from EC Directive 1272/2008 – Annex VI		



SECTION 4: FIRST AID MEASURES	
4.1 Description of first aid measures	
Eye contact:	Accidental spillage on the eyes should be washed off with plenty of water. If pain or irritation occurs, seek medical advice and show the package leaflet or the label to the medical practitioner.
Skin contact:	Accidental spillage on the skin should be washed off with plenty of water. If irritation occurs, seek medical advice and show the package leaflet or the label to the medical practitioner.
Inhalation:	Inhalation is highly unlikely due to the nature of the product and how it is packaged and administered. If irritation or difficulty in breathing occurs, seek urgent medical advice and show the package leaflet or the label to the medical practitioner. Remove the patient from the contaminated area. Lay the patient down, keep warm and rested.
Ingestion:	Ingestion is highly unlikely due to the nature of the product and how it is packaged and administered. If swallowed, seek urgent medical advice and show the package leaflet or the label to the medical practitioner. Remove material and give water to rinse out mouth, then provide liquid slowly and as much as casualty can comfortably drink.
Self-injection:	Care should be taken when handling the product to avoid self-injection, especially by pregnant or breast feeding women. Read the package leaflet before use for full instructions and user warnings.
4.2 Most important symptoms and effects, both acute and delayed	
Eye contact:	Not expected to cause any eye irritation
Skin contact:	Hypersensitivity to the active substance or excipients may occur after prolonged or repeated exposure. Entry into the blood-stream, through cuts, abrasions or lesions, may produce systemic injury with harmful effects.
Ingestion:	Not expected to cause any gastrointestinal problems.
Self-injection:	Although risk from a one-off accidental exposure is considered low, pregnant or breastfeeding women should take care to avoid contact with the veterinary medicinal product, in particular to avoid accidental self-injection.
See Section 11 for more detailed information	



4.3 Indication of immediate medical attention and special treatment needed

Treat symptomatically.

When used in human medicine, tetracosactide is contraindicated in patients with allergic disorders, such as asthma, due to an increased risk of development of more severe hypersensitivity disorders. In particular, if you have an allergic disorder and develop symptoms following exposure such as skin reactions, dizziness, nausea, vomiting, urticaria, pruritus, flushing, malaise, dyspnoea, angioneurotic oedema or Quincke's oedema, or exhibit any signs of anaphylactic shock, you should seek medical advice immediately and show the doctor this warning.

Tetracosactide has not been tested in reproductive or developmental toxicity studies, but the pharmacological effects on the hypothalamic-pituitary-adrenal axis can have adverse effects in pregnancy. Although risk from a one-off accidental exposure is considered low, pregnant or breastfeeding women should take care to avoid contact with the veterinary medicinal product, in particular to avoid accidental self-injection. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or label to the physician.

SECTION 5: FIRE FIGHTING MEASURES

5.1 Extinguishing media

Suitable:	Select extinguishing media suitable for surrounding area
Unsuitable:	There is no restriction on the type of extinguisher which may be used

5.2 Special hazards arising from the substance or mixture

Fire incompatibility:	None known
------------------------------	------------

5.3 Special protective actions for fire-fighters:

Firefighting:	Use water delivered as a fine spray to control fire and cool adjacent area. Do not approach containers suspected to be hot. Cool fire exposed containers with water spray from a protected location. If safe to do so, remove containers from path of fire. Equipment should be thoroughly decontaminated after use.
Fire / explosion hazard:	Non-combustible. Not considered a significant fire risk, however containers may burn.



SECTION 6: ACCIDENTAL RELEASE MEASURES	
6.1 Personal precautions, protective equipment and emergency procedures	
For information on protective equipment, see section 8	
6.2 Environmental Precautions	
See section 12	
6.3 Methods and material for containment and cleaning up	
Spills are unlikely due to the nature of the product and how it is packaged	
Minor Spills:	Clean up all spills immediately. Avoid breathing vapours and contact with skin and eyes. Control personal contact with the substance, by using protective equipment. Contain and absorb spill with sand, earth, inert material or vermiculite. Place in a suitable, labelled container for waste disposal.
Major Spills:	Clear area of personnel and move upwind. Alert Fire Brigade and tell them location and nature of the hazard. Contain and absorb spill with sand, earth, inert material or vermiculite. Prevent, by any means available, spillage from entering drains or water course.

SECTION 7: HANDLING AND STORAGE	
7.1 Precautions for safe handling	
Safe Handling:	Wear suitable protection gloves and clothing when handling the product. When handling, DO NOT eat, drink or smoke. Always wash hands with water after handling. In case of accidental self-injection seek medical advice immediately and show the package leaflet or the label to the physician. Observe manufacturer's storage and handling recommendations.
Other Information:	Store in a refrigerator (2°C - 8°C). Keep the vial in the outer carton in order to protect from light. Keep out of the reach and sight of children.
7.2 Conditions for safe storage, including any incompatibilities	
Suitable Container:	Check that containers are clearly labelled. Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Storage incompatibility:	No known incompatibilities.



7.3 Specific end uses
Not available

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control parameters

DERIVED NO EFFECT LEVEL – DNEL (EU)
--

Not Available

PREDICTED NO EFFECT LEVEL – PNEC (EU)
--

Not Available

OCCUPATIONAL EXPOSURE LIMITS (OEL)


INGREDIENT DATA

Not Available

EMERGENCY LIMITS (EU/US):

Ingredient	Material Name	TEEL-1	TEEL-2	TEEL-3
Sodium chloride	Sodium chloride	0.5 ppm	2 ppm	20 ppm
Sodium acetate trihydrate	Sodium acetate trihydrate	11 mg/m ³	120 mg/m ³	690 mg/m ³

Ingredient	Original IDLH	Revised IDLH
Tetracosactin	Not Available	Not Available
Sodium chloride	Not Available	Not Available
Sodium acetate trihydrate	Not Available	Not Available
Water	Not Available	Not Available

8.2 Exposure controls	
Appropriate engineering controls:	The basic types of engineering controls are: Process controls which involve changing the way a job activity or process is done to reduce the particular risk.
Personal protection:	
Eye and face protection:	Safety glasses with side shields / chemical goggles
Skin protection:	See hand protection below
Hands/ feet protection:	No special equipment needed when handling small quantities. OTHERWISE: Wear chemical protective gloves
Body protection:	Wear appropriate clothing
Other protection:	No special equipment needed when handling small quantities
Thermal hazards:	Not applicable
Respiratory protection:	Not applicable
8.3 Environmental exposure controls	
See Section 12	

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance: Liquid

Container: Carton containing Type I clear glass vial (containing 1 ml) with a coated rubber stopper and aluminium seal. One vial per cardboard box.

Physical state: Liquid

Odour: Not available

Odour Threshold: Not available

pH (as supplied): Not available

Melting point / freezing point (degrees C): Not available

Initial boiling point and boiling range: Not available

Flash Point: In water – no flash point

Evaporation rate: Not available

Flammability: Not available

Upper/lower flammability or explosive limits: Not available

Vapour pressure: Not available

Relative Density (at degrees C): Not available

Solubility in water and solvents (mg/l): Water: miscible

Vapour density: Not available

Auto ignition temperature (degrees C): Not available

Decomposition temperature (degrees C): Not available

Viscosity: (degrees C): Not available

Explosive properties: Not available

Oxidising properties: Not available

Partition Coefficient: Not available

Molecular weight: Not available

Taste: Not available

Surface tension: Not available

Volative component: Not available

Gas group: Not available

pH as a solution: Not available

VOC g/L: Not available

9.2 Other information

Not Available



SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity:	See Section 7.
10.2 Chemical stability:	Product is considered stable. Hazardous polymerisation will not occur.
10.3 Possibility of hazardous reactions:	The product is not considered to be hazardous if used as per instructions. Hazardous polymerisation will not occur.
10.4 Conditions to avoid:	Protect from light.
10.5 Incompatible materials:	See section 7.
10.6 Hazardous decomposition:	See Section 5.

SECTION 11: TOXICOLOGICAL INFORMATION

Inhalation:	Not normally a hazard due to non-volatile nature of product.	
Ingestion:	Not classified as 'harmful by ingestion'	
Skin contact:	<p>The material may cause skin irritation after prolonged or repeated exposure. Hypersensitivity to the active substance or excipients may occur.</p> <p>Skin contact with the material may damage the health of the individual; systemic effects may result following absorption.</p> <p>Open cuts, abraded or irritated skin should not be exposed to this material.</p> <p>Entry into the blood-stream, through cuts, abrasions or lesions, may produce systemic injury with harmful effects. Examine the skin prior to the use of the material and ensure that any external damage is suitably protected.</p>	
Eye contact:	Not expected to cause eye irritation.	
Chronic:	Long term exposure is not expected to cause chronic adverse effects	
Self-injection:	Tetracosactide has not been tested in reproductive or developmental toxicity studies, but the pharmacological effects on the hypothalamic-pituitary-adrenal axis can have adverse effects in pregnancy. Although risk from a one-off accidental exposure is considered low, pregnant or breastfeeding women should take care to avoid contact with the veterinary medicinal product, in particular to avoid accidental self-injection.	
CosACTHen:	Toxicity	Irritation
	Not available	Not available



Tetracosactide:	Toxicity	Irritation
	Not available	Not available
Sodium chloride:	Acute toxicity	Irritation
	Oral (rat) LD ₅₀ : 3000 mg/kg ²	Eye (Rabbit): 10 mg – moderate Skin (rabbit): 500 mg/24h - mild
Sodium acetate:	Acute toxicity	Irritation
	Oral (rat) LD ₅₀ : 3530 mg/kg ²	Eye (Rabbit): 10 mg – mild Skin (rabbit): 550 mg/24h - mild
<i>1.* Value obtained from manufacturer's SDS. Unless otherwise specified, data extracted from RTECS - Register of Toxic Effect of chemical Substances</i>		
Skin corrosion/irritation:		
Not expected to cause skin corrosion/ irritation		
Serious eye damage/irritation:		
Not expected to cause eye damage/ irritation		
Respiratory or skin sensitization:		
Not expected to be a respiratory sensitization. May cause skin irritation after prolonged or repeated exposure. Hypersensitivity to the active substance or excipients may occur.		
Germ cell mutagenicity:		
Not mutagenic in Ames, in vitro or in vivo tests		
Carcinogenicity:		
Not expected to be carcinogenic.		
Reproductive toxicity:		
Tetracosactide has not been tested in reproductive or developmental toxicity studies, but the pharmacological effects on the hypothalamic-pituitary-adrenal axis can have adverse effects in pregnancy.		
STOT – single exposure:		
Not available		
STOT–repeated exposure:		
Not available		
Aspiration hazard:		
Not available		



SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Ingredient	Endpoint	Test duration (hr)	Species	Value	Source
Tetracosactide	Not available	Not available	Not available	Not available	Not available
Sodium chloride	LC50 EC50 EC50 NOEC	96 48 96 6	Fish Crustacea Algae or other aquatic plants Fish	5-840 mg/l 402.6 mg/l 2430 mg/l 0.001 mg/l	2 4 4 4
Acetic acid	LC50 EC50 EC50 NOEC	96 48 72 72	Fish Crustacea Algae or other aquatic plants Algae or other aquatic plants	>1 mg/l >1 mg/l >1 mg/l 1 mg/l	2 2 2 2
Sodium acetate	LC50 EC50 EC50 NOEC	96 48 72 72	Fish Crustacea Algae or other aquatic plants Algae or other aquatic plants	>100 mg/l >1 mg/l >1 mg/l 1 mg/l	2 2 2 2
Legend:	1. EPIWIN Suite V3.12 (QSAR) - Aquatic Toxicity Data (Estimated) 2. US EPA, Ecotox database - Aquatic Toxicity Data 2. IUCLID Toxicity data 3. Europe ECHA Registered Substances – Ecotoxicological Information – Aquatic Toxicity 4. US EPA, Ecotox database – Aquatic Toxicity Data				

DO NOT discharge into sewer or waterways.

12.2 Persistence and degradability

Ingredient	Persistence: Water/Soil	Persistence: Air
Sodium chloride	LOW	LOW
Acetic acid	LOW	LOW
Sodium acetate	LOW	LOW



12.3 Bioaccumulative potential	
Ingredient	Bioaccumulative Potential
Sodium chloride	LOW (LogKOW = 0.5392)
Acetic acid	LOW (LogKOW = -0.17)
Sodium acetate	HIGH (BCF = 29100)
12.4 Mobility in Soil	
Ingredient	Mobility
Sodium chloride	LOW (KOC = 14.3)
Acetic acid	HIGH (KOC = 1)
Sodium acetate	HIGH (KOC = 1)
12.5 Results of PBT and vPvB assessment	
Not Available	
12.6 Other adverse effects	
Not Available	

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods	
Product / packaging disposal:	<p>Any unused veterinary medicinal product or waste material derived from such veterinary medicinal products should be disposed of in accordance with national requirements.</p> <p>Legislation addressing waste disposal requirements may differ by country, state and/or territory. Each user must refer to laws operating in their area.</p> <p>Recycle wherever possible or consult manufacturer for recycling options. Consult State Land Waste Management Authority for disposal. Bury residue in an authorised landfill. Recycle containers if possible, or dispose of in an authorised landfill.</p> <p>Shelf life considerations should also be applied in making decisions of this type. Note that properties of a material may change in use, and recycling or reuse may not always be appropriate. Where in doubt contact the responsible authority.</p> <p>Ensure that the disposal of material is carried out in accordance with Hazardous Products Regulations (Canada, 2015).</p>
Waste Treatment Options:	Not Available



Sewage Disposal Options:	Not Available
---------------------------------	---------------

SECTION 14: TRANSPORT INFORMATION

Labels required:

Marine pollutant:	NO
Hazchem:	Not Applicable

Land transport (EU: ADR / US: DOT): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

Air transport (ICAO-IATA / DGR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

Sea transport (IMDG-Code / GGVSee): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

Inland waterways transport (ADN): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

SECTION 15: REGULATORY INFORMATION

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

SODIUM CHLORIDE IS FOUND ON THE FOLLOWING REGULATORY LISTS:

EU: EC / ECHA / EINECS / IMO / IOELVs / AND / GESAMP/EHS / IMO IBC / IMO MARPOL / IATA / IMDG Code
 US: IMO / DOE / OSHA / TSCA

ACETIC ACID IS FOUND ON THE FOLLOWING REGULATORY LISTS:

EU: EC / REACH / AND / ECHA / EINECS / GESAMP/EHS / IMO IBC / IMO MARPOL / IATA / IMDG Code
 US: GESAMP/EHS/ IMO IBC / IMO MARPOL / TLV / WEELs / TEELs / RELs / PELs / USPS / DOE/ DOT / OSHA / TSCA

SODIUM ACETATE IS FOUND ON THE FOLLOWING REGULATORY LISTS:

EU: EC / ECHA / EINECS / GESAMP/EHS / IMO IBC
 US: GESAMP/EHS/ IMO IBC / DOE/ DOT / OSHA / TSCA

TETRACOSACTIN IS FOUND ON THE FOLLOWING REGULATORY LISTS:

EU: EC / ECHA / EINECS
 US: OSHA

This safety data sheet is in compliance with the following EU legislation and its adaptations - as far as applicable: 98/24/EC, 92/85/EC, 94/33/EC, 91/689/EEC, 1999/13/EC, Commission Regulation (EU) 2015/830, Regulation (EC) No 1272/2008 and their amendments.



FEDERAL REGULATIONS:	
Superfund Amendments and Reauthorization Act of 1986 (SARA)	
Section 311/312 Hazard Categories	
Immediate (acute) health hazard	NO
Delayed (chronic) health hazard	YES
Fire hazard	NO
Pressure hazard	NO
Reactivity hazard	NO
US. EPA Cercla Hazardous Substances and Reportable Quantities (40 CFR 302.4) None reported	
STATE REGULATIONS:	
US. CALIFORNIA PROPOSITION 65 None reported	
15.2 Chemical Safety Assessment	

ECHA SUMMARY

Ingredient	CAS number	Index Number	ECHA Dossier
Sodium chloride	7647-14-5	Not Available	01-2119485491-33-XXXX

Harmonization (C&L Inventory)	Hazard Class and Category Code(s)	Pictograms Signal Word Code(s)	Hazard Statement Code(s)
1	Not classified	Not available	Not available
Harmonization Code 1 = The most prevalent classification. Harmonization Code 2 = The most severe classification			

Ingredient	CAS number	Index Number	ECHA Dossier
Acetic acid	64-19-7	607-002-00-6	01-2119475328-30-XXXX

Harmonization (C&L Inventory)	Hazard Class and Category Code(s)	Pictograms Signal Word Code(s)	Hazard Statement Code(s)
1	Flam. Liq. 3; Skin Corr. 1A	GHS02; GHS05; Dgr	H226; H314
Harmonization Code 1 = The most prevalent classification. Harmonization Code 2 = The most severe classification			



Ingredient	CAS number	Index Number	ECHA Dossier
Sodium acetate	6131-90-4	Not Available	01-2119485123-42-XXXX

Harmonization (C&L Inventory)	Hazard Class and Category Code(s)	Pictograms Signal Word Code(s)	Hazard Statement Code(s)
1	Not classified	Not available	Not available
Harmonization Code 1 = The most prevalent classification. Harmonization Code 2 = The most severe classification			

Ingredient	CAS number	Index Number	ECHA Dossier
Tetracosactin	16960-16-0	Not Available	Not Available

Harmonization (C&L Inventory)	Hazard Class and Category Code(s)	Pictograms Signal Word Code(s)	Hazard Statement Code(s)
1	Not classified	Not available	Not available
Harmonization Code 1 = The most prevalent classification. Harmonization Code 2 = The most severe classification			



National Inventory	Status
Australia - AICS	Yes
Canada - DSL	Yes
Canada - NDSL	No (tetracosactide, water, sodium chloride, sodium acetate)
China - IECSC	No (tetracosactide)
Europe - EINEC / ELINCS / NLP	Yes
Japan - ENCS	No (tetracosactide)
Korea - KECI	No (tetracosactide)
New Zealand - NZIoC	No (tetracosactide)
Philippines - PICCS	No (tetracosactide)
USA - TSCA	No (tetracosactide)
Taiwan – TCSI	Yes
Mexico – INSQ	No (tetracosactide)
Vietnam – NCI	No (tetracosactide)
Russia - ARIPS	No (tetracosactide)
Legend:	<i>Y = All ingredients are on the inventory N = Not determined or one or more ingredients are not on the inventory and are not exempt from listing (see specific ingredients in brackets)</i>



SECTION 16: OTHER INFORMATION

The SDS is written in accordance to guidelines specified by REACH, GHS, OSHA and ECHA.

Other Information

For detailed advice on Personal Protective Equipment, refer to the following EU CEN Standards:

- EN 166 Personal eye-protection
- EN 340 Protective clothing
- EN 374 Protective gloves against chemicals and micro-organisms
- EN 13832 Footwear protecting against chemicals
- EN 133 Respiratory protective devices

Definitions and abbreviations

- PC—TWA: Permissible Concentration-Time Weighted Average
- PC—STEL: Permissible Concentration-Short Term Exposure Limit
- STEL: Short Term Exposure Limit
- TEEL: Temporary Emergency Exposure Limit
- IDLH: Immediately Dangerous to Life or Health Concentrations

The information provided in this Safety Data Sheet has been compiled by Dechra Limited using a number of different sources, and is correct to the best of its knowledge, information and belief as at the date of its publication. However, Dechra Limited makes no warranties, express or implied, in relation to the information set out in this Safety Data Sheet, including, without limitation, as to its accuracy or completeness.

The information provided is not a quality specification, and is prepared by way of guidance as to the safe handling, use, processing, storage, transportation, disposal and release of the relevant products referred to. The user is responsible for determining whether or not the product is fit for any particular purpose and/or suitable for the user's proposed method of use and application.

Copyright, 2019, Dechra Limited. All rights reserved.

Copying and/or downloading of this information for the purpose of properly utilizing Dechra Limited products is permitted provided that: (1) the information is copied in full with no changes unless prior written agreement is obtained from Dechra Limited, and (2) neither the copy nor the original is resold or otherwise distributed for the purposes of making a profit thereon.