



SECTION 1: IDENTIFICATION	
1.1 Product identifier	
Product name:	Sedaxylan® (20mg/ml solution for injection for dogs, cats, horses and cattle)
Synonyms:	Also known as: SEDAXYLAN VET, SEDAMUN, or XYLAZ
Proper Shipping name:	Not Available
Other means of identification:	None
1.2 Relevant identified uses of the substances or mixture and uses advised against	
Recommended uses:	For the sedation of dogs, cats, horses and cattle.
Uses advised against:	<p>Not for human use.</p> <p>Pregnant women should not handle the product.</p> <ul style="list-style-type: none"> • Do not use in the later stages of pregnancy. • Do not use in animals with oesophageal obstruction, and torsion of the stomach, as the muscle relaxant properties of the drug appear to accentuate the effects of the obstruction, and because of possible vomiting. <ul style="list-style-type: none"> • Do not use in animals with renal or hepatic impairment, respiratory dysfunction, cardiac abnormalities, hypotension and/or shock. Do not use in diabetic animals. • Do not use in calves younger than 1 week of age, foals younger than 2 weeks or in puppies and kittens younger than 6 weeks. See also <i>Use during pregnancy and lactation</i>. • Do not use in the later stages of pregnancy (particularly in cattle and cats), because xylazine causes uterine contractions and it may induce premature labour. • Do not use in cattle receiving ovum transplants as the increased uterine tone may reduce the chance of implantation of the ovum.
1.3 Details of the supplier of the substance or mixture	
Registered company name:	Dechra Ltd
Address:	Snaygill Industrial Estate Keighley Road Skipton North Yorkshire BD23 2RW UK



Telephone:	+44 (0) 1756 791311
Fax:	+44 (0) 1756 798604
Email:	Not available
1.4 Emergency Telephone Numbers	
	+44 (0) 1756 791311

SECTION 2: HAZARDS IDENTIFICATION	
2.1 Classification of the substance or mixture	
DSD Classification (EU):	Not Available
DPD Classification (EU):	Not Available
Classification according to regulation (EC) No 1272/2008 [CLP] (EU):	Not Available
2.2 Label Elements	
Signal Word:	Not Available
Hazard Statement(s)	
Not Available	
Additional Statement(s)	
Not Available	
Precautionary Statement(s) Prevention:	
Not Available	
Precautionary Statement(s) Response:	
Not Available	
Precautionary Statement(s) Storage:	
Not Available	
Precautionary Statement(s) Disposal:	
Not Available	
2.3 Other Hazard Information	
Not Available	

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	% w/v	Name	Classification according to regulations (EC) No 1272/2008 [CLP] (EU)
1. 23076-35-9 2. 245-417-0 3. Not Available 4. Not Available	2.3	Xylazine hydrochloride	Not Available
N/a	Proprietary	Other ingredients determined not to be hazardous	N/a

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

Eye contact:	In the case of accidental projection of the product into the eyes, rinse abundantly with fresh water. Seek medical attention if irritation persists, showing the package leaflet or the label to the medical practitioner. Remove contaminated clothes.
Skin contact:	In case of accidental contact of the product with the skin rinse abundantly with fresh water. Remove contaminated clothing. Seek medical attention if irritation occurs, showing the package leaflet or the label to the medical practitioner.
Inhalation:	If fumes or combustion products are inhaled remove from contaminated area. Get medical aid if cough or other symptoms appear.
Ingestion:	In the case of accidental oral intake or self-injection, seek medical advice immediately and show the package insert to the medical practitioner but DO NOT DRIVE as sedation and changes in blood pressure may occur.
Self-injection:	In the case of accidental oral intake or self-injection, seek medical advice immediately and show the package insert to the medical practitioner but DO NOT DRIVE as sedation and changes in blood pressure may occur.

4.2 Most important symptoms and effects, both acute and delayed

See Section 11

4.3 Indication of immediate medical attention and special treatment needed

Advice to doctors: Xylazine is an α -adrenoreceptor agonist whose toxicity may cause clinical effects including sedation, respiratory depression and coma, bradycardia and hypotension and hyperglycaemia. Ventricular arrhythmias have also been reported. Treatment should be supportive with appropriate intensive therapy.

SECTION 5: FIRE FIGHTING MEASURES

5.1 Extinguishing media

Suitable: All systems may be used.

Unsuitable: None.

5.2 Special hazards arising from the substance or mixture

Fire incompatibility: None known.

5.3 Special protective actions for fire-fighters:

Firefighting: Alert Fire Brigade and tell them location and nature of hazard. Wear full breathing apparatus and self-contained breathing apparatus.

Fire / explosion hazard: Irritating and highly toxic gases may be generated from thermal decomposition or combustion. May be flammable at high temperatures.

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

Do not allow product to reach sewage system or any water course.

6.3 Methods and material for containment and cleaning up

Minor Spills: Absorb solution and place into a suitable disposal container.

Major Spills: Clean up all spills immediately. Absorb solution and place into a suitable disposal container. Control personal contact with the substance, by using protective equipment. Avoid contact with skin and eyes.



SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Safe Handling:	Avoid skin contact and wear impermeable gloves when handling the product. Wash the exposed skin immediately after exposure with large amounts of water. When handling, DO NOT eat, drink or smoke. Observe manufacturer's storage and handling recommendations.
Other Information:	Keep out of the reach and sight of children.

7.2 Conditions for safe storage, including any incompatibilities

Suitable Container:	Shelf life of the veterinary medicinal product as packaged for sale: 3 years. Shelf life after first opening the immediate packaging: 28 days.
Storage incompatibility:	In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

7.3 Specific end uses

Not available

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control parameters

DERIVED NO EFFECT LEVEL - DNEL

Not Available


PREDICTED NO EFFECT LEVEL - PNEC

Not Available

OCCUPATIONAL EXPOSURE LIMITS (OEL)

INGREDIENT DATA:

Not Available

EMERGENCY LIMITS:				
Ingredient	Material Name	TEEL-1	TEEL-2	TEEL-3
Not Available				
Ingredient	Original IDLH		Revised IDLH	
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: Sedaxylan®: Clear and colourless solution
Container: Glass Type II vial; volume: 30ml and 50ml, contents: 25ml and 50ml. Bromobutyl rubber stopper type I, secured with aluminium cap.
Physical state: Liquid
Odour: Not available
Odour Threshold: Not available
pH (as supplied): Not available
Melting point / freezing point (degrees C): Xylazine HCl melting point: 165 - 169°C
Initial boiling point and boiling range: Not available
Flash Point: Not available
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): Miscible in water
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: Xylazine HCl: 256.8
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

10: REACTIVITY AND STABILITY

10.1 Reactivity:	See Section 7
10.2 Chemical stability:	Product is considered stable.
10.3 Possibility of hazardous reactions:	Stable under normal temperatures and conditions.
10.4 Conditions to avoid:	None known.
10.5 Incompatible materials:	See section 7.

10.6 Hazardous decomposition:	See Section 5.
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SECTION 11: TOXICOLOGICAL INFORMATION	
Inhalation:	Not expected to cause respiratory tract irritation.
Ingestion:	Accidental oral intake or self-injection may cause sedation and changes in blood pressure.
Skin contact:	Irritation, sensitisation, contact dermatitis and systemic effects cannot be excluded after skin contact.
Eye contact:	Not expected to cause eye irritation.
Chronic:	Prolonged exposure to the product is not expected to cause chronic effects that are harmful to health (in the classification according to EC standards based on animal models); However, exposure through all routes should be minimised.
Sedaxylan®:	Acute toxicity
	Not Available
	Irritation
	Not Available
Xylazine Hydrochloride:	Acute toxicity
	Not Available
	Irritation
	Not Available
Skin corrosion / irritation:	
Not expected to cause serious skin corrosion or irritation.	
Serious eye damage / irritation:	
Not expected to cause serious eye damage or irritation.	
Respiratory or skin sensitization:	
Not expected to be a skin sensitizer.	
Germ cell mutagenicity:	
Not expected to be a mutagen.	
Carcinogenicity:	
Not expected to be carcinogenic.	
Reproductive toxicity:	
Although laboratory studies in rats have not shown any evidence of teratogenic or foetotoxic effects, the use of the product during the first two trimesters of pregnancy should only be made according to the benefit/risk assessment by the responsible veterinarian.	
STOT – single exposure:	



SECTION 11: TOXICOLOGICAL INFORMATION

Not available
STOT–repeated exposure:
Not available
Aspiration hazard:
Not available

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
No data available
12.6 Other adverse effects
No data 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>Ensure that the disposal of material is carried out in accordance with Hazardous Substances (Disposal) Regulations 2001.</p>

Waste Treatment Options:	Not Available
Sewage Disposal Options:	No environmental effects are anticipated.

SECTION 14: TRANSPORT INFORMATION

Labels required:	None	
Marine pollutant:	NO	
Hazchem:	Not Applicable	
Land transport (ADR):		
14.1 UN Number	N/a	
14.2 UN Proper Shipping Name	N/a	
14.3 Transport hazard class(es)	Class	N/a
	Sub risk	N/a
14.4 Packing group	N/a	
14.5 Environmental hazards	N/a	
14.6 Special precautions for user	Special provisions	N/a
	Classification code	N/a
	Hazard Label	N/a
	Special provisions	N/a
	Limited quantity	N/a

14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	N/a
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Air transport (ICAO-IATA / DGR):

14.1 UN Number	N/a	
14.2 UN Proper Shipping Name	N/a	
14.3 Transport hazard class(es)	ICAO/IATA Class	N/a
	ICAO / IATA Sub risk	N/a
	ERG Code	N/a

14.4 Packing group	N/a	
14.5 Environmental hazards	N/a	
14.6 Special precautions for user	Special provisions	N/a
	Cargo only packing instructions	N/a
	Cargo only maximum qty/pack	N/a
	Passenger and cargo packaging instructions	N/a
	Passenger and cargo maximum qty/pack	N/a
	Passenger and cargo limited quantity packing instructions	N/a
	Passenger and cargo limited maximum qty/pack	N/a
14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	N/a	
Sea transport (IMDG-Code / GGVSee):		
14.1 UN Number	N/a	
14.2 UN Proper Shipping Name	N/a	
14.3 Transport hazard class(es)	IMDG Class	N/a
	IMDG Sub risk	N/a
14.4 Packing group	N/a	
14.5 Environmental hazards	N/a	
14.6 Special precautions for user	EMS Number	N/a
	Special provisions	N/a
	Limited quantities	N/a



14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	N/a	
Inland waterways transport (ADN):		
14.1 UN Number	N/a	
14.2 UN Proper Shipping Name	N/a	
14.3 Transport hazard class(es)	N/a	N/a
14.4 Packing group	N/a	
14.5 Environmental hazard	N/a	
14.6 Special precautions for user	Classification Code	N/a
	Special provisions	N/a
	Limited quantity	N/a
	Equipment required	N/a
	Fire cones number	N/a
14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	N/a	

SECTION 15: REGULATORY INFORMATION

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

XYLAZINE HYDROCHLORIDE (23076-35-9) IS FOUND ON THE FOLLOWING REGULATORY LISTS:

- European Union-the European inventory of existing chemical substances (EINECS) (English)



15.2 Chemical Safety Assessment

ECHA SUMMARY

Ingredient	CAS number	Index Number	ECHA Dossier
Xylazine Hydrochloride	23076-35-9	Not Available	Not Available

Harmonization (C&L Inventory)	Hazard Class and Category Code(s)	Pictograms Signal Word Code(s)	Hazard Statement Code(s)
1	Acute Tox. 3, Skin Irrit. 2, Eye Irrit. 2, STOT SE 3	GHS06, Dgr	H301, H315, H319, H335
2	Acute Tox. 3, Skin Irrit. 2, Eye Irrit. 2, STOT SE 3, Eye Dam. 1, Aquatic Chronic 3, Acute Tox. 4, Acute Tox. 2	GHS06, Dgr, GHS09, GHS05	H335, H318, H412, H314, H311, H331, H300

Harmonization Code 1 = The most prevalent classification. Harmonization Code 2 = The most severe classification

Australia - AICS	Y
Canada - DSL	N
Canada - NDSL	N (Xylazine hydrochloride)
China - IECSC	N
Europe - EINEC / ELINCS / NLP	Y
Japan - ENCS	N (Xylazine hydrochloride)
Korea - KECI	N
New Zealand - NZIoC	Y
Philippines - PICCS	N (Xylazine hydrochloride)
USA - TSCA	N (Xylazine hydrochloride)
Legend:	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)

SECTION 16: OTHER INFORMATION

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

Ingredients with multiple CAS numbers:

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

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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

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