



SECTION 1: IDENTIFICATION	
<b>1.1 Product identifier</b>	
<b>Product name:</b>	Nerfasin vet. 20 mg/ml, solution for injection for cattle, horses, dogs and cats (AT, BE, CZ, DK, EL, FI, FR, HU, IS, LU, NL, NO, PL, SE, and SK)  Nerfasin 20 mg/ml, solution for injection for cattle, horses, dogs and cats (ES, IE, IT, PT and UK)  Nerfasin 20 <sup>®</sup> 20 mg/mL, solution for injection for cattle, dogs and cats (CA)
<b>Synonyms:</b>	None
<b>Proper Shipping name:</b>	Not applicable
<b>Other means of identification:</b>	None
<b>1.2 Relevant identified uses of the substances or mixture and uses advised against</b>	
<b>Recommended uses:</b>	Sedation. Pre-medication in combination with an anesthetic
<b>Uses advised against:</b>	<b>Not for human use.</b>
<b>1.3 Details of the supplier of the substance or mixture</b>	
<b>Registered company name (EU):</b>	Le Vet Beheer B.V.
<b>Address:</b>	Wilgenweg 7 3421 TV Oudewater The Netherlands
<b>Telephone:</b>	+31 (0)348 565858
<b>Fax:</b>	+31 (0)348 565454
<b>Website:</b>	<a href="http://www.dechra.com">www.dechra.com</a>
<b>Email:</b>	Not available
<b>Distributor name (Canada):</b>	Dechra Veterinary Products
<b>Address:</b>	1 Holiday Ave, East Tower, Suite 345 Pointe-Claire, QC H9R 5N3, Canada
<b>Telephone:</b>	+1 (855) 332-9334
<b>Website:</b>	<a href="http://www.dechra.ca">www.dechra.ca</a>
<b>Email:</b>	Not Available



<b>1.4 Emergency Telephone Numbers</b>	
<b>Dechra (EU):</b>	+31 (0)348 565858
<b>Dechra (CA):</b>	+1 (855) 332-9334

## SECTION 2: HAZARDS IDENTIFICATION

**2.1 Classification of the substance or mixture**  
**This product is exempted from Regulation according to article 1(5) of Reg. (EC) No 1272/2008 and their amendments, because it is a veterinary medicinal products as defined in Directive 2001/82/EC, which is in the finished state, intended for the final user. Not classified as Dangerous Goods for transport purposes (EU).**

<b>Classification according to regulation (EC) No 1272/2008 [CLP] (EU)<sup>1</sup>:</b>	Not applicable
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### 2.2 Label Elements

<b>Hazard Pictogram:</b>	Not applicable
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<b>Signal Word:</b>	Not applicable
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<b>Hazard statement(s):</b>	
	Not applicable

<b>Supplementary Statement(s) EU:</b>	
	Not applicable

<b>Precautionary Statement(s) Prevention:</b>	
	Not applicable

<b>Precautionary Statement(s) Response:</b>	
	Not applicable

<b>Precautionary Statement(s) Storage:</b>	
	Not applicable

<b>Precautionary Statement(s) Disposal:</b>	
	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)
1.23076-35-9 2.245-417-0 3. Not Available 4. Not Available	1-5	Xylazine hydrochloride	Not applicable
1.7647-14-5 2.231-598-3 3. Not Available 4.01-2119485491-33-XXXX	<1	Sodium chloride	Skin Corrosion/Irritation Category 2, Specific target organ toxicity - single exposure Category 3 (respiratory tract irritation), Eye Irritation Category 2; H315, H335, H319 [1]
Not available	Not specified	Ingredients determined not be hazardous	Not applicable
<b>Legend:</b>	1. Classified by Chemwatch; 2. Classification drawn from Regulation (EU) No 1272/2008 - Annex VI; 3. Classification drawn from C&L; * EU IOELVs available		

### SECTION 4: FIRST AID MEASURES

#### 4.1 Description of first aid measures

<b>Eye contact:</b>	If accidental eye contamination occurs, flush gently with fresh running water for 15 minutes. Medical advice should be sought if irritation persists.
<b>Skin contact:</b>	In the event of accidental skin contamination, contaminated clothing should be removed and the area washed with large amounts of soap and water. Medical advice should be sought if irritation persists.
<b>Inhalation:</b>	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, remove the patient from the contaminated area. Seek medical advice if irritation persists and show the package leaflet or the label to the medical practitioner.



<b>Ingestion:</b>	If swallowed, do not induce vomiting and immediately give water. If discomfort persists, seek medical advice and show the package leaflet or the label to medical practitioner.
<b>Self-injection:</b>	Care should be taken to avoid self-injection. In case of accidental self-injection, seek medical advice immediately and show the package leaflet to the physician, but DO NOT DRIVE as sedation and change in blood pressure may occur. Symptomatic treatment may be required.
<b>4.2 Most important symptoms and effects, both acute and delayed</b>	
<b>Eye contact:</b>	May cause eye irritation.
<b>Skin contact:</b>	May cause skin irritation.
<b>Ingestion:</b>	May cause discomfort if ingested in large quantities
<b>Self-injection:</b>	If pregnant women handle the product, special caution should be observed not to self-inject as uterine contractions and decreased foetal blood pressure may occur after accidental systemic exposure.
See Section 11 for more detailed information	
<b>4.3 Indication of immediate medical attention and special treatment needed</b>	
Xylazine is an $\alpha$ 2-adrenoreceptor agonist, symptoms after absorption may involve clinical effects including dose-dependent sedation, respiratory depression, bradycardia, hypotension, a dry mouth and hyperglycaemia. Ventricular arrhythmias have also been reported. Respiratory and haemodynamic symptoms should be treated symptomatically.	

<b>SECTION 5: FIRE FIGHTING MEASURES</b>	
<b>5.1 Extinguishing media</b>	
<b>Suitable:</b>	Select extinguishing media suitable for surrounding area
<b>Unsuitable:</b>	There is no restriction on the type of extinguisher which may be used
<b>5.2 Special hazards arising from the substance or mixture</b>	
<b>Fire incompatibility:</b>	None known
<b>5.3 Special protective actions for fire-fighters:</b>	
<b>Firefighting:</b>	Use water delivered as a fine spray to control fire and cool adjacent area. 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.
<b>Fire / explosion hazard:</b>	Non-combustible.



**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

<b>Minor Spills:</b>	Clean up all spills immediately. Avoid breathing vapours and contact with skin and eyes. Control personal contact with the substance, by using protective equipment. Place in a suitable, labelled container for waste disposal.
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<b>Major Spills:</b>	Clear area of personnel and move upwind. Alert Fire Brigade and tell them location and nature of the hazard. Prevent, by any means available, spillage from entering drains or water course.
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**SECTION 7: HANDLING AND STORAGE**

**7.1 Precautions for safe handling**

<b>Safe Handling:</b>	When handling, <b>DO NOT</b> eat, drink or smoke Always wash hands with water after handling. Observe manufacturer's storage and handling recommendations.
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<b>Other Information:</b>	Keep the vial in the outer carton in order to protect from light. This veterinary medicinal product does not require any special temperature storage conditions. Keep out of the reach and sight of children.
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**7.2 Conditions for safe storage, including any incompatibilities**

<b>Suitable Container:</b>	10 ml, 30 ml and 50 ml clear type II glass vials closed with a bromobutyl rubber stopper and aluminium cap in a carton box containing 10 ml, 25 ml and 50 ml product, respectively.
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<b>Storage incompatibility:</b>	Avoid contamination of water or food stuffs.
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**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**

Source	Ingredient	Material name	TWA	STEL	Peak	Notes
Not available						

**EMERGENCY LIMITS (EU):**

Ingredient	Material Name	TEEL-1	TEEL-2	TEEL-3
Sodium chloride	chloride	0.5 ppm	2 ppm	20 ppm

Ingredient	Original IDLH	Revised IDLH
Xylazine hydrochloride	Not available	Not available
Sodium chloride	Not available	Not available

**8.2 Exposure controls**

**Appropriate engineering controls:** Engineering controls are used to remove a hazard or place a barrier between the worker and the hazard. Well-designed engineering controls can be highly effective in protecting workers and will typically be independent of worker interactions to provide this high level of protection. The basic types of engineering controls are:  
 Process controls which involve changing the way a job activity or process is done to reduce the risk.  
 Enclosure and/or isolation of emission source which keeps a selected hazard "physically" away from the worker and ventilation that strategically "adds" and "removes" air in the work environment.

**Personal protection:**



**Eye and face protection:** Safety glasses with side shields / chemical goggles



<b>Skin protection:</b>	See hand protection below
<b>Hands/ feet protection:</b>	Wear chemical protective gloves
<b>Body protection:</b>	Wear appropriate clothing
<b>Other protection:</b>	Wear appropriate clothing
<b>Thermal hazards:</b>	Not applicable
<b>Respiratory protection:</b>	Not applicable
<b>8.3 Environmental exposure controls</b> See Section 12	

<b>SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES</b>
<b>9.1 Information on basic physical and chemical properties</b>
<p><b>Appearance:</b> Solution for injection  <b>Container:</b> 10 ml, 30 ml and 50 ml clear type II glass vials closed with a bromobutyl rubber stopper and aluminium cap in a carton box containing 10 ml, 25 ml and 50 ml product, respectively.  <b>Physical state:</b> Liquid  <b>Odour:</b> Not available  <b>Melting point / freezing point (degrees C):</b> Not available  <b>Initial boiling point and boiling range:</b> Not applicable  <b>Flash Point:</b> Not applicable  <b>Evaporation rate:</b> Not applicable  <b>Flammability:</b> Not available  <b>Upper/lower flammability or explosive limits:</b> Not available  <b>Vapour pressure:</b> Not applicable  <b>Specific Gravity:</b> Not available  <b>Solubility in water and solvents (mg/l):</b> Miscible in water  <b>Auto ignition temperature (degrees C):</b> Not available  <b>Decomposition temperature (degrees C):</b> Not available  <b>Viscosity: (degrees C):</b> Not available  <b>Explosive properties:</b> Not available  <b>Oxidising properties:</b> Not available  <b>Partition Coefficient:</b> Not available  <b>Taste:</b> Not applicable  <b>Surface tension:</b> Not available  <b>Volatile component:</b> Not available  <b>Gas group:</b> Not applicable  <b>pH:</b> 4.9 – 5.1  <b>VOC g/L:</b> Not applicable</p>
<b>9.2 Other information</b> Not Available



SECTION 10: STABILITY AND REACTIVITY	
<b>10.1 Reactivity:</b>	See Section 7.
<b>10.2 Chemical stability:</b>	Unstable in the presence of incompatible materials. Product is considered stable otherwise. Hazardous polymerisation will not occur.
<b>10.3 Possibility of hazardous reactions:</b>	The product is not considered to be hazardous if used as per instructions.
<b>10.4 Conditions to avoid:</b>	Protect from light.
<b>10.5 Incompatible materials:</b>	See section 7.
<b>10.6 Hazardous decomposition:</b>	See Section 5.

SECTION 11: TOXICOLOGICAL INFORMATION	
<b>Inhalation:</b>	Due to the nature of the product, the material is not thought to produce either adverse health effects or irritation of the respiratory tract following inhalation.
<b>Ingestion:</b>	Xylazine is an $\alpha$ 2-adrenoreceptor agonist, symptoms after absorption may involve clinical effects including dose-dependent sedation, respiratory depression, bradycardia, hypotension, a dry mouth and hyperglycaemia. Ventricular arrhythmias have also been reported.
<b>Skin contact:</b>	May cause skin irritation following contact. Open cuts, abraded or irritated skin should not be exposed to this material. Entry into the blood-stream, through, for example, 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.
<b>Eye contact:</b>	May cause eye irritation following contact.
<b>Chronic:</b>	Substance accumulation, in the human body, may occur and may cause some concern following repeated or long-term occupational exposure.

<b>Nerfasin vet /Nerfasin 20 mg/ml Solution for Injection for Horses, Cattle, Dogs and Cats</b>	<b>Toxicity</b>	<b>Irritation</b>
	Not available	May cause skin or eye irritation
Xylazine hydrochloride	<b>Toxicity</b>	<b>Irritation</b>
	Not available	Not available



Sodium chloride	<b>Toxicity</b>	<b>Irritation</b>
	Oral (rat) LD50: 3000 mg/kg <sup>2</sup>	Eye (rabbit): 10 mg - Moderate Skin (rabbit): 500mg/24h – mild
<p><i>1. Value obtained from Europe ECHA Registered Substances - Acute toxicity 2. * Value obtained from manufacturer's SDS. Unless otherwise specified data extracted from RTECS - Register of Toxic Effect of chemical Substances</i></p>		
<p><b>Skin corrosion/irritation:</b></p>		
<p>May cause skin corrosion/ irritation.</p>		
<p><b>Serious eye damage/irritation:</b></p>		
<p>May cause eye damage/ irritation</p>		
<p><b>Respiratory or skin sensitization:</b></p>		
<p>Due to nature of product, not expected to cause respiratory sensitization. Not expected to cause skin sensitization.</p>		
<p><b>Germ cell mutagenicity:</b></p>		
<p>Not available</p>		
<p><b>Carcinogenicity:</b></p>		
<p>Not available.</p>		
<p><b>Reproductive toxicity:</b></p>		
<p>If pregnant women handle the product, special caution should be observed not to self-inject as uterine contractions and decreased foetal blood pressure may occur after accidental systemic exposure.</p>		
<p><b>STOT – single exposure:</b></p>		
<p>Not available</p>		
<p><b>STOT–repeated exposure:</b></p>		
<p>Not available</p>		
<p><b>Aspiration hazard:</b></p>		
<p>Not available</p>		

## SECTION 12: ECOLOGICAL INFORMATION

### 12.1 Toxicity

	Endpoint	Test duration (hr)	Species	Value	Source
Nerfasin vet/Nerfasin 20 mg/ml Solution for Injection for Horses, Cattle, Dogs and Cats	Not available	Not available	Not available	Not available	Not available
Xylazine hydrochloride	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

Legend: Extracted from 1. IUCLID Toxicity Data 2. Europe ECHA Registered Substances - Ecotoxicological Information - Aquatic Toxicity 3. EPIWIN Suite V3.12 (QSAR) - Aquatic Toxicity Data (Estimated) 4. US EPA, Ecotox database - Aquatic Toxicity Data 5. ECETOC Aquatic Hazard Assessment Data 6. NITE (Japan) - Bioconcentration Data 7. METI (Japan) - Bioconcentration Data 8. Vendor Data

**DO NOT discharge into sewer or waterways.**

### 12.2 Persistence and degradability

Ingredient	Persistence: Water/Soil	Persistence: Air
Sodium chloride	LOW	LOW

### 12.3 Bioaccumulative potential

Ingredient	Bioaccumulative Potential
Sodium chloride	LOW (LogKOW = 0.5392)

### 12.4 Mobility in Soil

Ingredient	Mobility
Sodium chloride	LOW (KOC = 14.3)



<b>12.5 Results of PBT and vPvB assessment</b> Not Applicable
<b>12.6 Other adverse effects</b> Not Available

**SECTION 13: DISPOSAL CONSIDERATIONS**

<b>13.1 Waste treatment methods</b>	
<b>Product / packaging disposal:</b>	<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>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>Disposal of this product must be done according to the law that regulates certain drugs and other substances (Canada).</p>
<b>Waste Treatment Options:</b>	Not Available
<b>Sewage Disposal Options:</b>	Not Available

**SECTION 14: TRANSPORT INFORMATION**

<b>Labels required:</b> None	
<b>Marine pollutant:</b>	NO
<b>Hazchem:</b>	Not applicable
<b>Land transport (EU: ADR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS</b>	
<b>Air transport (ICAO-IATA / DGR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS</b>	
<b>Sea transport (IMDG-Code / GGVSee): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS</b>	



**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**

**Xylazine hydrochloride**

Europe EC Inventory / EINECS

**Sodium chloride**

Europe EC Inventory / EINECS

DSL / WHMIS GHS

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.

**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

Harmonisation Code 1 = the most prevalent classification.

Harmonisation Code 2 = The most severe classification

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 available	Not available	Not available

Harmonisation Code 1 = the most prevalent classification.

Harmonisation Code 2 = The most severe classification



<b>National Inventory</b>	<b>Status</b>
Australia – AICS	Yes
Canada – DSL	No (xylazine hydrochloride)
Canada – NDSL	No (xylazine hydrochloride, sodium chloride)
China – IECSC	No (xylazine hydrochloride)
Europe - EINEC / ELINCS / NLP	Yes
Japan – ENCS	No (xylazine hydrochloride)
Korea – KECI	No (xylazine hydrochloride)
New Zealand – NZIoC	Yes
Philippines – PICCS	No (xylazine hydrochloride)
USA – TSCA	No (xylazine hydrochloride)
Taiwan – TCSI	Yes
Mexico – INSQ	No (xylazine hydrochloride)
Vietnam – NCI	No (xylazine hydrochloride)
Russia – ARIPS	No (xylazine hydrochloride)
<b>Legend:</b>	<i>Yes = All ingredients are on the inventory          No = 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.

### Full text Risk and Hazard codes:

<b>H301</b>	Toxic if swallowed.
<b>H316</b>	Causes skin irritation
<b>H319</b>	Causes serious eye irritation

### 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

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