Product Name: Nerfasin vet/Nerfasin 100 mg/ml Solution

Issue Date: 06/2020

Version No: 1 Page 1 of 14



SECTION 1: IDENTIFICATION				
1.1 Product identifier				
Product name:	Nerfasin vet. 100 mg/ml, solution for injection for cattle and horses			
	(AT, BE, CZ, DK, EL, FI, FR, HU, IS, LU, NL, NO, PL, SE, and SK)			
	Nerfasin 100 mg/ml, solution for injection for cattle and horses (ES, IE, IT, PT and UK)			
	Nerfasin 100 [™] 100 mg/mL, solution for injection for horses (CA)			
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:	Sedation. Pre-medication in combination with an anesthetic			
Uses advised against:	Not for human use.			
1.3 Details of the supplier of	f the substance or mixture			
Registered company name (EU):	Le Vet Beheer B.V.			
Address:	Wilgenweg 7 3421 TV Oudewater The Netherlands			
Telephone:	+31 (0)348 565858			
Fax:	+31 (0)348 565454			
Website:	www.dechra.com			
Email:	Not available			
Distributor name (Canada):	•			
	1 Holiday Ave, East Tower, Suite 345 Pointe-Claire, QC H9R 5N3 Canada			

Product Name: Nerfasin vet/Nerfasin 100 mg/ml Solution

Issue Date: 06/2020

Version No: 1 Page 2 of 14



Telephone:	+1 (855) 332-9334		
Website:	www.dechra.ca		
Email:	Not Available		
1.4 Emergency Telephone Numbers			
Dechra (UE):	+31 (0)348 565858		
Dechra (CA):	+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).

Classification according to Not applicable regulation (EC) No 1272/2008 [CLP] (EU)1: 2.2 Label Elements Hazard Pictogram: Not applicable Signal Word: Not applicable **Hazard statement(s):** Not applicable Supplementary Statement(s) EU: Not applicable **Precautionary Statement(s) Prevention:** Not applicable **Precautionary Statement(s) Response:** Not applicable **Precautionary Statement(s) Storage:** Not applicable **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.

Product Name: Nerfasin vet/Nerfasin 100 mg/ml Solution

Issue Date: 06/2020

Version No: 1 Page 3 of 14



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		
Not available	Not specified	Ingredients determined not be hazardous	Not applicable		
Legend:	d: 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	d measures		
Eye contact:	If accidental eye contamination occurs, flush gently with fresh running water for 15 minutes. Medical advice should be sought if irritation persists.		
Skin contact:	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.		
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, 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.		
Ingestion:	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.		
Self-injection:	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		

Product Name: Nerfasin vet/Nerfasin 100 mg/ml Solution

Issue Date: 06/2020

Version No: 1 Page 4 of 14



	and change in blood pressure may occur. Symptomatic treatment may be required.			
4.2 Most important symp	toms and effects, both acute and delayed			
Eye contact:	May cause eye irritation.			
Skin contact:	May cause skin irritation.			
Ingestion:	May cause discomfort if ingested in large quantities			
Self-injection:	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				

4.3 Indication of immediate medical attention and special treatment neededXylazine is an α2-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.

SECTION 5: FIRE FIGHTING MEASURES					
5.1 Extinguishing media	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 acti	ons for fire-fighters:				
Firefighting:	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.				
Fire / explosion hazard:	Non-combustible.				

Product Name: Nerfasin vet/Nerfasin 100 mg/ml Solution

Issue Date: 06/2020

Version No: 1 Page 5 of 14



SECTION 6: ACCIDENTAL RELEASE MEASURES				
6.1 Personal precautions, protective equipment and emergency procedures				
For information on pr	For information on protective equipment, see section 8			
6.2 Environmental P	6.2 Environmental Precautions			
See sect	ion 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. 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. Prevent, by any means available, spillage from entering drains or water course.			

SECTION 7: HANDLING AND STORAGE			
7.1 Precautions for safe ha	andling		
Safe Handling:	When handling, DO NOT eat, drink or smoke. Always wash hands with water after handling. Observe manufacturer's storage and handling recommendations.		
Other Information:	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.		
7.2 Conditions for safe sto	orage, including any incompatibilities		
Suitable Container:	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.		
Storage incompatibility:	Avoid contamination of water or food stuffs.		
7.3 Specific end uses			
Not available			

Product Name: Nerfasin vet/Nerfasin 100 mg/ml Solution

Issue Date: 06/2020

Xylazine hydrochloride

Version No: 1 Page 6 of 14



Not available

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION										
8.1 Control pa	8.1 Control parameters									
DERIVED NO	EFFE	CT LEVEL	_ – DN	EL (EU)						
Not Available										
PREDICTED N	O EFI	FECT LEV	/EL –	PNEC (EU)						
Not Available	Not Available									
OCCUPATIONAL EXPOSURE LIMITS (OEL)										
INGREDIENT	DATA									
Source	Ingredient Material name TWA STE			STEL	Peak		Notes			
Not available	Not a	t available Not		available	Not available		Not available	Not available		Not available
EMERGENCY	EMERGENCY LIMITS (EU):									
Ingredient Material Name			TEEL-1		TEEL-2			TEEL-3		
Sodium chloride chloride		0.5 ppm		2 ppm			20 ppm			
Ingredient	Ingredient Original IDLH Revised IDLH									

Not available

8.2 Exposure 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
Skin protection:	See hand protection below

Product Name: Nerfasin vet/Nerfasin 100 mg/ml Solution

Issue Date: 06/2020

Version No: 1 Page 7 of 14



Hands/ feet protection:	Wear chemical protective gloves	
Body protection:	Wear appropriate clothing	
Other protection:	Wear appropriate clothing	
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: Solution for injection

Container: 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.

Physical state: Liquid Odour: Not available

Melting point / freezing point (degrees C): Not available Initial boiling point and boiling range: Not applicable

Flash Point: Not applicable **Evaporation rate** Not applicable Flammability: Not available

Upper/lower flammability or explosive limits: Not available

Vapour pressure: Not applicable Specific Gravity: Not available

Solubility in water and solvents (mg/l): Miscible in water 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

Taste: Not applicable

Surface tension: Not available Volatile component: Not available

Gas group: Not applicable

pH: 4.9 - 5.1

VOC g/L: Not applicable

9.2 Other information

Not Available

Product Name: Nerfasin vet/Nerfasin 100 mg/ml Solution

Issue Date: 06/2020

Version No: 1 Page 8 of 14



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

SECTION 11: TOXIC	COLOGICAL INFORMATION
Inhalation:	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.
Ingestion:	Xylazine is an α2-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.
Skin contact:	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.
Eye contact:	May cause eye irritation following contact.
Chronic:	Substance accumulation, in the human body, may occur and may cause some concern following repeated or long-term occupational exposure.

Product Name: Nerfasin vet/Nerfasin 100 mg/ml Solution

Issue Date: 06/2020

Version No: 1 Page 9 of 14



Nerfasin vet /Nerfasin	Toxicity	Irritation	
100 mg/ml Solution for Injection for Horses and Cattle	Not available	May cause skin or eye irritation	
Xylazine hydrochloride	Toxicity	Irritation	
	Not available	Not available	
	urer's SDS. Unless othe	d Substances - Acute toxicity 2.* Value rwise specified data extracted from RTECS -	
Skin corrosion/irritatio	n:		
May cause skin corrosio	n/ irritation.		
Serious eye damage/ir	ritation:		
May cause eye damage	/ irritation		
Respiratory or skin sei	nsitization:		
Due to nature of product, cause skin sensitization.	not expected to cause r	espiratory sensitization. Not expected to	
Germ cell mutagenicity	/ :		
Not available			
Carcinogenicity:			
Not available.			
Reproductive toxicity:			
		caution should be observed not to self-inject ood pressure may occur after accidental	
STOT - single exposur	e:		
Not available			
STOT-repeated expos	ure:		
Not available			
Aspiration hazard:			

Product Name: Nerfasin vet/Nerfasin 100 mg/ml Solution

Issue Date: 06/2020

Version No: 1 Page 10 of 14



SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

	Endpoint	Test duration (hr)	Species	Value	Source
Nerfasin vet /Nerfasin 100 mg/ml Solution for Injection for Horses and Cattle	Not available	Not available	Not available	Not available	Not available
Xylazine hydrochloride	Not available	Not available	Not available	Not available	Not available

Legend: Extracted from 1. IUCLID Toxicity Data 2. Europe ECHA Regis402.6 mg/ltered 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	
Not available		Not available	Not available	
12.3 Bioaccumulative potential				
Ingredient	Bioaccun	Bioaccumulative Potential		
Not available	Not availa	Not available		
12.4 Mobility in S	oil			
Ingredient	Mobility	Mobility		
Not available	Not availa	Not available		
12.5 Results of P Not Applicable	BT and vPv	B assessment		
12.6 Other adver	se effects			
Not Available				

Product Name: Nerfasin vet/Nerfasin 100 mg/ml Solution

Issue Date: 06/2020

Version No: 1 Page 11 of 14



SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

disposal:

Product / Any unused veterinary medicinal product or waste material derived from packaging such veterinary medicinal products should be disposed of in accordance with national requirements.

> Legislation addressing waste disposal requirements may differ by country, state and/or territory. Each user must refer to laws operating in their area.

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.

Ensure that the disposal of material is carried out in accordance with Hazardous Products Regulations (Canada, 2015).

Waste Treatment | Not Available **Options:**

Sewage Disposal Not Available

Options:

SECTION 14: TRANSPORT INFORMATION

Labels required: None

Marine pollutant: NO

Hazchem: Not applicable

Land transport (EU: ADR): 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**

Product Name: Nerfasin vet/Nerfasin 100 mg/ml Solution

Issue Date: 06/2020

Version No: 1 Page 12 of 14



SECTION 15: REGULATORY INFORMATION

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

Xylazine hydrochloride

Europe EC Inventory / EINECS

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)		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

National Inventory	Status
Australia – AICS	Yes
Canada – DSL	No (xylazine hydrochloride)
Canada – NDSL	No (xylazine hydrochloride)
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)

Product Name: Nerfasin vet/Nerfasin 100 mg/ml Solution

Issue Date: 06/2020

Version No: 1 Page 13 of 14



USA – TSCA	No (xylazine hydrochloride)
Taiwan – TCSI	Yes
Mexico – INSQ	No (xylazine hydrochloride)
Vietnam – NCI	No (xylazine hydrochloride)
Russia – ARIPS	No (xylazine hydrochloride)
Legend:	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)

Product Name: Nerfasin vet/Nerfasin 100 mg/ml Solution

Issue Date: 06/2020

Version No: 1 Page 14 of 14



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:

H301	Toxic if swallowed.	
H316	Causes skin irritation	
H319	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

The information provided in this Safety Data Sheet has been compiled by Le Vet Beheer B.V. 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, Le Vet Beheer B.V. 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, 2020, Le Vet Beheer B.V.. All rights reserved.

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