



SECTION 1: IDENTIFICATION

1.1 Product identifier

Product name:	Nimatek® (Solution for Injection 5ml, 10ml, 20ml, 25ml, 30ml and 50ml)
Synonyms:	Anesketin
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 use in animals only. Solution for injection, as sole agent for restraint or to induce anaesthesia in combination with sedatives and muscle relaxants for dogs, cats and horses.
Uses advised against:	Not for human use. Particular care should be taken to avoid accidental self-administration. People with known hypersensitivity to ketamine or any of the excipients should avoid contact with the veterinary medicinal product.

1.3 Details of the supplier of the substance or mixture

Registered company name(NL):	Eurovet Animal Health BV
Address:	Handelsweg 25 5531 AE Bladel The Netherlands
Telephone:	+31 (0) 497 544 300
Fax:	+31 (0) 497 544 302
Website:	www.dechra.com
Email:	Not available

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Considered a hazardous mixture according to Reg. (EC) No 1272/2008 and their amendments. Not classified as Dangerous Goods for transport purposes (EU).

Classification according to regulation (EC) No 1272/2008 [CLP] (EU)¹:	H315 - Skin Corrosion/Irritation Category 2 H319 - Eye Irritation Category 2
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	H351 - Carcinogenicity Category 2, H335 - Specific target organ toxicity - single exposure Category 3 (respiratory tract irritation)
2.2 Label Elements	
GHS Label Elements:	N/a
Signal Word:	WARNING
Hazard statement(s):	
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H351	Suspected of causing cancer.
H335	May cause respiratory irritation
Supplementary statement(s):	
EUH208	Contains 4-chloro-m-cresol. May produce an allergic reaction.
Precautionary Statement(s) Prevention:	
P201	Obtain special instructions before use.
Precautionary Statement(s) Response:	
P312	Call a POISON CENTER or doctor/physician if you feel unwell.
P308 + P313	IF exposed or concerned: Get medical advice/attention.
P337 + P313	If eye irritation persists: Get medical advice/attention.
P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
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. 1867-66-9 2. 245-078-9 3. Not Available 4. Not Available	11.5	Ketamine Hydrochloride (equivalent to 100mg ketamine)	Acute Toxicity (Oral) Category 4, Skin Corrosion/Irritation Category 2, Eye Irritation Category 2, Carcinogenicity Category 2, Specific target organ toxicity - single exposure Category 3 (respiratory tract irritation); H302, H315, H319, H351, H335 ¹
1. 59-50-7 2. 200-431-6 3. 604-014-00-3 4. 01-2119938953-25-XXXX	0.1	4-chloro-m-cresol	Acute Toxicity (Dermal) Category 4, Acute Toxicity (Oral) Category 4, Serious Eye Damage Category 1, Skin Sensitizer Category 1, Acute Aquatic Hazard Category 1; H312, H302, H318, H317, H400 ³
N/a	Proprietary	Other ingredients	N/a
Legend:	1. Classified by Chemwatch; 2. Classification drawn from EC Directive 1272/2008 – Annex VI; 3. Classification drawn from EC Directive 1272/2008		

SECTION 4: FIRST AID MEASURES	
4.1 Description of first aid measures	
Eye contact:	In case of accidental spillage onto eyes, immediately wash the affected area with water. If irritation or swelling of eyes occurs, seek urgent medical advice and show the package leaflet or the label to the medical practitioner.
Skin contact:	In case of accidental spillage onto skin, immediately wash the affected area with water. If irritation or swelling occurs, seek urgent 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 attention. Remove material and flush mouth with water. Never give liquid to a person showing signs of being sleepy or with reduced awareness; i.e. becoming unconscious. Give water to rinse out mouth, then provide liquid slowly and as much as casualty can comfortably drink.
Self-injection:	In the event of accidental self-administration, by injection or skin absorption, seek urgent medical assistance and show the package leaflet or label to the medical practitioner. DO NOT DRIVE.
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 Treat symptomatically. Advice to doctors: Do not leave patient unattended. Maintain airways and give symptomatic and supportive treatment.	

SECTION 5: FIRE FIGHTING MEASURES

5.1 Extinguishing media	
Suitable:	Select extinguishing media suitable for surrounding area.
Unsuitable:	There are no restrictions on the type of extinguishing media 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:	Wear breathing apparatus plus protective gloves in the event of a fire. Prevent, by any means available, spillage from entering drains or water courses DO NOT approach containers suspected to be hot. Equipment should be thoroughly decontaminated after use.
Fire / explosion hazard:	The material is not readily combustible under normal conditions. However, the container may get damaged under fire conditions and the organic component may burn. Irritating and highly toxic gases may then be generated from thermal decomposition, including Carbon Dioxide (CO ₂), Hydrogen Chloride (HCl), Phosgene, Nitrogen Oxides (NO _x) or other pyrolysis products typical of burning organic material. Heat may cause expansion or decomposition with violent rupture of containers.

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. 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. Wear breathing apparatus plus protective gloves. Contain and absorb spill with sand, earth, inert material or vermiculite.



	Collect recoverable product into labelled containers for recycling. 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

Safe Handling:	<p>Care should be taken to avoid accidental self-administration. Wear suitable protection gloves and clothing when handling the product. Avoid contact with the skin and eyes. Adverse effects on the foetus cannot be excluded. Pregnant women should avoid 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.</p>
Other Information:	Keep out of the reach and sight of children.

7.2 Conditions for safe storage, including any incompatibilities

Suitable Container:	<p>Glass vial in a cardboard box. Protect from light. Shelf life of the veterinary medicinal product as packaged for sale: 3 years. Shelf life after first opening the immediate packaging: 28 days.</p>
Storage incompatibility:	N/a

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 (EU):
Not Available

EMERGENCY LIMITS (EU):

Ingredient	Material Name	TEEL-1	TEEL-2	TEEL-3
4-chloro-m-cresol	Chloro-m-cresol, 4-	5.5 mg/m ³	60 mg/m ³	360 mg/m ³

Ingredient	Original IDLH	Revised IDLH
Ketamine Hydrochloride	Not Available	Not Available
4-chloro-m-cresol	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:	No special equipment for minor exposure i.e. when handling small quantities. OTHERWISE: Safety glasses with side shields.
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 For emergencies: vinyl coat
Other protection:	No special equipment needed when handling small quantities
Thermal hazards:	Not applicable
Respiratory protection:	Not applicable

8.3 Environmental exposure controls
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See Section 12

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance: Nimatek: Clear, colourless liquid
 Ketamine Hydrochloride: A white or almost white crystalline powder
Container: 5ml, 10ml, 20ml, 25ml, 30ml and 50ml multidose glass vials with rubber stopper and aluminium caps.
Physical state: Liquid
Odour: Not available
Odour Threshold: Not available
pH (as supplied): Not available
Melting point / freezing point (degrees C): Ketamine Hydrochloride: 262.5
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): Ketamine Hydrochloride: freely soluble 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: Ketamine Hydrochloride: 274.19
Taste: Not available
Surface tension: Not available
Volative component: Not available
Gas group: Not available
pH as a solution: Not available
VOC g/L: Ketamine Hydrochloride: 1.22

9.2 Other information
 Not Available

10: REACTIVITY AND STABILITY

10.1 Reactivity:	See Section 7
10.2 Chemical stability:	Unstable in the presence of incompatible materials. 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:	See Section 7.



10.5 Incompatible materials:	See section 7.
10.6 Hazardous decomposition:	See Section 5.

SECTION 11: TOXICOLOGICAL INFORMATION

Inhalation:	The material can cause respiratory irritation in some persons. The body's response to such irritation can cause further lung damage. Not normally a hazard due to non-volatile nature of product.
Ingestion:	Accidental ingestion of the material may be damaging to the health of the individual. Ketamine is a dissociative anaesthetic agent. Ketamine induces a state of catalepsy with amnesia and analgesia; muscle tone is maintained including the pharyngeal and laryngeal reflexes. The heart rate, blood pressure and cardiac output are increased. Ketamine does not cause significant respiratory depression at usual doses, but at higher doses it can cause respiratory rates to decrease.
Skin contact:	This material can cause inflammation of the skin on contact in some persons. The material may accentuate any pre-existing dermatitis condition 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.
Eye contact:	This material can cause eye irritation and damage in some persons.
Chronic:	There has been concern that this material can cause cancer or mutations, but there is not enough data to make an assessment. Long-term exposure to respiratory irritants may result in disease of the airways involving difficult breathing and related systemic problems. Repeated exposures of animals to concentrations of about 34 ppm HCl produced no immediate toxic effects. Workers exposed to hydrochloric acid suffered from gastritis and a number of cases of chronic bronchitis have also been reported. Repeated or prolonged exposure to dilute solutions of HCl may cause dermatitis.
Self-injection:	Ketamine is a dissociative anaesthetic agent. Ketamine induces a state of catalepsy with amnesia and analgesia; muscle tone is maintained including the pharyngeal and laryngeal reflexes. The heart rate, blood pressure and cardiac output are increased. Ketamine does not cause significant respiratory depression at usual doses, but at higher doses it can cause respiratory rates to decrease.



Nimatek:	Toxicity	Irritation
	Not Available	Not Available
Ketamine Hydrochloride:	Acute toxicity	Irritation
	Oral (rat) LD ₅₀ : 447 mg/kg ²	Not Available
4-chloro-m-cresol:	Acute toxicity	Irritation
	Oral (rat) LD ₅₀ : 1830 mg/kg ²	Not Available
<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>		
Skin corrosion/irritation:		
Not Available.		
Serious eye damage/irritation:		
Not Available		
Respiratory or skin sensitization:		
Not Available		
Germ cell mutagenicity:		
Not Available		
Carcinogenicity:		
Not Available.		
Reproductive toxicity:		
Not Available		
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
4-chloro-m-cresol	LC ₅₀	96	Fish	0.917mg/L	3
4-chloro-m-cresol	EC ₅₀	48	Crustacea	1.5mg/L	3
4-chloro-m-cresol	EC ₅₀	72	Algae or other aquatic plants	4.2mg/L	1
4-chloro-m-cresol	EC ₅₀	48	Crustacea	1.5mg/L	2
4-chloro-m-cresol	NOEC	96	Fish	0.366mg/L	1
			Legend:	<i>Extracted from 1. IUCLID Toxicity Data 2. Europe ECHA Registered Substances - Ecotoxicological Information - Aquatic Toxicity 3. US EPA, Ecotox database - Aquatic Toxicity Data</i>	
DO NOT discharge into sewer or waterways.					
12.2 Persistence and degradability					
Ingredient	Persistence: Water/Soil		Persistence: Air		
4-chloro-m-cresol	LOW (Half-life = 49 days)		LOW (Half-life = 0.67 days)		
12.3 Bioaccumulative potential					
Ingredient	Bioaccumulative Potential				
Ketamine Hydrochloride	LOW (LogKOW = 2.18)				
4-chloro-m-cresol	LOW (BCF = 13)				
12.4 Mobility in Soil					
Ingredient	Mobility				
4-chloro-m-cresol	LOW (KOC = 717.6)				
12.5 Results of PBT and vPvB assessment					
Not Applicable					
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>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:	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

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
	Limited quantity	N/a

14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code N/a

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

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): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS		
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): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS		
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

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
Ketamine Hydrochloride	1867-66-9	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. 4; Skin Irrit. 2; STOT SE 3	GHS07, Wng	H302, H315, H319; H335
Ingredient	CAS number	Index Number	ECHA Dossier
4-chloro-m-cresol	59-50-7	604-014-00-3	Not Available
Harmonization (C&L Inventory)	Hazard Class and Category Code(s)	Pictograms Signal Word Code(s)	Hazard Statement Code(s)



1	Acute Tox. 4; Skin Sens. 1; Eye Dam. 1; Aquatic Acute 1	GHS09, GHS05; Dgr	H302, H312, H317, H400
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National Inventory	Status
Australia - AICS	Y
Canada - DSL	N (Ketamine hydrochloride)
Canada - NDSL	N (Ketamine hydrochloride; 4-chloro-m-cresol)
China - IECSC	N (Ketamine hydrochloride)
Europe - EINEC / ELINCS / NLP	Y
Japan - ENCS	N (Ketamine hydrochloride)
Korea - KECI	N (Ketamine hydrochloride)
New Zealand - NZIoC	Y
Philippines - PICCS	Y
USA - TSCA	N (Ketamine hydrochloride)
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, and ECHA.

Full text Risk and Hazard codes:

H302	Harmful if swallowed
H312	Harmful in contact with skin
H315	Skin Corrosion/Irritation Category 2
H317	May cause an allergic skin reaction
H308	Causes serious eye damage
H319	Eye Irritation Category 2
H335	May cause respiratory irritation
H351	Suspected of causing cancer
H400	Very toxic to aquatic life

Relevant risk statements are found in section 2.1

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 microorganisms
- EN 13832 - Protective footwear against chemicals
- EN 133 - Respiratory protection

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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