



SECTION 1: IDENTIFICATION	
1.1 Product identifier	
Product name:	Dormazolam 5 mg/ml Solution for Injection
Synonyms:	Dormaquin
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:	Intravenous co-induction of anaesthesia with ketamine for smooth induction and intubation and profound muscle relaxation during anaesthesia.
Uses advised against:	Not for human use.
1.3 Details of the supplier of the substance or mixture	
Registered company name:	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
1.4 Emergency Telephone Numbers	
	+31 (0)348 565858



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 regulation (EC) No 1272/2008 [CLP] (EU)¹:	May cause skin-, serious eye- or respiratory- irritation
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2.2 Label Elements

Signal Word:	WARNING
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Hazard statement(s):

	H315 Causes skin irritation H319 Causes serious eye irritation H335 May cause respiratory irritation
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Supplementary Statement(s) EU:

	Not applicable
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Precautionary Statement(s) Prevention:

	P280 Wear protective gloves / protective clothing/ eye protection/ face protection
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Precautionary Statement(s) Response:

	P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing P337+P313 If eye irritation persists, get medical advice/ attention P302+P352 IF ON SKIN: Wash with plenty of water and soap
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Precautionary Statement(s) Storage:

	P405 Store locked up P403+P233 Store in a well ventilated place. Keep container tightly closed.
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Precautionary Statement(s) Disposal:

	P501 Dispose of contents/ container in accordance with local regulations
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2.3 Other Hazard Information
 Inhalation and or ingestion may produce health damage.
 Cumulative effects may result following exposure.



May possibly be harmful to the foetus/embryo.
 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 impaired muscular function may occur.
 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)
1.100-51-6 2.202-859-9 3.603-057-00-5 4.01-2119492630-38-XXXX 01-2120762094-56-XXXX	Not specified	Benzyl alcohol	Acute Toxicity (Oral) Category 4, Acute Toxicity (Inhalation) Category 4; H302, H332 [2]
1.7647-14-5 2.231-598-3 3.Not Available 4.01-2119485491-33-XXXX	Not specified	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]
1.59467-70-8 2.261-774-5 3.Not Available 4.Not Available	0.5	Midazolam	Acute Toxicity (Oral) Category 4; H302
1.7647-01-0 2.231-595-7 3.017-002-00-2 017-002-01-X 4.01-2119484862-27-XXXX 01-2120762784-43-XXXX 01-2120066883-46-	Not specified	Hydrochloric acid	Specific target organ toxicity - single exposure Category 3 (respiratory tract irritation), Skin Corrosion/Irritation Category 1B; H335, H314 [2]



XXXX			
Not available	Not specified	Ingredients determined not be hazardous	
Legend:	; 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

Eye contact:	Accidental spillage on the eyes should be washed off immediately with plenty of water. Remove contact lenses if possible. Seek medical advice if pain and irritation persists and show the package leaflet or the label to the medical practitioner.
Skin contact:	Avoid contact with skin. In the case of contact with skin, wash with soap and water. If irritation persists, seek medical advice. Wash hands after use.
Inhalation:	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 and impaired muscular function may occur.

4.2 Most important symptoms and effects, both acute and delayed

Eye contact:	May eye irritation.
Skin contact:	May cause skin irritation.
Ingestion:	May cause discomfort if ingested in large quantities
Self-injection:	Midazolam is a CNS depressant and can cause sedation and induction of sleep

See Section 11 for more detailed information

4.3 Indication of immediate medical attention and special treatment needed

Like other benzodiazepines, midazolam commonly causes drowsiness, ataxia, dysarthria anterograde amnesia, and nystagmus. Overdose of midazolam is seldom life-threatening if



the drug is taken alone, but may lead to areflexia, apnoea, hypotension, cardiorespiratory depression and in rare cases to coma.
 Monitor the patient's vital signs and institute supportive measures as indicated by the patient's clinical state. Respiratory and haemodynamic symptoms should be treated symptomatically.

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.
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5.3 Special protective actions for fire-fighters:

Firefighting:	Use water delivered as a fine spray to control fire and cool adjacent area. Alert Fire Brigade and tell them location and nature of hazard. Wear breathing apparatus plus protective gloves in the event of a fire. Prevent, by any means available, spillage from entering drains or water courses. Use fire fighting procedures suitable for surrounding area.
Fire / explosion hazard:	Non combustible. Not considered a significant fire risk, however containers may burn. May emit poisonous fumes. May emit corrosive fumes.

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.. Wear breathing apparatus plus protective gloves. 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:	.Avoid all personal contact including inhalation and avoid self-injection 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 storage, including any incompatibilities	
Suitable Container:	Colorless type I glass vials of 5 ml, 10 ml, 20 ml and 50 ml closed with a rubber stopper and aluminium cap in a carton box.
Storage incompatibility:	Avoid contamination of water or food stuffs.
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
EU Consolidated List of Indicative Occupational Exposure Limit Values (IOELVs)	Hydrochloric acid	Hydrogen chloride	5 ppm / 8 mg/m ³	15 mg/m ³ / 10 ppm	Not available	Not available

EMERGENCY LIMITS (EU):

Ingredient	Material Name	TEEL-1	TEEL-2	TEEL-3
Benzyl alcohol	Benzyl alcohol	30 ppm	52 ppm	740 ppm
Sodium chloride	Chloride	0.5 ppm	2 ppm	20 ppm
Hydrochloric acid	Hydrochloride chloride	Not available	Not available	Not available
Hydrochloric acid	Deuterium chloride	1.8 ppm	22 ppm	100 ppm

Ingredient	Original IDLH	Revised IDLH
Benzyl alcohol	Not Available	Not Available
Sodium Chloride	Not Available	Not Available
Midzolam	Not Available	Not Available
Hydrochloric acid	50 ppm	Not Available
Water	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
Skin protection:	See hand protection below
Hands/ feet protection:	Wear chemical protective gloves
Body protection:	Wear appropriate clothing
Other protection:	Wear appropriate clothing
Thermal hazards:	Not applicable
Respiratory protection:	See personal protection symbols for engineering
8.3 Environmental exposure controls	
See Section 12	

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance: Clear, colourless, Solution for injection

Container: Glass vials of 5 ml, 10 ml, 20 ml and 50 ml with a rubber stopper and aluminium cap in a carton box.

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: 2.5 -3.5

VOC g/L: Not applicable

9.2 Other information

Not Available

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 stale 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: TOXICOLOGICAL INFORMATION	
Inhalation:	May cause irritation of the respiratory tract following inhalation.
Ingestion:	Accidental ingestion of the material may be damaging to the health of the individual. Benzodiazepine overdose is frequent, but serious poisonings are uncommon, sometimes even in high doses. The most common side-effects are drowsiness, dizziness and inco-ordination. GABA agonists increase the action at the GABA receptor, producing sedative effects, and may also reduce anxiety and relax muscle.
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. Examine the skin prior to the use of the material and ensure that any external damage is suitably protected.
Eye contact:	This material can cause eye irritation and damage in some persons.
Chronic:	Substance accumulation, in the human body, may occur and may cause some concern following repeated or long-term occupational exposure. Based on experience with animal studies, there is a possibility that exposure to the material may result in toxic effects to the development of the foetus, at levels which do not cause significant toxic effects to the mother. Prolonged use of benzodiazepines can lead to alcoholism-like dependence. Tolerance and withdrawal symptoms are seen in long-term treatment in high doses.

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Dormazolon / Dormaquin vet 5 mg/ml Solution for Injection for Horses	Toxicity	Irritation
	Not available	May cause skin and eye irritation
Benzyl alcohol	Toxicity	Irritation
	Dermal (rabbit); 2000 mg/kg ² Oral (rat) LD50: 1230 mg/kg ²	Eye (rabbit): 0.75 mg open severe Eye: adverse effect observed (irritation) ¹ Skin (man): 16 mg/48h-mild Skin (rabbit): 10 mg/24h open-mild
Sodium hydroxide	Toxicity	Irritation
	Oral (rat) LD50: 3000 mg/kg ²	Eye (rabbit): 10mg – moderate Eye (rabbit): 100mg/24h – moderate Skin (rabbit): 500 mg/24h – mild
Midazolam	Toxicity	Irritation
	Oral (rat) LD50: 215 mg/kg ²	Not available
Hydrochloric acid	Toxicity	Irritation
	Dermal (rabbit) LD50: >5010 mg/kg ² Oral (rat) LD50: 700 mg/kg ²	Eye (rabbit): 5 mg/30s – mild Eye: adverse effect observed (irritating) ¹ Skin: adverse effect observed (corrosive) ¹ Skin: adverse effect observed (irritating) ¹

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

Skin corrosion/irritation:

May cause any skin corrosion/ irritation.

Serious eye damage/irritation:

May cause eye irritation

Respiratory or skin sensitization:

People with known sensitivity to midazolam or the excipients should avoid contact with the veterinary medicinal product.

Germ cell mutagenicity:

Not available

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Carcinogenicity:
Not available.
Reproductive toxicity:
Midazolam and its metabolites may be harmful for the unborn child, and are secreted into breastmilk in small amounts, thereby exerting a pharmacological effect on the nursing neonate.
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
Dormazolam / Dormaquin vet 5 mg/ml Solution for Injection	Not available	Not available	Not available	Not available	Not available
Benzyl alcohol	LC50	96	Fish	10 mg/l	2
	EC50	48	Crustacea	230 mg/l	2
	EC50	96	Algae or other aquatic plants	76.828 mg/l	2
	NOEC	336	Fish	5.1 mg/l	2
Sodium chloride	LC50	96	Fish	5-840 mg/l	2
	EC50	48	Crustacea	402.6 mg/l	4
	EC50	96	Algae or other aquatic plants	2430 mg/l	4
	NOEC	6	Fish	0.001 mg/l	4
Midazolam	LC50	96	Fish	0.073 mg/l	3
	EC50	96	Algae or other aquatic plants	0.100 mg/l	3
Hydrochloric acid	LC50	96	Fish	70.057 mg/l	3
	EC50	96	Algae or other aquatic plants	344.947 mg/l	3
	NOEC	0.08	Fish	10 mg/l	4
<p>Legend: <i>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</i></p>					
DO NOT discharge into sewer or waterways.					



12.2 Persistence and degradability		
Ingredient	Persistence: Water/Soil	Persistence: Air
Benzyl alcohol	LOW	LOW
Sodium chloride	LOW	LOW
Midazolam	HIGH	HIGH
Hydrochloric acid	LOW	LOW
12.3 Bioaccumulative potential		
Ingredient	Bioaccumulative Potential	
Benzyl alcohol	LOW (LogKOW = 1.1)	
Sodium chloride	LOW (LogKOW = 0.5392)	
Midazolam	HIGH (LogKOW = 6.8094)	
Hydrochloric acid	LOW (LogKOW = 0.5392)	
12.4 Mobility in Soil		
Ingredient	Mobility	
Benzyl alcohol	LOW (KOC = 15.66)	
Sodium chloride	LOW (KOC = 14.3)	
Midazolam	LOW (KOC = 3556000)	
Hydrochloric acid	LOW (KOC = 14.3)	
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: None

Marine pollutant: NO

Hazchem: Not applicable

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

14.1 UN Number Not applicable

14.2 UN Proper Shipping Name Not applicable

14.3 Transport hazard class(es)	ICAO/ IATA Class	Not applicable
	ERG Code	Not applicable

14.4 Packing group Not applicable

14.5 Environmental hazards Not applicable

14.6 Special precautions for user	Hazard Identification (Kemler)	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



Air transport (ICAO-IATA / DGR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS		
14.1 UN Number	Not applicable	
14.2 UN Proper Shipping Name	Not applicable	
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	Not applicable	
14.2 UN Proper Shipping Name	Not applicable	
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	Not applicable			
14.2 UN Proper Shipping Name	Not applicable			
14.3 Transport hazard class(es)	Not applicable	Not applicable		
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	Source	Product Name	Pollution Category	Ship Type
		Benzyl alcohol	Y	3

SECTION 15: REGULATORY INFORMATION

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

Benzyl alcohol (100-51-6)

ADN – European agreement concerning international carriage of Dangerous goods by inland waterways

European agreement concerning international carriage of dangerous goods by road

EU (EC No 1223/2009) – Annex III

ECHA / Europe EC Inventory / ECICS

GESAMP/EHS Composite list

IMO IBC / IMO MARPOL

IATA

IMDG Code

Sodium chloride (7647-14-5)

Europe EC Inventory

ECHA / ECICS/ EINECS

Midazolam (59467-70-8)

ADN – European agreement concerning international carriage of Dangerous goods by inland waterways

Europe EC Inventory

European agreement concerning international carriage of dangerous goods by road

ECHA / ECICS / EINECS / IATA / IMDG Code

Hydrochloric acid (7647-01-0)

ADN – European agreement concerning international carriage of Dangerous goods by inland waterways

European agreement concerning international carriage of dangerous goods by road

IOELVs / ECHA / Europe EC Inventory / ECICS

GESAMP/EHS Composite list

IMO IBC / IMO MARPOL

IATA / IARC / IMDG Code

15.2 Chemical Safety Assessment

ECHA SUMMARY

Ingredient	CAS number	Index Number	ECHA Dossier
Benzyl alcohol	100-51-6	603-057-00-5	01-2119492630-38-XXXX 01-2120762094-56-XXXX

Harmonization (C&L Inventory)	Hazard Class and Category Code(s)	Pictograms Signal Word Code(s)	Hazard Statement Code(s)
1	Acute Tox 4	GHS08; Wng	H302, H332

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 classified	Not available	Not available

Harmonisation Code 1 = the most prevalent classification. Harmonisation Code 2 = The most severe classification

Ingredient	CAS number	Index Number	ECHA Dossier
Midazolam	59467-70-8	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	GHS06; Dgr	H301

Harmonisation Code 1 = the most prevalent classification. Harmonisation Code 2 = The most severe classification

Ingredient	CAS number	Index Number	ECHA Dossier
Hydrochloric acid	7647-01-0	017-002-00-2 017-002-01-X	01-2119484862-27-XXXX 01-2120762784-43-XXXX 01-2120066883-46-XXXX



Harmonization (C&L Inventory)	Hazard Class and Category Code(s)	Pictograms Signal Word Code(s)	Hazard Statement Code(s)
1	Skin Corr. 1A ; Acute tox 3	GHS05; GHS04; GHS06; Dgr	H314; H331; H335
Harmonisation Code 1 = the most prevalent classification. Harmonisation Code 2 = The most severe classification			

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
Harmonisation Code 1 = the most prevalent classification. Harmonisation Code 2 = The most severe classification			

National Inventory	Status
Australia – AICS	No (Midazolam)
Canada – DSL	No (Midazolam)
Canada – NDSL	No (Benzyl alcohol, Midazolam, hydrochloric acid, sodium chloride)
China – IECSC	No (Midazolam)
Europe - EINEC / ELINCS /NLP	Yes
Japan – ENCS	No (Midazolam)
Korea – KECI	No (Midazolam)
New Zealand – NZIoC	Yes
Philippines – PICCS	No (Midazolam)
USA – TSCA	No (Midazolam)
Taiwan – TCSI	Yes
Mexico – INSQ	No (Midazolam)
Vietnam – NCI	No (Midazolam)
Russia – ARIPS	No (Midazolam)
Thailand - TECI	Yes
Legend:	<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

Full text Risk and Hazard codes:

H302	Harmful if swallowed.
H314	Causes severe skin burns and eye damage
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H332	Harmful if inhaled.
H335	May cause respiratory 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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