


SECTION 1: IDENTIFICATION	
1.1 Product identifier	
Product name	Zenalpa injection
Chemical name	Not Applicable
Synonyms	Medetomidine and vatinoxan hydrochlorides injection, Zenalpa 0.5 mg/mL and 10 mg/mL injection
Chemical formula	Not Applicable
Other means of identification	Not Available
1.2 Recommended use of the chemical and restrictions on use	
Relevant identified uses	Indicated for use as a sedative and analgesic in dogs. Not for human use.
1.3 Details of the supplier of the substance or mixture	
Registered company name (Canada)	Dechra Veterinary Products
Address	1 Holiday Ave. East Tower, Suite 345 Point Claire, QZ, H9R 5N3, Canada
Telephone	855-332-9334
Fax	Not Available
Email	Not Available
1.4 Emergency telephone numbers	
Dechra (Canada)	855-332-9334

SECTION 2: HAZARD(S) IDENTIFICATION	
2.1 Classification of the substance or mixture	
NFPA 704 diamond	
	Note: The hazard category numbers found in GHS classification in section 2 of this SDSs are NOT to be used to fill in the NFPA 704 diamond. Blue = Health Red = Fire Yellow = Reactivity White = Special (Oxidizer or water reactive substances)
Canadian WHMIS Symbols	
Classification	Not Applicable
2.2 Label elements	
Hazard pictogram(s)	Not Applicable
Signal word	Not Applicable
Hazard statement(s) Not Applicable	
Physical and health hazard(s) not otherwise classified Not Applicable	
Precautionary statement(s) Prevention Not Applicable	
Precautionary statement(s) Response Not Applicable	
Precautionary statement(s) storage Not Applicable	
Precautionary statement(s) disposal Not Applicable	

SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS		
3.1 Substances		
See section below for composition of Mixtures.		
3.2 Mixtures		
CAS No.	% [weight]	Name
99-76-3	Not Specified	<u>methyl paraben</u>
94-13-3	Not Specified	<u>propyl paraben</u>
86347-15-1	Not Specified	<u>medetomidine hydrochloride</u>
7647-14-5	Not Specified	<u>sodium chloride</u>
69-65-8	Not Specified	<u>mannitol</u>
68-04-2	Not Specified	<u>sodium citrate</u>
130466-38-5	Not Specified	<u>vatinoxan hydrochloride</u>
7732-18-5	Not Specified	<u>water</u>
The specific chemical identity and/or exact percentage (concentration) of composition has been withheld as a trade secret.		

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	In the case of contact with skin, wash with soap and water. If irritation persists, seek medical advice. Wash hands after use.

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 and changes in blood pressure may occur.
4.2 Indication of immediate medical attention and special treatment needed	
Treatment of overdose of oral sympathomimetics should be symptomatic and supportive Not expected to cause eye/skin irritation. May cause systemic effect of the drug (sedation etc.). Medetomidine is a CNS depressant and can cause sedation and changes in blood pressure. Pregnant women, or persons with known hypersensitivity to any of the ingredients, should exercise special caution to avoid exposure. Uterine contractions and decreased fetal blood pressure may occur after accidental systemic exposure.	

SECTION 5: FIRE FIGHTING MEASURES

5.1 Extinguishing media	
Use water spray or fog, foam dry powder, Bromochlorodifluoromethane (BCF) (where regulations permit), carbon dioxide.	
5.2 Special hazards arising from the substance or mixture	
Fire incompatibility	Avoid contamination with oxidising agents i.e. nitrates, oxidising acids, chlorine bleaches, pool chlorine etc. as ignition may result.
5.3 Special protective actions for fire-fighters:	
Firefighting	Alert Fire Brigade and tell them location and nature of hazard. May be violently or explosively reactive. Wear breathing apparatus plus protective gloves. Prevent, by any means available, spillage from entering drains or water course. If safe, switch off electrical equipment until vapor fire hazard removed. Use water delivered as a fine spray to control fire and cool adjacent area. Avoid spraying water onto liquid pools. DO NOT approach containers suspected to be hot. Cool fire exposed containers with water spray from a protected location. If safe to do so, remove containers from path of fire.
Fire / explosion hazard	Combustible. Slight fire hazard when exposed to heat or flame. Heat may cause expansion or decomposition with violent rupture of containers. On combustion. May emit toxic fumes of carbon monoxide carbon dioxide, nitrogen oxides, and other pyrolysis products typical of burning organic material. May emit acrid smoke. Mists containing combustible materials may be explosive.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures	
See section 8.	
6.2 Environmental precautions	
See Section 12.	
6.3 Methods and material for containment and cleaning up	
Minor spills	Remove all ignition sources. Clean up all spills immediately. Avoid 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. Wipe up. Place in a suitable, labelled container for waste disposal.
Major spills	Moderate hazard. Clear area of personnel and move upwind. Alert Fire Brigade and tell them location and nature of hazard. Wear breathing apparatus plus protective gloves. Prevent, by any means available, spillage from entering drains or water course. No smoking, naked lights or ignition sources. Increase ventilation. Stop leak if safe to do so. Contain spill with sand, earth or vermiculite. Collect recoverable product into labelled containers for recycling. Absorb remaining product with sand, earth or vermiculite. Collect solid residues and seal in labelled drums for disposal. Wash area and prevent runoff into drains. If contamination of drains or waterways occurs, advise emergency services.
Personal Protective Equipment advice is contained in Section 8 of the SDS.	

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling	
Safe handling	Avoid all personal contact, including inhalation. Wear protective clothing when risk of exposure occurs. Use in a well-ventilated area. Prevent concentration in hollows and sumps. DO NOT enter confined spaces until atmosphere has been checked. Avoid smoking, naked lights or ignition sources. Avoid contact with incompatible materials. When handling, DO NOT eat, drink or smoke. Keep containers securely sealed when not in use. Avoid physical damage to containers. Always wash hands with soap and water after handling. Work clothes should be laundered separately. Use good occupational work practice. Observe manufacturer's storage and handling recommendations contained within this SDS. Atmosphere should be regularly checked against established exposure standards to ensure safe working conditions.
Other information	Store in original containers. Keep containers securely sealed. No smoking, naked lights or ignition sources. Store in a cool, dry, well-ventilated area. Store away from incompatible materials and foodstuff containers. Protect containers against physical damage and check regularly for leaks. Observe manufacturer's storage and handling recommendations contained within this SDS.
7.2 Conditions for safe storage, including any incompatibilities	
Suitable container	Zenalpha is supplied in cardboard outer box containing 1, 5 or 10 clear multidose glass vials of 10 mL fill volume. Check all containers are clearly labelled and free from leaks.

Storage incompatibility	Avoid contamination of water, foodstuffs, feed or seed. Avoid reaction with oxidising agents
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SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control parameters

Occupational exposure limits (OEL)

Source	Ingredient	Material name	TWA	STEL	Peak	Notes
Canada - Saskatchewan Occupational Health and Safety Regulations - Contamination Limits	propyl paraben	Particles (Insoluble or Poorly Soluble) Not Otherwise Specified: Inhalable fraction	10 mg/m ³	20 mg/m ³	Not Available	Not Available
Canada - Ontario Occupational Exposure Limits	propyl paraben	PNOS (Insoluble or Poorly Soluble) (Inhalable fraction)	10 mg/m ³	Not Available	Not Available	(I) Inhalable fraction: means that size fraction of the airborne particulate deposited anywhere in the respiratory tract and collected during air sampling with a particle size-selective device that, (a) meets the ACGIH particle size-selective sampling criteria for airborne particulate matter; and (b) has the cut point of 100 µm at 50 per cent collection efficiency.
Canada - Ontario Occupational Exposure Limits	propyl paraben	PNOS (Insoluble or Poorly Soluble) (Respirable fraction)	3 mg/m ³	Not Available	Not Available	(R) Respirable fraction: means that size fraction of the airborne particulate deposited in the gas-exchange region of the respiratory tract and collected during air sampling with a particle size-selective device that, (a) meets the ACGIH particle size-selective sampling criteria for airborne particulate matter; and (b) has the cut point of 4 µm at 50 per cent collection efficiency.
Canada - Nova Scotia Occupational Exposure Limits	propyl paraben	PNOS (Insoluble or Poorly Soluble) Respirable particles	3 mg/m ³	Not Available	Not Available	See Appendix B current TLV/BEI Book
Canada - Nova Scotia Occupational Exposure Limits	propyl paraben	PNOS (Insoluble or Poorly Soluble) Inhalable particles	10 mg/m ³	Not Available	Not Available	See Appendix B current TLV/BEI Book
Canada - Alberta Occupational Exposure Limits	propyl paraben	PNOS Total	10 mg/m ³	Not Available	Not Available	3 - Occupational exposure limit is based on irritation effects and its adjustment to compensate for unusual work schedules is not required.
Canada - Alberta Occupational Exposure Limits	propyl paraben	PNOS Respirable	3 mg/m ³	Not Available	Not Available	3 - Occupational exposure limit is based on irritation effects and its adjustment to compensate for unusual work schedules is not required.
Canada - Northwest Territories Occupational Exposure Limits	propyl paraben	PNOS (Insoluble or Poorly Soluble) Respirable fraction	3 mg/m ³	6 mg/m ³	Not Available	Not Available
Canada - Northwest Territories Occupational Exposure Limits	propyl paraben	PNOS (Insoluble or Poorly Soluble) Inhalable fraction	10 mg/m ³	20 mg/m ³	Not Available	Not Available
Canada - Quebec Permissible Exposure Values for Airborne Contaminants	propyl paraben	Particles Not Otherwise Classified - Total dust	10 mg/m ³	Not Available	Not Available	Note 1: The standard corresponds to dust containing no asbestos and the percentage in crystalline silica is less than 1%.

Emergency limits

Ingredient	TEEL-1	TEEL-2	TEEL-3
sodium chloride	0.5 ppm	2 ppm	20 ppm
sodium citrate	9.3 mg/m ³	100 mg/m ³	610 mg/m ³

Ingredient	Original IDLH	Revised IDLH
	Not Available for any ingredient	Not Available for any ingredient





Occupational Exposure Banding

Ingredient	Occupational Exposure Band Rating	Occupational Exposure Band Limit
methyl paraben	E	≤ 0.01 mg/m ³
medetomidine hydrochloride	E	≤ 0.01 mg/m ³
sodium chloride	E	≤ 0.01 mg/m ³

Notes: Occupational exposure banding is a process of assigning chemicals into specific categories or bands based on a chemical's potency and the adverse health outcomes associated with exposure. The output of this process is an occupational exposure band (OEB), which corresponds to a range of exposure concentrations that are expected to protect worker health.

MATERIAL DATA

8.2 Exposure controls

Appropriate engineering controls	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. 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.
Personal protection	   

Eye and face protection	Use chemical goggles [AS/NZS 1337.1, EN166 or national equivalent] or safety glasses with side shields. Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants.
Skin protection	See Hand protection below.
Hands/feet protection	Wear chemical protective gloves.
Body protection	Wear appropriate clothing.
Other protection	No special equipment needed when handling small quantities. OTHERWISE: Overalls, barrier cream, eyewash unit.
Respiratory protection	Type A Filter of sufficient capacity. (AS/NZS 1716 & 1715, EN 143:2000 & 149:2001, ANSI Z88 or national equivalent).

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance: Liquid	Vapor density: Not Available
Physical state: Liquid	Auto ignition temperature (°C): Not Available
Odor: Not Available	Decomposition temperature (°C): Not Available
Odor threshold: Not Available	Viscosity (°C): Not Available
pH (as supplied): 3.6-4.0	Explosive properties: Not Available
Melting point / freezing point (°C): Not Available	Oxidizing properties: Not Available
Initial boiling point and boiling range (°C): Not Available	Partition coefficient: Not Available
Flash point (°C): Not Available	Molecular weight: Not Available
Evaporation rate: Not Available	Taste: Not Available
Flammability: Not Available	Surface tension: Not Available
Upper/lower flammability or explosive limits: Not Available	Volatile component (%vol): Not Available
Vapor pressure: Not Available	Gas group: Not Available
Relative density (Water = 1): : Not Available	pH as a solution: Not Available
Solubility in water (mg/l): Miscible	VOC g/L: Not Available
	Specific gravity @ 20°C (water = 1): Not Available

SECTION 10: STABILITY AND REACTIVITY

Reactivity	See Section 7
Chemical stability	Product is considered stable. Hazardous polymerization will not occur.
Possibility of hazardous reactions	See Section 7
Conditions to avoid	See Section 7
Incompatible materials	See Section 7
Hazardous composition	See Section 5

SECTION 11: TOXICOLOGICAL INFORMATION

Information on toxicological effects

Inhalation	The material is not thought to produce adverse health effects or irritation of the respiratory tract (as classified by EC Directives using animal models). Nevertheless, good hygiene practice requires that exposure be kept to a minimum and that suitable control measures be used in an occupational setting.
Ingestion	The material has NOT been classified by EC Directives or other classification systems as "harmful by ingestion". This is because of the lack of corroborating animal or human evidence. The material may still be damaging to the health of the individual, following ingestion, especially where pre-existing organ (e.g. liver, kidney) damage is evident. Gastrointestinal tract discomfort may produce nausea and vomiting. In an occupational setting however, ingestion of insignificant quantities is not thought to be cause for concern.
Skin contact	The material is not thought to produce adverse health effects or skin irritation following contact (as classified by EC Directives using animal models). Nevertheless, good hygiene practice requires that exposure be kept to a minimum and that suitable gloves be used in an occupational setting.
Eye	Although the liquid is not thought to be an irritant (as classified by EC Directives), direct contact with the eye may produce transient discomfort characterised by tearing or conjunctival redness (as with windburn).
Chronic	Long-term exposure to the product is not thought to produce chronic effects adverse to health (as classified by EC Directives using animal models); nevertheless exposure by all routes should be minimised as a matter of course.

Zenalpha injection	Toxicity Not Available	Irritation Not Available
methyl paraben	Toxicity Oral (mouse) LD ₅₀ : 2100 mg/kg ^[2]	Irritation Eye: no adverse effect observed (not irritating) ^[1] Skin: no adverse effect observed (not irritating) ^[1]
propyl paraben	Toxicity Oral (Rat) LD ₅₀ : >5000 mg/kg ^[1]	Irritation Not Available
medetomidine hydrochloride	Toxicity Oral (rat) LD ₅₀ : 31 mg/kg ^[2]	Irritation Not Available
sodium chloride	Toxicity dermal (rabbit) LD ₅₀ : >10000 mg/kg ^[1] Inhalation (rat) LD ₅₀ : >10.5 mg/kg ^[1] Oral (Rat) LD ₅₀ : 3000 mg/kg ^[2]	Irritation Eye (rabbit): 10 mg – moderate Eye (rabbit):100 mg/24h – moderate Skin (rabbit): 500 mg/24h - mild

mannitol	Toxicity		Irritation		
		Oral (rat) LD ₅₀ : 13500 mg/kg ^[2]	Not Available		
sodium citrate	Toxicity		Irritation		
		dermal (rat) LD ₅₀ : >2000 mg/kg ^[1] Oral (mouse) LD ₅₀ : 5000-6000 mg/kg ^[2]	Not Available		
vatinoxan hydrochloride		Toxicity		Irritation	
		Not Available		Not Available	
water	Toxicity		Irritation		
		Oral (rat) LD ₅₀ : >90000 mg/kg ^[2]	Not Available		
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					
Acute Toxicity		*	Carcinogenicity		*
Skin Irritation/Corrosion		*	Reproductivity		*
Serious Eye Damage/Irritation		*	STOT – Single Exposure		*
Respiratory or Skin Sensitization		*	STOT – Repeated Exposure		*
Mutagenicity		*	Aspiration Hazard		*
* - Data either not available or does not fill the criteria for classification, ✓ - Data available to make classification.					

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Zenalpha injection	Endpoint	Test Duration	Species	Value	Source
	Not Available	Not Available	Not Available	Not Available	Not Available
methyl paraben	Endpoint	Test duration	Species	Value	Source
	NOEC(ECx)	504 h	Crustacea	0.2 mg/L	2
	EC50	72h	Algae or other aquatic plants	5-16mg/l	4
	LC50	96h	Fish	59.5mg/l	2
propyl paraben	Endpoint	Test duration	Species	Value	Source
	EC50(ECx)	48h	Crustacea	5.73-22mg/l	4
	EC50	72h	Algae or other aquatic plants	0-1.0 mg/L	4
	LC50	96h	Fish	7.6 mg/L	2
medetomidine hydrochloride	Endpoint	Test duration	Species	Value	Source
	Not Available	Not Available	Not Available	Not Available	Not Available
sodium chloride	Endpoint	Test duration	Species	Value	Source
	NOEC(ECx)	6h	Fish	0.01 mg/L	4
	EC50	72h	Algae or other aquatic plants	1110.36 mg/mL	4
	EC50	72h	Algae or other aquatic plants	20.76-36.17mg/	4
	LC50	96h	Fish	1000 mg/L	4
mannitol	Endpoint	Test duration	Species	Value	Source
	EC50	48h	Crustacea	0.00439-0.00565mg/ml	4
	EC50	72h	Algae or other aquatic plants	4773.64 mg/mL	4
	EC50	96h	Algae or other aquatic plants	> 50 mg/L	2
sodium citrate	Endpoint	Test duration	Species	Value	Source
	EC50	48	Crustacea	> 50 mg/L	2
	EC50	96	Algae or other aquatic plants	> 18000-32000 mg/L	1
vatinoxan hydrochloride	Endpoint	Test duration	Species	Value	Source
	Not Available	Not Available	Not Available	Not Available	Not Available
water	Endpoint	Test duration	Species	Value	Source
	Not Available	Not Available	Not Available	Not Available	Not Available

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
methyl paraben	LOW	LOW
propyl paraben	LOW	LOW
sodium chloride	LOW	LOW
mannitol	LOW	LOW
water	LOW	LOW
methyl paraben	LOW	LOW

12.3 Bioaccumulative potential

Ingredient	Bioaccumulation
methyl paraben	LOW (LogKOW = 1.96)
propyl paraben	LOW (LogKOW = 3.04)
sodium chloride	LOW (LogKOW = 0.5392)
mannitol	LOW (LogKOW = -3.0108)

12.4 Mobility in soil

Ingredient	Mobility
methyl paraben	LOW (KOC = 125.6)

propyl paraben	LOW (KOC = 427.2)
sodium chloride	LOW (KOC = 14.3)
mannitol	LOW (KOC = 10)

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product/packaging disposal	<p>Legislation addressing waste disposal requirements may differ by country, state and/ or territory. Each user must refer to laws operating in their area. In some areas, certain wastes must be tracked. A Hierarchy of Controls seems to be common - the user should investigate: Reduction, Reuse Recycling, Disposal (if all else fails).</p> <p>This material may be recycled if unused, or if it has not been contaminated so as to make it unsuitable for its intended use. If it has been contaminated, it may be possible to reclaim the product by filtration, distillation or some other means. 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.</p> <p>DO NOT allow wash water from cleaning or process equipment to enter drains. In all cases disposal to sewer may be subject to local laws and regulations and these should be considered first. Recycle wherever possible or consult manufacturer for recycling options. Consult State Land Waste Authority for disposal. Bury or incinerate residue at an approved site.</p>
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SECTION 14: TRANSPORT INFORMATION

Labels required

Marine pollutant	NO
Land transport (TDG): 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	
Transport in bulk according to Annex II of MARPOL and the IBC code Not Applicable	
14.8 Transport in bulk in accordance with MARPOL Annex V and the IMSBC Code	
Product name	Group
	Not Available for any ingredient
14.9 Transport in bulk in accordance with ICG Code	
Product name	Group
	Not Available for any ingredient

SECTION 15: REGULATORY INFORMATION

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

This product has been classified in accordance with the hazard criteria of the Hazardous Products Regulations and the SDS contains all the information required by the Hazardous Products Regulations.

methyl paraben is found on the following regulatory lists
 Canada Categorization decisions for all DSL substances, Canada Domestic Substances List (DSL)

propyl paraben is found on the following regulatory lists
 Canada Categorization decisions for all DSL substances, Canada Domestic Substances List (DSL), International WHO List of Proposed Occupational Exposure Limit (OEL) Values for Manufactured Nanomaterials (MNMS)

medetomidine hydrochloride is found on the following regulatory lists
 Not Applicable

sodium chloride is found on the following regulatory lists
 Canada Categorization decisions for all DSL substances, Canada DSL, Canada Toxicological Index Service - Workplace Hazardous Materials Information System - WHMIS GHS

mannitol is found on the following regulatory lists
 Canada Categorization decisions for all DSL substances, Canada DSL, Canada Toxicological Index Service - WHMIS GHS

sodium citrate is found on the following regulatory lists
 Canada Categorization decisions for all DSL substances, Canada DSL, Canada Non-Domestic Substances List (NDSL), Canada Toxicological Index Service - WHMIS GHS

vatinoxan hydrochloride is found on the following regulatory lists
 Not Applicable

water is found on the following regulatory lists
 Canada Categorization decisions for all DSL substances, Canada DSL, Canada Toxicological Index Service - Workplace Hazardous Materials Information System - WHMIS GHS

National Inventory Status

Australia - AIIC / Australia Non-Industrial Use	No (medetomidine hydrochloride; vatinoxan hydrochloride)
Canada - DSL	No (medetomidine hydrochloride; vatinoxan hydrochloride)
Canada - NDSL	No (methyl paraben; propyl paraben; medetomidine hydrochloride; sodium chloride; mannitol; vatinoxan hydrochloride; water)
China - IECSC	No (medetomidine hydrochloride; vatinoxan hydrochloride)

Europe - EINEC / ELINCS /NLP	No (medetomidine hydrochloride; vatinoxan hydrochloride)
Japan - ENCS	No (medetomidine hydrochloride; vatinoxan hydrochloride)
Korea - KECI	No (medetomidine hydrochloride; vatinoxan hydrochloride)
New Zealand - NZIoC	No (vatinoxan hydrochloride)
Philippines - PICCS	No (medetomidine hydrochloride; vatinoxan hydrochloride)
USA - TSCA	No (medetomidine hydrochloride; vatinoxan hydrochloride)
Taiwan - TCSI	No (medetomidine hydrochloride; vatinoxan hydrochloride)
Mexico - INSQ	No (medetomidine hydrochloride; vatinoxan hydrochloride)
Vietnam - NCI	No (medetomidine hydrochloride; vatinoxan hydrochloride)
Russia - FBEPH	No (methyl paraben; medetomidine hydrochloride; vatinoxan hydrochloride)
Yes = All CAS declared ingredients are on the inventory No = One or more of the CAS listed ingredients are not on the inventory. These ingredients may be exempt or will require registration	

SECTION 16: OTHER INFORMATION

Revision Date: June 2023 Classification change due to full database hazard calculation/update, SDS created for Canada
 Initial date: April 2021 – Initial classification for UK

Classification of the preparation and its individual components has drawn on official and authoritative sources as well as independent review by the Chemwatch Classification committee using available literature references. The SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings. Risks may be determined by reference to Exposures Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered.

Definitions and abbreviations

PC—TWA: Permissible Concentration-Time Weighted Average	STEL: Short Term Exposure Limit
PC—STEL: Permissible Concentration-Short Term Exposure Limit	TEEL: Temporary Emergency Exposure Limit
IARC: International Agency for Research on Cancer	ES: Exposure Standard
ACGIH: American Conference of Governmental Industrial Hygienists	OSF: Odor Safety Factor
IDLH: Immediately Dangerous to Life or Health Concentrations	NOAEL :No Observed Adverse Effect Level
AIC: Australian Inventory of Industrial Chemicals	LOAEL: Lowest Observed Adverse Effect Level
IECSC: Inventory of Existing Chemical Substance in China	TLV: Threshold Limit Value
EINECS: European Inventory of Existing Commercial chemical Substances	LOD: Limit Of Detection
ELINCS: European List of Notified Chemical Substances	OTV: Odor Threshold Value
ENCS: Existing and New Chemical Substances Inventory	BCF: BioConcentration Factors
PICCS: Philippine Inventory of Chemicals and Chemical Substances	BEI: Biological Exposure Index
INSQ: Inventario Nacional de Sustancias Químicas	DSL: Domestic Substances List
NCI: National Chemical Inventory	NDSL: Non-Domestic Substances List
FBEPH: Russian Register of Potentially Hazardous Chemical and Biological Substances	NLP: No-Longer Polymers
NZIoC: New Zealand Inventory of Chemicals	KECI: Korea Existing Chemicals Inventory
	TSCA: Toxic Substances Control Act
	TCSI: Taiwan Chemical Substance Inventory

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