



SECTION 1: IDENTIFICATION	
1.1 Product identifier	
Product name:	ZENALPHA® (Medetomidine and Vatinoxan)
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:	For intramuscular use in dogs for sedation and analgesia.
Uses advised against:	Not for human use.
1.3 Details of the supplier of the substance or mixture	
Registered company name:	Dechra Ltd
Address:	Snaygill Industrial Estate Keighley Road Skipton North Yorkshire BD23 2RW UK
Telephone:	+44 (0) 1756 791311
Fax:	+44 (0) 1756 798604
Website:	www.dechra.com
Email:	Dechra Ltd
1.4 Emergency Telephone Numbers	
	+44 (0) 1756 791311

SECTION 2: HAZARDS IDENTIFICATION	
2.1 Classification of the substance or mixture	
Not 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:	Not applicable
2.2 Label Elements	
Hazard Pictogram:	Not applicable
Signal Word:	Not applicable



Hazard statement(s):
Not applicable
Supplementary Statement(s):
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
2.3 Other Hazard Information RECh – 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 'Composition of mixtures' in Section 3.2

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)
1.99-76-3 2.202-785-7 3.Not Available 4.01-2119463264-40-XXXX 01-2120065912-54-XXXX	Not specified	Methyl paraben	Skin Corrosion/Irritation Category 2, Serious Eye Damage/Eye Irritation Category 2, Specific Target Organ Toxicity – Single Exposure (Respiratory Tract Irritation) Category 3, Hazardous to the Aquatic Environment Long-Term Hazard Category 2; H315, H319, H335, H411 ^[1]
1.94-13-3 2.202-307-7 3.Not Available 4.01-2119969462-29-XXXX	Not specified	Propyl paraben	Skin Corrosion/Irritation Category 2, Serious Eye Damage/Eye Irritation Category 2, Specific Target Organ Toxicity – Single Exposure (Respiratory Tract Irritation) Category 3, Hazardous to the Aquatic Environment Long-Term Hazard Category 2; H315, H319, H335, H411 ^[1]



1.86347-15-1 2.Not Available 3.Not Available 4.Not Available	Not specified	Medetomidine hydrochloride	Acute Toxicity (Oral) Category 3, Reproductive Toxicity Category 2; H301, H361d [1]
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, Serious Eye Damage/Eye Irritation Category 2, Specific Target Organ Toxicity – Single Exposure (Respiratory Tract Irritation) Category 3; H315, H319, H335 [1]
1.69-65-8 2.200-711-8 3.Not Available 4.Not Available	Not specified	Mannitol	Not applicable
1.68-04-2 2.200-675-3 3.Not Available 4.01-2120760175-56-XXXX 01-2119457027-40-XXXX	Not specified	Sodium Citrate	Not applicable
1.130466-38-5 2.Not Available 3.Not Available 4.Not Available	Not specified	Vatinoxan hydrochloride	Not applicable
1.7732-18-5 2.231-791-2 3.Not Available 4.Not Available	Not specified	Water	Not applicable
1. Classified by Chemwatch; 2. Classification drawn from Regulation (EU) No 1272/2008 - Annex VI; 3. Classification drawn from C&L; * EU IOELVs available			

SECTION 4: FIRST AID MEASURES	
4.1 Description of first aid measures	
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 Most important symptoms and effects, both acute and delayed	
Eye contact:	Not expected to cause eye irritation
Skin contact:	Not expected to cause skin irritation
Ingestion:	May cause systemic effect of the drug (sedation etc.)
Self-injection:	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.
See Section 11 for more detailed information	
4.3 Indication of immediate medical attention and special treatment needed	
Treatment of overdose of oral sympathomimetics should be symptomatic and supportive	

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:	Avoid contamination with oxidising agents.
5.3 Special protective actions for fire-fighters:	
Firefighting:	Use water delivered as a fine spray to control fire and cool adjacent area. 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. Equipment should be thoroughly decontaminated after use.
Fire/explosion hazard:	Combustible Slight fire hazard when exposed to heat or flame. On combustion, may emit toxic fumes of carbon monoxide.



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. 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 handling	
Safe Handling:	Wear suitable protection gloves and clothing when handling the product. 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. Store below 86°F (30°C) In use shelf life: 28 days at 77°F (25°C). Keep out of the reach and sight of children.
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. Each mL contains 0.5 mg medetomidine hydrochloride and 10 mg vatinoxan hydrochloride.
Storage incompatibility:	Avoid contamination of water, foodstuffs, feed or seed. Avoid reaction with oxidising agents
7.3 Specific end uses	
Not available	



SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control parameters

Ingredient	SNELs Exposure Pattern Worker	PNECs Compartment
Methyl paraben	Dermal 9.8 mg/kg bw/day (Systemic, Chronic) Inhalation 58.76 mg/m ³ (Systemic, Chronic) <i>Dermal 4.2 mg/kg bw/day (Systemic, Chronic)*</i> <i>Inhalation 14.49 mg/m³ (Systemic, Chronic)*</i> <i>Oral 4.16 mg/kg bw/day (Systemic, Chronic)*</i>	2.4 µg/L (Fresh Water) 0.24 µg/L (Water - Intermittent release) 0.112 mg/L (Water (Marine)) 63.2 µg/kg sediment dw (Sediment (Fresh Water)) 6.32 µg/kg sediment dw (Sediment (Marine)) 11.5 µg/kg soil dw (Soil) 2 mg/L (STP)
Propyl paraben	Dermal 675.6 mg/kg bw/day (Systemic, Chronic) Inhalation 88.2 mg/m ³ (Systemic, Chronic) <i>Dermal 338 mg/kg bw/day (Systemic, Chronic)*</i> <i>Inhalation 43.47 mg/m³ (Systemic, Chronic)*</i> <i>Oral 43.47 mg/kg bw/day (Systemic, Chronic)*</i>	0.017 mg/L (Fresh Water) 0.002 mg/L (Water - Intermittent release) 0.064 mg/L (Water (Marine)) 0.115 mg/kg sediment dw (Sediment (Fresh Water)) 0.011 mg/kg sediment dw (Sediment (Marine)) 0.052 mg/kg soil dw (Soil) 2 mg/L (STP)
Sodium chloride	Dermal 295.52 mg/kg bw/day (Systemic, Chronic) Inhalation 2 068.62 mg/m ³ (Systemic, Chronic) Dermal 295.52 mg/kg bw/day (Systemic, Acute) Inhalation 2 068.62 mg/m ³ (Systemic, Acute) <i>Dermal 126.65 mg/kg bw/day (Systemic, Chronic)*</i> <i>Inhalation 443.28 mg/m³ (Systemic, Chronic)*</i> <i>Oral 126.65 mg/kg bw/day (Systemic, Chronic)*</i> <i>Dermal 126.65 mg/kg bw/day (Systemic, Acute)*</i> <i>Inhalation 443.28 mg/m³ (Systemic, Acute)*</i> <i>Oral 126.65 mg/kg bw/day (Systemic, Acute)*</i>	5 mg/L (Fresh Water) 19 (Water (Marine)) 4.86 mg/kg soil dw (Soil) 500 mg/L (STP)
Sodium citrate	Not Available	0.44 mg/L (Fresh Water) 0.044 mg/L (Water - Intermittent release) 34.6 mg/kg sediment dw (Sediment (Fresh Water)) 3.46 mg/kg sediment dw (Sediment (Marine)) 33.1 mg/kg soil dw (Soil) 1000 mg/L (STP)

* Values for General Population

OCCUPATIONAL EXPOSURE LIMITS (OEL)

INGREDIENT DATA

Source	Ingredient	Material name	TWA	STEL	Peak	Notes
Not available	N/A	N/A	N/A	N/A	N/A	N/A

Not applicable

EMERGENCY LIMITS (EU):

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
All other ingredients	Not available	Not available	Not available

Occupational Exposure Banding

Ingredient	Occupational Exposure Band Rating	Occupational Exposure Band Limit
methyl paraben	E	≤ 0.01 mg/m ³
propyl 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.

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 "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:	No special equipment needed when handling small quantities. 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: Liquid
Container: Zenalpha is supplied in cardboard outer box containing 1, 5 or 10 clear multidose glass vials of 10 mL fill volume. Each mL contains 0.5 mg medetomidine hydrochloride and 10 mg vatinoxan hydrochloride.
Physical state: Liquid
Odor: 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
Vapor 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
Oxidizing properties: Not available
Partition Coefficient: Not available
Taste: Not applicable
Surface tension: Not available
Volatile component: Not available
Gas group: Not applicable
pH: 3.6 – 4.0
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:	Product is considered stable. Hazardous polymerisation will not occur.
10.3 Possibility of hazardous reactions:	See Section 7.
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:	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:	Due to the nature of the product, it is unlikely large quantities will be ingested. However, oral ingestion of sulphonamides following prolonged times has caused nausea, vomiting, diarrhoea, abdominal pain, loss of appetite, inflammation of the mouth cavity, impaired folic acid absorption, exacerbation of porphyria, acidosis, liver damage with impaired blood clotting, jaundice and inflammation of the pancreas.
Skin contact:	Not expected to cause skin irritation, however, 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 bloodstream, through for example, cuts, abrasions or lesions, may produce systemic effects with harmful effects. Examine the skin prior to the use of the material and ensure that any external damage is suitably protected.
Eye contact:	Not expected to cause eye irritation, however, this material can cause eye irritation and damage in some persons.
Chronic:	Due to the nature of the product, it is likely that humans will be exposed for long periods.

ZENALPHA® (Medetomidine and Vatinoxan)	Toxicity	Irritation
	Not available	Not Available
Methyl paraben	Toxicity	Irritation
	Oral (rat) LD ₅₀ : >2000 mg/kg ²	Eye: no adverse effect observed (not irritating) ^[1]
Propyl paraben	Toxicity	Irritation
	Oral (rat) LD ₅₀ : >5000 mg/kg ^[1]	Not available
Medetomidine hydrochloride	Toxicity	Irritation
	Oral (rat) LD ₅₀ : 31 mg/kg ^[2]	Not available
Sodium chloride	Toxicity	Irritation
	Dermal (rabbit) LD ₅₀ : >10000 mg/kg ^[1] Inhalation (rat) LC ₅₀ : >10.5 mg/kg ^[1] Oral (rat) LD ₅₀ : 3000 mg/kg ^[2]	Eye (rabbit): 10mg – 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					
Ingredient	Endpoint	Test duration (hr)	Species	Value	Source
ZENALPHA® (Medetomidine and Vatinoxan)	Not available	Not available	Not available	Not available	Not available
Methyl paraben	LC50	96	Fish	59.5 mg/L	2
	EC50	48	Crustacea	5.73-22 mg/L	4
	EC50	72	Algae or other aquatic plants	15-18 mg/L	4
	NOEC(ECx)	504	Crustacea	0.2 mg/L	2
Propyl paraben	LC50	96	Fish	6.4 mg/L	2
	EC50	48	Crustacea	7.97-32.3 mg/L	2
	EC50	72	Algae or other aquatic plants	7.6 mg/k	2
	EC10(ECx)	48	Algae or other aquatic plants	0.1-0.13 mg/L	4
Medetomidine hydrochloride	Not available	Not available	Not available	Not available	Not available



Sodium citrate	EC50(ECx) EC50 EC50	48 48 96	Crustacea Crustacea Algae or other aquatic plants	>50 mg/L >50 mg/L >18000-32000 mg/L	2 2 1
Mannitol	EC10(ECx)	168	Algae or other aquatic plants	4773 mg/L	4
Sodium citrate	EC50(ECx) EC50 EC50	48 48 96	Crustacea Crustacea Algae or other aquatic plants	>50 mg/L >50 mg/L >18000-32000 mg/L	2 2 1
Vatinoxan hydrochloride	Not available	Not available	Not available	Not available	Not available
Water	Not available	Not available	Not available	Not available	Not available
<p>Legend: Extracted from 1. IUCLID Toxicity Data 2. Europe ECHA Registered Substances - Ecotoxicological Information - Aquatic Toxicity 3. EPIWIN Suite V3.12 (QSAR) - Aquatic Toxicity Data (Estimated) 4. US EPA, Ecotox database - Aquatic Toxicity Data 5. ECETOC Aquatic Hazard Assessment Data 6. NITE (Japan) - Bioconcentration Data 7. METI (Japan) - Bioconcentration Data 8. Vendor Data</p>					
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
12.3 Bioaccumulative potential		
Ingredient	Bioaccumulative Potential	
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)	



12.5 Results of PBT and vPvB assessment			
	P	B	T
Relevant available data	Not Available	Not Available	Not Available
PBT	x	x	x
vPvB	x	x	x
PBT Criteria fulfilled?		No	
vPvB		No	
12.6. Endocrine Disruption Properties			
Not Available			
12.7 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>Recycle wherever possible or consult manufacturer for recycling options.</p> <p>Consult State Land Waste Management Authority for disposal.</p> <p>Bury residue in an authorised landfill.</p> <p>Recycle containers if possible or dispose of in an authorised landfill.</p> <p>Shelf life considerations should also be applied in making decisions of this type. Note that properties of a material may change in use, and recycling or reuse may not always be appropriate. Where in doubt contact the responsible authority.</p> <p>Disposal of this product is controlled by the Misuse of Drugs 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): 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)	Class Subrisk	N/A N/A
14.4 Packing group	Not applicable	
14.5 Environmental hazards	Not applicable	
14.6 Special precautions for user	Hazard Identification (Kemler) Classification code Hazard label Special provisions Limited quantity Tunnel Restriction Code	N/A N/A N/A N/A N/A N/A
14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable	
14.8. Transport in bulk in accordance with MARPOL Annex V and the IMSBC Code	Not applicable	
14.9. Transport in bulk in accordance with the ICG Code	Not applicable	
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 ICAO / IATA Sub risk ERG Code	N/A N/A N/A
14.4 Packing group	Not applicable	
14.5 Environmental hazards	Not applicable	
14.6 Special precautions for user	Special provisions Cargo only packing instructions Cargo only maximum qty/pack Passenger and cargo packaging instructions	N/A N/A N/A N/A



	Passenger and cargo maximum qty/pack Passenger and cargo limited quantity packing instructions Passenger and cargo limited maximum qty/pack	N/A N/A N/A
14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable	
14.8. Transport in bulk in accordance with MARPOL Annex V and the IMSBC Code	Not applicable	
14.9. Transport in bulk in accordance with the ICG Code	Not applicable	
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 IMDG Sub risk	N/A N/A
14.4 Packing group	Not applicable	
14.5 Environmental hazards	Not applicable	
14.6 Special precautions for user	EMS Number Special provisions Limited quantities	N/A N/A N/A
14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable	
14.8. Transport in bulk in accordance with MARPOL Annex V and the IMSBC Code	Not applicable	
14.9. Transport in bulk in accordance with the ICG Code	Not applicable	
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	Not applicable	
14.5 Environmental hazard	Not applicable	



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	Not applicable	
14.8. Transport in bulk in accordance with MARPOL Annex V and the IMSBC Code	Not applicable	
14.9. Transport in bulk in accordance with the ICG Code	Not applicable	

SECTION 15: REGULATORY INFORMATION

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

Mannitol (69-65-8)

Europe EC Inventory / EU - European Inventory of Existing Commercial Chemical Substances (EINECS)

Sodium chloride (7647-14-5)

Europe EC Inventory / EINECS

Methyl paraben (99-76-3)

EU European Chemicals Agency (ECHA) Community Rolling Action Plan (CoRAP) List of Substances / Europe EC Inventory / EINECS

Medetomidine hydrochloride (86347-15-1)

Not applicable

Vatinoxan hydrochloride (130466-38-5)

Not applicable

Propyl paraben (94-13-3)

EU ECHA Community Rolling Action Plan (CoRAP) List of Substances / Europe EC Inventory / EINECS

Water (7732-18-5)

Europe EC Inventory / EINECS

This SDS is in compliance with the following EU legislation and its adaptations, as far as applicable: Directives 98/24/EC, 92/85/EEC, 94/33/EC, 2008/98/EC, 2010/75/EU; Commission Regulation (EU) 2020/878; Regulation (EC) No 1272/2008 as updated through ATPs.

15.2 Chemical Safety Assessment

ECHA SUMMARY

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	Water-react. 1; Eye Irrit. 2	GHS02; GHS07; Dgr	H260; H319
2	Water-react. 1; Eye Irrit. 2	GHS02; GHS07; Dgr	H260; H319
Harmonisation Code 1 = the most prevalent classification. Harmonisation Code 2 = The most severe classification			
Ingredient	CAS number	Index Number	ECHA Dossier
Water	7732-18-5	Not available	Not available
Harmonization (C&L Inventory)	Hazard Class and Category Code(s)	Pictograms Signal Word Code(s)	Hazard Statement Code(s)
1	Skin Irrit. 2; Eye Irrit. 2; Aquatic Chronic 2	GHS07; Wng	H315; H319; H411
2	Skin Irrit. 2; Eye Irrit. 2; Aquatic Chronic 2	GHS07; Wng	H315; H319; H411
Harmonisation Code 1 = the most prevalent classification. Harmonisation Code 2 = The most severe classification			
National Inventory	Status		
Austrália – AICS / 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 (medetomidine hydrochloride, vatinoxan 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)	



SECTION 16: OTHER INFORMATION

The SDS is written in accordance to guidelines specified by REACH and ECHA.

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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