

Midazolam Injection, USP

Steriscience Specialties Pvt Ltd

Chemwatch: 37-59831
Version No: 3.1
Safety Data Sheet

Chemwatch Hazard Alert Code: 2

Issue Date: 20/08/2021
Print Date: 24/11/2023
S.GHS.IND.EN

SECTION 1 Identification of the substance / mixture and of the company / undertaking

Product Identifier

Product name	Midazolam Injection, USP
Chemical Name	Not Applicable
Synonyms	Midazolam Hydrochloride; Midazolam Injection
Chemical formula	Not Applicable
Other means of identification	Not Available

Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses	Pharmaceutical.
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Details of the manufacturer or supplier of the safety data sheet

Registered company name	Steriscience Specialties Pvt Ltd	
Address	Opp IIMB, Bilekahalli, Dorasani Palya, Begur Hobli, Bannerghata Road, BENGALURU Karnataka 560076 India	
Telephone	+91 80 67840000	
Fax	+91 80 67840700	
Website	www.steri-science.com	
Email	info@steriscience.com	

Emergency telephone number

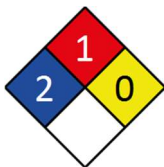
Association / Organisation	Steriscience Specialties Pvt Ltd	CHEMWATCH EMERGENCY RESPONSE (24/7)
Emergency telephone numbers	+91 80 69093100	+918000403230
Other emergency telephone numbers	Not Available	+61 3 9573 3188

Once connected and if the message is not in your preferred language then please dial 01

SECTION 2 Hazards identification

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)

Classification	Skin Corrosion/Irritation Category 2, Serious Eye Damage/Eye Irritation Category 2
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Label elements

Hazard pictogram(s)	
Signal word	Warning

Hazard statement(s)

H315	Causes skin irritation.
H319	Causes serious eye irritation.

Precautionary statement(s) Prevention

P280	Wear protective gloves, protective clothing, eye protection and face protection.
P264	Wash all exposed external body areas thoroughly after handling.

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.
P332+P313	If skin irritation occurs: Get medical advice/attention.
P362+P364	Take off contaminated clothing and wash it before reuse.

Precautionary statement(s) Storage

Not Applicable

Precautionary statement(s) Disposal

Not Applicable

SECTION 3 Composition / information on ingredients**Substances**

See section below for composition of Mixtures

Mixtures

CAS No	%[weight]	Name
7727-37-9.	NotSpec	<u>nitrogen</u>
7647-14-5	NotSpec	<u>sodium chloride</u>
7647-01-0	NotSpec	<u>hydrochloric acid</u>
59467-96-8	NotSpec	<u>midazolam</u>
1310-73-2	NotSpec	<u>sodium hydroxide</u>
7732-18-5	NotSpec	<u>Water for Injection</u>

SECTION 4 First aid measures**Description of first aid measures**

Eye Contact	<p>If this product comes in contact with the eyes:</p> <ul style="list-style-type: none"> ▶ Wash out immediately with fresh running water. ▶ Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids. ▶ Seek medical attention without delay; if pain persists or recurs seek medical attention. ▶ Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.
Skin Contact	<p>If skin contact occurs:</p> <ul style="list-style-type: none"> ▶ Immediately remove all contaminated clothing, including footwear. ▶ Flush skin and hair with running water (and soap if available). ▶ Seek medical attention in event of irritation.
Inhalation	<ul style="list-style-type: none"> ▶ If fumes or combustion products are inhaled remove from contaminated area. ▶ Lay patient down. Keep warm and rested. ▶ Prostheses such as false teeth, which may block airway, should be removed, where possible, prior to initiating first aid procedures. ▶ Apply artificial respiration if not breathing, preferably with a demand valve resuscitator, bag-valve mask device, or pocket mask as trained. Perform CPR if necessary. ▶ Transport to hospital, or doctor, without delay.
Ingestion	<ul style="list-style-type: none"> ▶ Immediately give a glass of water. ▶ First aid is not generally required. If in doubt, contact a Poisons Information Centre or a doctor.

Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5 Firefighting measures**Extinguishing media**

- ▶ Water spray or fog.
- ▶ Foam.
- ▶ Dry chemical powder.
- ▶ BCF (where regulations permit).
- ▶ Carbon dioxide.

Special hazards arising from the substrate or mixture

Fire Incompatibility	<ul style="list-style-type: none"> ▶ Avoid contamination with oxidising agents i.e. nitrates, oxidising acids, chlorine bleaches, pool chlorine etc. as ignition may result
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Advice for firefighters

Fire Fighting	<ul style="list-style-type: none"> ▶ 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 courses. ▶ 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	<ul style="list-style-type: none"> ▶ Combustible. ▶ Slight fire hazard when exposed to heat or flame. ▶ Heating may cause expansion or decomposition leading to violent rupture of containers. ▶ On combustion, may emit toxic fumes of carbon monoxide (CO). ▶ May emit acrid smoke. ▶ Mists containing combustible materials may be explosive. <p>Combustion products include: carbon monoxide (CO) carbon dioxide (CO₂) nitrogen oxides (NO_x) other pyrolysis products typical of burning organic material. May emit poisonous fumes. May emit corrosive fumes.</p>

SECTION 6 Accidental release measures**Personal precautions, protective equipment and emergency procedures**

See section 8

Environmental precautions

See section 12

Methods and material for containment and cleaning up

Minor Spills	<ul style="list-style-type: none"> ▶ Clean up all spills immediately. ▶ Avoid breathing vapours/ aerosols/ or dusts and 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. ▶ Place in a suitable, labelled container for waste disposal.
Major Spills	<p>Minor hazard.</p> <ul style="list-style-type: none"> ▶ Clear area of personnel. ▶ Alert Fire Brigade and tell them location and nature of hazard. ▶ Control personal contact with the substance, by using protective equipment as required. ▶ Prevent spillage from entering drains or water ways. ▶ Contain spill with sand, earth or vermiculite. ▶ Collect recoverable product into labelled containers for recycling. ▶ Absorb remaining product with sand, earth or vermiculite and place in appropriate containers for disposal. ▶ Wash area and prevent runoff into drains or waterways. ▶ 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**Precautions for safe handling**

Safe handling	<ul style="list-style-type: none"> ▶ 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. ▶ DO NOT allow material to contact humans, exposed food or food utensils. ▶ 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. Launder contaminated clothing before re-use. ▶ 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 are maintained.
Other information	<ul style="list-style-type: none"> ▶ 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.

Conditions for safe storage, including any incompatibilities

Suitable container	<ul style="list-style-type: none"> ▶ Polyethylene or polypropylene container. ▶ Packing as recommended by manufacturer. ▶ Check all containers are clearly labelled and free from leaks.
Storage incompatibility	<p>Hydrogen chloride:</p> <ul style="list-style-type: none"> ▶ reacts strongly with strong oxidisers (releasing chlorine gas), acetic anhydride, caesium cyanotridecahydrodecaborate(2-), ethylidene difluoride, hexalithium disilicide, metal acetylide, sodium, silicon dioxide, tetraselenium tetranitride, and many organic materials ▶ is incompatible with alkaline materials, acetic anhydride, acetylides, aliphatic amines, alkanolamines, alkylene oxides, aluminium, aluminium-titanium alloys, aromatic amines, amines, amides, 2-aminoethanol, ammonia, ammonium hydroxide, borides, calcium phosphide, carbides, carbonates, cyanides, chlorosulfonic acid, ethylenediamine, ethyleneimine, epichlorohydrin, formaldehyde, isocyanates, metals, metal oxides, metal hydroxides, metal acetylides, metal carbides, oleum, organic anhydrides, potassium permanganate, perchloric acid, phosphides, 3-propiolactone, silicides, sulfides, sulfites, sulfuric acid, uranium phosphide, vinyl acetate, vinylidene fluoride ▶ attacks most metals forming flammable hydrogen gas, and some plastics, rubbers and coatings ▶ reacts with zinc, brass, galvanised iron, aluminium, copper and copper alloys <p>▶ Avoid reaction with oxidising agents</p>

SECTION 8 Exposure controls / personal protection

Control parameters

Occupational Exposure Limits (OEL)

INGREDIENT DATA

Source	Ingredient	Material name	TWA	STEL	Peak	Notes
India Permissible Levels of Certain Chemical Substances in Work Environment	hydrochloric acid	Hydrogen chloride	Not Available	Not Available	5 ppm / 7 mg/m ³	Not Available
India Permissible Levels of Certain Chemical Substances in Work Environment	sodium hydroxide	Sodium hydroxide	Not Available	Not Available	2 mg/m ³	Not Available

Emergency Limits

Ingredient	TEEL-1	TEEL-2	TEEL-3
nitrogen	7.96E+05 ppm	8.32E+05 ppm	8.69E+05 ppm
sodium chloride	0.5 ppm	2 ppm	20 ppm
hydrochloric acid	1.8 ppm	22 ppm	100 ppm
sodium hydroxide	Not Available	Not Available	Not Available

Ingredient	Original IDLH	Revised IDLH
nitrogen	Not Available	Not Available
sodium chloride	Not Available	Not Available
hydrochloric acid	50 ppm	Not Available
midazolam	Not Available	Not Available
sodium hydroxide	10 mg/m ³	Not Available
Water for Injection	Not Available	Not Available

Occupational Exposure Banding


Ingredient	Occupational Exposure Band Rating	Occupational Exposure Band Limit
sodium chloride	E	≤ 0.01 mg/m ³
hydrochloric acid	E	≤ 0.01 mg/m ³
sodium hydroxide	E	≤ 0.1 ppm
Notes:	<i>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.</i>	

Exposure controls

Appropriate engineering controls	<p>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:</p> <p>Process controls which involve changing the way a job activity or process is done to reduce the risk.</p> <p>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. Ventilation can remove or dilute an air contaminant if designed properly. The design of a ventilation system must match the particular process and chemical or contaminant in use.</p> <p>Employers may need to use multiple types of controls to prevent employee overexposure.</p>
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	<p>General exhaust is adequate under normal operating conditions. Local exhaust ventilation may be required in special circumstances. If risk of overexposure exists, wear approved respirator. Supplied-air type respirator may be required in special circumstances. Correct fit is essential to ensure adequate protection. Provide adequate ventilation in warehouses and enclosed storage areas. Air contaminants generated in the workplace possess varying "escape" velocities which, in turn, determine the "capture velocities" of fresh circulating air required to effectively remove the contaminant.</p> <table border="1"> <tr> <td>Type of Contaminant:</td> <td>Air Speed:</td> </tr> <tr> <td>solvent, vapours, degreasing etc., evaporating from tank (in still air).</td> <td>0.25-0.5 m/s (50-100 f/min)</td> </tr> <tr> <td>aerosols, fumes from pouring operations, intermittent container filling, low speed conveyer transfers, welding, spray drift, plating acid fumes, pickling (released at low velocity into zone of active generation)</td> <td>0.5-1 m/s (100-200 f/min.)</td> </tr> <tr> <td>direct spray, spray painting in shallow booths, drum filling, conveyer loading, crusher dusts, gas discharge (active generation into zone of rapid air motion)</td> <td>1-2.5 m/s (200-500 f/min.)</td> </tr> <tr> <td>grinding, abrasive blasting, tumbling, high speed wheel generated dusts (released at high initial velocity into zone of very high rapid air motion)</td> <td>2.5-10 m/s (500-2000 f/min.)</td> </tr> </table> <p>Within each range the appropriate value depends on:</p> <table border="1"> <tr> <td>Lower end of the range</td> <td>Upper end of the range</td> </tr> <tr> <td>1: Room air currents minimal or favourable to capture</td> <td>1: Disturbing room air currents</td> </tr> <tr> <td>2: Contaminants of low toxicity or of nuisance value only.</td> <td>2: Contaminants of high toxicity</td> </tr> <tr> <td>3: Intermittent, low production.</td> <td>3: High production, heavy use</td> </tr> <tr> <td>4: Large hood or large air mass in motion</td> <td>4: Small hood-local control only</td> </tr> </table> <p>Simple theory shows that air velocity falls rapidly with distance away from the opening of a simple extraction pipe. Velocity generally decreases with the square of distance from the extraction point (in simple cases). Therefore the air speed at the extraction point should be adjusted, accordingly, after reference to distance from the contaminating source. The air velocity at the extraction fan, for example, should be a minimum of 1-2 m/s (200-400 f/min) for extraction of solvents generated in a tank 2 meters distant from the extraction point. Other mechanical considerations, producing performance deficits within the extraction apparatus, make it essential that theoretical air velocities are multiplied by factors of 10 or more when extraction systems are installed or used.</p>	Type of Contaminant:	Air Speed:	solvent, vapours, degreasing etc., evaporating from tank (in still air).	0.25-0.5 m/s (50-100 f/min)	aerosols, fumes from pouring operations, intermittent container filling, low speed conveyer transfers, welding, spray drift, plating acid fumes, pickling (released at low velocity into zone of active generation)	0.5-1 m/s (100-200 f/min.)	direct spray, spray painting in shallow booths, drum filling, conveyer loading, crusher dusts, gas discharge (active generation into zone of rapid air motion)	1-2.5 m/s (200-500 f/min.)	grinding, abrasive blasting, tumbling, high speed wheel generated dusts (released at high initial velocity into zone of very high rapid air motion)	2.5-10 m/s (500-2000 f/min.)	Lower end of the range	Upper end of the range	1: Room air currents minimal or favourable to capture	1: Disturbing room air currents	2: Contaminants of low toxicity or of nuisance value only.	2: Contaminants of high toxicity	3: Intermittent, low production.	3: High production, heavy use	4: Large hood or large air mass in motion	4: Small hood-local control only
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4: Large hood or large air mass in motion	4: Small hood-local control only																				
Individual protection measures, such as personal protective equipment																					
Eye and face protection	<ul style="list-style-type: none"> ▶ Safety glasses with side shields. ▶ Chemical goggles. [AS/NZS 1337.1, EN166 or national equivalent] ▶ Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lenses or restrictions on use, should be created for each workplace or task. This should include a review of lens absorption and adsorption for the class of chemicals in use and an account of injury experience. Medical and first-aid personnel should be trained in their removal and suitable equipment should be readily available. In the event of chemical exposure, begin eye irrigation immediately and remove contact lens as soon as practicable. Lens should be removed at the first signs of eye redness or irritation - lens should be removed in a clean environment only after workers have washed hands thoroughly. [CDC NIOSH Current Intelligence Bulletin 59]. 																				
Skin protection	See Hand protection below																				
Hands/feet protection	<ul style="list-style-type: none"> ▶ Wear chemical protective gloves, e.g. PVC. ▶ Wear safety footwear or safety gumboots, e.g. Rubber 																				
Body protection	See Other protection below																				
Other protection	<ul style="list-style-type: none"> ▶ Overalls. ▶ P.V.C apron. ▶ Barrier cream. ▶ Skin cleansing cream. ▶ Eye wash unit. 																				

Recommended material(s)

GLOVE SELECTION INDEX

Glove selection is based on a modified presentation of the:

"Forsberg Clothing Performance Index".

The effect(s) of the following substance(s) are taken into account in the **computer-generated** selection:

Sagent Midazolam Injection, USP

Material	CPI
BUTYL	C
BUTYL/NEOPRENE	C
HYPALON	C
NAT+NEOPR+NITRILE	C
NATURAL RUBBER	C
NATURAL+NEOPRENE	C
NEOPRENE	C
NEOPRENE/NATURAL	C
NITRILE	C
NITRILE+PVC	C
PE	C
PE/EVAL/PE	C
PVA	C

Respiratory protection

Type AB-P Filter of sufficient capacity. (AS/NZS 1716 & 1715, EN 143:2000 & 149:2001, ANSI Z88 or national equivalent)

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PVC	C
SARANEX-23	C
SARANEX-23 2-PLY	C
TEFLON	C
VITON	C
VITON/CHLOROBUTYL	C
VITON/NEOPRENE	C

* CPI - Chemwatch Performance Index

A: Best Selection

B: Satisfactory; may degrade after 4 hours continuous immersion

C: Poor to Dangerous Choice for other than short term immersion

NOTE: As a series of factors will influence the actual performance of the glove, a final selection must be based on detailed observation. -

* Where the glove is to be used on a short term, casual or infrequent basis, factors such as "feel" or convenience (e.g. disposability), may dictate a choice of gloves which might otherwise be unsuitable following long-term or frequent use. A qualified practitioner should be consulted.

Selection of the Class and Type of respirator will depend upon the level of breathing zone contaminant and the chemical nature of the contaminant. Protection Factors (defined as the ratio of contaminant outside and inside the mask) may also be important.

Required minimum protection factor	Maximum gas/vapour concentration present in air p.p.m. (by volume)	Half-face Respirator	Full-Face Respirator
up to 10	1000	AB-AUS / Class1 P2	-
up to 50	1000	-	AB-AUS / Class 1 P2
up to 50	5000	Airline *	-
up to 100	5000	-	AB-2 P2
up to 100	10000	-	AB-3 P2
100+			Airline**

* - Continuous Flow ** - Continuous-flow or positive pressure demand

A(All classes) = Organic vapours, B AUS or B1 = Acid gasses, B2 = Acid gas or hydrogen cyanide(HCN), B3 = Acid gas or hydrogen cyanide(HCN), E = Sulfur dioxide(SO₂), G = Agricultural chemicals, K = Ammonia(NH₃), Hg = Mercury, NO = Oxides of nitrogen, MB = Methyl bromide, AX = Low boiling point organic compounds(below 65 degC) (76ab-p)

SECTION 9 Physical and chemical properties

Information on basic physical and chemical properties

Appearance	Clear colorless to light yellow liquid; mixes with water.		
Physical state	Liquid	Relative density (Water = 1)	Not Available
Odour	Not Available	Partition coefficient n-octanol / water	Not Available
Odour threshold	Not Available	Auto-ignition temperature (°C)	Not Available
pH (as supplied)	2.5-3.5	Decomposition temperature (°C)	Not Available
Melting point / freezing point (°C)	Not Available	Viscosity (cSt)	Not Available
Initial boiling point and boiling range (°C)	159	Molecular weight (g/mol)	Not Applicable
Flash point (°C)	Not Available	Taste	Not Available
Evaporation rate	Not Available	Explosive properties	Not Available
Flammability	Not Available	Oxidising properties	Not Available
Upper Explosive Limit (%)	Not Available	Surface Tension (dyn/cm or mN/m)	Not Available
Lower Explosive Limit (%)	Not Available	Volatile Component (%vol)	Not Available
Vapour pressure (kPa)	Not Available	Gas group	Not Available
Solubility in water	Miscible	pH as a solution (1%)	Not Available
Vapour density (Air = 1)	Not Available	VOC g/L	Not Available

SECTION 10 Stability and reactivity

Reactivity	See section 7
Chemical stability	Product is considered stable and hazardous polymerisation will not occur.
Possibility of hazardous reactions	See section 7
Conditions to avoid	See section 7
Incompatible materials	See section 7
Hazardous decomposition products	See section 5

SECTION 11 Toxicological information

Information on toxicological effects

Inhaled	<p>The material can cause respiratory irritation in some persons. The body's response to such irritation can cause further lung damage. Hydrogen chloride (HCl) vapour or fumes present a hazard from a single acute exposure. Exposures of 1300 to 2000 ppm have been lethal to humans in a few minutes.</p> <p>Inhalation of HCl may cause choking, coughing, burning sensation and may cause ulceration of the nose, throat and larynx. Fluid on the lungs followed by generalised lung damage may follow.</p> <p>Breathing of HCl vapour may aggravate asthma and inflammatory or fibrotic pulmonary disease.</p> <p>High concentrations cause necrosis of the tracheal and bronchial epithelium, pulmonary oedema, atelectasis and emphysema and damage to the pulmonary blood vessels and liver.</p>
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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.	
Skin Contact	This material can cause inflammation of the skin on contact in some persons. The material may accentuate any pre-existing dermatitis condition Skin contact is not thought to have harmful health effects (as classified under EC Directives); the material may still produce health damage following entry through wounds, lesions or abrasions. 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	This material can cause eye irritation and damage in some persons.	
Chronic	Long-term exposure to respiratory irritants may result in airways disease, involving difficulty breathing and related whole-body problems. Substance accumulation, in the human body, may occur and may cause some concern following repeated or long-term occupational exposure. Chronic minor exposure to hydrogen chloride (HCl) vapour or fume may cause discolouration or erosion of the teeth, bleeding of the nose and gums; and ulceration of the mucous membranes of the nose. Workers exposed to hydrochloric acid suffered from stomach inflammation and a number of cases of chronic bronchitis (airway inflammation) have also been reported. Repeated or prolonged exposure to dilute solutions of hydrogen chloride may cause skin inflammation.	
Midazolam Injection, USP	TOXICITY	IRRITATION
	Not Available	Not Available
nitrogen	TOXICITY	IRRITATION
	Not Available	Not Available
sodium chloride	TOXICITY	IRRITATION
	Dermal (rabbit) LD50: >10000 mg/kg ^[1]	Eye (rabbit): 10 mg - moderate
hydrochloric acid	Inhalation(Rat) LC50: >10.5 mg/l4h ^[1]	Eye (rabbit):100 mg/24h - moderate
	Oral (Rat) LD50: 3000 mg/kg ^[2]	Skin (rabbit): 500 mg/24h - mild
	TOXICITY	IRRITATION
	dermal (mouse) LD50: 1449 mg/kg ^[2]	Eye (rabbit): 5mg/30s - mild
	Oral (Rat) LD50: 900 mg/kg ^[2]	Eye: adverse effect observed (irritating) ^[1]
		Skin: adverse effect observed (corrosive) ^[1]
		Skin: adverse effect observed (irritating) ^[1]
midazolam	TOXICITY	IRRITATION
	Not Available	Not Available
sodium hydroxide	TOXICITY	IRRITATION
	Dermal (rabbit) LD50: 1350 mg/kg ^[2]	Eye (rabbit): 0.05 mg/24h SEVERE
	Oral (Rabbit) LD50: 325 mg/kg ^[1]	Eye (rabbit):1 mg/24h SEVERE
		Eye (rabbit):1 mg/30s rinsed-SEVERE
		Eye: adverse effect observed (irritating) ^[1]
		Skin (rabbit): 500 mg/24h SEVERE
Legend:		Skin: adverse effect observed (corrosive) ^[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	
SODIUM CHLORIDE	The material may produce moderate eye irritation leading to inflammation. Repeated or prolonged exposure to irritants may produce conjunctivitis.	

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HYDROCHLORIC ACID	For acid mists, aerosols, vapours Test results suggest that eukaryotic cells are susceptible to genetic damage when the pH falls to about 6.5. Cells from the respiratory tract have not been examined in this respect. Mucous secretion may protect the cells of the airway from direct exposure to inhaled acidic mists (which also protects the stomach lining from the hydrochloric acid secreted there). The material may be irritating to the eye, with prolonged contact causing inflammation. Repeated or prolonged exposure to irritants may produce conjunctivitis. The substance is classified by IARC as Group 3: NOT classifiable as to its carcinogenicity to humans. Evidence of carcinogenicity may be inadequate or limited in animal testing.
MIDAZOLAM	Intravenous (child) TDLo: 22 mg/kg/4d - I Intravenous (man) 0.071 mg/kg Dermatitis after systemic exposure, primary irritation after topical exposure, urticaria, allergic rhinitis, serum sickness recorded, liver changes, change in clotting factors recorded.
SODIUM HYDROXIDE	The material may produce severe irritation to the eye causing pronounced inflammation. Repeated or prolonged exposure to irritants may produce conjunctivitis. The material may cause severe skin irritation after prolonged or repeated exposure and may produce on contact skin redness, swelling, the production of vesicles, scaling and thickening of the skin. Repeated exposures may produce severe ulceration.
NITROGEN & HYDROCHLORIC ACID	No significant acute toxicological data identified in literature search.
SODIUM CHLORIDE & HYDROCHLORIC ACID & SODIUM HYDROXIDE	Asthma-like symptoms may continue for months or even years after exposure to the material ends. This may be due to a non-allergic condition known as reactive airways dysfunction syndrome (RADS) which can occur after exposure to high levels of highly irritating compound. Main criteria for diagnosing RADS include the absence of previous airways disease in a non-atopic individual, with sudden onset of persistent asthma-like symptoms within minutes to hours of a documented exposure to the irritant. Other criteria for diagnosis of RADS include a reversible airflow pattern on lung function tests, moderate to severe bronchial hyperreactivity on methacholine challenge testing, and the lack of minimal lymphocytic inflammation, without eosinophilia. RADS (or asthma) following an irritating inhalation is an infrequent disorder with rates related to the concentration of and duration of exposure to the irritating substance. On the other hand, industrial bronchitis is a disorder that occurs as a result of exposure due to high concentrations of irritating substance (often particles) and is completely reversible after exposure ceases. The disorder is characterized by difficulty breathing, cough and mucus production.
SODIUM CHLORIDE	The material may cause skin irritation after prolonged or repeated exposure and may produce on contact skin redness, swelling, the production of vesicles, scaling and thickening of the skin.
Acute Toxicity	✗
Skin Irritation/Corrosion	✓
Serious Eye Damage/Irritation	✓
Respiratory or Skin sensitisation	✗
Mutagenicity	✗
Carcinogenicity	✗
Reproductivity	✗
STOT - Single Exposure	✗
STOT - Repeated Exposure	✗
Aspiration Hazard	✗

Legend: ✗ – Data either not available or does not fill the criteria for classification
✓ – Data available to make classification

SECTION 12 Ecological information

Toxicity

Midazolam Injection, USP	Endpoint	Test Duration (hr)	Species	Value	Source
	Not Available	Not Available	Not Available	Not Available	Not Available
nitrogen	Endpoint	Test Duration (hr)	Species	Value	Source
	Not Available	Not Available	Not Available	Not Available	Not Available
sodium chloride	Endpoint	Test Duration (hr)	Species	Value	Source
	EC50	72h	Algae or other aquatic plants	20.76-36.17mg/L	4
	EC50	48h	Crustacea	0.00439-0.00565mg/l	4
	EC50	96h	Algae or other aquatic plants	1110.36mg/L	4
	LC50	96h	Fish	1000mg/l	4
	NOEC(ECx)	6h	Fish	0.001mg/l	4
hydrochloric acid	Endpoint	Test Duration (hr)	Species	Value	Source
	LC50	96h	Fish	334.734mg/L	4
	EC50(ECx)	9.33h	Fish	0.51mg/L	4
midazolam	Endpoint	Test Duration (hr)	Species	Value	Source
	Not Available	Not Available	Not Available	Not Available	Not Available
	EC50	48h	Crustacea	34.59-47.13mg/l	4
sodium hydroxide	Endpoint	Test Duration (hr)	Species	Value	Source
	LC50	96h	Fish	144-267mg/l	4
	EC50(ECx)	48h	Crustacea	34.59-47.13mg/l	4

Continued...

Water for Injection	Endpoint	Test Duration (hr)	Species	Value	Source
	Not Available	Not Available	Not Available	Not Available	Not Available

Legend: Extracted from 1. IUCLID Toxicity Data 2. Europe ECHA Registered Substances - Ecotoxicological Information - Aquatic Toxicity 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.

Persistence and degradability

Ingredient	Persistence: Water/Soil	Persistence: Air
sodium chloride	LOW	LOW
hydrochloric acid	LOW	LOW
sodium hydroxide	LOW	LOW
Water for Injection	LOW	LOW

Bioaccumulative potential

Ingredient	Bioaccumulation
sodium chloride	LOW (LogKOW = 0.5392)
hydrochloric acid	LOW (LogKOW = 0.5392)
sodium hydroxide	LOW (LogKOW = -3.8796)

Mobility in soil

Ingredient	Mobility
sodium chloride	LOW (KOC = 14.3)
hydrochloric acid	LOW (KOC = 14.3)
sodium hydroxide	LOW (KOC = 14.3)

SECTION 13 Disposal considerations

Waste treatment methods

Product / Packaging disposal	<ul style="list-style-type: none"> ▶ Recycle wherever possible or consult manufacturer for recycling options. ▶ Consult State Land Waste Authority for disposal. ▶ Bury or incinerate residue at an approved site. ▶ Recycle containers if possible, or dispose of in an authorised landfill.
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SECTION 14 Transport information

Labels Required

Marine Pollutant	NO
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Land transport (UN): 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

14.7.1. Transport in bulk according to Annex II of MARPOL and the IBC code

Not Applicable

14.7.2. Transport in bulk in accordance with MARPOL Annex V and the IMSBC Code

Product name	Group
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Product name	Group
nitrogen	Not Available
sodium chloride	Not Available
hydrochloric acid	Not Available
midazolam	Not Available
sodium hydroxide	Not Available
Water for Injection	Not Available

14.7.3. Transport in bulk in accordance with the IGC Code

Product name	Ship Type
nitrogen	Not Available
sodium chloride	Not Available
hydrochloric acid	Not Available
midazolam	Not Available
sodium hydroxide	Not Available
Water for Injection	Not Available

SECTION 15 Regulatory information

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

nitrogen is found on the following regulatory lists

Not Applicable

sodium chloride is found on the following regulatory lists

Not Applicable

hydrochloric acid is found on the following regulatory lists

India Permissible Levels of Certain Chemical Substances in Work Environment

International Agency for Research on Cancer (IARC) - Agents Classified by the IARC Monographs - Not Classified as Carcinogenic

midazolam is found on the following regulatory lists

Chemical Footprint Project - Chemicals of High Concern List

sodium hydroxide is found on the following regulatory lists

India Permissible Levels of Certain Chemical Substances in Work Environment

water for Injection is found on the following regulatory lists

Not Applicable

Additional Regulatory Information

Not Applicable

National Inventory Status

National Inventory	Status
Australia - AIC / Australia Non-Industrial Use	No (midazolam)
Canada - DSL	No (midazolam)
Canada - NDSL	No (nitrogen; sodium chloride; hydrochloric acid; midazolam; sodium hydroxide; water for Injection)
China - IECSC	No (midazolam)
Europe - EINEC / ELINCS / NLP	Yes
Japan - ENCS	No (nitrogen; midazolam)
Korea - KECI	No (midazolam)
New Zealand - NZIoC	Yes
Philippines - PICCS	No (midazolam)
USA - TSCA	No (midazolam)
Taiwan - TCSI	Yes

National Inventory	Status
Mexico - INSQ	No (midazolam)
Vietnam - NCI	No (midazolam)
Russia - FBEPH	No (midazolam)
Legend:	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	20/08/2021
Initial Date	12/12/2020

SDS Version Summary

Version	Date of Update	Sections Updated
2.1	15/12/2020	Toxicological information - Acute Health (eye), Toxicological information - Acute Health (inhaled), Toxicological information - Acute Health (skin), Toxicological information - Acute Health (swallowed), Physical and chemical properties - Appearance, Toxicological information - Chronic Health, Hazards identification - Classification, Disposal considerations - Disposal, Ecological Information - Environmental, Firefighting measures - Fire Fighter (extinguishing media), Firefighting measures - Fire Fighter (fire/explosion hazard), Firefighting measures - Fire Fighter (fire fighting), First Aid measures - First Aid (eye), Composition / information on ingredients - Ingredients, Stability and reactivity - Instability Condition, Exposure controls / personal protection - Personal Protection (hands/feet), Accidental release measures - Spills (major), Accidental release measures - Spills (minor), Handling and storage - Storage (storage incompatibility), Handling and storage - Storage (suitable container), Identification of the substance / mixture and of the company / undertaking - Supplier Information, Transport information - Transport, Transport Information, Identification of the substance / mixture and of the company / undertaking - Use
3.1	20/08/2021	Classification change due to full database hazard calculation/update.

Other information

Ingredients with multiple cas numbers

Name	CAS No
sodium chloride	7647-14-5, 14762-51-7, 16887-00-6, 8028-77-1
hydrochloric acid	7647-01-0, 113962-65-5, 218625-68-4, 51005-19-7, 61674-62-2
sodium hydroxide	1310-73-2, 12200-64-5

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

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