

## Vardenafil Hydrochloride Trihydrate

### Apollo Scientific

Part Number: **OR1029857**

Version No: **1.1**

Safety Data Sheet (Conforms to Annex II of REACH (1907/2006) - Regulation 2020/878)

Chemwatch Hazard Alert Code: **3**

Initial Date: **09/07/2025**

Revision Date: **09/07/2025**

Print Date: **09/07/2025**

S.REACH.GB-NIR.EN

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

### 1.1. Product Identifier

Product name	Vardenafil Hydrochloride Trihydrate
Synonyms	Not Available
Proper shipping name	TOXIC SOLID, ORGANIC, N.O.S.
Chemical formula	C23H39ClN6O7S
Other means of identification	Not Available
CAS number	330808-88-3
EC number	685-133-8

### 1.2. Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses	Use according to manufacturer's directions.
Uses advised against	No specific uses advised against are identified.

### 1.3. Details of the manufacturer or importer of the safety data sheet

Registered company name	Apollo Scientific
Address	Unit 3 & 4 Parkway, Denton, Manchester M34 3SG United Kingdom
Telephone	01614060505
Fax	0161 406 0506
Website	<a href="https://www.apolloscientific.co.uk/">https://www.apolloscientific.co.uk/</a>
Email	sales@apolloscientific.co.uk

### 1.4. Emergency telephone number



Association / Organisation	Apollo Scientific
Emergency telephone number(s)	+44(0)7353099330
Other emergency telephone number(s)	Not Available

## SECTION 2 Hazards identification

### 2.1. Classification of the substance or mixture

Classification according to regulation (EC) No 1272/2008 [CLP] and amendments <sup>[1]</sup>	H301 - Acute Toxicity (Oral) Category 3, H373 - Specific Target Organ Toxicity - Repeated Exposure Category 2
Legend:	1. Classified by Chemwatch; 2. Classification drawn from Regulation (EU) No 1272/2008 - Annex VI

### 2.2. Label elements

Hazard pictogram(s)	 
Signal word	<b>Danger</b>

**Vardenafil Hydrochloride Trihydrate**

**Hazard statement(s)**

<b>H301</b>	Toxic if swallowed.
<b>H373</b>	May cause damage to organs through prolonged or repeated exposure. (Cardiovascular system)

**Supplementary statement(s)**

Not Applicable

**Precautionary statement(s) Prevention**

<b>P260</b>	Do not breathe dust/fume.
<b>P264</b>	Wash all exposed external body areas thoroughly after handling.
<b>P270</b>	Do not eat, drink or smoke when using this product.

**Precautionary statement(s) Response**

<b>P301+P310</b>	IF SWALLOWED: Immediately call a POISON CENTER/doctor/physician/first aider.
<b>P330</b>	Rinse mouth.
<b>P314</b>	Get medical advice/attention if you feel unwell.

**Precautionary statement(s) Storage**

<b>P405</b>	Store locked up.
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**Precautionary statement(s) Disposal**

<b>P501</b>	Dispose of contents/container to authorised hazardous or special waste collection point in accordance with any local regulation.
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Material contains Vardenafil Hydrochloride Trihydrate.

**2.3. Other hazards**

Inhalation and/or ingestion may produce health damage\*.

\*LIMITED EVIDENCE

REACH - Art.57-59: The mixture does not contain Substances of Very High Concern (SVHC) at the SDS print date.

This substance/mixture does not meet the criteria for classification as Persistent, Bioaccumulative, and Toxic (PBT) in accordance with Annex XIII, Commission Delegated Regulation (EU) 2017/2100, and Commission Regulation (EU) 2018/605.

This substance/mixture does not meet the criteria for classification as very Persistent and very Bioaccumulative (vPvB) in accordance with Annex XIII, Commission Delegated Regulation (EU) 2017/2100, and Commission Regulation (EU) 2018/605.

This substance/mixture does not meet the criteria for classification as Persistent, Mobile and Toxic (PMT) in accordance with Commission Delegated Regulation (EU) 2023/707.

This substance/mixture does not meet the criteria for classification as very Persistent and very Mobile (vPvM) in accordance with Commission Delegated Regulation (EU) 2023/707.

The substance/mixture does not contain components considered to have endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605, nor is it included in the list established under REACH Article 59(1), at concentrations equal to or greater than 0.1% (w/w).

**SECTION 3 Composition / information on ingredients**

**3.1.Substances**

1. CAS No 2.EC No 3.Index No 4.REACH No	% [weight]	Name	Classification according to regulation (EC) No 1272/2008 [CLP] and amendments	SCL / M-Factor	Nanoform Particle Characteristics
1. 330808-88-3 2.685-133-8 3.Not Available 4.Not Available	100	<u>Vardenafil Hydrochloride Trihydrate</u>	Acute Toxicity (Oral) Category 3, Specific Target Organ Toxicity - Repeated Exposure Category 2; H301, H373 <sup>[1]</sup>	SCL: Not Available  Acute M factor: Not Applicable  Chronic M factor: Not Applicable	Not Available

**Legend:** 1. Classified by Chemwatch; 2. Classification drawn from Regulation (EU) No 1272/2008 - Annex VI; 3. Classification drawn from C&L; \* EU IOELVs available; [e] Substance identified as having endocrine disrupting properties

**3.2.Mixtures**

See 'Information on ingredients' in section 3.1

**SECTION 4 First aid measures**

**4.1. Description of first aid measures**

<b>Eye Contact</b>	<p>If this product comes in contact with the eyes:</p> <ul style="list-style-type: none"> <li>▶ Immediately hold eyelids apart and flush the eye continuously with running water.</li> <li>▶ 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.</li> <li>▶ Continue flushing until advised to stop by the Poisons Information Centre or a doctor, or for at least 15 minutes.</li> <li>▶ Transport to hospital or doctor without delay.</li> <li>▶ Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.</li> </ul>
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**Vardenafil Hydrochloride Trihydrate**

<b>Skin Contact</b>	<p>If skin or hair contact occurs:</p> <ul style="list-style-type: none"> <li>▶ Flush skin and hair with running water (and soap if available).</li> <li>▶ Seek medical attention in event of irritation.</li> </ul>
<b>Inhalation</b>	<ul style="list-style-type: none"> <li>▶ If fumes, aerosols or combustion products are inhaled remove from contaminated area.</li> <li>▶ Other measures are usually unnecessary.</li> </ul>
<b>Ingestion</b>	<ul style="list-style-type: none"> <li>▶ <b>IF SWALLOWED, REFER FOR MEDICAL ATTENTION, WHERE POSSIBLE, WITHOUT DELAY.</b></li> <li>▶ For advice, contact a Poisons Information Centre or a doctor.</li> <li>▶ Urgent hospital treatment is likely to be needed.</li> <li>▶ In the mean time, qualified first-aid personnel should treat the patient following observation and employing supportive measures as indicated by the patient's condition.</li> <li>▶ If the services of a medical officer or medical doctor are readily available, the patient should be placed in his/her care and a copy of the SDS should be provided. Further action will be the responsibility of the medical specialist.</li> <li>▶ If medical attention is not available on the worksite or surroundings send the patient to a hospital together with a copy of the SDS.</li> </ul> <p><b>Where medical attention is not immediately available or where the patient is more than 15 minutes from a hospital or unless instructed otherwise:</b></p> <ul style="list-style-type: none"> <li>▶ <b>INDUCE</b> vomiting with fingers down the back of the throat, <b>ONLY IF CONSCIOUS</b>. Lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration.</li> </ul> <p><b>NOTE:</b> Wear a protective glove when inducing vomiting by mechanical means.</p>

**4.2 Most important symptoms and effects, both acute and delayed**

See Section 11

**4.3. Indication of any immediate medical attention and special treatment needed**

As in all cases of suspected poisoning, follow the ABCDEs of emergency medicine (airway, breathing, circulation, disability, exposure), then the ABCDEs of toxicology (antidotes, basics, change absorption, change distribution, change elimination).

For poisons (where specific treatment regime is absent):

**BASIC TREATMENT**

- ▶ Establish a patent airway with suction where necessary.
- ▶ Watch for signs of respiratory insufficiency and assist ventilation as necessary.
- ▶ Administer oxygen by non-rebreather mask at 10 to 15 L/min.
- ▶ Monitor and treat, where necessary, for pulmonary oedema.
- ▶ Monitor and treat, where necessary, for shock.
- ▶ Anticipate seizures.
- ▶ **DO NOT** use emetics. Where ingestion is suspected rinse mouth and give up to 200 ml water (5 ml/kg recommended) for dilution where patient is able to swallow, has a strong gag reflex and does not drool.

**ADVANCED TREATMENT**

- ▶ Consider orotracheal or nasotracheal intubation for airway control in unconscious patient or where respiratory arrest has occurred.
- ▶ Positive-pressure ventilation using a bag-valve mask might be of use.
- ▶ Monitor and treat, where necessary, for arrhythmias.
- ▶ Start an IV D5W TKO. If signs of hypovolaemia are present use lactated Ringers solution. Fluid overload might create complications.
- ▶ Drug therapy should be considered for pulmonary oedema.
- ▶ Hypotension with signs of hypovolaemia requires the cautious administration of fluids. Fluid overload might create complications.
- ▶ Treat seizures with diazepam.
- ▶ Proparacaine hydrochloride should be used to assist eye irrigation.

BRONSTEIN, A.C. and CURRANCE, P.L.

EMERGENCY CARE FOR HAZARDOUS MATERIALS EXPOSURE: 2nd Ed. 1994

**SECTION 5 Firefighting measures****5.1. Extinguishing media**

- ▶ There is no restriction on the type of extinguisher which may be used.
- ▶ Use extinguishing media suitable for surrounding area.

**5.2. Special hazards arising from the substrate or mixture**

<b>Fire Incompatibility</b>	None known.
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**5.3. Advice for firefighters**

<b>Fire Fighting</b>	<ul style="list-style-type: none"> <li>▶ Alert Fire Brigade and tell them location and nature of hazard.</li> <li>▶ Wear breathing apparatus plus protective gloves in the event of a fire.</li> <li>▶ Prevent, by any means available, spillage from entering drains or water courses.</li> <li>▶ Use fire fighting procedures suitable for surrounding area.</li> <li>▶ <b>DO NOT</b> approach containers suspected to be hot.</li> <li>▶ Cool fire exposed containers with water spray from a protected location.</li> <li>▶ If safe to do so, remove containers from path of fire.</li> <li>▶ Equipment should be thoroughly decontaminated after use.</li> </ul>
<b>Fire/Explosion Hazard</b>	<ul style="list-style-type: none"> <li>▶ Non combustible.</li> <li>▶ Not considered a significant fire risk, however containers may burn.</li> </ul> <p>May emit poisonous fumes.</p>

**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**

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<b>Minor Spills</b>	<ul style="list-style-type: none"> <li>▶ Remove all ignition sources.</li> <li>▶ Clean up all spills immediately.</li> <li>▶ Avoid contact with skin and eyes.</li> <li>▶ Control personal contact with the substance, by using protective equipment.</li> <li>▶ Use dry clean up procedures and avoid generating dust.</li> <li>▶ Place in a suitable, labelled container for waste disposal.</li> </ul>
<b>Major Spills</b>	

**6.4. Reference to other sections**

Personal Protective Equipment advice is contained in Section 8 of the SDS.

**SECTION 7 Handling and storage**

**7.1. Precautions for safe handling**

<b>Safe handling</b>	<ul style="list-style-type: none"> <li>▶ Avoid all personal contact, including inhalation.</li> <li>▶ Wear protective clothing when risk of exposure occurs.</li> <li>▶ Use in a well-ventilated area.</li> <li>▶ Prevent concentration in hollows and sumps.</li> <li>▶ <b>DO NOT enter confined spaces until atmosphere has been checked.</b></li> <li>▶ <b>DO NOT allow material to contact humans, exposed food or food utensils.</b></li> <li>▶ Avoid contact with incompatible materials.</li> <li>▶ <b>When handling, DO NOT eat, drink or smoke.</b></li> <li>▶ Keep containers securely sealed when not in use.</li> <li>▶ Avoid physical damage to containers.</li> <li>▶ Always wash hands with soap and water after handling.</li> <li>▶ Work clothes should be laundered separately. Launder contaminated clothing before re-use.</li> <li>▶ Use good occupational work practice.</li> <li>▶ Observe manufacturer's storage and handling recommendations contained within this SDS.</li> <li>▶ Atmosphere should be regularly checked against established exposure standards to ensure safe working conditions are maintained.</li> </ul>
<b>Fire and explosion protection</b>	See section 5
<b>Other information</b>	<ul style="list-style-type: none"> <li>▶ Store in original containers.</li> <li>▶ Keep containers securely sealed.</li> <li>▶ Store in a cool, dry, well-ventilated area.</li> <li>▶ Store away from incompatible materials and foodstuff containers.</li> <li>▶ Protect containers against physical damage and check regularly for leaks.</li> <li>▶ Observe manufacturer's storage and handling recommendations contained within this SDS.</li> </ul>

**7.2. Conditions for safe storage, including any incompatibilities**

<b>Suitable container</b>	<ul style="list-style-type: none"> <li>▶ Lined metal can, lined metal pail/ can.</li> <li>▶ Plastic pail.</li> <li>▶ Polyliner drum.</li> <li>▶ Packing as recommended by manufacturer.</li> <li>▶ Check all containers are clearly labelled and free from leaks.</li> </ul> <p>For low viscosity materials</p> <ul style="list-style-type: none"> <li>▶ Drums and jerricans must be of the non-removable head type.</li> <li>▶ Where a can is to be used as an inner package, the can must have a screwed enclosure.</li> </ul> <p>For materials with a viscosity of at least 2680 cSt. (23 deg. C) and solids (between 15 C deg. and 40 deg C.):</p> <ul style="list-style-type: none"> <li>▶ Removable head packaging;</li> <li>▶ Cans with friction closures and</li> <li>▶ low pressure tubes and cartridges</li> </ul> <p>may be used.</p> <p>-</p> <p>Where combination packages are used, and the inner packages are of glass, there must be sufficient inert cushioning material in contact with inner and outer packages *.</p> <p>-</p> <p>In addition, where inner packagings are glass and contain liquids of packing group I and II there must be sufficient inert absorbent to absorb any spillage *.</p> <p>-</p> <p>* unless the outer packaging is a close fitting moulded plastic box and the substances are not incompatible with the plastic.</p>
<b>Storage incompatibility</b>	None known
<b>Hazard categories in accordance with Regulation (EC) No 2012/18/EU (Seveso III)</b>	Not Available
<b>Qualifying quantity (tonnes) of dangerous substances as referred to in Article 3(10) for the application of</b>	Not Available

**7.3. Specific end use(s)**

See section 1.2

**SECTION 8 Exposure controls / personal protection**

**8.1. Control parameters**

Ingredient	DNELs Exposure Pattern Worker	PNECs Compartment
Not Available	Not Available	Not Available

\* Values for General Population

**Occupational Exposure Limits (OEL)**

**INGREDIENT DATA**

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Source	Ingredient	Material name	TWA	STEL	Peak	Notes
Not Available	Not Available	Not Available	Not Available	Not Available	Not Available	Not Available

Not Applicable

Ingredient	Original IDLH	Revised IDLH
Vardenafil Hydrochloride Trihydrate	Not Available	Not Available

**8.2. Exposure controls**

Engineering controls are used to remove a hazard or place a barrier between the worker and the hazard. Well-designed engineering controls can be highly effective in protecting workers and will typically be independent of worker interactions to provide this high level of protection. The basic types of engineering controls are:  
 Process controls which involve changing the way a job activity or process is done to reduce the risk.  
 Enclosure and/or isolation of emission source which keeps a selected hazard 'physically' away from the worker and ventilation that strategically 'adds' and 'removes' air in the work environment. 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.  
 Employers may need to use multiple types of controls to prevent employee overexposure.

Local exhaust ventilation usually required. If risk of overexposure exists, wear approved respirator. Correct fit is essential to obtain adequate protection. Supplied-air type respirator may be required in special circumstances. Correct fit is essential to ensure adequate protection. An approved self contained breathing apparatus (SCBA) may be required in some situations.  
 Provide adequate ventilation in warehouse or closed storage area. 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.

**8.2.1. Appropriate engineering controls**

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.)

Within each range the appropriate value depends on:

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

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.

**8.2.2. Individual protection measures, such as personal protective equipment**



**Eye and face protection**

- ▶ 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**

The selection of suitable gloves does not only depend on the material, but also on further marks of quality which vary from manufacturer to manufacturer. Where the chemical is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.  
 The exact break through time for substances has to be obtained from the manufacturer of the protective gloves and has to be observed when making a final choice.  
 Personal hygiene is a key element of effective hand care. Gloves must only be worn on clean hands. After using gloves, hands should be washed and dried thoroughly. Application of a non-perfumed moisturiser is recommended.  
 Suitability and durability of glove type is dependent on usage. Important factors in the selection of gloves include:  
 - frequency and duration of contact,  
 - chemical resistance of glove material,  
 - glove thickness and  
 - dexterity  
 Select gloves tested to a relevant standard (e.g. Europe EN 374, US F739, AS/NZS 2161.1 or national equivalent).  
 - When prolonged or frequently repeated contact may occur, a glove with a protection class of 5 or higher (breakthrough time greater than 240 minutes according to EN 374, AS/NZS 2161.10.1 or national equivalent) is recommended.  
 - When only brief contact is expected, a glove with a protection class of 3 or higher (breakthrough time greater than 60 minutes according to EN 374, AS/NZS 2161.10.1 or national equivalent) is recommended.  
 - Some glove polymer types are less affected by movement and this should be taken into account when considering gloves for long-term use.  
 - Contaminated gloves should be replaced.

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	<p>As defined in ASTM F-739-96 in any application, gloves are rated as:</p> <ul style="list-style-type: none"> <li>· Excellent when breakthrough time &gt; 480 min</li> <li>· Good when breakthrough time &gt; 20 min</li> <li>· Fair when breakthrough time &lt; 20 min</li> <li>· Poor when glove material degrades</li> </ul> <p>For general applications, gloves with a thickness typically greater than 0.35 mm, are recommended.</p> <p>It should be emphasised that glove thickness is not necessarily a good predictor of glove resistance to a specific chemical, as the permeation efficiency of the glove will be dependent on the exact composition of the glove material. Therefore, glove selection should also be based on consideration of the task requirements and knowledge of breakthrough times.</p> <p>Glove thickness may also vary depending on the glove manufacturer, the glove type and the glove model. Therefore, the manufacturers technical data should always be taken into account to ensure selection of the most appropriate glove for the task.</p> <p>Note: Depending on the activity being conducted, gloves of varying thickness may be required for specific tasks. For example:</p> <ul style="list-style-type: none"> <li>· Thinner gloves (down to 0.1 mm or less) may be required where a high degree of manual dexterity is needed. However, these gloves are only likely to give short duration protection and would normally be just for single use applications, then disposed of.</li> <li>· Thicker gloves (up to 3 mm or more) may be required where there is a mechanical (as well as a chemical) risk i.e. where there is abrasion or puncture potential</li> </ul> <p>Gloves must only be worn on clean hands. After using gloves, hands should be washed and dried thoroughly. Application of a non-perfumed moisturiser is recommended.</p> <ul style="list-style-type: none"> <li>▶ Wear chemical protective gloves, e.g. PVC.</li> <li>▶ Wear safety footwear or safety gumboots, e.g. Rubber</li> </ul>
<b>Body protection</b>	See Other protection below
<b>Other protection</b>	<ul style="list-style-type: none"> <li>▶ Overalls.</li> <li>▶ Eyewash unit.</li> <li>▶ Barrier cream.</li> <li>▶ Skin cleansing cream.</li> </ul>

**Respiratory protection**

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

Required Minimum Protection Factor	Half-Face Respirator	Full-Face Respirator	Powered Air Respirator
up to 10 x ES	P1 Air-line*	- -	PAPR-P1 -
up to 50 x ES	Air-line**	P2	PAPR-P2
up to 100 x ES	-	P3 Air-line*	- -
100+ x ES	-	Air-line**	PAPR-P3

\* - Negative pressure demand \*\* - Continuous flow

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(SO<sub>2</sub>), G = Agricultural chemicals, K = Ammonia(NH<sub>3</sub>), Hg = Mercury, NO = Oxides of nitrogen, MB = Methyl bromide, AX = Low boiling point organic compounds(below 65 degC)

- Respirators may be necessary when engineering and administrative controls do not adequately prevent exposures.
- The decision to use respiratory protection should be based on professional judgment that takes into account toxicity information, exposure measurement data, and frequency and likelihood of the worker's exposure - ensure users are not subject to high thermal loads which may result in heat stress or distress due to personal protective equipment (powered, positive flow, full face apparatus may be an option).
- Published occupational exposure limits, where they exist, will assist in determining the adequacy of the selected respiratory protection. These may be government mandated or vendor recommended.
- Certified respirators will be useful for protecting workers from inhalation of particulates when properly selected and fit tested as part of a complete respiratory protection program.
- Where protection from nuisance levels of dusts are desired, use type N95 (US) or type P1 (EN143) dust masks. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU)
- Use approved positive flow mask if significant quantities of dust becomes airborne.
- Try to avoid creating dust conditions.

**8.2.3. Environmental exposure controls**

See section 12

**SECTION 9 Physical and chemical properties****9.1. Information on basic physical and chemical properties**

<b>Appearance</b>	Not Available		
<b>Physical state</b>	Solid	<b>Relative density (Water = 1)</b>	Not Available
<b>Odour</b>	Not Available	<b>Partition coefficient n-octanol / water</b>	Not Available
<b>Odour threshold</b>	Not Available	<b>Auto-ignition temperature (°C)</b>	Not Available
<b>pH (as supplied)</b>	Not Available	<b>Decomposition temperature (°C)</b>	Not Available
<b>Melting point / freezing point (°C)</b>	183-218	<b>Viscosity (cSt)</b>	Not Available
<b>Initial boiling point and boiling range (°C)</b>	Not Available	<b>Molecular weight (g/mol)</b>	Not Available
<b>Flash point (°C)</b>	Not Available	<b>Taste</b>	Not Available
<b>Evaporation rate</b>	Not Available	<b>Explosive properties</b>	Not Available
<b>Flammability</b>	Not Applicable	<b>Oxidising properties</b>	Not Available
<b>Upper Explosive Limit (%)</b>	Not Available	<b>Surface Tension (dyn/cm or mN/m)</b>	Not Applicable
<b>Lower Explosive Limit (%)</b>	Not Available	<b>Volatile Component (%vol)</b>	Not Available
<b>Vapour pressure (kPa)</b>	Not Available	<b>Gas group</b>	Not Available

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<b>Solubility in water</b>	Not Available	<b>pH as a solution (1%)</b>	Not Available
<b>Vapour density (Air = 1)</b>	Not Available	<b>VOC g/L</b>	Not Available
<b>Heat of Combustion (KJ/g)</b>	Not Available	<b>Ignition Distance (cm)</b>	Not Available
<b>Flame Height (cm)</b>	Not Available	<b>Flame Duration (s)</b>	Not Available
<b>Enclosed Space Ignition Time Equivalent (s/m3)</b>	Not Available	<b>Enclosed Space Ignition Deflagration Density (g/m3)</b>	Not Available
<b>Nanoform Solubility</b>	Not Available	<b>Nanoform Particle Characteristics</b>	Not Available
<b>Particle Size</b>	Not Available		

## 9.2. Other information

Not Available

## SECTION 10 Stability and reactivity

<b>10.1.Reactivity</b>	See section 7.2
<b>10.2. Chemical stability</b>	<ul style="list-style-type: none"> <li>▶ Unstable in the presence of incompatible materials.</li> <li>▶ Product is considered stable.</li> <li>▶ Hazardous polymerisation will not occur.</li> </ul>
<b>10.3. Possibility of hazardous reactions</b>	See section 7.2
<b>10.4. Conditions to avoid</b>	See section 7.2
<b>10.5. Incompatible materials</b>	See section 7.2
<b>10.6. Hazardous decomposition products</b>	See section 5.3

## SECTION 11 Toxicological information

## 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

<b>a) Acute Toxicity</b>	There is sufficient evidence to classify this material as acutely toxic.
<b>b) Skin Irritation/Corrosion</b>	Based on available data, the classification criteria are not met.
<b>c) Serious Eye Damage/Irritation</b>	Based on available data, the classification criteria are not met.
<b>d) Respiratory or Skin sensitisation</b>	Based on available data, the classification criteria are not met.
<b>e) Mutagenicity</b>	Based on available data, the classification criteria are not met.
<b>f) Carcinogenicity</b>	Based on available data, the classification criteria are not met.
<b>g) Reproductivity</b>	Based on available data, the classification criteria are not met.
<b>h) STOT - Single Exposure</b>	Based on available data, the classification criteria are not met.
<b>i) STOT - Repeated Exposure</b>	There is sufficient evidence to classify this material as toxic to specific organs through repeated exposure
<b>j) Aspiration Hazard</b>	Based on available data, the classification criteria are not met.

<b>Inhaled</b>	The material is not thought to produce either adverse health effects or irritation of the respiratory tract following inhalation (as classified by EC Directives using animal models). Nevertheless, adverse systemic effects have been produced following exposure of animals by at least one other route and good hygiene practice requires that exposure be kept to a minimum and that suitable control measures be used in an occupational setting.
<b>Ingestion</b>	<b>Toxic effects</b> may result from the accidental ingestion of the material; animal experiments indicate that ingestion of less than 40 gram may be fatal or may produce serious damage to the health of the individual.
<b>Skin Contact</b>	Skin contact is not thought to produce harmful health effects (as classified under EC Directives using animal models). Systemic harm, however, has been identified following exposure of animals by at least one other route and 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.
<b>Eye</b>	Although the material is not thought to be an irritant (as classified by EC Directives), direct contact with the eye may cause transient discomfort characterised by tearing or conjunctival redness (as with windburn). Slight abrasive damage may also result.
<b>Chronic</b>	Repeated or long-term occupational exposure is likely to produce cumulative health effects involving organs or biochemical systems.  Harmful: danger of serious damage to health by prolonged exposure through inhalation, in contact with skin and if swallowed. This material can cause serious damage if one is exposed to it for long periods. It can be assumed that it contains a substance which can produce severe defects.

<b>Vardenafil Hydrochloride Trihydrate</b>	<b>TOXICITY</b>	<b>IRRITATION</b>
	Not Available	Not Available

**Legend:** 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

<b>Acute Toxicity</b>	✓	<b>Carcinogenicity</b>	✗
<b>Skin Irritation/Corrosion</b>	✗	<b>Reproductivity</b>	✗
<b>Serious Eye Damage/Irritation</b>	✗	<b>STOT - Single Exposure</b>	✗

Continued...

**Vardenafil Hydrochloride Trihydrate**

Respiratory or Skin sensitisation	✗	STOT - Repeated Exposure	✓
Mutagenicity	✗	Aspiration Hazard	✗

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

**11.2 Information on other hazards**

**11.2.1. Endocrine disrupting properties**

No evidence of endocrine disrupting properties were found in the current literature.

**11.2.2. Other information**

See Section 11.1

**SECTION 12 Ecological information**

**12.1. Toxicity**

Vardenafil Hydrochloride Trihydrate	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.**

**12.2. Persistence and degradability**

Ingredient	Persistence: Water/Soil	Persistence: Air
	No Data available for all ingredients	No Data available for all ingredients

**12.3. Bioaccumulative potential**

Ingredient	Bioaccumulation
	No Data available for all ingredients

**12.4. Mobility in soil**

Ingredient	Mobility
	No Data available for all ingredients

**12.5. Results of PBT and vPvB assessment**

	P	B	T	PBT criteria fulfilled?	vP	vB	vPvB criteria fulfilled?
Vardenafil Hydrochloride Trihydrate	No data available	No data available	No data available	No	No data available	No data available	No

**12.6. Endocrine disrupting properties**

No evidence of endocrine disrupting properties were found in the current literature.

**12.7. Other adverse effects**

No evidence of ozone depleting properties were found in the current literature.


**SECTION 13 Disposal considerations**

**13.1. Waste treatment methods**

<b>Product / Packaging disposal</b>	<ul style="list-style-type: none"> <li>▶ Containers may still present a chemical hazard/ danger when empty.</li> <li>▶ Return to supplier for reuse/ recycling if possible.</li> </ul> Otherwise: <ul style="list-style-type: none"> <li>▶ If container can not be cleaned sufficiently well to ensure that residuals do not remain or if the container cannot be used to store the same product, then puncture containers, to prevent re-use, and bury at an authorised landfill.</li> <li>▶ Where possible retain label warnings and SDS and observe all notices pertaining to the product.</li> <li>▶ Recycle wherever possible or consult manufacturer for recycling options.</li> <li>▶ Consult State Land Waste Management Authority for disposal.</li> <li>▶ Bury residue in an authorised landfill.</li> <li>▶ Recycle containers if possible, or dispose of in an authorised landfill.</li> </ul>
<b>Waste treatment options</b>	Not Available
<b>Sewage disposal options</b>	Not Available

**SECTION 14 Transport information**

**Labels Required**

	
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## Vardenafil Hydrochloride Trihydrate

Marine Pollutant	NO
HAZCHEM	2X

## Land transport (ADR-RID)

14.1. UN number or ID number	2811	
14.2. UN proper shipping name	TOXIC SOLID, ORGANIC, N.O.S.	
14.3. Transport hazard class(es)	Class	6.1
	Subsidiary Hazard	Not Applicable
14.4. Packing group	III	
14.5. Environmental hazard	Not Applicable	
14.6. Special precautions for user	Hazard identification (Kemler)	60
	Classification code	T2
	Hazard Label	6.1
	Special provisions	274 614
	Limited quantity	5 kg
	Transport Category	2
	Tunnel Restriction Code	E

## Air transport (ICAO-IATA / DGR)

14.1. UN number	2811	
14.2. UN proper shipping name	Toxic solid, organic, n.o.s. *	
14.3. Transport hazard class(es)	ICAO/IATA Class	6.1
	ICAO / IATA Subsidiary Hazard	Not Applicable
	ERG Code	6L
14.4. Packing group	III	
14.5. Environmental hazard	Not Applicable	
14.6. Special precautions for user	Special provisions	A3 A5
	Cargo Only Packing Instructions	677
	Cargo Only Maximum Qty / Pack	200 kg
	Passenger and Cargo Packing Instructions	670
	Passenger and Cargo Maximum Qty / Pack	100 kg
	Passenger and Cargo Limited Quantity Packing Instructions	Y645
	Passenger and Cargo Limited Maximum Qty / Pack	10 kg

## Sea transport (IMDG-Code / GGVSee)

14.1. UN number	2811	
14.2. UN proper shipping name	TOXIC SOLID, ORGANIC, N.O.S.	
14.3. Transport hazard class(es)	IMDG Class	6.1
	IMDG Subsidiary Hazard	Not Applicable
14.4. Packing group	III	
14.5. Environmental hazard	Not Applicable	
14.6. Special precautions for user	EMS Number	F-A , S-A
	Special provisions	223 274
	Limited Quantities	5 kg

## Inland waterways transport (ADN)

14.1. UN number	2811	
14.2. UN proper shipping name	TOXIC SOLID, ORGANIC, N.O.S.	
14.3. Transport hazard class(es)	6.1	Not Applicable
14.4. Packing group	III	
14.5. Environmental hazard	Not Applicable	
14.6. Special precautions for user	Classification code	T2
	Special provisions	274; 614; 802
	Limited quantity	5 kg

## Vardenafil Hydrochloride Trihydrate

Equipment required	PP, EP
Fire cones number	0

**14.7. Maritime transport in bulk according to IMO instruments****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
Vardenafil Hydrochloride Trihydrate	Not Available

**14.7.3. Transport in bulk in accordance with the IGC Code**

Product name	Ship Type
Vardenafil Hydrochloride Trihydrate	Not Available

**SECTION 15 Regulatory information****15.1. Safety, health and environmental regulations / legislation specific for the substance or mixture**

Vardenafil Hydrochloride Trihydrate is found on the following regulatory lists

Not Applicable

**Additional Regulatory Information**

Not Applicable

This safety data sheet 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.

**Information according to 2012/18/EU (Seveso III):**

Seveso Category	Not Available

**15.2. Chemical safety assessment**

For further information please look at the Chemical Safety Assessment and Exposure Scenarios prepared by your Supply Chain if available.

**National Inventory Status**

National Inventory	Status
Australia - AIIIC / Australia Non-Industrial Use	No (Vardenafil Hydrochloride Trihydrate)
Canada - DSL	No (Vardenafil Hydrochloride Trihydrate)
Canada - NDLS	No (Vardenafil Hydrochloride Trihydrate)
China - IECSC	No (Vardenafil Hydrochloride Trihydrate)
Europe - EINEC / ELINCS / NLP	No (Vardenafil Hydrochloride Trihydrate)
Japan - ENCS	No (Vardenafil Hydrochloride Trihydrate)
Korea - KECI	No (Vardenafil Hydrochloride Trihydrate)
New Zealand - NZIoC	No (Vardenafil Hydrochloride Trihydrate)
Philippines - PICCS	No (Vardenafil Hydrochloride Trihydrate)
USA - TSCA	No (Vardenafil Hydrochloride Trihydrate)
Taiwan - TCSI	No (Vardenafil Hydrochloride Trihydrate)
Mexico - INSQ	No (Vardenafil Hydrochloride Trihydrate)
Vietnam - NCI	Yes
Russia - FBEPH	No (Vardenafil Hydrochloride Trihydrate)
<b>Legend:</b>	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	09/07/2025
Initial Date	09/07/2025

**Full text Risk and Hazard codes****Other information**

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.

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
- ▶ 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
- ▶ MARPOL: International Convention for the Prevention of Pollution from Ships
- ▶ IMSBC: International Maritime Solid Bulk Cargoes Code
- ▶ IGC: International Gas Carrier Code
- ▶ IBC: International Bulk Chemical Code
  
- ▶ AIIC: 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
- ▶ KECI: 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

**Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]**

<b>Classification according to regulation (EC) No 1272/2008 [CLP] and amendments</b>	<b>Classification Procedure</b>
Acute Toxicity (Oral) Category 3, H301	Expert judgement
Specific Target Organ Toxicity - Repeated Exposure Category 2, H373	Expert judgement

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