

## Safety Data Sheet

# Vardenafil hydrochloride trihydrate

Version : V2.0.0.1

Report No. : BWJ5831-2016-MSDS-US

Creation Date : 2025/10/13

Revision Date : -



\*Prepared according to American OSHA HCS-2024 (29 CFR 1910.1200)

## 1 Identification

### Product identifier

Product Name	Vardenafil hydrochloride trihydrate
Cat No.	BWJ5831-2016
CAS No.	330808-88-3
EC No.	-
Molecular Formula	C23H35ClN6O5S

### Recommended use of the product and restrictions on use

Relevant identified uses	Please consult manufacturer.
Uses advised against	Please consult manufacturer.

### Details of the supplier of the Safety Data Sheet

Name of the company	Weiyel Inc
Address of the company	Hedian Light Industrial Park, Chengguan Town, Shangcheng County, Xinyang City, Henan Province, China
Post code	465350
Telephone number	010-58103678
Fax number	010-84840368
E-mail address	info@weiyel.com

### Emergency phone number

Emergency phone number	010-58103678
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## 2 Hazard(s) identification

### Hazard classification according to 29 CFR 1910.1200

Acute Toxicity - Oral	Category 4
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### Label elements

Hazard pictograms	
Signal word	<b>Warning</b>

### Hazard statements

H302	Harmful if swallowed
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**Precautionary statements**

## ◆ Prevention

<b>P264</b>	Wash hands and other parts of the body (if related) thoroughly after handling.
<b>P270</b>	Do not eat, drink or smoke when using this product.

## ◆ Response

<b>P330</b>	Rinse mouth.
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## ◆ Storage

<b>Storage</b>	Not applicable
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## ◆ Disposal

<b>P501</b>	Dispose of contents/container in accordance with local/regional/national/international regulations.
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**Other hazards**

	Not applicable.
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**Hazard description**

## ◆ Physical and chemical hazards

	No information available
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## ◆ Health hazards

<b>Inhaled</b>	Inhalation of the product may produce adverse health effects or irritation of the respiratory tract following discomfort.
<b>Ingestion</b>	Accidental ingestion of the product may be harmful.
<b>Skin Contact</b>	Entry into the blood-stream, through, for example, cuts, abrasions or lesions, may produce systemic injury with harmful effects.
<b>Eye</b>	This product may cause temporary discomfort following direct contact with the eye.

## ◆ Environmental hazards

	Please refer to 12th chapter of SDS.
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**3 Composition/information on ingredients****Substance/mixture**

	Substance
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Component	CAS No.	EC No.	Concentration (wt, %)
Vardenafil hydrochloride trihydrate	330808-88-3	-	98.5

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

<b>General advice</b>	Immediate medical attention is required. Show this safety data sheet (SDS) to the doctor in attendance.
<b>Eye contact</b>	Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician if feel uncomfortable.
<b>Skin contact</b>	Take off contaminated clothing and shoes immediately. Wash off with plenty of soap and water for at least 15 minutes and consult a physician if feel

	uncomfortable.
<b>Ingestion</b>	Never give anything by mouth to an unconscious person. Call a physician or Poison Control Center immediately.
<b>Inhalation</b>	Move victim into fresh air. If breathing is difficult, give oxygen. Do not use mouth to mouth resuscitation if victim ingested or inhaled the substance. If not breathing, give artificial respiration and consult a physician immediately.
<b>Protecting of first-aiders</b>	Ensure that medical personnel are aware of the substance involved. Take precautions to protect themselves and prevent spread of contamination.

### **| Most important symptoms/effects, acute and delayed**

1	Substance accumulation, in the human body, may occur and may cause some concern following repeated or long-term occupational exposure.
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### **| Indication of any immediate medical attention and special treatment needed**

1	Treat symptomatically.
2	Symptoms may be delayed.

## **5 Fire-fighting measures**

### **| Extinguishing media**

<b>Suitable extinguishing media</b>	Use extinguishing media suitable for surrounding area.
<b>Unsuitable extinguishing media</b>	There is no restriction on the type of extinguisher which may be used.

### **| Specific hazards arising from the substance or mixture**

1	Development of hazardous combustion gases or vapor possible in the event of fire.
2	May expansion or decompose explosively when heated or involved in fire.

### **| Special protective equipment and precautions for fire-fighters**

1	As in any fire, wear self-contained breathing apparatus (MSHA/NIOSH approved or equivalent) and full protective gear.
2	Fight fire from a safe distance, with adequate cover.
3	Prevent fire extinguishing water from contaminating surface water or the ground water system.

## **6 Accidental release measures**

### **| Personal precautions, protective equipment and emergency procedures**

1	Ensure adequate ventilation. Remove all sources of ignition. Take precautionary measures against static discharges.
2	Evacuate personnel to safe areas. Keep people away from and upwind of spill/leak.
3	Use personal protective equipment, do not breathe dust/fume.

### **| Environmental precautions**

1	Prevent further leakage or spillage if safe to do so.
2	Discharge into the environment must be avoided.

### **| Methods and materials for containment and cleaning up**

1	Cut off the source of the leak as much as possible.
2	Keep leaks in a ventilated place.
3	Isolation of contaminated areas and restrictions on access.
4	It is recommended that emergency personnel wear dust masks.

5	Collect the spill with a clean shovel and place it in a clean, dry, loosely closed container and move the container away from the leak.
6	Adhered or collected material should be promptly disposed of, in accordance with appropriate laws and regulations.

## 7 Handling and storage

### Precautions for safe handling

1	Handling is performed in a well ventilated place.
2	Wear suitable protective equipment.
3	Avoid contact with skin and eyes.
4	Keep away from heat/sparks/open flames/ hot surfaces.

### Conditions for safe storage, including any incompatibilities

1	Keep containers tightly closed.
2	Keep containers in a dry, cool and well-ventilated place.
3	Keep away from heat/sparks/open flames/hot surfaces.
4	Store away from incompatible materials and foodstuff containers.

## 8 Exposure controls/personal protection

### Control parameters

Occupational Exposure limit values	No relevant regulations
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### Engineering controls

1	Ensure adequate ventilation, especially in confined areas.
2	Ensure that eyewash stations and safety showers are close to the workstation location.
3	Use explosion-proof electrical/ventilating/lighting/equipment.
4	Set up emergency exit and necessary risk-elimination area.

### Personal protection equipment

General requirement	
Eye protection	Must wear appropriate safety goggles.
Hand protection	Must wear appropriate chemical protective gloves.
Respiratory protection	Must wear appropriate personal respiratory protective equipment.
Skin and body protection	Must wear appropriate chemical protective clothing and chemical resistant shoes.

## 9 Physical and chemical properties and safety characteristics

### Physical and chemical properties

Appearance (physical state, color, etc.)	White to light yellow crystalline powder
Odor	No information available
Odor threshold	No information available
pH	No information available

Melting point/freezing point(°C)	No information available
Initial boiling point and boiling range(°C)	No information available
Flash point(Closed cup, °C)	Not applicable
Evaporation rate	Not applicable
Flammability	No information available
Upper/lower explosive limits[%(v/v)]	Upper limit : No information available ; Lower limit : No information available
Vapor pressure	Not applicable
Vapor density(Air = 1)	Not applicable
Relative density(Water=1)	No information available
Solubility	No information available
n-octanol/water partition coefficient	No information available
Auto-ignition temperature(°C)	No information available
Decomposition temperature(°C)	No information available
Kinematic viscosity	Not applicable

## 10 Stability and reactivity

### | Stability and reactivity

Reactivity	Contact with incompatible substances can cause decomposition or other chemical reactions.
Chemical stability	Stable under proper operation and storage conditions.
Possibility of hazardous reactions	No information available.
Conditions to avoid	Incompatible materials, heat, flame and spark.
Incompatible materials	No information available.
Hazardous decomposition products	Under normal conditions of storage and use, hazardous decomposition products should not be produced.

## 11 Toxicological information

### | Acute toxicity

Acute toxicity	No information available
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### | Carcinogenicity

Component	List of carcinogens by the IARC Monographs	Report on Carcinogens by NTP	OSHA Carcinogen List
Vardenafil hydrochloride trihydrate	Not Listed	Not Listed	Not Listed

### | Others

Vardenafil hydrochloride trihydrate(Component)	
Skin corrosion/irritation	Based on available data, the classification criteria are not met
Serious eye damage/irritation	Based on available data, the classification criteria are not met
Skin sensitization	Based on available data, the classification criteria are not met
Respiratory sensitization	Based on available data, the classification criteria are not met

Reproductive toxicity	Based on available data, the classification criteria are not met
STOT-repeated exposure	Based on available data, the classification criteria are not met
Aspiration hazard	Based on available data, the classification criteria are not met
Germ cell mutagenicity	Based on available data, the classification criteria are not met

## 12 Ecological information

### | Acute aquatic toxicity

Acute aquatic toxicity	No information available
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### | Chronic aquatic toxicity

Chronic aquatic toxicity	No information available
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### | Persistence and degradability

Persistence and degradability	No information available
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### | Bioaccumulative potential

Bioaccumulative potential	No information available
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### | Mobility in soil

Mobility in soil	No information available
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## 13 Disposal considerations

### | Disposal considerations

Waste chemicals	Before disposal should refer to the relevant national and local laws and regulation. Recommend the use of incineration disposal.
Contaminated packaging	Containers may still present chemical hazard when empty. Keep away from hot and ignition source of fire. Return to supplier for recycling if possible.
Disposal recommendations	Refer to section waste chemicals and contaminated packaging.

## 14 Transport information

### | Label and Mark

Transporting Label	Not applicable
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### | IMDG-CODE

IMDG-CODE	NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS
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### | IATA-DGR

IATA-DGR	NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS
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### | UN-ADR

UN-ADR	NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS
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### | Transport in bulk according to IMO instruments

- ◆ Transport in bulk according to Annex II of MARPOL and the IBC code

	Not Available
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- ◆ Transport in bulk in accordance with MARPOL Annex V and the IMSBC Code

	Not Available
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## ◆ Transport in bulk in accordance with the IGC Code

Not Available

## | Others

## Precautions for transport

Transport vehicles should be equipped with the appropriate variety and quantity of fire equipment and emergency equipment leakage during transport. Before transport, should be preceded by checking whether container integrity, sealing. The transport unit must be placarded and marked in accordance with relevant transporting requirements.

## 15 Regulatory information

## | International chemical inventory

Component	A	B	C	D	E	F	G	H	I	J	K	L	M
Vardenafil hydrochloride trihydrate	x	x	x	x	x	x	x	x	x	x	x	√	x

- [A] China Inventory of Existing Chemical Substances(IECSC)  
 [B] European Inventory of Existing Commercial Chemical Substances(EC inventory)  
 [C] United States Toxic Substances Control Act Inventory(TSCA)  
 [D] Canadian Domestic Substances List(DSL)  
 [E] New Zealand Inventory of Chemicals(NZIoC)  
 [F] Philippines Inventory of Chemicals and Chemical Substances(PICCS)  
 [G] Korea Existing Chemicals Inventory(KECL)  
 [H] Australian. Inventory of Industrial Chemical (AIICS)  
 [I] Japan Inventory of Existing & New Chemical Substances(ENCS)  
 [J] Thailand Existing Chemicals Inventory(TECI)  
 [K] Mexico National Inventory of Chemical Substances (INSQ)  
 [L] Russia Inventory of Existing Substances(DRAFT)  
 [M] Inventory of Existing Chemical Substances in Taiwan, China (TCSI)

## | List of Chemical Substances under International Conventions

Component	A	B	C
Vardenafil hydrochloride trihydrate	x	x	x

- [A] The Montreal Protocol on Substances that Deplete the Ozone Layer  
 [B] Stockholm Convention on Persistent Organic Pollutants (POPs)  
 [C] Rotterdam Convention on the prior informed consent procedure for certain hazardous chemicals and pesticides in international trade

## | US chemical inventory

Component	A	B	C	D	E	F	G	H
Vardenafil hydrochloride trihydrate	x	x	x	x	x	x	x	x

- [A] US Clean Air Act (CAA)- Section 112, Hazardous Air Pollutants  
 [B] US SARA 302- Extremely Hazardous Substance List  
 [C] US CERCLA- Hazardous Substances List  
 [D] US Massachusetts Right-to-Know Substance List  
 [E] US New Jersey Right to Know Hazardous Substance List  
 [F] US Pennsylvania Right to Know Hazardous Substance List  
 [G] US New York City Right-to-Know Hazardous Substance List  
 [H] US California Proposition 65 List

Note:

“√” Indicates that the substance included in the regulations.

“x” No data or not included in the regulations.

## 16 Other information

### Information on revision

Creation Date	2025/10/13
Revision Date	-
Reason for revision	-

### Reference

- [1] IPCS: The International Chemical Safety Cards (ICSC), website: <http://www.ilo.org/dyn/icsc/showcard.home>.
- [2] IARC, website: <http://www.iarc.fr/>.
- [3] OECD: The Global Portal to Information on Chemical Substances, website: <https://www.echemportal.org/echemportal/>.
- [4] CAMEO Chemicals, website: <http://cameochemicals.noaa.gov/search/simple>.
- [5] NLM: ChemIDplus, website: <http://chem.sis.nlm.nih.gov/chemidplus/chemidlite.jsp>.
- [6] EPA: Integrated Risk Information System, website: <http://cfpub.epa.gov/iris/>.
- [7] U.S. Department of Transportation: ERG, website: <http://www.phmsa.dot.gov/hazmat/library/erg>.
- [8] Germany GESTIS-database on hazard substance, website: <http://gestis-en.itrust.de/>.

### Abbreviations and acronyms

CAS	Chemical Abstracts Service	UN	The United Nations
PC-STEL	Short term exposure limit	OECD	Organization for Economic Co-operation and Development
PC-TWA	Time Weighted Average	IMDG-CODE	International Maritime Dangerous Goods CODE
MAC	Maximum Allowable Concentration	IARC	International Agency for Research on Cancer
DNEL	Derived No Effect Level	ICAO	International Civil Aviation Organization
PNEC	Predicted No Effect Concentration	IATA	International Air Transportation Association
NOEC	No Observed Effect Concentration	ACGIH	American Conference of Governmental Industrial Hygienists
LC <sub>50</sub>	Lethal Concentration 50%	NFPA	National Fire Protection Association
LD <sub>50</sub>	Lethal Dose 50%	NTP	National Toxicology Program
EC <sub>50</sub>	Effective Concentration 50%	PBT	Persistent, Bioaccumulative, Toxic
EC <sub>x</sub>	Effective Concentration X%	vPvB	very Persistent, very Bioaccumulative
P <sub>ow</sub>	Partition coefficient Octanol: Water	CMR	Carcinogens, mutagens or substances toxic to reproduction
BCF	Bioconcentration factor	RPE	Respiratory Protective Equipment
ED	Endocrine disruptor	HCS	Hazard Communication Standard

### Disclaimer

This Safety Data Sheet (SDS) was prepared according to OSHA HCS-2024. The data included was derived from international authoritative database and provided by the enterprise. Other information was based on the present state of our knowledge. We try to ensure the correctness of all information. However, due to the diversity of information sources and the limitations of our knowledge, this document is only for user's reference. Users should make their independent judgment of suitability of this information for their particular purposes. We do not assume responsibility for loss, damage or expense arising out of or in any way connected with the handling, storage, use or disposal of the product.