

1. PRODUCT AND COMPANY IDENTIFICATION

1.1 Product identifiers

Product name : Vardenafil HCl

Product Number : 10-1152

Brand : Focus Biomolecules

CAS-No. : 224785-91-5

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

Identified uses : For Laboratory Research Use Only

1.3 Details of the supplier of the safety data sheet

Company : Focus Biomolecules
400 Davis Drive, Suite 600
Plymouth Meeting, PA 19462

Telephone : +1 855-362-8721

E-mail : support@focusbiomolecules.com

1.4 Emergency telephone number

Emergency Phone # : CHEMTREC within USA/Canada 1-800- 424-9300
CHEMTREC outside USA/Canada 1-703-527-3887

2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

GHS Classification in accordance with 29 CFR 1910 (OSHA HCS)

Acute toxicity, Oral (Category 3), H301

Specific Target Organ Toxicity, single exposure,(Category 2), H371

Specific Target Organ Toxicity, repeated exposure(Category 1), H372

Hazardous to the aquatic environment - chronic hazard (Category 2), H411

For the full text of the H-Statements mentioned in this Section, see Section 16.

GHS Label elements, including precautionary statements

2.2

Pictogram



Signal word Hazard statement(s)

H301
H371
H372
H411

Danger

Toxic if swallowed.

May cause damage to organs (eyes)

Causes damage to organs (cardiovascular, skin) through prolonged or repeated exposure

Toxic to aquatic life with long lasting effects

Precautionary statement(s)

P260

Do not breathe dust/fume/gas/mist/vapors/spray

P264	Wash hands thoroughly after handling
P270	Do not eat, drink, or smoke when using this product
P273	Avoid release to the environment
P301 + P310	IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician
P308 + P311	If exposed or concerned: call a POISON center or doctor
P314	Get medical advice/attention if you feel unwell
P330	Rinse mouth
P391	Collect spillage
P405	Store locked up
P501	Dispose of contents/container to hazardous or special waste collection point in accordance with local, regional, national, or international regulation

2.3 Hazards not otherwise classified (HNOC) or not covered by GHS - none

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Synonyms : 2-[2-Ethoxy-5-[(4-ethyl-1-piperazinyl)sulfonyl]phenyl]-5-methyl-7-propyl-imidazo[5,1-f][1,2,4]triazin-4(1H)-one, hydrochloride ; BAY 38-9456

Formula : $C_{23}H_{32}N_6O_4S \cdot HCl$

Molecular weight : 525.07 g/mol

CAS-No. : 224785-91-5

EC-No. : 106-529-4

:

Hazardous components

Component	Classification	Concentration
Vardenafil HCl	Acute Tox. 3 (H301) 2; STOT SE 2 (H371), STOT RE 1 (H372), Environ Haz 2 (H411)	100 %

For the full text of the H-Statements mentioned in this Section, see Section 16.

4. FIRST AID MEASURES

4.1 Description of first aid measures

General advice

In all cases of doubt, or when symptoms persist, seek medical attention.

If inhaled

Remove person to fresh air and keep comfortable for breathing. Allow the victim to rest. If the person feels unwell : Get medical advice/attention.

In case of skin contact

Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse

In case of eye contact

Rinse with water while holding the eyes wide open. Obtain medical attention if pain, blinking or redness persists.

If swallowed

Rinse mouth out with water (only if the person is conscious). Never give anything by mouth to an unconscious person. Immediately call a POISON CENTER/doctor

4.2

4.3

Indication of any immediate medical attention and special treatment needed

Treat symptomatically

5. FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

5.2 Special hazards arising from the substance or mixture

No data available

5.3 Advice for firefighters

Wear self-contained breathing apparatus for firefighting if necessary.

5.4 Further information

No data available

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Wear respiratory protection. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.

For personal protection see section 8.

6.2 Environmental precautions

Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided.

6.3 Methods and materials for containment and cleaning up

Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal.

Reference to other sections

6.4 For disposal see section 13.

7. HANDLING AND STORAGE

7.1 Precautions for safe handling

Wear personal protective equipment. Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Further processing of solid materials may result in the formation of combustible dusts. The potential for combustible dust formation should be taken into consideration before additional processing occurs.

Provide appropriate exhaust ventilation at places where dust is formed.

For precautions see section 2.2.

7.2 Conditions for safe storage, including any incompatibilities

Keep container tightly closed in a dry and well-ventilated place.

Keep in a dry place.

Storage class (TRGS 510): 6.1B: Non-combustible, acute toxic Cat. 3

7.3 Specific end use(s)

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Components with workplace control parameters

Contains no substances with occupational exposure limit values.

Hazardous components without workplace control parameters

8.2 Exposure controls

Appropriate engineering controls

Avoid contact with skin, eyes and clothing. Wash hands before breaks and immediately after handling the product.

Personal protective equipment

Eye/face protection

Face shield and safety glasses Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin protection

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

Full contact

Material: Nitrile rubber

Minimum layer thickness: 0.11 mm

Break through time: 480 min

Material tested:Dermatril® (KCL 740 / Aldrich Z677272, Size M)

Splash contact

Material: Nitrile rubber

Minimum layer thickness: 0.11 mm

Break through time: 480 min

Material tested:Dermatril® (KCL 740 / Aldrich Z677272, Size M)

data source: KCL GmbH, D-36124 Eichenzell, phone +49 (0)6659 87300, e-mail sales@kcl.de, test method: EN374

If used in solution, or mixed with other substances, and under conditions which differ from EN 374, contact the supplier of the CE approved gloves. This recommendation is advisory only and must be evaluated by an industrial hygienist and safety officer familiar with the specific situation of anticipated use by our customers. It should not be construed as offering an approval for any specific use scenario.

Body Protection

Complete suit protecting against chemicals, The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Respiratory protection

Where risk assessment shows air-purifying respirators are appropriate use a full-face particle respirator type N100 (US) or type P3 (EN 143) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Control of environmental exposure

Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

- | | |
|--|-------------------------------|
| a) Appearance | Form: powder
Colour: White |
| b) Odour | No data available |
| c) Odour Threshold | No data available |
| d) pH | No data available |
| e) Melting point/freezing point | No data available |
| f) Initial boiling point and boiling range | No data available |
| g) Flash point | No data available |
| h) Evaporation rate | No data available |
| i) Flammability (solid, gas) | No data available |
| j) Upper/lower flammability or | No data available |

explosive limits

k)	Vapour pressure	No data available
l)	Vapour density	No data available
m)	Relative density	No data available
n)	Water solubility	No data available
o)	Partition coefficient: n-octanol/water	No data available
p)	Auto-ignition temperature	No data available
q)	Decomposition temperature	No data available
r)	Viscosity	No data available
s)	Explosive properties	No data available
t)	Oxidizing properties	No data available

9.2 Other safety information

No data available

10. STABILITY AND REACTIVITY

10.1 Reactivity

No data available

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

No data available

10.4 Conditions to avoid

No data available

10.5 Incompatible materials

Strong oxidizing agents

10.6 Hazardous decomposition products

Hazardous decomposition products formed under fire conditions. - Carbon oxides, Nitrogen oxides (NO_x), sulfur oxides, hydrogen chloride. Other decomposition products - No data available
In the event of fire: see section 5

11. TOXICOLOGICAL INFORMATION 11.1

Information on toxicological effects

Acute toxicity LD50 oral rat: 190 mg/kg

Inhalation: Not classified

Dermal: Not classified

Serious eye damage/eye irritation

May cause irritation

Respiratory or skin sensitisation

Not classified

Germ cell mutagenicity

Not classified

STOT - single exposure

May cause damage to organs (eyes)

STOT - repeated exposure

Causes damage to organs (cardiovascular, skin) through prolonged or repeated exposure

In vitro tests showed mutagenic effects

Carcinogenicity

- IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.
- NTP: No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.
- OSHA: No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

Reproductive toxicity

Specific target organ toxicity - single exposure

No data available

Specific target organ toxicity - repeated exposure

No data available

Aspiration hazard

No data available

Additional Information

RTECS: NJ6154000

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

12. ECOLOGICAL

INFORMATION 12.1 Toxicity

Toxic to aquatic life with long lasting effects

12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

No data available

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

PBT/vPvB assessment not available as chemical safety assessment not required/not conducted

12.6 Other adverse effects

Toxic to aquatic life with long lasting effects.

An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.

13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product

Contact a licensed professional waste disposal service to dispose of this material. Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber. Offer surplus and non-recyclable solutions to a licensed disposal company.

Contaminated packaging

Dispose of as unused product.

14. TRANSPORT INFORMATION

DOT (US)

UN number: 2811 Class: 6.1 Packing group: III
shipping name: Toxic solids, n.o.s. (Vardenafil HCl), Environmentally
Hazardous

IMDG

UN number: 2811 Class: 6.1 Packing group: III
Proper shipping name: Toxic solids, n.o.s. (Vardenafil HCl), Environmentally
Hazardous

IATA

UN number: 2811 Class: 6.1 Packing group: III
Proper shipping name: Toxic solids, n.o.s. (Vardenafil HCl), Environmentally
Hazardous

Packing group: I Proper

15. REGULATORY INFORMATION

SARA 302 Components

	CAS-No.	Revision Date
Vardenafil HCl	224785-91-5	09-01-2026

SARA 313 Components

This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

SARA 311/312 Hazards

Acute Health Hazard, Chronic Health Hazard

Massachusetts Right To Know Components

	CAS-No.	Revision Date
Vardenafil HCl	224785-91-5	09-01-2026

Pennsylvania Right To Know Components

	CAS-No.	Revision Date
Vardenafil HCl	224785-91-5	09-01-2026

California Prop. 65 Components

	CAS-No.	Revision Date
	224785-91-5	09-01-2026

16. OTHER INFORMATION

Full text of H-Statements referred to under sections 2 and 3.

H301	Toxic if swallowed.
H371	May cause damage to organs (eyes)
H372	Causes damage to organs (cardiovascular, skin) through prolonged or repeated exposure
H411	Toxic to aquatic life with long lasting effects

.

Further information

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