

Volasertib Solution

Version 1.0 Revision Date: 06/03/2015 MSDS Number: 000000027397 Date of last issue: -
Date of first issue: 06/03/2015

SECTION 1. IDENTIFICATION

Product name : Volasertib Solution
Synonyms : Active ingredient: Volasertib <0,3%
Product code : 000000027397

Manufacturer or supplier's details

Company name of supplier : Boehringer-Ingelheim Pharmaceuticals, Incorporated
Address : 900 Ridgebury Road
Ridgefield, Connecticut
06877-0368
Emergency telephone number : +1-800-424-9300 CHEMTREC Emergency Phone Number
CHEMTREC – 24 Hours
Routine Contact Number : (203) 778-7759


Recommended use of the chemical and restrictions on use

Recommended use : Mixture for production of finished medicinal products.
Prepared by : Corp. Div. EHS & Sustainability / Global EHS Services
EHS-service@boehringer-ingelheim.com

SECTION 2. HAZARDS IDENTIFICATION**GHS Classification (Hazard Communication Standard (HCS) 29 CFR 1910.1200)**

Acute toxicity (Oral) : Category 4

GHS Label element (Hazard Communication Standard (HCS) 29 CFR 1910.1200)

Hazard pictograms : 

Signal word : Warning

Hazard statements : H302 Harmful if swallowed.

Precautionary statements : **Prevention:**
P264 Wash hands thoroughly after handling.
Response:
P301 + P312 IF SWALLOWED: Call a POISON CENTER or doctor/ physician if you feel unwell.
P330 Rinse mouth.

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Disposal:

P501 Dispose of contents/ container to an approved incineration plant.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Pure substance

Chemical Name	CAS-No.	Concentration (%)
Volasertib hydrochloride	946161-17-7	< 0.3

SECTION 4. FIRST AID MEASURES

- General advice : Remove from exposure, lie down.
Take off immediately all contaminated clothing.
Victim to lie down in the recovery position, cover and keep him warm.
First Aid responders should pay attention to self-protection and use the recommended protective clothing
- If inhaled : Move to fresh air.
Call a physician immediately.
- In case of skin contact : Wash off immediately with plenty of water.
Cover wound with sterile dressing.
Call a physician immediately.
- In case of eye contact : Rinse immediately with plenty of water for at least 15 minutes.
Keep eye wide open while rinsing.
Call a physician immediately.
- If swallowed : Rinse mouth.
Drink plenty of water.
Call a physician immediately.
- Most important symptoms and effects, both acute and delayed : Toxic if swallowed.
May damage fertility or the unborn child.
- Notes to physician : Observe the summary of product characteristics of proprietary medicinal products
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SECTION 5. FIREFIGHTING MEASURES

- Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
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Water
Foam
Dry chemical
Carbon dioxide (CO₂)

Specific hazards during fire-fighting : In case of fire and/or explosion do not breathe fumes.
Can be released in case of fire:
Carbon oxides
Nitrogen oxides (NO_x)

Further information : Collect contaminated fire extinguishing water separately. This must not be discharged into drains.
Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.
Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.

Special protective equipment for firefighters : Self-contained breathing apparatus (EN 133)
complete suit protecting against chemicals

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures : Wear personal protective equipment.
Keep people away from and upwind of spill/leak.
Ensure adequate ventilation.
Knock down dust with water spray jet.

Environmental precautions : Do not flush into surface water or sanitary sewer system.

Methods and materials for containment and cleaning up : Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder, sawdust).
Keep in suitable, closed containers for disposal.

SECTION 7. HANDLING AND STORAGE

Advice on protection against fire and explosion : No special protective measures against fire required. The product is not flammable.

Advice on safe handling : Provide sufficient air exchange and/or exhaust in work rooms.
Keep container closed when not in use.

Conditions for safe storage : Protect from heat and direct sunlight.
Keep container tightly closed.
Jointless smooth floor

Materials to avoid : Keep away from food, drink and animal feedingstuffs.
Advice on Segregation

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SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**Components with workplace control parameters**

Components	Basis	Factor	Category	Values	Remark
N-[trans-4-[4-(Cyclopropylmethyl)-1-piperazinyl]cyclohexyl]-4-[[[(7R)-7-ethyl-5,6,7,8-tetrahydro-5-methyl-8-(1-methylethyl)-6-oxo-2-p	ECL		3B	2.4 µg/m ³	
946161-17-7	BIPC		3		
ECL (BIPI Exposure Control Limit)					

Contains no substances with occupational exposure limit values.

Engineering measures : Local exhaust

Personal protective equipment

Respiratory protection : Respirator with a dust filter particle filter P3 (EN 143)

Use NIOSH approved respiratory protection.

Hand protection Material : Chemical resistant gloves made of butyl rubber or nitrile rubber category III according to EN 374.
Directive : Protective gloves against chemicals and micro-organisms

Eye protection : Safety glasses with side-shields
(Not necessary when using full face mask)

Skin and body protection : Laboratory: laboratory coat; factory: disposable Overall.

Protective measures : Avoid contact with skin, eyes and clothing.
Handle in accordance with good industrial hygiene and safety practice.

Hygiene measures : General industrial hygiene practice.
Wash hands and face before breaks and immediately after handling the product.
Keep working clothes separately.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : solid

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Colour : No data available

Odour : No data available

Odour Threshold : No data available

pH : No data available

Melting point/range : No data available

Boiling point/boiling range : Not applicable

Flash point : Not applicable

Evaporation rate : No data available

Flammability (solid, gas) : No data available

Upper explosion limit : No data available

Lower explosion limit : No data available

Vapour pressure : No data available

Relative vapour density : Not applicable

Relative density : No data available

Bulk density : No data available

Solubility(ies)
Water solubility : No data available

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity
Viscosity, dynamic : Not applicable

Explosive properties : Not tested

Oxidizing properties : No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity : No dangerous reaction known under conditions of normal use.

Chemical stability : No decomposition if stored and applied as directed.

Possibility of hazardous reactions : No dangerous reaction known under conditions of normal use.

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Conditions to avoid : Extremes of temperature and direct sunlight.

Incompatible materials : No data available

Hazardous decomposition products : No data available

SECTION 11. TOXICOLOGICAL INFORMATION**Acute toxicity**

Harmful if swallowed.

Components:**Volasertib hydrochloride:**

Acute oral toxicity : Acute toxicity estimate (Rat): = 1.7 - 16.9 mg/kg

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

Skin corrosion/irritation

Not classified based on available information.

Components:**Volasertib hydrochloride:**

Species: Rabbit

Result: Mild skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:**Volasertib hydrochloride:**

Remarks: No data available

Respiratory or skin sensitisation

Skin sensitisation: Not classified based on available information.

Respiratory sensitisation: Not classified based on available information.

Components:**Volasertib hydrochloride:**

Method: DEREK

Result: Alert for skin sensitization

Germ cell mutagenicity

Not classified based on available information.

Components:**Volasertib hydrochloride:**

Genotoxicity in vitro

: Test Type: Ames test I und II
Species: Salmonella typhimurium
Result: negative

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: Test Type: Mouse lymphoma assay
Species: mouse lymphoma cells
Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test
Species: Rat
Application Route: intravenous
Remarks: Possible risk of irreversible effects.

Carcinogenicity

Not classified based on available information.

Components:

Volasertib hydrochloride:
Remarks: No data available

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.

OSHA

No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

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.

Reproductive toxicity

May damage fertility or the unborn child.

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

Repeated dose toxicity**Components:**

Volasertib hydrochloride:
Species: Rat
NOAEL: < 0,5 mg/kg
Application Route: Oral

Aspiration toxicity

Not classified based on available information.

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SECTION 12. ECOLOGICAL INFORMATION**Ecotoxicity****Components:****Volasertib hydrochloride:**

Toxicity to fish : Remarks: No data available

Toxicity to daphnia and other aquatic invertebrates : Remarks: No data available

Toxicity to algae : Remarks: No data available

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : Remarks: No data available

Persistence and degradability

No data available

Bioaccumulative potential**Components:****Volasertib hydrochloride:**

Partition coefficient: n-octanol/water : Remarks: No data available

Mobility in soil

No data available

Other adverse effects**Product:**

Ozone-Depletion Potential : Regulation: 40 CFR Protection of Environment; Part 82 Protection of Stratospheric Ozone - CAA Section 602 Class I Substances
Remarks: This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

SECTION 13. DISPOSAL CONSIDERATIONS**Disposal methods**

Waste from residues : Dispose of in accordance with local regulations.

Contaminated packaging : Packs that cannot be cleaned should be disposed of in the same manner as the contents.
Uncontaminated packaging can be recycled.

SECTION 14. TRANSPORT INFORMATION**International Regulation**

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Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

National Regulations

SECTION 15. REGULATORY INFORMATION**EPCRA - Emergency Planning and Community Right-to-Know Act****SARA 311/312 Hazards** : No SARA Hazards**SARA 302** : No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.**SARA 313** : 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.**Clean Air Act**

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 12 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCM Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

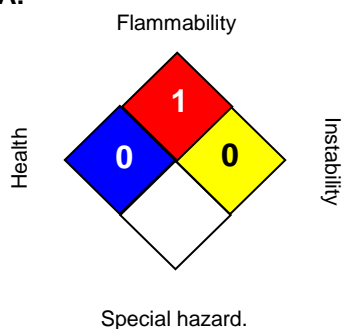
Massachusetts Right To Know

No components are subject to the Massachusetts Right to Know Act.

California Prop 65 : This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

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SECTION 16. OTHER INFORMATION**Further information****NFPA:****HMIS III:**

HEALTH	0
FLAMMABILITY	1
PHYSICAL HAZARD	0

0 = not significant, 1 =Slight,
2 = Moderate, 3 = High
4 = Extreme, * = Chronic

Vertical lines in the left hand margin indicate an amendment from the previous version. Refer to NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids, for safe handling. Sources of key data used to compile the Safety Data Sheet : The specifications are based on own tests and/or literature data.

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The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.