SAFETY DATA SHEET

1 PRODUCT AND COMPANY IDENTIFICATION

Product name: VORINOSTAT CAPSULES

SDS No: P00000020073

Synonyms, Trade Names:
ZOLINZA, MK-0683

IUPAC:
N-hydroxy-N'-phenyl-octanediamide

Manufacturer:
Merck
One Merck Drive P.O. Box 100
Whitehouse Station, NJ, USA 08889-0100

Telephone: 908-423-1000 (General Information Only)
Fax: 908-735-1496

Contact Person: EHS Data Steward
e-mail: MSDS@merck.com

Emergency telephone: 1-908-423-6000 (24/7/365) English Only

Intended Use: Finished pharmaceutical product

2 HAZARDS IDENTIFICATION

Emergency Overview:

Appearance:	
Form :	Capsules
Odor:	Odorless
Signal words	WARNING!
Potential Health Effects:	
General	Avoid contact with eyes, skin, and clothing. May cause harm to the unborn child. Wash thoroughly after handling.
Potential Physical / Chemical Effects:	None under normal conditions.
Inhalation:	Avoid breathing dust.
Skin:	Non-irritating to the skin.
Eye:	Non-irritating to the eyes.
Ingestion:	Practically non-toxic if swallowed.
Target Organs:	Blood, Lymph, testes, Gastrointestinal System
OSHA Regulatory Status	This product is hazardous according to OSHA 29CFR 1910.1200.
Environment:	Very toxic to aquatic organisms.

OTHER INFORMATION No additional information

3 COMPOSITION / INFORMATION ON INGREDIENTS

General information: The formulation for this product is proprietary information. Only hazardous ingredients in concentrations of 1% or greater and/or carcinogenic ingredients in concentrations of 0.1% or greater are listed in the composition table. Active ingredients in any concentration are listed.

Hazardous Component(s):

Chemical name	CAS-No.	Concentration
VORINOSTAT	149647-78-9	66.7%
CELLULOSE MICROCRYSTALLINE	9004-34-6	15 - 40%

* All concentrations are percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

4 FIRST AID MEASURES

Inhalation: Move to fresh air. For breathing difficulties, oxygen may be necessary. If breathing stops, provide artificial respiration. Get medical attention.

Skin contact: Wash skin thoroughly with soap and water. Get medical attention if irritation persists after washing.

Eye contact: Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention if symptoms occur.

Ingestion: Do not induce vomiting. Get medical attention if symptoms occur.

Notes to the physician:
Treatment: Treat supportively and symptomatically.

5 FIRE-FIGHTING MEASURES

Extinguishing media: Water spray, fog, CO2, dry chemical, or alcohol resistant foam.

Unsuitable extinguishing media: None known.

Unusual Fire & Explosion Hazards: Emits toxic fumes under fire conditions.

Special Fire Fighting Procedures: Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

Protective Measures: Prevent runoff from fire control or dilution from entering streams, sewers, or drinking water supply.

6 ACCIDENTAL RELEASE MEASURES

Personal precautions: Use personal protective equipment. Immediately contact emergency personnel. Keep unnecessary personnel away. Follow all fire fighting procedures.

Environmental precautions: Do not release into the environment.

Spill Cleanup Methods: Use a vacuum cleaner. If not possible, moisten dust with water before it is collected with shovel, broom or the like. Avoid dusty conditions and prevent wind dispersal. Collect in containers and seal securely. For waste disposal, see section 13 of the MSDS. Prevent runoff from entering drains, sewers, or streams.

7 HANDLING AND STORAGE

Handling: No specific hazard with intact tablets or capsules. In case of exposure to crushed or broken tablets/capsules, avoid contact with eyes and avoid prolonged or repeated contact with skin. Wash thoroughly after handling.

Storage: Keep container tightly closed in a cool, well-ventilated place.

8 EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure limits:

VORINOSTAT	TWA	5 µg/m3	Merck Occupational Exposure Band (OEB) or Wipe Test criteria
	Wipe Test	50 µg/100 cm2	Merck
	TWA	OEB Cat. 4	Merck

OEB Category 4 is an internal Merck control band and corresponds to the 8-hour TWA (time-weighted average) and concentration of 1 - <10 µg / m3. Refer to recommendations below.

Protective Measures: No special containment required with normal handling of finished product. Use local exhaust ventilation to control residual dust from broken or crushed tablets when handling in bulk quantities.

Respiratory Protection: No specific recommendation made, but respiratory protection must be used if the general level exceeds the Recommended Occupational Exposure Limit

Hand protection: Disposable chemical resistant gloves wherever the potential exists for direct exposure to residual dust from crushed or broken tablets or capsules.

Eye protection: If contact is likely, safety glasses with side shields are recommended.

Skin and Body Protection: Work uniform or laboratory coat when there is potential for direct contact with the residual dust from crushed or broken tablets.

Hygiene measures: Wash skin thoroughly with soap and water.

9 PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Appearance:
- **Physical State:** Solid
- **Form:** Capsules

Odor: Odorless

Flammability (solid, gas): Not relevant.

Other information:
- **VOC Content:** 0 g/l

10 STABILITY AND REACTIVITY

Possibility of hazardous reactions: Stable

Conditions to avoid: Moisture. Excessive heat.

Incompatible materials: None under normal conditions.

Hazardous decomposition products: Thermal decomposition or combustion may liberate carbon oxides and other toxic gases or vapors.

11 TOXICOLOGICAL INFORMATION

General information: The information presented below pertains to the individual ingredients, and not to the mixture(s) or final formulations.

Specified substance(s):

Acute Toxicity (Oral);

Name	**Test results**
VORINOSTAT	ALD50 (Mouse): > 2,000 mg/kg ALD50 (Rat): > 750 mg/kg

Inhalation: No data available.

Ingestion: No data available.

Skin corrosion/irritation: No data available.

Serious eye damage/eye irritation: No data available.

Respiratory sensitizer/Skin sensitizer: No data available.

Carcinogenicity: No data available.

Mutagenesis: No data available.

Reproductive toxicity: No data available.

12 ECOLOGICAL INFORMATION

General information: The information presented below pertains to the individual ingredients, and not to the mixture(s) or final formulations.

Ecotoxicity: The information presented below pertains to the individual ingredients, and not to the mixture(s) or final formulations.

Specified substance(s):

Acute toxicity(Fish):

Name	Test results
VORINOSTAT	LC 50 (Fathead Minnow, 96 h): > 10 mg/l LC 50 (Sheepshead Minnow, 96 h): 10 mg/l

Acute toxicity(Aquatic invertebrates):

Name	Test results
VORINOSTAT	LC 50 (Water flea (Daphnia magna), 48 h): > 10 mg/l LC 50 (Shrimp (Mysidopsis juniae), 96 h): 7.4 mg/l

Acute toxicity(Aquatic plants):

Name	Test results
VORINOSTAT	EC 50 (Green algae (Selenastrum capricornutum), 96 h): 0.080 mg/l

Persistence and degradability: No data available.

Bioaccumulative potential: No data available on bioaccumulation.

Mobility: No data available.

13 DISPOSAL CONSIDERATIONS

Disposal Methods: Do not allow runoff to sewer, waterway or ground. Discharge, treatment, or disposal may be subject to national, state, or local laws.

14 TRANSPORT INFORMATION

DOT - Department of Transportation

Not regulated.

IMDG - International Maritime Dangerous Goods Code

UN number	UN3077
Proper Shipping Name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.(VORINOSTAT)
Class	9
Packing group	III
Label(s)	9
Subsidiary risk label	
Marine Pollutant	Envir. Hazardous, Labels Only
EmS No.	F-A; S-F

IATA - International Air Transport Association

UN number	UN3077
Proper Shipping Name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.(VORINOSTAT)
Class	9
Packing group	III
Label(s)	9MI
Subsidiary risk label	

15 REGULATORY INFORMATION

US Regulations

- **CERCLA Hazardous Substance List (40 CFR 302.4):**
  None

- **Clean Water Act Section 311 Hazardous Substances (40 CFR 117.3):**
  None

- **Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130):**
  None

SARA Title III

- **Section 302 Extremely Hazardous Substance (40 CFR 355, Appendix A):**
  None

- **Section 313 Toxic Release Inventory (40 CFR 372):**
  None present or none present in regulated quantities.

State Regulations

- **California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65):**
  No ingredient regulated by CA Prop 65 present.

- **Massachusetts Right-To-Know List:**

CELLULOSE MICROCRYSTALLINE	Listed

- **New Jersey Right-To-Know List:**
  No ingredient regulated by NJ Right-to-Know Law present.

- **Pennsylvania Right-To-Know List:**

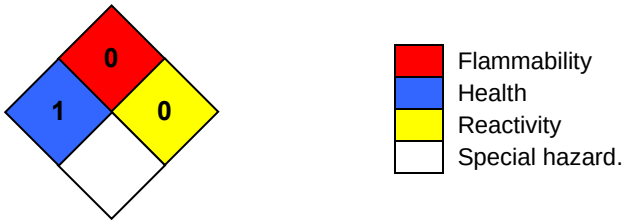
CELLULOSE MICROCRYSTALLINE	Listed

16 OTHER INFORMATION

OTHER INFORMATION

This SDS is written to provide health and safety information for individuals who will be handling the final product formulation during research, manufacturing, and distribution. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate SDS for each ingredient. Refer to the package insert or product label for handling guidance for the consumer.

NFPA Hazard ID



Hazard rating: 0 - Minimal; 1 - Slight; 2 - Moderate; 3 - Serious; 4 - Severe

Revision Information:	Not relevant.
Issue Date:	25.07.2011
Disclaimer:	This information is provided without warranty. The information is believed to be correct. This information should be used to make an independent determination of the methods to safeguard workers and the environment.