

SECTION 1: Identification

1.1. Identification

Product form : Mixture

Product name : Valstar

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

Use of the substance/mixture : Treatment of bladder cancer

1.3. Details of the supplier of the safety data sheet

Endo Pharmaceuticals, Inc.

1400 Atwater Drive

Malvern, PA 19355

T (484) 216-0000

www.endo.com

1.4. Emergency telephone number

Emergency number : 1-800-535-5053 (INFOTRAC)
24 hours

SECTION 2: Hazard(s) identification

2.1. Classification of the substance or mixture

GHS-US classification

Flammable liquids, Category 2

Germ cell mutagenicity, Category 1B

Reproductive toxicity, Category 2

2.2. Label elements

GHS-US labeling

Hazard pictograms (GHS-US) :



GHS02



GHS08

Signal word (GHS-US) :

Danger

Hazard statements (GHS-US) :

Highly flammable liquid and vapor
May cause genetic defects
Suspected of damaging fertility or the unborn child

Precautionary statements (GHS-US) :

Obtain special instructions before use
Do not handle until all safety precautions have been read and understood
Keep away from heat, sparks, open flames, hot surfaces. - No smoking
Keep container tightly closed
Ground/bond container and receiving equipment
Use explosion-proof ventilating equipment
Use only non-sparking tools
Take precautionary measures against static discharge
Wear protective gloves, eye protection
If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower
If exposed or concerned: Get medical advice/attention
In case of fire: Use Dry chemical, carbon dioxide (CO₂), foam to extinguish
Store in a well-ventilated place. Keep cool
Store locked up
Dispose of contents/container to comply with applicable local, national and international regulation

This product is FDA regulated. Its primary use is intended solely for medicinal purposes under the direction of a licensed physician experienced in the administering of intravesical cancer chemotherapeutic agents.

2.3. Other hazards

No additional information available

2.4. Unknown acute toxicity (GHS US)

Not applicable

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according to the federal final rule of hazard communication revised on 2012 (HazCom 2012)

SECTION 3: Composition/Information on ingredients

3.1. Substance

Not applicable

3.2. Mixture

Name	Product identifier	%	GHS-US classification
Castor oil	(CAS No) 8001-79-4	52.4	Not classified
Ethyl alcohol	(CAS No) 64-17-5	43.2	Flam. Liq. 2
Valrubicin	(CAS No) 56124-62-0	4.4	Muta. 1B Repr. 2

SECTION 4: First aid measures

4.1. Description of first aid measures

- First-aid measures after inhalation : Not expected to present a significant inhalation hazard under anticipated conditions of normal use. If prolonged concentrated exposure occurs, remove person to fresh air.
- First-aid measures after skin contact : Wash off immediately with soap and plenty of water.
- First-aid measures after eye contact : Rinse immediately with plenty of water for 15 minutes. Seek medical attention if ill effect or irritation persists.
- First-aid measures after ingestion : Rinse mouth. Seek medical attention immediately.

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

- Symptoms/injuries : May cause genetic defects. Suspected of damaging fertility or the unborn child.
- Symptoms/injuries after skin contact : Frequently or prolonged contact with skin may cause dermal irritation. May cause skin reaction.
- Symptoms/injuries after eye contact : May cause irritating and/or burning sensation in contact with eyes.
- Symptoms/injuries after ingestion : May be harmful if swallowed.

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

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

- Suitable extinguishing media : Foam. Dry powder. Carbon dioxide. Water spray.
- Unsuitable extinguishing media : Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

- Fire hazard : Highly flammable liquid and vapor.

5.3. Advice for firefighters

- Firefighting instructions : Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire-fighting water from entering environment.
- Protection during firefighting : Do not enter fire area without proper protective equipment, including SCBA protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

- General measures : Remove ignition sources. Use special care to avoid static electric charges. No open flames. No smoking.

6.1.1. For non-emergency personnel

- Emergency procedures : Evacuate unnecessary personnel.

6.1.2. For emergency responders

- Protective equipment : Equip cleanup crew with proper protection.
- Emergency procedures : Ventilate area.

6.2. Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

6.3. Methods and material for containment and cleaning up

- Methods for cleaning up : Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Use absorbent material for the solvent and sodium hydroxide to breakdown the Valrubicin. Collect spillage. Store away from other materials.

6.4. Reference to other sections

Refer to sections 8 and 13.

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SECTION 7: Handling and storage

7.1. Precautions for safe handling

- Additional hazards when processed : Handle empty containers with care because residual vapors are flammable.
- Precautions for safe handling : Procedures for proper handling and disposal of anticancer drugs should be used. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapor. No open flames. No smoking. Use only non-sparking tools. Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Remove all ignition sources.

7.2. Conditions for safe storage, including any incompatibilities

- Technical measures : Proper grounding procedures to avoid static electricity should be followed. Ground/bond container and receiving equipment. Use explosion-proof ventilating, equipment.
- Storage conditions : Keep only in the original container in a cool, well ventilated place away from: Heat sources, Incompatible materials. Keep in fireproof place. Keep container tightly closed. Do not freeze.
- Incompatible materials : Sources of ignition. Direct sunlight. Heat sources. Strong oxidizing agents.
- Storage temperature : 2 - 8 °C Do not freeze

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Ethyl alcohol (64-17-5)		
ACGIH	ACGIH STEL (ppm)	1000 ppm
OSHA	OSHA PEL (TWA) (mg/m ³)	1900 mg/m ³
OSHA	OSHA PEL (TWA) (ppm)	1000 ppm
IDLH	US IDLH (ppm)	3300 ppm (10% LEL)
NIOSH	NIOSH REL (TWA) (mg/m ³)	1900 mg/m ³
NIOSH	NIOSH REL (TWA) (ppm)	1000 ppm

For exposure guidelines, see "Patient Insert" and Section 16.

8.2. Exposure controls

- Appropriate engineering controls : Use aseptic techniques during administration. Provide adequate ventilation.
- Personal protective equipment : Avoid all unnecessary exposure. Dust/aerosol mask. Gloves. Protective clothing.



- Hand protection : Wear protective gloves.
- Eye protection : Chemical goggles or safety glasses.
- Skin and body protection : Wear suitable protective clothing or rubber apron.
- Respiratory protection : Wear appropriate mask.
- Other information : Do not eat, drink or smoke during use.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

- Physical state : Liquid
- Color : Red
- Odor : Odor of Ethanol
- Odor threshold : No data available
- pH : No data available
- Melting point : No data available
- Freezing point : No data available
- Boiling point : No data available
- Flash point : No data available
- Relative evaporation rate (butyl acetate=1) : No data available
- Flammability (solid, gas) : No data available

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Explosion limits	: No data available
Explosive properties	: No data available
Oxidizing properties	: No data available
Vapor pressure	: No data available
Relative density	: No data available
Relative vapor density at 20 °C	: No data available
Solubility	: No data available
Log Pow	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Stable under normal conditions of use.

10.2. Chemical stability

Highly flammable liquid and vapor. Stable under normal conditions of use.

10.3. Possibility of hazardous reactions

Hazardous polymerization will not occur.

10.4. Conditions to avoid

Direct sunlight. Extremely high or low temperatures. Open flame. Heat sources. Do not freeze.

10.5. Incompatible materials

Combustible materials, Strong oxidizing agents

10.6. Hazardous decomposition products

Possibly when heated under fire conditions.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Likely routes of exposure	: Skin and Eye contact
Acute toxicity	: Not classified
Skin corrosion/irritation	: Not classified
Serious eye damage/irritation	: Not classified
Respiratory or skin sensitization	: Not classified
Germ cell mutagenicity	: May cause genetic defects.
Carcinogenicity	: Not classified
Reproductive toxicity	: Suspected of damaging fertility or the unborn child.
Specific target organ toxicity (single exposure)	: Not classified
Specific target organ toxicity (repeated exposure)	: Not classified
Aspiration hazard	: Not classified
Potential Adverse human health effects and symptoms	: Based on available data, the classification criteria are not met.
Symptoms/injuries after skin contact	: Frequently or prolonged contact with skin may cause dermal irritation. May cause skin reaction.
Symptoms/injuries after eye contact	: May cause irritating and/or burning sensation in contact with eyes.
Symptoms/injuries after ingestion	: May be harmful if swallowed.

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general	: Avoid release to the environment.
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12.2. Persistence and degradability

Valstar	
Persistence and degradability	Not established.

12.3. Bioaccumulative potential

Valstar	
Bioaccumulative potential	Not established.
Ethyl alcohol (64-17-5)	
Log Pow	-0.32

12.4. Mobility in soil

No additional information available

12.5. Other adverse effects

Effect on the global warming : No additional information available
Other information : Avoid release to the environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste disposal recommendations : Dispose in a safe manner in accordance with local/national regulations. Dispose of contents/container to comply with applicable local, national and international regulation. Expired and used product should be transported by a licensed hauler and disposed of by a licensed waste disposal facility in accordance with local, state and federal guidelines. Procedures for proper handling and disposal of anticancer drugs should be used. It is the responsibility of the user to determine if this material is a RCRA Hazardous Waste at the time of disposal.

Additional information : Handle empty containers with care because residual vapors are flammable. Discard as medical waste

Ecology - waste materials : Avoid release to the environment.

SECTION 14: Transport information

This product is FDA regulated.

Department of Transportation (DOT)

In accordance with DOT

Transport document description : UN3248 Medicine, liquid, flammable, toxic, n.o.s. (Contains ethyl alcohol) , 3, II
UN-No.(DOT) : UN3248
Proper Shipping Name (DOT) : Medicine, liquid, flammable, toxic, n.o.s (Contains ethyl alcohol)
Class (DOT) : 3 - Class 3 - Flammable and combustible liquid 49 CFR 173.120
Subsidiary risk (DOT) : 6.1 - Class 6.1 - Poisonous materials 49 CFR 173.132
Hazard labels (DOT) : 3 - Flammable liquid
6.1 - Poison



Packing group (DOT) : II - Medium Danger
DOT Packaging Non Bulk (49 CFR 173.xxx) : 202
DOT Packaging Bulk (49 CFR 173.xxx) : None
DOT Special Provisions (49 CFR 172.102) : IB2 - Authorized IBCs: Metal (31A, 31B and 31N); Rigid plastics (31H1 and 31H2); Composite (31HZ1). Additional Requirement: Only liquids with a vapor pressure less than or equal to 110 kPa at 50 C (1.1 bar at 122 F), or 130 kPa at 55 C (1.3 bar at 131 F) are authorized
DOT Packaging Exceptions (49 CFR 173.xxx) : 150
DOT Quantity Limitations Passenger aircraft/rail (49 CFR 173.27) : 1 L
DOT Quantity Limitations Cargo aircraft only (49 CFR 175.75) : 60 L

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DOT Vessel Stowage Location	: B - (i) The material may be stowed "on deck" or "under deck" on a cargo vessel and on a passenger vessel carrying a number of passengers limited to not more than the larger of 25 passengers, or one passenger per each 3 m of overall vessel length; and (ii) "On deck only" on passenger vessels in which the number of passengers specified in paragraph (k)(2)(i) of this section is exceeded
DOT Vessel Stowage Other	: 40 - Stow "clear of living quarters"
Emergency Response Guide (ERG) Number	: 131
Other information	: No supplementary information available.

TDG

No additional information available

Transport by sea

UN-No. (IMDG)	: 3248
Proper Shipping Name (IMDG)	: MEDICINE, LIQUID, FLAMMABLE, TOXIC, N.O.S. (CONTAINS ETHYL ALCOHOL)
Class (IMDG)	: 3 - Flammable liquids
Packing group (IMDG)	: II - substances presenting medium danger
Subsidiary risks (IMDG)	: 6.1

Air transport

UN-No. (IATA)	: 3248
Proper Shipping Name (IATA)	: Medicine, liquid, flammable, toxic, n.o.s. (Contains ethyl alcohol)
Class (IATA)	: 3 - Flammable Liquids
Packing group (IATA)	: II - Medium Danger
Subsidiary risk (IATA)	: 6.1

SECTION 15: Regulatory information

15.1. US Federal regulations

Valstar	
SARA Section 311/312 Hazard Classes	Immediate (acute) health hazard Delayed (chronic) health hazard
SARA Section 313 - Emission Reporting	2.5 % Ethanol

Ethyl alcohol (64-17-5)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

Castor oil (8001-79-4)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

15.2. International regulations

CANADA

Ethyl alcohol (64-17-5)

Listed on the Canadian DSL (Domestic Substances List)

WHMIS Classification	Class B Division 2 - Flammable Liquid Class D Division 2 Subdivision B - Toxic material causing other toxic effects
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Castor oil (8001-79-4)

Listed on the Canadian DSL (Domestic Substances List)

WHMIS Classification	Uncontrolled product according to WHMIS classification criteria
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EU-Regulations

Ethyl alcohol (64-17-5)

Listed on the EEC inventory EINECS (European Inventory of Existing Commercial Chemical Substances)

Castor oil (8001-79-4)

Listed on the EEC inventory EINECS (European Inventory of Existing Commercial Chemical Substances)

National regulations

Valstar

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according to the federal final rule of hazard communication revised on 2012 (HazCom 2012)

Ethyl alcohol (64-17-5)

Listed on IARC (International Agency for Research on Cancer)
Listed on the AICS (Australian Inventory of Chemical Substances)
Listed on IECSC (Inventory of Existing Chemical Substances Produced or Imported in China)
Listed on the Japanese ENCS (Existing & New Chemical Substances) inventory
Listed on the Korean ECL (Existing Chemicals List)
Listed on NZIoC (New Zealand Inventory of Chemicals)
Listed on PICCS (Philippines Inventory of Chemicals and Chemical Substances)
Listed on the Canadian IDL (Ingredient Disclosure List)
Listed on INSQ (Mexican national Inventory of Chemical Substances)
Listed on CICR (Turkish Inventory and Control of Chemicals)

Castor oil (8001-79-4)

Listed on the AICS (Australian Inventory of Chemical Substances)
Listed on IECSC (Inventory of Existing Chemical Substances Produced or Imported in China)
Listed on the Korean ECL (Existing Chemicals List)
Listed on NZIoC (New Zealand Inventory of Chemicals)
Listed on PICCS (Philippines Inventory of Chemicals and Chemical Substances)
Listed on the Canadian IDL (Ingredient Disclosure List)
Listed on INSQ (Mexican national Inventory of Chemical Substances)
Listed on CICR (Turkish Inventory and Control of Chemicals)

15.3. US State regulations

California Proposition 65 - This product contains, or may contain, trace quantities of a substance(s) known to the state of California to cause cancer and/or reproductive toxicity

Ethyl alcohol (64-17-5)

U.S. - California - Proposition 65 - Carcinogens List	U.S. - California - Proposition 65 - Developmental Toxicity	U.S. - California - Proposition 65 - Reproductive Toxicity - Female	U.S. - California - Proposition 65 - Reproductive Toxicity - Male	Non-significant risk level (NSRL)
Yes	Yes	No	No	

SECTION 16: Other information

Date of Preparation : 03/03/2016

Other information : None.

Administration Precautions - As recommended with other cytotoxic agents, caution should be exercised in handling and preparing the solution of VALSTAR. Contact toxicity, common and severe with other anthracyclines, is not typical with VALSTAR and, when observed, has been mild. Skin reactions may occur with accidental exposure, and the use of gloves during dose preparation and administration is recommended. Irritation of the eye has also been reported with accidental exposure. If this happens, the eye should be flushed with water immediately and thoroughly.

PREPARATION INFORMATION: (SEE "PATIENT INSERT")

SDS US (GHS HazCom 2012)

Disclaimer: This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product