



SAFETY DATA SHEET

1. Identification

Product identifier	Ixabepilone System Suitability Mixture	
Other means of identification		
Catalog number	1354411	
Recommended use	For analytical laboratory use only.	
Recommended restrictions	Not for use as a drug. Not for administration to humans or animals.	
Manufacturer/Importer/Supplier/Distributor information		
Manufacturer		
Company name	U. S. Pharmacopeia	
Address	12601 Twinbrook Parkway Rockville MD 20852-1790 United States	
Telephone	Technical Services	301-816-8129
Website	www.usp.org	
E-mail	RSTECH@usp.org	
Emergency phone number	CHEMTREC within US & Canada	1-800-424-9300
	CHEMTREC outside US & Canada	+1 703-527-3887

2. Hazard(s) identification

Physical hazards	Not classified.	
Health hazards	Acute toxicity, oral	Category 2
	Sensitization, skin	Category 1
	Germ cell mutagenicity	Category 1
	Reproductive toxicity	Category 1
	Specific target organ toxicity, repeated exposure	Category 1
Environmental hazards	Not classified.	
OSHA defined hazards	Not classified.	
Label elements		



Signal word	Danger
Hazard statement	Fatal if swallowed. May cause an allergic skin reaction. May cause genetic defects. May damage fertility or the unborn child. Causes damage to organs through prolonged or repeated exposure.
Precautionary statement	
Prevention	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not breathe dust/fume/gas/mist/vapors/spray. Wash thoroughly after handling. Wear protective gloves/protective clothing/eye protection/face protection. Contaminated work clothing must not be allowed out of the workplace.
Response	If swallowed: Immediately call a poison center/doctor. Rinse mouth. If on skin: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. Take off contaminated clothing and wash it before reuse. If exposed or concerned: Get medical advice/attention. Get medical advice/attention if you feel unwell.
Storage	Store locked up.
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazard(s) not otherwise classified (HNOC)

This product is supplied in a small quantity which does not constitute a combustible dust hazard. The physical properties of this material indicate that in large quantities accumulated dust may be hazardous.

Supplemental information

Highly potent pharmacologically active material.

3. Composition/information on ingredients**Mixture**

Chemical name	Common name and synonyms	CAS number	%
Ixabepilone	Epothilone B analog	219989-84-1	96
Related Impurities		No Data	4

Information provided in the SDS is not specific to the lot provided. Refer to the label and USP Certificate/Product Information Sheet for the assigned value of a particular lot.

4. First-aid measures**Inhalation**

Move to fresh air. Call a physician if symptoms develop or persist.

Skin contact

Remove contaminated clothing immediately and wash skin with soap and water. In case of eczema or other skin disorders: Seek medical attention and take along these instructions.

Eye contact

Rinse with water. Get medical attention if irritation develops and persists.

Ingestion

Call a physician or poison control center immediately. Rinse mouth. Do not induce vomiting without advice from poison control center. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs. Do not use mouth-to-mouth method if substance is ingested. Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device.

Most important symptoms/effects, acute and delayed

Bone marrow depression. Highly potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.

Indication of immediate medical attention and special treatment needed

Provide general supportive measures and treat symptomatically.

General information

Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

5. Fire-fighting measures**Suitable extinguishing media**

Water. Foam. Dry chemical or CO₂. Use fire-extinguishing media appropriate for surrounding materials.

Unsuitable extinguishing media

Do not use water jet as an extinguisher, as this will spread the fire.

Specific hazards arising from the chemical

Explosion hazard: 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 and precautions for firefighters

Wear suitable protective equipment.

Fire fighting equipment/instructions

Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

Specific methods

Use standard firefighting procedures and consider the hazards of other involved materials.

General fire hazards

No unusual fire or explosion hazards noted.

6. Accidental release measures**Personal precautions, protective equipment and emergency procedures**

Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Keep unnecessary personnel away. Avoid inhalation of dust from the spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. For personal protection, see section 8 of the SDS. Wear appropriate personal protective equipment.

Methods and materials for containment and cleaning up

Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination. For waste disposal, see section 13 of the SDS.

Environmental precautions

Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling

As a general rule, when handling USP materials, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Avoid significant deposits of material, especially on horizontal surfaces, which may become airborne and form combustible dust clouds and may contribute to secondary explosions. Combustible dust clouds may be created where operations produce fine material (dust). Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential.

Conditions for safe storage, including any incompatibilities

Store in tight container. This material should be handled and stored per label instructions to ensure product integrity.

8. Exposure controls/personal protection

Occupational exposure limits

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

Exposure limit values

Industrial Use Components

	Type	Value
Ixabepilone (CAS 219989-84-1)	TWA	0.01 micrograms/m3

Biological limit values

No biological exposure limits noted for the ingredient(s).

Appropriate engineering controls

No open handling. For laboratory operations, conduct powder handling operations in an isolator or equivalent. Put powder into solution or a tightly capped container prior to removal from containment. Isolator should be equipped with bag out ports or transfer chamber. Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred.

Individual protection measures, such as personal protective equipment

Eye/face protection

Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.

Skin protection

Hand protection

Wear double gloves. Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent.

Other

Train employees in proper gowning and degowning practices. Wear disposable laboratory coat and disposable sleeve covers appropriate to the task, two pairs of gloves, and safety glasses with side shields. An anteroom or transition area is recommended for gowning and degowning. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do not wear protective garments in common areas (e.g., cafeterias) or out-of-doors.

Respiratory protection

Use a powered air-purifying respirator (PAPR) with HEPA filters, disposable outerware and head cover for spill cleanup. Choose respiratory protection appropriate to the task and the level of existing engineering controls.

Thermal hazards

Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations

Handling practices in this SDS are recommendations for laboratory use of USP materials.

9. Physical and chemical properties

Appearance

Appearance descriptions are general information and not specific to any USP lot.

Physical state

Solid.

Form

Powder.

Color

Not available.

Odor

Not available.

Odor threshold

Not available.

pH

Not available.

Melting point/freezing point

Not available.

Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not available.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	Not available.
Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Avoid temperatures exceeding the decomposition temperature. Contact with incompatible materials.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions. NOx. SOx.

11. Toxicological information

Information on likely routes of exposure

Inhalation	Knowledge about health hazard is incomplete.
Skin contact	May cause an allergic skin reaction.
Eye contact	Knowledge about health hazard is incomplete.
Ingestion	Fatal if swallowed.

Symptoms related to the physical, chemical and toxicological characteristics	Component: Systemic effects following injection or infusion: Numbness, pain, tingling, or weakness in hands or feet. Fatigue. Muscle pain. Bone pain. Nausea. Diarrhea. Stomach pain. Inflammation of mouth and throat. Swollen lips. Hair loss. Fever. Shortness of breath. Weakness. Lightheadedness. Headache. Pinpoint red spots on skin. Bleeding or bruising.
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Information on toxicological effects

Acute toxicity	Fatal if swallowed.
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Components	Species	Test Results
Ixabepilone (CAS 219989-84-1)		
<u>Acute</u>		
Oral		
LD50	Rat	37 mg/kg
Skin corrosion/irritation	Knowledge about health hazard is incomplete.	
Serious eye damage/eye irritation	Knowledge about health hazard is incomplete.	
Respiratory or skin sensitization		
Respiratory sensitization	Knowledge about health hazard is incomplete.	

Skin sensitization	May cause an allergic skin reaction. Rare occurrences of dermal hypersensitivity reactions with therapeutic use of a related material have been reported.
Germ cell mutagenicity	May cause genetic defects.
Mutagenicity Ixabepilone	Ames test Result: Negative. Chromosome aberration assay (primary human lymphocytes) Result: Negative. In vivo micronucleus assay Result: Clastogenic. Species: Rat
Carcinogenicity	Knowledge about carcinogenicity is incomplete.
IARC Monographs. Overall Evaluation of Carcinogenicity	
Not listed.	
OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)	
Not listed.	
US. National Toxicology Program (NTP) Report on Carcinogens	
Not listed.	
Reproductive toxicity	May damage fertility or the unborn child.
Reproductivity Ixabepilone	0.02 - 0.06 mg/kg Developmental study (intravenous) Result: Fetal effects include embryoletality. Maternal effects include increased resorptions and preimplantation loss. Species: Rat Developmental study (intravenous) Result: Adverse effects occur at maternally toxic doses. Species: Rabbit
Specific target organ toxicity - single exposure	Knowledge about health hazard is incomplete.
Specific target organ toxicity - repeated exposure	Causes damage to organs through prolonged or repeated exposure.
Aspiration hazard	Based on available data, the classification criteria are not met.
Further information	Highly potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.

12. Ecological information

Ecotoxicity	The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.
Persistence and degradability	No data is available on the degradability of any ingredients in the mixture.
Bioaccumulative potential	No data available.
Mobility in soil	No data available.
Other adverse effects	No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations

Disposal instructions	Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste.
Local disposal regulations	Dispose in accordance with all applicable regulations.
Hazardous waste code	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
Waste from residues / unused products	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
Contaminated packaging	Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT

UN number	UN2811
UN proper shipping name	Toxic solid, organic, n.o.s. (Ixabepilone)
Transport hazard class(es)	
Class	6.1
Subsidiary risk	-
Packing group	II

IATA

UN number	UN2811
UN proper shipping name	Toxic solid, organic, n.o.s. (Ixabepilone)
Transport hazard class(es)	
Class	6.1
Subsidiary risk	-
Packing group	II

Other information

Passenger and cargo aircraft Allowed with restrictions.

Cargo aircraft only Allowed with restrictions.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not applicable.

DOT; IATA



General information

It is the shipper's responsibility to determine the correct transport classification at the time of shipment.

15. Regulatory information

US federal regulations This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

Toxic Substances Control Act (TSCA)

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical Yes

Classified hazard categories Acute toxicity (any route of exposure)
Respiratory or skin sensitization
Reproductive toxicity
Specific target organ toxicity (single or repeated exposure)

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations**Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List**

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA)

Not regulated.

US state regulations**California Proposition 65**

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins. For more information go to www.P65Warnings.ca.gov.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date 07-19-2022

Revision date 07-19-2022

Version # 02

Further information 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.

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