Irinotecan Hydrochloride Trihydrate 20 mg and 80 mg Tablet

Safety Data Sheet

Prepared according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Revision date: 01/18/2019 Version: 1.0

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product name : Irinotecan Hydrochloride Trihydrate 20 mg and 80 mg Tablet

Product form : Film Coated Tablet

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

Use of the substance/mixture : Pharmaceutical drug product

1.3. Details of the supplier of the safety data sheet

Athenex Inc.
1001 Main Street, Suite 600
Buffalo, NY 14203 USA
Phone: 716-427-2950
Website: www.athenex.com
Email: EHS@athenex.com

1.4. Emergency telephone number

Emergency number : CHEMTREC within the US and Canada 1-800-424-9300 or CHEMTREC outside the US and Canada 1-703-527-3887

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

GHS-US classification

Carc. 2 H351
Comb. Dust

2.2. Label elements

GHS-US labelling

Hazard pictograms (GHS-US) :

GHS08

Signal word (GHS-US) : **Warning**

Hazard statements (GHS-US) : May form combustible dust concentrations in air
H351 - Suspected of causing cancer.

Precautionary statements (GHS-US) : P201 - Obtain special instructions before use.
P202 - Do not handle until all safety precautions have been read and understood.
P280 - Wear eye protection, protective gloves, protective clothing, respiratory protection
P308+P313 - If exposed or concerned: Get medical advice/attention.
P405 - Store locked up.
P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation

2.3. Other hazards

No additional information available

2.4. Unknown acute toxicity (GHS US)

No data available

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%
Cellulose (fine powder)	(CAS-No.) 9004-34-6	30 - 60*
D-Fructose	(CAS-No.) 57-48-7	7 - 13*
Polyvinyl pyrrolidone	(CAS-No.) 9003-39-8	1 - 5*
Titanium dioxide	(CAS-No.) 13463-67-7	0.5 - 5*

*In accordance with paragraph (i) of the OSHA Hazard Communication Standard (29 CFR §1910.1200), the specific chemical identity or exact weight % has been withheld as a trade secret

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general : If exposed or concerned, get medical attention/advice. Show this safety data sheet to the doctor in attendance. Wash contaminated clothing before re-use. Never give anything to an unconscious person.

First-aid measures after inhalation : IF INHALED: Remove to fresh air and keep at rest in a position comfortable for breathing. Get medical attention if breathing is affected. If breathing is difficult, supply oxygen.

First-aid measures after skin contact : IF ON SKIN (or clothing): Remove affected clothing and wash all exposed skin with water for at least 15 minutes. If irritation develops or persists, get medical attention.

First-aid measures after eye contact : IF IN EYES: Immediately flush with plenty of water for at least 15 minutes. Remove contact lenses if present and easy to do so. Continue rinsing if pain, blinking, or irritation develops or persists, get medical attention. Continue rinsing.

First-aid measures after ingestion : IF SWALLOWED: rinse mouth thoroughly. Do not induce vomiting without advice from poison control center. Get medical attention if you feel unwell.

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

Symptoms/effects : Suspected of causing cancer.

Symptoms/effects after inhalation : May cause respiratory irritation.

Symptoms/effects after skin contact : May cause skin irritation.

Symptoms/effects after eye contact : Direct contact with eyes is likely to be irritating.

Symptoms/effects after ingestion : May cause gastrointestinal irritation.

Chronic symptoms : Suspected of causing cancer.

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

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Water spray. Alcohol foam. Dry chemical. Carbon dioxide (CO_2).

5.2. Special hazards arising from the substance or mixture

Fire hazard : May form combustible dust concentrations in air. Heating may cause a fire.

Explosion hazard : Product is not explosive.

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

5.3. Advice for firefighters

Firefighting instructions : Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Do not dispose of fire-fighting water in the environment. Prevent human exposure to fire, fumes, smoke and products of combustion.

Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : Clean up any spills as soon as possible, using an absorbent material to collect it. Ventilate area. Do not handle until all safety precautions have been read and understood.

6.1.1. For non-emergency personnel

Protective equipment : Wear Protective equipment as described in Section 8.

Emergency procedures : Evacuate unnecessary personnel.

6.1.2. For emergency responders

Protective equipment : Wear suitable protective clothing, gloves and eye or face protection. Approved supplied-air respirator, in case of emergency.

6.2. Environmental precautions

Prevent entry to sewers and public waters. Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

For containment : Contain and collect as any solid. Avoid dust formation.

Methods for cleaning up : Sweep or shovel spills into appropriate container for disposal. Place in a suitable container for disposal in accordance with the waste regulations (see Section 13).

6.4. Reference to other sections

No additional information available

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Handle in accordance with good industrial hygiene and safety procedures. Do not handle until all safety precautions have been read and understood. Do not breathe dust. Avoid dust formation. Do not get in eyes, on skin, or on clothing. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Keep container closed when not in use. Store in a well-ventilated place. Keep cool.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

D-Fructose (57-48-7)	
Remark (ACGIH)	OELs not established
Remark (OSHA)	OELs not established

Cellulose (fine powder) (9004-34-6)	
ACGIH TWA (mg/m³)	10 mg/m³
OSHA PEL (TWA) (mg/m³)	5 mg/m³ (respirable fraction); 15 mg/m3 TWA (total dust)

Polyvinyl pyrrolidone (9003-39-8)	
Remark (ACGIH)	OELs not established
Remark (OSHA)	OELs not established

Titanium dioxide (13463-67-7)	
ACGIH TWA (mg/m³)	10 mg/m³
OSHA PEL (TWA) (mg/m³)	15 mg/m³ total dust

8.2. Exposure controls

Appropriate engineering controls : Provide adequate general and local exhaust ventilation. Use process enclosures, local exhaust ventilation, or other engineering controls to control airborne levels below recommended exposure limits. Use explosion-proof equipment with flammable materials. Ensure adequate ventilation, especially in confined areas.

Personal protective equipment : Gloves. Protective goggles. Protective clothing.

Hand protection : Use gloves chemically resistant to this material when prolonged or repeated contact could occur. Use gloves chemically resistant to this material when prolonged or repeated contact could occur. Gloves should be classified under Standard EN 374 or ASTM F1296. Suggested glove materials are: Neoprene, Nitrile/butadiene rubber, Polyethylene, Ethyl vinyl alcohol laminate, PVC or vinyl. Suitable gloves for this specific application can be recommended by the glove supplier.

Eye protection : Wear eye protection, including chemical splash goggles and a face shield when possibility exists for eye contact due to spraying liquid or airborne particles.

Skin and body protection : Wear long sleeves, and chemically impervious PPE/coveralls to minimize bodily exposure.

Respiratory protection : Use NIOSH (or other equivalent national standard) -approved dust/particulate respirator. Where vapor, mist, or dust exceed PELs or other applicable OELs, use NIOSH-approved respiratory protective equipment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Solid

Appearance : Tablet.

Color : No data available

Odor : No data available

Odor Threshold : No data available

pH : No data available

Relative evaporation rate (butylacetate=1) : No data available

Melting point : No data available

Freezing point : No data available

Boiling point	: No data available
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: No data available
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Solubility	: No data available
Log Pow	: No data available
Log Kow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No dangerous reactions known under normal conditions of use.

10.2. Chemical stability

Stable under recommended handling and storage conditions (see section 7).

10.3. Possibility of hazardous reactions

Stable under normal conditions of use.

10.4. Conditions to avoid

None known.

10.5. Incompatible materials

Strong oxidizing agents.

10.6. Hazardous decomposition products

If heated at elevated temperatures, emits toxic fumes such as carbon oxides and nitrogen oxides (NOx).

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified

Cellulose (fine powder) (9004-34-6)	
LD50 oral rat	> 5 g/kg
LD50 dermal rabbit	>
LC50 inhalation rat (mg/l)	> 5800 mg/m³ 4 h

Polyvinyl pyrrolidone (9003-39-8)	
LD50 oral rat	100 g/kg

Titanium dioxide (13463-67-7)	
LD50 oral rat	> 10000 mg/kg

Skin corrosion/irritation	: Not classified
Serious eye damage/irritation	: Not classified
Respiratory or skin sensitisation	: Not classified
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Suspected of causing cancer.

Titanium dioxide (13463-67-7)	
IARC group	2B - Possibly carcinogenic to humans

Reproductive toxicity	: Not classified
STOT-single exposure	: Not classified.
STOT-repeated exposure	: Not classified

Aspiration hazard	:	Not classified
Symptoms/effects after inhalation	:	May cause respiratory irritation.
Symptoms/effects after skin contact	:	May cause skin irritation.
Symptoms/effects after eye contact	:	Direct contact with eyes is likely to be irritating.
Symptoms/effects after ingestion	:	May cause gastrointestinal irritation.
Chronic symptoms	:	Suspected of causing cancer.

SECTION 12: Ecological information

12.1. Toxicity

No additional information available

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods	:	Do not discharge to public wastewater systems without permit of pollution control authorities.
Product/Packaging disposal recommendations	:	Disposal of unused or unusable oral or topical dosage forms of hazardous drugs should be performed in the same manner as for hazardous injectable dosage forms and waste. Dispose in a safe manner in accordance with local/national regulations. Do not allow the product to be released into the environment. Consider all contaminated PPE/waste materials as hazardous material with regard to disposal.

SECTION 14: Transport information

In accordance with DOT

Not hazardous for transport

Additional information

Other information	:	No supplementary information available.

Transport by sea (IMDG)

No additional information available

Air transport (IATA)

No additional information available

SECTION 15: Regulatory information

15.1. US Federal regulations

Irinotecan Hydrochloride Trihydrate 20 mg and 80 mg Tablet	
All chemical substances in this product are listed in the EPA (Environment Protection Agency) TSCA (Toxic Substances Control Act) Inventory or are exempt	
SARA Section 311/312 Hazard Classes	Health hazard - Carcinogenicity

15.2. International regulations

CANADA

No additional information available.

15.3. US State regulations

WARNING: This product can expose you to Titanium dioxide, which is known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.

Titanium dioxide (13463-67-7)				
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	No significant risk level (NSRL)
Yes	No	No	No	Not available

Cellulose (fine powder) (9004-34-6)
U.S. - Massachusetts - Right To Know List
U.S. - New Jersey - Right to Know Hazardous Substance List
U.S. - Pennsylvania - RTK (Right to Know) List

Titanium dioxide (13463-67-7)
U.S. - New Jersey - Right to Know Hazardous Substance List
U.S. - Massachusetts - Right To Know List
U.S. - Pennsylvania - RTK (Right to Know) List

SECTION 16: Other information

Indication of changes : Revision 1.0

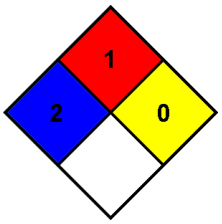
Revision date : 01/18/2019

Other information : Author: BCS.

NFPA health hazard : 2 - Materials that, under emergency conditions, can cause temporary incapacitation or residual injury.

NFPA fire hazard : 1 - Materials that must be preheated before ignition can occur.

NFPA reactivity : 0 - Material that in themselves are normally stable, even under fire conditions.



HMIS Hazard Rating

Health : 2

Flammability : 1

Physical : 0

Personal protection :

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