

## **Irinotecan hydrochloride trihydrate**

**Version:** 3.4

**Revision Date:** 22.01.2025

**SDS Number:** 100000000072

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

#### **1.1 Product identifier**

Trade name : Irinotecan hydrochloride trihydrate  
REACH Registration Number : -  
CAS-No. : 136572-09-3  
Unique Formula Identifier : -

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

Use of the Sub-  
stance/Mixture : Active pharmaceutical ingredients  
  
Recommended restrictions : No data available  
on use

#### **1.3 Details of the supplier of the safety data sheet**

Company : Fermion Oy  
Street address : Koivu-Mankkaan tie 6 A  
Post-office box: : P.O. Box 28  
Postcode : 02101 Espoo, Finland  
Telephone : +358 10 4261  
E-mail address of person : chemicalsafety@orion.fi  
responsible for the SDS  
VAT Reg. No: : FI18552129

#### **1.4 Emergency telephone number**

Poison Center : +358 800 147111  
+358 9 471 977

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### **SECTION 2: Hazards identification**

#### **2.1 Classification of the substance or mixture**

##### **Classification (REGULATION (EC) No 1272/2008)**

Acute toxicity, Category 4	H332: Harmful if inhaled. H312: Harmful in contact with skin. H302: Harmful if swallowed.
Germ cell mutagenicity, Category 1B	H340: May cause genetic defects.
Reproductive toxicity, Category 1B	H360D: May damage the unborn child.
Carcinogenicity, Category 2	H351: Suspected of causing cancer.
Eye irritation, Category 2	H319: Causes serious eye irritation.
Specific target organ toxicity - single exposure, Category 3	H335: May cause respiratory irritation.
Skin irritation, Category 2	H315: Causes skin irritation.

For explanation of abbreviations see section 16.

#### **2.2 Label elements**

##### **Labeling (REGULATION (EC) No 1272/2008)**

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Hazard pictograms



Signal Word

: Danger

**Hazard Statements**

H302	Harmful if swallowed.
H312	Harmful in contact with skin.
H332	Harmful if inhaled.
H340	May cause genetic defects.
H360D	May damage the unborn child.
H351	Suspected of causing cancer.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H315	Causes skin irritation.

**Precautionary Statements**

**General:**

P308 + P313 IF exposed or concerned: Get medical advice/ attention.  
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
P302 + P352 IF ON SKIN: Wash with plenty of soap and water.

**Prevention:**

P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.  
P261 Avoid breathing dust/ fume/ gas/ mist/ vapors/ spray.

**Disposal:**

P501 Dispose of contents according to national and local law.

**2.3 Other hazards**

Other hazards : No data available

PBT : No data available

vPvB : No data available

Endocrine disrupting properties : Ecological information: No data available

Toxicological information: No data available

**SECTION 3: Composition/information on ingredients**

**3.1 Substances**

Chemical name	CAS-No. EC-No. Registration-No	Concentration (% w/w)	M-Factor, SCL, ATE
Irinotecan hydrochloride trihydrate	136572-09-3	100	

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**Other information** : No data available

### **3.2 Mixtures**

Not applicable

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## **SECTION 4: First aid measures**

### **4.1 Description of first-aid measures**

General advice : Helpers should ensure their own protection.

If inhaled : IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.  
If appropriate, give artificial respiration or oxygen.  
Get medical advice/attention.

In case of skin contact : Remove/ Take off immediately all contaminated clothing.  
IF ON SKIN: Wash with plenty of soap and water.  
Get medical advice/ attention.

In case of eye contact : IF IN EYES: Rinse continuously with water for several minutes. Get medical advice/attention.

If swallowed : Rinse mouth.  
Do NOT induce vomiting.  
Get medical advice/attention.

### **4.2 Most important symptoms and effects, both acute and delayed**

Symptoms : See section 11 for symptoms of exposure.

Risks : No data available

### **4.3 Indication of any immediate medical attention and special treatment needed**

Treatment : No data available

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## **SECTION 5: Firefighting measures**

### **5.1 Extinguishing media**

Suitable extinguishing media : Carbon dioxide (CO<sub>2</sub>)  
Foam  
Powder  
Water spray

Unsuitable extinguishing media : No data available

### **5.2 Special hazards arising from the substance or mixture**

Specific hazards during fire fighting : May emit toxic fumes of oxides of carbon and nitrogen during heating or fire.

Hazardous combustion products : No data available

### **5.3 Advice for firefighters**

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Special protective equipment for fire-fighters	:	Isolating breathing apparatus eg. compressed breathing apparatus and protective clothing.
Specific extinguishing methods	:	No data available
Further information	:	No data available

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### **SECTION 6: Accidental release measures**

#### **6.1 Personal precautions, protective equipment and emergency procedures**

Personal precautions	:	Use personal protective equipment as required. Access of extra people to the spill area must be prevented.
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#### **6.2 Environmental precautions**

Environmental precautions	:	No data available
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#### **6.3 Methods and material for containment and cleaning up**

Methods for cleaning up	:	Collect spilled powder without dusting into tight closed container.
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#### **6.4 Reference to other sections**

See Section 8 and 13

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### **SECTION 7: Handling and storage**

#### **7.1 Precautions for safe handling**

Advice on safe handling	:	Handle in well-ventilated space. All exposure must be avoided. Do not get in eyes, on skin, or on clothing.
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#### **7.2 Conditions for safe storage, including any incompatibilities**

Packaging material	:	Suitable material: No data available Unsuitable material: No data available
Further information on storage conditions	:	Store in a well ventilated place. Keep container tightly closed. Keep cool. Protect from sunlight.

#### **7.3 Specific end use(s)**

Specific use(s)	:	No information identified.
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### **SECTION 8: Exposure controls/personal protection**

#### **8.1 Control parameters**

Contains no substances with occupational exposure limit values.

#### **8.2 Exposure controls**

Engineering measures	:	Wash hands thoroughly after handling. All exposure must be avoided. Avoid contact during pregnancy/while nursing.
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Handle in closed systems or use an efficient local exhaust if dust, vapours or mists may release into workplace air. If technical measures cannot prevent exposure, wear personal protective equipment.  
Handle in closed systems or use an efficient local exhaust if dust, vapours or mists may release into workplace air. If technical measures cannot prevent exposure, wear personal protective equipment.

### Personal protective equipment

- Respiratory protection : In open handling use respirator (P3) with a minimum protection factor of 200.  
See standard working procedures/instructions or department's instructions for more detailed protection measures.
- Eye/face protection : Use protective goggles.
- Hand protection  
Remarks : Use protective gloves (e.g. nitrile or neopren gloves).
- Skin and body protection : In dust making work use disposal overalls and extra throwaway sleeves.
- Protective measures : No data available

### Environmental exposure controls

- Air : Do not put into water system, drain or soil.

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## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

- Physical state : solid
- Color : yellow
- Odor : -
- Odor Threshold : No data available
- Melting point/range : 250 - 256 °C
- Boiling point/boiling range : No data available
- Flammability : No data available
- Upper explosion limit / Upper flammability limit : No data available
- Lower explosion limit / Lower flammability limit : No data available
- Flash point : No data available
- Autoignition temperature : No data available

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Decomposition temperature	:	No data available
Self-Accelerating decomposition temperature (SADT)	:	No data available
pH	:	No data available
Viscosity		
Viscosity, dynamic	:	No data available
Viscosity, kinematic	:	No data available
Flow time	:	No data available
Solubility(ies)		
Water solubility	:	completely soluble
Solubility in other solvents	:	No data available
Dissolution Rate	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Dispersion Stability	:	No data available
Vapor pressure	:	No data available
Relative density	:	No data available
Density	:	No data available
Bulk density	:	No data available
Relative vapor density	:	No data available
Dissociation constant	:	No data available
Particle characteristics	:	No data available

### **9.2 Other information**

Self-ignition	:	No data available
Hygroscopic properties	:	No data available
Henry's Constant	:	No data available
Further information	:	No data available

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## **SECTION 10: Stability and reactivity**

### **10.1 Reactivity**

No data available

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### **10.2 Chemical stability**

Stable when stored and handled according to instructions of use.

### **10.3 Possibility of hazardous reactions**

Hazardous reactions : Not expected to occur.

### **10.4 Conditions to avoid**

Conditions to avoid : Light  
Air  
Heat.

### **10.5 Incompatible materials**

Materials to avoid : Strong oxidants  
Bases

### **10.6 Hazardous decomposition products**

May emit toxic fumes of oxides of carbon and nitrogen during heating or fire.

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## **SECTION 11: Toxicological information**

### **11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008**

#### **Acute toxicity**

Health hazard information : Harmful if swallowed.  
Harmful in contact with skin.  
Harmful if inhaled.

Acute oral toxicity : LD50 (Rat): 867 mg/kg

Acute inhalation toxicity : No data available

Acute dermal toxicity : No data available

Acute toxicity (other routes of administration) : No data available

#### **Skin corrosion/irritation**

Result : Causes skin irritation.

#### **Serious eye damage/eye irritation**

Result : Causes serious eye irritation.

#### **Respiratory or skin sensitization**

No data available

#### **Germ cell mutagenicity**

Genotoxicity in vitro : May cause genetic defects.

Genotoxicity in vivo : No data available

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### **Carcinogenicity**

Result : Suspected of causing cancer.  
Remarks : Animal studies showed no carcinogenic effects.

### **Reproductive toxicity**

Effects on fertility : May damage the unborn child.

Effects on fetal development : No data available

### **STOT-single exposure**

Assessment : May cause respiratory irritation.

### **STOT-repeated exposure**

No data available

### **Repeated dose toxicity**

Remarks : Typical adverse effects include gastrointestinal disturbances like nausea and vomiting. May cause late diarrhea.

### **Aspiration toxicity**

No data available

## **11.2 Information on other hazards**

### **Endocrine disrupting properties**

No data available

### **Experience with human exposure**

General Information : No data available

Inhalation : No data available

Skin contact : No data available

Eye contact : No data available

Ingestion : No data available

### **Toxicology, Metabolism, Distribution**

Remarks : No data available

### **Neurological effects**

Remarks : No data available



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### **Further information**

Remarks : May cause respiratory irritation.

### **Other Health Hazards**

No data available

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## **SECTION 12: Ecological information**

### **12.1 Toxicity**

Toxicity to fish : No data available

Toxicity to daphnia and other aquatic invertebrates : No data available

Toxicity to algae/aquatic plants : No data available

Toxicity to fish (Chronic toxicity) : No data available

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

Toxicity to microorganisms : No data available

Toxicity to soil dwelling organisms : No data available

Plant toxicity : No data available

Sediment toxicity : No data available

Toxicity to terrestrial organisms : No data available

### **Ecotoxicology Assessment**

Acute aquatic toxicity : No data available

Chronic aquatic toxicity : No data available

Toxicity Data on Soil : No data available

Other organisms relevant to the environment : No data available

### **12.2 Persistence and degradability**

Biodegradability : No data available

Biochemical Oxygen Demand (BOD) : No data available

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Chemical Oxygen Demand (COD) : No data available

BOD/COD : No data available

ThOD : No data available

BOD/ThOD : No data available

Dissolved organic carbon (DOC) : No data available

Physico-chemical removability : No data available

Stability in water : No data available

Impact on Sewage Treatment : No data available

Photodegradation : No data available

### **12.3 Bioaccumulative potential**

Bioaccumulation : No data available

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

### **12.4 Mobility in soil**

Mobility : No data available

Distribution among environmental compartments : No data available

Stability in soil : No data available

### **12.5 Results of PBT and vPvB assessment**

Assessment : No data available

### **12.6 Endocrine disrupting properties**

No data available

### **12.7 Other adverse effects**

Environmental fate and pathways : No data available

Adsorbed organic bound halogens (AOX) : No data available

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Ozone-Depletion Potential : No data available

Additional ecological information : No data available

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### **SECTION 13: Disposal considerations**

#### **13.1 Waste treatment methods**

Chemical incinerator equipped with an afterburner and scrubber is the recommended method of disposal for this material. Observe all local and national regulations when disposing of this material.

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### **SECTION 14: Transport information**

#### **14.1 UN number**

ADR/RID: -

IMDG: -

IATA: -

#### **14.2 UN proper shipping name**

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#### **14.3 Transport hazard class(es) (ADR/RID, IMDG, ICAO/IATA)**

ADR/RID: This product is not regulated under the transport regulations.

IMDG: This product is not regulated under the transport regulations.

IATA: This product is not regulated under the transport regulations.

#### **14.4 Packing group**

ADR/RID: -

IMDG: -

IATA: -

#### **14.5 Environmental hazards**

ADR/RID: -

IMDG: -

IATA: -

#### **14.6 Special precautions for user**

Tunnel restriction code : No data available

Further information for transport : No data available

#### **14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC code**

Not applicable

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### **SECTION 15: Regulatory information**

#### **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**

The product has not been fully tested.

#### **15.2 Chemical Safety Assessment**

No

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### **SECTION 16: Other information**

#### **Full text of H-Statements**

H302	Harmful if swallowed.
H312	Harmful in contact with skin.
H332	Harmful if inhaled.
H340	May cause genetic defects.
H360D	May damage the unborn child.
H351	Suspected of causing cancer.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H315	Causes skin irritation.

#### **Full text of other abbreviations**

Acute Tox.	: Acute toxicity
Muta.	: Germ cell mutagenicity
Repr.	: Reproductive toxicity
Carc.	: Carcinogenicity
Eye Irrit.	: Eye irritation
STOT SE	: Specific target organ toxicity - single exposure
Skin Irrit.	: Skin irritation

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways

ADR - Agreement concerning the International Carriage of Dangerous Goods by Road

AIIC - Australian Inventory of Industrial Chemicals

ASTM - American Society for the Testing of Materials

bw - Body weight

CLP - Classification Labelling Packaging Regulation

Regulation (EC) No 1272/2008

CMR - Carcinogen, Mutagen or Reproductive Toxicant

DIN - Standard of the German Institute for Standardisation

DSL - Domestic Substances List (Canada)

ECHA - European Chemicals Agency

EC-Number - European Community number

ECx - Concentration associated with x% response

ELx - Loading rate associated with x% response

EmS - Emergency Schedule

ENCS - Existing and New Chemical Substances (Japan)

ErCx - Concentration associated with x% growth rate response

GHS - Globally Harmonized System

GLP - Good Laboratory Practice

IARC - International Agency for Research on Cancer

IATA - International Air Transport Association

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IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk

IC50 - Half maximal inhibitory concentration

ICAO - International Civil Aviation Organization

IECSC - Inventory of Existing Chemical Substances in China

IMDG - International Maritime Dangerous Goods

IMO - International Maritime Organization

ISHL - Industrial Safety and Health Law (Japan)

ISO - International Organisation for Standardization

KECI - Korea Existing Chemicals Inventory

LC50 - Lethal Concentration to 50 % of a test population

LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose)

MARPOL - International Convention for the Prevention of Pollution from Ships

n.o.s. - Not Otherwise Specified

NO(A)EC - No Observed (Adverse) Effect Concentration

NO(A)EL - No Observed (Adverse) Effect Level

NOELR - No Observable Effect Loading Rate

NZIoC - New Zealand Inventory of Chemicals

OECD - Organization for Economic Co-operation and Development

OPPTS - Office of Chemical Safety and Pollution Prevention

PBT - Persistent, Bioaccumulative and Toxic substance

PICCS - Philippines Inventory of Chemicals and Chemical Substances (Q)SAR - (Quantitative) Structure Activity Relationship

REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals

RID - Regulations concerning the International Carriage of Dangerous Goods by Rail

SADT - Self-Accelerating Decomposition Temperature

SDS - Safety Data Sheet

SVHC - substance of very high concern

TCSI - Taiwan Chemical Substance Inventory

TECI - Thailand Existing Chemicals Inventory

TRGS - Technical Rule for Hazardous Substances

TSCA - Toxic Substances Control Act (United States)

UN - United Nations

vPvB - Very Persistent and Very Bioaccumulative

### **Further information**

Other information : No data available

Sources of key data used to : Information provided by the supplier

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compile the Material Safety  
Data Sheet

Information which has been : Updated section / sections:  
added, deleted or revised 1,8

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.