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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
CAS-number: 136572-09-3

Reach registration number: NA

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

The uses of the chemical: Active pharmaceutical ingredients
Classification of the economic activities (NACE): 212
Use categories (UC62): 41

1.3. Details of the supplier of the safety data sheet:

Manufacturer/importer: Fermion Oy
Street address: Koivu-Mankkaan tie 6 A
Post-office box: P.O. Box 28
Postcode: 02101 Espoo, Finland
Telephone number: +358 10 4261
Telefax: +358 0 9452 1764
E-mail address: chemicalsafety@orion.fi
VAT Reg. No: FI18552129

1.4. Emergency telephone number

Poison Center: +358 9 471 977

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

Classification according to regulation EC 1272/2008	Acute Tox. 4 Muta. 1B Repr. 1B Carc. 2 Eye Irrit. 2 STOT SE 3 Skin Irrit. 2	H332,H312,H302, H340, H360D, H351, H319, H335, H315,
H Statements	Harmful if inhaled.	

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	<p>Harmful in contact with skin. Harmful if swallowed. May cause genetic defects. May damage the unborn child. Suspected of causing cancer. Causes serious eye irritation. May cause respiratory irritation. Causes skin irritation.</p>
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2.2. Label elements

Hazard Pictograms



Signal word

Danger

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.

P Statements

P308+P313 IF exposed or concerned: Get medical advice/attention.
P305+P351+P338 IF IN EYES: Rinse continuously with water for several minutes. Remove contact lenses if present and easy to do, continue rinsing.
P280 Wear protective gloves/protective clothing/eye protection.
P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
P302+P352 IF ON SKIN: Wash with soap and water.
P501 Dispose of contents according to national and local law.

2.3. Other hazards

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SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances

Name of the ingredient	CAS-number:	EC-number	Reach registration number:
Irinotecan hydrochloride trihydrate	136572-09-3	-	NA

Request for Confidentiality by Annex 2 No

Substance indicated Confidential No

Other information -

SECTION 4: FIRST AID MEASURES

4.1. Description of first aid measures

Special instructions Helpers should ensure their own protection.

Inhalation 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.

Skin contact Remove/Take off immediately all contaminated clothing. IF ON SKIN: Wash with soap and water. Get medical advice/attention.

Eye contact IF IN EYES: Rinse continuously with water for several minutes. Get medical advice/attention.

Ingestion Rinse mouth. Do NOT induce vomiting. Get medical advice/attention.

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

See section 11 for symptoms of exposure.

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

Data not available.

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing media

Suitable extinguishing media	Carbon dioxide
	Foam
	Powder
	Water spray

5.2. Special hazards arising from the substance or mixture

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

5.3. Advice for fire-fighters

Special protective equipment for fire-fighters	Isolating breathing apparatus eg. compressed breathing apparatus and isolating protective clothing.
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SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Use personal protective equipment as required.
Access of extra people to the spill area must be prevented.

6.2. Environmental precautions

Data not available.

6.3. Methods and material for containment and 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

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Handle in well-ventilated space.
 All exposure must be avoided.
 Do not get in eyes, on skin, or on clothing.

7.2. Conditions for safe storage, including any incompatibilities

Store in a well ventilated place. Keep container tightly closed.
 Keep cool.
 Protect from sunlight.
 See incompatible materials in section 10.5.

7.3. Specific end use(s)

No information identified.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

International OEL values	-
DNELs	-
PNECs	-

8.2. Exposure controls

Appropriate engineering controls

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

Respiratory protection

Use respirator, filtration P3. In laboratories work in fume hood or under dust control hood.
 See particular department's regulations of protection.

Hand protection

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Use protective gloves (e.g. nitrile or neopren gloves).

Eye protection

Use protective goggles.

Skin protection

In dust making work use disposal overalls and extra throwaway sleeves.

Environmental exposure controls

Do not put into water system, drain or soil.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Physical state	Powder
Colour	Yellowish
Odour	-
Odour threshold	-

9.1. Information on basic physical and chemical properties

Melting point 250 - 256 °C

Water solubility Freely soluble

9.2. Other information

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SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity

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10.2. Chemical stability

Stable when stored and handled according to instructions of use.

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10.3. Possibility of hazardous reactions

Not expected to occur.

10.4. Conditions to avoid

-

10.5. Incompatible materials

Strong oxidants

Bases

10.6 Hazardous decomposition products

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

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

Acute toxicity	Harmful if swallowed. Harmful in contact with skin. Harmful if inhaled. LD50 = 867 mg/kg (rat, oral).
Skin irritation and corrosion	Causes skin irritation.
Skin sensitization	Data not available.
Serious eye damage and irritation	Causes serious eye irritation.
Respiratory irritation	May cause respiratory irritation.
Respiratory sensitization	Data not available.
Carcinogenicity	Suspected of causing cancer. Animal tests have shown carcinogenic effects.
Germ cell mutagenicity	May cause genetic defects.

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Reproductive toxicity	May damage the unborn child.
STOT-single exposure	May cause respiratory irritation.
STOT-repeated exposure	Data not available.
Aspiration hazard	Data not available.
Repeated dose toxicity	Typical adverse effects include gastrointestinal disturbances like nausea and vomiting. May cause late diarrhea.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Aquatic toxicity

Data not available.

Toxic effects on other organisms

Data not available.

12.2. Persistence and degradability

Data not available.

12.3. Bioaccumulative potential

Octanol-water partition coefficient Data not available.

Bioconcentration factor Data not available.

12.4. Mobility in soil

Data not available.

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12.5. Results of PBT and vPvB assessment

Data not available.

12.6. Other adverse effects

Data not available.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Chemicals must be disposed of in compliance with the respective national regulations.

SECTION 14: TRANSPORT INFORMATION

14.1. UN Number

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14.2. UN Proper shipping name

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

This product is not regulated under the transport regulations.

14.4. Packing group

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14.5. Environmental hazard

-

14.6. Special precautions for user

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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 substance or mixture

The product has not been fully tested.

15.2. Chemical Safety Assessment

No

SECTION 16: OTHER INFORMATION

Further information

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. Fermion Oy shall not be held liable for any damage resulting from handling or from contact with the above product.

Sources of key data used to compile the Safety Data Sheet

Information provided by the supplier

Information which has been added, deleted or revised

Updated section / sections:

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