

Date: 7.11.2005 Supersedes: 26.8.2004

1. SUBSTANCE/PRODUCT AND COMPANY IDENTIFICATION

IRINOTECAN HYDROCHLORIDE TRIHYDRATE

Company:

Fermion Oy

Address

P.O. Box 28

FIN-02101 Espoo

Finland

Tel.Int.

+358-10-4291

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+358-9-452 1764

2. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical nature:

IRINOTECAN HYDROCHLORIDE TRIHYDRATE 98 - 100 %

Chemical name: Derivative of camptothecine

CAS:

136572-09-3

EINECS:

Product usage:

Drug substance. Antineoplastic.

3. HAZARD IDENTIFICATION

Harmful if swallowed. Possible risks of irreversible effects. May cause heritable genetic damage. May cause harm to the unborn child. Irritates skin, eyes and respiratory tract. May cause late diarrhea.

4. FIRST AID MEASURES

4.2 Inhalation:

Remove to fresh air.

4.3 Skin contact:

Wash with soap and plenty of water.

4.4 Eye contact:

Flush with plenty of water for at least 15 minutes. Seek medical

advice.

4.5 Ingestion:

Induce vomiting. Give activated charcoal. Seek medical advice

immediately.



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5. FIRE-FIGHTING MEASURES

5.1 Suitable extinguishing media:

The usual extinguishing methods are suitable.

5.3 Special exposure hazards in a fire:

Emits toxic fumes of nitrogen oxides in fire.

5.4 Special protective equipment for fire-fighters:

Self-contained breathing apparatus.

6. ACCIDENTIAL RELEASE MEASURES

6.1 Personal precautions: Warn other people about the danger of exposure. Put on the personal safety devices.

6.3 Methods for cleaning up:

Collect the material into tight containers avoiding all exposure. Ventilate the area and clean the place.

7. HANDLING AND STORAGE

7.1 Handling:

The material should be handled with care only by specially trained people avoiding all exposure and contamination. Pregnant women

should avoid handling this substance.

7.2 Storage:

Store in airtight containers at room temperature protected from

light.

8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

8.2 Exposure controls

8.2.1 Occupational exposure controls:

Use only in well-ventilated areas.

8.2.1.1 Respiratory protection:

Particle filtering device (P3) or compressed air line breathing apparatus.

fermion

MATERIAL SAFETY DATA SHEET IRINOTECAN HYDROCHLORIDE TRIHYDRATE

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8.2.1.2 Hand protection: Safety gloves.

8.2.1.3 Eye protection: Face shield or goggles.

8.2.1.4 Skin protection: Protective clothing.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 General information

Slightly yellowish crystalline powder.

9.2 Important health, safety and environmental information

9.2.1 pH-value:

9.2.2 Boiling point:

9.2.3 Flash point:

9.2.4 Flammability:

9.2.5 Explosive properties

9.2.5.1 Lower explosion point:

9.2.5.2 Upper explosion point:

9.2.6 Oxidising properties: -

9.2.7 Vapour pressure:

9.2.8 Relative density:

9.2.9 Solubility

9.2.9.1 Water solubility: Soluble in water.

9.2.9.2 Fat solubility (solvent-oil to be specified):

Slightly soluble in most organic solvents.

9.2.10 Partition coefficient: n-octanol/water:



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9.2.11 Viscosity:

9.2.12 Vapour density:

9.2.13 Evaporation rate:

9.3 Other information:

Melting point: 256 °C

10. STABILITY AND REACTIVITY

Stabile in normal conditions.

11. TOXICOLOGICAL INFORMATION

11.1 Acute toxicity:

 $LD_{50} = 867 \text{ mg/kg (rat, oral)}$

11.2 Irritation and corrosiveness:

Irritates skin, eyes and respiratory tract.

11.5 Empirical data on effects on humans:

Typical adverse effects include: gastrointestinal disturbances like nausea and vomiting. May cause late diarrhea. Animal tests have shown carcinogenic effects.

12. ECOLOGICAL INFORMATION

13. DISPOSAL CONSIDERATIONS

The packaging and other material that has been contaminated by Irinotecan should be handled as hazardous waste in accordance with local and state laws and instructions.

14. TRANSPORT INFORMATION

ADR/RID:

Not restricted.

IMDG:

Not restricted.

ICAO/IATA: Not restricted.



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15. REGULATORY INFORMATION

15.1 Information on the warning label

15.1.1 Letter code of the warning symbol and indications of danger for the preparation:

Xn Harmful

15.1.3 R-phrase(s):

R22 Harmful if swallowed.

R46 May cause heritable genetic damage.
R61 May cause harm to unborn child.
R68 Possible risks of irreversible effects.

15.1.4 S-phrase(s):

S22 Do not breathe dust.

S36/37/39 Wear suitable protective clothing, gloves and eye/face protection.

S45 In case of accident or if you feel unwell seek medical advice

immediately.

S51 Use only in well-ventilated areas.

S53 Avoid exposure – obtain special instructions before use.

16. OTHER INFORMATION

16.1 List of the relevant R phrases:

Harmful if swallowed.

May cause heritable genetic damage. May cause harm to unborn child. Possible risks of irreversible effects.

16.5 Sources of key data used:

Physicians Desk Reference, 53rd Edition, 1999.

Registry of Toxic Effects of Chemical Substances.

16.6 Information which has been added, deleted or revised:

Storage 7.2: Storage conditions have been corrected: in a cool place/at room temperature



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The information above is based on available knowledge, literature and experience and cannot be considered as complete. For further information, please contact:

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