Date: 26.08.2004 Supersedes: 29.01.2004

1. SUBSTANCE/PRODUCT AND COMPANY IDENTIFICATION

PROPAFENONE HYDROCHLORIDE

Company: Fermion Oy

Address P.O. Box 28 FIN-02101 Espoo Finland

Tel.Int. +358-10-4291 Telefax +358-9-452 1764

2. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical nature:

PROPAFENONE HYDROCHLORIDE 98 – 100 %

Chemical name: 1-Propanone, 1-{2-[2-Hydroxy-3-(propylamino)propoxy]phenyl}-3-phenyl hydrochloride CAS: 34183-22-7 (propafenone hydrochloride); 54063-53-5 (propafenone) EINECS: -

<u>Product usage:</u> Drug substance. Antiarrhytmic agent.

3. HAZARD IDENTIFICATION

Harmful if swallowed. Apparently harmful by inhalation and in contact with skin.

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:

Water, powder, foam or CO₂.

5.3 Special exposure hazards in a fire:

Emits toxic and highly corrosive fumes of nitrogen oxides and hydrogen chloride in fire.

6. ACCIDENTIAL RELEASE MEASURES

6.3 Methods for cleaning up:

Collect the material into containers. Ventilate the area and clean the place.

7. HANDLING AND STORAGE

- 7.1 Handling: Handle with care avoiding exposure and contamination.
- <u>7.2 Storage:</u> Store in airtight containers in a cool place 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.

- 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.

fermion

MATERIAL SAFETY DATA SHEET PROPAFENONE HYDROCHLORIDE

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9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 General information

White, crystalline powder; slightly hygroscopic.

9.2 Important health, safety and environmental information

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- 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 hot water. Slightly soluble in cold water.
- 9.2.9.2 Fat solubility (solvent-oil to be specified):

Soluble in methanol.

- 9.2.10 Partition coefficient: n-octanol/water:
- 9.2.11 Viscosity: -
- 9.2.12 Vapour density:
- 9.2.13 Evaporation rate: -

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9.3 Other information: Melting point: 172 – 175 °C

10. STABILITY AND REACTIVITY

Stabile in normal conditions.

11. TOXICOLOGICAL INFORMATION

<u>11.1 Acute toxicity:</u> $LD_{50} = 700 \text{ mg/kg} \text{ (rat, oral) (for Propafenone)}$

11.2 Irritation and corrosiveness:

May irritate skin, eyes and respiratory tract.

11.5 Empirical data on effects on humans:

The most common adverse effects include gastrointestinal disturbances, disturbed taste, dry mouth, blurred vision, headache and fatigue. Cardiovascular effects like hypotension and arrhythmias.

12. ECOLOGICAL INFORMATION

13. DISPOSAL CONSIDERATIONS

In accordance with local and state laws and instructions.

14. TRANSPORT INFORMATION

ADR/RID: Not restricted.

IMDG: Not restricted.

ICAO/IATA: Not restricted.

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:

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Xn	Harmful
<u>15.1.3 R-phrase(s):</u> R22 <u>15.1.4 S-phrase(s):</u> S22 S36/37 S51	Harmful if swallowed. Do not breathe dust. Wear suitable protective clothing and gloves. Use only in well-ventilated areas.

16. OTHER INFORMATION

16.1 List of the relevant R phrases:

Harmful if swallowed.

16.5 Sources of key data used:

Martindale: The Extra Pharmacopoeia, 31st Edition, The Pharmaceutical Press. London 1996; 935.

16.6 Information which has been added, deleted or revised:

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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