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SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING**1.1. Product identifier**

Trade name: Entacapone
CAS-number: 130929-57-6

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 9 452 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**

This product does not meet the classification requirements of the current European legislation on classification and labelling.

2.2. Label elements

-

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: |
|------------------------|-------------|-----------|----------------------------|
| Entacapone | 130929-57-6 | - | NA |

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.

Skin contact

IF ON SKIN: Rinse continuously with water for several minutes.

Eye contact

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

Ingestion

Induce vomiting.

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.

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SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing media

Suitable extinguishing media

- Carbon dioxide
- Foam
- Water
- Powder

5.2. Special hazards arising from the substance or mixture

May emit toxic fumes of oxides of 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 protective clothing.

Other instructions

Cool fire exposed containers with water jet.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Use personal protective equipment as required.

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.

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

Handle in well-ventilated space.

7.2. Conditions for safe storage, including any incompatibilities

Keep container tightly closed.
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 well-ventilated space.
Avoid contact with skin.

Respiratory protection

In open handling and dust making work use respirator (P3) with a minimum protection factor of 20.
See standard working procedures/instructions or department's instructions for more detailed protection measures.

Hand protection

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

Eye protection

Use protective goggles.

Skin protection

Use normal working clothes.

Environmental exposure controls

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Avoid release to the environment.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance

| | |
|-----------------|-------------|
| Physical state | Crystalline |
| Colour | Yellow |
| Odour | Odourless |
| Odour threshold | - |

9.1. Information on basic physical and chemical properties

| | |
|---------------|--------------|
| Melting point | 160 - 163 °C |
|---------------|--------------|

| | |
|------------------|------------------|
| Water solubility | Slightly soluble |
|------------------|------------------|

9.2. Other information

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SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity

-

10.2. Chemical stability

Stable when stored and handled according to instructions of use.

10.3. Possibility of hazardous reactions

Not expected to occur.

10.4. Conditions to avoid

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10.5. Incompatible materials

Metals

10.6 Hazardous decomposition products

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SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

| | |
|-----------------------------------|---------------------------------------|
| Acute toxicity | LD50 > 2000 mg/kg (rat, oral) |
| Skin irritation and corrosion | Data not available. |
| Skin sensitization | Data not available. |
| Serious eye damage and irritation | Data not available. |
| Respiratory irritation | Data not available. |
| Respiratory sensitization | Data not available. |
| Carcinogenicity | Data not available. |
| Germ cell mutagenicity | Ames-test: negative => not mutagenic. |
| Reproductive toxicity | Data not available. |
| STOT-single exposure | Data not available. |
| STOT-repeated exposure | Data not available. |
| Aspiration hazard | Data not available. |
| Repeated dose toxicity | Data not available. |

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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.

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

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**

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14.2. UN Proper shipping name

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

This product is not regulated under the transport regulations.

14.4. Packing group

-

14.5. Environmental hazard

-

14.6. Special precautions for user

-

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

Not applicable

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

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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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