according to Regulation (EC) No. 1907/2006



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

1.1 Product identifier

Trade name : Entacapone

REACH Registration Number : NA

CAS-No. : 130929-57-6

Unique Formula Identifier : -

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

Use of the Sub- : Active pharmaceutical ingredients

stance/Mixture

Recommended restrictions

on use

: No data available

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

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture according to Regulation (EC) No 1272/2008.

2.2 Label elements

Labeling (REGULATION (EC) No 1272/2008)

Hazard Statements

No classification

2.3 Other hazards

Other hazards : The product has not been fully tested.

PBT : No data available

vPvB : No data available

Endocrine disrupting pro- : Ecological information: No data available

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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
Entacapone	130929-57-6		

Other information : No data available

3.2 Mixtures

Not applicable

SECTION 4: First aid measures

4.1 Description of first-aid measures

General advice : Helpers should ensure their own protection.

Get medical advice/attention if you feel unwell.

If inhaled : IF INHALED: Remove victim to fresh air and keep at rest in a

position comfortable for breathing. If appropriate, give artificial respiration.

In case of skin contact : IF ON SKIN: Rinse continuously with water for several minu-

tes.

Remove/ Take off immediately all contaminated clothing. If skin irritation occurs: Get medical advice/ attention.

In case of eye contact : IF IN EYES: Rinse continuously with water for several minu-

tes. Get medical advice/attention.

If eye irritation persists:
Get medical advice/ attention.

If swallowed : Rinse mouth.

Do NOT induce vomiting.

If the patient is conscious, give plenty of water (2 - 4 glasses).

Get medical advice/attention if you feel unwell.

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 (CO2)

Foam Water Powder

Choose suitable extinguishing media according to the en-

vironment.

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 nitrogen during heating or

fire.

Hazardous combustion pro-

ducts

No data available

5.3 Advice for firefighters

Special protective equipment :

for fire-fighters

Isolating breathing apparatus eg. compressed breathing appa-

ratus and protective clothing.

Specific extinguishing me-

thods

No data available

Further information : Cool fire exposed containers with water jet.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment as required.

Provide sufficient ventilation.

6.2 Environmental precautions

Environmental precautions : Do not put into water system, drain or soil.

Do not flush into surface water. Avoid release to the environment.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Collect spilled powder without dusting into tight closed contai-

ner.

6.4 Reference to other sections

See Section 8 and 13

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Advice on safe handling : Handle in well-ventilated space.

Do not breathe dust/ fume/ gas/ mist/ vapors/ spray. Do not eat, drink or smoke when using this product.

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Wear protective gloves/ protective clothing/ eye protection/

face protection.

Wash contaminated clothing before reuse.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage

areas and containers

Keep container tightly closed.

CORROSIVE

Keep out of reach of children.

Keep in a dry place.

See incompatible materials in section 10.5.

Packaging material : Suitable material: No data available

Unsuitable material: No data available

7.3 Specific end use(s)

Specific use(s) : No information identified.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Contains no substances with occupational exposure limit values.

8.2 Exposure controls

Engineering measures : Handle in well-ventilated space.

Avoid contact with skin.

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 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.

Eye/face protection : Use protective goggles.

Hand protection

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

Skin and body protection : Use normal working clothes.

Protective measures : No data available

Environmental exposure

controls

No data available

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state : solid

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Color : yellow

Odor : odorless

Odor Threshold : No data available

Melting point/range : 160 - 163 °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

Decomposition temperature : No data available

Self-Accelerating decomposi-

tion 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 : slightly 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

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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

Molecular weight : 305 g/mol

Hygroscopic properties : No data available

Henry's Constant : No data available

Further information : No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

No data available

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 : No data available

10.5 Incompatible materials

Materials to avoid : Metals

Strong oxidants

10.6 Hazardous decomposition products

Carbon dioxide (CO2)

Carbon monoxide

Hydrogen cyanide (hydrocyanic acid)

Nitrogen oxides (NOx)

SECTION 11: Toxicological information

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

Acute toxicity

Acute oral toxicity : LD50 (Rat): 980 mg/kg

Acute inhalation toxicity : No data available

Acute dermal toxicity : No data available

according to Regulation (EC) No. 1907/2006



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Acute toxicity (other routes of : No data available

administration)

Skin corrosion/irritation

No data available

Serious eye damage/eye irritation

No data available

Respiratory or skin sensitization

No data available

Germ cell mutagenicity

Genotoxicity in vitro : Ames-test: negative => not mutagenic.

Genotoxicity in vivo : No data available

Carcinogenicity

No data available

Reproductive toxicity

Effects on fertility : No data available

Effects on fetal development : No data available

STOT-single exposure

No data available

STOT-repeated exposure

No data available

Repeated dose toxicity

No data available

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

according to Regulation (EC) No. 1907/2006



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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

Further information

Remarks : No data available

Other Health Hazards

No data available

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 toxi:

city)

No data available

Toxicity to daphnia and other :

aquatic invertebrates (Chro-

nic toxicity)

No data available

Toxicity to microorganisms : No data available

Toxicity to soil dwelling orga: :

nisms

No data available

Plant toxicity : No data available

Sediment toxicity : No data available

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Toxicity to terrestrial orga-

nisms

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 De-

mand (BOD)

No data available

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 removabili: :

tν

No data available

Stability in water : No data available

Impact on Sewage Treat-

ment

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 environ-

mental compartments

No data available

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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 pa-

thways

: No data available

Adsorbed organic bound

halogens (AOX)

: No data available

Ozone-Depletion Potential : No data available

Additional ecological informa: No data available

tion

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.

SECTION 14: Transport information

14.1 UN number

ADR/RID: -IMDG: -IATA: -

14.2 UN proper shipping name

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: -

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14.6 Special precautions for user

Tunnel restriction code : No data available

Further information for trans- : No data available

port

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 the substance or mixture

The product has not been fully tested.

15.2 Chemical Safety Assessment

No

SECTION 16: Other information

Full text of other abbreviations

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

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IARC - International Agency for Research on Cancer

IATA - International Air Transport Association

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

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Other information : No data available

Sources of key data used to compile the Material Safety

Data Sheet

Information provided by the supplier

Information which has been

Updated section / sections:

added, deleted or revised

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.