

**Nintedanib monoethanesulfonate**

**Version:** 3.7

**Revision Date:** 25.03.2025

**SDS Number:** 100000000204

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

**1.1 Product identifier**

Trade name : Nintedanib monoethanesulfonate  
REACH Registration Number : -  
CAS-No. : 656247-18-6  
Unique Formula Identifier : -

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

Use of the Sub-  
stance/Mixture : Active pharmaceutical ingredients  
  
Recommended restrictions : No data available  
on use

**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

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**SECTION 2: Hazards identification**

**2.1 Classification of the substance or mixture**



**Classification (REGULATION (EC) No 1272/2008)**

Reproductive toxicity, Category 1B	H360D: May damage the unborn child.
Specific target organ toxicity - repeated exposure, Category 2	H373: May cause damage to organs through prolonged or repeated exposure.
Long-term (chronic) aquatic hazard, Category 1	H410: Very toxic to aquatic life with long lasting effects.

For explanation of abbreviations see section 16.

**2.2 Label elements**

**Labeling (REGULATION (EC) No 1272/2008)**

Hazard pictograms :  

Signal Word : Danger

**Hazard Statements**

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H360D	May damage the unborn child.
H373	May cause damage to organs through prolonged or repeated exposure.
H410	Very toxic to aquatic life with long lasting effects.

### Precautionary Statements

#### General:

P308 + P313 IF exposed or concerned: Get medical advice/ attention.

P281 Use personal protective equipment as required.

P273 Avoid release to the environment.

### 2.3 Other hazards

Other hazards	:	No data available
PBT	:	No data available
vPvB	:	No data available
Endocrine disrupting properties	:	Ecological information: No data available 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
Nintedanib monoethanesulfonate	656247-18-6		

**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.
If inhaled	:	Remove victim to fresh air and keep at rest in a position comfortable for breathing. If experiencing respiratory symptoms: Get medical advice/attention. If the patient is unconscious, must be turned and kept on his/her side during transportation.
In case of skin contact	:	Remove/ Take off immediately all contaminated clothing. Rinse skin with water/shower.

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Get medical advice/attention.

In case of eye contact : IF IN EYES: Rinse continuously with water for several minutes. Get medical advice/attention.

If swallowed : Rinse mouth.  
If the patient is conscious, give plenty of water (2 - 4 glasses).  
Get medical advice/attention.

### **4.2 Most important symptoms and effects, both acute and delayed**

Symptoms : No data available

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 : Choose suitable extinguishing media according to the environment.  
Water spray  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical  
Foam

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 carbon, nitrogen and sulphur during heating or fire.

Hazardous combustion products : No data available

### **5.3 Advice for firefighters**

Special protective equipment for fire-fighters : Isolating breathing apparatus eg. compressed breathing apparatus and protective clothing.

Specific extinguishing methods : No data available

Further information : Do not breathe dust/ fume/ gas/ mist/ vapors/ spray.  
Extinguishing water must not be discharged into waterways, sewers, soil.

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## **SECTION 6: Accidental release measures**

### **6.1 Personal precautions, protective equipment and emergency procedures**

Personal precautions : Use personal protective equipment as required.  
Keep unprotected persons out of danger area.  
Provide sufficient ventilation.

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### **6.2 Environmental precautions**

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

### **6.3 Methods and material for containment and cleaning up**

Methods for 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**

Advice on safe handling : Handle in well-ventilated space.  
Keep away from heat/sparks/open flames/hot surfaces - No smoking.  
Protect from moisture.  
Wash hands and face thoroughly after handling.

### **7.2 Conditions for safe storage, including any incompatibilities**

Requirements for storage areas and containers : Keep away from heat/sparks/open flames/hot surfaces - No smoking.  
Protect from sunlight.  
Keep container tightly closed.  
Keep only in original container.  
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.

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## **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 accordance with good industrial hygiene and safety procedures.  
Do not breathe dust/ fume/ gas/ mist/ vapors/ spray.  
Do not get in eyes, on skin, or on clothing.  
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**

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Respiratory protection	:	In open handling use respirator (P3) with a minimum protection factor of 200. See standard working procedures/instructions or department's instructions for more detailed protection measures.
Eye/face protection	:	Use protective goggles.
Hand protection	:	
Remarks	:	Wear protective gloves.
Skin and body protection	:	Wear protective clothing.
Protective measures	:	No data available
Environmental exposure controls	:	No data available

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## **SECTION 9: Physical and chemical properties**

### **9.1 Information on basic physical and chemical properties**

Form	:	crystalline
Physical state	:	solid
Color	:	yellow
Odor	:	-
Odor Threshold	:	No data available
Melting point/range	:	No data available
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 decomposition temperature (SADT)	:	No data available
pH	:	No data available
Viscosity	:	
Viscosity, dynamic	:	No data available

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Viscosity, kinematic	:	No data available
Flow time	:	No data available
Solubility(ies)		
Water solubility	:	20 g/l insoluble
Solubility in other solvents	:	Solvent: 1 % HCl solution Description: Freely soluble Solvent: dimethylsulfoxide Description: soluble
Dissolution Rate	:	No data available
Partition coefficient: n-octanol/water	:	log Pow: 3,0
Dispersion Stability	:	No data available
Vapor pressure	:	No data available
Relative density	:	No data available
Density	:	No data available
Bulk density	:	No data available
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
Hygroscopic properties	:	No data available
Henry's Constant	:	No data available
Further information	:	No data available

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**SECTION 10: Stability and reactivity**

**10.1 Reactivity**

No data available

**10.2 Chemical stability**

No data available

**10.3 Possibility of hazardous reactions**

Hazardous reactions : Dust may form explosive mixture in air.

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**10.4 Conditions to avoid**

Conditions to avoid : No data available

**10.5 Incompatible materials**

Materials to avoid : No data available

**10.6 Hazardous decomposition products**

No data available

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**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): > 2 000 mg/kg  
LD50 (Mouse): > 2 000 mg/kg

Acute inhalation toxicity : No data available

Acute dermal toxicity : No data available

Acute toxicity (other routes of administration) : No data available

**Skin corrosion/irritation**

Result : Non-irritant (rabbit)

**Serious eye damage/eye irritation**

Species : Rabbit  
Remarks : slight irritation

**Respiratory or skin sensitization**

Routes of exposure : Dermal  
Result : Not sensitizing

**Germ cell mutagenicity**

Genotoxicity in vitro : In vitro experiments showed no mutagenic effects.

Genotoxicity in vivo : In vivo experiments showed no mutagenic effects.

**Carcinogenicity**

No data available

**Reproductive toxicity**

Effects on fertility : No data available

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Effects on fetal development : May damage the unborn child.  
Showed teratogenic and/or embryotoxic effects in animal experiments.

### **STOT-single exposure**

No data available

### **STOT-repeated exposure**

Assessment : May cause damage to organs through prolonged or repeated exposure.

### **Repeated dose toxicity**

Species : Rat  
NOAEL : 20 mg/kg  
Application Route : Oral  
Exposure time : 28 d

Species : Rat  
NOAEL : 3 mg/kg  
Application Route : Oral  
Exposure time : 13 Weeks

Species : Rat  
NOAEL : 5 mg/kg  
Application Route : Oral  
Exposure time : 26 Weeks

Species : Monkey  
NOAEL : 3 mg/kg  
Application Route : Oral  
Exposure time : 13 Weeks

Species : Monkey  
NOAEL : 10 mg/kg  
Application Route : Oral  
Exposure time : 52 Weeks

Species : Monkey  
NOAEL : 5 mg/kg  
Exposure time : 14 d

Remarks : intravenous

### **Aspiration toxicity**

No data available

## **11.2 Information on other hazards**

### **Endocrine disrupting properties**

No data available



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### **Experience with human exposure**

General Information : No data available

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

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## **SECTION 12: Ecological information**

### **12.1 Toxicity**

Toxicity to fish : NOEC (Fish): 0,038 mg/l  
LOEC : 0,12 mg/l

Toxicity to daphnia and other aquatic invertebrates : NOEC (Daphnia): 0,24 mg/l  
Exposure time: 21 d  
LOEC (Daphnia): 0,81 mg/l  
Exposure time: 21 d

Toxicity to algae/aquatic plants : EC50 (algae): > 1 mg/l  
Exposure time: 72 h  
Test Type: Growth rate  
NOEC (algae): >= 1 mg/l  
Test Type: Growth inhibition

Toxicity to fish (Chronic toxicity) : No data available

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : No data available

Toxicity to microorganisms : NOEC(activated sludge): >= 1 000 mg/l

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Exposure time: 3 h

Toxicity to soil dwelling organisms : No data available

Plant toxicity : No data available

Sediment toxicity : No data available

Toxicity to terrestrial organisms : No data available

### **Ecotoxicology Assessment**

Acute aquatic toxicity : Very toxic to aquatic life with long lasting effects.

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 Demand (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 removability : No data available

Stability in water : No data available

Impact on Sewage Treatment : No data available

Photodegradation : No data available

## **12.3 Bioaccumulative potential**

Bioaccumulation : No data available

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Partition coefficient: n-octanol/water	:	log Pow: 3,0 According to logP value this compound is not bioaccumulative.
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### **12.4 Mobility in soil**

Mobility	:	No data available
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Distribution among environmental compartments	:	No data available
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Stability in soil	:	No data available
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### **12.5 Results of PBT and vPvB assessment**

Assessment	:	No data available
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### **12.6 Endocrine disrupting properties**

No data available

### **12.7 Other adverse effects**

Environmental fate and pathways	:	No data available
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Adsorbed organic bound halogens (AOX)	:	No data available
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Ozone-Depletion Potential	:	No data available
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Additional ecological information	:	No data available
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## **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**

ADR/RID: UN 3077

IMDG: UN 3077

IATA: UN 3077

### **14.2 UN proper shipping name**

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (nintedanib monoethanesulfonate)

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

ADR/RID: 9

IMDG: 9

IATA: 9

### **14.4 Packing group**

ADR/RID: III

IMDG: III

IATA: III

### **14.5 Environmental hazards**

ADR/RID: -

IMDG: -

IATA: -

### **14.6 Special precautions for user**

Tunnel restriction code : No data available

Further information for transport : No data available

### **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 the substance or mixture**

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### **15.2 Chemical Safety Assessment**

No

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## **SECTION 16: Other information**

### **Full text of H-Statements**

H360D

May damage the unborn child.

H373

May cause damage to organs through prolonged or repeated exposure.

H410

Very toxic to aquatic life with long lasting effects.

### **Full text of other abbreviations**

Repr. : Reproductive toxicity

STOT RE : Specific target organ toxicity - repeated exposure

Aquatic Chronic : Long-term (chronic) aquatic hazard

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

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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  
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

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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**

Other information : Abbreviations:  
NOAEL = No Observed Adverse Effect Level  
NOEC = No Observed Effect Concentration  
LOEC = Lowest Observed Effect Concentration  
OEL: 60 µg/m<sup>3</sup> (Boehringer Ingelheim)

Sources of key data used to compile the Material Safety Data Sheet : Information provided by the supplier

Information which has been added, deleted or revised : Updated section / sections:  
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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.