

Effective Date 08.12.2015
Revision 2.0

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Trade name: Nintedanib
CAS-number: 656247-18-6

Reach registration number: -

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

The uses of the chemical: Research API
Classification of the economic activities (NACE): NA
Use categories (UC62): NA

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 0 9452 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

Classification according to regulation EC 1272/2008	Repr. 1B STOT RE 2 Aquatic Chronic 1	H360D, H373, H410,
H Statements	May damage the unborn child. May cause damage to organs through prolonged or repeated exposure. Very toxic to aquatic life with long lasting effects.	

Effective Date 08.12.2015
Revision 2.0

2.2. Label elements

Hazard Pictograms



Signal word Danger

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.

P Statements

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

-

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances

Name of the ingredient	CAS-number:	EC-number	Reach registration number:
Nintedanib	656247-18-6	-	-

Request for Confidentiality by Annex 2 No

Substance indicated Confidential No

Other information -

Effective Date 08.12.2015
Revision 2.0

SECTION 4: FIRST AID MEASURES

4.1. Description of first aid measures

Special instructions	Helpers should ensure their own protection.
Inhalation	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.
Skin contact	Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower. Get medical advice/attention.
Eye contact	IF IN EYES: Rinse continuously with water for several minutes. Get medical advice/attention.
Ingestion	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

Data not available.

4.3. Indication of any immediate medical attention and special treatment needed

Data not available.

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing media

Suitable extinguishing media	Choose suitable extinguishing media according to the environment. Water spray Carbon dioxide Dry Chemical
-------------------------------------	--

Effective Date 08.12.2015
Revision 2.0

Foam

5.2. Special hazards arising from the substance or mixture

May emit toxic fumes of oxides of carbon, nitrogen and sulphur 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 Do not breath dust/fume/gas/mist/vapours/spray.
Extinguishing water must not be discharged into waterways, sewers, soil.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

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

6.2. Environmental precautions

Do not put into water system, drain or soil.

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

Effective Date 08.12.2015
Revision 2.0

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for 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

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.

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

Respiratory protection

Use respirator, filtration P3. In laboratories work in fume hood or under dust control hood.
See particular department's regulations of protection.

Hand protection

Wear protective gloves.

Effective Date 08.12.2015
Revision 2.0

Eye protection

Use protective goggles.

Skin protection

Wear protective clothing.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**Appearance**

Physical state	Crystalline
Colour	Yellow
Odour	-
Odour threshold	-

9.1. Information on basic physical and chemical properties

Water solubility	Freely soluble
Partition coefficient: n-octanol/water	3,0

9.2. Other information

-

SECTION 10: STABILITY AND REACTIVITY**10.1. Reactivity**

-

10.2. Chemical stability

-

10.3. Possibility of hazardous reactions

Dust may form explosive mixtures with air.

Effective Date 08.12.2015
Revision 2.0

10.4. Conditions to avoid

-

10.5. Incompatible materials

-

10.6 Hazardous decomposition products

-

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

Acute toxicity	LD50: > 2000 mg/kg (rat, oral) LD50: > 2000 mg/kg (mouse, oral)
Skin irritation and corrosion	Non-irritant (rabbit)
Skin sensitization	Not sensitizing
Serious eye damage and irritation	Slightly irritating (rabbit)
Respiratory irritation	Data not available.
Respiratory sensitization	Data not available.
Carcinogenicity	Data not available.
Germ cell mutagenicity	In vitro experiments showed no mutagenic effects. In vivo experiments showed no mutagenic effects.
Reproductive toxicity	May damage the unborn child. Showed teratogenic and/or embryotoxic effects in animal experiments.

Effective Date 08.12.2015
Revision 2.0

STOT-single exposure

Data not available.

STOT-repeated exposure

May cause damage to organs through prolonged or repeated exposure.

Aspiration hazard

Data not available.

Repeated dose toxicity

NOAEL(28 days): 20 mg/kg (rat, oral)
NOAEL(13 weeks): 3 mg/kg (rat, oral)
NOAEL(26 weeks): 5 mg/kg (rat, oral)

NOAEL(13 weeks): 3 mg/kg (monkey, oral)
NOAEL(52 weeks): 10 mg/kg (monkey, oral)
NOAEL(14 days): 5 mg/kg (monkey, intravenous)

Effective Date 08.12.2015
Revision 2.0

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Aquatic toxicity

Very toxic to aquatic life with long lasting effects.

Toxicity to fish:

NOEC: 0,038 mg/l, fish

LOEC: 0,12 mg/l

Toxicity to daphnia:

NOEC(21 d): 0,24 mg/l, Daphnia

LOEC(21 d): 0,81 mg/l, Daphnia

Toxicity to algae:

EC50(72 h): > 1 mg/l, algae, growth rate

NOEC: >= 1 mg/l, algae, inhibition of growth

Toxicity to bacteria:

NOEC(3 h): >= 1000 mg/l, activated sludge

Toxic effects on other organisms

Data not available.

12.2. Persistence and degradability

Data not available.

12.3. Bioaccumulative potential

Octanol-water partition coefficient(KOW)

According to log Kow value this compound is not bioaccumulative.

Bioconcentration factor

Data not available.

12.4. Mobility in soil

Data not available.

Effective Date 08.12.2015
Revision 2.0

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.

SECTION 14: TRANSPORT INFORMATION

14.1. UN Number

UN 3077

14.2. UN Proper shipping name

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. ,(Nintedanib)

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

9

14.4. Packing group

III

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

Effective Date 08.12.2015
Revision 2.0

SECTION 15: REGULATORY INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for substance or mixture

-

15.2. Chemical Safety Assessment

No

SECTION 16: OTHER INFORMATION

Further information

Abbreviations:

NOAEL = No Observed Adverse Effect Level

NOEC = No Observed Effect Concentration

LOEC = Lowest Observed Effect Concentration

OEL: 60 µg/m³ (Boehringer Ingelheim)

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:

8