

**SAFETY DATA SHEET**

according to the OSHA Hazard Communication Standard

**TEPOTINIB 250 MG FILMTABLETTEN TF3**

Version	Revision Date:	SDS Number:	Date of last issue: 11/20/2023
2.1	04/11/2024	90MDGM349829	Date of first issue: 01/30/2023

**SECTION 1. IDENTIFICATION**

Product name : TEPOTINIB 250 MG FILMTABLETTEN TF3

**Manufacturer or supplier's details**

Company : EMD Serono, Inc.  
One Technology Place  
MA-02370 Rockland  
United States of America

Responsible Department : e-mail: HealthcareSDS@emdgroup.com

Emergency telephone number : 800-424-9300 CHEMTREC (USA)  
+1-703-527-3887 CHEMTREC (International)  
613-996-6666 CANUTEC (Canada)  
24 Hours/day; 7 Days/week

**Recommended use of the chemical and restrictions on use**

Recommended use : finished pharmaceutical

**SECTION 2. HAZARDS IDENTIFICATION****GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)**

Carcinogenicity : Category 2

Reproductive toxicity : Category 2

**GHS label elements**

Hazard pictograms :



Signal word : Warning

Hazard statements : H351 Suspected of causing cancer.  
H361fd Suspected of damaging fertility. Suspected of damaging the unborn child.

Precautionary statements : **Prevention:**  
P201 Obtain special instructions before use.  
P202 Do not handle until all safety precautions have been read and understood.  
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

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

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## TEPOTINIB 250 MG FILMTABLETTEN TF3

Version 2.1      Revision Date: 04/11/2024      SDS Number: 90MDGM349829      Date of last issue: 11/20/2023  
Date of first issue: 01/30/2023

### Storage:

P405 Store locked up.

### Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

### Other hazards

None known.

## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture  
Chemical nature : Mixture of inorganic and organic compounds

### Components

Chemical name	CAS-No.	Concentration (% w/w)
Tepotinib	1100598-30-8	$\geq 20 - < 30$
cellulose	9004-34-6	$\geq 5 - < 10$
magnesium distearate	557-04-0	$\geq 1 - < 5$
titanium(IV) oxide	13463-67-7	$\geq 0.1 - < 1$

Actual concentration is withheld as a trade secret

## SECTION 4. FIRST AID MEASURES

General advice : Move out of dangerous area.  
Show this safety data sheet to the doctor in attendance.  
Do not leave the victim unattended.

If inhaled : Move to fresh air.  
If symptoms persist, call a physician.

In case of skin contact : Rinse with water.  
Remove contaminated clothing.  
If symptoms persist, call a physician.

In case of eye contact : Flush eyes with water as a precaution.  
Remove contact lenses.  
Protect unharmed eye.  
Keep eye wide open while rinsing.  
If eye irritation persists, consult a specialist.

If swallowed : Keep respiratory tract clear.  
Do not give milk or alcoholic beverages.  
Never give anything by mouth to an unconscious person.  
If symptoms persist, call a physician.

Most important symptoms and effects, both acute and delayed : Cough  
Shortness of breath  
Vomiting

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## TEPOTINIB 250 MG FILMTABLETTEN TF3

Version	Revision Date:	SDS Number:	Date of last issue: 11/20/2023
2.1	04/11/2024	90MDGM349829	Date of first issue: 01/30/2023

---

Gastrointestinal discomfort  
Nausea  
Suspected of causing cancer.  
Suspected of damaging fertility. Suspected of damaging the unborn child.

Notes to physician : Treat symptomatically.

---

### SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media : Water  
Foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry powder

Unsuitable extinguishing media : For this substance/mixture no limitations of extinguishing agents are given.

Specific hazards during fire-fighting : Combustible.

Development of hazardous combustion gases or vapours possible in the event of fire.

Fire may cause evolution of:

nitrogen oxides

Further information : Standard procedure for chemical fires.  
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.  
Suppress (knock down) gases/vapours/mists with a water spray jet.  
(contamination risk)

Special protective equipment for firefighters : Wear self-contained breathing apparatus for firefighting if necessary.  
Use personal protective equipment.

---

### SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures : Advice for non-emergency personnel:  
Avoid inhalation of dusts.  
Evacuate the danger area, observe emergency procedures, consult an expert.  
Advice for emergency responders:  
Protective equipment see section 8.

Environmental precautions : Prevent product from entering drains.  
Prevent further leakage or spillage if safe to do so.  
If the product contaminates rivers and lakes or drains inform respective authorities.

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## TEPOTINIB 250 MG FILMTABLETTEN TF3

Version 2.1      Revision Date: 04/11/2024      SDS Number: 90MDGM349829      Date of last issue: 11/20/2023  
Date of first issue: 01/30/2023

Methods and materials for containment and cleaning up : Keep in suitable, closed containers for disposal. Cover drains. Collect, bind, and pump off spills. Observe possible material restrictions (see sections 7 and 10). Take up dry. Dispose of properly. Clean up affected area. Avoid generation of dusts.

### SECTION 7. HANDLING AND STORAGE

Technical measures : Install appropriate equipment and wear appropriate personal protective equipment (see "8. Exposure control/personal protection").

Local/Total ventilation : Ensure adequate ventilation.

Advice on protection against fire and explosion : Provide appropriate exhaust ventilation at places where dust is formed.

Advice on safe handling : Observe label precautions.  
Avoid formation of respirable particles.  
Do not breathe vapours/dust.  
For personal protection see section 8.  
Smoking, eating and drinking should be prohibited in the application area.  
Dispose of rinse water in accordance with local and national regulations.

Conditions for safe storage : Keep container tightly closed in a dry and well-ventilated place.  
Observe label precautions.  
Electrical installations / working materials must comply with the technological safety standards.

Further information on storage stability : No decomposition if stored and applied as directed.

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
cellulose	9004-34-6	TWA	10 mg/m <sup>3</sup>	ACGIH
		TWA (Respirable)	5 mg/m <sup>3</sup>	NIOSH REL
		TWA (total)	10 mg/m <sup>3</sup>	NIOSH REL
		TWA (total dust)	15 mg/m <sup>3</sup>	OSHA Z-1
		TWA (respirable fraction)	5 mg/m <sup>3</sup>	OSHA Z-1

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## TEPOTINIB 250 MG FILMTABLETTEN TF3

Version 2.1      Revision Date: 04/11/2024      SDS Number: 90MDGM349829      Date of last issue: 11/20/2023  
Date of first issue: 01/30/2023

		TWA (Total dust)	15 mg/m <sup>3</sup>	OSHA P0
		TWA (respirable dust fraction)	5 mg/m <sup>3</sup>	OSHA P0
magnesium distearate	557-04-0	TWA (Inhalable particulate matter)	10 mg/m <sup>3</sup>	ACGIH
		TWA (Respirable particulate matter)	3 mg/m <sup>3</sup>	ACGIH
titanium(IV) oxide	13463-67-7	TWA (total dust)	15 mg/m <sup>3</sup>	OSHA Z-1
		TWA (Total dust)	10 mg/m <sup>3</sup>	OSHA P0

**Engineering measures** : Technical measures and appropriate working operations should be given priority over the use of personal protective equipment.

See section 7.1.

### Personal protective equipment

Respiratory protection : required when dusts are generated.

Filter type : Filter P 3 (acc. to DIN 3181) for solid and liquid particles of toxic and very toxic substances

#### Hand protection

Material : Nitrile rubber  
Break through time : > 480 min  
Glove thickness : 0.11 mm  
Manufacturer : KCL 741 Dermatril® L

Remarks : The suitability for a specific workplace should be discussed with the producers of the protective gloves.

Eye protection : Eye wash bottle with pure water  
Tightly fitting safety goggles

Skin and body protection : Dust impervious protective suit  
Choose body protection according to the amount and concentration of the dangerous substance at the work place.

Protective measures : The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Hygiene measures : Wash hands before breaks and at the end of workday.  
Change contaminated clothing.

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## TEPOTINIB 250 MG FILMTABLETTEN TF3

Version 2.1      Revision Date: 04/11/2024      SDS Number: 90MDGM349829      Date of last issue: 11/20/2023  
Date of first issue: 01/30/2023

---

### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : solid

Colour : light pink

Odour : odourless

Odour Threshold : Not applicable

pH : No data available

Melting point/range : No data available

Boiling point/boiling range : No data available

Flash point : No data available

Evaporation rate : Not applicable

Flammability (solid, gas) : No data available

Self-ignition : No data available

Upper explosion limit / Upper flammability limit : Upper explosion limit  
No data available

Lower explosion limit / Lower flammability limit : Lower explosion limit  
No data available

Vapour pressure : No data available

Relative vapour density : No data available

Relative density : No data available

Density : No data available

Solubility(ies)  
Water solubility : No data available

Partition coefficient: n-octanol/water : No data available

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## TEPOTINIB 250 MG FILMTABLETTEN TF3

Version	Revision Date:	SDS Number:	Date of last issue: 11/20/2023
2.1	04/11/2024	90MDGM349829	Date of first issue: 01/30/2023

---

Viscosity, kinematic : No data available

Explosive properties : Not classified as explosive.

Oxidizing properties : none

---

### SECTION 10. STABILITY AND REACTIVITY

Reactivity : Risk of dust explosion.

Chemical stability : The product is chemically stable under standard ambient conditions (room temperature) .

Possibility of hazardous reactions : Violent reactions possible with:  
Strong oxidizing agents  
Strong acids and strong bases  
Generates dangerous gases or fumes in contact with:  
Acids

Conditions to avoid : no information available

Incompatible materials : Not applicable

Hazardous decomposition products : in the event of fire: See section 5.

---

### SECTION 11. TOXICOLOGICAL INFORMATION

#### Acute toxicity

Not classified due to lack of data.

#### Product:

Acute oral toxicity : Remarks: No data available  
Acute toxicity estimate: > 5,000 mg/kg  
Method: Calculation method

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available  
Acute toxicity estimate: > 5,000 mg/kg  
Method: Calculation method

#### Components:

#### Tepotinib:

Acute oral toxicity : LD50 (Rat, male and female): > 2,000 mg/kg  
GLP: yes  
Remarks: (own results)

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## TEPOTINIB 250 MG FILMTABLETTEN TF3

Version 2.1      Revision Date: 04/11/2024      SDS Number: 90MDGM349829      Date of last issue: 11/20/2023  
Date of first issue: 01/30/2023

---

Assessment: The substance or mixture has no acute oral toxicity

### **cellulose:**

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg  
Remarks: (RTECS)

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg  
Remarks: (RTECS)

Assessment: The substance or mixture has no acute dermal toxicity

### **magnesium distearate:**

Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg  
Remarks: (External MSDS)

Assessment: The substance or mixture has no acute oral toxicity

### **titanium(IV) oxide:**

Acute oral toxicity : LD50 (Rat): > 10,000 mg/kg  
Remarks: (External MSDS)

### **Skin corrosion/irritation**

Not classified due to lack of data.

### **Product:**

Remarks : No data available

### **Components:**

#### **titanium(IV) oxide:**

Species : Rabbit  
Result : No skin irritation  
Remarks : (IUCLID)

### **Serious eye damage/eye irritation**

Not classified due to lack of data.

### **Product:**

Remarks : No data available

### **Components:**

#### **titanium(IV) oxide:**

Species : Rabbit  
Result : No eye irritation  
Remarks : (IUCLID)



# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## TEPOTINIB 250 MG FILMTABLETTEN TF3

Version 2.1      Revision Date: 04/11/2024      SDS Number: 90MDGM349829      Date of last issue: 11/20/2023  
Date of first issue: 01/30/2023

---

### Respiratory or skin sensitisation

#### Skin sensitisation

Not classified due to lack of data.

#### Respiratory sensitisation

Not classified due to lack of data.

#### Product:

Remarks : No data available

### Germ cell mutagenicity

Not classified due to lack of data.

#### Product:

Genotoxicity in vitro : Remarks: No data available

Genotoxicity in vivo : Remarks: No data available

### Components:

#### Tepotinib:

Genotoxicity in vitro : Test Type: Ames test  
Method: OECD Test Guideline 476  
Result: negative

Genotoxicity in vivo : Test Type: In vivo micronucleus test  
Species: Rat  
Result: negative  
Remarks: (own results)

Germ cell mutagenicity - Assessment : Tests on bacterial or mammalian cell cultures did not show mutagenic effects., In vivo tests did not show mutagenic effects

### Carcinogenicity

Suspected of causing cancer.

**IARC** Group 2B: Possibly carcinogenic to humans  
titanium(IV) oxide 13463-67-7

**OSHA** No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

**NTP** No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

### Reproductive toxicity

Suspected of damaging fertility. Suspected of damaging the unborn child.

#### Product:

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## TEPOTINIB 250 MG FILMTABLETTEN TF3

Version	Revision Date:	SDS Number:	Date of last issue: 11/20/2023
2.1	04/11/2024	90MDGM349829	Date of first issue: 01/30/2023

---

Reproductive toxicity - Assessment : Evidence of harm to the unborn child.

### Components:

#### **Tepotinib:**

Reproductive toxicity - Assessment : Some evidence of adverse effects on development, based on animal experiments.

Some evidence of adverse effects on sexual function and fertility, based on animal experiments.

#### **STOT - single exposure**

Not classified due to lack of data.

#### **STOT - repeated exposure**

Not classified due to lack of data.

#### **Repeated dose toxicity**

#### Product:

Remarks : No data available

### Components:

#### **Tepotinib:**

Species : Rat, male and female  
NOAEL : 45 mg/kg  
Application Route : Oral  
Exposure time : 182 d  
GLP : yes  
Remarks : (own results)

#### **Aspiration toxicity**

Not classified due to lack of data.

#### **Further information**

#### Product:

Remarks : Physiologically active substance.

Remarks : Therapeutically used substance.

Remarks : Systemic effects:

Remarks : Liver toxicity

Remarks : Other dangerous properties can not be excluded.

Remarks : This substance should be handled with particular care.

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## TEPOTINIB 250 MG FILMTABLETTEN TF3

Version 2.1      Revision Date: 04/11/2024      SDS Number: 90MDGM349829      Date of last issue: 11/20/2023  
Date of first issue: 01/30/2023

---

### Components:

#### **Tepotinib:**

Remarks : The following applies to cyanogen compounds/ nitriles in general: utmost caution! Release of hydrocyanic acid is possible - blockade of cellular respiration. Cardiovascular disorders, dyspnoea, unconsciousness.

Remarks : Other dangerous properties can not be excluded.

Remarks : This substance should be handled with particular care.

#### **cellulose:**

Remarks : Substances which occur in nature

#### **titanium(IV) oxide:**

Remarks : Hazardous properties cannot be excluded but are unlikely when the product is handled appropriately.

Remarks : Inhalation of the dusts should be avoided as even inert dusts may impair respiratory organ functions.

Remarks : Handle in accordance with good industrial hygiene and safety practice.

---

## SECTION 12. ECOLOGICAL INFORMATION

### **Ecotoxicity**

#### Product:

Toxicity to fish : Remarks: No data available

Toxicity to daphnia and other aquatic invertebrates : Remarks: No data available

Toxicity to algae/aquatic plants : Remarks: No data available

Toxicity to fish (Chronic toxicity) : Remarks: No toxicity at the limit of solubility

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

Toxicity to microorganisms : Remarks: No data available

### Components:

#### **Tepotinib:**

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## TEPOTINIB 250 MG FILMTABLETTEN TF3

Version 2.1      Revision Date: 04/11/2024      SDS Number: 90MDGM349829      Date of last issue: 11/20/2023  
Date of first issue: 01/30/2023

---

Toxicity to algae/aquatic plants : NOEC (Pseudokirchneriella subcapitata (green algae)): 0.0316 mg/l  
Exposure time: 72 h  
Test Type: static test  
Method: Regulation (EC) No. 440/2008, Annex, C.3  
GLP: yes

ErC50 (Pseudokirchneriella subcapitata (green algae)): 0.992 mg/l  
Exposure time: 72 h  
Test Type: static test  
Method: Regulation (EC) No. 440/2008, Annex, C.3  
GLP: yes

M-Factor (Acute aquatic toxicity) : 1

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 0.531 mg/l  
End point: reproduction rate  
Exposure time: 21 d  
Test Type: semi-static test  
Method: OECD Test Guideline 211  
GLP: yes  
Remarks: (own results)

EC10 (Daphnia magna (Water flea)): 1.15 mg/l  
End point: reproduction rate  
Exposure time: 21 d  
Test Type: semi-static test  
Method: OECD Test Guideline 211  
GLP: yes  
Remarks: (own results)

M-Factor (Chronic aquatic toxicity) : 1

Toxicity to microorganisms : EC50 (activated sludge): 204 mg/l  
Exposure time: 3 h  
Test Type: static test  
Method: OECD Test Guideline 209  
GLP: yes

NOEC (activated sludge): 5.6 mg/l  
Exposure time: 3 h  
Test Type: static test  
Method: OECD Test Guideline 209  
GLP: yes

EC10 (activated sludge): 42.1 mg/l  
Exposure time: 3 h  
Test Type: static test  
Method: OECD Test Guideline 209  
GLP: yes

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## TEPOTINIB 250 MG FILMTABLETTEN TF3

Version	Revision Date:	SDS Number:	Date of last issue: 11/20/2023
2.1	04/11/2024	90MDGM349829	Date of first issue: 01/30/2023

---

### **titanium(IV) oxide:**

Toxicity to fish : LC50 (Cyprinodon variegatus (sheepshead minnow)): > 10,000 mg/l  
Exposure time: 96 h  
Test Type: semi-static test  
Method: OECD Test Guideline 203  
GLP: yes

NOEC (Cyprinodon variegatus (sheepshead minnow)): > 10,000 mg/l  
Exposure time: 96 h  
Test Type: semi-static test  
Method: OECD Test Guideline 203  
GLP: yes

Toxicity to microorganisms : EC50 (activated sludge): > 1,000 mg/l  
Exposure time: 3 h  
Test Type: static test  
Method: OECD Test Guideline 209  
GLP: yes

NOEC (activated sludge): > 1,000 mg/l  
Exposure time: 3 h  
Test Type: static test  
Method: OECD Test Guideline 209  
GLP: yes

### **Persistence and degradability**

No data available

### **Bioaccumulative potential**

#### **Components:**

#### **magnesium distearate:**

Partition coefficient: n-octanol/water : log Pow: 0.8  
Method: OECD Test Guideline 107  
Remarks: Bioaccumulation is not expected.

### **Mobility in soil**

No data available

### **Other adverse effects**

#### **Product:**

Ozone-Depletion Potential : Regulation: 40 CFR Protection of Environment; Part 82 Protection of Stratospheric Ozone - CAA Section 602 Class I Substances  
Remarks: This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

Additional ecological infor- : Discharge into the environment must be avoided.

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## TEPOTINIB 250 MG FILMTABLETTEN TF3

Version	Revision Date:	SDS Number:	Date of last issue: 11/20/2023
2.1	04/11/2024	90MDGM349829	Date of first issue: 01/30/2023

mation

### SECTION 13. DISPOSAL CONSIDERATIONS

#### Disposal methods

Waste from residues : Do not dispose of waste into sewer.  
Do not contaminate ponds, waterways or ditches with chemical or used container.  
Send to a licensed waste management company.

Waste material must be disposed of in accordance with the national and local regulations. Leave chemicals in original containers. No mixing with other waste. Handle uncleaned containers like the product itself.

Contaminated packaging : Empty remaining contents.  
Dispose of as unused product.  
Do not re-use empty containers.

### SECTION 14. TRANSPORT INFORMATION

#### International Regulations

##### UNRTDG

UN number : UN 3077  
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.  
(Tepotinib Hydrochlorid Monohydrat)  
Class : 9  
Packing group : III  
Labels : 9  
Environmentally hazardous : no

##### IATA-DGR

UN/ID No. : UN 3077  
Proper shipping name : Environmentally hazardous substance, solid, n.o.s.  
(Tepotinib Hydrochlorid Monohydrat)  
Class : 9  
Packing group : III  
Labels : Miscellaneous  
Packing instruction (cargo aircraft) : 956  
Packing instruction (passenger aircraft) : 956

##### IMDG-Code

UN number : UN 3077  
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.  
(Tepotinib Hydrochlorid Monohydrat)  
Class : 9

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## TEPOTINIB 250 MG FILMTABLETTEN TF3

Version	Revision Date:	SDS Number:	Date of last issue: 11/20/2023
2.1	04/11/2024	90MDGM349829	Date of first issue: 01/30/2023

---

Packing group : III  
Labels : 9  
EmS Code : F-A, S-F  
Marine pollutant : no

### Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

### National Regulations

#### Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

---

## SECTION 15. REGULATORY INFORMATION

### CERCLA Reportable Quantity

This material does not contain any components with a CERCLA RQ.

### SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

### SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

**SARA 311/312 Hazards** : Carcinogenicity  
Reproductive toxicity

**SARA 313** : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

### Clean Air Act

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCM I Intermediate or Final VOC's (40 CFR 60.489).

### Clean Water Act

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

This product does not contain any priority pollutants related to the U.S. Clean Water Act

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## TEPOTINIB 250 MG FILMTABLETTEN TF3

Version	Revision Date:	SDS Number:	Date of last issue: 11/20/2023
2.1	04/11/2024	90MDGM349829	Date of first issue: 01/30/2023

---

### US State Regulations

#### Massachusetts Right To Know

cellulose 9004-34-6

#### Pennsylvania Right To Know

D-mannitol 69-65-8  
Tepotinib 1100598-30-8  
cellulose 9004-34-6

#### Maine Chemicals of High Concern

Product does not contain any listed chemicals

#### Vermont Chemicals of High Concern

Product does not contain any listed chemicals

#### Washington Chemicals of High Concern

Product does not contain any listed chemicals

#### California List of Hazardous Substances

polymer of 1-vinyl-2-pyrrolidone 9003-39-8

#### California Permissible Exposure Limits for Chemical Contaminants

magnesium distearate 557-04-0

#### The components of this product are reported in the following inventories:

TCSI : Not in compliance with the inventory

TSCA : Product contains substance(s) not listed on TSCA inventory.

AIIC : Not in compliance with the inventory

DSL : This product contains the following components that are not on the Canadian DSL nor NDSL.

Tepotinib

iron oxides and iron hydroxides colourant

ENCS : Not in compliance with the inventory

ISHL : Not in compliance with the inventory

KECI : Not in compliance with the inventory

PICCS : Not in compliance with the inventory

IECSC : Not in compliance with the inventory

NZIoC : Not in compliance with the inventory

TECI : Not in compliance with the inventory

#### TSCA list

No substances are subject to a Significant New Use Rule.



# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## TEPOTINIB 250 MG FILMTABLETTEN TF3

Version 2.1      Revision Date: 04/11/2024      SDS Number: 90MDGM349829      Date of last issue: 11/20/2023  
Date of first issue: 01/30/2023

No substances are subject to TSCA 12(b) export notification requirements.

### SECTION 16. OTHER INFORMATION

#### Company internal Occupational Exposure Limit (MOEL)

: 14 µg/m<sup>3</sup>

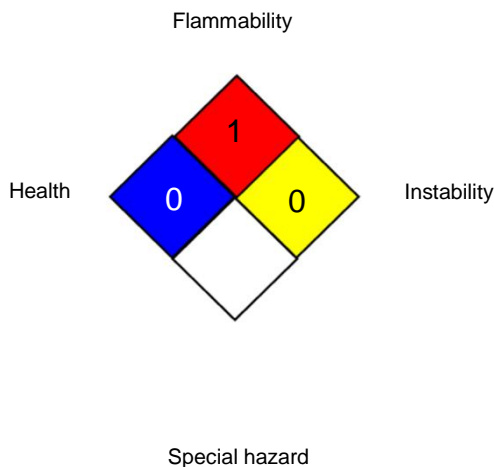
Short Term Exposure (15 min) Factor : 4

Pregnancy risk groups : D

Either there are no data for an assessment of damage to the embryo, or foetus or the currently available data are not sufficient for classification in one of the other groups.

#### Further information

##### NFPA 704:



##### HMIS® IV:

HEALTH	*	0
FLAMMABILITY		1
PHYSICAL HAZARD		0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "\*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

#### Full text of other abbreviations

- ACGIH : USA. ACGIH Threshold Limit Values (TLV)
- NIOSH REL : USA. NIOSH Recommended Exposure Limits
- OSHA P0 : USA. Table Z-1-A Limits for Air Contaminants (1989 vacated values)
- OSHA Z-1 : USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
- ACGIH / TWA : 8-hour, time-weighted average
- NIOSH REL / TWA : Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
- OSHA P0 / TWA : 8-hour time weighted average
- OSHA Z-1 / TWA : 8-hour time weighted average

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## TEPOTINIB 250 MG FILMTABLETTEN TF3

Version	Revision Date:	SDS Number:	Date of last issue: 11/20/2023
2.1	04/11/2024	90MDGM349829	Date of first issue: 01/30/2023

---

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Revision Date : 04/11/2024

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.

US / EN