



Material Safety Data Sheet

Product code: JANBER115777
Revision date: NOT AUTHORIZED

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

Supplier:
J&J Pharmaceutical Research & Development
A division of Janssen Pharmaceutica NV
Turnhoutseweg 30
2340 Beerse
Belgium

Emergency telephone number: +32 14 602444
Product name: TIPIFARNIB
Product code: JANBER115777
Synonyms: R 115777
Formula #: None.
EPA registry #: None.
RTECS #: None.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Components	CAS Number	Weight %	J&J - OEL Data (TWA - 8 hr)	J&J - OEL Data (STEL):	J&J - OEL Data (Ceiling Limit Value):	J&J - PBOEL
TIPIFARNIB	192185-72-1	100	23ug/m ³	Not Determined	Not Determined	3A

2. HAZARDS IDENTIFICATION

Emergency overview: Investigational drug substance, therefore the effects in humans have not been fully characterized.

Properties affecting health: None

Principle routes of exposure:

Oral: Unknown on investigational drug substance.
Eye contact: Unknown on investigational drug substance.
Skin contact: Unknown on investigational drug substance.
Ingestion: Unknown on investigational drug substance.
Inhalation: Unknown on investigational drug substance.

Physico-chemical properties: Unknown on investigational drug substance.

Hazard information:

Target organ effects: Not known
Reproductive effects: Unknown on investigational drug substance.

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Mutagenic effects: Unknown on investigational drug substance.
Sensitization: Unknown on product.

Carcinogenicity rating:

Components	CAS Number	J & J:	NTP:	IARC:	California Proposition 65 List:
TIPIFARNIB	192185-72-1	Not Determined	Not Determined	Not Determined	Not Determined

Signs and symptoms: Unknown on investigational drug substance.

Medical conditions aggravated by exposure: Unknown on investigational drug substance.

4. FIRST AID MEASURES

Eye contact: In the case of contact with eyes, rinse immediately with plenty of water for 15 minutes and seek medical attention.

Ingestion: If ingested, seek medical attention immediately and show the label.

Inhalation: Move to fresh air immediately. If experiencing difficulty breathing, seek medical attention.

Skin contact: After contact with skin, wash immediately with plenty of water. Immediately remove contaminated clothing and shoes. Wash contaminated clothing before reuse. Seek medical attention if symptoms appear.

Protection of first-aiders: No information available.

Notes to physician: Treat symptomatically.

5. FIRE-FIGHTING MEASURES

Flash point (°F):	Unknown on product.
Flash point (°C):	Unknown on product.
Autoignition temperature:	Unknown on product.
Flammable limits in air - lower (%):	Unknown on product.
NFPA rating:	Not determined
Fire fighting information:	
Suitable extinguishing media:	Water fog or mist. Carbon dioxide (CO2). Dry powder. Dry sand. Foam.
Extinguishing media which must not be used for safety reasons:	None.
Specific methods:	Collect contaminated fire extinguishing water separately. This must not be discharged into drains. Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.
Special protective equipment for firefighters:	Wear a self-contained breathing apparatus and full protective gear.
Hazardous combustion products:	None
Explosivity:	Unknown on investigational drug substance.
Explosion limits:	
lower:	None.
upper:	None.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions:	Wear appropriate eye, skin, respiratory protection, disposable dust impervious suit and shoe covers. Avoid dust formation.
Environmental precautions:	Do not allow material to contaminate ground water system.
Methods for cleaning up:	<p>Powder Spills: Evacuate area. Next, use disposable towels moistened with an appropriate cleaning agent (i.e. solvent, detergent and water, etc.) to complete cleaning process. A designated HEPA vacuum can be used as an alternative cleaning method for large spills. All waste must be placed in a sealable, properly labeled waste disposal bag. Over bag into a sealable, properly labeled waste disposal bag. Material must be disposed of as hazardous drug waste.</p> <p>Liquid Spills: Evacuate area. Next, use disposable towels moistened with an appropriate cleaning agent (i.e. solvent, detergent and water, etc.) to complete cleaning process. All waste must be placed in a sealable, properly labeled waste disposal bag. Over bag into a sealable, properly labeled waste disposal bag. Material must be disposed of as hazardous drug waste.</p>

7. HANDLING AND STORAGE

Handling:

Technical measures/precautions:	Use only in area provided with appropriate exhaust ventilation. Handle and store per labeled instructions
Safe handling advice:	Wear safety glasses and gloves. Clean work surfaces at the end of each day.

Storage:

Technical measures/storage conditions:	Store and transport in sealed bags contained within rigid drums or appropriate closed containers in a manner that minimizes the potential for spillage or container damage.
Incompatible products:	No special restrictions on storage with other products.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Engineering controls:	Ensure adequate ventilation. Use vented enclosures or fume hoods when weighing, handling, or transferring small quantities (<500mg) of powders. For large scale activities (greater than 500 mg), use glove boxes or contained processes supplemented with local exhaust at contaminant release points.
Eye protection:	Wear safety glasses with side-shields. Goggles recommended if potential exists for direct exposure to dust or splashes.
Hand protection:	Wear nitrile gloves when handling powders. When handling solutions, wear chemical-resistant gloves appropriate for the solvent(s) making up the solution.
Skin and body protection	Wear disposable dust impervious protective suit and shoe covers.
Respiratory protection:	Supplied air respirator required in the absence of effective local exhaust ventilation for control of airborne dusts. Respiratory protection dependent on airborne exposures. When handling small quantities, use a respirator equipped with filters approved for dusts, mists, fumes and radionuclides (HEPA/N100 or in EU ABEK-P3). When handling large quantities, use powered air-purifying respirators equipped with HEPA filters (ABEK-P3 in EU) or air supplied hood, helmet or hardcap.
Other/general protection:	Unknown on investigational drug substance.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state:	Powder
Color:	White crystalline
Odor:	Odorless
Molecular weight:	489.4
Decomposition temperature:	207 °C
Water solubility:	0.01
Partition coefficient (n-octanol/water):	4.41

10. STABILITY AND REACTIVITY

Chemical stability:	No data available.
Hazardous polymerization:	Hazardous polymerization does not occur.
Hazardous decomposition products:	Will not occur
Materials to avoid:	Oxidizing agents.

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Conditions to avoid:

Heat, flames and sparks.

11. TOXICOLOGICAL INFORMATION

Acute toxicity

LD50/oral/mouse (mg/kg) = >1280

Local effects

Oral: Not known
Eye irritation: Not known
Skin irritation: Not known
Inhalation: Not known

Chronic toxicity

Oral: Not known
Inhalation: Not known

Dermal: Not known

Subchronic toxicity

Oral: In a 3 month toxicity study in rats, routine ophthalmological examination after 1 month revealed opacities at the posterior pole of the lens. Reversibility of lens changes was not observed within the 6 week recovery period following 7 weeks exposure. Lens opacities remained unchanged in some rats and progressed in other rats despite discontinuation of dosing. Data from dogs indicated that reversible myelosuppression occurred from 10 mg/kg onwards.

Dermal: Not known

Specific effects

Corrosive effects: Not known

Sensitization: Not known

Target organ effects: Not known

Mutagenic effects: Not mutagenic in ames test.

Mouse lymphoma test (mammalian cell gene mutation test).

R115777 induced no chromosome - breaking action in the in vivo micronucleus test in mice up to a single oral dose of 320 mg/kg. At the very high myelotoxic dose of 640 mg/kg, however, an increased number of micronuclei (chromosome - breaking action) were observed in polychromatic erythrocytes.

Reproductive effects: Not known

Developmental effects: Not known

Carcinogenic effects: Not known

12. ECOLOGICAL INFORMATION

Ecotoxicity:

Ecotoxicity effects: No data available

Aquatic toxicity effects: No data available.

Mobility: No data available

Persistence / degradability: No data available.

Bioaccumulation: No data available

Degradation: No data available.

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13. DISPOSAL CONSIDERATIONS

Waste from residues / unused products:	In accordance with local and national regulations. Should not be released into the environment.
Contaminated packaging:	Empty packing materials should be handled according to local current procedures or according to local bye-laws or national laws.
Methods for cleaning up:	<p>Powder Spills: Evacuate area. Next, use disposable towels moistened with an appropriate cleaning agent (i.e. solvent, detergent and water, etc.) to complete cleaning process. A designated HEPA vacuum can be used as an alternative cleaning method for large spills. All waste must be placed in a sealable, properly labeled waste disposal bag. Over bag into a sealable, properly labeled waste disposal bag. Material must be disposed of as hazardous drug waste.</p> <p>Liquid Spills: Evacuate area. Next, use disposable towels moistened with an appropriate cleaning agent (i.e. solvent, detergent and water, etc.) to complete cleaning process. All waste must be placed in a sealable, properly labeled waste disposal bag. Over bag into a sealable, properly labeled waste disposal bag. Material must be disposed of as hazardous drug waste.</p>

14. TRANSPORT INFORMATION

DOT:	
DOT UN-No:	UN 2811
DOT shipping name:	Toxic solids, Organic, n.o.s.; 6.1; UN2811, PG III
Hazard class:	6.1
Subsidiary risk (hazard class):	No data is available on the investigational drug substance itself.
Packing group:	III
DOT reportable quantity (lbs):	No data is available on the investigational drug substance itself.
IMO/IMDG:	
Hazard class:	6.1
IMDG page:	Not regulated
IMDG-labels:	6.1
Packing group:	III
MFAG table No.:	Not regulated
Proper shipping name:	Toxic Solid, organic, n.o.s.(TIPIFARNIB)
UN/Id No.:	UN 2811
ADR/RID:	
Hazard class/packing group:	6.1, III
Item:	Not applicable
ADR/RID-labels:	6.1
UN/Id No.:	UN 2811
Proper shipping name:	Toxic solid, organic, n.o.s. (TIPIFARNIB)
TREM-card:	61GT2-III

IATA/ICAO:

Hazard class: 6.1
Packing group: III
Proper shipping name: Toxic solid, organic, n.o.s. (TIPIFARNIB)
ID/UN No.: UN 2811
IATA - label: 6.1
ERG # No data is available on the product itself.

TDG (Canada):

Status: No data is available on the product itself.
Packing group: No data is available on the product itself.

15. REGULATORY INFORMATION**SARA (311, 312) hazard class:**

Immediate health: None
Delayed health: None
Fire: None
Sudden Release of Pressure Hazard: None
Reactivity: None

TSCA inventory list: Listed under TSCA: Yes

WHMIS:

WHMIS trade secret: None
WHMIS hazard class: None

Canada DSL inventory list: Listed on DSL: Yes

Notes:

1. SARA = Superfund Amendments and the Reauthorization Act.
2. CERCLA = Comprehensive Environmental Response, Compensations and Liability Act.
3. FIFRA = Federal Insecticide, Fungicide and Rodenticide Act
4. TSCA = Toxic Substance Control Act
5. WHMIS = Canadian Workplace Hazardous Materials Information System
6. This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations (CPR) and the MSDS contains all of the information required by the CPR.

16. OTHER INFORMATION**This data sheet contains changes from the previous version in section(s):**

None

Additional advice None

Literary Reference: OEL global list VTL summary. List of active Janssen R-Compounds. EC direction 67/548 and all adaptations. Toxicology department Janssen Pharmaceutica. ARAB art. 723-bis Medical service department. ADR 2003 PC-TA Result 98-067 PC-CHAR 98-001 PC-CHAR Result 98-131

MSDS format: North American Format - U.S. and Canada
This Material Safety Data Sheet was prepared in accordance with OSHA 29 CFR 1910.1200.

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End of Safety Data Sheet