

SAFETY DATA SHEET**IVOSIDENIB (TIBSOVO® Active Ingredient)**
**SECTION 1: Identification of the substance/mixture and of the company/
undertaking**
1.1 Product identifier

Product name : IVOSIDENIB (TIBSOVO® Active Ingredient)
CAS number : 1448347-49-6
Chemical name : Not available.
Product description : Active pharmaceutical ingredient
Product type : Powder.

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

Not applicable.

1.3 Details of the supplier of the safety data sheet

Manufacturer / Distributor : LES LABORATOIRES SERVIER
 50, rue Carnot
 92284 SURESNES CEDEX
 FRANCE
 Tel.: +(33) (0)1 55 72 60 00

e-mail address of person responsible for this SDS : mail.reachoril@servier.com

1.4 Emergency telephone number**National advisory body/Poison Centre**

Telephone number : +(33) (0)1 40 05 48 48

Supplier

Emergency telephone number (with hours of operation) : Permanence téléphonique DRD: +(33) (0)1 55 72 60 00
 Numéro ORFILA: 01 45 42 59 59
 (working days and hours)

SECTION 2: Hazards identification
2.1 Classification of the substance or mixture

Product definition : Mono-constituent substance

Classification according to Regulation (EC) No. 1272/2008 [CLP/GHS]

Repr. 1B, H360FD (Fertility and Unborn child)

STOT RE 2, H373 (gastrointestinal tract, haematopoietic system, heart, kidneys, liver, lungs and thyroid)

See Section 16 for the full text of the H statements declared above.

See Section 11 for more detailed information on health effects and symptoms.

2.2 Label elements

Hazard pictograms :



Signal word : Danger

Hazard statements : May damage fertility. May damage the unborn child.
 May cause damage to organs through prolonged or repeated exposure.
 (gastrointestinal tract, haematopoietic system, heart, kidneys, liver, lungs, thyroid)

Additional warning phrases : Not available.

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SECTION 2: Hazards identification**Precautionary statements**

- Prevention** : Obtain special instructions before use. Use personal protective equipment as required. Do not breathe dust or mist.
- Response** : Get medical attention if you feel unwell. IF exposed or concerned: Get medical attention.
- Storage** : Store locked up.
- Disposal** : Dispose of contents and container in accordance with all local, regional, national and international regulations.

2.3 Other hazards

- Other hazards which do not result in classification** : Fine dust clouds may form explosive mixtures with air. Handling and/or processing of this material may generate a dust which can cause mechanical irritation of the eyes, skin, nose and throat.

SECTION 3: Composition/information on ingredients

Substance/mixture : Mono-constituent substance

Product/ingredient name	Identifiers	%	Classification Regulation (EC) No. 1272/2008 [CLP]	Type
IVOSIDENIB (TIBSOVO® Active Ingredient)	CAS: 1448347-49-6	100	Repr. 1B, H360FD (Fertility and Unborn child) STOT RE 2, H373 (gastrointestinal tract, haematopoietic system, heart, kidneys, liver, lungs and thyroid) See Section 16 for the full text of the H statements declared above.	[A]

There are no additional ingredients present which, within the current knowledge of the supplier, are classified and contribute to the classification of the substance and hence require reporting in this section.

Type

[A] Constituent

[B] Impurity

[C] Stabilising additive

SECTION 4: First aid measures**4.1 Description of first aid measures**

- Inhalation** : Move affected person to fresh air. Keep person warm and at rest. Consult immediately a doctor in case of pregnancy or nursing. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. Get medical advice/attention. If unconscious, place in recovery position and get medical attention immediately.
- Ingestion** : Wash out mouth with water. Keep person warm and at rest. Consult immediately a doctor in case of pregnancy or nursing. Seek medical attention.
- Skin contact** : Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Consult immediately a doctor in case of pregnancy or nursing. Seek medical attention.
- Eye contact** : Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for at least 10 minutes. Seek medical attention.
- Protection of first-aiders** : Put on appropriate personal protective equipment (see Section 8). No action shall be taken involving any personal risk or without suitable training.

4.2 Most important symptoms and effects, both acute and delayed

See section 11 for details.

4.3 Indication of any immediate medical attention and special treatment needed

SECTION 4: First aid measures

Notes to physician : Treat symptomatically.

SECTION 5: Firefighting measures**5.1 Extinguishing media**

Suitable extinguishing media : Use dry chemical or CO₂.

Unsuitable extinguishing media : None known.

5.2 Special hazards arising from the substance or mixture

Hazards from the substance or mixture : Fine dust clouds may form explosive mixtures with air. Runoff to sewer may create fire or explosion hazard.

Hazardous combustion products : No specific data.

5.3 Advice for firefighters

Special precautions for fire-fighters : Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. Move containers from fire area if this can be done without risk. Use water spray to keep fire-exposed containers cool.

Special protective equipment for fire-fighters : Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

SECTION 6: Accidental release measures**6.1 Personal precautions, protective equipment and emergency procedures**

Protection of fire-fighters : Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilled material. Shut off all ignition sources. Avoid breathing dust. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment (see Section 8).

6.2 Environmental precautions

Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

6.3 Methods and material for containment and cleaning up

Spill : Prevent entry into sewers, water courses, basements or confined areas. Use a tool to scoop up solid or absorbed material and place into appropriate labelled waste container.

6.4 Reference to other sections

: See Section 1 for emergency contact information.
See Section 8 for information on appropriate personal protective equipment.
See Section 13 for additional waste treatment information.

SECTION 7: Handling and storage**7.1 Precautions for safe handling**

Protective measures : Must be handled preferentially under strictly containment. Avoid contact during pregnancy or while nursing. Put on appropriate personal protective equipment (see Section 8). Use spark-proof tools and explosion-proof equipment. Avoid exposure - obtain special instructions before use. Do not get in eyes or on skin or clothing. Avoid breathing dust. Use only with adequate ventilation. Wear appropriate respirator when ventilation is inadequate.

Advice on general occupational hygiene : Remove contaminated clothing and protective equipment before entering eating areas. Workers should wash hands and face before eating, drinking and smoking.

SECTION 7: Handling and storage

7.2 Conditions for safe storage, including any incompatibilities : Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Store locked up. Use appropriate containment to avoid environmental contamination. Keep container tightly closed and sealed until ready for use.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational exposure limits

Product/ingredient name	Exposure limit values
IVOSIDENIB (TIBSOVO® Active Ingredient)	EU OEL (Europe, 8/2025). OEL: 40 µg/m ³

8.2 Exposure controls

Appropriate engineering controls : If this product contains ingredients with exposure limits, use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure below any recommended or statutory limits.

Individual protection measures

- Hygiene measures** : Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period.
- Respiratory protection** : Must be handled preferentially under strictly containment. Use a type 3 dust mask.
- Eye/face protection** : Goggles should be worn.
- Hand protection** : Wear suitable gloves. If used in a solvent, choose gloves appropriated to solvent.
- Body protection** : Wear clothes dedicated to handling of chemical products. Suitable protective footwear. Disposable outer garments when there is a risk of contact with the material.
- Environmental exposure controls** : In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state : Solid. [Powder.]

SECTION 10: Stability and reactivity

10.1 Reactivity : No specific test data related to reactivity available for this product or its ingredients.

10.2 Chemical stability : The product is stable.

10.3 Possibility of hazardous reactions : Under normal conditions of storage and use, hazardous reactions will not occur.

10.4 Conditions to avoid : Avoid the creation of dust when handling and avoid all possible sources of ignition (spark or flame). Take precautionary measures against electrostatic discharges.

10.5 Incompatible materials : Reactive or incompatible with the following materials:
oxidizing materials

SECTION 10: Stability and reactivity

10.6 Hazardous decomposition products : Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

Product/ingredient name	Result	Species	Dose	Exposure
IVOSIDENIB (TIBSOVO® Active Ingredient)	LD50 Oral	Monkey	>500 mg/kg	-
	LD50 Oral	Rat	>1000 mg/kg	-

Irritation/Corrosion

Conclusion/Summary : Not available.

Sensitiser

Conclusion/Summary : Not available.

Mutagenicity

Product/ingredient name	Test	Experiment	Result
IVOSIDENIB (TIBSOVO® Active Ingredient)	OECD 471 Bacterial Reverse Mutation Test	Experiment: In vitro Subject: Bacteria	Negative
	474 Mammalian Erythrocyte Micronucleus Test	Experiment: In vitro Subject: Mammalian-Human	Negative
	474 Mammalian Erythrocyte Micronucleus Test	Experiment: In vivo Subject: Mammalian-Animal	Negative

Conclusion/Summary : No mutagenic effect.

Carcinogenicity

Conclusion/Summary : Not available.

Reproductive toxicity

Conclusion/Summary : In studies of embryo-fetal development in rats, the maternal NOAEL was 500 mg/kg/day, and a maternal LOAEL was not defined. The fetal NOAEL occurred at a maternal dosage of 100 mg/kg/day, and the fetal LOAEL occurred at a maternal dosage of 500 mg/kg/day. In studies of embryo-fetal development in rabbits, the maternal NOAEL was 90 mg/kg/day, and the maternal LOAEL was 180 mg/kg/day. The fetal NOAEL occurred at a maternal dosage of 90 mg/kg/day, and the fetal LOAEL occurred at a maternal dosage of 180 mg/kg/day. The potential to affect fertility has not been studied.

Teratogenicity

Conclusion/Summary : No teratogenic effect.

Specific target organ toxicity (single exposure)

Not available.

Specific target organ toxicity (repeated exposure)

Product/ingredient name	Category	Route of exposure	Target organs
IVOSIDENIB (TIBSOVO® Active Ingredient)	Category 2	Not determined	gastrointestinal tract, haematopoietic system, heart, kidneys, liver, lungs and thyroid

Aspiration hazard

Not available.

SECTION 11: Toxicological information

Potential acute health effects

Potential chronic health effects

Product/ingredient name	Result	Species	Dose	Exposure
IVOSIDENIB (TIBSOVO® Active Ingredient)	Chronic NOAEL Oral	Rat	<100 mg/kg/j	28 days
	Chronic NOAEL Oral	Monkey	90 mg/kg/j	28 days
	Chronic LOAEL Oral	Rat	20 mg/kg/j	3 months
	Chronic LOAEL Oral	Monkey	30 mg/kg/j	3 months

General : May cause damage to organs through prolonged or repeated exposure. Repeated or prolonged inhalation of dust may lead to chronic respiratory irritation.

SECTION 12: Ecological information

12.1 Toxicity

Conclusion/Summary : Not available.

12.2 Persistence and degradability

Conclusion/Summary : Not available.

12.3 Bioaccumulative potential

Not available.

12.4 Mobility in soil

Soil/water partition coefficient (K_{oc}) : Not available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Methods of disposal : Send to an appropriate hazardous waste incineration facility, in compliance with legislation. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Care should be taken when handling emptied containers that have not been cleaned or rinsed out. Empty containers or liners may retain some product residues. Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers.

Hazardous waste : The classification of the product may meet the criteria for a hazardous waste.

SECTION 14: Transport information

	ADR/RID	IATA
14.1 UN number	Not regulated.	Not regulated.
14.2 UN proper shipping name	-	-
14.3 Transport hazard class(es)	-	-
14.4 Packing group	-	-
14.5 Environmental hazards	No.	No.

SECTION 14: Transport information

14.6 Special precautions for user	Transport within user's premises: always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.	Transport within user's premises: always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.
Additional information	-	-

SECTION 15: Regulatory information

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

EU Regulation (EC) No. 1907/2006 (REACH)

Annex XIV - List of substances subject to authorisation

Substances of very high concern

None of the components are listed.

Annex XVII - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles

Restricted to professional users.

Other EU regulations

Europe inventory : Not determined.

Product/ingredient name	Carcinogenic effects	Mutagenic effects	Developmental effects	Fertility effects
IVOSIDENIB (TIBSOVO® Active Ingredient)	-	-	Repr. 1B, H360D (Unborn child)	Repr. 1B, H360F (Fertility)

SECTION 16: Other information

✔ Indicates information that has changed from previously issued version.

Abbreviations and acronyms

- : ATE = Acute Toxicity Estimate
- : CLP = Classification, Labelling and Packaging Regulation [Regulation (EC) No. 1272/2008]
- : DNEL = Derived No Effect Level
- : EUH statement = CLP-specific Hazard statement
- : PNEC = Predicted No Effect Concentration
- : RRN = REACH Registration Number

Procedure used to derive the classification according to Regulation (EC) No. 1272/2008 [CLP/GHS]

Classification	Justification
✔ Repr. 1B, H360FD (Fertility and Unborn child) STOT RE 2, H373 (gastrointestinal tract, haematopoietic system, heart, kidneys, liver, lungs and thyroid)	Expert judgment based on generated data. Expert judgment based on generated data.

Full text of abbreviated H statements

- : ✔ H360FD May damage fertility. May damage the unborn child.
(Fertility and Unborn child)
- : H373 May cause damage to organs through prolonged or repeated exposure.
(gastrointestinal tract, haematopoietic system, heart, kidneys, liver, lungs and thyroid)

SECTION 16: Other information

Full text of classifications [CLP/GHS] : Repr. 1B, H360FD (Fertility and Unborn child) TOXIC TO REPRODUCTION (Fertility and Unborn child) - Category 1B
STOT RE 2, H373 (gastrointestinal tract, haematopoietic system, heart, kidneys, liver, lungs and thyroid) SPECIFIC TARGET ORGAN TOXICITY (REPEATED EXPOSURE) (gastrointestinal tract, haematopoietic system, heart, kidneys, liver, lungs and thyroid) - Category 2

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Notice to reader

The information provided herein is derived from tests carried out by **SERVIER** or accredited laboratories.

To the best of our knowledge, the information contained herein is accurate.

All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.