

SAFETY DATA SHEET**1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING****Product identifier****IRESSA TABLETS**

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Alternative Names

Gefitinib tablets

CAS No. : Not applicable
 Use : Anti-tumour agent

2. HAZARDS IDENTIFICATION**Classification of the substance or mixture**

Classification UN GHS		
Hazard class	Category	Hazard statements
Acute toxicity	5	H303
Skin irritation	2	H315
Serious eye damage	1	H318
Carcinogenicity	2	H351
Reproductive toxicity	2	H361
Specific target organ toxicity - repeated exposure	2	H373
Acute aquatic toxicity	2	H401
Chronic aquatic toxicity	2	H410
		# Refer to Section 16 'Other Information'

Label elements	
Signal word Danger	

Hazard statements

- H303 : May be harmful if swallowed.
- H315 : Causes skin irritation.
- H318 : Causes serious eye damage.
- H351 : Suspected of causing cancer.
- H361 : Suspected of damaging fertility.
- H373 : May cause damage to organs through prolonged or repeated exposure if swallowed.
- H410 : Very toxic to aquatic life with long lasting effects.

Precautionary statements

- P201 Obtain special instructions before use.
- P273 Avoid release to the environment.
- P280 Wear protective gloves/ eye protection/ face protection.
- P302 + P352 : IF ON SKIN: Wash with plenty of soap and water.
- P308 + P313 : IF exposed or concerned: Get medical advice/ attention.
- P501 : Dispose of contents/ container to an approved incineration plant.

Other hazards

See Section 11.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Component	%	CAS No.		
Gefitinib	49	184475-35-2		
	Hazard class #	Category	Hazard statements #	
	Acute toxicity	4	H302	
	Skin corrosion/irritation	2	H315	
	Serious eye damage/eye irritation	1	H318	
	Carcinogenicity	2	H351	
	Reproductive toxicity	2	H361	
	Specific target organ toxicity - repeated exposure	2	H373	
	Acute aquatic toxicity	2	H401	
Chronic aquatic toxicity	2	H411		

Refer to Section 16 'Other Information'

4. FIRST-AID MEASURES

Description of first aid measures

- Inhalation : Remove patient from exposure, keep warm and at rest. Obtain medical attention if ill effects occur.
- Skin Contact : Remove contaminated clothing. Wash skin with water. If symptoms (irritation or blistering) occur obtain medical attention.
- Eye Contact : Immediately irrigate with eyewash solution or clean water, holding the eyelids apart, for at least 10 minutes. Obtain immediate medical attention. Continue irrigation until medical attention can be obtained.
- Ingestion : Wash out mouth with water and give 200-300ml of water to drink. Do NOT induce vomiting as a First-Aid measure. Obtain medical attention.

Most important symptoms and effects, both acute and delayed

Refer to sections 2 and 11

Indication of any immediate medical attention and special treatment needed

Symptomatic treatment and supportive therapy as indicated. For further detail consult the prescribing information.

5. FIRE-FIGHTING MEASURES

- Extinguishing Media (suitable) : water spray, foam, dry powder or CO₂.
- Extinguishing Media (unsuitable) : -
- Special hazards arising from the substance or mixture : If involved in a fire, it may burn and emit noxious and toxic fumes.
- Special protective actions for fire-fighters : A self contained breathing apparatus and suitable protective clothing should be worn in fire conditions. Prevent fire extinguishing water from contaminating surface water or the ground water system.

6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Ensure suitable personal protection during removal of spillages. See Section 8.
- Environmental Precautions : Prevent entry into drains, sewers or watercourses. Collect spillage.

Methods and material for containment and cleaning up : Transfer spilled tablets to a suitable container for disposal. Wash the spillage area with water. Avoid release to the environment. See section 13.

7. HANDLING AND STORAGE

Precautions for safe handling : Do not breathe dust. Avoid contact with skin and eyes. Wash hands after use. The product may form flammable dust clouds in air, if dust from crushed tablets is allowed to accumulate. Dust clouds may be extremely sensitive to ignition by electrostatic discharge and other ignition sources. Ensure good earthing of equipment and personnel.

Conditions for safe storage, including any incompatibilities : Keep container tightly closed. Protect from light.

Specific end use(s) : Not applicable, refer to Section 1

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Occupational Exposure Limit Value

Components	Value	Control parameters	Comments
Gefitinib	0,1 mg/m ³	LTEL 8hr TWA	COM, HYG

Exposure Controls

The specific controls will depend on local circumstances and should be based on the risk assessment. Appropriate controls to reduce exposure may include engineering controls, for example ventilation, procedural controls and the use of personal protection equipment. Prevent entry into drains, sewers or watercourses. See Section 6 for environmental precautions.

Occupational exposure controls

The recommended personal protective equipment (PPE) is based on preventing the potential adverse health effects from exposure to the active pharmaceutical ingredient (API). The risk of exposure to the API in the formulation/product needs to be taken into consideration.

Decisions about whether the use of personal protective equipment (PPE) is appropriate as part of the control strategy should be based on the workplace risk assessment and should take account of local legislative requirements for selection and use. There are multiple factors that will affect the specific requirements such as amount and concentration of the material, duration of exposure, frequency of exposure, external environmental conditions, the task, the user etc.

The information below should not be used in isolation and should be considered in the context of the workplace risk assessment on a case by case basis.

Respiratory protection

Use an air fed hood for occasional exposures or for repeated exposures use a self-contained breathing apparatus if the risk assessment does not support the selection of other protection.

Skin protection

Use impervious clothing to protect against direct contact with the product if the risk assessment does not support the selection of other protection. Use impervious protective gloves to protect against direct contact with the product. If the product is dissolved or wetted use a glove material that is resistant to the solvent/liquid.

Eye protection

Use goggles to protect against direct contact with the product if the risk assessment does not support the selection of other protection.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Form : film-coated tablets
 Colour : brown

Other information**No other data available****10. STABILITY AND REACTIVITY**

Reactivity	:	No known reactivity hazard under normal conditions.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	None known.
Conditions to avoid	:	No conditions producing hazardous situations known.
Incompatible materials	:	None known.
Hazardous decomposition products	:	No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

This health hazard assessment is based on a consideration of the composition of this product.

Inhalation	:	May cause effects as described under repeated exposure.(STOT)
Skin Contact	:	Causes skin irritation.
Eye Contact	:	Causes serious eye damage.
Ingestion	:	May be harmful if swallowed. May cause effects as described under repeated exposure.(STOT)
Specific Target Organ Toxicity (STOT)	:	Single exposure No information available. Repeated exposure Exposure routes: Oral Target Organs: See below. May cause damage to organs through prolonged or repeated exposure. Studies in animals have shown that repeated doses produce adverse effects on many tissues and organs, including the eye.
Sensitisation	:	Inadequate information to assess skin sensitisation potential in man.
Carcinogenicity	:	Suspected of causing cancer. Studies in animals have shown that repeated doses produce cancer in rats and mice.
Mutagenicity	:	There is no evidence of genotoxic potential in in vitro and in vivo tests.
Reproductive toxicity	:	Suspected of damaging fertility. A study in animals has shown that repeated exposures cause adverse effects on fertility. (female rats)

12. ECOLOGICAL INFORMATION

Very toxic to aquatic life with long lasting effects. No information on this preparation. The following information refers to active ingredient:

Toxicity	:	EbC50 green algae 72 H 1,02 mg/l ErC50 green algae 72 H > 2,2 mg/l NOEC green algae 72 H 0,23 mg/l EC50 Daphnia magna 48 H 3,1 mg/l NOEC Daphnia magna 21 d 0,52 mg/l NOEC Freshwater midge, Chironomus riparius 28 d 13 mg/l NOEC Pimephales promelas (fathead minnow) 32 d 0,032 mg/l
Effect on Effluent Treatment	:	There is no evidence of inhibition to the aerobic treatment process at the solubility limit.
Persistence and degradability	:	Not rapidly degradable. Biodegradability, 28 days, (OECD 301F) <5%.
Bioaccumulative potential	:	The substance has low potential for bioaccumulation.
Mobility in soil	:	Solid with low volatility. The substance has low mobility in soil. Water solubility >= 1 mg/l.
Other adverse effects	:	No information available.

13. DISPOSAL CONSIDERATIONS

Waste treatment methods	:	Disposal should be in accordance with local, state or national legislation. Waste, even small quantities, should never be poured down drains, sewers or water courses. This material and/or its container must be disposed of as hazardous waste. Normal waste disposal is via incineration operated by an accredited disposal contractor.
Contaminated Packaging	:	Empty container will retain product residue. Observe all hazard precautions.

14. TRANSPORT INFORMATION

RESTRICTED FOR TRANSPORT

ICAO/IATA

UN No.	:	3077
Proper Shipping Name	:	Environmentally hazardous substance, solid, n.o.s. (GEFITINIB)
Class	:	9
Packing Group	:	III
Environmental hazards	:	Environmentally hazardous

IMO/IMDG

UN No.	:	3077
Proper Shipping Name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (GEFITINIB)

Class : 9
Packing Group : III
Marine pollutant : Marine pollutant

ADR

UN No. : 3077
Proper Shipping Name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
(GEFITINIB)
Class : 9
Label(s) : 9
Packing Group : III
Environmental hazards : Environmentally hazardous

15. REGULATORY INFORMATION

In order to comply with legal duties it is necessary to consult local and national legislation.

16. OTHER INFORMATION

Hazard statements H302 : Harmful if swallowed.
H303 : May be harmful if swallowed.
H315 : Causes skin irritation.
H318 : Causes serious eye damage.
H351 : Suspected of causing cancer.
H361 : Suspected of damaging the unborn child.
H373 : May cause damage to organs through prolonged or repeated exposure.
H401 : Toxic to aquatic life.
H411 : Toxic to aquatic life with long lasting effects.

The following sections contain revisions or new statements :

New significant SHE information:

- 2. New classification
- 11. New classification
- 11. Carcinogenicity
- 11. Reproductive toxicity
- 12. New classification

Minor changes: , 2, 3, 6, 7, 8, 13, 16

GLOSSARY

COM	:	In-house occupational exposure limit
LTEL	:	Long-term exposure limit (8 hour TWA (time-weighted average))
STEL	:	Short-term exposure limit (15-minute TWA (time-weighted average))
TLV	:	Threshold Limit Value (ACGIH)
TLV-C	:	Threshold Limit Value - Ceiling limit (ACGIH)
HYG	:	An in-house analytical method for occupational exposure monitoring is available
Sk	:	Can be absorbed through skin, thus contributing to systemic effects
Sen	:	Capable of causing respiratory sensitisation

This Glossary is applicable to Substances for which Hazardous Ingredients/Occupational Exposure Limits are assigned.