Version	Revision Date:	SDS Number:	Date of last issue: 27.11.2018
7.0	19.03.2020	1927	Date of first issue: 17.08.2017

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

1.1 Product identifier

IRESSA TABLETS

Details of the supplier of the safety data sheet : ASTRAZENECA PTY LTD
PO Box 131
66 Talavera Rd, North Ryde
NSW 2113
AUSTRALIA
+61 2 9978 3500

SafetyDataSheets.AlderleyPark@astrazeneca.com

Emergency Telephone
+44 (0) 1235 239 670

Alternative Names
Gefitinib tablets
CAS No. : Not applicable

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

Use of the Substance/Mixture : Anti-tumour agent

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

Skin corrosion/irritation	:	Category 2
Serious eye damage/eye irritation	:	Category 1
Carcinogenicity	:	Category 2
Reproductive toxicity	:	Category 1B
Specific target organ toxicity - repeated exposure (Oral)	:	Category 2
Short-term (acute) aquatic hazard	:	Category 2
Long-term (chronic) aquatic hazard	:	Category 1

GHS label elements

Hazard pictograms :

Signal word : Danger

Hazard statements : H315 Causes skin irritation.
H318 Causes serious eye damage.
H351 Suspected of causing cancer.

H360 May damage fertility or the unborn child.
H373 May cause damage to organs through prolonged or repeated exposure if swallowed.
H401 Toxic to aquatic life.
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements : **Prevention:**

P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P260 Do not breathe dust/ fume/ gas/ mist/ vapours/ spray.
P264 Wash skin thoroughly after handling.
P273 Avoid release to the environment.
P280 Wear protective gloves/ eye protection/ face protection.
P281 Use personal protective equipment as required.

Response:

P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER or doctor/ physician.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P332 + P313 If skin irritation occurs: Get medical advice/ attention.
P362 Take off contaminated clothing and wash before reuse.
P391 Collect spillage.

Disposal:

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

Other hazards which do not result in classification

The product may form flammable dust clouds in air, if dust from crushed tablets is allowed to accumulate.
See Section 11.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Gefitinib	184475-35-2	49
Celluloses	9004-34-6	< 20
Magnesium stearate	557-04-0	< 2

SECTION 4. FIRST AID MEASURES

If inhaled : Remove patient from exposure, keep warm and at rest.
Obtain medical attention if ill effects occur.

In case of skin contact : Remove contaminated clothing.

		Wash skin with water. If symptoms (irritation or blistering) occur obtain medical attention.
In case of 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.
If swallowed	:	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 Causes skin irritation. Causes serious eye damage. Suspected of causing cancer. May damage fertility or the unborn child. May cause damage to organs through prolonged or repeated exposure if swallowed.
Notes to physician	:	Symptomatic treatment and supportive therapy as indicated. For further detail consult the prescribing information.

SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media	:	water spray, foam, dry powder or CO2.
Unsuitable extinguishing media	:	Avoid high pressure media which could cause the formation of a potentially explosible dust-air mixture.
Specific hazards during firefighting	:	If involved in a fire, it may burn and emit noxious and toxic fumes.
Special protective equipment for firefighters	:	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.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	:	Avoid dispersal of dust in the air. Ensure suitable personal protection during removal of spillages. See Section 8.
Environmental precautions	:	Prevent entry into drains, sewers or watercourses. Collect spillage.
Methods and materials 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.

SECTION 7. HANDLING AND STORAGE

Advice on safe handling : Do not breathe dust.
Avoid contact with skin and eyes.
Wash hands after use.
Minimize dust generation and accumulation.
The material may form explosible dust-air mixture if dispersed.
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 : Keep container tightly closed.
Protect from light.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Gefitinib	184475-35-2	TWA	0.1 mg/m3	COM; HYG
Celluloses	9004-34-6	TWA	10 mg/m3	AU OEL
	Further information: This value is for inhalable dust containing no asbestos and < 1% crystalline silica			
		TWA	10 mg/m3	ACGIH
Magnesium stearate	557-04-0	TWA	10 mg/m3	AU OEL
	Further information: This value is for inhalable dust containing no asbestos and < 1% crystalline silica			
		TWA (Inhalable fraction)	10 mg/m3	ACGIH
		TWA (Respirable fraction)	3 mg/m3	ACGIH

Engineering measures : 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.

Personal protective equipment

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.

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

protection.

Skin and body 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.

Protective measures : 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.
All the information above should not be used in isolation and should be considered in the context of the workplace risk assessment on a case by case basis.

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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	film-coated tablets
Colour	:	brown
Odour	:	No data available
Odour Threshold	:	No data available
pH	:	No data available
Melting point/range	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	No data available
Evaporation rate	:	No data available
Flammability (solid, gas)	:	No data available
Upper explosion limit / Upper	:	No data available

flammability limit		
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	No data available
Relative vapour density	:	No data available
Relative density	:	No data available
Solubility(ies)		
Water solubility	:	No data available
Solubility in other solvents	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, dynamic	:	No data available
Viscosity, kinematic	:	No data available
Explosive properties	:	No data available
Oxidizing properties	:	No data available

SECTION 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.

SECTION 11. TOXICOLOGICAL INFORMATION

11.1 Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity	:	Acute toxicity estimate: > 2,000 mg/kg

Method: Calculation method

Components:

Gefitinib:

Acute oral toxicity	:	LD50 Oral (Rat): 2,000 mg/kg
Acute inhalation toxicity	:	Remarks: May cause effects as described under repeated exposure.(STOT)
Acute dermal toxicity	:	Remarks: No information available.

11.2 Skin corrosion/irritation

Causes skin irritation.

Components:

Gefitinib:

Result	:	Skin irritation

11.3 Serious eye damage/eye irritation

Causes serious eye damage.

Components:

Gefitinib:

Result	:	Irreversible effects on the eye

11.4 Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:

Gefitinib:

Remarks	:	It is not a moderate or strong skin sensitiser in animal tests. Inadequate information to assess skin sensitisation potential in man.

Chronic toxicity

11.5 Germ cell mutagenicity

Not classified based on available information.

Components:

Gefitinib:

Germ cell mutagenicity - Assessment	:	There is no evidence of genotoxic potential in in vitro and in vivo tests.

11.6 Carcinogenicity

Suspected of causing cancer.

Components:

Gefitinib:

Carcinogenicity - Assessment	:	Limited evidence of carcinogenicity in animal studies, Studies in animals have shown that repeated doses produce cancer in rats and mice.

11.7 Reproductive toxicity

May damage fertility or the unborn child.

Components:

Gefitinib:

Reproductive toxicity - Assessment	:	Clear evidence of adverse effects on sexual function and fertility, based on animal experiments., Some evidence of adverse effects on development, based on animal experiments., A study in animals has shown that repeated exposures cause adverse effects on fertility., female

11.8 STOT - single exposure

Not classified based on available information.

Components:

Gefitinib:

Remarks	:	May cause effects as described under repeated exposure.(STOT)

11.9 STOT - repeated exposure

May cause damage to organs through prolonged or repeated exposure if swallowed.

Components:

Gefitinib:

Exposure routes	:	Oral
Assessment	:	The substance or mixture is classified as specific target organ toxicant, repeated exposure, category 2.
Remarks	:	Studies in animals have shown that repeated doses produce adverse effects on many tissues and organs, including the eye.

11.10 Aspiration toxicity

Not classified based on available information.

Components:

Gefitinib:

No information available.

Further information

Product:

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

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Gefitinib:

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 3.1 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : ErC50 (Selenastrum capricornutum (green algae)): > 2.2 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (Selenastrum capricornutum (green algae)): 0.23 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Toxicity to fish (Chronic toxicity) : NOEC (Pimephales promelas (fathead minnow)): 0.032 mg/l
Exposure time: 32 d
Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 0.52 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 202

NOEC (Chironomus riparius (harlequin fly)): 13 mg/l
Exposure time: 28 d
Method: (OECD 218)

M-Factor (Chronic aquatic toxicity) : 1

Toxicity to microorganisms : NOEC (Sewage sludge organisms): > 100 mg/l
Exposure time: 3 h
Method: OECD Test Guideline 209

Ecotoxicology Assessment

Chronic aquatic toxicity : Very toxic to aquatic life with long lasting effects.

Persistence and degradability

Components:

Gefitinib:

Biodegradability : Result: not rapidly degradable
Biodegradation: < 5 %
Exposure time: 28 d
Method: OECD Test Guideline 301F

Stability in water : Degradation half life: >= 1 y (25 °C) pH: 4 - 9
Hydrolysis: < 10 % at50 °C(5 d)
Method: OECD Test Guideline 111
Remarks: Hydrolyses slowly.

Bioaccumulative potential

Components:

Gefitinib:

Bioaccumulation : Remarks: The substance has low potential for bioaccumulation.

Mobility in soil

Components:

Gefitinib:

Mobility : Remarks: Solid with low volatility.
The substance has low mobility in soil.
Water solubility >= 1 mg/l.

Distribution among environmental compartments : Remarks: No information available.

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : 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.
Dispose of contents/ container to an approved incineration plant.

Contaminated packaging : Empty container will retain product residue. Observe all hazard precautions.

SECTION 14. TRANSPORT INFORMATION

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

SECTION 15. REGULATORY INFORMATION

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

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

Standard for the Uniform Scheduling of Medicines and Poisons : No poison schedule number allocated

Prohibition/Licensing Requirements : There is no applicable prohibition or notification/licensing requirements, including for carcinogens under Commonwealth, State or Territory legislation.

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

TCSI : Not listed

TSCA : Substance(s) not listed on TSCA inventory

AICS : Not listed

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

		Gefitinib
ENCS	:	Not listed
ISHL	:	Not listed
KECI	:	Not listed
IECSC	:	Not listed
CHINV	:	Not in compliance with the inventory
REACH	:	Not in compliance with the inventory
TRINV	:	Not in compliance with the inventory

SECTION 16. OTHER INFORMATION

Further information

Revision Date	:	19.03.2020
Other information	:	Full Review - minor changes 12 15
Date format	:	dd.mm.yyyy

Full text of other abbreviations

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
AU OEL	:	Australia. Workplace Exposure Standards for Airborne Contaminants.
ACGIH / TWA	:	8-hour, time-weighted average
AU OEL / TWA	:	Exposure standard - time weighted average

AICS - Australian Inventory of Chemical Substances; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CHINV - China Inventory; CMR - Carcinogen, Mutagen or Reproductive Toxicant; COM – In-house occupational exposure limit; CPR - Controlled Products Regulations; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; 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; HYG – Analytical method for occupational exposure monitoring; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; 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; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety

and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; Sen – Capable of causing respiratory sensitization; Sk – Can be absorbed through skin, thus contributing to systemic effects; STEL – Short-term exposure limit 15-minutes time-weighted average; TLV – Threshold Limit Value (ACGIH); TLV-C – Threshold Limit Value Ceiling limit (ACGIH); TRINV - Turkey Inventory; TSCA - Toxic Substances Control Act (United States); TWA – Long-term exposure limit 8h time-weighted average; UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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.

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