

Version	Revision Date:	SDS Number:	Date of last issue: -
1.0	06.07.2017	21115	Date of first issue: 06.07.2017

---

## SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

### 1.1 Product identifier

## ONGLYZA TABLETS

Details of the supplier of the safety data sheet	: ASTRAZENECA PTY LTD PO Box 131 Alma Road, North Ryde NSW 2113 AUSTRALIA +61 2 9978 3500	Emergency Telephone +44 (0) 1235 239 670
	SafetyDataSheets.AlderleyPark@astrazeneca.com	

### Alternative Names

Saxagliptin 2.5mg and 5mg tablets	
BMS 477118-11	
Saxagliptin Tablets	
CAS No.	: Not applicable

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

Use of the Substance/Mixture	: Treatment of diabetes
------------------------------	-------------------------


---

## SECTION 2. HAZARDS IDENTIFICATION

### GHS Classification

Respiratory sensitisation	: Category 1
Skin sensitisation	: Category 1
Specific target organ toxicity - repeated exposure (Oral)	: Category 2 (Endocrine system, Immune system, Skin)

### GHS label elements

Hazard pictograms	: 
Signal word	: Danger
Hazard statements	: H317 May cause an allergic skin reaction. H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled. H373 May cause damage to organs (Endocrine system, Immune system, Skin) through prolonged or repeated exposure if swallowed.
Precautionary statements	: <b>Prevention:</b> P260 Do not breathe dust/ fume/ gas/ mist/ vapours/ spray. P272 Contaminated work clothing should not be allowed out of the workplace.

Version 1.0      Revision Date: 06.07.2017      SDS Number: 21115      Date of last issue: -  
 Date of first issue: 06.07.2017

P280 Wear protective gloves.  
 P285 In case of inadequate ventilation wear respiratory protection.

**Response:**

P302 + P352 IF ON SKIN: Wash with plenty of soap and water.  
 P304 + P341 IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.  
 P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.  
 P342 + P311 If experiencing respiratory symptoms: Call a POISON CENTER or doctor/ physician.

**Disposal:**

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

**Other hazards which do not result in classification**

May form explosive dust-air mixture if dispersed.  
 See Section 11.

**SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Mixture

**Hazardous components**

Chemical name	CAS-No.	Concentration (% w/w)
Celluloses	9004-34-6	>= 30 - < 40
Titanium dioxide	13463-67-7	>= 1 - < 10
Saxagliptin	945667-22-1	>= 1 - < 10

**SECTION 4. FIRST AID MEASURES**

If inhaled : Remove patient from exposure, keep warm and at rest.  
 OBTAIN IMMEDIATE MEDICAL ATTENTION.

In case of skin contact : Take off all contaminated clothing immediately.  
 After contact with skin, wash immediately with plenty of water.  
 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 medical attention.

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 if ill effects occur.

Most important symptoms and effects, both acute and delayed : Refer to sections 2 and 11  
 May cause an allergic skin reaction.  
 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

# SAFETY DATA SHEET



Version 1.0      Revision Date: 06.07.2017      SDS Number: 21115      Date of last issue: -  
Date of first issue: 06.07.2017

---

Notes to physician : May cause damage to organs through prolonged or repeated exposure if swallowed.  
: 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 CO<sub>2</sub>.  
Unsuitable extinguishing media : Do not use water jet. 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.

---

## SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures : Ensure suitable personal protection during removal of spillages. Avoid dispersal of dust in the air. See Section 8.  
Environmental precautions : Prevent entry into drains, sewers or watercourses.  
Methods and materials for containment and cleaning up : Avoid dust generation. Transfer spilled tablets to a suitable container for disposal. Wash the spillage area with water.

---

## SECTION 7. HANDLING AND STORAGE

Advice on safe handling : Avoid contact with skin and eyes. Avoid breathing dust. Wear protective gloves. Minimize dust generation and accumulation. The product may form flammable dust clouds in air, if dust from crushed tablets is allowed to accumulate.  
Conditions for safe storage : Store in a well-ventilated place. Keep container tightly closed. Keep away from heat, sources of ignition and direct sunlight. Protect from light.  
Recommended storage temperature : 20 - 25 °C

---

## SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

**Components with workplace control parameters**

# SAFETY DATA SHEET



Version 1.0      Revision Date: 06.07.2017      SDS Number: 21115      Date of last issue: -  
 Date of first issue: 06.07.2017

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Celluloses	9004-34-6	TWA	10 mg/m <sup>3</sup>	AU OEL
	Further information: This value is for inhalable dust containing no asbestos and < 1% crystalline silica			
		TWA	10 mg/m <sup>3</sup>	ACGIH
Titanium dioxide	13463-67-7	TWA	10 mg/m <sup>3</sup>	AU OEL
	Further information: This value is for inhalable dust containing no asbestos and < 1% crystalline silica			
Saxagliptin	945667-22-1	TWA	10 µg/m <sup>3</sup>	COM

**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.

## Personal protective equipment

**Eye protection** : Use safety glasses to protect against direct contact with the substance if the risk assessment does not support the selection of other protection.

**Skin and body protection** : Use full chemical protective suit to protect against direct contact with the product if the risk assessment does not support the selection of other protection. If the product is dissolved or wetted use a glove material that is resistant to the solvent/liquid. Take note of the information given by the PPE producer/supplier concerning permeability and breakthrough times and special workplace conditions.

**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.

# SAFETY DATA SHEET



Version 1.0      Revision Date: 06.07.2017      SDS Number: 21115      Date of last issue: -  
Date of first issue: 06.07.2017

---

## SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : coated tablets

Colour : light yellow, pink

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 : No data available

Lower explosion 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

Molecular weight : Not applicable

Version 1.0      Revision Date: 06.07.2017      SDS Number: 21115      Date of last issue: -  
Date of first issue: 06.07.2017

---

## 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

### 11.1.1 Acute toxicity

Not classified based on available information.

**Product:**

Acute oral toxicity : Remarks: Low acute oral toxicity.

**Components:**

**Saxagliptin:**

Acute oral toxicity : LD50 Oral (Rat): > 300 mg/kg  
Assessment: The substance or mixture has no acute oral toxicity

Acute inhalation toxicity : Remarks: May cause effects as described under sensitisation.

Acute dermal toxicity : Remarks: No data available

### 11.1.2 Skin corrosion/irritation

Not classified based on available information.

**Components:**

**Saxagliptin:**

Remarks: Unlikely to cause skin irritation.

### 11.1.3 Serious eye damage/eye irritation

Not classified based on available information.

**Components:**

**Saxagliptin:**

Remarks: Unlikely to cause eye irritation.

Version 1.0      Revision Date: 06.07.2017      SDS Number: 21115      Date of last issue: -  
Date of first issue: 06.07.2017

---

## 11.1.4 Respiratory or skin sensitisation

### **Skin sensitisation**

May cause an allergic skin reaction.

### **Respiratory sensitisation**

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

### **Components:**

#### **Saxagliptin:**

Result: The product is a skin sensitiser, sub-category 1A.

Result: The product is a respiratory sensitiser, sub-category 1A.

## 11.1.5 Germ cell mutagenicity

Not classified based on available information.

### **Components:**

#### **Saxagliptin:**

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

## 11.1.6 Carcinogenicity

Not classified based on available information.

### **Components:**

#### **Saxagliptin:**

Carcinogenicity - Assessment : Studies in animals have shown that repeated doses produce no carcinogenic effects.

## 11.1.7 Reproductive toxicity

Not classified based on available information.

### **Components:**

#### **Saxagliptin:**

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

## 11.1.8 STOT - single exposure

Not classified based on available information.

### **Components:**

#### **Saxagliptin:**

Exposure routes: Oral, Inhalation

Remarks: High exposure effects include hyperactivity and increased respiration.

May cause effects as described under sensitisation.

Version 1.0      Revision Date: 06.07.2017      SDS Number: 21115      Date of last issue: -  
Date of first issue: 06.07.2017

---

#### 11.1.9 STOT - repeated exposure

May cause damage to organs (Endocrine system, Immune system, Skin) through prolonged or repeated exposure if swallowed.

##### Components:

##### **Saxagliptin:**

Exposure routes: Oral

Target Organs: Endocrine system, Immune system, Skin

Assessment: Causes damage to organs through prolonged or repeated exposure.

Remarks: Studies in animals have shown that repeated doses produce adverse effects on the heart, kidneys and liver.

Ingestion studies in animals have shown that repeated doses produce adverse effects on the gastrointestinal tract.

May cause headache, nausea, vomiting, diarrhoea and skin rash.

May cause a decreased white blood cell count.

#### 11.1.10 Aspiration toxicity

Not classified based on available information.

##### Components:

##### **Saxagliptin:**

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:

##### **Saxagliptin:**

- Toxicity to fish : EC50 (Brachydanio rerio (zebrafish)): > 91 mg/l  
Exposure time: 96 H
- Toxicity to algae : ErC50 (green algae): > 140 mg/l  
Exposure time: 72 H  
Test Type: growth rate
- Toxicity to fish (Chronic toxicity) : NOEC (Pimephales promelas (fathead minnow)): 9.5 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)): 35 mg/l  
Exposure time: 21 d
- Toxicity to bacteria : NOEC (Sewage sludge organisms): 821 mg/l

Version 1.0      Revision Date: 06.07.2017      SDS Number: 21115      Date of last issue: -  
Date of first issue: 06.07.2017

---

Exposure time: 3 H  
Method: OECD Test Guideline 209

#### **Persistence and degradability**

##### **Components:**

##### **Saxagliptin:**

Biodegradability : aerobic  
Result: Not readily biodegradable.  
Biodegradation: 5.9 %  
Exposure time: 28 d  
Method: OECD Test Guideline 310  
Remarks: Carbon dioxide evolution

#### **Bioaccumulative potential**

##### **Components:**

##### **Saxagliptin:**

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

#### **Mobility in soil**

##### **Components:**

##### **Saxagliptin:**

Mobility : Remarks: The substance has high mobility in soil.  
Hydrolysed by water.

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**

Version	Revision Date:	SDS Number:	Date of last issue: -
1.0	06.07.2017	21115	Date of first issue: 06.07.2017

---

Not classified as dangerous in the meaning of transport regulations.

---

## 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.

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:

REACH : Not listed

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

Saxagliptin 945667-22-1

AICS : Not listed

ENCS : Not listed

ISHL : Not listed

IECSC : Not listed

TCSI : Not listed

TSCA : Not On TSCA Inventory

---

## SECTION 16. OTHER INFORMATION

### Full text of other abbreviations

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; 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

# SAFETY DATA SHEET

AstraZeneca 

 MedImmune

Version	Revision Date:	SDS Number:	Date of last issue: -
1.0	06.07.2017	21115	Date of first issue: 06.07.2017

---

- 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); 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

Date format : dd.mm.yyyy

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.

AU / EN