

Version 4.0 Revision Date: 07.03.2018 SDS Number: 21115 Date of last issue: 31.05.2017
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SECTION 1. IDENTIFICATION

1.1 Product identifier

ONGLYZA TABLETS

Details of the supplier of the
safety data sheet

: ASTRAZENECA Phone (24 hr.) Medical :
P.O. Box 15437 (800) 236-9933
Wilmington, DE 19850-5437 (24 hr.) Chemical / Spill Emergency:
USA INFOTRAC - (800) 535-5053

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 in accordance with 29 CFR 1910.1200

Respiratory sensitization : Category 1
Skin sensitization : Category 1
Reproductive toxicity : Category 2
Specific target organ
systemic toxicity - repeated
exposure (Oral) : Category 1 (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.
H361 Suspected of damaging fertility or the unborn child.
H372 Causes damage to organs (Endocrine system, Immune system, Skin) through prolonged or repeated exposure if swallowed.

Precautionary Statements : **Prevention:**
P201 Obtain special instructions before use.

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P202 Do not handle until all safety precautions have been read and understood.
 P260 Do not breathe dust/ fume/ gas/ mist/ vapors/ spray.
 P264 Wash skin thoroughly after handling.
 P272 Contaminated work clothing must not be allowed out of the workplace.
 P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
 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 person to fresh air and keep comfortable for breathing.
 P308 + P313 IF exposed or concerned: Get medical advice/ attention.
 P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.

Disposal:

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

Other hazards

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

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Hazardous ingredients

Chemical name	CAS-No.	Concentration (% w/w)
Talc	14807-96-6	< 60
Celluloses	9004-34-6	< 40
Titanium dioxide	13463-67-7	< 5
Saxagliptin	945667-22-1	>= 1 - <= 2

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.

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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.
Suspected of damaging fertility or the unborn child.
Causes 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.
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SECTION 5. FIRE-FIGHTING MEASURES

- Suitable extinguishing media : water spray, foam, dry chemical or CO₂.
- 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 fire fighting : If involved in a fire, it may burn and emit noxious and toxic fumes.
- Special protective equipment for fire-fighters : A self contained breathing apparatus and suitable protective clothing should be worn in fire conditions.
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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.
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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 and if it is dispersed.
- Conditions for safe storage : Store in a well-ventilated place. Keep container tightly closed.
Keep away from heat, sources of ignition and direct sunlight.
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Protect from light.

Recommended storage temperature : 68 - 77 °F

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Ingredients	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Talc	14807-96-6	TWA (Dust)	20 Million particles per cubic foot	OSHA Z-3
		TWA (respirable dust fraction)	2 mg/m ³	OSHA P0
		TWA (Respirable)	2 mg/m ³	NIOSH REL
		TWA	0.1 fibres per cubic centimeter	ACGIH
		TWA (Respirable fraction)	2 mg/m ³	ACGIH
Celluloses	9004-34-6	TWA	10 mg/m ³	ACGIH
		TWA (Respirable)	5 mg/m ³	NIOSH REL
		TWA (total)	10 mg/m ³	NIOSH REL
		TWA (total dust)	15 mg/m ³	OSHA Z-1
		TWA (respirable fraction)	5 mg/m ³	OSHA Z-1
		TWA (Total dust)	15 mg/m ³	OSHA P0
		TWA (respirable dust fraction)	5 mg/m ³	OSHA P0
Titanium dioxide	13463-67-7	TWA (total dust)	15 mg/m ³	OSHA Z-1
		TWA (Total dust)	10 mg/m ³	OSHA P0
		TWA (Titanium dioxide)	10 mg/m ³	ACGIH
Saxagliptin	945667-22-1	TWA	10 µg/m ³	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.

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Personal protective equipment

- Respiratory protection : As necessary, use NIOSH approved respiratory protection device consistent with the work place risk assessment. Consult a qualified safety and health professional for additional guidance, as needed.
- 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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

- Appearance : coated tablets
- Color : light yellow, pink
- Odor : No data available
- Odor Threshold : No data available
- pH : No data available
- Melting point/range : No data available
- Initial boiling point and boiling range : No data available

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Flash point : No data available

Evaporation rate : No data available

Flammability (solid, gas) : No data available

Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Vapor pressure : No data available

Relative vapor 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

Autoignition 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

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.

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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 : Remarks: Low acute oral toxicity.

Ingredients:

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 sensitization.

Acute dermal toxicity : Remarks: No data available

11.2 Skin corrosion/irritation

Not classified based on available information.

Ingredients:

Saxagliptin:

Remarks: Unlikely to cause skin irritation.

11.3 Serious eye damage/eye irritation

Not classified based on available information.

Ingredients:

Saxagliptin:

Remarks: Unlikely to cause eye irritation.

11.4 Respiratory or skin sensitization

Skin sensitization

May cause an allergic skin reaction.

Respiratory sensitization

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

Ingredients:

Saxagliptin:

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

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

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11.5 Germ cell mutagenicity

Not classified based on available information.

Ingredients:**Saxagliptin:**

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

11.6 Carcinogenicity

Not classified based on available information.

Ingredients:**Saxagliptin:**

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

IARC

Group 1: Carcinogenic to humans

Talc 14807-96-6

Group 2B: Possibly carcinogenic to humans

Titanium dioxide 13463-67-7

OSHA

No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

NTP

Known to be human carcinogen

Talc 14807-96-6

11.7 Reproductive toxicity

Suspected of damaging fertility or the unborn child.

Ingredients:**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.

11.8 STOT-single exposure

Not classified based on available information.

Ingredients:**Saxagliptin:**

Routes of exposure: Oral, Inhalation

Remarks: High exposure effects include hyperactivity and increased respiration. May cause effects as described under sensitization.

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11.9 STOT-repeated exposure

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

Ingredients:**Saxagliptin:**

Routes of exposure: 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.

11.10 Aspiration toxicity

Not classified based on available information.

Ingredients:**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****Ingredients:****Saxagliptin:**

Toxicity to fish	:	EC50 (Brachydanio rerio (zebrafish)): > 91 mg/l Exposure time: 96 H
Toxicity to algae	:	ErC50 (green algae): > 140 mg/l 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 microorganisms	:	NOEC (Sewage sludge organisms): 821 mg/l Exposure time: 3 H

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Method: OECD Test Guideline 209

Persistence and degradability**Ingredients:****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**Ingredients:****Saxagliptin:**

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

Mobility in soil**Ingredients:****Saxagliptin:**

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

Distribution among environmental compartments : Remarks: No information available.

Other adverse effects**Product:**

Ozone-Depletion Potential : Regulation: 40 CFR Protection of Environment; Part 82
 Protection of Stratospheric Ozone - CAA Section 602 Class I Substances
 Remarks: This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

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.

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

SECTION 14. TRANSPORT INFORMATION

Not classified as dangerous in the meaning of transport regulations.

SECTION 15. REGULATORY INFORMATION

EPCRA - Emergency Planning and Community Right-to-Know

CERCLA Reportable Quantity

This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

Ingredients	CAS-No.	Component TPQ (lbs)
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SARA 311/312 Hazards : No SARA Hazards

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Clean Air Act

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCM Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

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US State Regulations**Massachusetts Right To Know**

Talc	14807-96-6
Celluloses	9004-34-6
Titanium dioxide	13463-67-7

Pennsylvania Right To Know

Talc	14807-96-6
Celluloses	9004-34-6
Titanium dioxide	13463-67-7

New Jersey Right To Know

Talc	14807-96-6
Celluloses	9004-34-6
Titanium dioxide	13463-67-7
Saxagliptin	945667-22-1

California Prop. 65

WARNING! This product contains a chemical known in the State of California to cause cancer.

California List of Hazardous Substances

Talc	14807-96-6
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California Permissible Exposure Limits for Chemical Contaminants

Talc	14807-96-6
Celluloses	9004-34-6
Titanium dioxide	13463-67-7

California Regulated Carcinogens

Talc	14807-96-6
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The ingredients 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
AICS	:	Not listed
ENCS	:	Not listed
ISHL	:	Not listed
IECSC	:	Not listed
TCSI	:	Not listed
TSCA	:	Not On TSCA Inventory

TSCA list

No substances are subject to a Significant New Use Rule.

No substances are subject to TSCA 12(b) export notification requirements.

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SECTION 16. OTHER INFORMATION**Further information****Full text of other abbreviations**

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
 NIOSH REL : USA. NIOSH Recommended Exposure Limits
 OSHA P0 : USA. OSHA - TABLE Z-1 Limits for Air Contaminants - 1910.1000
 OSHA Z-1 : USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
 OSHA Z-3 : USA. Occupational Exposure Limits (OSHA) - Table Z-3 Mineral Dusts
 ACGIH / TWA : 8-hour, time-weighted average
 NIOSH REL / TWA : Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
 OSHA P0 / TWA : 8-hour time weighted average
 OSHA Z-1 / TWA : 8-hour time weighted average
 OSHA Z-3 / TWA : 8-hour time weighted average
 AGW – Arbeitsplatzgrenzwert (Germany TRGS 900); AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; COM – In-house occupational exposure limit; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; HMIS - Hazardous Materials Identification System; 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); MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; 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

New significant SHE information:

8. New Occupational Exposure Limit Value

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Minor changes:

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The information provided in this Material 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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