

SAFETY DATA SHEET



Version Revision Date: SDS Number: Date of last issue: 01.02.2019
4.0 09.04.2019 23225 Date of first issue: 07.03.2017

SECTION 1. IDENTIFICATION

1.1 Product identifier

SODIUM ZIRCONIUM CYCLOSILICATE

Details of the supplier of the safety data sheet

: ASTRAZENECA
P.O. Box 15437
Wilmington, DE 19850-5437
USA

Phone (24 hr.) Medical :
(800) 236-9933
(24 hr.) Chemical / Spill Emergency:
INFOTRAC - (800) 535-5053

SafetyDataSheets.AlderleyPark@astrazeneca.com

Alternative Names

ZS-9
AZD7270
Hydrogen sodium zirconium (IV) silicate hydrate
Lokelma
CAS No. : 242800-27-7

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

Use of the Substance/Mixture : Pharmaceutical active:, Treatment of hyperkalemia

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with 29 CFR 1910.1200

Not a hazardous substance or mixture.

GHS label elements

Not a hazardous substance or mixture.

Other hazards

Repeated exposure by inhalation may produce pulmonary edema.
See Section 11.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Components

Chemical name	CAS-No.	Concentration (% w/w)
Sodium zirconium cyclosilicate	242800-27-7	>= 95 - <= 100

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 immediately all contaminated clothing.
After contact with skin, wash immediately with plenty of water.
Obtain immediate 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.

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- If swallowed : Provided the patient is conscious, wash out mouth with water and give 200-300 ml of water to drink.
Do NOT induce vomiting as a First-Aid measure.
Obtain immediate medical attention.
- Most important symptoms and effects, both acute and delayed : Refer to sections 2 and 11
- Notes to physician : Symptomatic treatment and supportive therapy as indicated.
Emergency medical treatment advice varies within different countries.
For further information consult the Local National Poisons Information Services.
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SECTION 5. FIRE-FIGHTING MEASURES

- Suitable extinguishing media : water spray, foam, dry chemical or CO₂.
- Unsuitable extinguishing media : 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.
See Section 8.
- Environmental precautions : Prevent entry into drains, sewers or watercourses.
- Methods and materials for containment and cleaning up : Moisten spillages with water.
Transfer to a 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 inhalation.
- Conditions for safe storage : Keep container tightly closed.
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SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis

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Sodium zirconium cyclosilicate	242800-27-7	TWA	5 mg/m3	COM; HYG
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Engineering measures : Use appropriate controls (e.g. containment, ventilation) as specified in the workplace risk assessment to ensure that the defined occupational exposure limit is not exceeded.
Prevent entry into drains, sewers or watercourses.

Personal protective equipment

Respiratory protection : Use a negative pressure air purifying respirator (half face mask) with filter class P3 if the risk assessment does not support the selection of other protection.

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

Eye protection : Wear appropriate eye protection.

Skin and body protection : Wear appropriate protective clothing and gloves.

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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : Crystalline powder

Color : white

Odor : none

Odor Threshold : No data available

pH : No data available

Melting point/range : Decomposes before melting.

Initial boiling point and boiling range : No data available

Flash point : No data available

Evaporation rate : No data available

Flammability (solid, gas) : Does not sustain combustion.

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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.

Components:

Sodium zirconium cyclosilicate:

Acute oral toxicity : LD50 Oral (Rat): > 2,000 mg/kg
Assessment: The component/mixture is minimally toxic after single ingestion.

Acute inhalation toxicity : Remarks: Exposure to the dust may cause irritation to the respiratory tract by analogy with other inorganic materials.

Acute dermal toxicity : Remarks: No data available

11.2 Skin corrosion/irritation

Not classified based on available information.

Components:

Sodium zirconium cyclosilicate:

Remarks : Unlikely to cause skin irritation.

11.3 Serious eye damage/eye irritation

Not classified based on available information.

Components:

Sodium zirconium cyclosilicate:

Remarks : Dust may cause irritation by analogy with other inorganic materials.

11.4 Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:

Sodium zirconium cyclosilicate:

Species : Guinea pig
Method : Buehler Test
Result : Did not cause sensitization on laboratory animals.

11.5 Germ cell mutagenicity

Not classified based on available information.

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Components:**Sodium zirconium cyclosilicate:**

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

11.6 Carcinogenicity

Not classified based on available information.

Components:**Sodium zirconium cyclosilicate:**

Carcinogenicity - Assessment : Weight of evidence does not support classification as a carcinogen, It is unlikely to present a carcinogenic hazard to man.

IARC No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

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 No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

11.7 Reproductive toxicity

Not classified based on available information.

Components:**Sodium zirconium cyclosilicate:**

Reproductive toxicity - Assessment : No evidence of adverse effects on sexual function and fertility, or on development, based on animal experiments.

11.8 STOT-single exposure

Not classified based on available information.

Components:**Sodium zirconium cyclosilicate:**

Assessment : The substance or mixture is not classified as specific target organ toxicant, single exposure.

11.9 STOT-repeated exposure

Not classified based on available information.

Components:**Sodium zirconium cyclosilicate:**

Routes of exposure : Oral
Remarks : Based on human experience, repeated doses may produce oedema and hypokalaemia.

11.10 Aspiration toxicity

Not classified based on available information.

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Components:

Sodium zirconium cyclosilicate:

No information available.

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Sodium zirconium cyclosilicate:

Toxicity to fish : Remarks: No information available.

Persistence and degradability

Components:

Sodium zirconium cyclosilicate:

Biodegradability : Remarks: No degradation data available. The substance is assumed not to be rapidly degradable.

Bioaccumulative potential

Components:

Sodium zirconium cyclosilicate:

Bioaccumulation : Remarks: Bioaccumulation is unlikely.

Mobility in soil

Components:

Sodium zirconium cyclosilicate:

Mobility : Remarks: No information available.

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).

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SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

- Waste from residues : Disposal should be in accordance with local, state or national legislation.
- Contaminated packaging : Empty container will retain 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

Components	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.

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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

US State Regulations

Massachusetts Right To Know

No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know

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Maine Chemicals of High Concern

This product does not contain any chemicals that are listed as Maine Chemicals of High Concern.

New Jersey Right To Know

Sodium zirconium cyclosilicate 242800-27-7

California Prop. 65

This product does not contain any chemicals known to the State of California to cause cancer, birth, or any other reproductive defects.

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.
Sodium zirconium cyclosilicate

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.

SECTION 16. OTHER INFORMATION

Full text of other abbreviations

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

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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. Occupational Exposure Limit Value

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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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