



Revision Number: 8

# LUMAKRAS®

## Safety Data Sheet

Date Issued 29-Jul-2022

### 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERSTANDING

#### 1.1 Product identifier

**Product Name:** LUMAKRAS®  
**Common Name:** Sotorasib  
**Chemical Name:** 6-fluoro-7-(2-fluoro-6-hydroxyphenyl)-(1M)-1-[4-methyl-2-(propan-2-yl)pyridin-3-yl]-4-[(2S)-2-methyl-4-(prop-2-enoyl)piperazin-1-yl]pyrido[2,3-d]pyrimidin-2(1H)-one  
**Synonyms:** LUMAKRAS® (US), LUMYKRAS® (EU), Sotorasib, AMG 510

#### 1.2 LUMAKRAS® (US), LUMYKRAS® (EU), Sotorasib, AMG 510

**Recommended Use:** Pharmaceutical  
**Uses advised against:** No information available

<b>Manufacturer:</b> Amgen Inc. One Amgen Center Drive Thousand Oaks, California 91320-1799 1-805-447-7233 1-805-447-1000	<b>Emergency Telephone Number:</b> Chemtrec NORTH AMERICA 1-800-424-9300, INTERNATIONAL 1-703-527-3887
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### 2. HAZARDS IDENTIFICATION

#### Emergency Overview

Pharmaceutical product intended for clinical and commercial manufacturing purposes only. Product contains an active pharmaceutical ingredient, sotorasib, intended for treatment of locally advanced or metastatic non-small cell lung cancer (NSCLC). Avoid inhalation, skin contact, eye contact, and accidental ingestion. Does not meet GHS classification criteria and therefore is not classified.

#### 2.1 - Classification of the drug substance or mixture (drug product in final form, not applicable) REGULATION (EC) No 1272/2008

Does not meet GHS classification criteria and therefore is not classified. Not classified

#### 2.2 Label elements

Does not meet GHS classification criteria and therefore is not classified. Not classified

#### 2.3 Other Hazards No information available



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### 3. COMPOSITION/INFORMATION ON INGREDIENTS

#### 3.1 Substances

<b>Ingredients:</b>	Proprietary information
<b>Chemical Name:</b>	6-fluoro-7-(2-fluoro-6-hydroxyphenyl)-(1M)-1-[4-methyl-2-(propan-2-yl)pyridin-3-yl]-4-[(2S)-2-methyl-4-(prop-2-enoyl)piperazin-1-yl]pyrido[2,3-d]pyrimidin-2(1H)-one
<b>CAS-No:</b>	2296729-00-3

### 4. FIRST AID MEASURES

#### 4.1 Description of first-aid measures

<b>Eye Contact:</b>	In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
<b>Skin Contact:</b>	Wash off immediately with soap and plenty of water removing all contaminated clothes and shoes. Consult a physician if necessary.
<b>Inhalation:</b>	Move to fresh air. If symptoms persist, call a physician.
<b>Ingestion:</b>	If symptoms persist, call a physician. Do not induce vomiting without medical advice. Never give anything by mouth to an unconscious person.
<b>Notes to Physician:</b>	Treat symptomatically.

### 5. FIRE-FIGHTING MEASURES

#### 5.1 Extinguishing media

<b>Flammable Properties:</b>	No information available.
<b>Extinguishing Media:</b>	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

#### 5.2 Special hazards arising from the substance or mixture

<b>Hazardous Combustion Products:</b>	No information available.
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#### 5.3 Advice for firefighters

<b>Protective Equipment and Precautions for Firefighters:</b>	As in any fire, wear self-contained breathing apparatus pressure-demand, NIOSH (approved) and full protective gear.
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### 6. ACCIDENTAL RELEASE MEASURES

#### 6.1 Personal precautions, protective equipment and emergency procedures

**Spill Procedures:**

If material is released or spilled, cordon off spill area. Take proper precautions to minimize exposure by using appropriate personal protective equipment in cleaning up a spill. If in powder form, wet down spilled material to minimize airborne dispersion. Soak up material with absorbent e.g., paper towels, and wash spill area thoroughly with appropriate cleaning materials. Dispose of collected material in accordance with applicable waste disposal regulations. Avoid release to the environment.

### 7. HANDLING AND STORAGE

#### 7.1 Precautions for Safe Handling

**Handling and Storage:**

Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke in work areas. Use adequate ventilation to minimize exposure. Wash hands, face and other potentially exposed areas immediately after handling this material. Remove contaminated clothing prior to entering eating areas. Clean protective equipment thoroughly after each use. Store in a well ventilated area.



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### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### 8.1 Control parameters

**Occupational Exposure Limit:** No exposure guidelines established by ACGIH, NIOSH or OSHA. Amgen recommends an occupational exposure limit (OEL) of 24 µg/m<sup>3</sup> as an 8-hour time weighted average over a 40-hour work week. The OEL is designed as an acceptable airborne concentration of a substance for which it is believed that workers may be repeatedly exposed day after day without adverse health effects. Sotorasib has been classified per Amgen's Hazard Classification System as an Occupational Exposure Band 3 compound (20 µg/m<sup>3</sup> - 100 µg/m<sup>3</sup>).

**Engineering Controls:** When practicable, handle material in enclosed processes or in processes with effective local exhaust ventilation or within a chemical hood.

#### 8.2 Exposure controls

##### Personal Protective Equipment

**Eye/face Protection:** Wear safety glasses with side shields, chemical splash goggles, or safety glasses with side shields and a full-face shield to prevent contact with eyes. The choice of protection should be based on the job activity and potential for exposure to the eyes and face.

**Skin Protection:** Use gloves or other appropriate personal protective equipment if skin contact with formulation is possible. Wear lab coat or other protective over garment if splashing is possible. The choice of protection should be based on the job activity and potential for skin contact.

**Respiratory Protection:** When possible, handle material in enclosed processes or containers. If it is properly handled with effective local exhaust ventilation or containment, respiratory protection may not be needed. For procedures involving larger quantities or dust/aerosol generating procedures such as weighing or a large transfer of liquids, an air-purifying respirator with NIOSH approval for dusts and mists may be needed. The choice of protection should be based on the job activity and the potential for exposure.

**Other:** Wash hands, face and other potentially exposed areas after handling material (especially before eating, drinking or smoking). Clean protective equipment thoroughly after each use.

#### 8.3 Environmental exposure controls

**Environmental Exposure Controls** Avoid release to the environment.



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### 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Appearance:</b>	White to Light Brown
<b>Physical State:</b>	Powder
<b>Molecular Weight:</b>	560 Da
<b>Odor:</b>	No information available
<b>Odor Threshold:</b>	No information available
<b>pH:</b>	5.6
<b>Melting point (°C) VALUE</b>	No information available
<b>Flash Point:</b>	No information available
<b>Evaporation Rate:</b>	No information available
<b>Lower explosive limit:</b>	No information available
<b>Upper explosive limit:</b>	No information available
<b>Vapor Pressure:</b>	No information available
<b>Vapor Density (air = 1):</b>	No information available
<b>Relative density:</b>	No information available
<b>Water Solubility:</b>	Water (pH 7= 0.01 g/L)
<b>Partition Coefficient (log Kow):</b>	pH 5 - 2.36, pH 7 - 2.44, and pH 9 - 1.77
<b>Viscosity:</b>	No information available



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### 10. STABILITY AND REACTIVITY

<b>10.1 Reactivity</b>	No information available
<b>10.2 Chemical stability</b>	No information available
<b>10.3 Possibility of hazardous reactions</b>	No information available
<b>10.4 Conditions to avoid</b>	<p>Warning: the active pharmaceutical ingredient in Sotorasib (AMG 510), can form combustible dust concentrations in air during processing and present an explosion hazard risk.</p> <ul style="list-style-type: none"><li>- Minimize dust generation and accumulation. Fine dust dispersed in air in sufficient concentrations and in the presence of an ignition source is a potential dust explosion hazard.</li><li>- Routine housekeeping should be instituted to ensure that dusts do not accumulate on surfaces.</li><li>- Dry powders are sensitive to electrostatic ignition. Provide adequate precautions, such as electrical grounding, bonding, or inert atmospheres for process equipment, and grounding and bonding of personnel who are open handling the powder.</li><li>- Appropriately classified electrical equipment should be used.</li><li>- Explosion hazards should be considered when using dust control equipment, such as local exhaust ventilation, air material separators, portable vacuums, etc.</li><li>- Antistatic or fire-retardant PPE maybe required for the task dependent on risk assessment.</li><li>- Grounding, anti-static tools, and/or an electrically rated vacuum should be used to clean up spills.</li><li>- Refer to NFPA 652, Standard on the Fundamentals of Combustible Dust</li></ul>
<b>10.5 Incompatible materials</b>	No information available
<b>10.6 Hazardous decomposition products</b>	No information available
<b>10.7 Other information</b>	
<b>Dust Explosion Properties:</b>	<p>AMG 510 Ungranulated Pre-Blend (20%): P<sub>max</sub> (bar) - 7.5 K<sub>st</sub> (bar m/s) - 195 MIE (mJ) 10 - 30 Other information: Moisture content - 3.0% by weight, particle size - 74% &lt; 75 µm, Max rate of pressure 718 bar/s</p>
<b>Other:</b>	<p>AMG 510 Ungranulated Pre-Blend (32%): P<sub>max</sub> (bar) - 8.1 ± 10% K<sub>st</sub> (bar m/s) - 80 ± 12% MIE (mJ) 300 &lt; MIE &lt; 1000 Other information: Moisture content - 3.0% by weight, particle size - 40% &lt; 75 µm</p>



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### 11. TOXICOLOGICAL INFORMATION

#### 11.1 Information on toxicological effects

<b>Acute Toxicity:</b>	No information available
<b>Skin corrosion/irritation:</b>	Not corrosive or irritating to the skin per the in vitro EpiDerm assays (UN GHS No Category).
<b>Serious eye damage/eye irritation:</b>	Not corrosive or irritating to the eye per the in vitro BCOP assay (UN GHS No Category).
<b>Respiratory or skin sensitization:</b>	Not a skin sensitizer based on rLLNA assay (UN GHS No Category).
<b>Germ cell mutagenicity:</b>	Not mutagenic or genotoxic in a battery of in vitro and in vivo studies. GHS classification criteria are not met.
<b>Carcinogenicity:</b>	No information available
<b>Reproductive toxicity:</b>	Not a reproductive/development toxicant, GHS classification criteria are not met.
<b>STOT - single exposure:</b>	No information available
<b>STOT - repeated exposure:</b>	No information available
<b>Aspiration Hazard:</b>	No information available

### 12. ECOLOGICAL INFORMATION

#### 12.1 Toxicity

<b>Ecotoxicity effects:</b>	- NOEC (Growth) Algae 8.4 mg/L (OECD 201) - NOEC Daphnia magna (Reproduction) 10 mg/L (OECD 211) - NOEC Fish (fathead minnow) 11 mg/L (OECD 210) - NOEC Activated Sludge Respiration Inhibition Test 1000 mg/L (OECD 209)
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#### 12.2 Persistence and degradability

<b>Persistence/Degradability:</b>	Sotorasib is considered to be very persistent (vP) based on the OECD 308 study results.
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#### 12.3 Bioaccumulative potential

<b>Bioaccumulation/ Accumulation:</b>	The bioaccumulation potential is expected to be low based on the OECD 107 results (log Kow <3)
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#### 12.4 Mobility in soil

<b>Mobility in Environmental Media:</b>	Mobility in Environmental Media: Sotorasib does not significantly adsorb to soil (OECD 106).
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#### 12.5 Results of PBT and vPvB assessment

<b>Results of PBT and vPvB assessment:</b>	Sotorasib should be considered as being very persistent (vP) in freshwater sediment.
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#### 12.6 Other adverse effects

<b>Other Adverse Effects:</b>	Other Adverse Effects: Koc in sewage sludge is < 1000 L/kg, sotorasib is unlikely to reach the soil compartment as a result of spreading of sewage sludge onto agricultural land (OECD 106).
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### 13. DISPOSAL CONSIDERATIONS

#### 13.1 Waste treatment methods

**Waste Disposal Method:** Dispose of waste according to prescribed federal, state, local and competent authority guidelines.

### 14. TRANSPORT INFORMATION

**DOT:** Not regulated by U.S. DOT, IATA, or IMDG.

### 15. REGULATORY INFORMATION

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

##### International Inventories

TSCA:	-
EINECS/ELINCS	-
DSL/NDSL	-
PICCS:	-
ENCS:	-
CHINA:	-
AICS:	-
KECL:	-

##### Legend

**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory  
**EINECS/ELINCS** - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances  
**DSL/NDSL** - Canadian Domestic Substances List/Non-Domestic Substances List  
**PICCS** - Philippines Inventory of Chemicals and Chemical Substances  
**ENCS** - Japan Existing and New Chemical Substances  
**IECSC** - China Inventory of Existing Chemical Substances  
**AICS** - Australian Inventory of Chemical Substances  
**KECL** - Korean Existing and Evaluated Chemical Substances

##### State Regulations

**California Proposition 65:** This product does not contain any Proposition 65 chemicals.

#### 15.2 Chemical safety assessment

No CSA has been conducted.





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### 16. OTHER INFORMATION

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To the best of our knowledge, the information provided here is accurate as of the date of the Safety Data Sheet (SDS). The information is specific to the material that is the subject of this SDS and may not be valid when this material is used in combination with any other materials or in any process. Each user should review the information provided here in the context of the user's intended manner of handling, using, processing, storing, transporting, and disposing of the material.

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