

1. PRODUCT AND COMPANY IDENTIFICATION

1.1 Product identifiers

Product name : Alpelisib

Product Number : 10-4167

Brand : Focus Biomolecules

CAS-No. : 1217486-61-7

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

Identified uses : For Laboratory Research Use Only

1.3 Details of the supplier of the safety data sheet

Company : Focus Biomolecules
400 Davis Drive, Suite 600
Plymouth Meeting, PA 19462

Telephone : +1 855-362-8721

E-mail : support@focusbiomolecules.com

1.4 Emergency telephone number

Emergency Phone # : CHEMTREC within USA/Canada 1-800- 424-9300
CHEMTREC outside USA/Canada 1-703-527-3887

2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

GHS Classification in accordance with 29 CFR 1910 (OSHA HCS)

Skin irritation (Category 2), H315

Reproductive toxicity (Category 1B), H360

Specific Target organ toxicity - repeated exposure (Category 1), H372

Chronic aquatic toxicity (Category 2), H411

For the full text of the H-Statements mentioned in this Section, see Section 16.

2.2 GHS Label elements, including precautionary statements

Pictogram



Signal word Hazard

Danger

statement(s)

H315

Causes skin irritation.

H360

May damage fertility or the unborn child.

H372

Causes damage to organs through prolonged or repeated exposure

H411

Toxic to aquatic life with long lasting effects.

Precautionary statement(s)

P201

Obtain special instructions before use.

P202

Do not handle until all safety precautions have been read and understood.

P264

Wash skin thoroughly after handling.

P270	Do not eat, drink or smoke when using this product.
P273	Avoid release to the environment.
P280	Wear protective gloves/ protective clothing/ eye protection/ face protection.
P302 + P352	If of skin: Wash with plenty of water
P308 + P313	IF exposed or concerned: Get medical advice/ attention.
P314	Get medical attention if you feel unwell
P391	Collect spillage.
P405	Store locked up.
P501	Dispose of contents/ container to an approved waste disposal plant.

2.3 Hazards not otherwise classified (HNOC) or not covered by GHS - none

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Synonyms	: BYL719; NVP-BYL719 (2S)-1-N-[4-Methyl-5-[2-(1,1,1-trifluoro-2-methylpropan-2-yl)pyridine-4-yl]-1,3-thiazol-2-yl]pyrrolidine-1,2-dicarboxamide
Formula	: C ₁₉ H ₂₂ F ₃ N ₅ O ₂ S
Molecular weight	: 441.47 g/mol
CAS-No.	: 1217486-61-7
EC-No.	: 806-598-7

Hazardous components

Component	Classification	Concentration
Alpelisib		
	Skin Irrt. 2; Repr. 1B; Spec Org Tox 1; Aquatic Chronic 2; H315, H360, H372, H411	90 - 100 %

For the full text of the H-Statements mentioned in this Section, see Section 16.

4. FIRST AID MEASURES

4.1 Description of first aid measures

General advice

Consult a physician. Show this safety data sheet to the doctor in attendance. Move out of dangerous area.

If inhaled

If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

In case of skin contact

Wash off with soap and plenty of water. Take victim immediately to hospital. Consult a physician.

In case of eye contact

Flush eyes with water as a precaution.

If swallowed

Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

4.2 Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11

4.3 Indication of any immediate medical attention and special treatment needed

No data available

5. FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

5.2 Special hazards arising from the substance or mixture

No data available

5.3 Advice for firefighters

Wear self-contained breathing apparatus for firefighting if necessary.

5.4 Further information

No data available

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Wear respiratory protection. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.

For personal protection see section 8.

6.2 Environmental precautions

Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided.

6.3 Methods and materials for containment and cleaning up

Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal.

Reference to other sections

6.4 For disposal see section 13.

7. HANDLING AND STORAGE

7.1 Precautions for safe handling

Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Further processing of solid materials may result in the formation of combustible dusts. The potential for combustible dust formation should be taken into consideration before additional processing occurs.

Provide appropriate exhaust ventilation at places where dust is formed.

For precautions see section 2.2.

7.2 Conditions for safe storage, including any incompatibilities

Keep container tightly closed in a dry and well-ventilated place.

Keep in a dry place.

Storage class (TRGS 510): 6.1B: Non-combustible

7.3 Specific end use(s)

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Components with workplace control parameters

Contains no substances with occupational exposure limit values.

Hazardous components without workplace control parameters

8.2 Exposure controls

Appropriate engineering controls

Avoid contact with skin, eyes and clothing. Wash hands before breaks and immediately after handling the product.

Personal protective equipment

Eye/face protection

Face shield and safety glasses Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin protection

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

Full contact

Material: Nitrile rubber

Minimum layer thickness: 0.11 mm

Break through time: 480 min

Material tested:Dermatril® (KCL 740 / Aldrich Z677272, Size M)

Splash contact

Material: Nitrile rubber

Minimum layer thickness: 0.11 mm

Break through time: 480 min

Material tested:Dermatril® (KCL 740 / Aldrich Z677272, Size M)

data source: KCL GmbH, D-36124 Eichenzell, phone +49 (0)6659 87300, e-mail sales@kcl.de, test method: EN374

If used in solution, or mixed with other substances, and under conditions which differ from EN 374, contact the supplier of the CE approved gloves. This recommendation is advisory only and must be evaluated by an industrial hygienist and safety officer familiar with the specific situation of anticipated use by our customers. It should not be construed as offering an approval for any specific use scenario.

Body Protection

Complete suit protecting against chemicals, The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Respiratory protection

Where risk assessment shows air-purifying respirators are appropriate use a full-face particle respirator type N100 (US) or type P3 (EN 143) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Control of environmental exposure

Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

- | | |
|--|-------------------------------|
| a) Appearance | Form: powder
Colour: white |
| b) Odour | No data available |
| c) Odour Threshold | No data available |
| d) pH | No data available |
| e) Melting point/freezing point | No data available |
| f) Initial boiling point and boiling range | No data available |
| g) Flash point | No data available |
| h) Evaporation rate | No data available |
| i) Flammability (solid, gas) | No data available |
| j) Upper/lower flammability or | No data available |

explosive limits

- | | | |
|----|--|----------------------|
| k) | Vapour pressure | No data available |
| l) | Vapour density | No data available |
| m) | Relative density | No data available |
| n) | Water solubility | slightly soluble log |
| o) | Partition coefficient: n-octanol/water | No data available |
| p) | Auto-ignition temperature | No data available |
| q) | Decomposition temperature | No data available |
| r) | Viscosity | No data available |
| s) | Explosive properties | No data available |
| t) | Oxidizing properties | No data available |

9.2 Other safety information

No data available

10. STABILITY AND REACTIVITY

10.1 Reactivity

No data available

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

No data available

10.4 Conditions to avoid

No data available

10.5 Incompatible materials

Bases, Strong oxidizing agents, Acid anhydrides, Acid chlorides

10.6 Hazardous decomposition products

Hazardous decomposition products formed under fire conditions. - Carbon oxides, Nitrogen oxides (NO_x), sulfur oxides, hydrogen fluoride. Other decomposition products - No data available
In the event of fire: see section 5

11. TOXICOLOGICAL INFORMATION 11.1

Information on toxicological effects

Acute toxicity No data available

Inhalation: No data available

Dermal: No data available

No data available

Skin corrosion/irritation

No data available

Serious eye damage/eye irritation

No data available

Respiratory or skin sensitisation

Prolonged or repeated exposure may cause allergic reactions in certain sensitive individuals.

Germ cell mutagenicity

Laboratory experiments have shown reproductive effects.

Carcinogenicity

- IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.
- NTP: No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.
- OSHA: No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

Reproductive toxicity

May cause congenital malformation in the fetus.

Presumed human reproductive toxicant

No data available

Specific target organ toxicity - single exposure

No data available

Specific target organ toxicity - repeated exposure

No data available

Aspiration hazard

No data available

Additional Information

RTECS: N/A

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

12. ECOLOGICAL

INFORMATION 12.1 Toxicity

No data available

12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

No data available

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

PBT/vPvB assessment not available as chemical safety assessment not required/not conducted

12.6 Other adverse effects

Toxic to aquatic life with long lasting effects.

An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.

13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product

Contact a licensed professional waste disposal service to dispose of this material. Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber. Offer surplus and non-recyclable solutions to a licensed disposal company.

Contaminated packaging

Dispose of as unused product.

14. TRANSPORT INFORMATION

DOT (US)

UN number: 3077 Class: 6.1 Packing group: III Proper
shipping name: Toxic solids, organic, n.o.s. (Alpelisib) Reportable Quantity
(RQ):
Poison Inhalation Hazard: No

IMDG

UN number: 3077 Class: 6.1 Packing group: III Proper EMS-No: F-A, S-A
shipping name: TOXIC SOLID, ORGANIC, N.O.S. (Alpelisib) Marine
pollutant:yes

IATA

UN number: 3077 Class: 6.1 Packing group: III Proper
shipping name: Toxic solid, organic, n.o.s. (Alpelisib)

15. REGULATORY INFORMATION

SARA 302 Components

	CAS-No.	Revision Date
Alpelisib	1217486-61-7	04/16/2025

SARA 313 Components

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.

SARA 311/312 Hazards

Acute Health Hazard, Chronic Health Hazard

Massachusetts Right To Know Components

	CAS-No.	Revision Date
Alpelisib	1217486-61-7	04/16/2025

Pennsylvania Right To Know

Components

	CAS-No.	Revision Date
Alpelisib	1217486-61-7	04/16/2025

Alpelisib

California Prop. 65 Components

	CAS-No.	Revision Date
Alpelisib	1217486-61-7	04/16/2025

, which is/are known to the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.
Alpelisib

16. OTHER INFORMATION

Full text of H-Statements referred to under sections 2 and 3.

H315	Causes skin irritation
H360	May damage fertility or the unborn child.
H372	Causes damage to organs through prolonged or repeated exposure
H411	Toxic to aquatic life with long lasting effects.

Further information

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