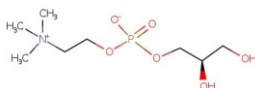


SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product form : Substance
Substance name : ALPHASIZE 100P
EC-No. : 248-962-2
CAS-No. : 28319-77-9
Formula : C₈H₂₀NO₆P
Chemical structure :



Distributed by:

Univar Solutions USA

3075 Highland Pkwy Ste 200
Downers Grove, IL 60515
Telephone: 1-855-429-2661
Emergency phone number:
CHEMTREC 1-800-424-9300

Synonyms : sn-Glycero-3-phosphorylcholine
GLYCERYLPHOSPHORYLCOLINE
Alfa GPC 100%

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

1.2.1. Relevant identified uses

Use of the substance/mixture : Ingredient for pharmaceutical industry - Nootropic nutrient

1.2.2. Uses advised against

Restrictions on use : Other uses are not expected

1.3. Details of the supplier of the safety data sheet

Chemi S.p.A.
via Vadisi, 5
03100 Patrica (FR)
Italy
T +39-0775-2581

f.cameracanna@italfarmacogroup.com

E-mail address of competent person responsible for the SDS : a.conto@chemsafe-consulting.com (Dr. Antonio Conto)

1.4. Emergency telephone number

Emergency number : +39-0775-2581
Office schedule

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not classified

Adverse physicochemical, human health and environmental effects

Under normal conditions of use, the mixture does not cause adverse effects to humans and to the environment. Any additional information concerning the risks for health and/or the environment are given in sections 11 and 12 of this sheet.

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

No labelling applicable

2.3. Other hazards

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII
This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

The substance is not included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605

SECTION 3: Composition/information on ingredients

3.1. Substances

Substance type : Mono-constituent
Name : ALPHASIZE 100P
CAS-No. : 28319-77-9
EC-No. : 248-962-2

Name	Product identifier	Conc. % w/w	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Choline Alfoscerate	CAS-No.: 28319-77-9 EC-No.: 248-962-2	100	Not classified

3.2. Mixtures

Not applicable

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing.
First-aid measures after skin contact : Wash skin with plenty of water.
First-aid measures after eye contact : Rinse eyes with water as a precaution.
First-aid measures after ingestion : Call a poison center or a doctor if you feel unwell.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/effects after skin contact : May be irritant for skin.
Symptoms/effects after eye contact : May cause eye irritation.
Symptoms/effects after ingestion : Ingestion may cause abdominal and stomach pain.

4.3. Indication of any immediate medical attention and special treatment needed

Based on the risk assessment of dangerous chemical agents, the competent physician will adopt the most appropriate medical monitoring protocol to protect the health status of workers, in accordance with Article 10 of Directive 98/24/CEE (Title IX of Legislative Decree 81 of 9 April 2008 and subsequent amendments).

No specific antidotes and contraindications are known.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Water spray. Dry powder. Foam. Carbon dioxide.
Unsuitable extinguishing media : No unsuitable extinguishing media were identified.

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire : Thermal decomposition or combustion may generate toxic and hazardous fumes of COx, NOx.

5.3. Advice for firefighters

Protection during firefighting : Do not try to extinguish the fire without using an autonomous respiratory device (SCBA) and suitable protective clothing. Wear boots, gloves, overalls, eye and face protection, suitable respirators, compliant with the relevant UNI / EN standards. Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Protective equipment : Wear recommended personal protective equipment.
Emergency procedures : Ventilate spillage area. Avoid breathing vapours, fume.

6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

Avoid release to the environment. Prevent entry to sewers and public waters.

6.3. Methods and material for containment and cleaning up

For containment : Stop leak without risks if possible.
Methods for cleaning up : Mechanically recover the product.
Other information : Dispose of materials or solid residues at an authorized site.

6.4. Reference to other sections

For further information refer also to sections 8 and 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Ensure good ventilation of the work station. Wear personal protective equipment. Handle in a well ventilated place, and away from sparks and flames - sources of ignition. Keep the mixture away from drains, surface or ground waters. Avoid contact with incompatible materials. Wear suitable Personal Protection Equipment (see section 8).
Hygiene measures : Remove contaminated clothing and personal protective equipments (PPE) before entering eating areas. Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a dry place. Store in original container. Keep container tightly closed. Store in a well-ventilated place. Keep cool.
Storage temperature : 15 – 25 °C
Heat and ignition sources : Keep away from heat sources and direct sunlight.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection**8.1. Control parameters****8.1.1 National occupational exposure and biological limit values**

No additional information available

8.1.2. Recommended monitoring procedures**Monitoring methods****Monitoring methods**

The measurement of substances in the workplace must be carried out with standardized methods (e.g. UNI EN 689:2019: Workplace atmospheres - Guide for assessment of exposure by inhalation to chemical agents for comparison with limit values and measurement strategy; UNI EN 482:2015: Workplace exposure - General requirements for the performance of procedures for the measurement of chemical agents) or, failing that, with appropriate methods.

8.1.3. Air contaminants formed

No additional information available

8.1.4. DNEL and PNEC

No additional information available

8.1.5. Control banding

No additional information available

8.2. Exposure controls**8.2.1. Appropriate engineering controls****Appropriate engineering controls:**

Appropriate risk management measures, that must be adopted at the workplace, have to be selected and applied, following the risks assessment carried out by the employer, in connection with his working activity. If the results of this evaluation show that the general and collective prevention measures are not sufficient to reduce the risk, and if you cannot prevent exposure to the mixture by other means, adequate personal protective equipment must be adopted, complying with the relevant technical national/international standards. Ensure good ventilation of the work station.

8.2.2. Personal protection equipment**Personal protective equipment:**

Wear recommended personal protective equipment.

8.2.2.1. Eye and face protection**Eye protection:**

Wear protective tightly fitting glasse or protective visor (EN 166).

8.2.2.2. Skin protection**Skin and body protection:**

Choose the appropriate protective medium according to the activity and the exposure, e.g. apron, boots, suitable clothing according to EN 13982 in case of powders.

Hand protection:

Wear protective gloves complying with Directive 89/686/CEE and the standards EN 374. Consider the manufacturer's information regarding permeability, time of penetration, and workplace conditions (mechanical stress, time of contact). The use of a proper cream may prevent skin dryness.

8.2.2.3. Respiratory protection**Respiratory protection:**

In case of insufficient ventilation, wear suitable respiratory equipment

8.2.2.4. Thermal hazards**Thermal hazard protection:**

No additional information available.

8.2.3. Environmental exposure controls

Environmental exposure controls:

Avoid release to the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Colour	: white.
Appearance	: Crystalline powder.
Molecular mass	: 257.1 g/mol
Odour	: characteristic.
Odour threshold	: Not available
Melting point	: 141 °C
Freezing point	: Not applicable
Boiling point	: 480 °C
Flammability	: Non flammable.
Explosive properties	: Not explosive.
Explosive limits	: Not applicable
Lower explosion limit	: Not applicable
Upper explosion limit	: Not applicable
Flash point	: Not applicable
Auto-ignition temperature	: Not applicable
Decomposition temperature	: Not available
pH	: 5 – 7
pH solution	: Not available
Viscosity, kinematic	: Not applicable
Solubility	: Water: Soluble Organic solvent: Soluble in methanol
Partition coefficient n-octanol/water (Log Kow)	: Not available
Partition coefficient n-octanol/water (Log Pow)	: -5.15 at 25°C
Vapour pressure	: Not available
Vapour pressure at 50 °C	: Not available
Density	: Not available
Relative density	: 1.27
Relative vapour density at 20 °C	: Not applicable
Particle size	: Not available
Particle size distribution	: Not available
Particle shape	: Not available
Particle aspect ratio	: Not available
Particle aggregation state	: Not available
Particle agglomeration state	: Not available
Particle specific surface area	: Not available
Particle dustiness	: Not available

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

Keep away from heat and light. Air contact. Moisture.

10.5. Incompatible materials

Strong oxidizing agents.

10.6. Hazardous decomposition products

Thermal decomposition or combustion may generate toxic and hazardous fumes of CO_x, NO_x.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral) : Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (dermal) : Not classified (Data not available in the bibliographic research performed.)
Acute toxicity (inhalation) : Not classified (Data not available in the bibliographic research performed.)

ALPHASIZE 100P (28319-77-9)

LD50 oral	> 13000 mg/kg mouse
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Choline Alfoscerate (28319-77-9)

LD50 oral	> 13000 mg/kg mouse
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Skin corrosion/irritation : Not classified (Data not available in the bibliographic research performed.)
pH: 5 – 7

Additional information : Choline Alfoscerate: tests performed had shown no skin irritation potential.

Choline Alfoscerate (28319-77-9)

pH	5 – 7
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Serious eye damage/irritation : Not classified (Data not available in the bibliographic research performed.)
pH: 5 – 7

Choline Alfoscerate (28319-77-9)

pH	5 – 7
----	-------

Respiratory or skin sensitisation : Not classified (Data not available in the bibliographic research performed.)
Germ cell mutagenicity : Not classified (Data not available in the bibliographic research performed.)
Additional information : Choline Alfoscerate: no mutagenic potential seen after performing in vitro and in vivo tests.
Carcinogenicity : Not classified (Data not available in the bibliographic research performed.)
Reproductive toxicity : Not classified (Data not available in the bibliographic research performed.)

ALPHASIZE 100P (28319-77-9)

Additional information	No effects seen in animals; not teratogenic in rats or rabbits.
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Choline Alfoscerate (28319-77-9)

Additional information	No effects seen in animals; not teratogenic in rats or rabbits.
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STOT-single exposure : Not classified (Data not available in the bibliographic research performed.)
STOT-repeated exposure : Not classified (Data not available in the bibliographic research performed.)
Aspiration hazard : Not classified (Data not available in the bibliographic research performed.)

ALPHASIZE 100P (28319-77-9)

Viscosity, kinematic	Not applicable
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11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Adverse health effects caused by endocrine disrupting properties

: On the basis of the available data, the substance does not meet the criteria for the identification of substances having properties of interference with the endocrine system, in accordance with Article 59, paragraph 1 of the REACH Regulation and the criteria established in the Delegated Regulation (EU) 2017 / 2100 of the Commission or in Commission Regulation (EU) 2018/605.

11.2.2. Other information

No additional information available

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general	: The product is not considered harmful to aquatic organisms nor to cause long-term adverse effects in the environment.
Hazardous to the aquatic environment, short-term (acute)	: Not classified (Data not available in the bibliographic research performed.)
Hazardous to the aquatic environment, long-term (chronic)	: Not classified (Data not available in the bibliographic research performed.)

12.2. Persistence and degradability

ALPHASIZE 100P (28319-77-9)

Persistence and degradability	Not biodegradable.
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Choline Alfoscerate (28319-77-9)

Persistence and degradability	Not biodegradable.
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12.3. Bioaccumulative potential

ALPHASIZE 100P (28319-77-9)

Partition coefficient n-octanol/water (Log Pow)	-5.15 at 25°C
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Choline Alfoscerate (28319-77-9)

Partition coefficient n-octanol/water (Log Pow)	-5.15 at 25°C
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12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

ALPHASIZE 100P (28319-77-9)

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

12.6. Endocrine disrupting properties

Adverse effects on the environment caused by endocrine disrupting properties

: On the basis of the available data, the substance does not meet the criteria for the identification of substances having properties of interference with the endocrine system, in accordance with Article 59, paragraph 1 of the REACH Regulation and the criteria established in the Delegated Regulation (EU) 2017 / 2100 of the Commission or in Commission Regulation (EU) 2018/605.

12.7. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Regional legislation (waste)

: Disposal must be done according to official regulations.

Waste treatment methods

: Dispose of contents/container in accordance with licensed collector's sorting instructions.

Ecology - waste materials

: Avoid release to the environment.

SECTION 14: Transport information

In accordance with ADR / IMDG / IATA / RID

ADR	IMDG	IATA	RID
14.1. UN number or ID number			
Not applicable	Not applicable	Not applicable	Not applicable
14.2. UN proper shipping name			
Not applicable	Not applicable	Not applicable	Not applicable
14.3. Transport hazard class(es)			
Not applicable	Not applicable	Not applicable	Not applicable
14.4. Packing group			
Not applicable	Not applicable	Not applicable	Not applicable
14.5. Environmental hazards			
Not applicable	Not applicable	Not applicable	Not applicable
No supplementary information available			

14.6. Special precautions for user

Overland transport

Not applicable

Transport by sea

Not applicable

Air transport

Not applicable

Rail transport

Not applicable

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

Other information, restriction and prohibition regulations

: Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work (Official Journal L 183, 29/06/1989 P. 0001 – 0008) and following amendment and National reinforcements.
REGULATION (EU) 2016/425 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC.
Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) Official Journal L 131, 05/05/1998 P. 0011 – 0023.

REACH Annex XVII (Restriction List)

No REACH Annex XVII restrictions

REACH Annex XIV (Authorisation List)

ALPHASIZE 100P is not on the REACH Annex XIV List

REACH Candidate List (SVHC)

ALPHASIZE 100P is not on the REACH Candidate List

PIC Regulation (Prior Informed Consent)

ALPHASIZE 100P is not subject to Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals.

POP Regulation (Persistent Organic Pollutants)

ALPHASIZE 100P is not subject to Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants

Ozone Regulation (1005/2009)

ALPHASIZE 100P is not subject to REGULATION (EU) No 1005/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 September 2009 on substances that deplete the ozone layer.

Explosives Precursors Regulation (2019/1148)

Contains no substance subject to Regulation (EU) 2019/1148 of the European Parliament and of the Council of 20 June 2019 on the marketing and use of explosives precursors.

Drug Precursors Regulation (273/2004)

Contains no substance subject to Regulation (EC) 273/2004 of the European Parliament and of the Council of 11 February 2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances.

15.1.2. National regulations

Germany

Employment restrictions : Observe restrictions according Act on the Protection of Working Mothers (MuSchG).
Observe restrictions according Act on the Protection of Young People in Employment (JArbSchG).
Water hazard class (WGK) : Not classified according to Regulation Governing Systems for Handling Substances Hazardous to Waters (AwSV).
Hazardous Incident Ordinance (12. BImSchV) : Is not subject of the Hazardous Incident Ordinance (12. BImSchV)

Netherlands

SZW-lijst van kankerverwekkende stoffen : The substance is not listed

SZW-lijst van mutagene stoffen : The substance is not listed
SZW-lijst van reprotoxische stoffen – Borstvoeding : The substance is not listed
SZW-lijst van reprotoxische stoffen – : The substance is not listed
Vruchtbaarheid
SZW-lijst van reprotoxische stoffen – Ontwikkeling : The substance is not listed

Switzerland

Storage class (LK) : NG - Non-hazardous

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Indication of changes:

Edition 01, dated 9/23/2015;

Version 01, dated 11/4/2015 : In accordance with Regulation (EU) no. 2015/830;

Version 02, dated 6/17/2022 : Changes from the previous version of the following sections: 1-16, according to Regulation 2020/878.

Abbreviations and acronyms:	
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ATE	Acute Toxicity Estimate
BCF	Bioconcentration factor
BLV	Biological limit value
BOD	Biochemical oxygen demand (BOD)
COD	Chemical oxygen demand (COD)
DMEL	Derived Minimal Effect level
DNEL	Derived-No Effect Level
EC-No.	European Community number
EC50	Median effective concentration
EN	European Standard
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
NOAEC	No-Observed Adverse Effect Concentration
NOAEL	No-Observed Adverse Effect Level
NOEC	No-Observed Effect Concentration
OECD	Organisation for Economic Co-operation and Development
OEL	Occupational Exposure Limit
PBT	Persistent Bioaccumulative Toxic

Abbreviations and acronyms:

PNEC	Predicted No-Effect Concentration
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
SDS	Safety Data Sheet
STP	Sewage treatment plant
ThOD	Theoretical oxygen demand (ThOD)
TLM	Median Tolerance Limit
VOC	Volatile Organic Compounds
CAS-No.	Chemical Abstract Service number
N.O.S.	Not Otherwise Specified
vPvB	Very Persistent and Very Bioaccumulative
ED	Endocrine disrupting properties

Data sources : ECHA Database. SDS suppliers. ChemIDplus Lite.

Training advice : Adequately train workers potentially exposed to this substance on the basis of the contents of this safety data sheet. The training of workers must include contents, updates and duration according to the risk profiles assigned to the working sectors to which they belong, according to the procedures provided for by Legislative Decree 81/2008.

Safety Data Sheet (SDS), EU

The document aims to provide guidance for appropriate handling and precaution of this product by qualified personnel or operating under the supervision of personnel trained in handling chemicals. The product should not be used for purposes other than those mentioned in section 1, unless they are given adequate written information received on how to handle the material.

The provider of this document cannot provide any warnings related to the dangers of using, interaction with other materials or chemicals or user's safe use of the product, the suitability of the product for which is applied or its proper disposal. The information above should not be considered a declaration or guarantee, either expressed or implied, of merchantability, fitness for a particular purpose, quality, or any other.