

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

1.1. Product identifier

Chemical type : Mixture
 Trade name : Calcium Carbonate CS95 Granulation
 SDS code : E089

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

1.2.1. Relevant identified uses

Use of the substance/preparation : Food/pharmaceutical products.

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

SPI Pharma
 Chemin du Vallon du Maire
 Septemes – France
 T 33 4 91 96 36 00 - F 33 4 91 65 39 03
CBlasquez@spipharma.com

SPI Pharma, Inc. Emergency: (800) 424-9300 CHEMTREC

1.4. Emergency telephone number

No additional information available

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Not classified

Classification according to Directive 67/548/EEC or 1999/45/EC

Not classified

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements

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

No labelling applicable

Labelling according to Directive 67/548/EEC or 1999/45/EC

No labelling applicable

2.3. Other hazards

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

other hazards which do not result in classification : Excessive ingestion of calcium carbonate may cause hypercalcemia, alkalosis, nephrocalcinosis and azotemia.

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%	Classification according to Directive 67/548/EEC
Calcium carbonate	(CAS No.) 471-34-1 (EC no) 207-439-9	96	Not classified
Cornstarch	(CAS No.) 9005-25-8 (EC no) 232-679-6	4	Not classified
Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Calcium carbonate	(CAS No.) 471-34-1 (EC no) 207-439-9	96	Not classified
Cornstarch	(CAS No.) 9005-25-8 (EC no) 232-679-6	4	Not classified

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according to Regulation (EC) No. 453/2010

SECTION 4: First aid measures

4.1. Description of first aid measures

- First-aid measures after inhalation : If respiratory irritation occurs upon inhalation, remove to fresh air. Seek medical attention if symptoms develop or persist.
- First-aid measures after skin contact : Wash with water and soap. If skin irritation persists, seek medical attention.
- First-aid measures after eye contact : Immediately flush eyes thoroughly with water for at least 15 minutes. If eye irritation persists, take medical advice.
- First-aid measures after ingestion : If a large quantity has been ingested : Immediately get medical attention. Do not induce vomiting. Never give anything by mouth to an unconscious person.

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

- Symptoms/injuries after inhalation : Overexposure may be irritating to the respiratory system.
- Symptoms/injuries after skin contact : Not expected to be an irritant. Repeated or prolonged skin contact may cause irritation.
- Symptoms/injuries after eye contact : Dust from this product may cause eyes irritation. Significant irritation would not be expected.
- Symptoms/injuries after ingestion : Ingestion of small amounts would not be expected to produce toxicity.

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

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

- Suitable extinguishing media: : carbon dioxide (CO₂), dry chemical powder, foam. Water spray.
- Unsuitable extinguishing media : Do not use a solid water stream as it may scatter and spread fire.

5.2. Special hazards arising from the substance or mixture

- Fire hazard : Carbon dioxide. On combustion forms: Carbon monoxide. Calcium oxides. irritating gases.
- Reactivity : This product can react with oxidizing materials. calcium carbonate ignites on contact with fluorine.

5.3. Advice for firefighters

- Protective equipment for firefighters : Extra personal protection: complete protective clothing including self-contained breathing apparatus.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

- Protective equipment : Refer to section 8.

6.1.2. For emergency responders

- Protective equipment : Refer to section 8. Wear suitable protective clothing.
- Emergency procedures : If possible, stop flow of product. This may cause a slippery condition on floors.

6.2. Environmental precautions

Avoid discharge to the environment. Do not discharge into drains or the environment. Do not discharge into surface water.

6.3. Methods and material for containment and cleaning up

- For containment : contain the discharged material.
- Methods for cleaning up : Collect spills and put it into appropriated container. Thoroughly wash the area with water after a spill or leak clean-up. Wear suitable protective clothing.
- Other information : If spilled, may cause the floor to be slippery.

6.4. Reference to other sections

Refer to sections 8 and 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

- Precautions for safe handling : avoid breathing dust. Avoid contact with skin and eyes. Prevent physical damage to package.
- Hygiene measures : Wash hands thoroughly after handling. Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

- Storage condition(s) : Store container in a well ventilated position. Keep container tightly closed and dry. keep away from incompatible materials.
- Incompatible materials : Strong acid. Strong bases. Oxidizing agent. Fluorine. ammonium salts.
- Special rules on packaging : Prevent physical damage to package.

7.3. Specific end use(s)

No additional information available

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SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Calcium carbonate (471-34-1)		
France	VME (mg/m ³)	10 mg/m ³
France	Note (FR)	inhalable aerosol
Italy - Portugal - USA ACGIH	ACGIH TWA (mg/m ³)	10 mg/m ³
USA NIOSH	NIOSH REL (TWA) (mg/m ³)	10.5 mg/m ³
Spain	VLA-ED (mg/m ³)	10 mg/m ³
Spain	Notes	inhalable aerosol
Switzerland	VME (mg/m ³)	3 mg/m ³
Switzerland	Remark (CH)	respirable aerosol
The Netherlands	MAC TGG 8H (mg/m ³)	10 mg/m ³
The Netherlands	MAC C (mg/m ³)	5 mg/m ³ Inhalable dust - VME :
United Kingdom	WEL TWA (mg/m ³)	10 mg/m ³ inhalable aerosol 4 mg/m ³ respirable aerosol
Hungary	AK-érték	10 mg/m ³
Hungary	Megjegyzések (HU)	inhalable aerosol
Poland	NDS (mg/m ³)	10 mg/m ³
Poland	Remark (PL)	pyly
Canada (Quebec)	VEMP (mg/m ³)	10 mg/m ³

Cornstarch (9005-25-8)		
Belgium	Limit value (mg/m ³)	10 mg/m ³
Italy - Portugal - USA ACGIH	ACGIH TWA (mg/m ³)	10 mg/m ³
Spain	VLA-ED (mg/m ³)	10 mg/m ³
Switzerland	VME (mg/m ³)	3 mg/m ³
United Kingdom	WEL TWA (mg/m ³)	10 total inhalable
United Kingdom	WEL TWA (mg/m ³)	4 mg/m ³ total respirable
Ireland	OEL (8 hours ref) (mg/m ³)	10 mg/m ³ total inhalable
Ireland	OEL (8 hours) (mg/m ³)	4 mg/m ³ total respirable

8.2. Exposure controls

Appropriate engineering controls : Provide local exhaust or general room ventilation to minimize exposure to dust.
 Personal protective equipment : Safety glasses. Gloves.



Hand protection : Wear impervious gloves for prolonged contact.
 Eye protection : Safety glasses with side-shield. Chemical goggles if dust is generated.
 Respiratory protection : In case of insufficient ventilation, wear suitable respiratory equipment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Solid
 Appearance : free-flowing powder. granular.
 Colour : white.
 Odour : slight.
 Odour threshold : No data available
 pH : 9.9
 Melting point : No data available
 Solidification point : No data available
 Boiling point : No data available
 Flash point : No data available
 Relat. evapor. rate comp. to butylacetate : No data available
 Flammability (solid, gas) : 380 °C dust/air (Starch <200 mesh)
 Explosive limits : No data available

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Vapour pressure	: Not applicable
Relative vapour density at 20 °C	: Not applicable
Relative density	: 2.7 g/cm ³ Calcium carbonate
Solubility	: Water: 13 mg/l Calcium carbonate
Log Pow	: No data available
Self ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

This product can react with oxidizing materials. calcium carbonate ignites on contact with fluorine.

10.2. Chemical stability

Stable at ambient temperature and under normal conditions of use.

10.3. Possibility of hazardous reactions

Hazardous polymerization has not occurred under normal temperatures and pressures.

10.4. Conditions to avoid

Avoid raising powdered materials into airborne dust.

10.5. Incompatible materials

Oxidizing agents. Strong acids, bases. Fluorine (F). ammonium salts.

10.6. Hazardous decomposition products

Carbon dioxide. Carbon monoxide. Calcium oxides. irritating gases.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified

Calcium carbonate (471-34-1)	
LD50 oral rat	6450 mg/kg
LD50 dermal rat	> 2000 mg/kg
LC50 inhalation rat (mg/l)	> 3 mg/l/4h

Skin corrosion/irritation : Not classified
pH: 9.9

Serious eye damage/irritation : Not classified
pH: 9.9

Respiratory or skin sensitisation : Not classified

Germ cell mutagenicity : Not classified

Carcinogenicity : Not classified

Reproductive toxicity : Not classified

Specific target organ toxicity (single exposure) : Not classified

Specific target organ toxicity (repeated exposure) : Not classified

Aspiration hazard : Not classified

SECTION 12: Ecological information

12.1. Toxicity

Calcium carbonate (471-34-1)	
LC50 fishes	> 200 mg/l 96 hours

12.2. Persistence and degradability

No additional information available

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12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

Granukote ® Calcium Carbonate 1551-95P

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

12.6. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste disposal recommendations : Comply with applicable local, national and international regulation.
Additional information : Empty containers should be taken for recycle, recovery or waste in accordance with local regulation.

SECTION 14: Transport information

Not a dangerous good in sense of transport regulations.

SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

No ingredients included in the REACH Candidate list

Other regulations, restrictions and prohibition regulations : Compliance with following regulations: Regulation (EC) 1907/2006 as amended. Regulation (EC) 1272/2008 as amended. Directive 67/548/EEC as amended. Directive 1999/45/EC as amended.

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

CSA has not been carried out

SECTION 16: Other information

Sources of Key data : SDS.
Abbreviations and acronyms : ACGIH (American Conference of Government Industrial Hygienists). CAS - Chemical Abstracts Service. CLP - Classification, Labelling and Packaging. CSR - Chemical Safety Report. EC - European Community. EEC - European Economic Community. GHS - Globally Harmonised System. MSDS - Material Safety Data Sheet. Occupational Safety and Health Administration (OSHA) : Overland transport (ADR). REACH - Registration, Evaluation, Authorisation and Restriction of Chemicals. SDS - Safety Data Sheet.

SDS EU (REACH Annex II)

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.