

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

#### 1.1. Product identifier

Chemical type : Mixture  
 Trade name : ADVANTOSE<sup>®</sup> FS95 Directly Compressible  
 SDS CODE : E031

#### 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 reliable data 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](mailto:CBlasquez@spipharma.com)

### SECTION 2: Hazards identification

#### 2.1. Classification of the substance or mixture

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

Not classified

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

Not classified

##### 2.1.3. Adverse physicochemical, human health and environmental effects

No reliable data available.

#### 2.2. Label elements

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

No labelling applicable

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

No labelling applicable

#### 2.3. Other hazards

No reliable data available.

### SECTION 3: Composition/information on ingredients

#### 3.1. Substances

Not applicable

#### 3.2. Mixtures

Name	Product identifier	%	Classification according to Directive 67/548/EEC
Fructose	(CAS No.) 57-48-7 (EC no) 200-333-3	95	Not classified
Comstarch	(CAS No.) 9005-25-8 (EC no) 232-679-6	5	Not classified
Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Fructose	(CAS No.) 57-48-7 (EC no) 200-333-3	95	Not classified
Comstarch	(CAS No.) 9005-25-8 (EC no) 232-679-6	5	Not classified

### SECTION 4: First aid measures

#### 4.1. Description of first aid measures

First-aid measures after inhalation : Remove casualty to fresh air and keep warm and at rest. If exposure symptoms persist, seek medical attention.  
 First-aid measures after skin contact : Remove contaminated clothes. Rinse immediately with plenty of water for 15 minutes.

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according to Regulation (EC) No. 453/2010

- 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 : Do not induce vomiting. In case of accident or if you feel unwell, seek medical advice immediately (show safety data sheet if possible).

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

- Symptoms/injuries after skin contact : direct contact may cause skin irritation.
- Symptoms/injuries after eye contact : Direct contact with the eyes is likely irritating.

### 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 (CO<sub>2</sub>), water, dry chemical powder.
- Unsuitable extinguishing media : None known.

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

- Fire hazard : Not combustible. minimal fire hazard. On combustion forms: carbon oxides (CO and CO<sub>2</sub>).
- Explosion hazard : Not identified.
- Reactivity : No data available.

### 5.3. Advice for firefighters

- Firefighting instructions : No data available.
- 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.

### 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 : Sweep up or vacuum up the product. Collect spills and put it into appropriated container.

### 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 contact with skin, eye and clothing. Wash hands thoroughly after handling.

### 7.2. Conditions for safe storage, including any incompatibilities

- Storage condition(s) : Keep container tightly closed. Store container in a well ventilated position. keep away from incompatible materials.
- Incompatible materials : Acids. Oxidizing agent.

### 7.3. Specific end use(s)

No reliable data available.

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

Starch (9005-25-8)		
Belgium	Limit value (mg/m <sup>3</sup> )	10 mg/m <sup>3</sup>
Italy - Portugal - USA ACGIH	ACGIH TWA (mg/m <sup>3</sup> )	10 mg/m <sup>3</sup>
Spain	VLA-ED (mg/m <sup>3</sup> )	10 mg/m <sup>3</sup>
United Kingdom	WEL TWA (mg/m <sup>3</sup> )	10 mg/m <sup>3</sup> total inhalable dust
United Kingdom	WEL TWA (mg/m <sup>3</sup> )	4 mg/m <sup>3</sup> respirable dust
Greece	TWA (mg/m <sup>3</sup> )	10 mg/m <sup>3</sup> total inhalable dust
Greece	TWA (mg/m <sup>3</sup> )	5 mg/m <sup>3</sup> respirable dust
Ireland	TWA (mg/m <sup>3</sup> )	10 mg/m <sup>3</sup> total inhalable dust

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Starch (9005-25-8)		
Ireland	TWA (mg/m <sup>3</sup> )	4 mg/m <sup>3</sup> respirable dust
Switzerland	TWA (mg/m <sup>3</sup> )	3 mg/m <sup>3</sup>

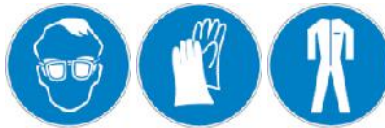
DNEL : No data available.

PNEC : No data available.

### 8.2. Exposure controls

Appropriate engineering controls : Engineering controls are not usually necessary if good hygiene practices are followed. Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure.

Personal protective equipment : Safety glasses. Gloves. Protective clothing.



Hand protection : protective gloves.

Eye protection : safety glasses with side-shields.

Skin and body protection : Wear suitable protective clothing. Wear long sleeves.

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	: Crystalline granules.
Colour	: white.
Odour	: None.
Odour threshold	: No data available
pH	: not applicable
Melting point	: Not available
Solidification point	: No data available
Boiling point	: Not available °C
Flash point	: not applicable
Relat. evapor. rate comp. to butylacetate	: Not applicable
Flammability (solid, gas)	: No data available
Explosive limits	: Not applicable vol %
Vapour pressure	: Not applicable
Relative vapour density at 20 °C	: not applicable
Relative density	: No data available
Density	: Not available
Solubility	: Water: partially soluble
Log Pow	: No data available
Self ignition temperature	: Not available
Decomposition temperature	: No data available
Viscosity	: kinematic: Not available

### 9.2. Other information

No reliable data available.

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

No data available.

### 10.2. Chemical stability

Stable at normal conditions.

### 10.3. Possibility of hazardous reactions

None known.

### 10.4. Conditions to avoid

No data available.

### 10.5. Incompatible materials

Acids. Oxidizing agents.

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### 10.6. Hazardous decomposition products

Carbon oxides (CO, CO<sub>2</sub>).

## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

No reliable data available.

## SECTION 12: Ecological information

### 12.1. Toxicity

ADVANTOSE <sup>™</sup> FS95 Directly Compressible	
LC50 fishes	(96 h, not tested)
LC50 micro-organisms	(5 h, not tested)
EC50 Daphnia	(48 h, not tested)
EC50 algae	(72 h, not tested)

### 12.2. Persistence and degradability

ADVANTOSE <sup>™</sup> FS95 Directly Compressible	
Persistence and degradability	No data available.

### 12.3. Bioaccumulative potential

ADVANTOSE <sup>™</sup> FS95 Directly Compressible	
Bioaccumulative Potential	No data available.

### 12.4. Mobility in soil

ADVANTOSE <sup>™</sup> FS95 Directly Compressible	
Ecology - soil	No data available.

### 12.5. Results of PBT and vPvB assessment

ADVANTOSE <sup>™</sup> FS95 Directly Compressible	
Results of PBT assessment	No data available

### 12.6. Other adverse effects

Other adverse effects : No data available.

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

Regional legislation (waste) : Dispose of contents/container to comply with applicable local, national and international regulations.

Waste disposal recommendations : Dispose of at authorized waste collection point. Dispose of contents/container to an industrial incineration plant.

## 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 reliable data available.

#### 15.1.2. National regulations

No reliable data available.

### 15.2. Chemical safety assessment

No reliable data available.

## SECTION 16: Other information

Sources of Key data : SDS - Safety Data Sheet.

Abbreviations and acronyms : ACGIH (American Conference of Government Industrial Hygienists). ASTM - American Society for Testing and Materials . CAS (Chemical Abstracts Service) number. CLP - Classification, Labelling and Packaging. CSR: Chemical Safety Report. EC - European Community. EEC: European Economic Community. GHS - Globally Harmonised System. IARC (International Agency for Research on Cancer). Overland transport (ADR). PVC (Polyvinyl chloride). REACH - Registration, Evaluation, Authorisation and Restriction of Chemicals. SDS - Safety Data Sheet.

*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.*