

# SAFETY DATA SHEET

In accordance with 1907/2006 annex II 2015/830 and 1272/2008  
(All references to EU regulations and directives are abbreviated into only the numeric term)

Issued 2018-08-24

Replaces issued SDS 2017-05-02

Version number 2.0



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

### 1.1. Product identifier

Trade name FabALACTICA™  
Article number A0-AG1-020

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

Identified uses Antibody fragmentation

### 1.3. Details of the supplier of the safety data sheet

Company Genovis AB  
Box 790  
22007 LUND  
Sweden  
Telephone +46 (0)46 10 12 30  
E-mail info@genovis.com

### 1.4. Emergency telephone number

Acute cases: Call 112, request poison information.

## SECTION 2: Hazards identification

### 2.1. Classification of the substance or mixture

Upon assessment, this mixture is not classified as hazardous according to 1272/2008.

### 2.2. Label elements

Hazard pictogram Not applicable  
Signal word Not applicable  
Hazard statement Not applicable

### 2.3. Other hazards

This product does not contain any substances that are assessed to be a PBT or a vPvB

## SECTION 3: Composition/information on ingredients

### 3.2. Mixtures

Note that the table shows known hazards of the ingredients in pure form. These hazards are reduced or eliminated when mixed or diluted, see Section 16d.

Constituent	Classification	Concentration
FabALACTICA™		
		1 - 20 %

Explanations to the classification and labelling of the ingredients are given in Section 16e. Official abbreviations are printed in normal font. Text in italics are specifications and/or complements used in the calculation of the classification of this mixture, see Section 16b.

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

#### Generally

In case of concern, or if symptoms occur, call a doctor/physician.

#### Upon breathing in

Fresh air and rest. If symptoms persist seek medical advice.

#### Upon eye contact

For safety reasons, flush eyes with water; If symptoms occur, seek medical advice.

If dust has come in contact with eyes, do not rub.

#### **Upon skin contact**

Normal washing of the skin is considered sufficient; If nevertheless symptoms do occur, contact a physician.

Remove contaminated clothes.

#### **Upon ingestion**

Rinse nose, mouth and throat with water.

Get medical attention if you feel unwell.

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

##### **Upon eye contact**

Irritation may occur due to mechanical abrasion.

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

Symptomatic treatment.

## **SECTION 5: Fire-fighting measures**

### **5.1. Extinguishing media**

Extinguish with water mist, powder, carbon dioxide or alcoholresistant foam.

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

The product is not hazardous in the flammable sense.

In case of fire gases detrimental to health (carbon monoxide and carbon dioxide) may form.

### **5.3. Advice for fire-fighters**

Protective measures should be taken regarding other material at the site of the fire.

In case of fire use a respirator mask.

Wear full protective clothing.

## **SECTION 6: Accidental release measures**

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

Avoid dust formation.

Do not inhale dust and avoid contact with skin, eyes and clothes when cleaning up spill.

Keep unauthorized and unprotected people at a safe distance.

Use recommended safety equipment, see section 8.

Ensure good ventilation.

### **6.2. Environmental precautions**

Avoid emissions into soil, water or air.

Avoid discharge into sewers.

### **6.3. Methods and material for containment and cleaning up**

Avoid dust formation and do not dry brush.

Carefully collect the product without generating dust and dispose of at a waste collection point.

Avoid stirring the material up so that it aerates.

Ensure good ventilation after sanitation.

Minor spills can be dried up with a damp cloth.

### **6.4. Reference to other sections**

See section 8 and 13 for personal protection equipment and disposal considerations.

## **SECTION 7: Handling and storage**

### **7.1. Precautions for safe handling**

Do not inhale dust and avoid contact with skin and eyes.

Avoid handling in a manner which will raise dust.

Handle in premises with good ventilation.

The usual precautions for handling chemicals should be observed.

Do not eat, drink or smoke in premises where this product is handled.

Wash your hands after using the product.

Remove clothes which have been splattered.

Handle in premises which have modern ventilation standards.

Treat the substance as potentially harmful to health.

Wash contaminated clothing before reuse.

Use recommended safety equipment, see section 8.

Use local extract ventilation or similar ventilation, as dust may be formed.

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

This product should be stored well out of reach of young children and kept safely apart from products intended for consumption.

The product should be stored in a manner which prevents hazards to health and the environment. Avoid exposure to humans and animals and do not discharge the product in a sensitive environment.

Store in a well-ventilated space.

Store only in the original package.

Store cool, in sealed package.

Store in a dry place at 2 - 8 °C.

Keep upright.

Always use sealed and visibly labeled packages.

## 7.3. Specific end uses

See identified uses in Section 1.2.

# SECTION 8: Exposure controls/personal protection

## 8.1. Control parameters

### 8.1.1. National limit values

All ingredients (cf. Section 3) lack occupational exposure limit values.

### DNEL

No data available.

### PNEC

No data available.

## 8.2. Exposure controls

Avoid dust formation.

To prevent occupational risks the health hazards for this product or any of the ingredients should be taken into account (see sections 2, 3 and 11), according to EU Directive 89/391 and 98/24 and national jurisdiction for occupational risks.

### 8.2.1. Appropriate engineering controls

Handle in premises with good ventilation.

Use local extract ventilation or similar ventilation, as dust may be formed.

### Eye/face protection

Use dust protective glasses when handling may create dust.

### Skin protection

Use protective gloves fulfilling the standard EN374 if there is a risk of direct contact.

Protective gloves are normally not needed due to the properties of this product, but may be necessary for other reasons, e.g. mechanical risks, temperature conditions or microbiological risks.

Use suitable protective clothing.

### Respiratory protection

Use proper protective breathing equipment in case of insufficient ventilation.

A protective mask, with a B filter (grey) or an IIb (P2) dust filter, may be required.

### 8.2.3. Environmental exposure controls

For limiting environmental exposure, see section 12.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

a) Appearance	Form: lyophilised powder. Colour: white.
b) Odour	Not indicated
c) Odour threshold	Not indicated
d) pH	Not indicated
e) Melting point/freezing point	Not indicated
f) Initial boiling point and boiling range	Not indicated
g) Flash point	Not indicated
h) Evaporation rate	Not indicated
i) Flammability (solid, gas)	Not applicable
j) Upper/lower flammability or explosive limits	Not indicated
k) Vapour pressure	Not indicated
l) Vapour density	Not indicated
m) Relative density	Not indicated
n) Solubility	Solubility in water: Soluble
o) Partition coefficient: n-octanol/water	Not applicable
p) Auto-ignition temperature	Not indicated
q) Decomposition temperature	Not indicated
r) Viscosity	Not indicated
s) Explosive properties	Not applicable
t) Oxidising properties	Not applicable

### 9.2. Other information

No data available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

The product contains no substances which can lead to hazardous reactions at normal use.

### 10.2. Chemical stability

The product is stable at normal storage and handling conditions.

### 10.3. Possibility of hazardous reactions

No hazardous reactions known during normal use.

### 10.4. Conditions to avoid

None in particular.

### 10.5. Incompatible materials

Avoid contact with strong acids.

Avoid contact with strong oxidizing agents.

### 10.6. Hazardous decomposition products

None under normal conditions.

## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

Not indicated.

#### Acute toxicity

The product is not classified as acute toxic.

#### Skin corrosion/irritation

The mixture is judged as a whole and is classified to be neither corrosive nor irritant to skin. Mild irritation may occur on prolonged or repeated exposure.

#### Serious eye damage/irritation

Dust may cause mechanical abrasion of the cornea.

The criteria for classification cannot be considered fulfilled based on available data.

#### Respiratory or skin sensitisation

The product does not contain any known allergens.

#### Germ cell mutagenicity

No mutagenic effects have been reported for the substance in this mixture.

#### Carcinogenicity

No carcinogenic effects have been reported for the substances in this product.

**Reproductive toxicity**

No toxic effects to reproduction have been reported for the substances in this mixture.

**STOT-single exposure**

Transient irritation of the airways may occur during brief/occasional inhalation of dust.

The criteria for classification cannot be considered fulfilled based on available data.

**STOT-repeated exposure**

Repeated or prolonged inhalation of dust can cause chronic irritation to the respiratory organs.

The criteria for classification cannot be considered fulfilled based on available data.

**Aspiration hazard**

The product is not classified as being toxic for aspiration.

## SECTION 12: Ecological information

**12.1. Toxicity**

No ecological damage is known or expected in the event of normal use.

Avoid larger spills in soil, water and drains.

**12.2. Persistence and degradability**

There is no information regarding persistence or degradability.

**12.3. Bioaccumulative potential**

There is no information regarding bioaccumulation.

**12.4. Mobility in soil**

Information about mobility in nature is not available.

**12.5. Results of PBT and vPvB assessment**

This product does not contain any substances that are assessed to be a PBT or a vPvB.

**12.6. Other adverse effects**

No known effects or hazards.

## SECTION 13: Disposal considerations

**13.1. Waste treatment methods****Waste handling of the product**

The product is not classified as hazardous waste.

Observe local regulations or contact the supplier for further information.

Avoid discharge into sewers.

See also national waste regulations.

## SECTION 14: Transport information

Where not otherwise stated the information applies to all of the UN Model Regulations, i.e. ADR (road), RID (railway), ADN (inland waterways), IMDG (sea), and ICAO (IATA) (air).

**14.1. UN number**

Not classified as dangerous goods

**14.2. UN proper shipping name**

Not applicable

**14.3. Transport hazard class(es)**

Not applicable

**14.4. Packing group**

Not applicable

**14.5. Environmental hazards**

Not applicable

**14.6. Special precautions for user**

Not applicable

**14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**

Not applicable

**14.8 Other transport information**

Not applicable

## SECTION 15: Regulatory information

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

Not indicated.

### 15.2. Chemical safety assessment

Assessment and chemical safety report in accordance with 1907/2006 Annex I has not yet been performed.

## SECTION 16: Other information

### 16a. Indication of where changes have been made to the previous version of the safety data sheet

#### Revisions of this document

Earlier versions

2017-05-02 Changes in section(s) 4, 5, 6, 7, 8, 10, 11, 12.

### 16b. Legend to abbreviations and acronyms used in the safety data sheet

#### Explanations of the abbreviations in Section 14

ADR European Agreement concerning the International Transport of Dangerous Goods by Road

RID Regulations concerning the International Transport of Dangerous Goods by Rail

IMDG International Maritime Dangerous Goods Code

ICAO International Civil Aviation Organization (ICAO, 999 University Street, Montreal, Quebec H3C 5H7, Canada)

IATA The International Air Transport Association

### 16c. Key literature references and sources for data

#### Sources for data

Primary data for the calculation of the hazards has preferentially been taken from the official European classification list, 1272/2008 Annex I, as updated to 2018-08-24.

Where such data was not available, alternative documentation used to establish the official classification was used, e.g. IUCLID (International Uniform Chemical Information Database). As a second alternative, information was used from reputable international chemical industries, and as a third alternative other available information was used, e.g. material safety data sheets from other suppliers or information from non-profit associations, where reliability of the source was assessed by expert opinion. If, in spite of this, reliable information could not be sourced, the hazards were assessed by expert opinions based on the known hazards of similar substances, and according to the principles in 1907/2006 and 1272/2008.

#### Full texts for Regulations mentioned in this Safety Data Sheet

1907/2006 REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

2015/830 COMMISSION REGULATION (EU) 2015/830 of 28 May 2015 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

1272/2008 REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

1907/2006 REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

### 16d. Methods of evaluating information referred to in 1272/2008 Article 9 which was used for the purpose of classification

Hazard calculation for this mixture has been performed as a cumulative assessment with the aid of expert assessments in accordance with 1272/2008 Annex I, where all available information which may be significant to establishing the hazards of the mixture was assessed together, and in accordance with 1907/2006 Annex XI.

### 16e. List of relevant hazard statements and/or precautionary statements

### 16f. Advice on any training appropriate for workers to ensure protection of human health and the environment

#### Warning for misuse

This product is not expected to cause severe harm to humans or the environment. However the manufacturer, the distributor or the supplier cannot be responsible for unusual or criminal use of the product.

#### Other relevant information

**Editorial information**

This material safety data sheet has been prepared and checked by KemRisk®, KemRisk Sweden AB, Platensgatan 8, SE-582 20 Linköping, Sweden, [www.kemrisk.se](http://www.kemrisk.se)