

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)

Revision date 2021-09-21

Replaces SDS issued 2021-05-14

Version number 4.0



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

Not indicated.

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®		
		≤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 persist, call a doctor/physician.

Upon breathing in

Allow the injured person to rest in a warm place with fresh air, if symptoms persist seek medical attention.

Upon eye contact

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

Rinse the eye for several minutes with lukewarm water. If irritation persists call a doctor.

Upon skin contact

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

Upon ingestion

Rinse nose, mouth and throat with water.

Upon ingestion of larger amounts, consult a doctor/physician.

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

Upon breathing in

Inhalation of dust may cause sneezing and burning pain in nose and throat.

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

In case of fire, substances hazardous to health, or substances harmful in other respects, may be dispersed.

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 proper breathing apparatus.

Wear full protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Use recommended safety equipment, see section 8.

Avoid inhalation and exposure to skin and eyes.

Avoid dust formation.

Ensure good ventilation.

6.2. Environmental precautions

Avoid discharge into soil, water or sewers.

6.3. Methods and material for containment and cleaning up

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

Rinse area thoroughly with water.

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

- Take the necessary preventive and protective measures for safe handling.
- Implement appropriate engineering controls if necessary, see Section 8.
- Use recommended safety equipment, see section 8.
- Store this product separately from food items and keep it out of the reach of children and pets.
- Do not eat, drink or smoke in premises where this product is handled.
- Avoid handling in a manner which will raise dust.
- Avoid spillage, inhalation and contact with eyes and skin.
- Wash your hands after using the product.
- Wash contaminated clothing before reuse.

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.
- Always use sealed and visibly labeled packages.
- Store in a well-ventilated space.
- Store in a cool and dry place (above freezing temperature and not greater than 30°C).

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.
- The risks posed by the product or its constituents must be considered in the task specific risk assessment, in accordance with current working environment legislation. The risk assessment should be reviewed regularly and updated if necessary.

8.2.1. Appropriate engineering controls

- The ventilation in the workplace must ensure an air quality that meets the requirements of the current working environment legislation. Local exhaust ventilation should be used to remove airborne contaminants at the source.

Eye/face protection

- Use dust protective glasses when handling may create dust.

Skin protection

- Wear suitable protective clothing when necessary.
- 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.
- The most suitable protective glove should be chosen in consultation with the glove supplier, taking into account the risk assessment for the specific task and the properties of the chemicals involved. Note that the breakthrough time of the material is affected by the duration of the exposure, temperature conditions, abrasion, etcetera.
- Based on the chemical properties of the product, the following glove materials are recommended (EN 374):
 - Nitrile rubber.

Respiratory protection

- Use appropriate respiratory protective equipment in case of insufficient ventilation.
- The most appropriate respiratory protective equipment should be decided in consultation with the appointed safety representative, taking into account the risk assessment for the specific task.
- Based on the physical and chemical properties of the product, the following filter type(s) and/or filter combination(s) are recommended:
 - P2.

8.2.3. Environmental exposure controls

For limitation of 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	When supplied, pH is: Not indicated In working solution the pH value is: >7.6 - <8
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

No data available.

10.5. Incompatible materials

Avoid contact with oxidizers.

10.6. Hazardous decomposition products

None under normal conditions.

SECTION 11: Toxicological information

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

Information on possible health hazards are based on experience and / or toxicological properties of several components in the product.

Acute toxicity

The product is not classified as acutely toxic.

Skin corrosion/irritation

The product is not classified for skin corrosion/irritation.

Serious eye damage/irritation

The product is not classified for serious eye damage/eye irritation.

Respiratory or skin sensitisation

The product is not classified as sensitising.

Germ cell mutagenicity

The product is not classified as mutagen.

Carcinogenicity

The product is not classified as carcinogenic.

Reproductive toxicity

The product is not classified as a reproductive toxicant.

STOT-single exposure

The product is not classified for specific organ toxicity after single exposure.

STOT-repeated exposure

The product is not classified for specific organ toxicity after repeated exposure.

Aspiration hazard

The product is not classified as being toxic for aspiration.

SECTION 12: Ecological information

12.1. Toxicity

The product is not to be labelled as an environmental hazard. However, it is not inconceivable that large emissions, or repeated small emissions, can have a harmful effect on the environment.

Prevent release on land, in 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

The product is soluble in water and is therefore mobile in soil and water.

12.5. Results of PBT and vPvB assessment

No data available.

12.6. Other adverse effects

Data lacking.

SECTION 13: Disposal considerations

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

Avoid discharge into sewers.

The product is not classified as hazardous waste.

Empty, rinsed packaging is sent for recycling where practicable.

See directive 2008/98/EC on waste. Observe national or regional provisions on waste management.

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

2021-05-14 Changes in section(s) 1, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 16.

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 2021-09-21.

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
- 2008/98/EC DIRECTIVE 2008/98/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 19 November 2008 on waste and repealing certain Directives

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

Not indicated.

Other relevant information

Not indicated

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