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 2017-01-31
Version number 2.0

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

1.1. Product identifier

Trade name	GlycINATOR®
Article number	A0-GL1-020, A0-GL8-020

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

Identified uses	Antibody deglycosylation reagent

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
SODIUM CHLORIDE		
CAS No: 7647-14-5 EC No: 231-598-3		<60 %
TRIS (HYDROXYMETHYL)-AMINOMETHANE		
CAS No: 77-86-1 EC No: 201-064-4		<40 %
GlycINATOR®		
		1 - 10 %

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

No special measures are considered to be necessary. If symptoms do occur however, 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

As a precaution, rinse the eye thoroughly with water; If symptoms occur, call a doctor/physician.

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.

If symptoms persist contact a doctor.

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

No further relevant information available.

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.

Gases detrimental to health can be spread in case of fire.

The product does not oxidise.

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 discharge into sewers.

6.3. Methods and material for containment and cleaning up

Sweep carefully and collect.

Avoid stirring the material up so that it aerates.

To be collected with caution and transported to a waste disposal facility.

Minor spills can be dried up with a damp cloth.

Contaminated products should be treated as chemical waste and declared as non-hazardous goods.

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.

Work in order to avoid spillage. If spillage does occur, address it immediately in accordance with the directions specified in Section 6 of this safety data sheet.

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

Use recommended safety equipment, see section 8.

7.2. Conditions for safe storage, including any incompatibilities

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.

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

Store in a well-ventilated space.

Store only in the original package.

Store cool, in sealed package.

Store in a dry place.

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

Normal working-clothes of cotton or synthetic material should be adequate. Clothing contaminated with this product should be washed immediately; avoid contact with the skin.

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.

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 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.
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

Do not expose to high temperatures.

Protect from moisture.

10.5. Incompatible materials

None known.

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.

SODIUM CHLORIDE

LD50 rabbit 24h: > 10000 mg/kg Dermally

LD50 rat 24h: 3000 mg/kg Orally

TRIS (HYDROXYMETHYL)-AMINOMETHANE

LD50 rat 24h: 5900 mg/kg Orally

Skin corrosion/irritation

The product is neither corrosive nor irritant.

Serious eye damage/irritation

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

Dust may cause mechanical abrasion of the cornea.

Respiratory or skin sensitisation

The product is not classified as sensitising.

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

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

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

STOT-repeated exposure

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

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

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.

SODIUM CHLORIDE

EC50 Freshwater water flea (Daphnia magna) 48 h: 1000 mg/l

LC50 Fish 96h: 17.9 mg/l

12.2. Persistence and degradability

The product degrades in the natural environment.

12.3. Bioaccumulative potential

It is not expected that this product or some of its ingredients will accumulate in nature.

12.4. Mobility in soil

The product is miscible with water and is therefore variable in soil and water.

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.

Avoid larger spills of undiluted product in drains. Smaller quantities of undiluted product can be washed into drains.

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

2017-01-31 Changes in section(s) 5, 6, 7, 8, 10, 11, 12, 13.

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