

SAFETY DATA SHEET

according to Regulation (EC) No 1907/2006 (REACH) as amended

Lyophilized allergen extract / Recombinant allergen

Date of creation	09 August 2016	Version	2
Date of revision	06 May 2019		

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

- 1.1 Product identifier**
Substance / mixture Lyophilized allergen extract / Recombinant allergen mixture
Catalog number see product label
Other names of the mixture
- 1.2 Relevant identified uses of the substance or mixture and uses advised against**
Intended use of the mixture diagnostic reagent
- The use descriptors**
SU 20 Health services
SU 24 Scientific research and development
PC 21 Laboratory chemicals
PROC 15 Use as laboratory reagent
- Not recommended use of the mixture The product should not be used in ways other than those referred in Section 1.
- 1.3 Details of the supplier of the safety data sheet**
- Manufacturer**
Name or trade name EXBIO Praha a.s.
Address Nad Safinou II 341, Vestec, 25250
Česká republika
Phone +420 261090 666
Fax +420 261090 660
Email orders@exbio.cz
Web address www.exbio.cz
- Competent person responsible for the safety data sheet**
Name EXBIO Praha a.s.
Email orders@exbio.cz
- 1.4 Emergency telephone number**
Poisoning information centre, Na Bojišti 1, Praha, Czech Republic, Tel.: non-stop +420 224 919 293 or +420 224 915 402, Information on health risks only - acute poisoning of humans and animals

SECTION 2: Hazards identification

- 2.1. Classification of the substance or mixture**
Classification of the mixture in accordance with Regulation (EC) No 1272/2008
The mixture is not classified as dangerous according to Regulation (EC) No 1272/2008
- The most serious adverse physico-chemical effects**
Unknown
- The most serious adverse effects on human health and the environment**
Unknown
- 2.2 Label elements**
none
- 2.3. Other hazards**
Substance does not meet the criteria for PBT or vPvB in accordance with Annex XIII of Regulation (EC) No 1272/2008.

SECTION 3: Composition/information on ingredients

- 3.2. Mixtures**
Chemical characterization
Mixture of substances specified below and non-hazardous additives.
- Mixture contains these hazardous substances and substances with the highest permissible concentration in the working environment**

Identification numbers	Name of the substance	Content in % weight	Classification according to Regulation (EC) No 1272/2008	Note
-	-	-	-	-

Full text of all classifications and H-phrases is given in the section 16.

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SECTION 4: First aid measures

4.1. Description of first aid measures

If any health problems are manifested or if in doubt, inform a doctor and show him information from this Safety Data Sheet. If unconscious, put the person in the stabilized (recovery) position on his side with his head slightly bent backwards and make sure that airways are free; never induce vomiting. If the person vomits by himself, make sure that the vomit is not inhaled. In life threatening conditions first of all provide resuscitation of the affected person and ensure medical assistance. Respiratory arrest - provide artificial respiration immediately. Cardiac arrest - provide indirect cardiac massage immediately.

Inhalation

In case of problems following the vapours/aerosols inhalation, remove the affected persons to a fresh air. For those providing assistance, avoid exposure to yourself or others. Use adequate respiratory protection. If respiratory irritation, dizziness, nausea, or unconsciousness occurs, seek immediate medical assistance. If breathing has stopped, assist ventilation with a mechanical device or use mouth-to-mouth resuscitation. Call immediately medical emergency.

Skin contact

Immediately remove all soiled or stained clothing. Wash the affected area immediately and repeatedly with soap and water. Use appropriate regenerating cream. Seek medical advice if the skin irritation persists.

Eye contact

Keep eyelids open and rinse immediately and repeatedly with copious amount of water for at least 10 - 15 minutes. Remove contact lenses, if present and easy to do. Seek medical advice if the eye irritation persists.

Ingestion

If swallowed, rinse mouth with water (only if the person is conscious). Do not induce vomiting! In case of spontaneous vomiting avoid aspiration of the vomits. Get medical attention immediately and show product package or label!

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

Inhalation

Possible irritation of airways, cough, headache.

Skin contact

May cause an allergic reaction..

Eye contact

Not expected.

Ingestion

Irritation, nausea.

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

Symptomatic treatment.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

alcohol-resistant foam, carbon dioxide, powder, water spray jet, water mist

Unsuitable extinguishing media

water - full jet

5.2. Special hazards arising from the substance or mixture

Non-flammable - aqueous solution. After evaporation of water, harmful gases / smoke (carbon dioxide, aldehydes, carbon black, other decomposition products) can be produced during thermal decomposition at high temperatures or with insufficient combustion.

5.3. Advice for firefighters

Use a self-contained breathing apparatus and full-body protective clothing. Closed containers with the product near the fire should be cooled with water. Do not allow run-off of contaminated fire extinguishing material to enter drains or surface and ground water.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

The mixture is non-flammable. Provide sufficient ventilation. Use gloves in case of prolonged contact. Follow the instructions in Sections 7 and 8.

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6.2. Environmental precautions

Prevent contamination of the soil and entering surface or ground water. Do not allow to enter drains.

6.3. Methods and material for containment and cleaning up

Spilled product should be covered with suitable (non-flammable) absorbing material (sand, diatomaceous earth, earth and other suitable absorption materials); to be contained in well closed containers and removed as per Section 13. Collected material should be disposed of in accordance with locally valid regulations. Upon an escape of large quantities of the product, inform the Fire Department and the Environmental Department of the Municipal Authority with extended scope of competencies. After removal of the product, wash the contaminated site with plenty of water or another suitable cleaning material. Do not use solvents.

6.4. Reference to other sections

7., 8. and 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Observe all user considerations, safety measures and exposure limits. Avoid contact with skin, eyes and mucous membranes. See Section 8 for advice on the minimum requirements for personal protective equipment. Avoid breathing decomposition products or mists/aerosols. Use only with adequate ventilation.

7.2. Conditions for safe storage, including any incompatibilities

Store in tightly closed containers in cold, dry and well ventilated areas designated for this purpose. Do not expose to sunlight.

The specific requirements or rules relating to the substance/mixture

none

7.3. Specific end use(s)

Diagnostic reagent

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Czech Republic

Name of the substance (komponent)	Type	Time of exposure	Value	Note	Source
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European union

Name of the substance (komponent)	Type	Time of exposure	Value	Note	Source
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8.2. Exposure controls

Follow usual measures for health protection at work and especially for good ventilation. This can be achieved only by local suction or efficient general ventilation. If exposure limits cannot be observed in this mode, suitable protection of airways must be used. Do not eat, drink and smoke during work. Wash your hands thoroughly with water and soap after work and before breaks for a meal and rest.

Eye/face protection

Protective goggles or face shield (based on the nature of the work performed).

Skin protection

Hand protection: Protective gloves resistant against the product. Observe recommendations of the particular manufacturer of the gloves in the choice of their appropriate thickness, material and permeability. Use barrier creams for skin protection, they should however not be applied once exposure has occurred. Observe other recommendations of the manufacturer. Other protection: Protective antistatic clothing made of natural fibres (cotton) or synthetic fibres resistant against elevated temperatures. Contaminated skin should be washed thoroughly.

Respiratory protection

Mask with a filter against organic vapours or a self-contained breathing apparatus as appropriate if exposure limit values of toxic substances are exceeded or in a poorly ventilated environment.

Thermal hazard

not available

Environmental exposure controls

Observe usual measures for protection of the environment, see Section 6.2.

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SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	small lyophilization cake
Physical state	solid
Color	white to creamy
odour	no odour
odour treshold	data not available
pH	data not available
Melting point/freezing point	data not available
Initial boiling point and boiling range	data not available
Flash point	data not available
Evaporation rate	data not available
Flammability (solid, gas)	data not available
Upper/lower flammability or explosive limits	data not available
flammability limits	data not available
explosive limits	data not available
Vapour pressure	data not available
Vapour density	data not available
Relative density	data not available
Solubility(ies)	soluble
solubility in water	data not available
solubility in fats	data not available
Partition coefficient: n-octanol/water	data not available
Auto-ignition temperature	data not available
Decomposition temperature	data not available
Viscosity	data not available
Explosive properties	data not available
Oxidising properties	data not available

9.2. Další informace

Density	data not available
auto-ignition temperature	data not available

SECTION 10: Stability and reactivity

10.1. Reactivity

Not reactive under normal conditions of storage and manipulation.

10.2. Chemical stability

The product is stable under normal conditions.

10.3. Possibility of hazardous reactions

Not known.

10.4. Conditions to avoid

The product is stable and no degradation occurs under normal use. Protect against flames, sparks, overheating and against frost.

10.5. Incompatible materials

Protect against strong acids, bases and oxidizing agents. Thereby a dangerous exothermic reaction will be prevented.

10.6. Hazardous decomposition products

Not developed under normal uses. Dangerous products are formed at high temperature and in fire, such as carbon monoxide and carbon dioxide, heavy smoke and nitrogen oxides.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

No toxicological data is available for the mixture

Acute toxicity

Based on available data the classification criteria are not met.

Skin corrosion/irritation

Based on available data the classification criteria are not met.

Serious eye damage/irritation

Based on available data the classification criteria are not met.

Respiratory or skin sensitisation

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May cause an allergic reaction.

Germ cell mutagenicity

Based on available data the classification criteria are not met.

Carcinogenicity

Based on available data the classification criteria are not met.

Reproductive toxicity

Based on available data the classification criteria are not met.

Toxicity for specific target organ - single exposure

Based on available data the classification criteria are not met.

Toxicity for specific target organ - repeated exposure

Based on available data the classification criteria are not met.

Aspiration hazard

Based on available data the classification criteria are not met.

SECTION 12: Ecological information

12.1. Toxicity

Acute toxicity

Not for the mixture. Based on composition and calculation methods, the mixture is not classified as hazardous to the environment.

12.2. Persistence and degradability

Methods for determining biodegradability do not apply to inorganic substances.

12.3. Bioaccumulative potential

Insignificant.

12.4. Mobility in soil

The product is soluble and mobile in water and soil. Contamination of water courses may occur in case of rain.

12.5. Results of PBT and vPvB assessment

The product is not classified as PBT or vPvB.

12.6. Other adverse effects

not available

SECTION 13: Disposal considerations

Hazard of environmental contamination; remove waste in accordance with local and/or national regulations.

13.1. Waste treatment methods

Proceed in accordance with valid regulations on waste disposal. Any unused product and contaminated packaging should be put in labelled containers for waste collection and submitted for disposal to an authorised person for waste removal (specialized company) authorised for such activity. Do not empty unused product in drainage systems. The product must not be disposed of with municipal waste. Empty containers may be used at waste incinerators to produce energy or deposited in a dump with appropriate classification. Perfectly cleaned containers can be submitted for recycling.

Legislation of waste

Council Directive 75/442/EEC on waste, as amended. Council Directive 91/689/EEC on hazardous waste, as amended. Decision 94/3/EC establishing a list of wastes, as amended.

SECTION 14: Transport information

The mixture **is not** classified as dangerous for transport according to ADR/RID/IMDG/ICAO/IATA.

14.1. UN number

Not subject to ADR.

14.2. UN proper shipping name

not available

14.3. Transport hazard class(es)

not available

14.4. Packing group

not available

14.5. Environmental hazards

not available

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14.6. Special precautions for user

Reference in Sections 4 to 8.

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

not available

SECTION 15: Regulatory information

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

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, as amended. 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, as amended.

15.2. Chemical safety assessment

not available

SECTION 16: Other information

Changes made to the previous version of the safety data sheet

Removing company logo, revisions of sections 1,4,7,11,14,16, minor corrections in text, change in header

A list of standard risk phrases used in the safety data sheet

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Other important information about human health protection

The product must not be - unless specifically approved by the manufacturer/importer - used for purposes other than as per Section 1. The user is responsible for adherence to all related health protection regulations.

Key to abbreviations and acronyms used in the safety data sheet

ADR	European agreement concerning the international carriage of dangerous goods by road
BCF	Bioconcentration Factor
CAS	Chemical Abstract Service
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substance and mixtures
DNEL	Derived no-effect level
EC50	Concentration of a substance when it is affected 50% of the population
EINECS	European Inventory of Existing Commercial Chemical Substances
EMS	Emergency plan
ES	Identification code for each substance listed in EINECS
EU	European Union
IATA	International Air Transport Association
IBC	International Code For The Construction And Equipment of Ships Carrying Dangerous Chemicals
IC50	Concentration causing 50 % blockade
ICAO	International Civil Aviation Organization
IMDG	International Maritime Dangerous Goods Transport
INCI	International Nomenclature of Cosmetic Ingredients
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
LC50	Lethal concentration of a substance in which it can be expected death of 50% of the population
LD50	Lethal dose of a substance in which it can be expected death of 50% of the population
LOAEC	Lowest observed adverse effect concentration
LOAEL	Lowest observed adverse effect level
Log Kow	Octanol-water partition coefficient
MARPOL	International Convention for the Prevention of Pollution From Ships
MFAG	First Aid Manual
NOAEC	No observed adverse effect concentration
NOAEL	No observed adverse effect level

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NOEC	No observed effect concentration
NOEL	No observed effect level
OEL	Occupational Exposure Limits
PBT	Persistent, Bioaccumulative and Toxic
PEL	Permissible Exposure Limit
PNEC	Predicted no-effect concentration
PPM	Parts per million
REACH	Registration, Evaluation, Authorisation and Restriction of chemicals (EP and Council Regulation (EC) No 1907/2006)
RID	Agreement on the transport of dangerous goods by rail
UN	Four-figure identification number of the substance or article taken from the UN Model Regulations
UVCB	Substances of unknown or variable composition, complex reaction products or biological materials
VOC	Volatile organic compounds
vPvB	Very Persistent and very Bioaccumulative
W/W	Weight by weight
Acute. Tox.	Acute toxicity
Aquatic Chronic	Hazardous to the aquatic environment
STOT RE	Specific target organ toxicity - repeated exposure

Training guidelines

Inform the personnel about the recommended ways of use, mandatory protective equipment, first aid and prohibited ways of handling the product.

Recommended restrictions of use

not available

Information about data sources used to compile the Safety Data Sheet

REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL (REACH) as amended.
REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL as amended.
Publication of "Zásady pro poskytování první pomoci při expozici chemickým látkám" (doc. MUDr. Daniela Pelclová, CSc., MUDr. Alexandr Fuchs, CSc., MUDr. Miroslava Hornyčová, CSc., MUDr. Zdeňka Trávníčková, CSc., Jiřina Fridrichovská, prom. chem.). Data from the manufacturer of the substance / mixture, if available - information from registration dossiers.

Statement

The safety data sheet provides information aimed at ensuring safety and health protection at work and environmental protection. The provided information corresponds to the current status of knowledge and experience and complies with valid legal regulations. The information should not be understood as guaranteeing the suitability and usability of the product for a particular application.
