

# SAFETY DATA SHEET

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

## Lyophilized allergen extract / Recombinant allergen

Creation date	09th August 2016	Version	3
Revision date	01st August 2022		

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

**1.1. Product identifier** Lyophilized allergen extract / Recombinant allergen  
Substance / mixture mixture

**1.2. Relevant identified uses of the substance or mixture and uses advised against**  
**Mixture's intended use**

Allergen extract or recombinant allergen for in vitro stimulation of basophilic granulocytes.

#### The use descriptors

SU 24 Scientific research and development  
PC 21 Laboratory chemicals  
PROC 15 Use as laboratory reagent

#### Mixture uses advised against

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 Czech Republic
Phone	+420261090666
E-mail	orders@exbio.cz
Web address	www.exbio.cz

#### Competent person responsible for the safety data sheet

Name	EXBIO Praha, a.s.
E-mail	orders@exbio.cz

**1.4. Emergency telephone number**

European emergency number: 112

### 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.

Full text of all classifications and hazard statements is given in the section 16.

**2.2. Label elements**

none

**2.3. Other hazards**

The mixture does not contain substances with endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605. Mixture does not contain any substance meet the criteria for PBT or vPvB in accordance with Annex XIII of Regulation (EC) No. 1907/2006 (REACH) as amended.

### SECTION 3: Composition/information on ingredients

**3.2. Mixtures**

#### Mixture contains these hazardous substances and substances with the highest permissible concentration in the working environment

none

### SECTION 4: First aid measures

**4.1. Description of first aid measures**

Take care of your own safety. If any health problems are manifested or if in doubt, inform a doctor and show him information from this safety data sheet.

#### If inhaled

Terminate the exposure immediately; move the affected person to fresh air.

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### **If on skin**

Remove contaminated clothes.

### **If in eyes**

Rinse eyes immediately with a flow of running water, open the eyelids (also using force if needed); remove contact lenses immediately if worn by the affected person.

### **If swallowed**

Rinse out the mouth with clean water. In the event of issues, find medical help.

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

### **If inhaled**

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

### **If on skin**

May cause an allergic skin reaction.

### **If in eyes**

Possible irritation.

### **If swallowed**

Stomach pain, nausea, diarrhoea.

## **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**

Accommodate extinguishing components to the location of fire.

#### **Unsuitable extinguishing media**

Water - full jet.

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

In the event of fire, carbon monoxide, carbon dioxide and other toxic gases may arise. Inhalation of hazardous degradation (pyrolysis) products may cause serious health damage.

### **5.3. Advice for firefighters**

Self-Contained Breathing Apparatus (SCBA) with chemical resistant gloves. Use a self-contained breathing apparatus and full-body protective clothing.

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

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

Follow the instructions in the Sections 7 and 8.

### **6.2. Environmental precautions**

Prevent contamination of the soil and entering surface or ground water.

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

Place the product mechanically in an appropriate manner. Dispose of the collected material according to the instructions in the section 13.

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

See the Section 7, 8 and 13.

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

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

Use personal protective equipment as per Section 8. Observe valid legal regulations on safety and health protection.

### **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.

### **7.3. Specific end use(s)**

Allergen extract or recombinant allergen for in vitro stimulation of basophilic granulocytes.

## **SECTION 8: Exposure controls/personal protection**

### **8.1. Control parameters**

The mixture contains no substances for which occupational exposure limits are set.

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### 8.2. Exposure controls

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.

#### Skin protection

Hand protection: Protective gloves resistant to the product.

#### Respiratory protection

Mask with a filter in a poorly ventilated environment.

#### Thermal hazard

Not available.

#### Environmental exposure controls

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

## SECTION 9: Physical and chemical properties

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

Physical state	solid
Colour	white to cream
Odour	without fragrance
Melting point/freezing point	data not available
Boiling point or initial boiling point and boiling range	data not available
Flammability	data not available
Lower and upper explosion limit	data not available
Flash point	data not available
Auto-ignition temperature	data not available
Decomposition temperature	data not available
pH	data not available
Kinematic viscosity	data not available
Solubility in water	soluble
Partition coefficient n-octanol/water (log value)	data not available
Vapour pressure	data not available
Density and/or relative density	data not available
Relative vapour density	data not available
Particle characteristics	data not available

### 9.2. Other information

not available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

not available

### 10.2. Chemical stability

The product is stable under normal conditions.

### 10.3. Possibility of hazardous reactions

Unknown.

### 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.

### 10.6. Hazardous decomposition products

Not developed under normal uses. Dangerous outcomes such as carbon monoxide and carbon dioxide are formed at high temperature and in fire.

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### SECTION 11: Toxicological information

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

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

Based on available data the classification criteria are not met.

##### 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.

#### 11.2. Information on other hazards

The mixture does not contain substances with endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

### SECTION 12: Ecological information

#### 12.1. Toxicity

##### Acute toxicity

#### 12.2. Persistence and degradability

not available

#### 12.3. Bioaccumulative potential

Not available.

#### 12.4. Mobility in soil

Not available.

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

Product does not contain any substance meeting the criteria for PBT or vPvB in accordance with the Annex XIII of Regulation (EC) No 1907/2006 (REACH) as amended.

#### 12.6. Endocrine disrupting properties

The mixture does not contain substances with endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

#### 12.7. Other adverse effects

Not available.

### SECTION 13: Disposal considerations

#### 13.1. Waste treatment methods

Hazard of environmental contamination; dispose of the waste in accordance with the local and/or national regulations. 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 a person authorised for waste removal (a specialized company) that is entitled 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.

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### Waste management legislation

Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste, as amended.  
Decision 2000/532/EC establishing a list of wastes, as amended.

### SECTION 14: Transport information

- 14.1. UN number or ID number**  
not subject to transport regulations
- 14.2. UN proper shipping name**  
not relevant
- 14.3. Transport hazard class(es)**  
not relevant
- 14.4. Packing group**  
not relevant
- 14.5. Environmental hazards**  
not relevant
- 14.6. Special precautions for user**  
Reference in the Sections 4 to 8.
- 14.7. Maritime transport in bulk according to IMO instruments**  
not relevant

### 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 18th December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing the 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 as amended.
- 15.2. Chemical safety assessment**  
not available

### SECTION 16: Other information

#### 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 the 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 Abstracts Service
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substance and mixtures
EINECS	European Inventory of Existing Commercial Chemical Substances
EmS	Emergency plan
ES	Identification code for each substance listed in EINECS
EU	European Union
EuPCS	European Product Categorisation System
IATA	International Air Transport Association
IBC	International Code For The Construction And Equipment of Ships Carrying Dangerous Chemicals
ICAO	International Civil Aviation Organization
IMDG	International Maritime Dangerous Goods
INCI	International Nomenclature of Cosmetic Ingredients
ISO	International Organization for Standardization

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IUPAC	International Union of Pure and Applied Chemistry
log K <sub>ow</sub>	Octanol-water partition coefficient
MARPOL	International Convention for the Prevention of Pollution from Ships
OEL	Occupational Exposure Limits
PBT	Persistent, Bioaccumulative and Toxic
ppm	Parts per million
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
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

### 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. Data from the manufacturer of the substance / mixture, if available - information from registration dossiers.

### The changes (which information has been added, deleted or modified)

Overall revision of the safety data sheet according to Commission Regulation (EU) 2020/878.

### More information

Classification procedure - calculation method.

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### 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.

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