



## SAFETY DATA SHEET

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### **Annurtrofil® - Annurca apple fruit dry extract**

Date of the issue: January 2023

Version 1

## **1 IDENTIFICATION OF THE SUBSTANCE AND OF THE COMPANY**

### **1.1 Identification of the product**

Identification of the preparation: Annurtrofil® - Annurca apple fruit dry extract  
Product Code: SSDMPMAC0500900A

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

Preparation for food, dietetic and nutritional use.

### **1.3 Company Identification**

Name: EVRA S.r.l.  
Address: Galdo- zona ind.le Lauria- 85044 Lauria (PZ)  
Telephone no.: (+39) 0973 624687  
Telefax: (+39) 0973 624687  
E-mail address of Scientific  
Department: cto@evraitalia.it

### **1.4 Emergency telephone number**

Main Poison Centers in Italy:  
- Milan (+39) 02 66101029  
- Pavia (+39) 0382 24444  
- Bergamo (+39) 800 883300  
- Florence (+39) 055 7947819  
- Rome (+39) 06 3054343  
- Rome (+39) 06 49978000  
- Naples (+39) 081 7472870

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## **2. HAZARDS IDENTIFICATION**

### **2.1 Classification of the substance**

Classification according to Regulation 1272/2008/CE.  
Main dangerous effects: see 9 – 12 sections.

### **2.2 Label Elements**



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Hazard Pictogram / Signal Word:

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Hazard Statement:

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Precautionary Statement Prevention:

P223: Protect from moisture.

P233: Keep container tightly closed.

P261: Avoid breathing dust / fumes.

P264: Wash hands thoroughly after use.

P280: Wear gloves, protective clothing; protect eyes and face.

P314: If you feel unwell, consult a doctor.

P301 + 312: In case of ingestion, if you feel unwell, contact a doctor / poison control center.

P302 + 352: in case of contact with skin, wash with plenty of water.

P304 + P340: in case of inhalation, transport the injured person to fresh air and keep him at rest in a position that favors breathing.

P330: Rinse mouth

P333 + P313: If skin irritation or rash occurs, seek medical attention.

P362 + P364: Remove all contaminated clothing and wash them before wearing them again.

P403 + P235: Store in a cool, well-ventilated place.

P402 + P404: Store in a dry place and in a tightly closed container

P410: Protect from sunlight

P411 + P235: Store in a cool place at temperatures not exceeding 21 ° C), in dry conditions (humidity <55%).

P501: Dispose of product / container in accordance with regulations.

### 2.3 Other hazards

As a powder product, the non-compliance with the appropriate manufacturing practices and handling, can cause eye and respiratory tract irritation.

This substance / mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at concentrations of 0.1% or higher.

### 2.4 Special indications of danger to man and the environment

Do not dispose of the product in the environment

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## 3. COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Substances

n.a.

### 3.2 Mixture

- Product Identifier: Dry extract of the Annurca apple fruit (*Malus pumila Miller cv Annurca*).

- Botanical name: *Malus pumila Miller cv Annurca*.



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- Composition: Annurca apple fruit dry extr.  
Maltodextrin

For a correct evaluation, take into consideration the normal substances naturally present in the plant.

The product may contain unresearched substances, deriving from the plant matrix used. For a correct evaluation, take into account the normal substances naturally present in the plant and the concentration / titration ratio of the extract (see technical data sheet).

### 4. FIRST AID MEASURES

#### 4.1 Description of first aid measures

Relevant routes of exposure:

- Inhalation: movement of the exposed individual from the area to fresh air is recommended. If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing;
- Skin contact: Take off contaminated clothing and wash before reuse. Removal and handling of clothing and shoes from the individual is recommended.
- Eye contact: Rinse cautiously with water for several minutes. Consult an ophthalmologist in case the eye irritation occurs and persists.
- Ingestion: Rinse mouth. Do NOT induce vomiting. (Only if large amounts were swallowed consult a doctor). Call a POISON CENTER and doctor/physician if you feel unwell

#### 4.2 Indication of any immediate medical attention and special treatment needed

See 4.1 paragraph.

### 5. FIREFIGHTING MEASURES

#### 5.1 Extinguishing media

No particular levels of danger are foreseeable.

Suitable extinguishing media: water spray, CO<sub>2</sub>, chemical powder or foam.

Unsuitable extinguishing media: water direct jet

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

Do not breathe gas/vapours/spray.

#### 5.3 Advice for fire-fighters

Special protective equipment (see also section 8):

- Use respiratory protection;
- Wear full equipment;

Protective measures to be taken:



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- Prevent the formation of dust clouds, avoid the accumulation of electrostatic charges.
- Remove containers from the fire area, if this is possible without risk;
- Damaged containers must be handled only by authorized expert personnel;

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## **6. ACCIDENTAL RELEASE MEASURES**

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

#### - For non-emergency personnel:

Keep people not involved in the emergency away from the affected area. Alert the internal emergency workers or firefighters. If immediate action is required, refer to the indications / instructions for emergency personnel.

#### - For emergency responders:

Wearing suitable personal protective clothing: self-contained breathing apparatus with air reserve or full-face gas mask with dust filter;

Stop the source of ignition if the operation permits. Provide adequate ventilation of the premises concerned. Whenever possible, operate above wind.

Avoid contact with eyes and skin. Avoid inhalation. Wear suitable clothing, half masks with approved filter, gloves and goggles (see also section 8).

### **6.2 Environmental precautions**

Minimize the affected area by containing the leak. Prevent the product from entering the sewer system, wells and waterways. If the product is escaped into a water course, into the sewer system or has contaminated the ground or vegetation, contact the competent authorities.

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

Recommendations on how to contain a spill:

- avoid the generation of dust, for example moisten the dust with water;

Recommendations on remediation methods:

- quickly collect the product, wearing a suitable mask and protective clothing, for reuse, if possible, or for elimination;

Introduce the material in clean and labelled containers:

- after collection, ventilate and wash the affected area with water before allowing access.

Any other information relating to spills and leaks, techniques "not recommended" for containment or remediation:

- none

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

If necessary, see section 8 to 13.

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## **7 HANDLING AND STORAGE**

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

Avoid contact with eyes, skin and clothing. Avoid prolonged and repeated exposure. Avoid eating or drinking while using the product. Contaminated work clothing should be changed before entering eating areas. Handle containers with care. Do not reuse empty containers



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before they have been cleaned. Before carrying out transfer operations, make sure that there are no residues of incompatible substances inside the tank.

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

Store away from direct sunlight, at room temperature ( $\leq 21^{\circ}\text{C}$ ), in dry conditions (humidity  $<55\%$ ) and in airtight unopened packaging.

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

See section 1.2

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## **8 EXPOSURE CONTROLS / PERSONAL PROTECTION**

### **8.1 Control parameters**

Limit values for occupational exposure DNEL/PNEC:

- TLW-TWA (powders): N.A. mg/m<sup>3</sup>

### **8.2 Exposure controls**

Adequate technical controls: the rooms where the substance is stored / handled must be equipped with an aspirator, adequately ventilated, cool and dry.

Individual protection measures, such as personal protective equipment:

- Eye protection: use suitable devices for eye protection (eg safety glasses) tested and approved according to the requirements of appropriate technical standards, such as NIOSH (USA) or EN 166 (EU).
- Skin protection: full skin protection clothing (PVC, viton, cotton, rubber).
- Hand protection: protective gloves (PVC, neoprene, rubber) compliant with the provisions of EU directive 89/686 / EEC and the resulting EN 374 standards. Gloves must be checked before use. Use an appropriate technique for removing the gloves (without touching the external surface) to avoid contact with the skin of the product. After use, dispose of the protective gloves as required by current legislation and according to good laboratory and production practices. Wash your hands after use.
- Respiratory protection: filter half mask (CEN / FFP-2 (S) or CEN / FFP-3 (S)). Use respirators and components tested and approved by the competent standardization bodies, such as NIOSH (USA) the CEN (EU) .
- Physical protection: adopt physical protection suitable for current legislation and prepared on the basis of the concentration, quantity of hazardous substances and the job covered.  
Environmental exposure controls: operate in a room provided with aspirator.

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## **9 FISICAL AND CHEMICAL PROPERTIES**

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

Appearance:

Fine powder



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|   |  |
|---|--|
| Colour:   | Brownish, brown-yellowish  |
| Odour:  | Characteristic   |
| pH:   | n.a.   |
| Melting point / Freezing point (°C):                  | n.a.   |
| Initial boiling point/range (°C):                     | n.a.   |
| Flash point (° C):                                    | n.a.   |
| Evaporation rate:                                     | n.a.   |
| Upper / lower flammability limit<br>or explosiveness: | n.a.   |
| Vapor pressure:                                       | n.a.   |
| Tapped Density:                                       | about 0.5 g/mL   |
| Solubility in water:                                  | n.a.   |
| Solubility in oils or organic solvents:               | n.d.   |
| Octanol / water partition coefficient:                | n.d.   |
| Auto-ignition temperature:                            | n.a.   |
| Decomposition temperature:                            | n.d.   |
| Viscosity (mPa x s):                                  | n.a.   |
| Ethanol content:                                      | n.a.   |
| Explosive Properties:                                 | may form flammable/explosive<br>vapour-air mixture in presence of large<br>quantity of product with flames, static<br>electricity. |

### **9.2 Other information**

None

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## **10 STABILITY AND REACTIVITY**

### **10.1 Reactivity**

n.a.

### **10.2 Chemical stability**

Stable in the normal condition.

### **10.3 Possibility of hazardous reactions**

n.a.

### **10.4 Condition to avoid**

Keep cool. Protect from sunlight. Avoid the formation of cloud of dust and accumulation of electrostatic charges.

### **10.5 Incompatible Materials**

Keep/Store away from any incompatible materials, as well as strong antioxidants.

### **10.6 Hazardous decomposition products**

Carbon Oxide and other unidentified organic compounds may be formed upon combustion.



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### 11 TOXICOLOGICAL INFORMATION

#### 11.1 Information on toxicological effects

Based on the data available, no toxicological data are available on the product as such. Therefore, keep in mind the characteristics of the naturally present components in order to evaluate the toxicological effects deriving from exposure to the product.

The toxicological information regarding the main substances naturally present in the product and / or substances with correlable chemical composition are shown below:

- Based on available data, the classification criteria are not met.

However, we invite to consult the following EFSA, EMEA, ECHA and National Library of Medicine databases regarding the possible risks deriving from the substances present in the extract.

As this is a powder product, failure to observe adequate manufacturing and handling practices can cause eye and respiratory tract irritation.

In case of ingestion of large quantities, phenomena such as vomiting, abdominal pain and diarrhea may occur.

#### 11.2 Skin corrosion / skin irritation

Based on available data, the classification criteria are not met.

#### 11.3 Eye damage / irritation

Based on available data, the classification criteria are not met.

#### 11.4 Sensitization of the respiratory tract and skin

Based on available data, the classification criteria are not met.

#### 11.5 Cell mutagenicity

Based on available data, the classification criteria are not met.

#### 11.6 Carcinogenicity

Based on available data, the classification criteria are not met.

#### 11.7 Toxicity to the reproductive system

Based on available data, the classification criteria are not met.

#### 11.8 STOT - single exposure

Based on available data, the classification criteria are not met.

#### 11.9 STOT - repeated exposure

Based on available data, the classification criteria are not met.

#### 11.10 Aspiration hazard

Based on available data, the classification criteria are not met.

#### 11.11 Toxic-kinetics

n.a.



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### 11.12 Probable routes of exposure

n.a.

### 11.13 Symptoms related to physiological and toxicological characteristics

n.a.

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## 12 ECOLOGICAL INFORMATION

### 12.1 Toxicity

No relevant test data are available. Generally, the preparation and its products of degradation are not ecotoxic, nor hazardous for plants and animals and have not any effect on the activity of micro-organism. It is available to avoid the uncontrolled scattering into the environment.

### 12.2 Persistence and biodegradability

n.a.

### 12.3 Bioaccumulative potential

n.a.

### 12.4 Mobility in soil

n.a.

### 12.5 PBT e vPvB Valuation

n.a.

### 12.6 Other adverse effects

n.a.

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## 13 DISPOSAL CONSIDERATIONS

### 13.1 Waste treatment methods

To dispose of this product, contact a specialized waste disposal company. Comply with all European, state and local regulations on environmental protection. For handling and measures in the event of accidental dispersion of the waste, the provisions provided in sections 6 and 7 apply.

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## 14 TRANSPORT INFORMATION

The substance is not hazardous for road, sea and air transport and is not subject to transport regulations.

### 14.1 UN Number

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### 14.2 UN Proper Shipping Name





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### 14.3 Transport Hazard Class

ADR/RID/ADN: --  
Code IMDG: --  
IATA/ICAO: --

### 14.4 Packing Group:

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### 14.5 Environmental Hazard:

ADR/RID- : --  
Marine pollutant: --

### 14.6 Special precaution for user

ADR/RID Tunnel Restriction Code: --  
IATA - Passenger Aircraft: --  
IATA -Cargo Aircraft: --  
IATA - Special Disposal: --  
IATA - ERG: --  
IMDG-EMS: --  
IMDG-Storage Category: --

### 14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Environment Pollutant: No

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## 15. REGULATORY INFORMATION

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

Directive 67/548/CE and amended;  
Reg. n°1907/2006/CE (REACH);  
Reg. n° 1272/2008/CE (CLP);  
Reg. n° 790/2009/CE;

### 15.2 Chemical safety assessment

No

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## 16 OTHER INFORMATION

Labelling according to current regulations:

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List of relevant classification phrases:

- H315: Causes skin irritation.
- H319: Causes serious eye irritation
- H335: May cause respiratory irritation



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The product is not intended to be consumed as such. This safety data sheet is intended for Operators in the Food and/or Cosmetic Sector.

The information above is based on present level of our knowledge. It does not, however, represent any guarantee of the properties or of the use of the product it accompanies. Users should make their own investigations to determine the suitability of the information for their particular purposes.

NVH Italia s.r.l. shall not be held liable for any damage resulting from the incorrect handling or from contact with the above preparation.

The changes made concern the following information:

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**This Safety Data Sheet replaces any previous version and it complies to Reg. (EU) n. 830/2015.**

|             |  |
|-------------|--|
| ADR:        | European Agreement concerning the International Carriage of Dangerous Goods by Road    |
| CAS:        | Chemical Abstracts Service   |
| CLP:        | Classificazione, Etichettatura, Imballaggio.   |
| DNEL:       | Derived No Effect Level  |
| EINECS:     | European Inventory of Existing Commercial Chemical Substances                          |
| GefStoffVO: | Gefahrstoffverordnung Hazardous Substances Ordinance, Germany                          |
| GHS:        | Globally Harmonized System   |
| IATA:       | International Air Transport Association  |
| IATA-DGR:   | International Air Transport Association - Dangerous Goods Regulation                   |
| ICAO:       | International Civil Aviation Organization  |
| ICAO-TI:    | International Civil Aviation Organization – Technical Instructions                     |
| IMDG:       | International Maritime Dangerous Goods   |
| INCI:       | International Nomenclature of Cosmetic Ingredients                                     |
| KSt:        | Strickler coefficient  |
| LC50:       | Lethal Concentration 50%   |
| LD50:       | Lethal Dose 50%  |
| PNEC:       | Predicted No Effect Concentration  |
| RID:        | International Rule for Transport of Dangerous Substances by Railway                    |
| STEL:       | Limite d'esposizione a corto termine.  |
| STOT:       | Specific Target Organ Toxicity   |
| TLV:        | Threshold Limit Value  |
| TWA/TLV:    | Time wighted average: average exposure on the basis of a 8/day, 40h/week work schedule |
| WGK:        | Wassergefährdungsklassen – German water hazard classes                                 |