



# SAFETY DATA SHEET

Based upon Regulation (EC) No 1907/2006, as amended by Regulation (EU) No 2015/830

## UNGENTUM SIMPLEX

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

#### 1.1. Product identifier

**Product name** : UNGENTUM SIMPLEX  
**Synonyms** : EENVOUDIGE ZALF; ONGUENT SIMPLE  
**Registration number REACH** : Not applicable (mixture)  
**Product type REACH** : Mixture

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

##### 1.2.1 Relevant identified uses

This raw material is purchased by a pharmacist and after distribution will be delivered to the patient as such or processed in a magistral or official preparation  
External use

##### 1.2.2 Uses advised against

No uses advised against known

#### 1.3. Details of the supplier of the safety data sheet

##### Supplier of the safety data sheet

Pannoc NV/SA  
Lammerdries-oost 23  
B-2250 Olen  
☎ +32 14 21 70 18  
info@pannoc.eu

#### 1.4. Emergency telephone number

During business hours, 8:00-16:30 (CET) :  
+32 14 21 70 18

### SECTION 2: Hazards identification

#### 2.1. Classification of the substance or mixture

Not classified as dangerous according to the criteria of Regulation (EC) No 1272/2008

#### 2.2. Label elements

Not classified as dangerous according to the criteria of Regulation (EC) No 1272/2008

#### 2.3. Other hazards

No other hazards known

### SECTION 3: Composition/information on ingredients

#### 3.1. Substances

Not applicable

#### 3.2. Mixtures

This mixture does not contain any notifiable substances

### SECTION 4: First aid measures

#### 4.1. Description of first aid measures

##### General:

If you feel unwell, seek medical advice.

##### After inhalation:

Remove the victim into fresh air. Respiratory problems: consult a doctor/medical service.

##### After skin contact:

Rinse with water. Do not apply (chemical) neutralizing agents without medical advice. Soap may be used. Take victim to a doctor if irritation persists.

##### After eye contact:

Rinse with water. Remove contact lenses, if present and easy to do. Continue rinsing. Do not apply (chemical) neutralizing agents without medical advice.  
Take victim to an ophthalmologist if irritation persists.

##### After ingestion:

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Rinse mouth with water. Do not apply (chemical) neutralizing agents without medical advice. Do not induce vomiting. Consult a doctor/medical service if you feel unwell.

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

### 4.2.1 Acute symptoms

#### After inhalation:

No effects known.

#### After skin contact:

No effects known.

#### After eye contact:

No effects known.

#### After ingestion:

No effects known.

### 4.2.2 Delayed symptoms

No effects known.

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

If applicable and available it will be listed below.

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

#### 5.1.1 Suitable extinguishing media:

Small fire: Quick-acting ABC powder extinguisher, Quick-acting BC powder extinguisher, Quick-acting class B foam extinguisher, Quick-acting CO2 extinguisher.

Major fire: Class B foam (not alcohol-resistant).

#### 5.1.2 Unsuitable extinguishing media:

Small fire: Water (quick-acting extinguisher, reel); risk of puddle expansion.

Major fire: Water; risk of puddle expansion.

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

Upon combustion: CO and CO2 are formed.

### 5.3. Advice for firefighters

#### 5.3.1 Instructions:

No specific fire-fighting instructions required.

#### 5.3.2 Special protective equipment for fire-fighters:

Gloves (EN 374). Protective clothing (EN 14605 or EN 13034). Heat/fire exposure: compressed air apparatus (EN 136 + EN 137).

## SECTION 6: Accidental release measures

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

No naked flames.

#### 6.1.1 Protective equipment for non-emergency personnel

See heading 8.2

#### 6.1.2 Protective equipment for emergency responders

Gloves (EN 374). Protective clothing (EN 14605 or EN 13034).

#### Suitable protective clothing

See heading 8.2

### 6.2. Environmental precautions

Contain released product.

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

Scoop solid spill into closing containers. Clean contaminated surfaces with a soap solution. Wash clothing and equipment after handling.

### 6.4. Reference to other sections

See heading 13.

## SECTION 7: Handling and storage

The information in this section is a general description. If applicable and available, exposure scenarios are attached in annex. Always use the relevant exposure scenarios that correspond to your identified use.

### 7.1. Precautions for safe handling

Keep away from naked flames/heat. Observe normal hygiene standards. Keep container tightly closed.

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

#### 7.2.1 Safe storage requirements:

Storage temperature: 15 °C - 25 °C. Store in a dark area. Meet the legal requirements.

#### 7.2.2 Keep away from:

Heat sources.

#### 7.2.3 Suitable packaging material:

Polypropylene.

#### 7.2.4 Non suitable packaging material:

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No data available

## 7.3. Specific end use(s)

If applicable and available, exposure scenarios are attached in annex. See information supplied by the manufacturer.

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

#### 8.1.1 Occupational exposure

##### a) Occupational exposure limit values

If limit values are applicable and available these will be listed below.

##### b) National biological limit values

If limit values are applicable and available these will be listed below.

#### 8.1.2 Sampling methods

If applicable and available it will be listed below.

#### 8.1.3 Applicable limit values when using the substance or mixture as intended

If limit values are applicable and available these will be listed below.

#### 8.1.4 Threshold values

If applicable and available it will be listed below.

#### 8.1.5 Control banding

If applicable and available it will be listed below.

### 8.2. Exposure controls

The information in this section is a general description. If applicable and available, exposure scenarios are attached in annex. Always use the relevant exposure scenarios that correspond to your identified use.

#### 8.2.1 Appropriate engineering controls

Keep away from naked flames/heat.

#### 8.2.2 Individual protection measures, such as personal protective equipment

Observe normal hygiene standards. Do not eat, drink or smoke during work.

##### a) Respiratory protection:

Respiratory protection not required in normal conditions.

##### b) Hand protection:

Protective gloves against chemicals (EN 374).

##### c) Eye protection:

Eye protection not required in normal conditions.

##### d) Skin protection:

Protective clothing (EN 14605 or EN 13034).

#### 8.2.3 Environmental exposure controls:

See headings 6.2, 6.3 and 13

## SECTION 9: Physical and chemical properties

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

|                           |  |
|---------------------------|--|
| Physical form             | Paste  |
|                           | Homogeneous ointment                                   |
| Odour                     | No data available on odour                             |
| Odour threshold           | No data available in the literature                    |
| Colour                    | Yellow to light yellow                                 |
| Particle size             | No data available in the literature                    |
| Explosion limits          | No data available in the literature                    |
| Flammability              | Not classified as flammable                            |
| Log Kow                   | Not applicable (mixture)                               |
| Dynamic viscosity         | No data available in the literature                    |
| Kinematic viscosity       | No data available in the literature                    |
| Melting point             | No data available in the literature                    |
| Boiling point             | No data available                                      |
| Evaporation rate          | No data available                                      |
| Relative vapour density   | No data available in the literature                    |
| Vapour pressure           | No data available in the literature                    |
| Solubility                | Water ; insoluble                                      |
| Relative density          | No data available in the literature                    |
| Decomposition temperature | No data available in the literature                    |
| Auto-ignition temperature | No data available in the literature                    |
| Flash point               | No data available in the literature                    |
| Explosive properties      | No chemical group associated with explosive properties |
| Oxidising properties      | No chemical group associated with oxidising properties |
| pH                        | No data available in the literature                    |

### 9.2. Other information

|                  |                                     |
|------------------|-------------------------------------|
| Surface tension  | No data available in the literature |
| Absolute density | No data available in the literature |

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## SECTION 10: Stability and reactivity

### 10.1. Reactivity

Heating increases the fire hazard.

### 10.2. Chemical stability

No data available.

### 10.3. Possibility of hazardous reactions

No data available.

### 10.4. Conditions to avoid

#### Precautionary measures

Keep away from naked flames/heat.

### 10.5. Incompatible materials

No data available.

### 10.6. Hazardous decomposition products

Upon combustion: CO and CO<sub>2</sub> are formed.

## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

#### 11.1.1 Test results

#### Acute toxicity

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No (test)data on the mixture available

##### Conclusion

Not classified for acute toxicity

#### Corrosion/irritation

##### UNGUENTUM SIMPLEX

No (test)data on the mixture available

##### Conclusion

Not classified as irritating to the skin

Not classified as irritating to the eyes

Not classified as irritating to the respiratory system

#### Respiratory or skin sensitisation

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No (test)data on the mixture available

##### Conclusion

Not classified as sensitizing for skin

Not classified as sensitizing for inhalation

#### Specific target organ toxicity

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No (test)data on the mixture available

##### Conclusion

Not classified for subchronic toxicity

#### Mutagenicity (in vitro)

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No (test)data on the mixture available

#### Mutagenicity (in vivo)

##### UNGUENTUM SIMPLEX

No (test)data on the mixture available

##### Conclusion

Not classified for mutagenic or genotoxic toxicity

#### Carcinogenicity

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No (test)data on the mixture available

##### Conclusion

Not classified for carcinogenicity

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## Reproductive toxicity

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No (test)data on the mixture available

#### Conclusion

Not classified for reprotoxic or developmental toxicity

## Toxicity other effects

### UNGUENTUM SIMPLEX

No (test)data on the mixture available

## Chronic effects from short and long-term exposure

### UNGUENTUM SIMPLEX

No effects known.

## SECTION 12: Ecological information

### 12.1. Toxicity

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No (test)data on the mixture available

#### Conclusion

Not classified as dangerous for the environment according to the criteria of Regulation (EC) No 1272/2008

### 12.2. Persistence and degradability

Contains non readily biodegradable component(s)

### 12.3. Bioaccumulative potential

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##### Log Kow

| Method | Remark                   | Value | Temperature | Value determination |
|--------|--------------------------|-------|-------------|---------------------|
|        | Not applicable (mixture) |       |             |                     |

#### Conclusion

Contains bioaccumulative component(s)

### 12.4. Mobility in soil

No (test)data on mobility of the components available

### 12.5. Results of PBT and vPvB assessment

Due to insufficient data no statement can be made whether the component(s) fulfil(s) the criteria of PBT and vPvB according to Annex XIII of Regulation (EC) No 1907/2006.

### 12.6. Other adverse effects

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##### Greenhouse gases

None of the known components is included in the list of fluorinated greenhouse gases (Regulation (EU) No 517/2014)

##### Ozone-depleting potential (ODP)

Not classified as dangerous for the ozone layer (Regulation (EC) No 1005/2009)

## SECTION 13: Disposal considerations

The information in this section is a general description. If applicable and available, exposure scenarios are attached in annex. Always use the relevant exposure scenarios that correspond to your identified use.

### 13.1. Waste treatment methods

#### 13.1.1 Provisions relating to waste

##### European Union

Can be considered as non hazardous waste according to Directive 2008/98/EC, as amended by Regulation (EU) No 1357/2014 and Regulation (EU) No 2017/997.

Waste material code (Directive 2008/98/EC, Decision 2000/0532/EC).

07 05 99 (wastes from the MFSU of pharmaceuticals: wastes not otherwise specified). Depending on branch of industry and production process, also other waste codes may be applicable.

#### 13.1.2 Disposal methods

Remove waste in accordance with local and/or national regulations. Do not discharge into drains or the environment. Dispose of at authorized waste collection point.

#### 13.1.3 Packaging/Container

##### European Union

Waste material code packaging (Directive 2008/98/EC).

15 01 02 (plastic packaging).

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## SECTION 14: Transport information

Road (ADR), Rail (RID), Inland waterways (ADN), Sea (IMDG/IMSBC), Air (ICAO-TI/IATA-DGR)

|  |  |   |
|--|--|---|
| 14.1. UN number  | Transport                                | Not subject                             |
| 14.2. UN proper shipping name  |  |   |
| 14.3. Transport hazard class(es)   |  |   |
|  | Hazard identification number             |   |
|  | Class                                    |   |
|  | Classification code                      |   |
| 14.4. Packing group  |  |   |
|  | Packing group                            |   |
|  | Labels                                   |   |
| 14.5. Environmental hazards  |  |   |
|  | Environmentally hazardous substance mark | no                                      |
| 14.6. Special precautions for user                                       |  |   |
|  | Special provisions                       |   |
|  | Limited quantities                       |   |
| 14.7. Transport in bulk according to Annex II of Marpol and the IBC Code |  |   |
|  | Annex II of MARPOL 73/78                 | Not applicable, based on available data |

## SECTION 15: Regulatory information

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

European legislation:

VOC content Directive 2010/75/EU

| VOC content | Remark            |
|-------------|-------------------|
|             | No data available |

National legislation Belgium

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No data available

National legislation The Netherlands

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Waterbezwaarlijkheid Z (1); Algemene Beoordelingsmethodiek (ABM)

National legislation France

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No data available

National legislation Germany

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WGK 1; Verordnung über Anlagen zum Umgang mit wassergefährdenden Stoffen (AwSV) - 18. April 2017

National legislation United Kingdom

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No data available

Other relevant data

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No data available

15.2. Chemical safety assessment

No chemical safety assessment has been conducted for the mixture.

## SECTION 16: Other information

|              |  |
|--------------|--|
| (*)          | INTERNAL CLASSIFICATION BY BIG   |
| ADI          | Acceptable daily intake  |
| AOEL         | Acceptable operator exposure level   |
| CLP (EU-GHS) | Classification, labelling and packaging (Globally Harmonised System in Europe) |
| DMEL         | Derived Minimal Effect Level   |
| DNEL         | Derived No Effect Level  |
| EC50         | Effect Concentration 50 %  |
| ErC50        | EC50 in terms of reduction of growth rate                                      |
| LC50         | Lethal Concentration 50 %  |
| LD50         | Lethal Dose 50 %   |
| NOAEL        | No Observed Adverse Effect Level   |
| NOEC         | No Observed Effect Concentration   |
| OECD         | Organisation for Economic Co-operation and Development                         |
| PBT          | Persistent, Bioaccumulative & Toxic  |

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|      |  |
|------|--|
| PNEC | Predicted No Effect Concentration      |
| STP  | Sludge Treatment Process               |
| vPvB | very Persistent & very Bioaccumulative |

The information in this safety data sheet is based on data and samples provided to BIG. The sheet was written to the best of our ability and according to the state of knowledge at that time. The safety data sheet only constitutes a guideline for the safe handling, use, consumption, storage, transport and disposal of the substances/preparations/mixtures mentioned under point 1. New safety data sheets are written from time to time. Only the most recent versions may be used. Unless indicated otherwise word for word on the safety data sheet, the information does not apply to substances/preparations/mixtures in purer form, mixed with other substances or in processes. The safety data sheet offers no quality specification for the substances/preparations/mixtures in question. Compliance with the instructions in this safety data sheet does not release the user from the obligation to take all measures dictated by common sense, regulations and recommendations or which are necessary and/or useful based on the real applicable circumstances. BIG does not guarantee the accuracy or exhaustiveness of the information provided and cannot be held liable for any changes by third parties. This safety data sheet is only to be used within the European Union, Switzerland, Iceland, Norway and Liechtenstein. Any use outside of this area is at your own risk. Use of this safety data sheet is subject to the licence and liability limiting conditions as stated in your BIG licence agreement or when this is failing the general conditions of BIG. All intellectual property rights to this sheet are the property of BIG and its distribution and reproduction are limited. Consult the mentioned agreement/conditions for details.

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