SAFETY DATA SHEET

(REACH regulation (EC) n° 1907/2006 - n° 2020/878)

SECTION 1 : IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product name : PURESSENTEL RESPIRATOIRE SPRAY NASAL DECONGESTIONNANT

Product code : CTG190227/00.

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

MEDICAL DEVICE

1.3. Details of the supplier of the safety data sheet

Registered company name : Laboratoire PURESSENTIEL®.

Address : Avenue Molière 144. 1050. Bruxelles. BELGIUM

Telephone : +32 (0) 2 896 44 88

Mail : reglementaire@puressentiel.com

1.4. Emergency telephone number : +33 (0)1.45.42.59.59.

Association/Organisation : INRS/ORFILA http://www.centres-antipoison.net.

SECTION 2 : HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

In compliance with EC regulation No. 1272/2008 and its amendments.

Not applicable

2.2. Label elements

Not applicable

2.3. Other hazards

Not applicable

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

Composition : See labeling

SECTION 4 : FIRST AID MEASURES

As a general rule, in case of doubt or if symptoms persist, always call a doctor.

NEVER induce swallowing by an unconscious person.

4.1. description of first aid measures

In the event of exposure by inhalation :

In the event of an allergic reaction, seek medical attention.

In the event of splashes or contact with skin :

In the event of an allergic reaction, seek medical attention.

In the event of swallowing :

Seek medical attention, showing the label.

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

No data available.

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

No data available.

SECTION 5 : FIREFIGHTING MEASURES

Non-flammable.

5.1. Extinguishing media

5.2. Special hazards arising from the substance or mixture

A fire will often produce a thick black smoke. Exposure to decomposition products may be hazardous to health.

Do not breathe in smoke.

5.3. Advice for firefighters

No data available.

SECTION 6 : ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Consult the safety measures listed under headings 7 and 8.

For first aid worker

First aid workers will be equipped with suitable personal protective equipment (See section 8).

6.2. Environmental precautions

Contain and control the leaks or spills with non-combustible absorbent materials such as sand, earth, vermiculite, diatomaceous earth in drums for waste disposal.

Prevent any material from entering drains or waterways.

6.3. Methods and material for containment and cleaning up

Clean preferably with a detergent, do not use solvents.

6.4. Reference to other sections

No data available.

SECTION 7 : HANDLING AND STORAGE

Requirements relating to storage premises apply to all facilities where the mixture is handled.

7.1. Precautions for safe handling

Always wash hands after handling.

Remove and wash contaminated clothing before re-using.

Fire prevention :

Prevent access by unauthorised personnel.

Recommended equipment and procedures :

For personal protection, see section 8.

Observe precautions stated on label and also industrial safety regulations.

Prohibited equipment and procedures :

No smoking, eating or drinking in areas where the mixture is used.

7.2. Conditions for safe storage, including any incompatibilities

No data available.

Storage

Keep out of reach of children.

Packaging

Always keep in packaging made of an identical material to the original.

7.3. Specific end use(s)

No data available.

SECTION 8 : EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

No data available.

8.2. Exposure controls

Personal protection measures, such as personal protective equipment

Use personal protective equipment that is clean and has been properly maintained.

Store personal protective equipment in a clean place, away from the work area.

Never eat, drink or smoke during use. Remove and wash contaminated clothing before re-using. Ensure that there is adequate ventilation, especially in confined areas.

- Eye / face protection

Avoid contact with eyes.

Use eye protectors designed to protect against liquid splashes

Before handling, wear safety goggles in accordance with standard EN166.

- Hand protection

Wear suitable protective gloves in the event of prolonged or repeated skin contact.

Use suitable protective gloves that are resistant to chemical agents in accordance with standard EN ISO 374-1.

Gloves must be selected according to the application and duration of use at the workstation.

Protective gloves need to be selected according to their suitability for the workstation in question : other chemical products that may be handled, necessary physical protections (cutting, pricking, heat protection), level of dexterity required.

Type of gloves recommended :
- Natural latex
- Nitrile rubber (butadiene-acrylonitrile copolymer rubber (NBR))
- PVC (polyvinyl chloride)
- Butyl Rubber (Isobutylene-isoprene copolymer)

- Body protection

Work clothing worn by personnel shall be laundered regularly.
After contact with the product, all parts of the body that have been soiled must be washed.

SECTION 9 : PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical state	
Physical state :	Fluid liquid.
Colour	
Unspecified	
Odour	
Odour threshold :	Not stated.
Melting point	
Melting point/melting range :	Not specified.
Freezing point	
Freezing point / Freezing range :	Not stated.
Boiling point or initial boiling point and boiling range	
Boiling point/boiling range :	Not specified.
Flammability	
Flammability (solid, gas) :	Not stated.
Lower and upper explosion limit	
Explosive properties, lower explosivity limit (%) :	Not stated.
Explosive properties, upper explosivity limit (%) :	Not stated.
Flash point	
Flash Point Interval :	FP > 100°C.
Auto-ignition temperature	
Self-ignition temperature :	Not specified.
Decomposition temperature	
Decomposition point/decomposition range :	Not specified.
pH	
pH :	3.00 0.2. Slightly acidic.
pH (aqueous solution) :	Not stated.
Kinematic viscosity	
Viscosity :	Not stated.
Viscosity:	v < 7 mm2/s (40°C)
Solubility	
Water solubility :	Dilutable.
Fat solubility :	Not stated.
Partition coefficient n-octanol/water (log value)	
Partition coefficient: n-octanol/water :	Not stated.
Vapour pressure	
Vapour pressure (50°C) :	Below 110 kPa (1.10 bar).
Density and/or relative density	
Density :	= 1

Relative vapour density

Vapour density : Not stated.

9.2. Other information

No data available.

9.2.1. Information with regard to physical hazard classes

No data available.

9.2.2. Other safety characteristics

No data available.

SECTION 10 : STABILITY AND REACTIVITY

10.1. Reactivity

No data available.

10.2. Chemical stability

This mixture is stable under the recommended handling and storage conditions in section 7.

10.3. Possibility of hazardous reactions

No data available.

10.4. Conditions to avoid

Avoid :

- frost

10.5. Incompatible materials

No data available.

10.6. Hazardous decomposition products

No data available.

SECTION 11 : TOXICOLOGICAL INFORMATION

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

No data available.

11.1.1. Substances

Acute toxicity :

EUCALYPTOL (CAS: 470-82-6)

Oral route : LD50 = 2480 mg/kg

11.1.2. Mixture

Respiratory or skin sensitisation :

Contains at least one sensitising substance. May cause an allergic reaction.

11.2. Information on other hazards

Monograph(s) from the IARC (International Agency for Research on Cancer) :

CAS 5989-27-5 : IARC Group 3 : The agent is not classifiable as to its carcinogenicity to humans.

CAS 123-35-3 : IARC Group 2B : The agent is possibly carcinogenic to humans.

CAS 5989-27-5 : IARC Group 3 : The agent is not classifiable as to its carcinogenicity to humans.

CAS 64-17-5 : IARC Group 1 : The agent is carcinogenic to humans.

CAS 64-17-5 : IARC Group 1 : The agent is carcinogenic to humans.

SECTION 12 : ECOLOGICAL INFORMATION

12.1. Toxicity

12.1.2. Mixtures

No aquatic toxicity data available for the mixture.

12.2. Persistence and degradability

No data available.

12.3. Bioaccumulative potential

No data available.

12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

No data available.

12.6. Endocrine disrupting properties

No data available.

12.7. Other adverse effects

No data available.

SECTION 13 : DISPOSAL CONSIDERATIONS

Proper waste management of the mixture and/or its container must be determined in accordance with Directive 2008/98/EC.

13.1. Waste treatment methods

Do not pour into drains or waterways.

Waste :

Waste management is carried out without endangering human health, without harming the environment and, in particular without risk to water, air, soil, plants or animals.

Recycle or dispose of waste in compliance with current legislation, preferably via a certified collector or company.

Do not contaminate the ground or water with waste, do not dispose of waste into the environment.

Soiled packaging :

Empty container completely. Keep label(s) on container.

Give to a certified disposal contractor.

SECTION 14 : TRANSPORT INFORMATION

Exempt from transport classification and labelling.

14.1. UN number or ID number

-

14.2. UN proper shipping name

-

14.3. Transport hazard class(es)

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14.4. Packing group

-

14.5. Environmental hazards

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14.6. Special precautions for user

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SECTION 15: Regulatory information

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

- Classification and labelling information included in section 2:

Not applicable.

- Container information:

No data available.

- Particular provisions :

No data available.

15.2. Chemical safety assessment

No data available.

SECTION 16 : OTHER INFORMATION

Since the user's working conditions are not known by us, the information supplied on this safety data sheet is based on our current level of knowledge and on national and community regulations.

The mixture must not be used for other uses than those specified in section 1 without having first obtained written handling instructions.

It is at all times the responsibility of the user to take all necessary measures to comply with legal requirements and local regulations.

The information in this safety data sheet must be regarded as a description of the safety requirements relating to the mixture and not as a guarantee of the properties thereof.

Abbreviations :

LD50 : The dose of a test substance resulting in 50% lethality in a given time period.

REACH : Registration, Evaluation, Authorization and Restriction of Chemical Substances.

ATE : Acute Toxicity Estimate

BW : Body Weight

STEL : Short-term exposure limit

TWA : Time Weighted Averages

TMP : French Occupational Illness table

TLV : Threshold Limit Value (exposure)

AEV : Average Exposure Value.

ADR : European agreement concerning the international carriage of dangerous goods by Road.

IMDG : International Maritime Dangerous Goods.

IATA : International Air Transport Association.

ICAO : International Civil Aviation Organisation

RID : Regulations concerning the International carriage of Dangerous goods by rail.

WGK : Wassergefahrdungsklasse (Water Hazard Class).

PBT: Persistent, bioaccumulable and toxic.

vPvB : Very persistent, very bioaccumulable.

SVHC : Substances of very high concern.