

	<b>MATERIAL SAFETY DATA SHEET</b> <i>For a given mixture not exist legal duty to provide a Material Safety Data Sheet. Material Safety Data Sheet is prepared voluntarily and may not comply with all the requirements of Commission Regulation (EU) No. 830/2015.</i>	Date of issue: 2.9.2015
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## **SECTION 1: Identification of substance/mixture and company/undertaking**

### **1. 1. Identification of substance or mixture**

*Trade name:* **Panthenol spray**  
*Product code:* Z110001  
*CAS number:* -  
*ES (EINECS) number:* -  
*Other product names:* -

### **1.2. Relevant intended uses of the substance/mixture and uses recommended**

Medical device - for skin treatment after excessive sunbathing in form of foam spray.

### **1.3. Detailed data on the supplier of the Material Safety Data Sheet:**

*Manufacturer:* **AVEFLOR, a.s.**  
*Address:* Budčeves 26  
 507 32 Kopidlno, Czech Republic  
*Identification number:* Company ID No.: 64259838  
*Telephone:* + 420 493 551111  
*Fax:* + 420 493 551112  
*E-mail:* aveflor@aveflor.cz

**Professionally competent person responsible for the Material Safety Data Sheet:**  
 registrace@aveflor.cz

### **1.4. Emergency information:**

<b>Emergency telephone No. Country</b>	<b>Organisation/Company</b>	<b>Address</b>	<b>Emergency number</b>
CZECH REPUBLIC	Toxikologické informační středisko	Na Bojišti 1, 128 08 Praha 2 <a href="http://www.tis-cz.cz">http://www.tis-cz.cz</a>	+420 224 919 293 +420 224 915 402
AUSTRIA	Vergiftungsinformationszentrale (Poisons Information Centre)	Allgemeines Krankenhaus Waehringer Geurtel 18-20 1090 Vienna	+43 1 406 43 43
BELGIUM	Centre Anti-Poisons/Antigifcentrum c/o Hôpital Central de la Base - Reine Astrid	Rue Bruyn B -1120 Brussels	+32 70 245 245

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FRANCE	ORFILA	<a href="http://www.centres-antipoison.net">http://www.centres-antipoison.net</a>	+33 (0)1 45 42 59 59
GERMANY	Berliner Betrieb für Zentrale Gesundheitliche Aufgaben Institut für Toxikologie, Klinische Toxikologie und Giftnotruf Berlin	Oranienburger Strasse 285 13437 Berlin	+49 30 19240
GREECE	Poison Information Centre Children's Hospital P&A Kyriakou	11762 Athens	+30 21 07 79 37 77
HUNGARY	Országos Kémiai Biztonsági Intézet (National Institute of Chemical Safety) Egészségügyi Toxikológiai Tájékoztató Szolgálat (Health Toxicological Information Service)	1437 Budapest PO Box 839 1097 Budapest, Nagyvárad tér 2	+36 80 20 11 99
ITALY	Centro Antiveleni Ospedale Niguarda Ca' Granda	Piazza Ospedale Maggiore 3 20162 Milano	+39 02 6610 1029
NEDERLAND	Nationaal Vergiftigingen Informatie Centrum (Uitsluitend bestemd om artsen te informeren bij accidentele vergiftigingen)	Heidelberglaan 100 3584 CX Utrecht	+31 30 274 88 88
POLAND	Warsaw Poison Control and Information Centre Praski Hospital	Al. Solidarnosci 67 P-03 401 Warszawa	+48 22 619 66 54 +48 22 619 08 97
PORTUGAL	Centro de Informação Antivenenos – Dra Arlinda Borges Instituto Nacional de Emergência Médica (INEM)	Rua Almirante Barroso, 36 1000-013 Lisboa	808 250 143 (for use only in Portugal), +351 21 330 3284
SPAIN	Servicio de Información Toxicológica Instituto Nacional de Toxicología, Departamento de Madrid	Calle Luis Cabrera 9 E-28002 Madrid	+34 91 562 04 20
UNITED KINGDOM	National Poisons Information Service (Birmingham Centre) City Hospital	Dudley Road B18 7QH Birmingham	0870 600 6266 (UK only)
RUSSIA	Информационно-консультативный центр по токсикологии (РТИАС) Министерство здравоохранения Российской Федерации	3 Сухаревская Площадь Блок 7 129090 г. Москва	+7 495 628 1687 (только на русском)

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Emergency telephone No. Country	Organisation/Company	Address	Emergency number
RUSSIA	Аварийный номер телефона (международная)		112

## **SECTION 2: Hazard identification**

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

Medical device – according to Act. No. 350/2011 Coll Act on chemical substances and mixtures and amendments to certain other acts (the Chemical Act) is not subject to classification, labelling or packaging according to Regulation of the European Parliament and of the Council (EC) no. 1272/2008 (CLP), as amended.

#### **The most serious unfavourable physical and chemical effects and effects on human health and the environment:**

Extremely flammable. Risk of explosion if heated under confinement.

### **2.2. Label elements**

**Signal word:**                      **Danger**    **GHS02**



#### **Labelling of aerosol products pursuant to Direction No. 2013/10/EU.:**

##### **Hazard statement:**

H222 Extremely flammable aerosol.  
H229 Pressurised container: May burst if heated.

##### **Precautionary statements:**

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.  
P211 Do not spray on an open flame or other ignition source.  
P251 Do not pierce or burn, even after use.  
P410 Protect from sunlight.  
P412 Do not expose to temperatures exceeding 50°C/122°F  
P102 Keep out of reach of children.

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**Other hazards:**

The spray creates an explosive mixture when mixed with air. Containers may explode if overheated.

EUH066 Repeated exposure may cause skin dryness or cracking.

**SECTION 3: Composition/information on ingredients**

The product contains the following hazardous ingredients:

Substance name	ES No. (EINECS)	CAS No.	Classification according to Regulation 1272/2008 (CLP)	Content in weight %
Butane	203-448-7	106-97-8	Press. Gas Flam. Gas 1, H220, H280	40.0-50.0
Propane	200-827-9	74-98-6	Press. Gas Flam. Gas 1, H220, H280	10.0-20.0
Isobutane	200-857-2	75-28-5	Press. Gas Flam. Gas 1, H220, H280	1.0-10.0
1-Propanaminium, N,N,N-trimethyl-3-[(1-oxohexadecyl)amino]-, chloride	257-104-6	51277-96-4	Eye Dam. 1, H318	1.0-10.0
2-Phenoxyethanol	204-589-7	122-99-6	Acute Tox. 4, H302 Eye Irrit. 2, H319	0.1-0.5
Ethylhexylglycerin	408-080-2	70445-33-9	Acute Tox. 4, H332 Aquatic Chronic 3, H412 Eye Dam. 1, H318	0.01-0.05
Parfum	-	-	Skin Sens. 1, H317 Repr. 3, H360 Aquatic Chronic 2, H411	0.01-0.10

The remaining ingredients are not classified as hazardous pursuant to Act No. 350/2011 Coll. as amended.

Full wording of all classifications, standard R-statements is provided in section 16.

**SECTION 4: First Aid instructions**

**4.1. First Aid description**

**Upon inhalation**

Take the injured person to fresh air and safeguard physical as well as mental peace. Do not let the person get cold. If the irritation persists, seek for medical help.

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#### **Upon skin contact**

Remove the stained clothes. Wash using plenty of warm water and soap immediately. If the irritation persists, seek for medical help.

#### **Upon eye contact**

Remove contact lenses. Rinse the eye thoroughly with running water (for a period of 15 minutes) and seek for medical help.

#### **Upon ingestion**

Rinse the mouth with water, never provoke vomiting. Drink large quantities of water. Seek for medical help without any undue delay and show the packaging of label of the product.

**4.2. The most important acute and delayed symptoms** Not stated

#### **4.3. Instruction concerning immediate medical help and special treatment**

If health troubles occur, or in case of doubts, inform the attending physician and provide him with this Material Safety Data Sheet.

### **SECTION 5: Fire-fighting measures**

#### **5.1. Extinguishing media**

Suitable extinguishing media: CO<sub>2</sub>, foam, powder, sand or soil.

Unsuitable extinguishing media: Direct flow of water.

#### **5.2. Special hazard arising from substance or mixture**

Vapours of the product are heavier than air; they gather above ground and form explosive mixture with air. Under conditions of uncontrollable fire, complex aerosol mixtures are formed with gas, which may contain carbon monoxide, nitrogen oxides, soot, sulphur dioxide, hydrogen oxide and organic compounds.

#### **5.3. Instructions for fire-fighters**

Fire-resistant protective clothing. Upon powerful development of smoke or vapours, use autonomous breathing apparatus, independent of air supply.

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

### **6.1. Measures to be taken to protect persons, protective means and emergency procedures**

Remove possible sources of ignition. No smoking. Use gas-mask with filter against organic gases and vapours. Air the affected rooms thoroughly. Prevent contact with eyes and skin. Take persons, who are not involved, away.

### **6.2. Measures to be taken to protect the environment**

Prevent contamination of waste waters or watercourses with the liquid or liquid gas. Upon leakage into water or waste water, inform the responsible persons.

### **6.3. Methods and materials to prevent leakage and to perform cleaning**

Cover the product with suitable (flammable) absorbing material and collect it into well-closed containers and perform disposal in accordance with sect. 13. Neutralize the collected material in accordance with the local applicable regulations. Upon leakage of large quantities of the product, inform the fire rescue service and the environment protection department of the municipal authority with extended powers. After removal of the mixture, wash the contaminated place with plenty of water. After work, clean the clothing and equipment.

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

Proceed according to the instructions contained in chapters 7, 8 and 13.

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

### **7.1. Measures for safe handling**

While working with open form of spray, do not eat, drink or smoke. Use the product only in places, where it is not in contact with open fire and other sources of ignition or heat. Protect against direct solar radiation. Use only in well-aired areas. Protect against the possibility of inhaling and damage to eyes by direct contact with spray. Protect against the possibility of ingestion. Keep out of the reach of children.

### **7.2. Conditions for safe storing**

Keep in storage in cool, well-aired place, at the temperature of 5 - 25 °C. Do not expose to solar radiation and temperatures exceeding 50 °C. Keep out of the reach of ignition sources - No smoking. Keep out of the reach of children.

### **7.3. Specific final application(s)**

Medical device - for skin treatment after excessive sunbathing.

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## 8. Exposure controls / personal protection

### 8.1. Control parameters of components

Component	CAS-No	Value	Basis
2-Phenoxyethanol	122-99-6	AGW: 110 mg/m <sup>3</sup> AGW: 20 ppm	TRGS 900

### 8.2. Exposure controls

Adhere to standard measures to be taken for the protection of health at work and in particular, thorough airing. It can be realized by effective overall airing. Do not eat, drink and smoke while working. After work and before break for refreshment and rest, wash your hands thoroughly with soap and water.

#### Protection of respiratory tract

In case of occurrence of higher concentrations, use individual breathing mask with filter against organic vapours.

#### Skin protection

Protective clothing and footwear, protective PVC or rubber gloves. Use protective hand cream after work.

#### Protection of face and eyes

In case of risk of spray burst, use protective goggles or face shield.

#### Thermal hazard

Not stated

#### Limitation of the environment exposure

Adhere to standard measures taken to protect the environment, see subsection 6.2.

## SECTION 9: Physical and chemical properties

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

State of matter (at 20 °C):	compressed liquefied gas (aerosol)
Colour:	white to slightly yellow
Odour:	parfum-like
pH value:	5,0-7,0
Melting point (°C):	Not determined
Boiling point interval (°C):	Not determined
Flash point (DIN 51 794):	cca -69 až -60°C (for propellant)
Lower explosion limit (volume %):	approx. 1.5 (for propellant)
Upper explosion limit (volume %):	approx. 9.5 (for propellant)

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Vapour pressure (at 50 °C):	approx. 1.2 MPa
Aerosol density (at 20 °C) :	approx. 1,000-1,015 g/cm <sup>3</sup>
Solubility in water (at 20 °C):	Not determined
Partition coefficient n-octanol / water (log POW) :	Not determined
Viscosity (at 20 °C) :	Not determined

## **SECTION 10: Stability and reactivity**

### **10.1. Reactivity**

Forms explosive gas mixture with air.

### **10.2. Chemical stability**

Not stated

### **10.3. Possible hazardous reactions**

Not stated

### **10.4. Conditions which shall be avoided**

Possible risk of fire in contact with sources of heat and ignition.

### **10.5. Incompatible materials**

Powerful oxidizing agent, acetylene chloride, peroxides, acids, chlorides, anhydrides, alkali metals.

### **10.6. Hazardous products of decomposition**

Under standard storage conditions, no hazardous decomposition products occur. Upon thermal decomposition carbon oxides are liberated.

## **SECTION 11: Toxicological information**

### **11.1. Information on toxicological effects**

*The values provided below have been determined for individual ingredients of the spray based on source materials submitted by the manufacturer of individual ingredients.*

#### **Acute toxicity of mixture ingredients:**

Mixture propane-butane	LC <sub>50</sub> (by inhalation, rat, 4 h):	658.000 mg/m <sup>3</sup>
1-Propanaminium, N,N,N-trimethyl-3-[(1-oxohexadecyl)amino]-, chloride	LD <sub>50</sub> (rat):	<2,000 mg/kg

#### **Irritation**

Upon contact with eyes, risk of serious damage exists.



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### **Corrosion**

Upon contact with eyes, risk of serious damage exists.

### **Sensitization**

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

### **Toxicity of repeated dose**

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

### **Carcinogenicity**

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

### **Mutagenicity**

Found in laboratory animals and bacteria.

### **Toxicity for reproduction**

Found in laboratory animals.

### **Other information**

Inhalation may cause drowsiness and dizziness.

Repeated or long-term exposure to the aerosol may lead to nausea, weariness and headache. Upon contact with eyes, risk of serious damage exists.

## **SECTION 12: Ecological information**

**Toxicity:** Not determined

**Toxicity of mixture ingredients:** Not determined

**Persistence and degradability:** The propane-butane mixture in the air is oxidized photochemically.

**Bio-accumulation potential:** Not stated

**Mobility in soil:** Under standard conditions of the product, assessment of mobility is negligible. Under emergency circumstances concerning large quantity of the product, the packaging material of the product bursts due to high internal pressure of the spray and the content vaporizes quickly into the atmosphere. In addition, under emergency circumstances, partial leakage of the liquid ingredient of the spray into underground water may be considered. With respect to the small quantity of liquid residual portion after disintegration of the spray, however, this possibility is negligible.

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**Results of PBT and vPvB assessment:** Not applicable, based on available data.

**Other adverse effects:** Not known

### **SECTION 13: Instructions for disposal**

#### **13.1. Methods of waste disposal**

Spray the filled up aerosol product until without pressure. Hand over the empty container to the organization licensed to perform disposal thereof. Unused or empty containers shall be handed over in the hazardous waste collecting station.

Waste type code: 15 01 10\*  
Waste type name: Spray container

#### **Legal regulations concerning waste**

Act No. 185/2001 Coll. to regulate waste and Act No. 188/2004 Coll. to amend Act No. 185/2001 Coll.; Act No.185/2001 Coll. to regulate waste, as amended and Act No. 188/2004 Coll. to amend Act No. 185/2001 Coll.; Act No. 477/2001 Coll. to regulate packaging materials and to amend the relating acts (Packaging Materials Act), as amended; Decree No. 376/2001 Coll. to regulate assessment of hazardous properties of waste, as amended; Decree No. 381/2001 Coll., (Waste Catalogue) as amended.

### **SECTION 14: Information for transport**

**14.1. UN number:** UN 1950  
**14.2. The respective UN title for consignment:** AEROSOLS  
**14.3. Class(es) of dangerousness for transport:** 2 (Gases)  
**14.4. Packaging group:** Not stated  
**14.5. Dangerousness for the environment:** NO  
**14.6. Special safety measures for users:** Not stated  
**14.7. Bulk transport pursuant to annex II to MARPOL73/78 and IBC regulation:**  
Not stated

#### **Additional information for road transport ADR/RID:**

Class: 2 (Gases)  
Classification code: 5F  
Packaging group: -  
Tunnel code: (D)

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**Additional information for sea transport IMDG:**

Class: 2 (Gases)  
 Packaging group: -  
 Ems code: F-D, S-U  
 Substance contaminating sea: Not stated

**Additional information for air transport ICAO/IATA-DGR:**

Class: 2 (Gases)  
 Packaging group: -

**SECTION 15: Information on legal regulations**

**15.1. Regulations concerning safety, health and the environment/specific legal regulations concerning 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. Directive 67/548/EEC as amended and Directive 1999/45/EC as amended. Act No. 350/2011 Coll. to regulate chemical substances and chemical agents, as amended. Act No. 22/1997 Coll., Directive 93/42/EEC, Decree of the Government of the Czech Republic No. 336/2004 Coll., Decree of the Government of the Czech Republic No. 194/2001 Coll., as amended. Decree No. 232/2004 Coll. to regulate implementation of certain provisions of the act to regulate chemical substances and chemical agents and to amend the relating acts, concerning classification, packaging and labelling of hazardous chemical substances and chemical agents, as amended. Decree of the Government of the Czech Republic No. 361/2007 Coll. to regulate conditions for protection of health at work. Act No. 20/1966 Coll. to regulate care for public health, as amended. Act No. 258/2000 Coll. to regulate care for public health, as amended. Decree No. 355/2002 Coll. to regulate emission limits, as amended. ČSN 65 0201 - Flammable liquids, operations and storages. Decree No. 246/2001 Coll. to regulate fire prevention. Act No. 185/2001 Coll. to regulate waste, as amended, and its implementing regulations. Act No. 86/2002 Coll. to regulate protection of the atmosphere, as amended and its implementing regulations.

**15.2. Chemical safety Assessment**

No chemical safety assessment was executed for the mixture.

**SECTION 16: Additional information**

**Changes in the Material Safety Data Sheet:** 3rd issue, correction of labeling in section 2.2

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### Legend to abbreviations and acronyms

CAS	Unambiguous numerical identifier of chemical substances
ES (EINECS)	Existing substances (European Inventory of Existing Commercial Substances)
NPK-P	The highest allowable value of concentration in working environment
PEL	Allowable exposure limit
PBT	Persistent, bio-accumulative and toxic substances
vPvB	Very persistent and very bio-accumulative substances
Eye Dam. 1	Serious eye damage, category 1
Eye Irrit. 2	Serious eye irritation, category 2
Acute Tox. 4	Acute toxicity, category 4
Aquatic Chronic 3	Hazardous to the aquatic environment, category 3
Aquatic Chronic 2	Hazardous to the aquatic environment, category 2
Skin Sens. 1	Skin sensitization, category 1
Repr. 3	Reproductive toxicity, category 3

### Important references to bibliography and sources of data:

Information provided herein is based on our best knowledge and the applicable legislation.

### List of standard statements of hazard (H-statements), precautionary instructions (P-statements) used in this Material Safety Data Sheet:

H220	Extremely flammable gas.
H302	Harmful if swallowed.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H332	Harmful if inhaled.
H411	Toxic to aquatic life with long-lasting effects.
H280	Contains gas under pressure; may explode if heated.
H229	Pressurised container: May burst if heated.
P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P211	Do not spray on an open flame or other ignition source.
P251	Do not pierce or burn, even after use.
P410	Protect from sunlight.
P412	Do not expose to temperatures exceeding 50 °C/122 °F.
P102	Keep out of reach of children.

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**Declaration:**

**According to REACH** – EC Regulation (EC) No 1907/2006, TITLE I, Chapter 1, Article 2, par. 6 **the producer of medical device is not obliged to supply the Material Safety Data Sheet to the recipient.**

**According to CLP** – Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures, Title I, Article 1, par. 5 **this Regulation shall not apply to medical device.**

The Material Safety Data Sheet contains data for safeguarding of occupational safety and protection of health at work and protection of the environment. The data stated herein comply with the current stated of knowledge and experience and are in accordance with the applicable legal regulations. The supplier shall not be liable for any damage, which may be sustained due to incorrect use of the mixture. Any amendments to the Material Safety Data Sheet are forbidden without consent of the professionally competent person.