

	MATERIAL SAFETY DATA SHEET <i>For a given mixture does 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. 2020/878.</i>		Date of issue: 3.2.2022
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SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Trade name: **Trioderm® CARE Cooling Spray**
 Product code: Z38, SZ85, SZ90
 CAS code: -
 ES code (EINECS): -
 UFI code: shall not apply to medical device
 Basic UDI-DI: 859401370Z38NT
 Other names of substance/mixture: Trioderm® CARE Chladicí sprej
 Sensomed® Kälte-Spray
 sensiplast® Kältespray
 sensiplast® Cooling spray/Kylsprej/Kylmäsuihke
 sensiplast® Spray Frío
 sensiplast® COOLING SPRAY
 SOS Sport-Eis-Spray
 SPOPHY COOLANT SPRAY
 DermaPlast® ACTIVE Ice spray
 Trioderm® CARE Cooling spray

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

The cooling spray that is used for the relief of pain associated with a contusion of muscles, joints and other injuries.

1.3. Details of the supplier of the safety data sheet

Manufacturer: **AVEFLOR, a.s.**
 Address: Budčevy 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 telephone number

Emergency telephone No. Country	Organisation/Company	Address	Emergency number
CZECH REPUBLIC	Toxikologické informační středisko	Na Bojišti 1, 128 08 Praha 2 http://www.tis-cz.cz	+420 224 919 293 +420 224 915 402

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Emergency telephone No. Country	Organisation/Company	Address	Emergency number
AUSTRIA	Vergiftungsinformationszentrale (Poisons Information Centre)	Allgemeines Krankenhaus Währinger 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	070 245 245 (prefix)+32
FRANCE	CENTRES ANTIPOISON France	http://www.centres-antipoison.net	ANGERS 02 41 48 21 21 BORDEAUX 05 56 96 40 80 LILLE 08 00 59 59 59 LYON 04 72 11 69 11 MARSEILLE 04 91 75 25 25 NANCY 03 83 22 50 50 PARIS 01 40 05 48 48 TOULOUSE 05 61 77 74 47 (prefix) +33
GERMANY	Giftnotruf der Charité - Universitätsmedizin Berlin Campus Benjamin Franklin	Hindenburgdamm 30 12203 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, Albert Flórián út 2-6	+36 80 20 11 99
ITALY	Centro Nazionale Informazione Tossilologica Istituti Clinici Scientifici Maugeri Spa - Società Benefit - Via Salvatore	Maugeri 10 27100 Pavia	+39 0382 24444
POLAND	Jagiellonian University Medical College	ul. Jakubowskiego 2 31-501 Kraków	+48 12 411 99 99

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PORTUGAL	Poison Information Center National Institute of Medical Emergency	Rua Almirante Barroso, 36 1000-013 Lisbon	808 250 250 (prefix) +351
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	111 (urgent) 999 (less urgent) (prefix) +44
RUSSIA	Информационно- консультативный центр по токсикологии (RTIAC) Министерство здравоохранения Российской Федерации	3 Сухаревская Площадь Блок 7 129090 г. Москва	8 495 628 1687
RUSSIA	Аварийный номер телефона (международная)		112
Switzerland	Tox Info Suisse Freiestrasse 16 8032 Zürich	Freiestrasse 16 8032 Zürich	+41 145

SECTION 2: Hazards identification

2.1. Classification of substance or mixture

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

Can cause frostbite and cold burns. Risk of explosion if heated under confinement.

2.2. Label elements

Signal word: **Danger**

Hazard pictogram: **GHS02**



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Labelling of aerosol products pursuant to Direction No. 75/324/EEC:

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.

3.2 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.

None of the ingredients of the mixture is listed in REACH, Annex XIII resp. XIV - that means that none of them meets PBT or vPvB criteria resp. has endocrine disrupting properties.

SECTION 3: Composition/information on ingredients

3.1. Substance

N/A

3.2. Mixture

The product contains the following hazardous ingredients:

Substance name	CAS No. ES No. (EINECS) Index No. Reg. No. REACH	Classification acc. to Regulation 1272/2008 (CLP)	Specific conc. limits / Multiply factors / ATE	Content (weight %)
Propane	74-98-6 200-827-9 601-003-00-5 01-2119486944-21-xxxx	Flam. Gas 1, H220 Press. Gas, H280	unspecified / unspecified / unspecified	< 20.0
Butane	106-97-8 203-448-7 601-004-00-0 01-2119474691-32-xxxx	Flam. Gas 1, H220 Press. Gas, H280	unspecified / unspecified / unspecified	< 80.0
Isobutane	75-28-5 200-857-2 601-004-00-0 01-2120102843-65-xxxx	Flam. Gas 1, H220 Press. Gas, H280	unspecified / unspecified / unspecified	< 10.0

The full text of classifications, standard phrases and R-phrases is provided in section 16.

SECTION 4: First aid measures

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4.1. First Aid description

Upon inhalation

Take the injured person to fresh air. Do not let the person get cold. If necessary, ensure the artificial breathing and oxygen supply. If symptoms persist, call the medical help.

Upon skin contact

Only when the contact is repeated and long-term: remove the stained clothes; wash the skin using water and soap or a brush and rinse. Cover frostbitten spots with sterile aid. If irritation persists, seek medical help.

Upon eye contact

Rinse the eye thoroughly with running water (for a period of 15 minutes), also under the eyelids. If eye irritation persists, consult a specialist.

Upon ingestion

Rinse mouth with water immediately (only provided that the injured person is conscious). Never try to induce vomiting. Seek medical help immediately and show the doctor the product case or label.

4.2. The most important acute and delayed symptoms

Eye and skin irritation.

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: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media: CO₂, foam, powder, water
Unsuitable extinguishing media: full water jet

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 when mixed with air.
Under conditions of uncontrollable fire, complex aerosol mixtures form which may contain carbon oxides.

5.3. Instructions for fire-fighters

Wear fire-resistant protective clothing, use autonomous breathing apparatus, independent of air supply.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Remove possible sources of ignition. No smoking. Give good airing to affected rooms. Prevent contact of the filling with the eyes or skin. Take persons who are not to be involved away.

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6.2. Environmental precautions

Prevent contamination of the sewerage system or watercourses with the liquid or liquid gas. Upon leakage into water or the sewerage system, inform the persons concerned.

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

Ventilate affected area.

In case not all the product evaporated: Cover the product with suitable (non-flammable) absorbing material; collect in well-closed containers and dispose of pursuant to sec. 13. Dispose of the collected material in accordance with applicable local regulations. If leakage of large quantities of the product occurs, inform the fire rescue service and the environmental protection department of a municipal authority with extended powers.

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

Prevent the contact of decomposed fumes to hot appliances, connected electric appliances. Keep without contact to hot surfaces and reactive materials (chapter 10). Protect against a possibility of inhalation and damage of eyes with a direct interference of the spray. Keep out of reach of children. Keep away from water. Use only in well-ventilated areas.

7.2. Conditions for safe storing

Keep in storage in cool, well-aired place, at the temperature of 5 - 25 °C. The container is under pressure: 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)

The cooling spray that is used for the relief of pain associated with a contusion of muscles, joints and other injuries.

SECTION 8: Exposure controls / personal protection

Under normal conditions of use the check of exposure and protection of persons is useless.

8.1. Control parameters

Chemical formula	CAS	ml/m ³	mg/m ³	Category
butane	106-97-8	-	1810 1450	WEL - Short term value WEL - Long term value

DNEL values (levels of exposure to a substance above which humans should not be exposed)

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DNEL values (levels of exposure to a substance above which humans should not be exposed)				
Substance CAS	Oral mg/kg b.w./day	Inhalation mg/m ³	Dermal mg/kg b.w./day	Note
Butan 106-97-8	Not stated Not stated	Not stated Not stated	Not stated Not stated	Professionals Users
Propan 74-98-6	Not stated Not stated	Not stated Not stated	Not stated Not stated	Professionals Users
Isobutan 75-28-5	Not stated Not stated	Not stated Not stated	Not stated Not stated	Professionals Users

PNEC (concentration of a chemical which marks the limit at which below no adverse effects of exposure in an ecosystem are measured)				
Substance CAS	Drinking water mg/l	Sea water mg/l	Soil mg/kg	Air mg/kg
Butan 106-97-8 Propan 74-98-6 Isobutan 75-28-5	No hazard identified	No hazard identified	No hazard identified	No hazard identified

8.2. Exposure controls

Follow standard measures for protection of health at work and ensure, in particular, thorough ventilation. This may be achieved by effective general ventilation. Wear protective gloves during application. Avoid inhaling the aerosol. Do not eat, drink or smoke during application. After work and before refreshment and rest break, wash your hands thoroughly with soap and water.

Protection of respiratory tract

Not necessary under standard conditions of use. If higher concentrations occur, use a protective mask with a filter against organic vapours.

Skin protection

Wear protective gloves during application. If an accident occurs, prevent a long-lasting contact with the skin. Protective long-sleeve apparel, protective PVC or rubber gloves. Treat hands with a protective cream after work.

Protection of face and eyes

Where there's a risk of dispersion of the spray, use protective goggles.

Thermal hazard

Containers may explode if overheated.

Limitation of the environment exposure

Ensure that standard measures are taken to protect the environment, see subsection 6.2.

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10.3. Possible hazardous reactions

Forms explosive gas mixture with air. Danger of containers bursting because of high vapour pressure. Used empty containers may contain product gases which form explosive mixtures with air.

10.4. Conditions which shall be avoided

No further relevant information available.

10.5. Incompatible materials

Strong oxidizing agents, peroxides.

10.6. Hazardous products of decomposition

Carbon oxides – CO, CO₂.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Under common use according to recommended instructions the manufacturer does not expect an origin of damage of health. The product composition includes a component, whose general toxicological profile in application in the specified concentration for the given purpose does not represent for the user a risk to health. The application of the product in case of healthy persons under normal conditions or normally foreseen conditions, or possibly by means of a designed way does not represent a risk of irritation, sensibilization or other local or system, toxicologically undesirable effects. Laboratory protocols of skin tolerance prove the health harmlessness and a good local tolerance.

The values provided below for individual ingredients are based on MSDS submitted by the manufacturer.

The classification of product is based on ingredients of the mixture (additivity formula acc. to EU Regulation 1272/2008).

Hazzard class	Information	Ingredient / Mixture
Acute toxicity	LC ₅₀ (inhal., rat / 4 hrs) 658 mg/l	Butane
	Shall not be classified	Mixture
Skin corrosion/irritation	Shall not be classified	Mixture
Serious eye damage/irritation	Shall not be classified	Mixture
Respiratory or skin sensitisation	Shall not be classified	Mixture
Germ cell mutagenicity	Shall not be classified	Mixture
Carcinogenicity	Shall not be classified	Mixture
Reproductive toxicity	Shall not be classified	Mixture
STOT-single exposure	Shall not be classified	Mixture
STOT-repeated exposure	Shall not be classified	Mixture
Aspiration hazard	Shall not be classified	Mixture

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11.2 Information on other hazards

11.2.1. Endocrine disrupting properties

None of the ingredients of the mixture is listed in REACH, Annex XIV - that means that none of them has endocrine disrupting properties.

11.2.2. Other information

Not available.

SECTION 12: Ecological information

Under normal conditions of use in accordance with the instructions of the manufacturer the product is not toxic for the environment.

The values provided below for individual ingredients are based on MSDS submitted by the manufacturer.

The classification of product is based on ingredients of the mixture (additivity formula acc. to EU Regulation 1272/2008).

Parameter	Information	Ingredient / Mixture
Toxicity	LC50 27.98 mg/l, (fish, 96 hours)	Butane
	EC50 7.71 mg/l, (algae, 96 hours)	
	LC50 27.98 mg/l, (fish, 96 hours)	Propane
	EC50 7.71 mg/l, (algae, 96 hours)	
	LC50 27.98 mg/l, (fish, 96 hours)	Isopropane
	EC50 7.71 mg/l, (algae, 96 hours)	
	Shall not be classified.	Mixture
Persistence and degradability	Data are not available.	Mixture
Bio-accumulative potential	Data are not available.	Mixture
Mobility in soil	Not applicable.	Mixture
Results of PBT and vPvB assessment	None of the ingredients meets the criteria as PBT or vPvB substances.	Mixture
Endocrine disrupting properties	None of the ingredients of the mixture is listed in REACH, Annex XIV - that means that none of them has endocrine disrupting properties.	Mixture

SECTION 13: Disposal considerations

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.

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

Legal regulations concerning waste
Act No. 541/2020 Coll. Law regarding waste as amended.

SECTION 14: Transport information

- 14.1. UN number or ID number: UN 1950
14.2. UN proper shipping name: **AEROSOLS, flammable**
14.3. Transport hazard class(es): 2 (Gases)
14.4. Packing group: Not stated
14.5. Environmental hazards: NO
14.6. Special precautions for user: Not stated
14.7. Maritime transport in bulk according to IMO instruments:
Not stated. The product is carried packed in limited quantities.

Additional information for road transport ADR/RID:

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

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.

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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. Act No. 356/2003 Coll. to regulate chemical substances and chemical agents, as amended.

Act No. 22/1997 Coll. as amended.

REGULATION (EU) 2017/745 of the EP AND OF THE COUNCIL on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

Government Regulation No. 194/2001 Coll. On aerosol sprays, as amended.

Act No. 350/2001 Coll. on chemical substances and chemical mixtures (chemical act), as amended.

Government Regulation No. 361/2007 Coll. laying down the conditions for the protection of health at work, as amended.

Act No. 372/2011 Coll. on health services and conditions of their provision, as amended.

Act No. 258/2000 Coll. on public health protection, as amended.

Decree No. 337/2010 Coll. on emission limits and other conditions of operation of other stationary sources of air pollution emitting and using volatile organic compounds and on the method of handling products containing volatile organic compounds, as amended.

Decree No. 246/2001 Coll. on fire prevention.

Act No. 541/2020 Coll. on wastes, as amended.

Act No. 201/2012 Coll. on atmosphere, as amended.

15.2. Chemical Safety Assessment

For the mixture was prepared the Final Report of Clinical Evaluation for Medical Device Z38 Trioderm® CARE Cooling spray.

SECTION 16: Other information

Changes in the Material Safety Data Sheet:

2nd issue, update of section 1.1 (correction of Basic UDI-DI, three brand names addition)

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
Flam. Gas 1	Flammable gas, category 1
Press. Gas	Gases under pressure

Important references to bibliography and sources of data:

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

SK050001 MSDS Aeron mixture, Scharr, 2016-03-03

ECHA websites <https://echa.europa.eu/cs/information-on-chemicals>

Regulation EU 1907/2006, Annex XIII and Annex XIV

Methods of evaluating information referred to in Article 9 of Regulation (EC) No 1272/2008 was used for the purpose of classification:

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The classification of the mixture given in Section 2.1 has been carried out according to Article 9, paragraph 1, i.e. Annex I, Part I upto Part V, using the concept of additivity.

List of relevant hazard statements and/or precautionary statements.:

- H220 Extremely flammable gas.
- H280 Contains gas under pressure; may explode if heated.
- H222 Extremely flammable aerosol.
- 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.

Training Instructions:

Familiarize workers with the recommended use, mandatory protective equipment, prohibited product handling, and recommended disposal of the product and its contaminated containers.

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.