	MATERIAL SAFETY DATA SHEET <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. 453/2010.</i>	Issue date: 4.12.2014
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SECTION 1: Identification of the substance/mixture and the company/enterprise

1.1. Product identifier

Trade name: **Kubatul® Pix 45,2 mg/g cutaneous spray, solution**
 Product code: *V16 (150 ml), V42 (250 ml), V43 (500 ml)*
 CAS code: -
 ES code (EINECS): -
 Other names of the substance/mixture: -

1.2. Relevant intended uses of the substance/mixture and uses not recommended

Veterinary medicinal product for dermal application with disinfecting effect.
 Not intended for food producing animals. Do not use on severely bleeding wounds or severely suppurating areas. Do not administer to cats.

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: ID: 64259838
 Phone: + 420 493 551111
 Fax: + 420 493 551112
 E-mail: aveflor@aveflor.cz
 Web: <http://www.aveflor.cz>

Qualified professional responsible for the Material Safety Data Sheet:
registrace@aveflor.cz

1.4. Emergency phone contact

Emergency telephone number	Organisation/Company	Address	Emergency number
Country AUSTRIA	Vergiftungsinformationszentrale (Poisons Information Centre)	Allgemeines Krankenhaus Wahringer 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
FRANCE	ORFILA	http://www.centres-antipoison.net	+33 (0)1 45 42 59 59

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Emergency telephone number	Organisation/Company	Address	Emergency number
Country 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)

SECTION 2: Hazard identification

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2.1. Classification of the 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 veterinary medicinal products.

The most severe adverse physical and chemical effects and effects on human health and the environment: In case of contact with the eyes, risk of severe irritation of eyes. Long-term targeted application may cause frostbites. Extremely flammable.

2.2. Label elements

Labeling for aerosol products acc. to Directive 2013/10/EU as amended

Signal word: **Danger**



GHS02

Labeling acc. to 2001/82/ES as amended:

Wear gloves during treatment. Avoid inhaling aerosol. Do not spray into open flames or onto hot objects. When you have finished, wash your hands with soap and water carefully. Do not pierce or burn, even after use. The product is extremely flammable.

Avoid contact with skin, eyes and mucous membranes. In the event of splashes or contact with your skin or mucosa, wash the exposed body part with a huge amount of water immediately after the exposure. IF IN EYES: Rinse cautiously with plenty of potable water. If symptoms of irritation (rash), allergic reaction or system effects occur, seek medical care.

The product should not come into direct contact with food, potable water, children`s toys.

Store at the temperature up to 25 °C.

Pressurized container: protect from sunlight and do not expose to temperatures exceeding 50°C.

Store away of source of ignition – No smoking.

2.3. Other hazards:


The spray creates an explosive mixture when mixed with air. Containers may explode if overheated. Avoid direct contact with food, drinking water, children's toys.

EUH066 Repeated exposure may cause skin dryness or cracking.

SECTION 3: Composition/information on ingredients

3.1. Substances

Mixture.

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3.2. Mixtures:

The product contains the following hazardous ingredients:

Chemical formula	ES code (EINECS)	CAS code	Classification according to Regulation (EC) 1272/2008 (CLP)	Content in weight %
Ethyl acetate	205-500-4	141-78-6	Flam. Liq. 2; Eye Irrit. 2; STOT SE 3; H225, H319, H336, EUH066	50 - 60
Dimethyl ether	204-065-8	115-10-6	Press. Gas; Flam. Gas 1; H220, H280	25 - 35
Ethanol	200-578-6	64-17-5	Flam. Liq. 2; H225, H319	5 - 10
Beech tar (Pix fagi)	-	-	Skin Irrit., H315 Eye Irrit. 2; H319	< 5

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

SECTION 4: First aid measures

4.1. First Aid description

In case of health complications or doubts, inform your doctor and provide them with the product label or this Material Safety Data Sheet.

Upon inhalation

Take the injured person to fresh air and ensure they are both physically and mentally calm. Do not let the person get cold. If they inhale the product, provide rescue breathing and seek 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 and rinse. Cover frostbitten spots with sterile aid. If irritation persists, seek medical help.

Upon eye contact

Immediately rinse the eye thoroughly with running water (for 15 minutes). Seek medical help.

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 label.

4.2. Most important acute and delayed symptoms and effects

Irritating to eyes, skin, and respiratory organs. Long-term targeted application may cause frostbites and skin dryness or cracking.

4.3. Instruction concerning immediate medical help and special treatment

Proceed symptomatically.

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SECTION 5: Fire-fighting measures

5.1. Extinguishing media

Suitable extinguishing media: Foam, powder, sand or soil.
 Unsuitable extinguishing media: Direct flow of water.

5.2. Special hazard arising from the 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

Fire-resistant protective clothing. If heavy smoke or vapours form, use self-contained closed-circuit breathing apparatus.

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.

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 perform cleaning

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. After the mixture has been removed, wash the contaminated place with plenty of water. After work, clean the clothing and equipment.


6.4. Reference to other sections

Follow instructions provided in chapters 7, 8 and 13.

SECTION 7: Handling and storage

7.1. Measures for safe handling

While applying the spray, do not eat, drink or smoke. Use the product only in places where it does not get into contact with open fire and other sources of ignition or heat. Protect against direct sunlight. Prevent inhaling or injury to eyes by direct contact with the spray. Prevent ingestion.

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7.2. Safe storage conditions

Keep in a cool, well-ventilated place at temperature not exceeding 25 °C. Do not expose to sunlight or temperatures exceeding 50 °C. Keep out of the reach of ignition sources - No smoking. Keep out of reach of children. The product must not get into direct contact with food, potable water or children's toys.

7.3. Specific end uses

For external use and for animals only.

SECTION 8: Exposure controls/ personal protection

8.1. Control parameters

Data for the product is not available. Exposure limits for individual ingredients in the spray:

CAS	Chemical formula	Limit	Category
141-78-6	Ethyl acetate	700 mg/m ³ 900 mg/m ³	PEL NPK-P
115-10-6	Dimethyl ether	TWA 1000 mg/m ³ TLV-C 2000 mg/m ³	CZ OEL CZ OEL
64-17-5	Ethanol	1000 mg/m ³ 3000 mg/m ³	PEL NPK-P

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.

Respiratory tract protection


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.

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Thermal hazard

Containers may explode if overheated.

Limitation of exposure of the environment

Ensure that standard measures are 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:	brown
Smell:	beech-tar-like
pH value:	not determined
Melting temperature (°C):	not determined
Boiling point range (°C):	not determined
Ignition temperature (DIN 51 794):	⊕ 400 °C
Flash point:	from -69 to -60°C (for propane-butane mixture)
Lower explosion limit (vol. %):	approx. 2.5
Upper explosion limit (vol. %):	approx. 11.5
Vapour tension (at 50 °C):	⊳ 1.2 MPa
Density (at 20 °C):	0.915 – 0.930 g/cm ³ (for a solution with no propellant gas)
Water solubility (at 20 °C):	insoluble
Octanol-Water Partition Coefficient (log POW):	not applicable
Viscosity (20 °C):	not determined

SECTION 10: Stability and reactivity

10.1. Reactivity

The spray creates an explosive mixture when mixed with air.

10.2. Chemical stability

Data not available.

10.3. Possible hazardous reactions


Data not available.

10.4. Conditions which need to be prevented

Do not expose to sources of heat, sunlight or temperatures exceeding 50 °C. Protect from open fire or other sources of ignition. Containers may explode if overheated.

10.5. Incompatible materials

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

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10.6. Hazardous products of decomposition

Under standard storage conditions, no hazardous decomposition products are created.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Standard usage in accordance with the recommended instructions of the manufacturer is not expected to cause injury to the health of the animal or the staff. The product contains ingredients with general toxicological profiles which represent no health risks, provided they are used in the given concentration and for the given purpose. Application of the product in case of healthy people or animals under standard or reasonably predictable conditions in the way prescribed does not represent a risk of irritation, sensitization or other adverse local or system effects of toxicological nature.

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

Acute toxicity of ingredients in the mixture:

Ethyl acetate	LC ₅₀ (orally, rat):	5620 mg/kg
	LD ₅₀ (dermally, rabbit):	> 20 mg/kg
	LC ₅₀ (by inhalation, for gases and vapours; rat):	45 mg/l/2 hour
Dimethyl ether	LC ₅₀ (by inhalation, rat):	164 000 ppm
Ethanol	LD ₅₀ (oral, rat):	> 15 800 mg/kg
	LC ₅₀ (by inhalation, rat):	30 000 mg/m ³

Irritability

Irritating to eyes, skin, and respiratory organs.

Corrosion

Based on available data, criteria for classification have not been met.

Sensitization

Data not available.

Toxicity of repeated dose

Data nejsou k dispozici.

Carcinogenicity


Based on available data, criteria for classification have not been met.

Mutagenicity

Based on available data, criteria for classification have not been met.

Toxicity for reproduction

Based on available data, criteria for classification have not been met.

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Other information

Vapours may cause nausea, drowsiness or dizziness.

SECTION 12: Environmental information

Toxicity:	not determined
Toxicity of ingredients in the mixture:	
Ethyl acetate	fish: LC50 = 270 - 330 mg/l/48 hrs. LC50 = 220 - 250 mg/l/96 hrs. (Pimephales promelas) invertebrates: EC50 = >3090 mg/l/24 hrs. (Daphnia sp.) algae: EC50 = >15 mg/l/168 hrs.
Ethanol:	fish: LC50 = 8140 mg/l/48 hrs. (L. idus) invertebrates: EU50 = 9268 - 14221 mg/l/48 hrs. (Daphnia magna) algae: IC5 = 5000 mg/l/7 days (Scenedesmus quadricauda)
Persistence and decomposability:	Data not available.
Bio-accumulation potential:	Data not available.
Mobility in soil:	Data not available.
Results of PBT and vPvB assessment:	Not applicable, based on available data.
Other adverse effects:	Data not available.

SECTION 13: Disposal considerations


13.1. Methods of waste disposal

Dispose of in accordance with applicable regulations. Spray the aerosol out from the container until there's no pressure. Hand over the unused product or the empty container to an entity licensed to perform the disposal.

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

Legal regulations governing waste

Act No. 185/2001 Sb. on waste and Act No. 188/2004 Sb. amending Act No. 185/2001 Sb.; Act No. 185/2001 Sb. on waste, as amended and Act No. 188/2004 Sb. amending Act No. 185/2001 Sb.; Act No. 477/2001 Sb. on packaging and amendments to certain other acts (Packaging Act), as amended; Decree No. 376/2001 Sb. on assessment of hazardous properties of waste, as amended; Decree No. 381/2001 Sb., (Waste Catalogue) as amended.

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SECTION 14: Transport information

- 14.1. **UN number:** UN 1950
- 14.2. **The respective UN title for consignment:** AEROSOLS, flammable
- 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 Marpol 73/78 Annex II and IBC regulation:**
not stated

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)
Packing group: -

SECTION 15: Information on legal regulations

15.1. Regulations concerning safety, health and the environment/specific legal regulations concerning the substance or mixture

Regulation (EC) No. 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, as amended.
Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products, as amended.
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. 350/2011 Sb. on chemical substances and chemical agents, as amended.

Czech Republic Government Decree No. 80/2014 Sb. laying down technical requirements for aerosol dispensers, as amended.

Act No. 185/2001 Sb. on waste, as amended, and related implementing regulations.

15.2. Chemical safety assessment

No assessment of chemical safety has been performed for the mixture.

SECTION 16: Additional information

Changes in the Material Safety Data Sheet: revision in section 2.2 acc. to information for users registered by Institute for State Control of Veterinary of Biologicals and Medicines

Explanatory notes to abbreviations and acronyms


CAS	Unambiguous numerical identifier of chemical substances
ES (EINECS)	Existing substances (European Inventory of Existing Commercial Chemical Substances)
NPK-P	The highest permissible value of concentration in working environment
PEL	Permissible exposure limit
PBT	Persistent, bio-accumulative and toxic substances
vPvB	Very persistent and very bio-accumulative substances
Eye Irrit. 2	Caustic effect and irritability to eyes, category 2
Flam. Gas 1	Flammable gas, category 1
Press. Gas	Pressurized gases
Eye Irrit. 2	Eye irritation, category 2
Skin Irrit. 2	Skin irritation, category 2
Flam. Liq. 2	Flammable liquid, category 2
STOT SE 3	Specific target organ toxicity – single exposure, category 3

Important bibliographical references and data sources:

The information provided herein is based on our best knowledge and applicable current legislation.

List of hazard symbols, standard hazard phrases (H-phrases), safe handling instructions (P-phrases) used in this Material Safety Data Sheet:

H220	Extremely flammable gas
H280	Contains gas under pressure; may explode if heated
H225	Highly flammable liquid and vapour
H315	Causes skin irritation

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H319 Causes serious eye irritation
H336 May cause drowsiness or dizziness
EUH066 Repeated exposure may cause skin dryness or cracking.

Declaration:

According to REACH – EC Regulation (EC) No 1907/2006, TITLE I, Chapter 1, Article 2, par. 6 the producer of veterinary medicinal product 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 veterinary medicinal products.

The Material Safety Data Sheet contains data for the purposes of ensuring occupational safety and protection of health at work and protection of the environment. The data provided herein correspond with the current state of knowledge and experience and is in accordance with applicable legal regulations. The supplier shall not be held liable for any damage which may be caused by incorrect use of the product. Any adjustments to the Material Safety Data Sheet not approved by a qualified professional are forbidden.