

	<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. 453/2010.</i>	Date of issue: 30.10.2013
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## 1. SECTION 1: Identification of the substance/mixture and of the company/undertaking

### 1.1 Product identifier

Trade name: **Blood stop spray alginat**  
Product code:  
CAS code: -  
ES code (EINECS): Registration -  
No.: -  
Other names of substance/mixture: -

### 1.2 Relevant identified uses of the substance or mixture and uses advised against Medical device. Blood stopper with herbal ingredients in a spray form to treat minor skin injuries.

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

1.3 **Produced for:** AlphraMedic AB  
Company and address: Kämpevägen 17 553  
02 Jönköping  
Sweden  
Telephone: + 46 36 340485  
Mobile: + 46 70 2737740  
E-mail: info@alphramedic.se  
Web site: www.alphramedic.se

## 2. SECTION 2: Hazards identification

### 2.1 Classification of substance or mixture

Medical device - pursuant to Act No. 350/2011 Coll. Act on Chemical Substances and Mixtures, and on amendment of some other acts (Chemical Act), as amended, is not subject to classification, labelling and packaging of substances and mixtures pursuant to Regulation (EC) No. 1272/2008 (CLP) of the European Parliament and of the Council, as amended.

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

Irritating to respiratory system. Risk of eye irritation by direct contact with the spray. Extremely flammable. Risk of explosion if heated - pressurized container.

### 2.2 Elements of identification

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



#### Hazard Class and Category Code:

Flam. Aerosol 1 Flammable aerosol, category 1

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

##### Hazard statement:

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

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**Precautionary:**

- 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.

**2.3 Other hazards:**

The spray may form an explosive mixture with air. Containers may explode if heated.

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

**3.1 Substance**

Mixture.

**3.2 Mixture**

The product contains the following hazardous ingredients:

Chemical formula	ES code (EINECS)	CAS code	Classification according to Regulation (EC) No. 1272/2008 (CLP)	Content in weight %
Dimethoxymethane	203-714-2	109-87-5	Flam. Liq. 2, H225	35.0 – 45.0
Butane	203-448-7	106-97-8	Flam. Gas 1, H220 Press. Gas, H280	30.0 – 35.0
Propane	200-827-9	74-98-6	Flam. Gas 1, H220 Press. Gas, H280	5.0 – 10.0
Isobutane	200-857-2	75-28-5	Flam. Gas 1, H220 Press. Gas, H280	1.0 – 5.0
Ethanol	200-578-6	64-17-5	Flam. Liq. 2, H225, H319	1.0 – 5.0
Menthol	218-690-9	2216-51-5	Skin Irrit. 2, H315 Eye Irrit. 2, H319	< 0.5

For full wording of classification, H-statements and R-phrases see Section 16.

**4. SECTION 4: First aid measures**

**4.1 First aid description**

In case of health problems or where there is doubt, contact a doctor and provide him/her with packaging of the preparation or this MSDS.

**Inhalation**

Take the injured person to fresh air and keep him/her calm. Do not let the person to get cold. If not breathing, give artificial respiration and seek medical advice.

**Upon skin contact**

In case of repeated contact: Remove contaminated clothing, wash skin with soap and water using a brush, and rinse. If irritation symptoms persist, seek medical attention.

**Eye contact**

Rinse immediately with plenty of running water (for 10 to 15 minutes). Seek medical advice.

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### **Ingestion**

In case of ingestion, rinse mouth with water or milk. Try to induce vomiting after drinking 0.25 litres of lukewarm water. If vomiting is not induced within 10 minutes, stop attempting its further invocation. If there are signs of shock (pallor, cold sweat, fear and rapid, irregular pulse), immediately consult a doctor.

#### **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**

Follow the symptoms.

### **5. SECTION 5: Firefighting measures**

#### **5.1 Extinguishing media**

Suitable extinguishing media: foam, dry powder, sand, soil  
 Unsuitable extinguishing media: direct water jet

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

Vapours of the product are heavier than air, they gather above ground. Risk of vapour explosion. Hazardous aerosol mixtures with gas are produced under conditions of uncontrolled fire which may contain carbon oxides, formaldehyde, methanol.

#### **5.3 Advice for fire fighters**

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

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

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

Remove possible sources of ignition. No smoking. Shut off the gas inlet. Avoid further release to the surrounding. Air the affected rooms thoroughly. Take persons, who are not involved, away. Prevent contact of the content with eyes and skin.

#### **6.2 Environmental precautions**

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 material for containment and cleaning up**

Depending on the situation, safely pump away, absorb into suitable porous material and take away for disposal in sealed containers. Dispose of in accordance with applicable laws and regulations. Once removed, clean the contaminated area thoroughly with plenty of water. Wash clothing and equipment.

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

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

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

### 7.1 **Precautions for safe handling**

While working with open form of spray, do not eat, drink or smoke. Avoid contact with open flames or hot objects. Protect against direct solar radiation. Use in well-aired areas. Avoid inhalation and eye damage by direct contact with the spray. Avoid contact with foodstuffs. Keep out of reach of children.

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

Store in dry, sheltered, clean storehouses, at temperatures ranging between 5 and 25 °C. Must not be exposed to direct sunlight or stored close to heating units. Keep away from sources of ignition. Keep out of reach of children.

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

Medical device. Blood stopper in spray form.

## 8. **SECTION 8: Exposure controls / personal protection**

### 8.1 **Control parameters**

Data for the preparation are not available. Exposure limits of the individual components of the spray:

CAS	Chemical formula	Limit	Category
109-87-5	Dimethoxymethane	1000 ppm	MAK (Germany)
64-17-5	Ethanol	1000 mg/m <sup>3</sup> 3000 mg/m <sup>3</sup>	PEL NPK-P

### 8.2 **Exposure control**

#### **Respiratory protection**

Not necessary under normal conditions of use. In the case of the occurrence of higher concentrations, use a protective mask with a filter for organic vapours.

#### **Skin protection**

Not necessary under normal conditions of use. In case of emergency, avoid contact of liquid solution or gas with the skin, use PVC or rubber gloves, protective clothing with long sleeves.

#### **Protection of face and eyes**


In case of risk of spray burst, use protective goggles.

#### **Thermal hazard**

Containers may explode if heated.

#### **Environmental exposure control**

Adhere to standard measures for environmental protection, see subsection 6.2.

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## 9. **SECTION 9: Physical and chemical properties**

### Information on basic physical and chemical properties

#### 9.1

Form (at 20 °C):	Suspension mixed with propellant (aerosol)
Colour:	Brownish-yellow
Odour:	Characteristic
pH value:	Not determined
Melting point (°C):	Not determined
Boiling range (°C):	Not determined
Flash point (DIN 51 794):	Not determined
Lower flammability limit (volume %):	Approx. 1.5 vol. % (for propellant)
Upper flammability limit (volume %):	Approx. 9.5 vol. % (for propellant)
Vapour pressure (at 20 °C):	Not determined
Density (at 20 °C):	0.99 – 1.02 g/cm <sup>3</sup> (solution without propellant)
Water solubility (at 20 °C):	Virtually insoluble
Separation factor n-octanol / water (log POW):	Not determined
Viscosity (20 °C):	Not determined

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

### 10.1 **Reactivity**

The spray forms an explosive mixture with air.

### 10.2 **Chemical stability**

No data available

### 10.3 **Possibility of hazardous reactions**

No data available

### 10.4 **Conditions to avoid**

Protect against sources of heat, sunlight and temperatures above 50 °C. Protect against open flame and other sources of ignition. Containers may explode if heated.

### 10.5 **Incompatible materials**

Strong oxidizing and reducing agents, acids, bases, alkali metals and their compounds.

### 10.6 **Hazardous decomposition products**


No hazardous decomposition products occur under standard storage conditions. Thermal decomposition leads to formation of carbon oxides, formaldehyde, methanol.

## 11. **SECTION 11: Toxicological information**

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

In normal use as recommended by manufacturer, no damage to the health of persons is expected. The composition of the product includes ingredients whose general toxicological profile in use with specified concentration for the intended purpose does not present a threat to the health of users. The use of the product by healthy persons under usual or generally foreseeable conditions in the prescribed manner does not present a risk of irritation, sensitization or other local or system, toxicological adverse 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.

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**Acute toxicity of mixture ingredients:**

Dimethoxymethane	LD <sub>50</sub> (dermal, rabbit)	> 5 000 mg/kg
	LD <sub>50</sub> (oral, rat)	6423 mg/kg
	LC <sub>50</sub> (inhalation, rat, gases or vapours)	15000 mg/kg

Butane	LD/LC <sub>50</sub> (inhalation, rat)	658 mg/l
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**Irritability**

May irritate eyes and respiratory system.

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

**Sensitization** No data available.

**Toxicity of repeated dose** No data available.

**Carcinogenicity** No data available.

**Mutagenicity** No data available.

**Toxicity for reproduction** No data available.

**Other information** No data available.

**12. SECTION 12: Ecological information**

**Toxicity:** Not determined

**Toxicity of mixture ingredients:**

Dimethoxymethane:	fish:	LC <sub>50</sub> > 1000 mg/l/96 hrs
	daphnia:	EC <sub>50</sub> > 1200 mg/l/48 hrs

Ethanol:	fish:	LC <sub>50</sub> = 8140 mg/l/48 hrs (L. idus)
	invertebrates:	EU <sub>50</sub> = 9268 - 14221 mg/l/48 hrs (Daphnia magna)
	algae:	IC <sub>50</sub> = 5,000 mg/l/7 days (Scenedesmus quadricauda)

**Persistence and degradability:** Not determined

**Bioaccumulative potential:** Not determined

**Mobility in soil:**

Assessment of product mobility is negligible under standard conditions. In exceptional circumstances, for large quantities of the product, due to rupture of the packaging material, high internal pressure, and leakage of the contents into the atmosphere. It is necessary to take into account the possibility of leakage of a large amount of product into the groundwater. Water forms a gel-like mass when mixed with the product.

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

**Other adverse effects:** No data available.

**13. SECTION 13: Disposal considerations**

**13.1 Methods of waste disposal**

Dispose of the product in accordance with applicable regulations. Spray the filled up aerosol product until without pressure. Hand over the unused product or empty container to the organization licensed to perform disposal thereof.

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Waste type code: 15 01 10\*  
Waste type name: spray container  
(aerosol can)

#### **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.

#### **14. SECTION 14: Transport information**

- 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 the 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)  
Packaging group: -

#### **15. SECTION 15: Information on legal regulations**

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

Act No. 123/2000 Coll. on medicinal devices and amendment to certain related acts, as subsequently 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 Coll. to regulate chemical substances and chemical agents, as amended. Government Order No. 194/2001 Coll., laying down technical requirements for aerosol sprayers, as amended. Act No. 185/2001 Coll., on Waste, as amended, and its implementing regulations.

## 15.2 Chemical safety assessment

No assessment of chemical safety was executed for the mixture.

## 16. SECTION 16: Other information

**Changes in the Material Safety Data Sheet:** 3<sup>rd</sup> edition

### 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
Press. Gas	Pressurized gases
Flam. Gas 1	Flammable gas, category 1
Flam. Liq. 2	Flammable liquid, category 2
Skin Irrit. 2	Skin irritation, category 2
Eye Irrit. 2	Eye irritation, category 2

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

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

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

H220	Extremely flammable gas
H225	Highly flammable liquid and vapour
H280	Contains gas under pressure; may explode if heated
H315	Causes skin irritation
H319	Causes serious eye irritation
H222	Extremely flammable aerosol.
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.

### Declaration:

This Material Safety Data Sheet contains data for assurance of occupational health and safety and environmental protection. The data stated herein comply with the current state 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 product. Any amendments to the Material Safety Data Sheet are forbidden without consent of the professionally competent person.