

<b>MATERIAL SAFETY DATA SHEET</b>		Date of issue: 15.4.2014
<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 revision: 24.4.2015
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## **SECTION 1: Identification of substance/mixture and company/undertaking**

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

Trade name: **Plastic Spray**  
 Product code: Z08  
 CAS code: -  
 ES code (EINECS): -  
 Other names of substance/mixture: -

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

Medical device. Plastic bandage based on acrylic copolymer in the form of sprays for treating small superficial wounds. Do not use on heavily bleeding wounds.

### **1.3. Company or undertaking identification:**

Identification of distributor:	Produced for:
Name or business name:	<b>AlphraMedic AB</b>
Address (place of business):	Kämpevägen 17 553 02 Jönköping Sweden
Telephone:	+ 46 36 340485
Mobile:	+46 70 2737740
E-mail:	info@alphramedic.se

## **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 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 serious damage to eyes. Harmful if swallowed.  
 Extremely flammable. Risk of explosion if heated under confinement.

### **2.2. Label elements**

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



#### **Identification of specific hazards:**

Press. Gas      Pressurized gases  
 Flam. Gas 1  
 Flam. Liq. 2  
 Eye Irrit. 2

#### **Hazard statement:**

H220	Extremely flammable gas.
H225	Highly flammable liquid and vapours.
H280	Contains gas under pressure; may explode if heated.
H319	Causes serious irritation of eyes.

#### **Precautionary:**

P233	Keep container tightly closed.
P240	Ground/bond container and receiving equipment.
P241	Use ventilating equipment.

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P242	Use only non-sparking tools.
P243	Take precautionary measures against static discharge.
P280	Wear protective gloves, clothing, eye and face protection.
P303+P361+P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/ shower.
P370+P378	In case of fire: Use Foam, powder, sand or soil to extinguish.
P264	Wash hands thoroughly after handling.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing.
P337+P313	If eye irritation persists get medical advice/attention.
P403+P235	Store in a well ventilated place. Keep cool.
P501	Dispose of contents/container to in the hazardous waste collecting station.

### Identification for aerosol packaging:

Extremely flammable aerosol. Pressurized container: may burst if heated. Keep out of reach of children. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Do not spray on an open flame or other ignition source. Do not pierce or burn, even after use. Protect from sunlight. Do not expose to temperatures exceeding 50 °C.

**Other hazards:** Not stated

### SECTION 3: Composition/information on ingredients

**3.1. Substance** Mixture.

**3.2. Mixture** The product contains the following hazardous ingredients:

Substance name	ES No. (EINECS)	CAS No.	Classification according to Directive 67/548/ECC	Classification according to Regulation 1272/2008 (CLP)	Content in weight %
Dimethyl ether	204-065-8	115-10-6	F+, R12	Flam. Gas 1, H220 Press. Gas, H280	30 - 40
Ethanol	200-578-6	64-17-5	F, R11	Flam. Liq. 2, H225, H319	30 - 40
1,3-dioxolane	211-463-5	646-06-0	F, R11	Flam. Liq. 2, H225	10 - 20

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

### 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 necessary, ensure the artificial breathing and oxygen supply. Call the medical help.

##### Upon skin contact

Remove the contaminated clothes. Only after long-term or repeated contact with skin: wash the skin with plenty of water with soap using a brush. If the irritation persists, consult with a physician.

##### Upon eye contact

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 or milk. If swallowed, drink 0.25 of lukewarm water and try to provoke vomiting. Stop trying vomiting, if vomiting does not come in ten minutes. In case of shock symptoms (turn pale, cold sweat, fast and irregular pulse) call immediately a physician.

#### 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.

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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 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 oxides, formaldehyde, methanol.

#### **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.

### **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 (inflammable) 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. Plastic dressing spray for wound treatment.

### **SECTION 8: Limitation of exposure / personal protective equipment**

Under normal conditions of use the check of exposure and protection of persons is useless. The data for the product itself are not available. Following data are stated for the components:

#### **8.1. Control parameters**

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Dimethyl ether (CAS:115-10-6) TWA 1920 mg/m<sup>3</sup> 1000 ppm (EU ELV)

TWA 1000 mg/m<sup>3</sup> (CZ OEL)

TLV-C 2000 mg/m<sup>3</sup> (CZ OEL)

## 8.2. Exposure controls

### Protection of respiratory tract

Under normal conditions of use is useless. In case of occurrence of higher concentrations, use individual breathing mask with filter against organic vapours.

### Skin protection

Under normal conditions of use is useless. In case of accident use protective PVC or rubber gloves. Treat the hands with a protective cream.

### Protection of face and eyes

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

### 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):	mixture of viscous liquid with compressed liquefied gas (aerosol)	
Colour:	yellowish to yellow	
Odour:	characteristic after dioxolane and ethanol	
pH value:	Not determined	
Melting point (°C):	Not determined	
Boiling point interval (°C):	Not determined	
Flash point (DIN 51 794):	- 41°C (for dimethyl ether)	
Lower explosion limit (volume %):	approx. 3.4 (for dimethyl ether)	
Upper explosion limit (volume %):	approx. 18 (for dimethyl ether)	
Vapour pressure (at 50 °C):	< 0.03 MPa (for dimethyl ether)	
Aerosol density (at 20 °C):	approx. 833 kg/m <sup>3</sup>	
Solubility in water (at 20 °C):	insoluble	
Partition coefficient n-octanol / water (log POW):	Not determined	
Viscosity:	Not determined	

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

Not stated

### 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. Risk of explosion if heated under confinement.

### 10.5. Incompatible materials

Powerful oxidizing agent, hydroxides, acids, alkali metals.

### 10.6. Hazardous products of decomposition

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

### **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 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:**

Dimethyl ether                      LC<sub>50</sub> (by inhalation, rat):                      164 000 ppm

Inhalation may cause narcosis, anaesthetic effects, heartbeats disorder.

1,3-dioxolane                      LC<sub>50</sub> (by inhalation, rabbit, for aerosols):                      68.4 (mg.l<sup>-1</sup>)

#### **Irritability**

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

#### **Causticity**

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

#### **Sensitization**

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

#### **Toxicity of repeated dose**

Not found

#### **Carcinogenicity**

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

#### **Mutagenicity**

Caused reverse mutations in bacteria (OECD TG 471)

#### **Toxicity for reproduction**

Not found.

#### **Other information**

- none

### **SECTION 12: Ecological information**

**Toxicity:** Not determined

**Toxicity of mixture ingredients:** Not determined

**Persistence and degradability:** Not determined

**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. The liquid forms a plastic film insoluble in water.

**Results of PBT and vPvB assessment:** Not applicable

**Other adverse effects:** Not known

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

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### 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:** CONTAINERS FOR PRESSURIZED 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:  
Safety code:

#### Additional information for sea transport IMDG:

Class: 2 (Gases)  
Packaging group:  
Safety code:  
Ems code:  
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

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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. 356/2003 Coll. to regulate chemical substances and chemical agents, as amended. Act No. 22/1997 Coll., Directive 93/42/EEC, 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 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 it's 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:** 3<sup>rd</sup> issue - revision according to Regulation (EC) No. 1907/2006

#### **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
Flam. Liq. 2	Highly flammable liquid
Press. Gas	Pressurized gases

#### **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
H225	Highly flammable liquid and vapours
H280	Contains gas under pressure; may explode if heated
H319	Causes serious irritation of eyes
P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P233	Keep container tightly closed.
P240	Ground/bond container and receiving equipment.
P241	Use ventilating equipment.
P242	Use only non-sparking tools.
P243	Take precautionary measures against static discharge.
P280	Wear protective gloves, clothing, eye and face protection.
P303+P361+P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/ shower.
P370+P378	In case of fire: Use Foam, powder, sand or soil to extinguish.
P264	Wash hands thoroughly after handling.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing.
P337+P313	If eye irritation persists get medical advice/attention.
P403+P235	Store in a well ventilated place. Keep cool.
P501	Dispose of contents/container to in the hazardous waste collecting station.

#### **Declaration:**

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

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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.