# **PAVIA FARMACEUTICI srl**

## **FFPAVIAFARM - SKIN REPAIR POWDER SPRAY**

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ΕN

## Safety data sheet

## SECTION 1. Identification of the substance/mixture and of the company/undertaking

#### 1.1. Product identifier

Code: **FFPAVIAFARM** Product name

SKIN REPAIR POWDER SPRAY

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

Intended use	SKIN REPAIR		
Identified Uses	Industrial	Professional	Consumer
MEDICAL DEVICE	-	-	$\checkmark$
1.3. Details of the supplier	of the safety data sheet		

#### **TOSVAR SRL** Name Full address VIA DEL LAVORO, 10 District and Country (MI) 20060 POZZO D'ADDA ITALIA 0039 -02-90960289 Tel. 0039-02-90968148 Fax e-mail address of the competent person responsible for the Safety Data Sheet msds@tosvar.it 1.4. Emergency telephone number For urgent inquiries refer to

0039-02-90960289 (8.00 am - 18 pm mon-fri) Per emergenze/For emergency only : +39 3420154736

## **SECTION 2. Hazards identification.**

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

The product is classified as hazardous pursuant to the provisions set forth in EC Regulation 1272/2008 (CLP) (and subsequent amendments and supplements). The product thus requires a safety datasheet that complies with the provisions of EC Regulation 1907/2006 and subsequent amendments.

Any additional information concerning the risks for health and/or the environment are given in sections 11 and 12 of this sheet.

Hazard classification and indication:

Aerosol, category 1	H222	Extremely flammable aerosol.
	H229	Pressurised container: may burst if heated.

#### 2.2. Label elements.

Hazard labelling pursuant to EC Regulation 1272/2008 (CLP) and subsequent amendments and supplements.

Hazard pictograms:



Danger Signal words:

Hazard statements: H222 H229	Extremely flammable aerosol. Pressurised container: may burst if heated.
Precautionary stateme	nts:
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+P412	Protect from sunlight. Do no expose to temperatures exceeding 50°C / 122°F.

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## SECTION 2. Hazards identification. .../>>

#### 2.3. Other hazards.

On the basis of available data, the product does not contain any PBT or vPvB in percentage greater than 0,1%.

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

#### 3.1. Substances.

Information not relevant.

#### 3.2. Mixtures.

#### Contains:

Identification. BUTANE		Conc. %.	Classification 1272/2008 (CLP).
CAS. EC.	106-97-8 203-448-7	30 - 50	Flam. Gas 1 H220, Note K
INDEX.	601-004-00-0		
CAS.		9 - 30	
EC.		0 00	
INDEX.			
PROPAN	E		
CAS.	74-98-6	9 - 30	Flam. Gas 1 H220, Note K
EC.	200-827-9		
INDEX.	601-003-00-5		
ISOBUTA	NE		
CAS.	75-28-5	9 - 30	Flam. Gas 1 H220, Note C K
EC.	200-857-2		
INDEX.	601-004-00-0		

Note: Upper limit is not included into the range. The full wording of hazard (H) phrases is given in section 16 of the sheet.

#### SECTION 4. First aid measures.

#### 4.1. Description of first aid measures.

No episodes of harm to the staff authorised to use the product have been reported. The following general measures should be adopted as necessary:

INHALATION: Remove to open air. If the subject stops breathing, administer artificial respiration. Get medical advice/attention. INGESTION: Get medical advice/attention. Induce vomiting only if indicated by the doctor. Do not give anything by mouth to an unconscious person.

EYES and SKIN: Wash with plenty of water. In the event of persistent irritation, get medical advice/attention.

#### 4.2. Most important symptoms and effects, both acute and delayed.

No episodes of damage to health ascribable to the product have been reported.

#### 4.3. Indication of any immediate medical attention and special treatment needed.

Information not available.

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

#### 5.1. Extinguishing media.

SUITABLE EXTINGUISHING EQUIPMENT The extinguishing equipment should be of the conventional kind: carbon dioxide, foam, powder and water spray. UNSUITABLE EXTINGUISHING EQUIPMENT None in particular.

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

HAZARDS CAUSED BY EXPOSURE IN THE EVENT OF FIRE If overheated, aerosol cans can deform, explode and be propelled considerable distances. Put a protective helmet on before approaching the fire. Do not breathe combustion products.

#### 5.3. Advice for firefighters.

GENERAL INFORMATION Use jets of water to cool the containers to prevent product decomposition and the development of substances potentially hazardous for health. Always wear full fire prevention gear. SPECIAL PROTECTIVE EQUIPMENT FOR FIRE-FIGHTERS

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Normal fire fighting clothing i.e. fire kit (BS EN 469), gloves (BS EN 659) and boots (HO specification A29 and A30) in combination with self-contained open circuit positive pressure compressed air breathing apparatus (BS EN 137).

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

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

Eliminate all sources of ignition (cigarettes, flames, sparks, etc.) from the leakage site. Send away individuals who are not suitably equipped. Wear protective gloves / protective clothing / eye protection / face protection.

#### 6.2. Environmental precautions.

Do not disperse in the environment.

#### 6.3. Methods and material for containment and cleaning up.

Use inert absorbent material to soak up leaked product. Make sure the leakage site is well aired. Contaminated material should be disposed of in compliance with the provisions set forth in point 13.

#### 6.4. Reference to other sections.

Any information on personal protection and disposal is given in sections 8 and 13.

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

#### 7.1. Precautions for safe handling.

Avoid bunching of electrostatic charges. Do not spray on flames or incandescent bodies. Vapours may catch fire and an explosion may occur; vapour accumulation is therefore to be avoided by leaving windows and doors open and ensuring good cross ventilation. Do not eat, drink or smoke during use. Do not breathe spray.

### 7.2. Conditions for safe storage, including any incompatibilities.

Store in a place where adequate ventilation is ensured, away from direct sunlight at a temperature below 50°C/122°F, away from any combustion sources.

#### 7.3. Specific end use(s).

Information not available.

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

#### 8.1. Control parameters.

Regulatory References:

TLV-ACGIH ACGIH 2014

				BU	TANE
Threshold Limit Value.					
Туре	Country	TWA/8h		STEL/15n	nin
		mg/m3	ppm	mg/m3	ppm
TLV-ACGIH			800		

				PRC	OPANE		
Threshold Limit Va	ue.						
Туре	Country	TWA/8h		STEL/15r	nin		
		mg/m3	ppm	mg/m3	ppm		
TLV-ACGIH			2500				

Legend:

(C) = CEILING ; INHAL = Inhalable Fraction ; RESP = Respirable Fraction ; THORA = Thoracic Fraction.

#### 8.2. Exposure controls.

As the use of adequate technical equipment must always take priority over personal protective equipment, make sure that the workplace is well aired through effective local aspiration. HAND PROTECTION None required. SKIN PROTECTION Wear category I professional long-sleeved overalls and safety footwear (see Directive 89/686/EEC and standard EN ISO 20344). Wash body with soap and water after removing protective clothing. EYE PROTECTION Wear airtight protective goggles (see standard EN 166).

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SECTION 8. Exposure controls/personal protection. .../>>

#### RESPIRATORY PROTECTION

If the threshold value (e.g. TLV-TWA) is exceeded for the substance or one of the substances present in the product, a mask with a type AX filter combined with a type P filter should be worn (see standard EN 14387).

Respiratory protection devices must be used if the technical measures adopted are not suitable for restricting the worker's exposure to the threshold values considered. The protection provided by masks is in any case limited.

ENVIRONMENTAL EXPOSURE CONTROLS.

The emissions generated by manufacturing processes, including those generated by ventilation equipment, should be checked to ensure compliance with environmental standards.

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

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

3.1. Information on basic physical and chemical p	operties.
Appearance	aerosol
Colour	colourless
Odour	typical
Odour threshold.	Not available.
pH.	ND
Melting point / freezing point.	Not available.
Initial boiling point.	Not applicable.
Boiling range.	Not available.
Flash point.	Not applicable.
Evaporation Rate	Not available.
Flammability of solids and gases	Not available.
Lower inflammability limit.	1,8 % (V/V).
Upper inflammability limit.	9,5 % (V/V).
Lower explosive limit.	Not available.
Upper explosive limit.	Not available.
Vapour pressure.	Not available.
Vapour density	Not available.
Relative density.	0,570 Kg/l
Solubility	partially soluble in water
Partition coefficient: n-octanol/water	Not available.
Auto-ignition temperature.	Not available.
Decomposition temperature.	Not available.
Viscosity	Not available.
Explosive properties	Not available.
Oxidising properties	Not available.
9.2. Other information.	
VOC (Directive 1999/13/EC) :	0
VOC (volatile carbon) :	0
Pressure (bar)	3-4 bar
Flash point	<- 60°C (ref. propellant)

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

#### 10.1. Reactivity.

There are no particular risks of reaction with other substances in normal conditions of use.

#### 10.2. Chemical stability.

The product is stable in normal conditions of use and storage.

#### 10.3. Possibility of hazardous reactions.

No hazardous reactions are foreseeable in normal conditions of use and storage.

#### **10.4. Conditions to avoid.** Avoid overheating.

Avoid overheating.

#### 10.5. Incompatible materials.

Strong reducing or oxidising agents, strong acids or alkalis, hot material.

## 10.6. Hazardous decomposition products.

Information not available.

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

According to currently available data, this product has not yet produced health damages. Anyway, it must be handled carefully according to good industrial practices. This product may have slight health effects on sensitive people, by inhalation and/or cutaneous absorption and/or contact with eyes and/or ingestion.

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SECTION 11. Toxicological information. .../>>

## 11.1. Information on toxicological effects.

Information not available.

## **SECTION 12. Ecological information.**

Use this product according to good working practices. Avoid littering. Inform the competent authorities, should the product reach waterways or contaminate soil or vegetation.

## 12.1. Toxicity.

Information not available.

- **12.2. Persistence and degradability.** Information not available.
- **12.3. Bioaccumulative potential.** Information not available.

## 12.4. Mobility in soil.

Information not available.

## 12.5. Results of PBT and vPvB assessment.

On the basis of available data, the product does not contain any PBT or vPvB in percentage greater than 0,1%.

## 12.6. Other adverse effects.

Information not available.

## **SECTION 13. Disposal considerations.**

### 13.1. Waste treatment methods.

Reuse, when possible. Product residues should be considered special hazardous waste. The hazard level of waste containing this product should be evaluated according to applicable regulations. Disposal must be performed through an authorised waste management firm, in compliance with national and local regulations.

Waste transportation may be subject to ADR restrictions.

CONTAMINATED PACKAGING

Contaminated packaging must be recovered or disposed of in compliance with national waste management regulations.

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

LIMITED QUANTITY TRANSPORT- ADR TRANSPORT IS NOT REQUIRED.

## 14.1. UN number.

ADR / RID, IMDG, IATA: 1950

## 14.2. UN proper shipping name.

ADR / RID:	AEROSOLS, FLAMMABLE
IMDG:	AEROSOLS
IATA:	AEROSOLS, FLAMMABLE

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### SECTION 14. Transport information. .../>>

	_			
14.3.	Transpor	t hazard	class	(es).

ADR / RID:	Class: 2	Label: 2.1
IMDG:	Class: 2	Label: 2.1
IATA:	Class: 2	Label: 2.1



#### 14.4. Packing group.

ADR / RID, IMDG, IATA:

#### 14.5. Environmental hazards.

ADR / RID:	NO
IMDG:	NO
IATA:	NO

#### 14.6. Special precautions for user.

ADR / RID:	HIN - Kemler:	Limited Quantities 1 L	Tunnel restriction code (D)
	Special Provision: -		
IMDG:	EMS: F-D, S-U	Limited Quantities 1 L	
IATA:	Cargo:	Maximum quantity: 150 Kg	Packaging instructions: 203
	Pass.:	Maximum quantity: 75 Kg	Packaging instructions: 203
	Special Instructions:	A145, A167, A802	

#### 14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code.

Information not relevant.

## **SECTION 15. Regulatory information.**

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

Seveso category.

Restrictions relating to the product or contained substances pursuant to Annex XVII to EC Regulation 1907/2006. None.

Substances in Candidate List (Art. 59 REACH). None. Substances subject to authorisarion (Annex XIV REACH). None. Substances subject to exportation reporting pursuant to (EC) Reg. 649/2012: None.

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Substances subject to the Rotterdam Convention: None.

Substances subject to the Stockholm Convention: None.

Healthcare controls. Information not available.

#### 15.2. Chemical safety assessment.

No chemical safety assessment has been processed for the mixture and the substances it contains.

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## **SECTION 16.** Other information.

CODICE PREPARATI PERICOLOSI ISS: SSICE01.

Text of hazard (H) indications mentioned in section 2-3 of the sheet:

Flam. Gas 1 Aerosol 1 Aerosol 2	Flammable gas, category 1 Aerosol, category 1 Aerosol, category 3
Aerosol 3 H220 H222	Extremely flammable gas. Extremely flammable aerosol.
H229	Pressurised container: may burst if heated.

LEGEND:

- ADR: European Agreement concerning the carriage of Dangerous goods by Road
- CAS NUMBER: Chemical Abstract Service Number
- CE50: Effective concentration (required to induce a 50% effect)
- CE NUMBER: Identifier in ESIS (European archive of existing substances)
- CLP: EC Regulation 1272/2008
- DNEL: Derived No Effect Level
- EmS: Emergency Schedule
- GHS: Globally Harmonized System of classification and labeling of chemicals
- IATA DGR: International Air Transport Association Dangerous Goods Regulation
- IC50: Immobilization Concentration 50%
- IMDG: International Maritime Code for dangerous goods
- IMO: International Maritime Organization
- INDEX NUMBER: Identifier in Annex VI of CLP
- LC50: Lethal Concentration 50%
- LD50: Lethal dose 50%
- OEL: Occupational Exposure Level
- PBT: Persistent bioaccumulative and toxic as REACH Regulation
- PEC: Predicted environmental Concentration
- PEL: Predicted exposure level
- PNEC: Predicted no effect concentration
- REACH: EC Regulation 1907/2006
- RID: Regulation concerning the international transport of dangerous goods by train
- TLV: Threshold Limit Value
- TLV CEILING: Concentration that should not be exceeded during any time of occupational exposure.
- TWA STEL: Short-term exposure limit
- TWA: Time-weighted average exposure limit
- VOC: Volatile organic Compounds
- vPvB: Very Persistent and very Bioaccumulative as for REACH Regulation
- WGK: Water hazard classes (German).

#### GENERAL BIBLIOGRAPHY

- 1. Regulation (EU) 1907/2006 (REACH) of the European Parliament
- 2. Regulation (EU) 1272/2008 (CLP) of the European Parliament
- 3. Regulation (EU) 790/2009 (I Atp. CLP) of the European Parliament
- 4. Regulation (EU) 2015/830 of the European Parliament
- 5. Regulation (EU) 286/2011 (II Atp. CLP) of the European Parliament
- 6. Regulation (EU) 618/2012 (III Atp. CLP) of the European Parliament
- 7. Regulation (EU) 487/2013 (IV Atp. CLP) of the European Parliament
- 8. Regulation (EU) 944/2013 (V Atp. CLP) of the European Parliament 9. Regulation (EU) 605/2014 (VI Atp. CLP) of the European Parliament
- The Merck Index. 10th Edition
- Handling Chemical Safety
- INRS Fiche Toxicologique (toxicological sheet)
- Patty Industrial Hygiene and Toxicology
- N.I. Sax Dangerous properties of Industrial Materials-7, 1989 Edition
- ECHA website

Note for users:

The information contained in the present sheet are based on our own knowledge on the date of the last version. Users must verify the suitability and thoroughness of provided information according to each specific use of the product.

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## SECTION 16. Other information. .../>>

This document must not be regarded as a guarantee on any specific product property.

The use of this product is not subject to our direct control; therefore, users must, under their own responsibility, comply with the current health and safety laws and regulations. The producer is relieved from any liability arising from improper uses.

Provide appointed staff with adequate training on how to use chemical products.