



INFORMATION SHEET FOR SAFETY USE

MASTER-AID STERILBLOCK EMOSTATIC SPRAY

Current review date: 11/12/2018

n° current review: 02

Previous revision date: 03/09/2014

n° previous review: 01

This information sheet for safety use is made for a Medical Device. This Medical Device is available for end-user and used in direct physical contact with the human body. The Medical Device for the following reasons:

- Article 2 (6)(c) of the Regulation (EC) No 1907/2006, and
- Article 1 (5) (d) of the Regulation (EC) No 1272/2008,

it's not included in this Regulations.

Nevertheless, the manufacturer considers it appropriate draw-up this information sheet for safety use in order to ensure a greater security for professional user of this product.

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Commercial name : **MASTER-AID STERILBLOCK EMOSTATIC SPRAY**
 Formula code : **021.10**
 Registration Ministry of Health : **167380**

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

Consumers uses : **For small wounds**
 Uses advised against : **All those not expressly identified on the label**

1.3 Details of the supplier of the safety data sheet

1.3.1 Manufacturer

PIETRASANTA PHARMA S.p.a. – Via di Caprino, 7 55012 CAPANNORI (LU) Tel. +39 0583 980498 – Fax +39 0583 981022 – Web www.pietrasantapharma.it
 e-mail competent person: info@pietrasantapharma.it

1.4 Emergency telephone number

PIETRASANTA PHARMA S.p.a. +39 0583 980498 (from 08.30 to 12.30 – from 13.30 to 17.00)

Section 16 of Information sheet for safety use contains contacts from some poison centers in Europe

SECTION 2: Hazards identification

2.1 Classification of the mixture

2.1.1 Classification in accordance in Regulation (EC) No 1272/2008:

Hazard pictogram(s) : GHS02



Class and danger category codes : Flam. Aerosol 1
 Hazard statement(s) : H222 – Extremely flammable aerosol
 H229 – Pressurised container: May burst if heated

2.1.2 Adverse effects

Adverse effects be show in documents of Medical Device.

2.2 Label elements

2.2.1 Label in accordance with Regulation (EC) No 1272/2008

Hazard pictogram(s) : GHS02



Signal words : DANGER
 Hazard statement(s) : H222 – Extremely flammable aerosol
 H229 – Pressurised container: May burst if heated
 Additional hazard statement(s) : Not applicable
 Precautionary statement(s) : Not applicable

DIRECTIVE 93/42/EEC

Pictogram(s) : BATCH CODE USE-BY DATE MANUFACTURER CE MARK CAUTION CATALOGUE NUMBER



DO NOT RE-USE



Use : Hemostasis od injury
Instructions for use : Clean and disinfect injurie. Shake the can before use. Spray from 10-15 cm from injury. Protect with gauze. In the case of abundant bleeding it is advisable to spray the product on the gauze and apply it on the wound, exerting a light pressure.
Precautions : Avoid contact with eyes. Do not use in case of artery injury. If the bleeding persists, consult your doctor.
Warnings : Extremely flammable aerosol. Pressurised container: May burst if heated. Keep away from heat/sparks/open flames/hot surfaces. - 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 no expose to temperatures exceeding 50°C/122°F. Keep out of reach of children. If medical advice is needed, have product container or label at hand. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Do not breathe spray. Use only outdoors or in a well-ventilated area. Short spray without extended distribution. Do not apply on injuries with derma breached or contaminated and burns. Do not use on face.

2.3 Other hazards

Overheated aerosol containers burst and can be projected remotely violently and a dangerous fire spreading mechanism can occur. Do not operate in areas that are not adequately ventilated and in places below ground. Gases, being heavier than air, tend to form dangerous accumulations.



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SECTION 3: Composition/information on ingredients

3.1 Mixtures

Refer to section 16 for full text of the hazard statements

Substance	Concentration	Classification	CAS	EINECS	REACH
Hydrocarbons, C3-4	75 % < [C] ≤ 100 %	GHS02 - Flam. Gas 1 – H220 ; GHS04 - Liquefied gas – H280	68476-40-4	270-681-9	01-2119486557-22

SECTION 4: First aid measures

4.1 Description of first aid measures

Inhalation: Move away from the contaminated area. Keep the victim at rest in a warm and ventilated environment. Consult the doctor in manifestly serious cases.

Skin (pure product): Remove contaminated clothing immediately and wash the affected area with plenty of running water. Contact a doctor if irritation persists.

Eyes (pure product): If present and if easily feasible, remove any contact lenses. Immediately and abundantly irrigate for about 15 minutes with running water holding the eyelids open. If necessary, seek specialized medical treatment.

Ingestion: It's extremely improbable, but in case, do not induce vomiting and do not administer anything without supervision of health personnel. Immediately seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

Data available on Technical file of Medical Device.

4.3 Indication of any immediate medical attention and special treatment needed

See point 4.1 "Description of first aid measures"

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media: Water spray, CO₂, alcohol resistant foam, chemical powders depending on the materials involved in the fire.

Unsuitable extinguishing media: Direct water jets

5.2 Special hazards arising from the substance or mixture

Overheated aerosol containers burst and can be projected remotely violently and a dangerous fire spreading mechanism can occur. Protect your head using a safety helmet. Pressurized product in sealed metal containers. Cool the containers with water spray trying to move them away from the fire.

5.3 Advice for firefighters

Use respiratory protection. Crash-helmet and protective clothing. Water spray can be used to protect involved in the fire extinguishing. It is also advisable to use self-contained breathing apparatus, above all, if operating in closed and poorly ventilated areas.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel: Move away from area surrounding the spill or release. Don't smoke.

For emergency responders: Given the airtightness of the aerosol can, it is very unlikely that significant spills will occur. However, in the event that any container suffers such damage as to cause a leak, isolate the cylinder in question by bringing it into the open air or covering it with inert and non-combustible material (eg sand, earth, vermiculite) and taking care to avoid any ignition point which could result in a serious fire risk. Prevent spilled product from reaching water courses and waste water, keep away any source of ignition, vapors propagate at ground level and can create risks of explosion or intoxication in areas below ground (basements, ditches, etc ...). Wear gloves and protective clothing. Eliminate all open flames and possible sources of ignition. Not smoking. Set up adequate ventilation. Evacuate the danger area and, if necessary, consult an expert.

6.2 Environmental precautions

Isolate the cylinder in question by taking it to the open air or covering it with inert and non-combustible material (eg sand, earth, vermiculite). Prevent spilled product from reaching water courses and waste water, keep away any source of ignition, vapors propagate at ground level and can create risks of explosion or intoxication in areas below ground (basements, ditches, etc ...).

6.3 Methods and material for containment and cleaning up

Deliver exclusively to specialized companies. Contain and absorb the spilled liquid with absorbing and non-combustible inert materials (sand, soil, vermiculite, sepiolite or other specifically product) and put the damaged containers in closed containers.

6.4 Reference to other sections

Refer to sections 8 and 13 for more information.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

The vapors are more thought of than air and can expand to the ground and form explosive mixtures with air. Prevent the formation of flammable or explosive concentrations in the air. Pressurized container. Protect from sunlight and do not expose to temperatures exceeding 50 ° C. Do not pierce or burn even after use. Do not spray on flames or incandescent bodies. Use in sufficiently ventilated areas.

7.2 Conditions for safe storage, including any incompatibilities

Keep the containers in a vertical and safe position avoiding the possibility of falls or bumps. Pressurized container. Store in ventilated areas, in original packaging, away from heat sources and sunlight. Always store in well-ventilated areas. Keep away from open flames, sparks and sources of heat. Avoid direct exposure to the sun. Avoid the accumulation of electrostatic charges.

7.3 Specific end use(s)

Pressurized container. Do not pierce or burn even after use. Do not spray on flames or incandescent bodies. Use in sufficiently ventilated areas. Store in ventilated areas, in original packaging, away from heat sources and sunlight.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

The analysis of possible individual exposure is in Technical file of Medical Device

8.2 Exposure controls

In accordance to DIRECTIVE 93/42/EEC there is the technical file of Medical Device to demonstrate the safety for human health if the product is used normal or reasonably foreseeable conditions of use. The information in this sheet relates only physical form of product. If after risk assessment and introduction of technical measures to prevent or organize collective protection there will be some risk for workers, it's mandatory give the PPE.



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A. EYE/FACE PROTECTION

PICTOGRAM	PPE	OBSERVATIONS
NO	Not necessary in normal use	--

B. HAND PROTECTION

PICTOGRAM	PPE	OBSERVATIONS
NO	Not necessary in normal use	--

C. BODY PROTECTION

PICTOGRAM	PPE	OBSERVATIONS
NO	Not necessary in normal use	--

D. RESPIRATORY PROTECTION

PICTOGRAM	PPE	OBSERVATIONS
NO	Not necessary in normal use	--

E. THERMAL HAZARDS

Keep dry and away from sunlight

F. ENVIRONMENTAL EXPOSURE CONTROLS

Avoid released into the environment.

SECTION 9: Physical and chemical properties**9.1 Information on basic physical and chemical properties**

Physical and chemical properties	Value
Appearance	Powder in suspension under pressure in a sealed metal container
Odour	Characteristic strong
Odour threshold	Not applicable
pH	Not available
Melting point/freezing point	Not available
Initial boiling point and boiling range	Not available
Flash point	< 23 °C
Evaporation rate	Not available
Flammability (solid, gas)	Extremely flammable
Upper/lower flammability or explosive limits	Not available
Vapour pressure	Not available
Relative density	Not available
Solubility(ies)	Partial in water
Partition coefficient: n-octanol/water	Not available
Auto-ignition temperature	Not applicable
Decomposition temperature	Not available
Viscosity	Not available
Explosive properties	Not available
Oxidising properties	Not available

9.2 Other information

Specific	Value
Can volume	75 ml
Product volume	50 ml
Can material	Alluminium

SECTION 10: Stability and reactivity**10.1 Reactivity**

In normal use and following recommended how to use, there isn't reactivity risk.

10.2 Chemical stability

The characteristic of product will be guarantee until use by-date.

10.3 Possibility of hazardous reactions

No possibility of hazardous reactions

10.4 Conditions to avoid

Urti e attrito	Contact with air	Heating	Sunlight	Humidity
YES	Nothing to report	No heating	Keep away from sunlight	Avoid exposing

10.5 Incompatible materials

Acid	Bases	Water	Oxidising/Reducing agents	Others
YES	YES	NO	YES	NO

10.6 Hazardous decomposition products

No one in normal condition of use or storage.

SECTION 11: Toxicological information**11.1 Information on toxicological effects**

In accordance to DIRECTIVE 93/42/EEC there is the technical file of Medical Device to demonstrate the safety for human health if the product is used normal or reasonably foreseeable conditions of use. Presentation, Labelling and instruction for use are present in technical file. Technical file guarantee use of medical device and exposure were considerate during the analysis. Risk assessment and clinical evaluation are make after technical file. All documents shall ensure:

MEDICAL DEVICE IS SAFE FOR HUMAN HEALTH IF USE IN NORMAL OR REASONABLY FORESEEABLE CONDITION OF USE CONSIDERING PRESENTATION, LABELLING, ISTRUCTION FOR USE AND INDICATION OR INFORMATION THAT EVENTUALLY THE MANUFACTURER CONSIDERED TO SHOW.



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SECTION 12: Ecological information

12.1 Toxicity

Use according to good working practices avoiding to disperse the product in the environment. Notify the competent authorities if the product has reached watercourses or sewers or if it has contaminated the soil or vegetation.

12.2 Persistence and degradability

Data not available

12.3 Bioaccumulative potential

Data not available

12.4 Mobility in soil

Data not available

12.5 Results of PBT and vPvB assessment

The mixtures does not contain PBT/vPvB substances according to Regulation (EC) 1907/2006, Annex XIII

12.6 Other adverse effects

Data available on technical information file

SECTION 13: Disposal considerations

13.1 Waste treatment methods

The residues must be disposed of in compliance with the regulations in force by delivering the empty containers to an authorized disposal company. Operate according to local and national regulations.

SECTION 14: Transport information

	ADR	IMDG	IATA
UN number		1950	
UN proper shipping name		AEROSOLS, FLAMMABLE	
Transport hazard class(es)		2	
Label		2.1	
Packing group		not expected	
Limited quantities - Inner packagings	1L		0.5L (P.I. Y203)
Limited quantities - External packagings	20-30 Kg		30 Kg
Tunnel restriction code	D	N.A.	N.A.
EmS	N.A.	F-D, S-U	N.A.
Stowage and segregation	N.A.	SW1/SW22 – SG69	N.A.
Environmental hazards		NO	
Marine pollutant		NO	
Special precautions for user	Transport must be carried out by vehicles authorized to transport dangerous goods according to the provisions of the current edition of the A.D.R./A.D.N. / IMDG and IATA and the applicable national provisions. The transport must be carried out in the original packagings and, in any case, in packagings that are made of materials that can not be attacked by the contents and are not likely to generate dangerous reactions with this. Attendants to the loading and unloading of dangerous goods must have received appropriate training on the risks presented by the preparation and on any procedures to be adopted in case of emergency situations		
Transport in bulk according to Annex II of Marpol and the IBC Code	It is not expected to transport bulk cargoes		

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the 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.

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

DIRECTIVE 2007/47/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 September 2007 amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market

COMMISSION DIRECTIVE 2013/10/EU of 19 March 2013 amending Council Directive 75/324/EEC on the approximation of the laws of the Member States relating to aerosol dispensers in order to adapt its labelling provisions to Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures

15.2 Chemical safety assessment

Chemical safety assessment is not foreseen

SECTION 16: Other information

16.1 Other information

Description of hazard statements in section 3

H220 = Extremely flammable gas

H280 = Contains gas under pressure; may explode if heated

Classification based on data from all components of the mixture

If necessary, there are the active telephone numbers of some 24 hours 24 poison control centers:

Country	AUSTRIA	Country	BELGIUM
Name of poison centre	Vergiftungsinformationszentrale (Poisons Information Centre)	Name of poison centre	Centre Antipoisons-Antigifocentrum
Emergency phone	+43 1 406 43 43	Emergency phone	+32 70 245 245
Website	www.giftinfo.org	Website	www.poisoncentre.be



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Country	CROATIA	Country	FRANCE
Name of poison centre	Poison Control Centre Zagreb	Name of poison centre	ORFILA_Liste des centres anti poison
Emergency phone	+358 1 2348 342	Emergency phone	+33 1 40 05 48 48
Website	www.imi.hr	Website	--
Country	FRANCE	Country	GERMANY
Name of poison centre	Centre antipoison et de toxicovigilance de Paris	Name of poison centre	Deutschland Notrufnummer
Emergency phone	+33 (0)1 40 05 48 48	Emergency phone	030 30 68 67 90
Website	www.centres-antipoison.net	Website	--
Country	ITALIA	Country	ITALIA
Name of poison centre	Centro Antiveleni di Firenze	Name of poison centre	Centro Antiveleni Genoa
Emergency phone	+39 55 79 47 819	Emergency phone	+39 10 56 36 12 45
Website	www.antiveleni.altervista.org	Website	--
Country	ITALIA	Country	ITALIA
Name of poison centre	Centro Antiveleni Ospedale Cardarelli	Name of poison centre	Servizio Antiveleni di Padova
Emergency phone	+39 081 74 72 870	Emergency phone	+39 49 82 75 078
Website	www.ospedecardarelli.it/ospedale/centro-anti-veleni	Website	--
Country	ITALIA	Country	ITALIA
Name of poison centre	Centro Antiveleni di Milano Niguarda	Name of poison centre	IRCCS Fondazione S.Maugeri
Emergency phone	+39 2 66 10 10 29	Emergency phone	+39 382 24 444
Website	www.centroantiveleni.org	Website	www.cavpavia.it
Country	ITALIA	Country	ITALIA
Name of poison centre	Centro Antiveleni Policlinico Gemelli	Name of poison centre	Centro Antiveleni Università "La Sapienza"
Emergency phone	+39 6 30 54 343	Emergency phone	+39 6 49 97 06 98
Website	www.tox.it	Website	www.uniroma1.it/cav_cartella
Country	ITALIA	Country	NETHERLANDS
Name of poison centre	Centro Antiveleni Torino	Name of poison centre	National Poisons Information Centre
Emergency phone	+39 11 66 37 637	Emergency phone	+31 30 274 88 88
Website		Website	www.vergiftingen.info
Country	SPAIN		
Name of poison centre	Emergencias y consultas toxicológicas		
Emergency phone	915 620 420		
Website	--		

MAIN BIBLIOGRAPHIC SOURCES

ECHA	European Chemicals Agency	OSHA	European Agency for Safety and Health at Work	IARC	International Agency for Research on Cancer
IPCS	International Programme on Chemical Safety (Cards)	NIOSH	Registry of toxic effects of chemical substances (1983)	ACGIH	American Conference of Governmental Industrial Hygienists
TOXNET	Toxicology Data Network	WHO	World Health Organization		

SIGLES AND ABBREVIATION USED

CAS:	Chemical Abstracts Service	GHS:	Globally Harmonized System	STOT:	Specific Target Organ Toxicity	ONU:	Organizzazione Nazione Unite
DNEL:	Derived no-effect level	PNEC:	Predicted no-effect level	WEC:	Waste European Catalogue	EC50:	Effective concentration 50
EC:	European Inventory of Existing Commercial Chemical Substances	K _{oc} :	Adsorption coefficient	STP:	Sewage treatment plant	TLV - TWA:	Threshold Limit Value - time-weighted average
TLV - STEL:	Threshold Limit Value- short-term exposure limit	EN:	European Normalization	SUVA:	Independent public-law company of the Swiss social security system.	VME:	Valeur Moyenne d'Exposition
VL:	Limit Value	D.Lgs.:	Decreto Legislativo (Italian Law)	DM:	Decreto Ministeriale (Italian Law)	EC:	European Community
PPE:	Personal Protective Equipment	UNI:	Ente Nazionale Italiano di Unificazione	ppm:	parts per million	ISO:	International Standard Organization
CEN:	European committee for standardization	ATEmix:	Acute toxicity estimate of mixture	LD50:	Letal dose 50	LC50:	Letal concentration 50
EINECS:	European Inventory of Existing Commercial Chemical Substances	PBT:	Persistent, Bioaccumulative and Toxic	vPvB:	very persistent and very bioaccumulative	IATA:	International Air Transport Association
ADR:	Accord europeen relatif au transport international des marchandises Dangereuses par Route	IMDG:	International Maritime Dangerous Goods	EmS:	Emergency Response Procedures for Ships Carrying Dangerous Goods	REACH:	Regulation concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency
N.O.S.:	Not Otherwise specification	N.D.:	Not available	N.A.:	Not applicable	DMEL:	Derived minimum effect level

This sheet completely replaces all previous versions.

The information in this information sheet for safe use has been obtained from the best available or of our knowledge on the market at the indicated revision date. Neither the Company that owns this card nor the subsidiary companies can accept complaints deriving from an improper use of the information indicated here or from an improper use in the application of the product. Pay particular attention to the use of the preparations because improper use can increase their dangerousness.