



INFORMATION SHEET FOR SAFETY USE

MASTER-AID SPORT ICE SPRAY

Current review date: 27/11/2018

n° current review: 01

Previous revision date: 18/08/2014

n° previous review: 00

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 SPORT ICE SPRAY**
 Formula code : **383.10**
 Registration Ministry of Health : **507429**

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

Consumers uses : **Ice Spray**
 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 GHS07



Class and danger category codes : Flam. Aerosol 1, Eye Irrit. 2, STOT SE 3
 Hazard statement(s) : H222 – Extremely flammable aerosol
 H229 – Pressurised container: May burst if heated
 H319 – Causes serious eye irritation
 H336 – May cause drowsiness or dizziness

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



Use : Acute treatment for external injuries, such as bruises and sprains.
Instructions for use : Ice spray can be sprayed directly on the affected parts of the skin and not on the clothing that covers it, at a minimum distance of 15 cm with short sprays and at intervals or at most until the formation of frost on the skin is observed. Ice spray can be used repeatedly.
Precautions : Dispose of contents/container in accordance with local/regional/national/international regulation
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 not 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. If you are not sure that the skin excrescence is due to a wart, consult your doctor before use. Do not use in case of diabetes or circulatory problems. Do not use during pregnancy or breastfeeding. Use the product exclusively with the application cannula. Do not reuse the cannula (single use). Do not use on particularly delicate areas of the body, such as the face, ocular areas, underarms, breasts, buttocks, genitals, mucous membranes. Stop use if irritation occurs. Improper use of the product can cause cold burns or blindness. Use only when unopened.

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 |
|-------------|-----------------|---|-----------|-----------|------------------|
| Propan-2-ol | 1% < [C] < 5% | Flam. Liq.2 – H225, Eye Irrit 2 – H319, SOT SE 3 – H336 | 67-63-0 | 200-661-7 | 01-2119457558-25 |
| Menthol | 0.1% < [C] < 1% | Skin Irrit. 2 – H315, Eye Irrit 2 – H319 (Specific concentration limit > 25% - Skin Irrit. 2, Eye Irrit 2) | 2216-51-5 | 218-690-9 | 01-2119458866-21 |

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



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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.

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 | Colorless liquid (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 | 270 ml |
| Product volume | 200 ml |
| Can material | Aluminium |

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

H225 = Highly flammable liquid and vapour

H319 = Causes serious eye irritation

H336 = May cause drowsiness or dizziness

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.