MATERIAL SAFETY DATA SHEET
CRYOS SPRAY

Doc. SDS_MDesSDS_00-1000923-Rev.03-2017_02_22

The mentioned product in this Safety Data Sheet is a Medical Device Class IIa Directive 93/42/EEC as amended and found to comply.

1. IDENTIFICATION OF THE MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Identification of the product

Commercial Code: COLD SPRAY
Commercial name of product: **CRYOS COLD SPRAY, CRYOS FARMA COLD SPRAY**

1.2 Use of the mixture

Consumers use: **CRYOS COLD SPRAY– Medical Device Class IIa – Can of ML 200 -ML 250 – ML 400**
Professional use: COLD SPRAY
Wrong use: those not indicated in the label

1.3 Information on Technical Data Sheet's manufacturer

PHYTO PERFORMANCE ITALIA s.r.l.
Via E. Fermi, 9 - 35030 VEGGIANO (PD) Italy
VAT no. IT00989110283
tel +39 0499001919 - fax +39 0499002668
info@phytoperformance.com

1.4 Emergency phone number

+39 049 9001919 (from 9.00-12.00/14.00-17.00 working days)
Point 16 are the reference phone no. of Italian Poison Center 24/24 hours.

2. HAZARDS IDENTIFICATION

2.1 Classification of the mixture as per REGULATION (CE) N. 1272/2008

Pictogram **:** GHS02
Hazard Classification : Flam. Aerosol 1

Specific Hazard Risks: **:** H222 - Extremely flammable aerosol.
H229 - Pressurized container: may burst if heated.

2.1.2 Negative effects

Aerosol that can easily burn even to low temperature, risk of fire. The repeated vapour inhalation could provoke drowsiness and dizziness. Pressurized container. Protect from sunlight and do not expose to temperatures exceeding 50° C/122°F. Aerosol cans may burst if heated and thrown with violence faraway and a fire could start.

2.2. Elements of the Label

2.2.1 Labelling conform to Regulation (CE) No. 1272/2008

Pictogram: GHS02

Warning: Danger
Danger advice:
H222 Extremely flammable aerosol.
H229 Pressurized container: may burst if heated.

Precautionary Statement:
Generals
P101 If medical advice is needed, have product container or label at hand.
P102 Keep out of reach of children.

Prevention

P210	Keep away from heat/sparks/open flames/hot surfaces – No smoking.
P211	Do not spray on an open flame or other ignition source.
P251	Do not pierce or burn, even after use.
P243	Take precautionary measures against static discharge.
P263	Avoid contact during pregnancy/while nursing.
P271	Use only outdoors or in a well-ventilated area.

Reactions

P305 +P351 +P338 +P313 - IF IN EYES:	Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical advice.

Storage

P410+P412	Protect from sunlight. Do not expose to temperatures exceeding 50°C/122°F.

2.3 Other Risks

The aerosol containers overheated burst and can be ejected with violence from a distance and can take place a dangerous mechanism of fire diffusion. Use in well ventilated areas. Gases, which are heavier than air, tend to form dangerous accumulations.

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substance

N/A

3.2 Mixtures

Refer to point 16 for the complete text of hazard (H) indications

INGREDIENTS	CONCENTRATION	CLASSIFICATION	CAS	EINECS	REACh
Liquefied petroleum gas (LPG) Hydrocarbons C3-C4	75%<[C]≤ 100%	GHS02- Flam. Gas 1-H220; GHS04 - Liquefied.Gas- H280	68476-40-4	270-681-9	01-2119486557-22

The definition of "Hydrocarbons C3-C4" includes Propane (C3) - Butane - Isobutane (C4).

4. FIRST AID MEASURES

4.1 First aid measures

Inhalation

Remove immediately the contaminated patient from the area and keep him at rest in a well warmed and ventilated area. Seek for medical advise in case of serious situation.

Direct contact (pure product) with:

Skin

Take contaminated clothing immediately off. Wash immediately with plenty of running water. Seek medical advise if irritation persist.

Eyes

If contact lenses are on and are easy to remove, take them off. Immediately flush eyes with a copious amount of running water for at least 15 minutes, keeping open eyelids; if necessary seek medical advice.

Ingestion

Extremely unlikely, but in the remote eventuality do not cause vomit, do not give anything and seek medical advise.

4.2 Main symptoms and effects

Datas not available.

4.3 Indications of need to seek medical advise

See point 4.1 First Aid Measures

5. FIRE FIGHTING MEASURES

5.1 Extinguishing methods

Indicated extinguishing methods:

Water mister, CO2, alcohol-resistant foam, chemical powders depending on material involved in the fire.

Extinguishing methods to be avoided:

Direct jets of water

5.2 Dangers due to the substance

The aerosol containers overheated burst and can be ejected with violence from a distance and can take place a dangerous mechanism of fire diffusion (protect head with a safety helmet). Product under pressure in sealed metal container. Cool containers with water spray trying to remove them from fire.

5.3 Special protective equipment for fire-fighters

Use appropriate protective equipment for the breathing apparatus. Safety helmet and protective clothes. The spray water can be used to protect the people involved in the extinction.

You may also use self respirator, especially when working in confined and poorly ventilated spaces and in any case if you use halogenated extinguishers.

6 . ACCIDENTAL RELEASE MEASURES

6.1 Personal precaution, PPE and emergency procedure in case of emergency

For those who are not directly involved

Leave contaminated area at the soonest. Do not smoke. Remember that aerosol containers overheated can burst and violently throw the container to a remarkable distance.

For those who are directly involved

Being the aerosol container hermetic, it is unlikely that remarkable spillage may occur. However, in case some container suffer a damage that can cause a leak, isolate the concerned can taking it outside or covering it with inert and non-combustible material (eg. sand, soil, vermiculite) and being careful to avoid any flash point that could lead to a serious fire hazard. Keep it away from rivers, away from any source of ignition, the vapour expand at ground level and could cause risks of explosions or intoxications. Wear protective gloves and clothes. Avoid free flames and any source of ignition. Do not smoke. Ventilate the area. Evacuate the dangerous site and eventually consult an expert.

6.2 Environmental precautions

Isolate the concerned can, cover it with inert and non-combustible material (eg sand, soil, vermiculite). being careful to avoid any flash point that could lead to a serious fire hazard. Keep it away from rivers, away from any source of ignition, the vapour expand at ground level and could cause risks of explosions or intoxications.

6.3 Clearance methods and materials

Give only to specialized companies. Contain and absorb spilled liquid with inert absorbent material (sand, soil, sepiolite and other specific products) store damaged cans in a container with closure.

6.4 Reference to other sections

Refer to point 8 and 13 for further clarification.

7 . HANDLING AND STORAGE

7.1 Precautions for safe handling

Vapours are heavier than air and may spread close to the ground and form explosive mixtures with air. Prevent formation of flammable or explosive concentrations in the air. Pressurized container. Protect from sunlight and keep at temperature not exceeding 50°C. Do not pierce or burn even after use. Do not spray on naked flame or incandescent. Use in areas adequately ventilated.

7.2 Precautions for safe storage

Keep the cans in vertical position avoiding any damage or fall. Pressurized container. Use in areas adequately ventilated in the original boxes, protected from heat and sunlight. Avoid free flames and any source of ignition. Take precautionary measures against static discharges.

7.3 Uses

Consumer uses

Pressurized container. Do not pierce or burn even after use. Do not spray on flames or incandescent bodies. Pressurized container. Use in areas adequately ventilated in the original boxes, protected from heat and sunlight.

8 . EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Referred to substances included

DNEL (workers)

Substance Identification			Short Term		Long Term	
			Sistemic	**Local**	**Sistemic**	**Local**
HYDROCARBONS, C3-4		EYES	N/A	N/A	N/A	N/A
CAS:	68476-40-4	SKIN	N/A	N/A	23.4 mg/kg bw/day	N/A
EC:	270-681-9	INHALATION	N/A	N/A	2.21 mg/m^3 (DMEL)	N/A

DMEL (population)

Substance Identification			Short Term		Long Term	
			Sistemic	**Local**	**Sistemic**	**Local**
HYDROCARBONS, C3-4		EYES	N/A	N/A	N/A	N/A
CAS:	68476-40-4	SKIN	N/A	N/A	N/A	N/A
EC:	270-681-9	INAHALATION	N/A	N/A	0.066 mg/m^3	N/A

PNEC
N/A

ACGIH (AAAA)
N/A

8.2 Exposure limit values

As per Directive 93/42/EEC the Technical documents of the Medical Device has been issued by the manufacturer to show the safety of human health if used in normal conditions or reasonably predictable. The following info refer to the physical properties of the product.

If after considering the risk evaluation and taking preventive/organizing protection measures it would result that there is still risk for the worker, it is therefore necessary to supply the worker with PPE.

A. EYE/FACE PROTECTION

PICTOGRAM	PPE	OBSERVATION
	The eye PPE belong to 2nd category and need to have the EEC marking + Notifiefied Body no. Norm EN166 specific PPE requirement.	MAsk glasses manufactured with ventilation system as not to allow liquid/powder penetration in the eye area.
Glasses		

B. HAND PROTECTION

PICTOGRAM	PPE	OBSERVATION
	Protective gloves from chemical substances. Norm EN374 Protective gloves against chemical products and microorganisms.	In normal using conditions hand PPE are not required.
Gloves		

C. BODY PROTECTION

PICTOGRAM	PPE	OBSERVATION
	Norm EN13688 Protection clothing – General requirements	During handling rather use antistatic cotton clothes.
Working clothing		

D. RESPIRATORY PROTECTION

PICTOGRAM	PPE	OBSERVATION
	The PPE selection must be conform to norm UNI EN 529:2006.	In normal working conditions, with air ventilation, PPI are not requested. They are required in case of limited ventilation.
Filter mask		

E. THERMAL DANGER

Protect from sunlight. Do not expose to a temperature exceeding 50°C.

F. ENVIRONMENTAL EXPOSURE CONTROL

Minimize the release of product in the environment.

9 . CHEMICAL AND PHYSICAL PROPERTIES

9.1 Fundamental chemical and physical properties

Chemical and physical properties

Aspect	Liquid colourless (under pressure in sealed metal container)
Odour	balsamic
pH	Not applicable
Initial boiling range	Not available
Flash point of liquid phase	>300°C
Evaporation limit	N/A
Flash point of propellant	Extremely Flammable
Upper/Lower flammability limit or explosivity	1,8% ÷ 9,5 % in volume
Vapour tension	N/A
Density of mixture	0,550 ± 0,025 g/cm^2
Water solubility	Insoluble
Autoflammability	~360°C
9.2 Other information	
Container volume	270 ml – 335 ml – 520 ml
Product volume	200 ml - 250 ml - 400 ml
Pressure at 20°C	3,0 bar
Pressure can test	15 bar
VOC (Volatile Organic Compounds)	100%

10. STABILITY AND REACTIVITY

10.1 Reactivity

Under normal use conditions no reactivity danger.

10.2 Chemical stability

The aerosol product is stable for a period of 60 months, under normal storage conditions cannot have dangerous reactions as the container is hermetically sealed.

10.3 Dangerous reaction possibilities

Danger reactions not intended.

10.4 Conditions to be avoided

IMPACTS AND FRICTION	AIR CONTACT	HEATING	SOLAR LIGHT	HUMIDITY
Yes	Nothing to report	Avoid heating	Do not expose to sunlight	Nothing to report

10.5. Incompatible material

Acid	Basic	Water	Oxidizing/Reducing	Other
Yes	Yes	NO	Yes	NO

10.6 Hazardous decomposition products

In case of thermal decomposition harmful smokes can be emitted.

11. TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

ATE (mix) oral = N/A mg/kg
ATE (mix) dermal = N/A mg/kg
ATE (mix) inhal = N/A mg/l/4h

	Risk Class	Classification
(a)	**Acute toxicity**	Non classified. On the data available the classification parameters are not satisfied.
(b)	**Skin corrosion/Skin irritation**	Non classified. On the data available the classification parameters are not satisfied.
(c)	**Serious ocular damage/ocular irritation**	Non classified. On the data available the classification parameters are not satisfied.
(d)	**Respiratory or skin sensitivity**	Non classified. On the data available the classification parameters are not satisfied.
(e)	**Mutagen germ cell**	Non classified. On the data available the classification parameters are not satisfied.
(f)	**Carcinogenic**	Non classified. On the data available the classification parameters are not satisfied.
(g)	**Reproduction toxicity**	Non classified. On the data available the classification parameters are not satisfied.
(h)	**Specific toxicity for each target (STOT)-single exposure**	Non classified. On the data available the classification parameters are not satisfied.
(i)	**Specific toxicity for each target (STOT)-repeted exposure**	Non classified. On the data available the classification parameters are not satisfied.
(j)	**Aspiration danger**	Non classified. On the data available the classification parameters are not satisfied.

12. ECOLOGICAL INFORMATION

12.1. Toxicity

Use in conformity of good working practises avoiding product diffusion in the environment. Inform competent Authorities if the product reaches rivers or drainage system or if it has polluted soil/greenery.

Substance identification			Severe toxicity	Species
HYDROCARBONS, C3-4		CL50	147.54 mg/L	Fish
CAS:	68476-40-4	EC50	8.57 mg/L	Green Algea
EC:	270-681-9	EC50	N.D.	N.D.

12.2. Persistence and degradability

Photochemical degradation in air proceeds at a moderate rate. Regarded as of little importance in episodic ozone formation.

12.3. Bio accumulative 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 as per Annex XIII of REACh: the product doesn't contain PBT/ vPvB substance.

12.6. Other adverse effects

Data available in the Manufacturer technical documents.

13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

The residues, after the same has been used in its typical use, must be disposed of in accordance with the regulations by delivering empty containers for final disposal and equipped for safe handling of containers containing pressurized liquid and gas residues. The empty container heated to temperatures exceeding 70°C may burst. Discard according to local and national legislations.

NB- the CER/EWC code (The European Waste Catalogue) is referred to the product without considering any eventual impurities possible after the use. It is advisable before disposal to reclassify the waste considering the origin. The CER/EWC code could be different.

CER/EWC code	Description	Note
15 01 10*	packaging containing residues of or contaminated by dangerous substances	HP3 - Flammable

14. TRANSPORT INFORMATION

	ADR	IMDG	IATA
ONU Number		1950	
ONU Shipping name	FLAMMABLE AEROSOL	AEROSOLS	AEROSOLS, FLAMMABLE
Classification of danger relative to transport	2		
Label	2.1		
			
Packing Group	N/A		

Limited Quantity			
Internal Packing	1L		
External Packing	20 o 30 Kg. 		
Tunnel restriction code	D	N.A.	N.A.
EmS	N.A.	F-D, S-U	N.A.
Stowage and separation	N.A.	SW1/SW22-SG69	N.A.
Environmental dangers	NO		
Marine Pollutant	NO		
Users special precautions for road transport	None		
Transport as per Annex II MARPOL 73/78 and IBC code	N/A		

15. REGULATORY INFORMATION

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

D.Lgs. Governo no. 52 of 03/02/1997
Council Directive 92/32/EEC of 30 April 1992 amending for the seventh time Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances
D.Lgs. Governo no. 65 of 14/03/2003
Directive 1999/45/EC and 2001/60/EEC- classification, packaging and labelling of dangerous preparations
D.Lgs. Governo no. 25 of 02/02/2002
Directive 98/24/EC - risks related to chemical agents at work
DM dtd 26/02/2004
Limit of professional exposition to chemical agents.
DM dtd 03/04/2007 Commission Directive 2006/8/EC of 23 January 2006
amending, for the purposes of their adaptation to technical progress, Annexes II, III and V to Directive 1999/45/EC of the European Parliament and of the Council concerning the approximation of the laws, regulations and

administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations.
Regulation (EC) No. 1907/2006 of 18 December 2006
Regulation concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing a European Chemicals Agency
Regulation (EC) No. 1272/2008 of 18 December 2008
Regulation 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
Commission Regulation (EC) No. 790/2009 of 10 August 2009
amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures.
Directive 93/42/EEC of 14 June 1993 regarding Medical Devices as amended and found to comply
Directive 75/324/EEC of 20 May 1975 with Directive 2013/10/EU of 19 March 2013 on the approximation of the laws of the Member States relating to aerosol dispensers in order to adapt its labelling and packaging of substances and mixtures
Regulation (EC) no. 528/2012 of the European Parliament and of the Council dtd 22 May 2012 concerning making available on the market and use of biocidal products
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

15.2 Chemical safety assessment
Chemical safety assessment not applicable.

16. OTHER INFORMATION

16.1 Other information

Text of hazard (H) indications mentioned in section 3 of the sheet:
H220 Extremely flammable gas
H280 It contains gas under pressure – it could explode if heated

Emergency Poison Centre 24h a day (Prefix for Italy "+39"):

(www.salute.gov.it/servizio/documenti/centri_antiveleni.pdf)

In caso di necessità, si segnalano **i recapiti telefonici attivi 24 ore su 24 di alcuni Centri Antiveleno**:
(www.salute.gov.it/servizio/documenti/centri_antiveleni.pdf)

FIRENZE	Centro Antiveleni di Firenze	(www.antiveleni.altervista.org)	055 7947819
GENOVA	Servizio Antiveleni		010 56361245
MILANO	Centro Antiveleni Niguarda	(www.centroantiveleni.org)	02 66101029
NAPOLI	Centro Antiveleni Osp. Cardarelli	(www.ospedalecardarelli.it/ospedale/centro-anti-veleni)	081 7472870
PADOVA	Servizio Antiveleni		049 8275078
PAVIA IRCCS	Fondazione S.Maugeri	(www.cavpavia.it)	0382 24444
ROMA	Centro Antiveleni Pol. Gemelli	(www.tox.it)	06 3054343
ROMA	Centro Antiveleni Univ."La Sapienza"	(www.uniroma1.it/cav_cartella)	06 49970698
TORINO	Centro Antiveleni Torino		011 6637637

BIBLIOGRAPHY

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		

ACRONYM AND ABBREVIATIONS USED IN THIS SDS

CAS	Chemical Abstracts Service	GHS	Globally harmonized system	EINECS	European inventory of existimg commercial chemical sustances	ONU	Organizzazione nazioni unite
DNEL	Derived no-effect level	PNEC	Predicted no-effect level	CER	Catalogo europeo rifiuti	EC50	Concentrazione effettiva 50
EC	European Inventory of existing commercial chemical substances	K_{oc}	Coefficiente di assorbimento di un composto nella sostanza organica	STP	Micro-organismi negli impianti di trattamento delle acque reflue	TLV-TWA	Valore limite di soglia – media ponderata nel tempo
TLV-STEL	Valore linite di soglia- limite per breve tempo di esposizione	EN	Sigla che identifica le norme elaborate dal CEN	SUVA	Azienda di diritto pubblico indipendente del sistema di sicurezza sociale svzzero	VME	Valore limite di esposizione media
VL	Valore limite di esposizione	D.Lgs	Decreto Legislativo	DM	Decreto ministeriale	CE	Comunità europea
DPI	Dispositivo di protezione individuale	UNI	Ente nazionale italiano di unificazione	Ppm	Parti per milione	ISO	International standard organization
CEN	Comitato europeo di normazione	ATEmix	Stima tossicità acuta nella miscela	DL50	Dose letale 50	CL50	Concentrazione letale 50
STOT	Specific Target Organ Toxicity	PBT	Persistent, bioaccumulative and toxic	vPvB	Very Persistent, and very bioaccumulative	IATA	International Air trasnport association
ADR	Accord europeen relatif au trasnport international des merchandises 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.A.S.	Non altrimenti specificato	N.D.	Non disponibile	N.A.	Non applicabile	DMEL	Derived minimum effect level

Safety Data Sheet conform to **Regulation (UE) no. 2015/830 of 29 May 2015** as amended and found to comply

Note for users:

The information contained in the present sheet are based on our own knowledge on the date of the last version.

Neither the owner of this Data Sheet nor any subsidiary company may accept complaints for an improper use of these information or for an improper use of the product. Special attention should be given to the correct use of the product, an improper use can increase the danger. The producer is relieved from any liability arising from improper uses.