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

1.1 Product identifier CICATRIDINA® SPRAY

1.2 Relevant identified uses of the mixture and uses advised against MEDICAL DEVICE - adjuvant treatment of reparative processes of the superficial and deep wounds (abrasions, lacerations, burns, surgical wounds, pressure sores and ulcers)

1.3 Details of the supplier of the safety data sheet

Producer / supplier FARMA-DERMA S.R.L.

Address Via dei Bersaglieri, 10 - 40010 Sala Bolognese (BO) ITALIA

telephone number +39 051.6814181

Fax number +39 051.6814833

Mail -

1.4 Emergency telephone number +39 051.6814181 – MON-TUE-WED-THU-FRI 08.30AM - 1.00PM 2.00PM – 5.00PM – SAT-SUN closed.

2. HAZARDS IDENTIFICATION

2.1 Classification of the mixture The product is a MEDICAL DEVICE and does not fall within scope of Regulation (CE) 1272/2008 CLP on the classification of dangerous mixtures.

The product is in the form of aerosol generator and so it is classified and labeled in accordance with Directive 75/324/EEC and further modifications, which refers to Regulation (CE) 1272/2008.

Classification (Regulation (CE) n° 1272/2008) H223 – flammable aerosol
H229 - Pressurised container: May burst if heated

2.2 Label elements GHS Pictograms:

Signal word: ATTENTION
Risk statements:
H223 – flammable aerosol
H229 - Pressurised container: May burst if heated.
Precautionary statements:
P102 - Keep out of the reach and sight of children
P210 - Keep away from heat/sparks/open flames/hot surfaces. — No smoking.
P251 - Do not pierce or burn, even after use
P410+P412 - Protect from sunlight. Do not expose to temperatures exceeding 50°C/122°F.

2.3 Other hazards Avoid contact with eyes
Do not swallow

For the full text, see Section 16

3. COMPOSITION/INFORMATION ON INGREDIENTS *

3.1 Substances

3.2 Mixtures

Hydrocarbons, C3-C4 (Propane, Isobutane, N-butane mixture)

CAS	68476-40-4
EINECS	270-681-4
REACH registration number	01-2119486557-22-XXXX
Classification (Reg 1272/2008/EC) - CLP	H220 - Flammable Gas cat 1 H280 – Gas under pressure: liquefied gas. May explode if heated
[%]	50-70

This mixture contains 1.3 butadiene <0.1%, H2S (hydrogen sulfide <0.1% and CO (carbon monoxide <0.3%)

Hexamethyldisiloxane

CAS	107-46-0
EINECS	203-492-7
REACH registration number	01-2119496108-31
Classification (Reg 1272/2008/EC) - CLP	H225 - Highly flammable liquid and vapour. H400 – Aquatic Acute 1 H411 - Aquatic Chronic 2
[%]	10 - 15

Citrus Limon Oil

CAS	8008-56-8
EINECS	284-515-8
REACH registration number	-
Classification (Reg 1272/2008/EC) - CLP	H226 - Flammable liquid and vapour H315 – Skin Irr 2 H317 – Skin Sen 1 H319 – Eye Irrit 2 H304 - May be fatal if swallowed and enters airways H410 – Aquatic Chronic 1
[%]	0,1 - 1

For the full text, see Section 16

4. FIRST AID MEASURES

4.1 Description of first aid measures

Skin contact: take-off contaminated clothing. Wash skin with plenty of soap and water. Get medical attention if it occurs irritation

Eyes contact: rinse thoroughly with plenty of water. Remove any contact lenses. Eyelids should be held away from the eyeball to ensure thorough rinsing. Get medical attention if you develop irritation.

Ingestion: rnse mouth with water in order to dilute the product, do not induce vomiting. Get medical attention immediately.

Inhalation: move the victim to fresh air, remove contaminated clothing, and if breathing is difficul. Get medical attention immediately.

4.2 Most important symptoms and effects, both acute and delayed

Inhalation: May cause fainting. Contains asphyxiant gas
Contact with eyes and skin: the contact with the liquefied gas or cold vapors can cause injury
Chronic Effects: None

4.3 Indication of any immediate medical attention and special treatment needed

Use of all products for topical use, especially if prolonged, may cause sensitisation; if this occurs, stop treatment and consult a doctor to start suitable therapy.

5. FIREFIGHTING MEASURES

5.1 Extinguishing media

5.2 Special hazards arising from the substance or mixture

Combustion Products: Smoke, CO and CO2 and other harmful vapors

5.3 Advice for firefighters

Cool the containers with water to prevent product decomposition and the development of potentially dangerous substance. Always wear full fire prevention equipment. Extinguishing water collected must not be discharged into drains. Dispose of the materials used for extinction according to current regulations.

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

If necessary wear breathing apparatus , suitable protective clothing such as safety glasses, gloves, etc., remove all sources of ignition and do not smoke. Wash hands after use

6.2 Environmental precautions

Contain the spill with an absorbent material such as sand or ground. Prevent product to contaminate waterways, groundwater and soil. In case of such events notify this to the competent authorities.

6.3 Methods and material for containment and cleaning up

Containment: Absorb with inert material (eg sand or absorbent mold/soil).
Reclamation: provide good ventilation and evaporate the product. Wash with water if necessary and / or suitable detergent avoiding solvents. Collect material in suitable containers and dispose of in

accordance with current regulations

6.4 Reference to other sections Refer to Sections 8 and 13 .

7. HANDLING AND STORAGE

7.1 Precautions for safe handling Spray with the bottle held upright at a distance of 10-15 cm, ensuring that the product is sprayed directly on the area to be treated
Do not smoke during use. Avoid contact with eyes. Avoid spraying on skin irritated and intentionally inhaling.

7.2 Conditions for safe storage, including any incompatibilities Store in a cool, ventilated area. Keep away from sunlight and do not expose to temperatures exceeding 50 ° C. Keep away from sources of heat, sparks, open flames, hot surfaces

7.3 Specific end use(s) -

8. EXPOSURE CONTROL/PERSONAL PROTECTION

8.1 Control parameters

occupational exposure limit values

Alkanes C1.C4 (ACGIH 2010): TLV-TWA 1000ppm

Hexamethyldisiloxane -Derived No Effect Level (DNEL)	**Compartment**	**Value:**
	worker; epidermal; systemic (acute) systemic (long term)	126 mg/kg/day
	worker; inhaled; systemic (acute)	890 mg/m³
	systemic (long term)	134 ppm
	consumer; epidermal; systemic (acute) systemic (long term)	25 mg/kg/day
	consumer; inhaled; systemic (acute) systemic (long term)	266 mg/m³ 40 ppm
	consumer; oral; systemic (long term)	25 mg/kg/day

Hexamethyldisiloxane - The predicted no-effect concentration (PNEC)	**Compartment**	**Value:**
	Soft water	0,008 mg/l
	Sea water	0,0008 mg/l
	intermittent discharge	0,05 mg/l
	Soft water sediment	0,065 mg/kg wet weight
	Seawater sediment	0,0065 mg/kg wet weight
	Soil	0,25 mg/kg wet weight
	Waste water treatment plant	10 mg/l
	secondary intoxication	67 mg/kg feeding

8.2 Exposure controls

Personal protective equipment

General protective and hygienic measures: Keep away from food, beverages and feed.
Immediately remove all contaminated clothes.
Wash hands before breaks and after work.
Avoid contact with eyes and skin.

Protective mask	not required
Protective gloves	not required
Protective eyewear	not required. Avoid contact with eyes.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance	Suspension
Color	white
Odour	no data available
Odour threshold;	no data available
pH	no data available
Melting point/freezing point;	no data available
Initial boiling point and boiling range	no data available
Flash point	no data available
Evaporation rate	no data available
Flammability (solid, gas)	extremely flammable
Upper/lower flammability or explosive limits	no data available
Specific weight	no data available
Vapour pressure	no data available
Vapour density;	1,070 ± 0.05 a 20°C g/ml
Relative density	0.661 a 20°C g/ml
Solubility(ies)	no data available
Partition coefficient: n-octanol/water	no data available
Auto-ignition temperature	no data available
Decomposition temperature	no data available
Viscosity	no data available
Explosive properties	no data available
Oxidising properties	no data available

9.2 Other information -

10. STABILITY AND REACTIVITY

10.1 Reactivity	This product has no additional hazards related to reactivity than those described below.
10.2 Chemical stability	The product is stable under normal use. Avoid heat and oxidizing agents

10.3 Possibility of hazardous reactions	Contact with strong oxidizing agents or exposure to high temperatures can cause a fire hazard
10.4 Conditions to avoid	Keep away from oxidizing agents. Prevent the accumulation of electrostatic charges. Keep away from heat, sparks, open flames
10.5 Incompatible materials	strong oxidizing agent
10.6 Hazardous decomposition products	The product does not decompose if used in an appropriate way

11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Product data

Skin Irritation	classified as NOT IRRITATING - EN ISO 10993
Corrosivity	classified as NOT CORROSIVE - EN ISO 10993
Cytotoxicity	classified as NOT CYTOTOXIC - EN ISO 10993
Sensitization	classified as NOT SENSITISING - EN ISO 10993
Other information	Use of all products for topical use, especially if prolonged, may cause sensitisation; if this occurs, stop treatment and consult a doctor to start suitable therapy

Substances data

Hydrocarbons, C3-C4 (Propane, Isobutane, N-butane mixture)

Acute toxicity - oral and skin	The product is a gas at room temperature and pressure, therefore oral and dermal toxicity considerations are not available
Acute toxicity - inhalation	RAT - inhalation (1) LC50 (15 min): 800000 ppm (males / females) LC50 (15 min): 14442738 mg/m3 (males / females) LC50 (15 min): 1443 mg/l (males / females) The smell is not detectable under 20,000 ppm (2%) and a concentration of 100,000 ppm produced slight irritation to eyes and respiratory system and caused slight dizziness in a few minutes (2)
Skin corrosion/irritation	Certain dose-response studies in humans show that propane and butane have not irritant and corrosive effects on skin and mucous membranes. Contact with liquefied gas may cause burns from cold
Respiratory or skin sensitisation	There are no studies that indicate this type of effect

CMR No evidence of genotoxicity. In addition, the product contains 1,3-butadiene <0.1% therefore is not classified as mutagenic in accordance with current European regulations.
Test in Vitro - test Ames in Salmonella strains (OECD TG 471): negative (3)
Test in Vitro - test Ames in Salmonella typhimurium (OECD TG 471): negative (4)
Test in Vivo - micronucleus test RAT - inhalation (OECD Guideline 474): negative (5)

No evidence of carcinogenicity. In addition, the product contains 1,3-butadiene <0.1% therefore is not classified as carcinogen according to local regulations.

Reproductive toxicity: most of the studies conducted for the REACH registration dossier showed no consistent evidence of toxicity for fertility, therefore the product is not classified as toxic to reproduction in accordance with EU regulations.
In vivo study - RAT - 13 week inhalation exposure., 6 h / d., 5 d / wk.) (OECD Guideline 413 EPA OPPTS 870.3465 (90): NOAEC: 10000 ppm (M / F) No effect on the menstrual cycle, on spermatogenesis, sperm count and mobility (6)

Developmental toxicity / teratogenicity: Most studies have not shown consistent evidence of developmental toxicity / teratogenicity. In addition, the product does not contain carbon monoxide in concentrations higher than 0.2%, therefore it is not classified toxic to reproduction in accordance with current European regulations.
In vivo study - RAT - Inhalation Exposure M: 2 weeks. prior to mating and 28 d. (minimum) after mating F: 2 weeks. prior to mating 0-19 g. of gestation 6 h / d., 5 d. per wk. Concentrations: 0, 1600, 5000 and 16000 ppm (OECD Guideline 422 EPA OPPTS 870.3650) NOAEC (maternal toxicity): 16000 ppm (no effects of systemic toxicity at the highest concentration tested) NOAEC (maternal toxicity): 19678 mg / m^3 air NOAEC (developmental toxicity): 16000 ppm (no effect on the development) NOAEC (developmental toxicity): 19678 mg / m^3 air (7)

Specific target organ toxicity

STOT-single exposure n/a

STOT-repeated exposure Inhalation
Methane: There is no dose-response studies
Propane: In a study conducted over a period of 6 weeks in male and female rats were not observed neurological effects, haematological, or clinical male animals showed a decrease of 25% of weight during the first week of exposure at doses of 12.000 ppm.
The lowest concentration at which adverse effects were observed (LOAEC) in this study is 12,000 ppm (equivalent to 21,641 mg/m3).

Aspiration hazard n/a

HEXAMETHYLDISILOXANE

Acute toxicity - oral and skin oral LD50: > 16 mg/L mg/kg Rat epidermic analysis report

LD50: > 2000 mg/kg rabbit OECD 403

Inhalation (gas / steam)): LC50: 106 mg/l; 4 h Rat OECD 403

Skin corrosion/irritation On the basis of the available data there is not a clinically significant skin irritation.
rabbit (OECD 404)

Serious eye damage/irritation On the basis of the available data it is not expected to a clinically relevant eye irritation ..
rabbit (OECD 405)

Respiratory or skin sensitisation On the basis of the available data is not provided for a sensitization reaction caused by this product.

Germ cell mutagenicity mutation assay (in vitro) bacterial cells(OECD 471): negative
mutation assay (in vitro) mammalian cells (OECD 476): negative
chromosome aberreation assay (in vitro) mammalian cells (OECD 473): negative
chromosome aberreation assay (in vivo) (OECD 475): negative

Carcinogenicity NOAEC: >= 33,2 mg/l
NOAEC = NOAEC (carcinogenic effects relevant for humans)
carcinogenicity study
Rat (F344)
inhalation (vapor)
2 a; 5 d/w; 6 h/day
(OECD 453)

Reproductive toxicity NOAEC: >= 33,2 mg/l
NOAEC = NOAEC (fertility) two generation study Rat (Sprague Dawley)
inhalation (vapor); 7 d/w; 6 h/day
EPA OPPTS 870.3800+870.6300

NOAEC (developmental): 10,6 mg/l
NOAEC (maternal): >= 33,2 mg/l
Symptoms :/ Effect: lack of habituation
Reproduction and Fertility Effects + Developmental Neurotoxicity Study
Ratto (Sprague Dawley)
inhalation (vapor); 7 d/w; 6 h/day EPA OPPTS 870.3800+870.6300

STOT-single exposure Experimental toxicological on the product are not available

STOT-repeated exposure In animal experiments with repeated exposure were not observed significant effects for humans.
RAT (OECD 407): NOAEL: >= 1000 mg/kg
RAT (OECD 410): NOAEL: >= 1000 mg/kg
RAT ; 6 h/d (OECD 453) : NOAEC: 33,2 mg/l

Aspiration hazard data not available

Citrus Limon Oil

Acute toxicity DL 50 (oral, rat): 2840 mg/kg (8)

Standard Draize test (mouse, period 100%): slight irritation (9)

Standard Draize test (rabbit, 500 mg/24h): moderate irritation (10)

Carcinogenicity TDL O (Rodent Mouse): 280 gm/kg/33W – I (11)

Tumorigenic - equivocal tumorigenic agent by RTECS criteria

12. ECOLOGICAL INFORMATION

Ecotoxicological data on the mixture are not avaiable. Following are shown ecotoxicological information regarding main substances in the mixture

12.1 Toxicity

Hydrocarbons, C3-C4 (Propane, Isobutane, N-butane mixture)	This product is made from gaseous substances at room temperature and pressure, which are mainly distributed in the air rather than water sediment and soil. Invertebrates - Daphnia Short Term LC50 48 / h: 14,22 mg / l Key study CAS 106-97-8 (Butane) USEPA OPP (2008) Invertebrates - Daphnia Short Term LC50 48 / h: 69,43 mg / l Key study CAS 74-82-8 (Methane) QSAR USEPA OPP (2008) Short-term Algae EC50 (96 h): 19,37 mg / l Key study CAS 74-82-8 (Methane) QSAR Short-term fish LC50 96 / h: 147,54 mg / l Key study CAS 74-82-8 (Methane) QSAR EPA 2008 Fish Short-term L50 96 / h: 24,11 mg / l Key study CAS 106-97-8 (Butane) QSAR EPA 2008
Hexamethyldisiloxane	Acute Toxicity: Very toxic to aquatic organisms. Prolonged Toxicity: Based on the physico-chemical properties are not expected long-term effects on aquatic organisms. Based on the current experiences, no negative effects are expected on water treatment plant LC50: 0,46 mg/l dynamic (Oncorhynchus mykiss) (96 h) (OECD 203) EC50: > 0,37 mg/l static Daphnia magna (48 h) (OECD 202) IC10: 0,14 mg/l static Selenastrum capricornutum (96 h) (OECD 201) IC50: > 0,55 mg/l static Selenastrum capricornutum (96 h) (OECD 201) EC50: >= 100 mg/l not known (OECD 209) NOEC (cronico): >= 0,04 mg/l dynamic carpa (Cyprinus carpio) (OECD 305) NOEC (reproduction): 0,08 mg/l semistatic Daphnia magna (21 day) (OECD 211)

12.2 Persistence and degradability

Hydrocarbons, C3-C4 (Propane, Isobutane, N-butane mixture)	abiotic degradation This product can contribute to the formation of ozone in the atmosphere near the surface. However, the photochemical formation of ozone depends on a complex interaction of air pollutants and other environmental conditions. Biotic degradation: QSAR studies were conducted with ethane which has a biodegradability of 100% in 16 days. The ethane is not a component of the gas oil but its structure is representative of the stream, and can be a read-across, therefore on the basis of what above mentioned product is biodegradable.

Hexamethyldisiloxane	The substance is biodegradable through non-biological chemical and physical processes (abiotic processes). Biodegradability: 2% / 28 day difficultly biodegradable - biological oxygen demand (OECD 301C) hydrolysis: half-life <2 h pH 4 (OECD 111) - half life: 120 h pH 7 (OECD 111) - half period: 12 h pH 9 (OECD 111)
12.3 Bioaccumulative potential	
Hydrocarbons, C3-C4 (Propane, Isobutane, N-butane mixture)	The log Pow for GPL is estimated in the range from 1.09 to 2.8, therefore the product does not bioaccumulate.
Hexamethyldisiloxane	log POW >= 3,0In experimental conditions, the substance showed a greater potential for bioaccumulation. Bioconcentration factor (BCF): 1290 - 2410 carp (Cyprinus carpio) (70 day; 0,04 mg/l) Bioconcentration factor (BCF): 776 - 1660 carp (Cyprinus carpio) (70 day; 0,004 mg/l)
12.4 Mobility in soil	
Hydrocarbons, C3-C4 (Propane, Isobutane, N-butane mixture)	Absorption Koc: Standard tests for this endpoint are not applicable to UVCBs
Hexamethyldisiloxane	the partition coefficient soil / water (logKoc) indicates a medium mobility in soil. log KOC: 2,53 Berechnung
12.5 Results of PBT and vPvB assessment	The product does not contain any relevant substances evaluated as persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative
12.6 Other adverse effects	not known

13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods	Recover if possible or send to approved plants or to incineration under controlled conditions. For handling and measures in case of accidental release of waste, apply in general to the information provided in sections 6 and 7. Precautions and specific actions must be assessed in relation to the composition of the waste. Operate according to local and national regulations.

14. TRANSPORT INFORMATION

4.1 UN number	1950
14.2 UN proper shipping name	ADR / IMDG / IATA: AEROSOLS, flammable
14.3 Transport hazard class(es)	ADR: 2 IMDG: 2 IATA: 2.1
14.4 Packing group	N/A
14.5 Environmental hazards	None

14.6 Special precautions for user	Code EmS: F-D, S-U
14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	N/A

15. REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture	Regulation n° 1907/2006/CE (REACH) Regulation n° 1272/2008/CE (CLP) and following ATP Regulation n° 453/2010/CE (concerning the preparation of safety data sheets) Regulation 830/2015/CE concerning the preparation of safety data sheets) D.Lgs 81/2008 (consolidated text on health protection and safety in the workplace) and further modifications Directive 75/324/CE (concernig aerosol) and further modifications
15.2 Chemical safety assessment	no data available

16. OTHER INFORMATION

list of relevant Hazard statements

H220 - Extremely flammable gas. Cat. 1
H223 - flammable aerosol. Cat. 2
H225 - Highly flammable liquid and vapour. Cat 2
H226 - Flammable liquid and vapour. Cat 3
H304 - May be fatal if swallowed and enters airways. Cat 1
H315 - Causes skin irritation. Cat 2
H317 - May cause an allergic skin reaction. Cat 1
H319 - Causes serious eye irritation. Cat 2
H280 - Contains gas under pressure; may explode if heated.
H400 – Very toxic to aquatic life. Cat 1
H410 - Very toxic to aquatic life with long lasting effects. Cat 1
H411 - Toxic to aquatic life with long lasting effects. Cat 2

Bibliography

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(3)	National Toxicology Program (1993)
(4)	Kirwin CJ and Thomas WC (1980)
(5)	Huntingdon Life Sciences (HLS) (2009b)
(6)	Huntingdon Life Sciences (HLS) (2009b)
(7)	Huntingdon Life Sciences (HLS) (2010a)
(8)	PHARAT Pharmazie VEB Verlag Volk und Gesundheit, Neue Gruenstr. 18, Berlin DDR - 1020 V. 1 -1946- Volume(issue) /page /year 14, 435, 59
9)	FCTXAV Food and Cosmetic Toxicology(London UK) V. 1 - 9, 1963 - 81 Volume(issue) / page / year 12, 727, 74

(10) FCTXAV Food and Cosmetic Toxicology(London UK) V. 1 - 9, 1963 - 81 Volume(issue) / page / year 12, 725, 74

(11) JNCIAM Journal of the National Cancer Institute (Washington, DC) V. 1 - 60 , 1940-78 Volume(issue)/ page/ year: 24, 1389, 60

ACGIH = American Conference of Governmental Industrial Hygienists
CSR = Chemical safety Report
DNEL = Derived no-effect level
EC50 = half maximal effective concnetration
IC50 = inibition concentration, 50%
LC50 = lethal concentration, 50%
LD50 = Lethal dose
PNEC = Predicted no effect concentration
n.a. = non applicable
PBT = Persistent, Bioaccumulative, Toxic
STOT = Single Toxicity Organ target
(STOT) RE = Repeated exposure
(STOT) SE = single exposure
TLV-TWA = Threshold limit value - time weighed average
TLV-STEL = Threshold limit value – short term exposure limit
UVCB = substances of Unknown or Variable composition
vPvB = very persistent and very bioaccumulative

*** Section revised** 3

The data and information relates only to the specific product.
The information is based on the knowledge in our possession in accordance with the current state and all applicable laws.
The user has the responsibility to use the product according to the instructions and take all necessary steps to meet the requirements of the laws and regulations relating to health, safety and hygiene at work, respect for the environment.
We decline all responsibility for damage caused by improper use of the product.