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|---------------|-------------------|----------------------|--------------|----------|---|
| Trade name: | CRYO SPRAY | | | | |
| Product code: | 08-SPRAY-2 | Date of compilation: | 26 June 2019 | Version: | 5 |

| SECTION 1: Identification of the substance/mixture and of the company/undertaking | | |
|--|---|---|
| 1.1. | Product identifier | |
| | Trade name: | CRYO SPRAY |
| | Chemical name: | - |
| | Catalogue number: | 08-SPRAY-2 |
| 1.2. | Relevant identified uses of the substance or mixture and uses advised against | |
| | Uses: | For freezing histological samples. |
| | Uses advised against: | Only the identified uses are advised. |
| | Reason why uses advised against: | The product is intended for use only as an <i>in vitro</i> diagnostic medical device and there is no reason to use it for other purposes. |
| 1.3. | Details of the supplier of the safety data sheet | |
| | Supplier: | BioGnost Ltd. |
| | Address: | Medjugorska 59, Zagreb |
| | Telephone number: | +385 1 2409997 |
| | Telefax: | +385 1 2404039 |
| | e-mail of competent person: | msds@biognost.hr |
| | National contact: | - |
| 1.4. | Emergency telephone numbers | |
| | National Protection and Rescue Directorate: | 112 |
| | Medical information: | +385 1 2348 342 |
| | Other information: | - |

| SECTION 2. Hazards identification | | |
|---|--|---|
| 2.1. | Classification of the substance or mixture | |
| 2.1.1. | Classification according to Regulation (EC) No 1272/2008 (CLP) | |
| | Hazard class and category code: | Hazard statements*: |
| | Aerosol, cat.1 | H222 Extremely flammable aerosol H229 Pressurised container: may burst if heated |
| 2.1.2. | Additional information | |
| | - | |
| * For full text of Hazard- and EU Hazard-statements: see SECTION 16 | | |
| 2.2. | Label elements | |
| | Product identification: | CRYO SPRAY |
| | Identification number: | - |
| | Authorisation number: | - |

| | | | | | |
|---------------|-------------------|----------------------|--------------|----------|---|
| Trade name: | CRYO SPRAY | | | | |
| Product code: | 08-SPRAY-2 | Date of compilation: | 26 June 2019 | Version: | 5 |

| | | |
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| Hazard pictograms: |  | |
| | GHS02 | |
| Signal word: | Danger | |
| Hazard statement: | H222 Extremely flammable aerosol H229 Pressurised container: may burst if heated | |
| Precautionary statements: | P210 Keep away from heat/sparks/open flames/hot surfaces. – Do not smoke P211 Do not spray on an open flame on other ignition source. P251 Do not pierce or burn, even after use. P410+P412 Protect from sunlight. Do not expose to temperatures exceeding 50°C/122°F | |
| Supplemental hazard information (EU): | - | |
| 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 | | | | |
|--|--------------------------|-----------------------------------|---------------------|---|
| CAS/ EC/ Index number | REACH Registration No | Weight % content (or range) | Identification name | Classification according to Regulation (EC) No 1272/2008 (CLP) |
| 106-97-8/ 203-448-7/ 601-004-00-0 | - | 50 ≤ x < 100 | Butane | Flam. Gas 1; H220 Press. Gas (Liq.) H280 |
| 74-98-6/ 200-827-9/ 601-003-00-5 | - | 9 ≤ x < 30 | Propane | Flam. Gas 1; H220 Press. Gas (Liq.) H280 |

| SECTION 4. First aid measures | | |
|--------------------------------------|---|--|
| 4.1. | Description of first aid measures | |
| General notes: | If the suggested first aid measures do not prove sufficient, seek medical attention. | |
| Following inhalation: | Carry the afflicted person out of the contaminated area into a well-ventilated area or out for fresh air. | |
| Following skin contact: | Immediately wash with plenty of water and soap. | |

| | | | | | |
|---------------|-------------------|----------------------|--------------|----------|---|
| Trade name: | CRYO SPRAY | | | | |
| Product code: | 08-SPRAY-2 | Date of compilation: | 26 June 2019 | Version: | 5 |

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| Following eye contact: | Rinse out with plenty of water with the eyelid held wide open for at least 15 minutes. If the symptoms remain, immediately call in ophthalmologist. |
| Following ingestion: | Get medical advice/attention. Induce vomiting only if indicated by the doctor. Do not give anything by mouth to an unconscious person. |
| Self-protection of the first aider | - |

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

| | |
|-------------------------|---|
| Following inhalation: | Specific information on symptoms and effects caused by the product are unknown. |
| Following skin contact: | Specific information on symptoms and effects caused by the product are unknown. |
| Following eye contact: | Specific information on symptoms and effects caused by the product are unknown. |
| Following ingestion: | Specific information on symptoms and effects caused by the product are unknown. |

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

| |
|---|
| - |
|---|

SECTION 5. Firefighting measures

5.1. Extinguishing media

| | |
|---------------------------------|--|
| Suitable extinguishing media: | CO ₂ , foam, powder and water spray |
| Unsuitable extinguishing media: | - |

5.2. Special hazards arising from the substance or mixture

| | |
|--------------------------------|--|
| Hazardous by products 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

| |
|--|
| 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. |
|--|

5.4. Additional information

| |
|---|
| - |
|---|

SECTION 6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

| | |
|------------------------------|--|
| Protective equipment: | Use personal protective equipment (see Section 8). |
| Accident prevention methods: | Evacuate members of all non-essential personnel and those members without protective equipment. Remove all sources of sparks and ignition. Do not smoke. |
| Emergency procedures: | Mark the area using proper signs. |

| | | | | | |
|---------------|-------------------|----------------------|--------------|----------|---|
| Trade name: | CRYO SPRAY | | | | |
| Product code: | 08-SPRAY-2 | Date of compilation: | 26 June 2019 | Version: | 5 |

| | | |
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| 6.1.2. | For emergency responders: | |
| | Normal fire fighting clothing i.e. fire kit (EN 469), gloves (EN 659) and boots (HO specification A29 and A30) in combination with self-contained open circuit positive pressure compressed air breathing apparatus (EN 137). | |
| 6.2. | Environmental precautions: | |
| | Do not dispose in the environment. | |
| 6.3. | Methods and materials for containment and cleaning up | |
| 6.3.1. | Bunding, covering of drains; capping procedures: | Sand or clay barriers. |
| 6.3.2. | 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. |
| 6.3.3. | Other information: | Do not use tools that may cause sparks. |
| 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 | |
| 7.1.1. | Protection measures | |
| | Measures to prevent fire: | Use in well ventilated storage rooms. 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. |
| | Measures to prevent aerosol and dust generation: | Secure proper ventilation. Do not breathe spray. |
| | Measures to protect the environment: | Prevent spilling into the sewage system and waterways. |
| | Other measures: | - |
| 7.1.2. | Advice on general occupational hygiene: | |
| | Do not eat, drink or smoke in the workspace. Thoroughly wash hands after work and before eating. | |
| 7.2. | Conditions for safe storage, including any incompatibilities | |
| | Technical measures and storage conditions: | Keep in tightly closed and upright set containers in a well ventilated storage rooms. |
| | Packaging materials: | Manufacturer's original packaging. |

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|---------------|-------------------|----------------------|--------------|----------|---|
| Trade name: | CRYO SPRAY | | | | |
| Product code: | 08-SPRAY-2 | Date of compilation: | 26 June 2019 | Version: | 5 |

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| Requirements for storage rooms and vessels: | 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. |
| Advices for storage equipment: | The storage must be made of hard material; floors must be resistant to chemicals. There must be no drain that directly leads into sewage system. Secure proper ventilation. |
| Further information on storage conditions: | Do not place the unused material in the storage room and do not use empty containers for storing other chemicals. Do not store with incompatible materials (see Section 9). |
| 7.3. Specific end use(s) | |
| Recommendations: | - |
| Industrial sector specific solutions: | - |

SECTION 8. Exposure controls/personal protection

8.1. Control parameters

| Substance | CAS No | Occupational exposure limit values/short term values | | Biological limit values |
|-----------|----------|--|-------------------|-------------------------|
| | | ppm | mg/m ³ | |
| Butane | 106-97-8 | 600 | 1450 | - |

| | |
|------------|---|
| Substance: | - |
| EC No: | - |
| CAS No: | - |

DNEL

Industrial

| Route of exposure: | Route of exposure: | Route of exposure: | Route of exposure: | Route of exposure: |
|--------------------|--------------------|--------------------|--------------------|--------------------|
| Oral | - | - | - | - |
| Inhalation | - | - | - | - |
| Dermal | - | - | - | - |

Critical physical parameters: solubility, flammability, corrosivity: -

Consumer

| Route of exposure: | Route of exposure: | Route of exposure: | Route of exposure: | Route of exposure: |
|--------------------|--------------------|--------------------|--------------------|--------------------|
| Oral | - | - | - | - |
| Inhalation | - | - | - | - |
| Dermal | - | - | - | - |

PNEC

| | | | | | |
|---------------|-------------------|----------------------|--------------|----------|---|
| Trade name: | CRYO SPRAY | | | | |
| Product code: | 08-SPRAY-2 | Date of compilation: | 26 June 2019 | Version: | 5 |

| Environmental protection target | PNEC |
|------------------------------------|--------------------------|
| Fresh water | No information available |
| Freshwater sediments | No information available |
| Marine water | No information available |
| Marine sediments | No information available |
| Food chain | No information available |
| Microorganisms in sewage treatment | No information available |
| Soil (agricultural) | No information available |
| Air | No information available |

| | | |
|----------|--|---|
| 8.2. | Exposure controls | |
| 8.2.1. | Appropriate engineering controls | |
| | Substance/mixture related measures to prevent exposure during identified uses: | Use the product in well ventilated rooms. Use personal protective equipment. Do not eat, drink or smoke in the workspace. |
| | Structural measures to prevent exposure: | No information available |
| | Organisational measures to prevent exposure: | Organization of work in order to reduce other worker's influence during work process. |
| | Technical measures to prevent exposure: | - |
| 8.2.2. | Personal protection equipment: | |
| 8.2.2.1. | Eye and face protection: | Wear airtight protective goggles (see standard EN 166). |
| 8.2.2.2. | Skin protection | |
| | Hand protection: | Non required. |
| | Other 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. |
| 8.2.2.3. | Respiratory protection: | If the threshold value 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 (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. |
| 8.2.2.4. | Thermal hazards: | No information available |
| 8.2.3. | Environmental exposure controls | |
| | Substance/mixture related measures to prevent exposure: | See Section 6 |

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|---------------|-------------------|----------------------|--------------|----------|---|
| Trade name: | CRYO SPRAY | | | | |
| Product code: | 08-SPRAY-2 | Date of compilation: | 26 June 2019 | Version: | 5 |

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|--|---|
| Structural measures to prevent exposure: | Use modern equipment. |
| Organisational measures to prevent exposure: | Adapt the work process to the required working conditions of the workplace. |
| Technical measures to prevent exposure: | See Section 6 |

SECTION 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

| | Value | Method |
|---|--------------------------|--------------------------|
| Physical state: | Aerosol | No information available |
| Colour: | Colorless | No information available |
| Odour: | Odourless | No information available |
| Odour threshold; | No information available | No information available |
| pH: | 7.0 | No information available |
| Melting point / freezing point; | Not available | No information available |
| Initial boiling point and boiling range: | Not available | No information available |
| Flash point: | Not available | No information available |
| Evaporation rate: | Not available | No information available |
| Flammability (solid, gas): | Not available | No information available |
| Upper/lower flammability or explosive limits: | 9,5% (V/V) 1,8% (V/V) | No information available |
| Vapour pressure: | 3,2 bar | No information available |
| Vapour density: | Not available | No information available |
| Relative density | 0,51 | No information available |
| Bulk density: | Not available | No information available |
| Solubility(ies): | Not available | No information available |
| Partition coefficient: n-octanol/water (log Kow): | Not available | No information available |
| Auto-ignition temperature: | Not available | No information available |
| Decomposition temperature: | Not available | No information available |
| Viscosity: | Not available | No information available |
| Explosive properties: | Not available | No information available |
| Oxidising properties: | Not available | No information available |

9.2. Other information

| | | | | | |
|---------------|-------------------|----------------------|--------------|----------|---|
| Trade name: | CRYO SPRAY | | | | |
| Product code: | 08-SPRAY-2 | Date of compilation: | 26 June 2019 | Version: | 5 |

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|--|
| VOC (Directive 2010/75/EC) 100,00% - 5006,00 g/litre |
| VOC (volatile carbon) – 82,35% - 416,69 g/litre |

| 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. |
| 10.5. | Incompatible materials: | Strong reducing or oxidising agents, strong acids or alkalis, hot material. |
| 10.6. | Hazardous decomposition products: | No information available |

| SECTION 11. Toxicological information | | | | | |
|---|--------------------------|--------------------------|---|--------------------------|--------------------------|
| 11.1. Information on toxicological effects | | | | | |
| Acute toxicity: | | | | | |
| Route of exposure: | Method | Species | Effective Dose LD ₅₀ /LC ₅₀ or ATE _{mixture} | Exposure time | Results |
| Oral: | No information available | No information available | No information available | No information available | No information available |
| Dermal: | No information available | No information available | No information available | No information available | No information available |
| Inhalation: | No information available | No information available | No information available | No information available | No information available |
| Specific target organ toxicity - single exposure (STOT-SE): | | | | | |
| | Specific effects | | Target organ | | Note |
| Oral: | No information available | | No information available | | |
| Dermal: | No information available | | No information available | | |
| Inhalation: | No information available | | No information available | | |
| Aspiration hazard: | | | | | |
| | | | No information available | | |
| Irritation and corrosion | | | | | |
| | Exposure time | Species | Evaluation | Method | Note |
| Skin corrosion/irritation | - | - | - | - | - |

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|---------------|-------------------|----------------------|--------------|----------|---|
| Trade name: | CRYO SPRAY | | | | |
| Product code: | 08-SPRAY-2 | Date of compilation: | 26 June 2019 | Version: | 5 |

| | | | | | | |
|---------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| Subacute inhalation | No information available | No information available | No information available | No information available | No information available | No information available |
|---------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|

Specific target organ toxicity - repeated exposure (STOT-RE):

| | Specific effects | Target organ | Note |
|-----------------------|--------------------------|--------------------------|------|
| Subacute inhalation | No information available | No information available | - |
| Subchronic oral | No information available | No information available | - |
| Subchronic dermal | No information available | No information available | - |
| Subchronic inhalation | No information available | No information available | - |
| Chronic oral | No information available | No information available | - |
| Chronic dermal | No information available | No information available | - |
| Chronic inhalation | No information available | No information available | - |
| Subacute oral | No information available | No information available | - |
| Subacute dermal | No information available | No information available | - |

CMR effects (carcinogenicity, mutagenicity, reproductive toxicity)

| | |
|--------------------------------|--------------------------|
| Carcinogenicity: | No information available |
| Mutagenicity <i>in-vitro</i> : | No information available |
| Genotoxicity: | No information available |
| Mutagenicity <i>in-vivo</i> : | No information available |
| Germ cell mutagenicity : | No information available |
| Reproductive toxicity: | No information available |

Summary of evaluation of the CMR properties; : No information available

| | |
|--------------|---|
| 11.2. | Practical experiences: |
| | Classification observations: No information available |
| | Other observations: No information available |

| | |
|--------------|---|
| 11.3. | General notes: |
| | According to currently available data, this product has not yet produced health damages. Anyway, it must be handled according to good industrial practices. |

SECTION 12. Ecological information

12.1. Toxicity

| | | | | | |
|---------------|-------------------|----------------------|--------------|----------|---|
| Trade name: | CRYO SPRAY | | | | |
| Product code: | 08-SPRAY-2 | Date of compilation: | 26 June 2019 | Version: | 5 |

| Acute (short-term) toxicity | Dose | Exposure time | Species | Method | Evaluation | Note |
|-----------------------------|------------------|---------------|--------------------------|--------------------------|--------------------------|--------------------------|
| Fish | LC ₅₀ | 96 hours | No information available | No information available | No information available | No information available |
| Crustacea: | EC ₅₀ | 48 hours | No information available | No information available | No information available | No information available |
| Algae/aquatic plants: | IC ₅₀ | 72 hours | No information available | No information available | No information available | No information available |
| Other organisms | - | - | No information available | No information available | No information available | No information available |

| Chronic (long-term) toxicity | Doza | Exposure time | Species | Method | Evaluation | Note |
|------------------------------|------------------|---------------|--------------------------|--------------------------|--------------------------|--------------------------|
| Fish | LC ₅₀ | 96 hours | No information available | No information available | No information available | No information available |
| Crustacea: | EC ₅₀ | 48 hours | No information available | No information available | No information available | No information available |
| Algae/aquatic plants: | IC ₅₀ | 72 hours | No information available | No information available | No information available | No information available |
| Other organisms | - | - | No information available | No information available | No information available | No information available |

12.2. Persistence and degradability

Abiotic degradation

| | Degradation half-lives | Method | Evaluation | Note |
|--------------|--------------------------|--------------------------|--------------------------|--------------------------|
| Marine water | No information available | No information available | No information available | No information available |
| Fresh water | No information available | No information available | No information available | No information available |
| Air | No information available | No information available | No information available | No information available |
| Soil | No information available | No information available | No information available | No information available |

Biodegradation

| % Degradation | Time (days) | Method | Evaluation | Note |
|---------------|-------------|--------|------------|------|
|---------------|-------------|--------|------------|------|

| | | | | | |
|---------------|-------------------|----------------------|--------------|----------|---|
| Trade name: | CRYO SPRAY | | | | |
| Product code: | 08-SPRAY-2 | Date of compilation: | 26 June 2019 | Version: | 5 |

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|---|---|---|----------------|--|
| - | - | - | 0,1 – 100 mg/l | Butane (solubility in water; rapidly degradable) |
| - | - | - | 0,1 – 100 mg/l | Butane (solubility in water; rapidly degradable) |

12.3. Bioaccumulative potential

Octanol-water partition coefficient (log Kow)

| Value | Concentration | pH | °C | Method | Evaluation | Note |
|-------|---------------|----|----|--------|------------|---------|
| 1,09 | - | - | - | - | - | Butane |
| 1,09 | - | - | - | - | - | Propane |

Bioconcentration Factor (BCF)

| Value | Species | Method | Evaluation | Note |
|--------------------------|--------------------------|--------------------------|--------------------------|------|
| No information available | No information available | No information available | No information available | - |

Chronic ecotoxicity

| Value | Dose | Exposure time | Species | Method | Evaluation | Note |
|---|------------------|--------------------------|--------------------------|--------------------------|--------------------------|------|
| Chronic toxicity on fish | LC ₅₀ | No information available | No information available | No information available | No information available | - |
| Chronic toxicity on crustacea (Daphnia) | EC ₅₀ | No information available | No information available | No information available | No information available | - |

12.4. Mobility in soil

Known or predicted distribution in environmental compartments:

No information available

Surface tension:

| Value | °C | Concentration | Method | Note |
|--------------------------|--------------------------|--------------------------|--------------------------|------|
| No information available | No information available | No information available | No information available | - |

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|---------------|-------------------|----------------------|--------------|----------|---|
| Trade name: | CRYO SPRAY | | | | |
| Product code: | 08-SPRAY-2 | Date of compilation: | 26 June 2019 | Version: | 5 |

| Adsorption / desorption | | | | | |
|-------------------------|-------------------------------------|--------------------------|--------------------------|--------------------------|------|
| Transport | A/D coefficient Henry's constant | log Kow | Evaporation rate | Method | Note |
| Soil-water | No information available | No information available | No information available | No information available | - |
| Water-air | No information available | No information available | No information available | No information available | - |
| Soil-air | No information available | No information available | No information available | No information 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

No information available

SECTION 13. Disposal considerations

13.1. Waste treatment methods

13.1.1. Product/Packaging disposal:

Submit for disposal to the legal person authorized by the Ministry of Environmental and Nature Protection.

13.1.2. Waste codes/waste designations according to Low:

No information available

13.1.3. Waste treatment – relevant information:

No information available

13.1.4. Sewage disposal – relevant information:

Waste must not be disposed of into the sewage system.

13.1.5. Other disposal recommendations:

Do not dispose of the product's remains into the sewage system. Submit the remains to the collectors authorized by the ministry in charge. Do not dispose of the packaging into the sewage system. Submit the packaging to the collectors authorized by the ministry in charge.

13.1.6. Relevant Community provisions:

-

| | | | | | |
|---------------|-------------------|----------------------|--------------|----------|---|
| Trade name: | CRYO SPRAY | | | | |
| Product code: | 08-SPRAY-2 | Date of compilation: | 26 June 2019 | Version: | 5 |

| SECTION 14. Transport information | |
|--|---------------------|
| Transporting/shipment by road (ADR) | |
| UN number: | 1950 |
| UN proper shipping name: | Aerosols, flammable |
| Transport hazard class(es): | 2.1 |
| Packing group: | - |
| Environmental hazards: | no |
| Special precautions for user: | - |
| Transporting/shipment by rail (RID) | |
| UN number: | 1950 |
| UN proper shipping name: | Aerosols, flammable |
| Transport hazard class(es): | 2.1 |
| Packing group: | - |
| Environmental hazards: | no |
| Special precautions for user: | - |
| Transporting/shipment by inland waterways (ADN) | |
| UN number: | 1950 |
| UN proper shipping name: | Aerosols, flammable |
| Transport hazard class(es): | 2.1 |
| Packing group: | - |
| Environmental hazards: | no |
| Special precautions for user: | - |
| Transporting/shipment by sea (IMDG) | |
| UN number: | 1950 |
| UN proper shipping name: | Aerosols |
| Transport hazard class(es): | 2.1 |
| Packing group: | - |
| Environmental hazards: | no |
| Special precautions for user: | - |
| Transport in bulk according to Annex II of MARPOL73/78 and the IBC code: | - |
| Transporting/shipment by air (ICAO-TI/IATA-DGR) | |
| UN number: | 1950 |
| UN proper shipping name: | Aerosols, flammable |
| Transport hazard class(es): | 2.1 |

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|---------------|-------------------|----------------------|--------------|----------|---|
| Trade name: | CRYO SPRAY | | | | |
| Product code: | 08-SPRAY-2 | Date of compilation: | 26 June 2019 | Version: | 5 |

| | |
|-------------------------------|----|
| Packing group: | - |
| Environmental hazards: | no |
| Special precautions for user: | - |
| Further information: | - |

| SECTION 15. Regulatory information | |
|---|--|
| 15.1. | Safety, health and environmental regulations/legislation specific for the substance or mixture |
| | EU regulations |
| | Authorisation and/or restrictions on use |
| | Authorisations: - |
| | Restrictions: - |
| | Other EU regulations: EC Regulation No. 1906/2007 and EC Regulation No. 1272/2008 of the European Parliament and the European Council; The European Commission Regulation No. 453/2006 of 2010 on changes and amendments to the Regulation (EC) No. 1907/2006 of the European Parliament and Council on registration, evaluation, authorization and restriction of chemical substances (REACH); EC Regulation No. 2037/2000 of the European Parliament and Council of 29 June 2000 on ozone-depleting substances; EC Regulation No. 689/2008 of the European Parliament and Council of 17 June 2008 concerning the export and import of dangerous chemicals; EC Regulation No. 850/2004 of the European Parliament and Council of 29 April 2004 on persistent organic pollutants; Directive 2008/98/EC of the European Parliament and Council of 19 November 2008 on waste and repealing certain Directives |
| | Information according 1999/13/EC about limitation of emissions of volatile organic compounds (VOC-guideline) |
| | National legislation: Chemicals Act, Regulation on classification, packaging and labeling of dangerous substances, Ordinance on occupational exposure limit values and on biological limit values, Regulation on categories, types and classification of waste with a waste catalog and list of hazardous waste, Ordinance on writing Material safety data sheet, Transport of Hazardous Substances Act |
| 15.2. | Chemical safety assessment |
| | None |

| SECTION 16. Other information | |
|--------------------------------------|------------------------|
| 16.1. | Indication of changes: |

| | | | | | |
|---------------|-------------------|----------------------|--------------|----------|---|
| Trade name: | CRYO SPRAY | | | | |
| Product code: | 08-SPRAY-2 | Date of compilation: | 26 June 2019 | Version: | 5 |

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| 16.2. | Abbreviations and acronyms: | and | PBT Stable, bioaccumulative and toxic vPvB Strongly stable and strongly bioaccumulative LD ₅₀ Lethal dose, 50% LC ₅₀ Lethal concentration, 50% STOT - SE Specific target organ toxicity - single exposure |
| 16.3. | Key literature references and source of data: | | IFA GESTIS website, ECHA |
| 16.4. | Classification and procedure used to derive the classification for mixture according to Regulation (EC) 1272/2008 (CLP) | | |
| | Classification | | Classification procedure |
| | - | | - |
| 16.5. | Relevant H statements (number and full text) | | |
| | H: | H220 H222 H229 H280 | Extremely flammable gas. Extremely flammable aerosol. Pressurised container: may burst if heated. Contains gas under pressure; may burst if heated. |
| 16.6. | Training advice: | | - |
| 16.7. | Further information: | | We are not responsible for consequences in case of failure to comply with instructions for use or improper use of the product described in this material safety data sheet. |

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| ANNEX: Exposure scenario resulting to Chemical safety assessment |
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