

EASY ICE - IMPLANT ICE

For the INSTANT ICE product, a safety data sheet is not required, as it is an article as defined in article 3, point 3) of EC regulation n. 1907/2006. Under normal and reasonably foreseeable conditions there is no exposure to the contents of the bag.

This document is provided to support users in the correct storage and disposal of the item consisting of bag and contents.

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier: EASY ICE - IMPLANT ICE

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

Relevant uses: medical device for cold therapy

Uses advised against (professional, Consumer use): Any use not specified in this sheet or on the label."

1.3 Details of the supplier of the safety data sheet:

DISPOTECH SRL

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1.4 Emergency telephone number: +39 0343 36711 business hours

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture:

For the INSTANT ICE (EASY ICE- IMPLANT ICE) product, classification and labelling according to CLP regulation is not required, as it is an article as defined in article 3, point 3) of EC regulation no. 1907/2006. Under normal and reasonably foreseeable conditions there is no exposure to the contents of the bag.

2.2 Label elements:

CLP Regulation (EC) No 1272/2008:

Hazard statements: Not applicable

Precautionary statements: Not applicable

Other hazards precautionary statements:

For external use only; disposable product. Do not use if the package is damaged. Do not break the bag and by all means prevent any content leakage. The content of the bag causes stains and irritation (in case of contact, rinse with water for 15 minutes), and is harmful (if swallowed seek immediate medical assistance).

Store at room temperature out of the reach of children and away from heat sources and flammable materials. Do not freeze the bag, do not use on injured skin. Contact your doctor in case of cardiovascular diseases, circulatory diseases, diabetes and/or cutaneous insensitivity (Raynaud's syndrome), if the product is used on infants, children and the elderly, or in case of doubt on how to perform the treatment and if the symptoms persist.

2.3 Other hazards:

Product does not meet PBT/vPvB criteria

Endocrine-disrupting properties: The product does not meet the criteria.

No hazards identified other than those driving classification.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substance:

Non-applicable

3.2 Mixture:

Chemical description: Water-based mixture of inorganic and organic compounds

Components:

In accordance with Annex II of Regulation (EC) No 1907/2006 (point 3), the product contains:

- CONTINUED ON NEXT PAGE -

EASY ICE - IMPLANT ICE

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS (continued)

Identification		Chemical name/Classification	Concentration
CAS: 7732-18-5 EC: 231-791-2 Index: Non-applicable REACH: Non-applicable	Water ⁽¹⁾ Regulation 1272/2008	Not classified	50 - <60 %
CAS: 57-13-6 EC: 200-315-5 Index: Non-applicable REACH: 01-2119463277-33-XXXX	Urea ⁽¹⁾ Regulation 1272/2008	Not classified	20 - <30 %
CAS: 12125-02-9 EC: 235-186-4 Index: 017-014-00-8 REACH: 01-2119489385-24-XXXX	ammonium chloride ⁽²⁾ Regulation 1272/2008	ATP CLP00 Acute Tox. 4: H302; Eye Irrit. 2: H319 - Warning	18 - <22 %

⁽¹⁾ Voluntarily-listed substance failing to meet any of the criteria set out in Regulation (EU) No. 2020/878⁽²⁾ Substances presenting a health or environmental hazard which meet criteria laid down in Regulation (EU) No. 2020/878

To obtain more information on the hazards of the substances consult sections 11, 12 and 16.

Specific concentration limits not available for the substances listed above

M-factor not available for substances listed above

Acute toxicity estimate for the substance in Part 3 of Annex VI to Regulation (EC) No 1272/2008 or as determined in accordance with Annex I to that Regulation:

Identification	Acute toxicity	Genus
ammonium chloride CAS: 12125-02-9 EC: 235-186-4	LD50 oral LD50 dermal LC50 inhalation	1410 mg/kg Not relevant Not relevant
		Rat

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures:

The symptoms resulting from intoxication can appear after exposure, therefore, in case of doubt, seek medical attention for direct exposure to the chemical product or persistent discomfort, showing the SDS of this product.

By inhalation:

This product does not contain substances classified as hazardous for inhalation, however, in case of symptoms of intoxication remove the person affected from the exposure area and provide with fresh air. Seek medical attention if the symptoms get worse or persist.

By skin contact:

In case of contact it is recommended to clean the affected area thoroughly with water and neutral soap. In case of changes to the skin (stinging, redness, rashes, blisters,...), seek medical advice with this Safety Data Sheet

By eye contact:

Rinse eyes thoroughly with water for at least 15 minutes. If the injured person uses contact lenses, these should be removed unless they are stuck to the eyes, in which case removal could cause further damage. In all cases, after cleaning, a doctor should be consulted as quickly as possible with the SDS for the product.

By ingestion/aspiration:

Do not induce vomiting, but if it does happen keep the head down to avoid aspiration. Keep the person affected at rest. Rinse out the mouth and throat, as they may have been affected during ingestion.

Under normal and reasonably foreseeable conditions there is no exposure to the contents of the bag.

Those who provide first aid to the exposed person to bag's content are advised to wear personal protective equipment to avoid exposure to the product.

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

Acute and delayed effects are indicated in sections 2 and 11.

Under normal and reasonably foreseeable conditions there is no exposure to the contents of the bag. The known acute effects are those dependent on the danger of the contained substance/mixture.

Ammonium chloride: H319:Causes serious eye irritation.

Delayed effects in case of exposure to the product are unknown.

- CONTINUED ON NEXT PAGE -

EASY ICE - IMPLANT ICE

SECTION 4: FIRST AID MEASURES (continued)

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

Any clinical tests, antidotes and medical monitoring must be established by a doctor, to be consulted in case of exposure above the occupational exposure limits.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media:

Suitable extinguishing media:

Product is non-flammable under normal conditions of storage, handling and use. In the case of combustion as a result of improper handling, storage or use preferably use polyvalent powder extinguishers (ABC powder), in accordance with the Regulation on fire protection systems.

Unsuitable extinguishing media:

Non-applicable

5.2 Special hazards arising from the substance or mixture:

As a result of combustion or thermal decomposition reactive sub-products are created that can become highly toxic and, consequently, can present a serious health risk.

5.3 Advice for firefighters:

Depending on the magnitude of the fire it may be necessary to use full protective clothing and self-contained breathing apparatus (SCBA). Minimum emergency facilities and equipment should be available (fire blankets, portable first aid kit,...) in accordance with Directive 89/654/EC.

Additional provisions:

Act in accordance with the Internal Emergency Plan and the Information Sheets on actions to take after an accident or other emergencies. Eliminate all sources of ignition. In case of fire, cool the storage containers and tanks for products susceptible to combustion, explosion or BLEVE as a result of high temperatures. Avoid spillage of the products used to extinguish the fire into an aqueous medium.

To limit damage in the event of fire or to dispose of extinguishing agent residues, it is recommended to isolate the affected area, to prevent leaks from occurring and the extinguishing agents from causing pollution of waterways. The methods of isolating the area cannot be specifically indicated as the situation will have to be assessed and managed by expert personnel depending on the fire to be put out.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures:

For non-emergency personnel:

Isolate leaks provided that there is no additional risk for the people performing this task. Personal protection equipment must be used against potential contact with the spilt product (See section 8). Evacuate the area and keep out those who do not have protection.

For emergency responders:

Wear protective equipment. Keep unprotected persons away. See section 8.

Other information:

Under normal and reasonably foreseeable conditions there is no exposure to the contents of the bag.

6.2 Environmental precautions:

This product is not classified as hazardous to the environment. Keep product away from drains, surface and ground water.

6.3 Methods and material for containment and cleaning up:

It is recommended:

Absorb the spillage using sand or inert absorbent and move it to a safe place. Do not absorb in sawdust or other combustible absorbents. For any concern related to disposal consult section 13.

6.4 Reference to other sections:

See sections 8 and 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling:

A.- General precautions for safe use

Comply with the current legislation concerning the prevention of industrial risks with regards manually handling weights. Maintain order, cleanliness and dispose of using safe methods (section 6).

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EASY ICE - IMPLANT ICE**SECTION 7: HANDLING AND STORAGE (continued)****B.- Technical recommendations for the prevention of fires and explosions**

Product is non-flammable under normal conditions of storage, handling and use. It is recommended to transfer at slow speeds to avoid the generation of electrostatic charges that can affect flammable products. Consult section 10 for information on conditions and materials that should be avoided.

C.- Technical recommendations on general occupational hygiene

Do not eat or drink during the process, washing hands afterwards with suitable cleaning products.

D.- Technical recommendations to prevent environmental risks

It is recommended to have absorbent material available at close proximity to the product (See subsection 6.3)

7.2 Conditions for safe storage, including any incompatibilities:**A.- Technical measures for storage**

Maximum Temp.: 0 °C

B.- General conditions for storage

Avoid sources of heat, radiation, static electricity and contact with food. For additional information see subsection 10.5

7.3 Specific end use(s):

The identified use of this product is a medical device for cold therapy. We do not recommend any use other than that indicated on the data sheet and label.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**8.1 Control parameters:**

Substances whose occupational exposure limits have to be monitored in the workplace (European OEL, not country-specific legislation):

There are no applicable occupational exposure limits for the substances contained in the product

DNEL (Workers):

Identification		Short exposure		Long exposure	
		Systemic	Local	Systemic	Local
Urea CAS: 57-13-6 EC: 200-315-5	Oral	Not relevant	Not relevant	Not relevant	Not relevant
	Dermal	580 mg/kg	Not relevant	580 mg/kg	Not relevant
	Inhalation	292 mg/m³	Not relevant	292 mg/m³	Not relevant
ammonium chloride CAS: 12125-02-9 EC: 235-186-4	Oral	Not relevant	Not relevant	Not relevant	Not relevant
	Dermal	Not relevant	Not relevant	128,9 mg/kg	Not relevant
	Inhalation	Not relevant	Not relevant	43,97 mg/m³	Not relevant

DNEL (General population):

Identification		Short exposure		Long exposure	
		Systemic	Local	Systemic	Local
Urea CAS: 57-13-6 EC: 200-315-5	Oral	42 mg/kg	Not relevant	42 mg/kg	Not relevant
	Dermal	580 mg/kg	Not relevant	580 mg/kg	Not relevant
	Inhalation	125 mg/m³	Not relevant	125 mg/m³	Not relevant
ammonium chloride CAS: 12125-02-9 EC: 235-186-4	Oral	55,2 mg/kg	Not relevant	55,2 mg/kg	Not relevant
	Dermal	Not relevant	Not relevant	55,2 mg/kg	Not relevant
	Inhalation	Not relevant	Not relevant	9,4 mg/m³	Not relevant

PNEC:

Identification					
Urea CAS: 57-13-6 EC: 200-315-5	ammonium chloride CAS: 12125-02-9 EC: 235-186-4	STP	Not relevant	Fresh water	0,47 mg/L
		Soil	Not relevant	Marine water	0,047 mg/L
		Intermittent	Not relevant	Sediment (Fresh water)	Not relevant
		Oral	Not relevant	Sediment (Marine water)	Not relevant
		STP	Not relevant	Fresh water	0,25 mg/L
		Soil	50,7 mg/kg	Marine water	0,025 mg/L
		Intermittent	0,43 mg/L	Sediment (Fresh water)	Not relevant
		Oral	Not relevant	Sediment (Marine water)	Not relevant

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EASY ICE - IMPLANT ICE**SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION (continued)****8.2 Exposure controls:**

Under normal and reasonably foreseeable conditions there is no exposure to the contents of the bag.

A.- Individual protection measures, such as personal protective equipment

As a preventative measure it is recommended to use basic Personal Protective Equipment, with the corresponding <>CE marking>> in accordance with Regulation (EU) 2016/425. For more information on Personal Protective Equipment (storage, use, cleaning, maintenance, class of protection,...) consult the information leaflet provided by the manufacturer. For more information see subsection 7.1. All information contained herein is a recommendation which needs some specification from the labour risk prevention services as it is not known whether the company has additional measures at its disposal.

B.- Respiratory protection: The use of protection equipment will be necessary if a mist forms or if the occupational exposure limits are exceeded.

C.- Specific protection for the hands: Not relevant

D.- Eye and face protection: Not relevant

E.- Body protection

Not relevant

F.- Additional emergency measures

It is not necessary to take additional emergency measures.

Environmental exposure controls:

In accordance with the community legislation for the protection of the environment it is recommended to avoid environmental spillage of both the product and its container. For additional information see subsection 7.1.D

Volatile organic compounds:

With regard to Directive 2010/75/EU, this product has the following characteristics:

V.O.C. (Supply): 0 % weight

V.O.C. density at 20 °C: 0 kg/m³ (0 g/L)

Average carbon number: Not relevant

Average molecular weight: Not relevant

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**9.1 Information on basic physical and chemical properties:**

For complete information see the product datasheet.

Appearance:

Physical state at 20 °C: Liquid

Appearance: Not available

Colour: White

Odour: Odourless

Odour threshold: Non-applicable *

Volatility:

Boiling point at atmospheric pressure: 100 °C

Vapour pressure at 20 °C: 2350 Pa

Vapour pressure at 50 °C: 12381,01 Pa (12,38 kPa)

Evaporation rate at 20 °C: Non-applicable *

Product description:

Density at 20 °C: 1394,3 kg/m³

Relative density at 20 °C: 1,394

Dynamic viscosity at 20 °C: 2,19 cP

*Non-applicable due to the nature of the product, not providing information property of its hazards.

- CONTINUED ON NEXT PAGE -

EASY ICE - IMPLANT ICE

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES (continued)

Kinematic viscosity at 20 °C:	1,57 mm ² /s
Kinematic viscosity at 40 °C:	Non-applicable *
Concentration:	Non-applicable *
pH:	Non-applicable *
Vapour density at 20 °C:	Non-applicable *
Partition coefficient n-octanol/water 20 °C:	Non-applicable *
Solubility in water at 20 °C:	Non-applicable *
Solubility properties:	Non-applicable *
Decomposition temperature:	Non-applicable *
Melting point/freezing point:	Non-applicable *
Flammability:	
Flash Point:	Non Flammable (>60 °C)
Flammability (solid, gas):	Non-applicable *
Autoignition temperature:	Non-applicable *
Lower flammability limit:	Non-applicable *
Upper flammability limit:	Non-applicable *
Particle characteristics:	
Median equivalent diameter:	Non-applicable

9.2 Other information:

Information with regard to physical hazard classes:

Explosive properties:	Non-applicable *
Oxidising properties:	Non-applicable *
Corrosive to metals:	Non-applicable *
Heat of combustion:	Non-applicable *
Aerosols-total percentage (by mass) of flammable components:	Non-applicable *

Other safety characteristics:

Surface tension at 20 °C:	Non-applicable *
Refraction index:	Non-applicable *

*Non-applicable due to the nature of the product, not providing information property of its hazards.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity:

No hazardous reactions are expected because the product is stable under recommended storage conditions. See section 7 from Safety Data Sheet.

10.2 Chemical stability:

Chemically stable under the indicated conditions of storage, handling and use.

10.3 Possibility of hazardous reactions:

Under the specified conditions, hazardous reactions that lead to excessive temperatures or pressure are not expected.

10.4 Conditions to avoid:

Applicable for handling and storage at room temperature:

Shock and friction	Contact with air	Increase in temperature	Sunlight	Humidity
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable

10.5 Incompatible materials:

Acids	Water	Oxidising materials	Combustible materials	Others
Avoid strong acids	Not applicable	Not applicable	Not applicable	Avoid alkalis or strong bases

- CONTINUED ON NEXT PAGE -

EASY ICE - IMPLANT ICE

SECTION 10: STABILITY AND REACTIVITY (continued)

10.6 Hazardous decomposition products:

See subsection 10.3, 10.4 and 10.5 to find out the specific decomposition products. Depending on the decomposition conditions, complex mixtures of chemical substances can be released: carbon dioxide (CO₂), carbon monoxide and other organic compounds.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008:

The experimental information related to the toxicological properties of the product itself is not available

Dangerous health implications:

In case of exposure that is repetitive, prolonged or at concentrations higher than the recommended occupational exposure limits, adverse effects on health may result, depending on the means of exposure:

A- Ingestion (acute effect):

- Acute toxicity: Based on available data, the classification criteria are not met, however, it contains substances classified as dangerous for consumption. For more information see section 3.
- Corrosivity/Irritability: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.

B- Inhalation (acute effect):

- Acute toxicity : Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for inhalation. For more information see section 3.
- Corrosivity/Irritability: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.

C- Contact with the skin and the eyes (acute effect):

- Contact with the skin: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for skin contact. For more information see section 3.
- Contact with the eyes: Based on available data, the classification criteria are not met. However, it does contain substances classified as hazardous for this effect. For more information see section 3.

D- CMR effects (carcinogenicity, mutagenicity and toxicity to reproduction):

- Carcinogenicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for the effects mentioned. For more information see section 3.
IARC: Not relevant
- Mutagenicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.
- Reproductive toxicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.

E- Sensitizing effects:

- Respiratory: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous with sensitising effects. For more information see section 3.
- Skin: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.

F- Specific target organ toxicity (STOT) - single exposure:

Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.

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

- Specific target organ toxicity (STOT)-repeated exposure: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.
- Skin: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.

H- Aspiration hazard:

Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.

Other information:

Not relevant

- CONTINUED ON NEXT PAGE -

EASY ICE - IMPLANT ICE

SECTION 11: TOXICOLOGICAL INFORMATION (continued)

Specific toxicology information on the substances:

Identification		Acute toxicity		Genus
ammonium chloride CAS: 12125-02-9 EC: 235-186-4	LD50 oral	1410 mg/kg (ATEI)		Rat
	LD50 dermal	>2000 mg/kg		
	LC50 inhalation	>5 mg/L		
Urea CAS: 57-13-6 EC: 200-315-5	LD50 oral	14300 mg/kg		Rat
	LD50 dermal	3200 mg/kg		Rabbit
	LC50 inhalation	>5 mg/L		
Water CAS: 7732-18-5 EC: 231-791-2	LD50 oral	>2000 mg/kg		
	LD50 dermal	>2000 mg/kg		
	LC50 inhalation	>20 mg/L		

11.2 Information on other hazards:

Endocrine disrupting properties

Endocrine-disrupting properties: The product does not meet the criteria.

Other information

Not relevant

SECTION 12: ECOLOGICAL INFORMATION

The experimental information related to the eco-toxicological properties of the product itself is not available

Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.

12.1 Toxicity:

Acute toxicity:

Identification		Concentration		Species	Genus
Urea CAS: 57-13-6 EC: 200-315-5	LC50	6810 mg/L (96 h)		N/A	Fish
	EC50	Not relevant			
	EC50	Not relevant			
ammonium chloride CAS: 12125-02-9 EC: 235-186-4	LC50	209 mg/L (96 h)		Cyprinus carpio	Fish
	EC50	101 mg/L (48 h)		Daphnia magna	Crustacean
	EC50	Not relevant			

Chronic toxicity:

Identification		Concentration		Species	Genus
Urea CAS: 57-13-6	NOEC	200 mg/L		Gambusia afinis	Fish
EC: 200-315-5	NOEC	Not relevant			

12.2 Persistence and degradability:

Substance-specific information:

Identification		Degradability		Biodegradability	
Urea CAS: 57-13-6 EC: 200-315-5	BOD5	Not relevant	Concentration	Not relevant	
	COD	Not relevant	Period	16 days	
	BOD5/COD	Not relevant	% Biodegradable	96 %	

12.3 Bioaccumulative potential:

Not available

12.4 Mobility in soil:

Not available

12.5 Results of PBT and vPvB assessment:

Product does not meet PBT/vPvB criteria

12.6 Endocrine disrupting properties:

Endocrine-disrupting properties: The product does not meet the criteria.

- CONTINUED ON NEXT PAGE -

EASY ICE - IMPLANT ICE**SECTION 12: ECOLOGICAL INFORMATION (continued)****12.7 Other adverse effects:**

Not described

SECTION 13: DISPOSAL CONSIDERATIONS**13.1 Waste treatment methods:**

Dispose of bag and contents together: do not open bag.

Type of waste (Regulation (EU) No 1357/2014): Not relevant

Waste management (disposal and evaluation):

Consult the authorized waste service manager on the assessment and disposal operations in accordance with Annex 1 and Annex 2 (Directive 2008/98/EC). As under 15 01 (2014/955/EC) of the code and in case the container has been in direct contact with the product, it will be processed the same way as the actual product. Otherwise, it will be processed as non-hazardous residue. Waste should not be disposed of to drains. See paragraph 6.2.

Regulations related to waste management:

In accordance with Annex II of Regulation (EC) No 1907/2006 (REACH) the community or state provisions related to waste management are stated

Community legislation: Directive 2008/98/EC, 2014/955/EU, Regulation (EU) No 1357/2014

SECTION 14: TRANSPORT INFORMATION**Transport of dangerous goods by land:**

With regard to ADR 2023 and RID 2023:

14.1 UN number or ID number:	Not relevant
14.2 UN proper shipping name:	Not relevant
14.3 Transport hazard class(es):	Not relevant
Labels:	Not relevant
14.4 Packing group:	Not relevant
14.5 Environmental hazards:	No
14.6 Special precautions for user	
Special regulations:	Not relevant
Tunnel restriction code:	Not relevant
Physico-Chemical properties:	see section 9
Limited quantities:	Not relevant
14.7 Maritime transport in bulk according to IMO instruments:	Not relevant

Transport of dangerous goods by sea:

With regard to IMDG 41-22:

14.1 UN number or ID number:	Not relevant
14.2 UN proper shipping name:	Not relevant
14.3 Transport hazard class(es):	Not relevant
Labels:	Not relevant
14.4 Packing group:	Not relevant
14.5 Marine pollutant:	No
14.6 Special precautions for user	
Special regulations:	Not relevant
EmS Codes:	
Physico-Chemical properties:	see section 9
Limited quantities:	Not relevant
Segregation group:	Not relevant
14.7 Maritime transport in bulk according to IMO instruments:	Not relevant

Transport of dangerous goods by air:

With regard to IATA/ICAO 2024:

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EASY ICE - IMPLANT ICE**SECTION 14: TRANSPORT INFORMATION (continued)**

14.1 UN number or ID number:	Not relevant
14.2 UN proper shipping name:	Not relevant
14.3 Transport hazard class(es):	Not relevant
Labels:	Not relevant
14.4 Packing group:	Not relevant
14.5 Environmental hazards:	No
14.6 Special precautions for user	
Physico-Chemical properties:	see section 9
14.7 Maritime transport in bulk according to IMO instruments:	Not relevant

SECTION 15: REGULATORY INFORMATION**15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture:**

- Article 95, REGULATION (EU) No 528/2012: Not relevant
- Candidate substances for authorisation under the Regulation (EC) No 1907/2006 (REACH): Not relevant
- Regulation (EC) No 1005/2009, about substances that deplete the ozone layer: Not relevant
- REGULATION (EU) No 649/2012, in relation to the import and export of hazardous chemical products: Not relevant
- Substances included in Annex XIV of REACH ("Authorisation List") and sunset date: Not relevant

Seveso III:

Not relevant

Limitations to commercialisation and the use of certain dangerous substances and mixtures (Annex XVII REACH, etc):

Not relevant

Specific provisions in terms of protecting people or the environment:

It is recommended to use the information included in this safety data sheet as a basis for conducting workplace-specific risk assessments in order to establish the necessary risk prevention measures for the handling, use, storage and disposal of this product.

Other legislation:

The product could be affected by sectorial legislation

- Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products
- Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents
- Commission Regulation (EC) No 907/2006 of 20 June 2006 amending Regulation (EC) No 648/2004 of the European Parliament and of the Council on detergents, in order to adapt Annexes III and VII
- Commission Regulation (EC) No 551/2009 of 25 June 2009 amending Regulation (EC) No 648/2004 of the European Parliament and of the Council on detergents, in order to adapt Annexes V and VI thereto (surfactant derogation)

15.2 Chemical safety assessment:

The supplier has not carried out evaluation of chemical safety.

SECTION 16: OTHER INFORMATION**Legislation related to safety data sheets:**

The SDS shall be supplied in an official language of the country where the product is placed on the market. This safety data sheet has been designed in accordance with ANNEX II-Guide to the compilation of safety data sheets of Regulation (EC) No 1907/2006 (COMMISSION REGULATION (EU) 2020/878).

Modifications related to the previous Safety Data Sheet which concerns the ways of managing risks.:

Not relevant

Texts of the legislative phrases mentioned in section 3:

The phrases indicated do not refer to the product itself; they are present merely for informative purposes and refer to the individual components which appear in section 3

CLP Regulation (EC) No 1272/2008:

Acute Tox. 4: H302 - Harmful if swallowed.

Eye Irrit. 2: H319 - Causes serious eye irritation.

Advice related to training:

Training is recommended in order to prevent industrial risks for staff using this product and to facilitate their comprehension and interpretation of this safety data sheet, as well as the label on the product.

- CONTINUED ON NEXT PAGE -

EASY ICE - IMPLANT ICE

SECTION 16: OTHER INFORMATION (continued)

Principal bibliographical sources:

<http://echa.europa.eu>

<http://eur-lex.europa.eu>

Abbreviations and acronyms:

ADR: European agreement concerning the international carriage of dangerous goods by road

IMDG: International maritime dangerous goods code

IATA: International Air Transport Association

ICAO: International Civil Aviation Organisation

COD: Chemical Oxygen Demand

BOD5: 5day biochemical oxygen demand

BCF: Bioconcentration factor

LD50: Lethal Dose 50

LC50: Lethal Concentration 50

EC50: Effective concentration 50

LogPOW: Octanolwater partition coefficient

Koc: Partition coefficient of organic carbon

UFI: unique formula identifier

IARC: International Agency for Research on Cancer

Product safety information sheet : this document does not constitute a Safety Data Sheet under Article 31 of Regulation (EC) No. 1907/2006, as a Safety Data Sheet is not mandatory for this product. The information contained in this sheet is based on sources, technical knowledge and current legislation at European and state level, without being able to guarantee its accuracy. This information cannot be considered a guarantee of the properties of the product, it is simply a description of the security requirements. The occupational methodology and conditions for users of this product are not within our awareness or control, and it is ultimately the responsibility of the user to take the necessary measures to obtain the legal requirements concerning the manipulation, storage, use and disposal of chemical products. The information on this safety data sheet only refers to this product, which should not be used for needs other than those specified.

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