

**FDS SECU 512 - 405000\_2**  
**SERUM PHYSIOLOGIQUE**

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

- 1.1 Product identifier:** FDS SECU 512 - 405000\_2  
SERUM PHYSIOLOGIQUE
- 1.2 Relevant identified uses of the substance or mixture and uses advised against:**  
Relevant uses: Miscellaneous  
Uses advised against: All uses not specified in this section or in section 7.3
- 1.3 Details of the supplier of the safety data sheet:**  
Laboratoires GILBERT  
avenue du Général de Gaulle  
14200 HEROUVILLE SAINT-CLAIR - FRANCE  
Phone.: 02.31.47.15.15 - Fax: 02.31.47.14.86  
se@groupebatteur.fr  
www.groupebatteur.fr
- 1.4 Emergency telephone number:** + 33.1.45.42.59.59 (n° ORFILA - FRANCE)

**SECTION 2: HAZARDS IDENTIFICATION**

- 2.1 Classification of the substance or mixture:**  
**CLP Regulation (EC) No 1272/2008:**  
The product is not classified as hazardous according to CLP Regulation (EC) No 1272/2008.
- 2.2 Label elements:**  
**CLP Regulation (EC) No 1272/2008:**  
**Hazard statements:**  
Non-applicable  
**Precautionary statements:**  
P101: If medical advice is needed, have product container or label at hand  
P102: Keep out of reach of children  
P501: Dispose of contents/container according to the separated collection system used in your municipality
- 2.3 Other hazards:**  
Product fails to meet PBT/vPvB criteria

**SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS**

- 3.1 Substance:**  
Non-applicable
- 3.2 Mixture:**  
**Chemical description:** Mixture of substances  
**Components:**  
In accordance with Annex II of Regulation (EC) No 1907/2006 (point 3), the product contains:

Identification	Chemical name/Classification	Concentration
CAS: 7647-14-5 EC: 231-598-3 Index: Non-applicable REACH: 01-2119485491-33-XXXX	<b>Sodium chloride<sup>(1)</sup></b> Regulation 1272/2008	Not classified  <1 %

<sup>(1)</sup> Main component

To obtain more information on the hazards of the substances consult sections 8, 11, 12, 15 and 16.

**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.

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**SECTION 4: FIRST AID MEASURES (continued)**

**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:**

This product does not contain substances classified as hazardous for eye contact. Rinse eyes thoroughly for at least 15 minutes with lukewarm water, ensuring that the person affected does not rub or close their eyes.

**By ingestion/aspiration:**

In case of consumption, seek immediate medical assistance showing the SDS for the product.

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

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

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

Non-applicable

**SECTION 5: FIREFIGHTING MEASURES**

**5.1 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. IT IS NOT RECOMMENDED to use full jet water as an extinguishing agent.

**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.

**SECTION 6: ACCIDENTAL RELEASE MEASURES**

**6.1 Personal precautions, protective equipment and emergency procedures:**

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.

**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.- Precautions for safe manipulation

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**SECTION 7: HANDLING AND STORAGE (continued)**

Comply with the current legislation concerning the prevention of industrial risks. Keep containers hermetically sealed. Control spills and residues, destroying them with safe methods (section 6). Avoid leakages from the container. Maintain order and cleanliness where dangerous products are used.

**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 to prevent ergonomic and toxicological risks**

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**

Minimum Temp.: 5 °C

Maximum Temp.: 30 °C

Maximum time: 36 Months

**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):**

Except for the instructions already specified it is not necessary to provide any special recommendation regarding the uses of this product.

**SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**

**8.1 Control parameters:**

Substances whose occupational exposure limits have to be monitored in the workplace

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

**DNEL (Workers):**

Identification		Short exposure		Long exposure	
		Systemic	Local	Systemic	Local
Sodium chloride CAS: 7647-14-5 EC: 231-598-3	Oral	Non-applicable	Non-applicable	Non-applicable	Non-applicable
	Dermal	295,52 mg/kg	Non-applicable	295,52 mg/kg	Non-applicable
	Inhalation	2068,62 mg/m <sup>3</sup>	Non-applicable	2068,62 mg/m <sup>3</sup>	Non-applicable

**DNEL (General population):**

Identification		Short exposure		Long exposure	
		Systemic	Local	Systemic	Local
Sodium chloride CAS: 7647-14-5 EC: 231-598-3	Oral	126,65 mg/kg	Non-applicable	126,65 mg/kg	Non-applicable
	Dermal	126,65 mg/kg	Non-applicable	126,65 mg/kg	Non-applicable
	Inhalation	443,28 mg/m <sup>3</sup>	Non-applicable	443,28 mg/m <sup>3</sup>	Non-applicable

**PNEC:**

Identification				
Sodium chloride CAS: 7647-14-5 EC: 231-598-3	STP	500 mg/L	Fresh water	5 mg/L
	Soil	4,86 mg/kg	Marine water	Non-applicable
	Intermittent	Non-applicable	Sediment (Fresh water)	Non-applicable
	Oral	Non-applicable	Sediment (Marine water)	Non-applicable

**8.2 Exposure controls:**

A.- General security and hygiene measures in the work place

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**SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION (continued)**



As a preventative measure it is recommended to use basic Personal Protective Equipment, with the corresponding <<CE marking>> in accordance with Directive 89/686/EC. 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**



Pictogram	PPE	Labelling	CEN Standard	Remarks
 Mandatory hand protection	Protective gloves against minor risks			Replace gloves in case of any sign of damage. For prolonged periods of exposure to the product for professional users/industrials, we recommend using CE III gloves in line with standards EN 420 and EN 374.

"As the product is a mixture of several substances, the resistance of the glove material can not be predicted in advance with total reliability and has therefore to be checked prior to the application"



**D.- Ocular and facial protection**

Pictogram	PPE	Labelling	CEN Standard	Remarks
 Mandatory face protection	Panoramic glasses against splash/projections.		EN 166:2001 EN ISO 4007:2018	Clean daily and disinfect periodically according to the manufacturer's instructions. Use if there is a risk of splashing.

**E.- Body protection**

Pictogram	PPE	Labelling	CEN Standard	Remarks
	Work clothing			Replace before any evidence of deterioration. For periods of prolonged exposure to the product for professional industrial users CE III is recommended, in accordance with the regulations in EN ISO 6529:2013, EN ISO 6530:2005, EN ISO 13688:2013, EN 464:1994.
	Anti-slip work shoes		EN ISO 20347:2012	Replace before any evidence of deterioration. For periods of prolonged exposure to the product for professional industrial users CE III is recommended, in accordance with the regulations in EN ISO 20345:2012 y EN 13832-1:2007

**F.- Additional emergency measures**

Emergency measure	Standards	Emergency measure	Standards
 Emergency shower	ANSI Z358-1 ISO 3864-1:2011, ISO 3864-4:2011	 Eyewash stations	DIN 12 899 ISO 3864-1:2011, ISO 3864-4:2011

**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/m <sup>3</sup> (0 g/L)
Average carbon number:	Non-applicable
Average molecular weight:	Non-applicable

**SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**

**9.1 Information on basic physical and chemical properties:**

\*Not relevant due to the nature of the product, not providing information property of its hazards.

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**SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES (continued)**

For complete information see the product datasheet.

**Appearance:**

Physical state at 20 °C:	Liquid
Appearance:	Not available
Colour:	Colourless
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:	1036,8 kg/m <sup>3</sup>
Relative density at 20 °C:	1,037
Dynamic viscosity at 20 °C:	1,05 cP
Kinematic viscosity at 20 °C:	1,01 cSt
Kinematic viscosity at 40 °C:	Non-applicable *
Concentration:	Non-applicable *
pH:	5 - 7
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 *
Explosive properties:	Non-applicable *
Oxidising properties:	Non-applicable *

**Flammability:**

Flash Point:	>230 °C
Flammability (solid, gas):	Non-applicable *
Autoignition temperature:	Non-applicable *
Lower flammability limit:	Non-applicable *
Upper flammability limit:	Non-applicable *

**Explosive:**

Lower explosive limit:	Non-applicable *
Upper explosive limit:	Non-applicable *

**9.2 Other information:**

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

\*Not relevant 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.

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**SECTION 10: STABILITY AND REACTIVITY (continued)**

**10.2 Chemical stability:**

Chemically stable under the 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

**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 (CO<sub>2</sub>), carbon monoxide and other organic compounds.

**SECTION 11: TOXICOLOGICAL INFORMATION**

**11.1 Information on toxicological effects:**

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, as it does not contain 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 dangerous 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 dangerous 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 dangerous 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 dangerous for skin contact. For more information see section 3.
- Contact with the eyes: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous 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 dangerous for the effects mentioned. For more information see section 3.  
IARC: Non-applicable
- Mutagenicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous 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 dangerous 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 dangerous with sensitizing effects. For more information see section 3.
- Cutaneous: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

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

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**SECTION 11: TOXICOLOGICAL INFORMATION (continued)**

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

**Other information:**

Non-applicable

**Specific toxicology information on the substances:**

Identification	Acute toxicity		Genus
	LD50 oral	LD50 dermal	
Sodium chloride	3000 mg/kg	Non-applicable	Rat
CAS: 7647-14-5	Non-applicable	Non-applicable	
EC: 231-598-3	Non-applicable	Non-applicable	

**SECTION 12: ECOLOGICAL INFORMATION**

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

**12.1 Toxicity:**

Identification	Acute toxicity		Species	Genus
	LC50	EC50		
Sodium chloride	9675 mg/L (96 h)	3412 mg/L (24 h)	Lepomis macrochirus	Fish
CAS: 7647-14-5	Non-applicable	Non-applicable	Daphnia magna	Crustacean
EC: 231-598-3	Non-applicable	Non-applicable		

**12.2 Persistence and degradability:**

Not available

**12.3 Bioaccumulative potential:**

Not available

**12.4 Mobility in soil:**

Not available

**12.5 Results of PBT and vPvB assessment:**

Product fails to meet PBT/vPvB criteria

**12.6 Other adverse effects:**

Not described

**SECTION 13: DISPOSAL CONSIDERATIONS**

**13.1 Waste treatment methods:**

Code	Description	Waste class (Regulation (EU) No 1357/2014)
	It is not possible to assign a specific code, as it depends on the intended use by the user	Non dangerous

**Type of waste (Regulation (EU) No 1357/2014):**

Non-applicable

**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-dangerous residue. We do not recommended disposal down the drain. See paragraph 6.2.

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**SECTION 13: DISPOSAL CONSIDERATIONS (continued)**

**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**

This product is not regulated for transport (ADR/RID,IMDG,IATA)

**SECTION 15: REGULATORY INFORMATION**

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

Candidate substances for authorisation under the Regulation (EC) No 1907/2006 (REACH): Non-applicable

Substances included in Annex XIV of REACH ("Authorisation List") and sunset date: Non-applicable

Regulation (EC) No 1005/2009, about substances that deplete the ozone layer: Non-applicable

Article 95, REGULATION (EU) No 528/2012: Non-applicable

REGULATION (EU) No 649/2012, in relation to the import and export of hazardous chemical products: Non-applicable

**Seveso III:**

Non-applicable

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

Non-applicable

**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

**Other information:**

This product is a medical device, it is therefore not subject to the rules on the classification, labelling and packaging of dangerous preparations.

**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:**

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 (Regulation (EC) No 2015/830)

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

Non-applicable

**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:**

Non-applicable

**Classification procedure:**

Non-applicable

**Advice related to training:**

Minimal 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.

**Principal bibliographical sources:**

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**SECTION 16: OTHER INFORMATION (continued)**

<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: 5-day biochemical oxygen demand  
BCF: Bioconcentration factor  
LD50: Lethal Dose 50  
LC50: Lethal Concentration 50  
EC50: Effective concentration 50  
Log-POW: Octanol-water partition coefficient  
Koc: Partition coefficient of organic carbon

CONFIDENTIEL

The information contained in this safety data 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.

- END OF SAFETY DATA SHEET -