



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

- 1.1 Product identifier:** Mediclean 520 Sanit Cream  
**Other means of identification:**  
Non-applicable
- 1.2 Relevant identified uses of the substance or mixture and uses advised against:**  
Relevant uses: Cleaner (pH > 9). For professional users only.  
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:**  
MEDISEPT Sp. z o.o.  
ul. Ludwika Spiessa 4  
20-270 Lublin - lubelskie - Polska  
Phone: +48 81 535 22 76  
p.brewczak@medisept.pl  
https://medisept.pl/
- 1.4 Emergency telephone number:** 112

## 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.  
**Supplementary information:**  
EUH208: Contains reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1). May produce an allergic reaction.  
EUH210: Safety data sheet available on request.
- 2.3 Other hazards:**  
Product fails to meet PBT/vPvB criteria  
Endocrine-disrupting properties: The product fails to meet the criteria.

\*\* Changes with regards to the previous version

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

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

Identification	Chemical name/Classification		Concentration
CAS: 68891-38-3 EC: 500-234-8 Index: Non-applicable REACH: 01-2119488639-16-XXXX	<b>Alcohols, C12-C14, ethoxylated, sulphate, sodium salt</b> <sup>1</sup>	Self-classified	2.5 - <10 %
	Regulation 1272/2008	Eye Dam. 1: H318; Skin Irrit. 2: H315 - Danger	

<sup>1</sup> Substances presenting a health or environmental hazard which meet criteria laid down in Regulation (EU) No. 2020/878



## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS (continued)

Identification	Chemical name/Classification	Concentration
CAS: 55965-84-9 EC: Non-applicable Index: 613-167-00-5 REACH: Non-applicable	<b>reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)</b> <sup>1</sup> ATP ATP13 Regulation 1272/2008 Acute Tox. 2: H310+H330; Acute Tox. 3: H301; Aquatic Acute 1: H400; Aquatic Chronic 1: H410; Eye Dam. 1: H318; Skin Corr. 1C: H314; Skin Sens. 1A: H317; EUH071 - Danger	<1 %

<sup>1</sup> 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.

**Other information:**

Identification	M-factor
reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) CAS: 55965-84-9 EC: Non-applicable	Acute 100 Chronic 100

Identification	Specific concentration limit
Alcohols, C12-C14, ethoxylated, sulphate, sodium salt CAS: 68891-38-3 EC: 500-234-8	% (w/w) >=10: Eye Dam. 1 - H318 5<= % (w/w) <10: Eye Irrit. 2 - H319
reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) CAS: 55965-84-9 EC: Non-applicable	% (w/w) >=0.6: Skin Corr. 1C - H314 0.06<= % (w/w) <0.6: Skin Irrit. 2 - H315 % (w/w) >=0.6: Eye Dam. 1 - H318 0.06<= % (w/w) <0.6: Eye Irrit. 2 - H319 % (w/w) >=0.0015: Skin Sens. 1A - H317

## 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 is not classified as hazardous through inhalation. However, in case of intoxication symptoms it is recommended to remove the person affected from the area of exposure, provide clean air and keep at rest. Request medical attention if symptoms persist.

**By skin contact:**

This product is not classified as hazardous when in contact with the skin. However, in case of skin contact it is recommended to remove contaminated clothes and shoes, rinse the skin or if necessary shower the affected person thoroughly with cold water and neutral soap. In case of serious reaction consult a doctor.

**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.

**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:****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:**

**SECTION 5: FIREFIGHTING MEASURES (continued)**

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.

**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.

**6.2 Environmental precautions:**

Avoid spillage into the aquatic environment as it contains substances potentially dangerous for this. Contain the product absorbed in hermetically sealed containers. In the case of serious spillage into the aquatic environment notify the relevant authority.

**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).

**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**

Minimum Temp.: 5 °C

Maximum Temp.: 25 °C

Maximum time: 36 Months



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

**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 (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
Alcohols, C12-C14, ethoxylated, sulphate, sodium salt CAS: 68891-38-3 EC: 500-234-8	Oral	Non-applicable	Non-applicable	Non-applicable	Non-applicable
	Dermal	Non-applicable	Non-applicable	2750 mg/kg	Non-applicable
	Inhalation	Non-applicable	Non-applicable	175 mg/m <sup>3</sup>	Non-applicable

**DNEL (General population):**

Identification		Short exposure		Long exposure	
		Systemic	Local	Systemic	Local
Alcohols, C12-C14, ethoxylated, sulphate, sodium salt CAS: 68891-38-3 EC: 500-234-8	Oral	Non-applicable	Non-applicable	15 mg/kg	Non-applicable
	Dermal	Non-applicable	Non-applicable	1650 mg/kg	Non-applicable
	Inhalation	Non-applicable	Non-applicable	52 mg/m <sup>3</sup>	Non-applicable

**PNEC:**

Identification		Short exposure		Long exposure	
		Systemic	Local	Systemic	Local
Alcohols, C12-C14, ethoxylated, sulphate, sodium salt CAS: 68891-38-3 EC: 500-234-8	STP	10000 mg/L	Fresh water	0,24 mg/L	
	Soil	7,5 mg/kg	Marine water	0,024 mg/L	
	Intermittent	0,071 mg/L	Sediment (Fresh water)	0,917 mg/kg	
	Oral	Non-applicable	Sediment (Marine water)	0,092 mg/kg	

**8.2 Exposure controls:**

**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**

Non-applicable

**D.- Eye and face protection**

Non-applicable

**E.- Body protection**

Non-applicable

**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



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

**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:**

For complete information see the product datasheet.

**Appearance:**

Physical state at 20 °C:	Liquid
Appearance:	Dense
Colour:	<input type="checkbox"/> White
Odour:	Citric
Odour threshold:	Non-applicable *

**Volatility:**

Boiling point at atmospheric pressure:	100 °C
Vapour pressure at 20 °C:	2349 Pa
Vapour pressure at 50 °C:	12378,63 Pa (12,38 kPa)
Evaporation rate at 20 °C:	Non-applicable *

**Product description:**

Density at 20 °C:	ca. 1300 kg/m <sup>3</sup>
Relative density at 20 °C:	1,3
Dynamic viscosity at 20 °C:	Non-applicable *
Kinematic viscosity at 20 °C:	Non-applicable *
Kinematic viscosity at 40 °C:	Non-applicable *
Concentration:	Non-applicable *
pH:	ca. 10
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:	225 °C
Lower flammability limit:	Non-applicable *
Upper flammability limit:	Non-applicable *

**Particle characteristics:**

Median equivalent diameter:	Non-applicable
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**9.2 Other information:**

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



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

**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 *

\*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.

**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	Avoid direct impact	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 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. However, it does 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. However, it contains substances classified as hazardous for inhalation. For more information see section 3.
- Corrosivity/Irritability: Prolonged inhalation of the product is corrosive to mucous membranes and the upper respiratory tract

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



**Mediclean 520 Sanit Cream**

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Version: 3 (Replaced 2)

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

- Contact with the skin: Based on available data, the classification criteria are not met. However, it contains 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: Non-applicable
  - 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. However, it contains substances classified as dangerous with sensitising effects. 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:**

Non-applicable

**Specific toxicology information on the substances:**

Identification	Acute toxicity		Genus
	LD50 oral	LD50 dermal	
Alcohols, C12-C14, ethoxylated, sulphate, sodium salt CAS: 68891-38-3 EC: 500-234-8	LD50 oral	4100 mg/kg	Rat
	LD50 dermal	2001 mg/kg	Rabbit
	LC50 inhalation	Non-applicable	
reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) CAS: 55965-84-9 EC: Non-applicable	LD50 oral	64 mg/kg	Rat
	LD50 dermal	87,12 mg/kg	Rabbit
	LC50 inhalation	0,33 mg/L (4 h)	Rat

**11.2 Information on other hazards:**

**Endocrine disrupting properties**

Endocrine-disrupting properties: The product fails to meet the criteria.

**Other information**

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:**

**Acute toxicity:**



## SECTION 12: ECOLOGICAL INFORMATION (continued)

Identification	Concentration		Species	Genus
Alcohols, C12-C14, ethoxylated, sulphate, sodium salt CAS: 68891-38-3 EC: 500-234-8	LC50	7,1 mg/L (96 h)	Danio rerio	Fish
	EC50	7,4 mg/L (48 h)	Daphnia magna	Crustacean
	EC50	27 mg/L (72 h)	Scenedesmus subspicatus	Algae
reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) CAS: 55965-84-9 EC: Non-applicable	LC50	>0.1 - 1 mg/L (96 h)		Fish
	EC50	>0.1 - 1 mg/L (48 h)		Crustacean
	EC50	>0.1 - 1 mg/L (72 h)		Algae

**Chronic toxicity:**

Identification	Concentration		Species	Genus
Alcohols, C12-C14, ethoxylated, sulphate, sodium salt CAS: 68891-38-3 EC: 500-234-8	NOEC	0,2 mg/L	Oncorhynchus mykiss	Fish
	NOEC	0,27 mg/L	Daphnia magna	Crustacean

**12.2 Persistence and degradability:****Substance-specific information:**

Identification	Degradability		Biodegradability	
	Alcohols, C12-C14, ethoxylated, sulphate, sodium salt CAS: 68891-38-3 EC: 500-234-8	BOD5	Non-applicable	Concentration
	COD	Non-applicable	Period	28 days
	BOD5/COD	Non-applicable	% Biodegradable	100 %

**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 Endocrine disrupting properties:**

Endocrine-disrupting properties: The product fails to meet the criteria.

**12.7 Other adverse effects:**

Not described

## SECTION 13: DISPOSAL CONSIDERATIONS

**13.1 Waste treatment methods:**

Code	Description	Waste class (Regulation (EU) No 1357/2014)
20 01 99	other fractions not otherwise specified	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. 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 2021 and RID 2021:





**SECTION 14: TRANSPORT INFORMATION (continued)**

- 14.1 UN number or ID number:** Non-applicable
- 14.2 UN proper shipping name:** Non-applicable
- 14.3 Transport hazard class(es):** Non-applicable  
Labels: Non-applicable
- 14.4 Packing group:** Non-applicable
- 14.5 Environmental hazards:** No
- 14.6 Special precautions for user**  
Special regulations: Non-applicable  
Tunnel restriction code: Non-applicable  
Physico-Chemical properties: see section 9  
Limited quantities: Non-applicable
- 14.7 Maritime transport in bulk according to IMO instruments:** Non-applicable

**Transport of dangerous goods by sea:**

With regard to IMDG 40-20:

- 14.1 UN number or ID number:** Non-applicable
- 14.2 UN proper shipping name:** Non-applicable
- 14.3 Transport hazard class(es):** Non-applicable  
Labels: Non-applicable
- 14.4 Packing group:** Non-applicable
- 14.5 Marine pollutant:** No
- 14.6 Special precautions for user**  
Special regulations: Non-applicable  
EmS Codes:  
Physico-Chemical properties: see section 9  
Limited quantities: Non-applicable  
Segregation group: Non-applicable
- 14.7 Maritime transport in bulk according to IMO instruments:** Non-applicable

**Transport of dangerous goods by air:**

With regard to IATA/ICAO 2023:

- 14.1 UN number or ID number:** Non-applicable
- 14.2 UN proper shipping name:** Non-applicable
- 14.3 Transport hazard class(es):** Non-applicable  
Labels: Non-applicable
- 14.4 Packing group:** Non-applicable
- 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:** Non-applicable

**SECTION 15: REGULATORY INFORMATION**

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

Regulation (EC) No 528/2012: contains a preservative to protect the initial properties of the treated article. Contains reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1).

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: reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (Product-type 2, 4, 6, 11, 12, 13)

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

**Regulation (EC) No 648/2004 on detergents:**

**SECTION 15: REGULATORY INFORMATION (continued)**

In accordance with this regulation the product complies with the following:

The tensoactives contained in this mixture comply with the biodegradability criteria stipulated in Regulation (EC) n°648/2004 on detergents. The information to prove this is available to the relevant authorities of the Member States and will be shown to them by direct request or the request of a detergent manufacturer.

**Labelling for contents:**

Component	Concentration interval
Anionic surfactants	% (w/w) < 5
perfumes	

Preservation agents: reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (METHYLCHLOROISOTHIAZOLINONE / METHYLISOTHIAZOLINONE).

**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

- 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.:**

CLP Regulation (EC) No 1272/2008 (SECTION 2, SECTION 16):

- Precautionary statements

**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. 2: H310+H330 - Fatal in contact with skin or if inhaled.
- Acute Tox. 3: H301 - Toxic if swallowed.
- Aquatic Acute 1: H400 - Very toxic to aquatic life.
- Aquatic Chronic 1: H410 - Very toxic to aquatic life with long lasting effects.
- Eye Dam. 1: H318 - Causes serious eye damage.
- Skin Corr. 1C: H314 - Causes severe skin burns and eye damage.
- Skin Irrit. 2: H315 - Causes skin irritation.
- Skin Sens. 1A: H317 - May cause an allergic skin reaction.

**Classification procedure:**

Non-applicable

**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.

**Principal bibliographical sources:**



MEDISEPT

Product safety information sheet  
according to REACH (article 32)

### Mediclean 520 Sanit Cream

Date of compilation: 04/02/2019

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Version: 3 (Replaced 2)

#### 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: 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 prepared in accordance with Article 32 of Regulation (EC) 1907/2006 (REACH); 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 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.

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