

Reference: Regulation (EC) 1907/2006 878/0020	MATERIAL SAFETY DATA SHEET (MSDS) Product: NDP Surfaclin	Version 11 Date last revision: 22.11.22 SHEET 1 of 9
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1. SECTION 1. IDENTIFICATION OF SUBSTANCE / MIXTURE AND OF THE COMPANY:

1.1 Product identifier: NDP Surfaclin

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

Use of the substance/preparation: Disinfectant for surfaces of non-invasive medical devices.

Product classification / Register Number: Medical Device Type IIa. CE mark, given by ON 0476, number: MED 31348

1.3. Details of the supplier of the safety data sheet

Manufacturer: Vesimin S.L.U. C/Aribau 230-240, 6^a planta, L-O – 08006 Barcelona
vesimin@vesimin.com

Telephone number: +34 934 095 301

Fax: +34 933 396 628

e-mail: vesimin@vesimin.com

1.4. Emergency number: +34 934 095 301 (working hours)

2. SECTION 2. HAZARDS IDENTIFICATION:

2.1. Classification of the substance or mixture

Regulation (CE) 1272/2008_CLP

ORAL ACUTE TOXICITY, category 4 (H302)

SKIN CORROSION, category 1A (H314)

EYE IRRITATION, category 1 (H318)

SKIN SENSITIZING, category 1 (subcategory 1A) (H317)

HAZARDOUS TO THE AQUATIC ENVIRONMENT – CHRONIC HAZARD. Category 2 (H411)

2.2. Label elements: according to CE Directives

Regulation (CE) 1272/2008_CLP

Hazard pictograms:



Signal Word: Danger

Hazard statements:

- Harmful if swallowed (H302)
- Causes severe skin burns and eye damage (H314)
- Causes serious eye damage (H318)
- May cause an allergic skin reaction (H317)
- Toxic to aquatic life with long lasting effects (H411)

Precautionary statements:

- Wash the skin thoroughly after handling (P264)
 - Do not eat, drink or smoke when using this product (P270)
 - Wear protective gloves/protective clothing/eye protection/face protection (P280)
 - Avoid release to the environment (P273)
 - IF SWALLOWED: rinse mouth. Do NOT induce vomiting (P301+P330+P331)
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- IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower (P303+P361+P353)
- If skin irritation or rash occurs: Get medical advice/attention (P333 + P313)
- Wash contaminated clothing before reuse (P363)
- IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing (P305+P351+P338)
- Collect spillage (P391)
- Immediately call a POISON CENTER/doctor/... (P310)
- Dispose of contents and/or container in accordance with dangerous residues regulations (P501)

2.3. Other hazards

No significant environmental or health risks if used under standard conditions of commercial and industrial use.

The concentrated product is harmful if swallowed, causes severe skin burns and eye damage and may cause an allergic skin reaction. It is not dangerous at use dilutions.

Effects of the product misuse: eye and skin splashes (irritation), intoxication (oral intake). We recommend the use of gloves and goggles for concentration product handling and dilutions preparation.

PBT: This product is not identified as PBT/vPvB

This mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal or greater than 0,1%.

3. SECTION 3. COMPONENT COMPOSITION / INFORMATION

3.2. Substance/Mixture: Mixture

Dangerous components:

Ingredient	N° CAS / N° Reg REACH	Classification 1272/2008	Concentration
Didecyl dimethyl ammonium chloride 70%	7173-51-5	Flamm. liq Cat.3: H226, Oral acute tox.Cat. 4:H302 Skin corr. Cat. 1B: H314 Chronic aquatic Cat 1.:H410	23.0%
2-Phenoxyethanol	122-99-6 / 01- 2119488943- 21-0000, 01- 2119488943- 21-0006	Oral acute tox. . Cat. 4:H302 Eye irrit. Cat. 2:H319	5.00%
Cinnamaldehyde	104-55-2 / 01- 2119935242- 45-0001	Skin acute tox. Cat.4:H312 Skin irrit. Cat 2. H315 Skin sens.Cat.1: H317	1.00%
Excipients and water	-	-	csp 100 %

* Complete text of H-phrases indicated in this Section are explained in Section 16.

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4. SECTION 4. FIRST AID MEASURES:

4.1. Description of first aid measures

First aid measures:

Swallowing: (*) Rinse mouth with water and require immediately medical assistance. Do not administer anything to an unconscious person.

Inhalation: Not applicable, it doesn't release vapours.

Skin contact: Take off contaminated clothes. In case of skin contact, wash with plenty of water & soap, and seek for medical advice.

Eye contact: Wash with plenty of water for at least 15 minutes. If irritation persists, consult an ophthalmologist.

(*) Information for the doctor: do not induce vomiting. Make a stomach-pumping previous addition of dimeticone (antifoam).

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

Effects and symptoms: No specific effects and/or symptoms are known

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

Therapeutic advice: In case of ingestion, consider making an endoscopy. Symptomatic treatment. See section 4.1.

5. SECTION 5. FIRE-FIGHTING MEASURES

5.1. Extinguishing media

Suitable extinguishing media: Foam, dry chemical powder, CO₂, sand and water spray fog.

Extinguishing media that do not have to be used for safety reasons: Not applicable.

5.2. Special hazards arising from the substance or mixture

Special exposure hazards arising from the substance or preparation itself, combustion products, and produced gases: Non flammable product. In case of fire of great magnitude, amine vapours could be generated.

5.3. Advice for firefighters

Special protective equipment for fire-fighters: Fire-fighters must be provided with adequate protective equipment.

6. SECTION 6. ACCIDENTAL RELEASE MEASURES:

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions: Take common precautions

6.2. Environmental precautions

Environmental precautions: Avoid pouring the product into the public drainage. If the product reaches a river course or a sewer, or it has contaminated the soil or vegetation, warn the Authorities. Collect it in plastic containers and eliminate it in appropriate places.

6.3. Methods and material for containment and cleaning up

Cleaning measures: Do not release product into drainpipes or in the environment. Eliminate the spilled product with materials that act as absorbents (sawdust, peat, or chemical chelating

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agents). Place the collected product in containers that can be closed. Clean the floor and all objects with this material using a damp cloth. Collect the cleaning materials and put them inside receptacles that can be closed.

6.4. Reference to other sections

Refer to sections 8, 12 and 13 of SDS.

7. SECTION 7. HANDLING AND STORAGE

7.1. Precautions for safe handling

Handling: Take measures to avoid splashing in the eyes and on skin.

7.2. Conditions for safe storage, including any incompatibilities

Storage: Store in high density polyethylene containers. Store at room temperature and avoid extreme temperatures and direct contact with sunlight. Store at an optimal temperature between 10° and 30°C. Store only in original containers.

7.3. Specific end use(s)

Surface disinfectant. For professional use only.

8. SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Non applicable. The mixture does not contain limit values for professional exposure.

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

Name of the substance	Final use	Route of exposure	Potential Health Effects	Value
2-phenoxyethanol	workers	Cutaneous	Long term – systemic effects	34.72mg/kg
	workers	Inhalation	Long term – local systemic effects	8.07mg/m ³
	Consumers	Cutaneous	Long term – systemic effects	20.83mg/kg
	Consumers	Inhalation	Long and short term – local effects	2.5mg/m ³
	Consumers	Oral	Long and short term – systemic effects	17.43mg/kg

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006

Name of the substance	Environmental compartment	Worth
2-phenoxyethanol	Sweet water	0.943mg/l
	Seawater	0.0943mg/l
	Sporadic release	3.44mg/l
	Sediment (fresh water)	7.2366mg/kg
	Sediment (sea water)	0.7237mg/kg
	Soil	1.26mg/kg
	Treatment plant	24.8mg/l

8.2. Exposure controls

Hygienic measures: Do not eat, drink or smoke during use.

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Exposure control: Avoid spilling, contact with eyes and ingestion.

Equipment to provide adequate personal protection: Hands protection (safety gloves) and eye protection (safety goggles).

9. SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Aspect (physical state, color): Liquid, transparent without colour

Odour: Perceptible

Melting point / freezing point: Not available

Boiling point : 97 – 102°C

Flammability: Non-flammable

Upper and lower explosive limit: Not available

Auto-ignition temperature: Not available

Decomposition temperature: Not available

pH (100% in water): 4 – 6 (20 °C)

Viscosity: Not available

Water solubility: 100% soluble

Partition coefficient n-octanol/water (Log K_{ow}): Not available

Vapour pressure: Not available

Density: 0,900 – 1,100 g/cc (20°C)

Relative density: Not available

Relative vapour density at 20°C: Not available

Particle characteristics: Not applicable

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

Not applicable

10. SECTION 10. STABILITY AND REACTIVITY

10.1. Reactivity

It does not present dangerous reactions. It does not react with acids, bases, oxidizing agents, organic peroxides or heavy metals. Unstable in presence of strong oxidizers or alkalins. It is not corrosive on different materials.

10.2. Chemical stability

Product is stable in recommended conditions of handling and storage.

10.3 Possibility of hazardous reactions

It does not present.

10.4. Conditions to avoid

Non applicable

10.5. Incompatible materials

Do not use or mix with products containing or that release chlorine (hypochlorites) and products that contain anionic surfactants.

10.6. Hazardous decomposition products

Non applicable.

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11. SECTION 11. TOXICOLOGICAL INFORMATION

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

Acute toxicity:

Oral route: Harmful by oral ingestion. (ref. DL₅₀ (oral route in rodents): 300 - 2000 mg/kg)

Inhalation route: Not applicable.

Through skin and/or eyes:

*Skin irritation: The concentrated product is skin corrosive. At use concentrations (2%) it is not irritating.

*Eye irritation: The concentrated product can cause severe eye damage. At use concentrations (2%) it does not irritate the eyes.

*Skin sensitisation: It does not cause hypersensitisation.

Substance data

Didecyl dimethyl ammonium chloride	
LD50 (rat), oral	238mg/kg
LD50 (rat), dermal	3,342mg/kg
ATE CLP (oral)	500mg/kg of body weight
Skin irritation (rabbit, 3 min)	Irritating
Sensitization (guinea pig)	Not sensitizing
in vitro genotoxicity	<i>Salmonella typhimurium</i> : Negative Chromosome aberration test: Negative Genetic mutation: Negative
In vivo genotoxicity	Chromosome aberration test: Negative

Cinnamaldehyde	
LD50 (rat), oral	2,220mg/kg
LC50 (rat), inhalation 4h	68.88mg/l
LD50 (rat), dermal	> 2000mg/kg
LD50 (rabbit), dermal	1260mg/kg
Skin corrosion and irritation	Causes skin irritation
Serious eye damage/irritation	Causes serious eye irritation
respiratory sensitization	Not classified
skin sensitization	May produce an allergic reaction on the skin
Germ cell mutagenicity	Not classified
In vitro genotoxicity	<i>Salmonella typhimurium</i> : Negative Micronucleus Assay: Negative
In vivo genotoxicity	no mutagenic effect
carcinogenicity	Not classified
NOAEL (rat, oral)	200 mg/kg bw/day
reproductive toxicity	Not classified
Effects on fertility / fetal development	LOAEL: 5 mg/kg body weight / LOAEL: 1200 body weight in mg/kg

2-phenoxyethanol	
LD50 (rat), oral	300 – 2000mg/kg
LD50 (rabbit), dermal	> 5000mg/kg
LD50 (rat), oral	2740mg/kg
ATE CLP (oral)	500mg/kg of body weight
Irritation	It is not irritating to the skin. Contact with eyes causes irritation
Respiratory / skin sensitization	Not sensitizing
Germ cell mutagenicity	not mutagenic
carcinogenicity	not carcinogenic

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Carcinogenicity: Not carcinogenic

Mutagenicity: Not mutagenic

Toxicity for reproduction: Not toxic for reproduction

11.2. Information on other hazards

11.2.1. Properties on endocrine alteration

No additional information available.

12. SECTION 12. ECOLOGICAL INFORMATION

12.1. Toxicity: Chronic aquatic toxicity:

The product is toxic to aquatic life with long lasting effects

In order to avoid human and environmental risks, follow the instructions for use.

Substance data

didecyl dimethyl ammonium chloride	
LC50, 96h (Pimephales promelas)	0.19mg/l
NOEC, 34d (Danio rerio)	0.032mg/l
EC50, 48h (Daphnia magna)	0.062mg/l
NOEC, 21d (Daphnia magna)	
ErC50, 96h (Pseudokirchneriella subcapitata)	0.026mg/l
Factor M (acute aquatic toxicity)	10
Factor M (chronic aquatic toxicity)	1
EC50, 3h (activated sludge)	11mg/l
biodegradability	easily biodegradable

Cinnamaldehyde	
LC50, 96h (Pimephales promelas)	105.76mg/l
EC50, 48h (Daphnia magna)	3.21mg/l
EC50, 48h (Daphnia magna)	119.56mg/l
NOEC, 72h (Pseudokirchneriella subcapitata)	37.23mg/l
EC50, 48h (Tetrahymena pyriformis)	131.19mg/l
biodegradability	easily biodegradable
Bioconcentration factor (BCF)	8.3
Mobility in soil: distribution between environmental compartments	Koc: 29,456 Log Koc: 1,469

2-fenoxiethanol	
CL50, 96h (Pimephales promelas)	> 100 mg/l
CE50, 48h (Daphnia magna)	> 100 mg/l
CE50, 72h (Scenedesmus subspicatus)	> 100 mg/l (biomass)
CE10, 17h (Pseudomonas putida)	> 100 mg/l
NOEC, 34d (Pimephales promelas)	> 1 mg/l
NOEC, 21d (Daphnia magna)	> 1 mg/l
Biodegradability	Easily biodegradable

12.2. Persistence and degradability

The product has a high bactericide and fungicide action, hence it could affect the EDAR microbial flora.

It is a surfactant and can cause foam in EDAR.

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12.3. Bioaccumulative potential

Not available.

2-Fenoxiethanol: Octanol-water partition coefficient (log Kow): 1,2

12.4. Movility in soil

Not available

12.5. Results of PBT and vPvB assessment

This product is not identified as a PBT/vPvB substance

12.6. Endocrine disrupting properties

No further information available. This substance does not have endocrine disrupting properties on non-target organisms, as it does not meet the criteria established in section B of Regulation (EU) No. 2017/2100.

12.7. Other adverse effects

Harmful to aquatic organisms

13. SECTION 13. DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Package product surplus or waste resulting from normal use. Label it for identification purposes and seal it. Dirty, empty recipients should be handled in the same manner. The product may be taken to a controlled incineration site, always according to local regulations (special residue). The product dilutions once used can be disposed to the sewer system. Product dilutions do not suppose any risk for the Environment according the 88/379/EEC Directive for Classification, Packaging and Labelling of Dangerous Preparations.

14. SECTION 14. TRANSPORT INFORMATION

14.1. UN number or ID number:

3082

14.2. UN proper shipping name

Environmentally hazardous substance, n.o.s. (contains Bis-3 (aminopropyl) dodecylamine)

14.3. Transport hazard class(es)

Class 9

14.4. Packaging group

Packing group III

14.5. Environmental hazards

Toxic to aquatic life with long lasting effects

14.6. Special precautions for user

Not applicable

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

For road transport (ADR) special provision 375 is used (these materials when transported in single or combined packaging containing a net quantity per inner or individual packaging of 5 liters or less for liquids or of 5 kg or less for solids , are not subject to any other provision of the ADR).

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For maritime transport (IMO), special provision 2.10.2.7 is also used for up to 5L containers.
For air transport (IATA), provision A197 is used for the same reason.

15. SECTION 15. REGULATORY INFORMATION

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

The information for safety and health with respect to the label of this product is in accordance with the European Union regulation: n° 1907/2006, 453/2010, 830/2015 and 878/2020..

European legislation: Regulation EC 1272/2008.

15.2. Chemical safety assessment: not required

16. SECTION 16. OTHER INFORMATION

Other information: The text in the SDS which has changed since the last version.

Complete text of hazard statements as referred to in sections 2 and 3:

- H226: Flammable liquid and vapour.
- H302: Harmful if swallowed
- H312: Harmful in contact with skin.
- H314: Causes severe skin burns and eye damage
- H315: Causes skin irritation
- H317: May cause an allergic skin reaction.
- H319: Causes serious eye irritation
- H410: Very toxic to aquatic life with long lasting effects

Formation advice:

The product must be handled by specialized personnel, following manufacturer instructions. Changes from last version refer to format and content of EC Regulation 453/2010. Calculation method determination according to Regulation 1272/2008 has been used for the classification of the mixture.

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