Reference: Regulation (EC) 1907/2006 878/2020	**MATERIAL SAFETY DATA SHEET** (MSDS) Product: **NDP Med Foam**	Version 07 Date last revision: 22.11.22 SHEET 1 of 10

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

1.1. Product identifier: NDP Med Foam
1.2. Relevant identified uses of the substance or mixture and uses advised against
Use of the substance/preparation: Disinfectant for sufaces of 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: Vesismin S.L.U. C/Aribau 230-240, 6th floor, L-O - 08006 Barcelona
vesismin@vesismin.com
Telephone number: +34 934 095 301
Fax: +34 933 396 628
e-mail: vesisimin@vesismin.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
Not classified

2.2. Label elements: according to EC Regulation num. 1272/2008 [CLP]
Hazard pictograms: not applicable
Signal Word: no applicable
Hazard statements: not applicable
Precautionary statements: not appliable

2.3. Other hazards
No significant environmental or health risks if used under standard conditions of commercial and industrial use.
The product is diluted and is not been classified as dangerous.

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. COMPOSITION / INFORMATION ON INGREDIENTS

3.2.Substance/Mixture: Mixture

Dangerous components:

Ingredients	CAS num. / REACH no.	Classification 1272/2008	Conc%
N-Duopropenide	308074-50-2	Oral acute tox. Cat. 4:H302, Eye irrit. Cat. 2:H319, Skin irrit. Cat. 2:H315, Chronic aquatic. Cat 2:H411	0.46%
Bis-3(aminopropyl) dodecilamine	2372-82-9 / 01-2119980592-29-XXXX	Oral acute tox. Cat. 3:H301, Skin corrosion. Cat. 1A:H314, STOT SE. Cat.2:H373, Chronic aquatic. Cat. 1:H410	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	0.1%
Excipients and water	-	-	Csp. 100

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

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

See section 4.1.

5. SECTION 5. FIRE-FIGHTING MEASURES

5.1. Extinguishing media

Suitable extinguishing media: Foam, dry chemical powder, CO_2, 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 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 containers that can be closed.

Additional information: the product is surfactant, it can produce a great quantity of foam.

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

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 10º and 30ºC. Store only in original containers.

7.3. Specific end use(s)

Endoscopes and surgical equipment 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
N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine	workers	Cutaneous	Long term – systemic effects	0.91mg/kg
	workers	Inhalation	Long term – systemic effects	2.35mg/m3
	Consumers	Cutaneous		0.54mg/kg
	Consumers	Inhalation	Long term – systemic effects	0.7mg/m3
	Consumers	Oral		0.2mg/kg

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/m3
	Consumers	Cutaneous	Long term – systemic effects	20.83mg/kg
	Consumers	Inhalation	Long and short term – local effects	2.5mg/m3
	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	Value
N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine	Sweet water	0.001mg/l
	Soil	45.34mg/kg
	Marine sediment	0.85mg/kg
	Freshwater sediment	8.5mg/kg
	Residual water treatment plant	1.33mg/l
	Discontinued release/use	0mg/l
	Seawater	0mg/l

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.
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, in amber colour – transparent yellow
Odour: Perceptible
Melting point / freezing point: Not available
Boiling point : Approximately 95 ºC
Flammability: Non-flammable
Upper and lower explosive limit: Not available
Auto-ignition temperature: Not available
Decomposition temperature: Not available
pH (100% in water): 6,5 – 8,5 (20 ºC)
Viscosity: 70-120 cP (20 ºC)
Water solubility: 100% soluble
Partition coefficient n-octanol/water (Log Know): Not available
Vapour pressure: Not available
Density: 0,90 – 1,10 g/cc (20ºC)
Relative density: Not available
Relative vapour density at 20ºC: Not available
Particle characteristics: Not applicable

(**) pH can be slightly reduced within the course of time, without reduction of germicide effect.

9.2. Other information
9.2.1. Information with regard to physical hazard classes
No additional information available
9.2.2. Other safety characteristics
Data for Active Substance (N-Duopropenide 45.52%)
Vapour pressure: P_v (20ºC) = 24.8 Pa
Octanol-water partition coefficient: log P_{ow} = 1.66

10. SECTION 10. STABILITY AND REACTIVITY

10.1. Reactivity
It does not present dangerous reactions. It does not react with heavy metals, except with mercury. Unstable in presence of strong oxidizers. It is not corrosive on different materials.
10.2. Chemical stability
The product is stable at recommended conditions of handling and storage.
10.3 Possibility of hazardous reactions
It does not present.
10.4. Conditions to avoid
Avoid temperatures above 30ºC and below 0ºC
10.5. Incompatible materials
Do not use or mix with products containing or that release chlorine (hypochlorites) and/or mercurial products, and products that contain anionic surfactants.
10.6. Hazardous decomposition products
Non applicable.

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. DL_{50} (oral route in rodents): > 2000 mg/kg
Inhalation route: Not applicable.
Through skin and/or eyes: DL50 (dermal): > 2000 mg/kg
*Skin irritation: Not classified
*Eye irritation: Not classified
*Skin sensitisation: It does not cause hypersensitisation.

Substance data

N-Duopropenide	
LD50 (rat), oral	264mg/kg
ATE CLP (oral)	500mg/kg of body weight
irritant effects	Does not irritate the skin or mucous membranes
allergenicity	not allergen
Mutagenicity	not mutagenic
genotoxicity	not genotoxic

N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine	
LD50 (rat, female), acute oral	243.6mg/kg
LD50 (rat, male), acute oral	280mg/kg
LD50 (rat), acute dermal	> 600mg/kg
ATE CLP (oral)	500mg/kg of body weight
Skin corrosion/irritation (rabbit)	Causes burns
Respiratory or skin sensitization	Not sensitizing
In vitro genotoxicity	Negative
carcinogenicity	not carcinogenic

Repeated dose toxicity	NOAEL: 9mg/kg (oral, rat) NOAEL: 20mg/kg (oral, dog) NOAEL: 15mg/kg (dermal, rat) NOAEL: 4mg/kg, LOAEL: 8mg/kg (oral, rat)

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

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

Substance data

N-Duopropenida	
CL50, 96h (-brachydanio rerio)	6,48 mg/l
CL50, 96h (Salmo gairdneri)	11,16 mg/l
CE50, 24h (Daphnia magna)	1,382 mg/l
CE50, 48h (Daphnia magna)	1,24 mg/l

N-(3-aminopropil)-N-dodecilpropano-1,3-diamina	
CL50, 96h (Oncorhynchus mykiss – Trucha irisada)	0,68 mg/l
CL50, 96h (Lepomis macrochirus (Pez-luna Blugill)	0,45 mg/l
CE50, 48h (Daphnia magna – Pulga de mar grande)	0,073 mg/l
NOEC, 21d (Daphnia magna)	0,024 mg/l
CE50r, 96h (Pseudokirchneriella subcapitata - alga verde)	0,054 mg/l
ErC10, 72h (Desmodesmus subspicatus – alga verde)	0,012 mg/l
NOEC, 72h (Desmodesmus suspicatus – alga verde)	0,0069 mg/l

CE50, 3h (lodos activados)	18 mg/l
CL50, 14d (Eisenia fétida – lombrices)	> 1000 mg/kg
NOEC, 28d (microflora del suelo)	1000 mg/kg
NOEC, 21d (plantas)	1000 mg/kg
Biodegradability	Easily biodegradable

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, virucide, fungicide and sporicide action, hence it could affect the EDAR microbial flora.
It is a surfactant and can cause foam in EDAR.

12.3. Bioaccumulative potential
Not available.
N-Duopropenide: Octanol-water partition coeficient (log Kow): 1,66
2-Fenoxiethanol: Octanol-water partition coeficient (log Kow): 1,2

12.4. Movility in soil
Mobility data for the Active Technical Ingredient (N-Duopropenide / Quaternary ammonium iodides in 45.52 %)

- Adsorption/desorption test: Adsorption coeficient, K': 0.198 / 0.564 / 0.692. Adorption coeficient, as organic carbon function K'_{oc}: 7.935 / 22.656 / 27.774. It is demonstrated the high affinity to soils, it is clear that in case of soil contamination, the ground-water contamination risk is very low.
- Octanol-water partition coeficient: log P_{ow} = 1.66

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

The product solutions once used can be disposed to the sewer system. Product solutions do not suppose any risk for the Environment according the EC Regulation 1272/2008 on classification, labelling and packaging of substances and mixtures.

14. SECTION 14. TRANSPORT INFORMATION

14.1. UN number or ID number:
Not applicable
Road/Train transport (ADR/RID): not applicable
Sea transport (IMDG): not applicable
Air transport (IATA): not applicable
The substance is not dangerous for transport (European Agreement on International Transport of Dangerous Goods)

14.2. UN proper shipping name
Not applicable.
14.3. Transport hazard class(es)
Not applicable
14.4. Packaging group
Not applicable
14.5. Environmental hazards
Not applicable
14.6. Special precautions for user
Not applicable
14.7. Maritime transport in bulk according to IMO instruments
Not applicable

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: nº 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:

H301: Toxic if swallowed
H302: Harmful if swallowed
H314: Causes severe skin burns and eye damage
H315: Causes skin irritation
H319: Causes serious eye irritation
H373: May cause damage to organs through prolonged or repeated exposure
H410: Very toxic to aquatic life with long lasting effects
H411: 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.