

Reference: Regulation (EC) 1907/2006 878/2020	MATERIAL SAFETY DATA SHEET (MSDS) Product: NDP Air Total + GLP CE	Version 05 Date last revision: 28.11.22 SHEET 1 of 11
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1. SECTION 1. IDENTIFICATION OF SUBSTANCE / MIXTURE AND OF THE COMPANY:

1.1 Product identifier: NDP Air Total + GLP CE

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

Use of the substance/preparation: Disinfection 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, 6th floor, L-O - 08006 Barcelona - info.vesimin@schuelke.com

Telephone number: +34 934 095 301

Fax: +34 933.396.628

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

2. SECTION 2. HAZARD IDENTIFICATION:

2.1. Classification of the substance or mixture

Classification according to CE Regulation num. 1272/2008 [CLP]

FLAMMABLE AEROSOL. Category 1 (H222)

FLAMMABLE AEROSOL. Category 1 (H229)

EYE IRRITATION. Category 2 (H319)

SPECIFIC TARGET ORGAN TOXICITY (SINGLE EXPOSURE). Category 3. (H336)

HAZARDOUS TO THE AQUATIC ENVIRONMENT – CHRONIC HAZARD.

Category 3 (H412)

2.2. Label elements: according to CE Regulation num. 1272/2008 [CLP]

Hazard pictograms:



Signal word : DANGER

Hazard statements:

- Extremely flammable aerosol (H222)
- Pressurised container: May burst if heated (H229)
- Causes serious eye irritation (H319)
- May cause drowsiness or dizziness (H336)
- Harmful to aquatic life with long lasting effects (H412)

Precautionary Statements

- Avoid breathing vapours (P261)
- Wear protective gloves/protective clothing/eye protection/face protection. Wash with the hands thoroughly after handling (P280 + P264)
- Do not spray on an open flame or other ignition source (P211)
- Do not pierce or burn, even after use (P251)

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- Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. (P210)
- IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing (P305 + P351 + P338)
- If eye irritation persists: Get medical advice/attention (P337 + P313)
- Store in a well-ventilated place. Keep container tightly closed (P403 + P233)
- Protect from sunlight. Do not expose to temperatures exceeding 50 °C/122 °F (P410 + P412)
- Avoid release to the environment (P273)
- Dispose of contents and/or container in accordance with dangerous residues regulations (P501)

2.3. Other hazards

Physical/chemical hazards: Pressurized bottle

Human health hazards: No significant health risks if used under standard conditions of commercial and industrial use. The product is irritating if it comes in contact with eyes, in this case it is recommended to wash immediately, with plenty of water.

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:

Ingredients	N° CAS / N° Reg REACH	Classification 1272/CE*	Conc%
Didecyl dimethyl ammonium chloride 70%	7173-51-5	Flam. liq. 3: H226 Acute tox. 4: H302; Skin corr. 1B: H314; Chronic aquatic 1: H410	0.46
2-Phenoxyethanol	122-99-6 / 01-2119488943-21-0000, 01-2119488943-21-0006	Acute tox. 4: H302; Eye irrit. 2: H319	0.10
Cinnamaldehyde	104-55-2 / 01-2119935242-45-0001	Skin corr 2: H315; Skin Sens. 1: H317; Aquatic tox 4: H312	0.02
Isopropyl alcohol	67-63-0	Flam. liq 2: H225; Eye irrit. 2: H319; STOT SE 3: H336	15 – 20
Excipients and propellant	-	-	Csp. 100

* Complete text of hazard statements 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: Transfer the patient to a non-contaminated atmosphere. Remove stained or splashed clothes. Rinse the eyes with abundant water for 15 minutes. Remove contact lens. Rinse the skin with abundant water and soap, do not rub. Do not induce vomiting. Control the breathing, artificial breathing if necessary. Transfer the patient to a hospital, and bring the label or container if possible.

Do not let alone the patient in any case.

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

Effects and symptoms: Non specific effects and/or symptoms are known

The intoxication can produce: eye, skin, respiratory tract and gastrointestinal irritation. Neuronal Central System alteration, headache, dizziness and hallucinations. Serious ventricular arrhythmia, palpitations and pulmonary oedema.

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 should not be used because of security reasons: Not applicable.

Special measures: Cool the bottles pulverizing water to them if they are exposed to fire. Do not use a jet of water. Keep away from sources of ignition – Do not smoke.

5.2. Special hazards arising from the substance or mixture

Special hazards of fire/explosion: At high temperatures the propellant is decomposed in toxic and corrosive products: hydrogen fluorides and carbon dioxides.

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

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.

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6.3. Methods and material for containment and cleaning up

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 floor and all objects with this material using a damp cloth. Collect the cleaning materials and put them inside containers 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: Do not smoke. Keep away from ignition sources.

IMPORTANT: Bottle under pressure. Avoid exposing it to sunlight and temperatures higher than 50°C. Do not perforate or burn, even after its use. Do not vaporize it near a flame or incandescent object. Handle it following hygienic and security rules.

7.2. Conditions for safe storage, including any incompatibilities

Storage: Store at room temperature. Avoid extreme temperatures (higher than 50°C) and direct contact with sunlight. Keep away from ignition sources. Do not keep in a place where high temperatures could be reached under the sun (i.e. vehicles).

7.3. Specific end use(s)

Surface disinfectant. For professional use only.

8. SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Threshold Limit Value (TLV) of Isopropyl alcohol:

- USA: the ACGIH recommends a TWA of 400 ppm (980 mg/m³) and a STEL of 500 ppm (1225 mg/m³).
- FRANCE INRS VLE 480ppm (980mg/m³)
- GERMANY MAK 200ppm (500mg/m³)

Exposition limit value for the propellant: 1000 ppm = 4420 mg/m³.

Considering the bottle content and the disinfecting volume, these limits are never exceeded.

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

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	Consumers	Oral	Long and short term – systemic effects	17.43mg/kg
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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.

Equipment to provide adequate personal protection: non specific protection equipment is required.

9. SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Aspect (physical state, color): Liquid (actives) + Gas (Propellant)

Odour: Characteristic (alcohol)

Melting point / freezing point: Not available

Boiling point : Not available

Flammability: 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 °C)

Viscosity: Not available

Water solubility: 100% soluble

Partition coefficient n-octanol/water (Log Know): Not available

Vapour pressure: Not available

Density (active product without propellant): 0,784 – 0,804 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

Data for Isopropyl Alcohol

Flash Point: 12 °C

Relative density of vapour: > 1.0

Octanol-water partition coefficient: log P_{ow} = 0.05

Data for the Propellant

Vapour pressure: P_v (20°C) = 5.0 bar

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Vapour density (air = 1): 4.32 (20°C)
Octanol-water partition coefficient: log P_{ow} = 1.06

10. SECTION 10. STABILITY AND REACTIVITY

10.1. Reactivity

It does not present dangerous reactions. The solutions don't react with acids, bases, oxidising agents, organic peroxides, molecules with sulfhydryc groups or heavy metals. It is non-stable in presence of strong oxidising agents or strong bases.

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

Keep the product far from Ignition and Heat Sources. The propellant can produce dangerous gases in case of decomposition, in contact with a flame or heat metal surfaces.

10.5. Incompatible materials

Non applicable

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: DL₅₀ (oral route) > 2000 mg/kg. It is not harmful by ingestion.

Inhalation route: The concentration during the use of the product has been studied, and has been correlated with its constituents' toxicity, resulting to be not toxic by inhalation way.

Through skin and/or eyes: LD₅₀ (dermal way) > 2000 mg/kg

*Skin irritation: It is not irritating. Pure isopropanol is irritating, but the product concentration is not irritating according to CLP Regulation.

*Eye irritation: It is irritating to the eyes. Pure isopropyl alcohol is irritating, and at the product concentration it is irritating according to CLP Regulation: the product is irritating for 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

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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

Isopropanol	
LD50 (rat), oral	5000 mg/kg
LD50 (rabbit), dermal	12.800 mg/kg
LC50 (rat), inhalation	500 mg/lg
Eye irritation	Irritating
Dermal irritation	Slightly irritating
Mutagenicity	Mutagenicity in germinal cells Genotoxicity in vitro: Negative
Carcinogenicity	Non carcinogenic
Toxicity for reproduction	Not known

The propellant is nearly not harmful by inhalation: LC₅₀/inhalation/4h/rodent > 500.000 ppm. As other volatile aliphatic halogenated compounds, the product can produce, by vapour accumulation and/or inhalation in great quantities, consciousness loss and heart disorders aggravated by stress and oxygen lack (mortal risk).

Pure isopropyl alcohol is irritating by inhalation and to the eyes. It is slightly toxic in contact with the skin.

Corrosiveness: Non corrosive.

Carcinogenicity: Non carcinogenic

Mutagenicity: Non mutagenic

Toxicity for reproduction: Non toxic for reproduction

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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 harmful 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

Isopropanol	
EC50/LC50, 48h (Daphnia magna)	> 100 mg/l
EC50, 72h (Scenedesmus subspicatus)	> 100 mg/l

12.2. Persistence and degradability

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

It contains surfactant and therefore 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

Isopropyl alcohol: Octanol-water partition coefficient (log Kow): ≤ 4

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

Summary ecological information:

Isopropyl alcohol

- *Mobility:*
 - The product is soluble in water and it will probably remain in water.
- *Persistence and degradability:*
 - Easily biodegradable, according to OECD standards.
 - Easily eliminated in a sewage treatment.
- *Bioaccumulation:*
 - A low acute toxicity is predicted for aquatic organisms.
 - No long-term effects are predicted for aquatic organisms.

Propellent :

- *Mobility:*
 - Evaporation: T_{1/2} life = 3 h (estimation)
- *Persistence and degradability:*
 - In water it is not easily biodegradable (3% after 28 days). Degradation in atmosphere: T_{1/2} life = 8.6 – 16.7 years. Ozone potential destruction: PDO (R11=1)=0. Potential global warming (PGW)=0.3.
- *Bioaccumulation:*
 - Almost non bioaccumulable, log P_{ow}=1.06

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.

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14. SECTION 14. TRANSPORT INFORMATION

14.1. UN number or ID number:

1950

14.2. UN proper shipping name

Flammable aerosol

14.3. Transport hazard class(es)

Class 2.1

14.4. Packaging group

N.A.

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

ONU number: 1950

ADR/RID Classification:

- Class: 2 (Gas)
- Classification: 5A Label: 2.1

IMDG Classification:

- Class: 2.1

Air (IATA/ICAO):

ONU 1950 – Flammable aerosol

Division 2.1 – Flammable gases

Special provision A145 / A167

Passenger aircraft: Packaging instructions 203/Y203

Max. net quantity 75 kg/30 kg

Cargo aircraft: Packaging instructions 203

Max. net quantity 150 kg

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) n° 1272/2008

15.2. Chemical safety assessment: not required

16. SECTION 16. OTHER INFORMATION

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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:

- H225: Highly flammable liquid and vapour
- 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 allergin skin reaction
- H319: Causes serious eye irritation
- H336: May cause drowsiness of dizziness
- 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 1272/2008 Regulation has been used for the classification of the mixture.

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