

Safety data sheet
According to 1907/2006/EC, Article 31

Printing date 09.04.2018

Version number 2

Revision: 09.04.2018

SECTION 1: Identification of the substance/mixture and of the company/undertaking

- **1.1 Product identifier**
- **Trade name:** QUITANET ULTRA
- **Article number / formula:** N119
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
- **Application of the substance / the preparation :** dental product
- **1.3 Details of the supplier of the safety data sheet**
Supplier:

IVOCLAR VIVADENT LTD.
12 Omega Street, Rosedale, Auckland 0632, New Zealand
PO Box 303011, North Harbour, Auckland 0751, New Zealand

Telephone: +649 914 9999
Fax: +649 914 9990

orders.nz@ivoclarvivadent.com
http://www.ivoclarvivadent.co.nz
- **1.4 Emergency telephone number:**
0800 764 766 (National Poisons Centre)

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008 :**



Eye Dam. 1 H318 Causes serious eye damage.



Aquatic Acute 1 H400 Very toxic to aquatic life.
Aquatic Chronic 1 H410 Very toxic to aquatic life with long lasting effects.



Skin Irrit. 2 H315 Causes skin irritation.

- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**
The product is classified and labelled according to the CLP regulation.

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Hazard pictograms



GHS05 GHS09

Signal word *Danger*

Hazard-determining components of labelling:

Alkyl polyglycoléther C8-10 (OE)
didecyldimethylammonium chloride
AMINES,N-C12-14-ALKYLTRIMETHYLENEDI-
D-gluconic acid, compound with N,N'-bis(4-chlorophenyl)-3,12-diimino-2,4,11,13-tetraazatetradecanediamidine (2:1)

Hazard statements

H315 Causes skin irritation.
H318 Causes serious eye damage.
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements

P102 Keep out of reach of children.
P273 Avoid release to the environment.
P280 Wear protective gloves.
P280 Wear eye protection / face protection.
P302+P352 IF ON SKIN: Wash with plenty of water.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310 Immediately call a POISON CENTER/doctor.
P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

2.3 Other hazards

Results of PBT and vPvB assessment

PBT: Not applicable.
vPvB: Not applicable.

SECTION 3: Composition/information on ingredients

3.2 Chemical characterisation: Mixtures

Description: Mixture: consisting of the following components.

Dangerous components:

CAS: 71060-57-6	Alkyl polyglycoléther C8-10 (OE) ☞ Eye Dam. 1, H318; ☠ Acute Tox. 4, H302	5-10%
CAS: 7173-51-5 EINECS: 230-525-2 Index number: 612-131-00-6 Reg.nr.: 01-2119945987-15	didecyldimethylammonium chloride ☞ Skin Corr. 1B, H314; ☠ Acute Tox. 4, H302	5-10%
CAS: 67-63-0 EINECS: 200-661-7 Index number: 603-117-00-0 RTECS: NT 8050000 Reg.nr.: 01-2119457558-25-xxxx	propan-2-ol ☞ Flam. Liq. 2, H225; ☠ Eye Irrit. 2, H319; STOT SE 3, H336	5-10%

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CAS: 90640-43-0 Reg.nr.: 01-2119957843-25	AMINES,N-C12-14-ALKYLTRIMETHYLENEDI- Acute Tox. 3, H301; STOT RE 1, H372; Skin Corr. 1B, H314; Aquatic Acute 1, H400 (M=100)	$\leq 2.5\%$
CAS: 18472-51-0 EINECS: 242-354-0 Reg.nr.: 01-2119946568-22-0001	D-gluconic acid, compound with N,N"-bis(4-chlorophenyl)-3,12-diimino-2,4,11,13-tetraazatetradecanediamidine (2:1) Eye Dam. 1, H318; Aquatic Acute 1, H400 (M=10); Aquatic Chronic 1, H410 (M=10)	$\leq 1\%$

· SVHC No

· Regulation 648/2004 on Detergents :

cationic surfactants

 $\geq 5 - < 15\%$

· Additional information: For the wording of the listed risk phrases, refer to section 16.

SECTION 4: First aid measures

· 4.1 Description of first aid measures

· General information:

Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.

· After excessive inhalation:

In case of unconsciousness place patient in a stable laying down side position for transportation.

· After skin contact: Immediately wash with water and soap and rinse thoroughly.

· After eye contact: Rinse opened eye for several minutes under running water. Then consult a doctor.

· After swallowing: Call for a doctor immediately.

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

No further relevant information available.

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

No further relevant information available.

SECTION 5: Firefighting measures

· 5.1 Suitable extinguishing agents:

CO₂, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

· 5.2 Special hazards arising from the substance or mixture : No further relevant information available.

· 5.3 Advice for firefighters

· Protective equipment: No special measures required.

SECTION 6: Accidental release measures

· 6.1 Personal precautions, protective equipment and emergency procedures : Not required.

· 6.2 Environmental precautions:

Do not allow product to reach sewage system or any water course.

Inform respective authorities in case of seepage into water course or sewage system.

Dilute with plenty of water.

Do not allow the product to enter sewers/ surface water or ground water.

· 6.3 Methods and material for containment and cleaning up:

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

Dispose contaminated material as waste according to item 13.

Ensure adequate ventilation.

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- **6.4 Reference to other sections :**
See Section 7 for information on safe handling.
See Section 8 for information on personal protective equipment.
See Section 13 for disposal information.

SECTION 7: Handling and storage

- **7.1 Precautions for safe handling :**
Ensure good ventilation/exhaustion at the workplace.
Prevent formation of aerosols.
- **Information about fire - and explosion protection:** No special measures required.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** No special requirements.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** None.
- **7.3 Specific end use(s) :** No further relevant information available.

SECTION 8: Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see section 7.
- **8.1 Control parameters**

· **Ingredients with limit values that require monitoring at the workplace:**

CAS: 67-63-0 propan-2-ol (5-10%)

WEL (Great Britain)	Short-term value: 1250 mg/m ³ , 500 ppm Long-term value: 999 mg/m ³ , 400 ppm
MAK (Switzerland)	Short-term value: 1000 mg/m ³ , 400 ppm Long-term value: 500 mg/m ³ , 200 ppm B SSc;

· **DNELs**

CAS: 67-63-0 propan-2-ol

Oral	DNEL Public long-term systemic	26 mg/kg bw/d
Dermal	DNEL Public long-term systemic	319 mg/kg bw/d
	DNEL Worker long-term systemic	888 mg/kg bw/d
Inhalative	DNEL Public long-term systemic	89 mg/m ³
	DNEL Worker long-term systemic	500 mg/m ³

· **PNECs**

CAS: 67-63-0 propan-2-ol

PNEC oral food	160 mg/kg
PNEC STP	2,251 mg/L
PNEC aqua (fresh water)	140.9 mg/L
PNEC aqua (intermittent releases)	140.9 mg/L
PNEC aqua (marine water)	140.9 mg/L
PNEC sediment (fresh water)	552 mg/kg
PNEC sediment (marine water)	552 mg/kg

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PNEC soil	28 mg/kg
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· Ingredients with biological limit values:

CAS: 67-63-0 propan-2-ol (5-10%)

BAT (Switzerland)	25 mg/l
	Medium: U Sampling time: b Parameter: Aceton
	25 mg/l
	Medium: B Sampling time: b Parameter: Aceton

· Additional information:

The most current valid lists have been used as a basis for the production of this document.

· 8.2 Exposure controls

· Personal protective equipment:

· General protective and hygienic measures:

Keep away from food, beverages and petfood.
Immediately remove all soiled and contaminated clothing
Wash hands before breaks and at the end of work.
Avoid all contact with the skin.
Avoid contact with the eyes and skin.

· Respiratory protection: Not required.

· Protection of hands:



Protective gloves

· Gloves material : Butyl rubber, BR

· Eye protection:



Tightly sealed goggles

SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· General Information

· Appearance:

Form:	Liquid
Colour:	Blue
· Odour:	Characteristic
· Odour threshold:	Not determined.

· pH-value:	7
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· Change in condition

· Melting point/freezing point:	Undetermined.
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Initial boiling point and boiling range:	Undetermined.
· Flash point:	60-93 °C
· Flammability (solid, gas):	Not applicable.
· Ignition temperature:	425 °C
· Decomposition temperature:	Not determined.
· Auto-ignition temperature:	Product is not self igniting.
· Explosive properties:	Product does not present an explosion hazard.
· Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
· Vapour pressure:	Not determined.
· Density at 20 °C:	1 g/cm ³
· Relative density :	Not determined.
· Vapour density :	Not determined.
· Evaporation rate :	Not determined.
· Solubility in / Miscibility with water:	Fully miscible.
· Segregation coefficient (n-octanol/water):	Not determined.
· Viscosity:	
Dynamic:	Not determined.
Kinematic:	Not determined.
· 9.2 Other information :	No further relevant information available.

SECTION 10: Stability and reactivity

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability**
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **10.3 Possibility of hazardous reactions :** No dangerous reactions known.
- **10.4 Conditions to avoid :** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:** No dangerous decomposition products known.

SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.

· **LD/LC50 values relevant for classification:**

CAS: 71060-57-6 Alkyl polyglycoléther C8-10 (OE)

Oral	LD50	500 mg/kg (ATE)
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CAS: 7173-51-5 didecyldimethylammonium chloride

Oral	LD50	410 mg/kg (rat)
Dermal	LD50	1,625 mg/kg (rat)

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CAS: 67-63-0 propan-2-ol

Oral	LD50	5,045 mg/kg (rat)
Dermal	LD50	12,800 mg/kg (rabbit)
Inhalative	LC50/4 h	30 mg/l (rat)

CAS: 90640-43-0 AMINES,N-C12-14-ALKYLTRIMETHYLENEDI-

Oral	LD50	100 mg/kg (ATE)
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CAS: 18472-51-0 D-gluconic acid, compound with N,N''-bis(4-chlorophenyl)-3,12-diimino-2,4,11,13-tetraazatetradecanediamidine (2:1)

Oral	LD50	>2,000 mg/kg (rat)
Dermal	LD50	>2,000 mg/kg (rabbit)

- **Primary irritant effect:**
- **On the skin:**
Causes skin irritation.
- **On the eyes:**
Causes serious eye damage.
- **Respiratory or skin sensitization** Based on available data, the classification criteria are not met.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

· **12.1 Toxicity**

· **Aquatic toxicity:**

CAS: 67-63-0 propan-2-ol

LC50 48h	8,970 mg/l (fish)
EC50 72h	>1,000 mg/l (Algae)

CAS: 18472-51-0 D-gluconic acid, compound with N,N''-bis(4-chlorophenyl)-3,12-diimino-2,4,11,13-tetraazatetradecanediamidine (2:1)

LC50 96h	2.08 mg/l (fish)
EC50 72h	0.081 mg/l (Algae)
EC50 48h	0.087 mg/l (Crustaceans)

- **12.2 Persistence and degradability** : No further relevant information available.
- **12.3 Bioaccumulative potential** : No further relevant information available.
- **12.4 Mobility in soil** : No further relevant information available.
- **Ecotoxicological effects:**
- **Remark:** Very toxic for fish
- **Additional ecological information:**
- **General notes:**
Water hazard class 3 (German Regulation) (Self-assessment): extremely hazardous for water
Do not allow product to reach ground water, water course or sewage system, even in small quantities.
Danger to drinking water if even extremely small quantities leak into the ground.
Also poisonous for fish and plankton in water bodies.
Very toxic for aquatic organisms

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- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Other adverse effects :** No further relevant information available.

SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation :**



Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

- **European waste catalogue**

18 00 00	WASTES FROM HUMAN OR ANIMAL HEALTH CARE AND/OR RELATED RESEARCH (EXCEPT KITCHEN AND RESTAURANT WASTES NOT ARISING FROM IMMEDIATE HEALTH CARE)
18 01 00	wastes from natal care, diagnosis, treatment or prevention of disease in humans
18 01 06*	chemicals consisting of or containing hazardous substances
HP 5	Specific Target Organ Toxicity (STOT)/Aspiration Toxicity
HP 8	Corrosive
HP 14	Ecotoxic

- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.
- **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

SECTION 14: Transport information

- **14.1 UN-Number**
- **ADR, IMDG, IATA** UN3082

- **14.2 UN proper shipping name**
- **ADR**

UN3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (AMINES, N-C12-14-ALKYLTRIMETHYLENEDI-, didecyldimethylammonium chloride, Alkyl polyglycoléther C8-10 (OE))

- **IMDG**

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (AMINES, N-C12-14-ALKYLTRIMETHYLENEDI-, didecyldimethylammonium chloride, Alkyl polyglycoléther C8-10 (OE), D-gluconic acid, compound with N,N''-bis(4-chlorophenyl)-3,12-diimino-2,4,11,13-tetraazatetradecanediamidine (2:1), MARINE POLLUTANT

- **IATA**

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (AMINES, N-C12-14-ALKYLTRIMETHYLENEDI-, didecyldimethylammonium chloride, Alkyl polyglycoléther C8-10 (OE))

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· **14.3 Transport hazard class(es)**

· **ADR**



· **Class** 9 (M6) Miscellaneous dangerous substances and articles.
· **Label** 9

· **IMDG**



· **Class** 9 Miscellaneous dangerous substances and articles.
· **Label** 9

· **IATA**



· **Class** 9 Miscellaneous dangerous substances and articles.
· **Label** 9

· **14.4 Packing group**

· **ADR, IMDG, IATA** III

· **14.5 Environmental hazards:**

Product contains environmentally hazardous substances:
AMINES,N-C12-14-ALKYLTRIMETHYLENEDI-

· **Marine pollutant:**

Yes

· **Special marking (ADR):**

Symbol (fish and tree)

Symbol (fish and tree)

· **14.6 Special precautions for user**

Warning: Miscellaneous dangerous substances and articles.

· **Danger code (Kemler):**

90

· **EMS Number:**

F-A,S-F

· **Stowage Category**

A

· **14.7 Transport in bulk according to Annex II of Marpol and the IBC Code**

Not applicable.

· **Transport/Additional information:**

· **ADR**

· **Limited quantities (LQ)**

5L

· **Excepted quantities (EQ)**

Code: E1

Maximum net quantity per inner packaging: 30 ml

Maximum net quantity per outer packaging: 1000 ml

· **Transport category**

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- | | |
|--|--|
| <ul style="list-style-type: none"> · IMDG · Limited quantities (LQ) · Excepted quantities (EQ) | <p>5L
Code: E1
Maximum net quantity per inner packaging: 30 ml
Maximum net quantity per outer packaging: 1000 ml</p> |
| <ul style="list-style-type: none"> · UN "Model Regulation": | <p>UN 3082 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (AMINES,N-C12-14-ALKYLTRIMETHYLENEDEI-, DIDECYLDIMETHYLAMMONIUM CHLORIDE, ALKYL POLYGLYCOLÉTHER C8-10 (OE)), 9, III</p> |

SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I** None of the ingredients is listed.
- **Seveso category E1** Hazardous to the Aquatic Environment
- **Qualifying quantity (tonnes) for the application of lower-tier requirements** 100 t
- **Qualifying quantity (tonnes) for the application of upper-tier requirements** 200 t
- **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3, 40

- **Regulation (EU) No 649/2012**

CAS: 7173-51-5 didecyldimethylammonium chloride

Annex I Part I

- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- **Relevant phrases**
- H225 Highly flammable liquid and vapour.
- H301 Toxic if swallowed.
- H302 Harmful if swallowed.
- H314 Causes severe skin burns and eye damage.
- H318 Causes serious eye damage.
- H319 Causes serious eye irritation.
- H336 May cause drowsiness or dizziness.
- H372 Causes damage to organs through prolonged or repeated exposure.
- H400 Very toxic to aquatic life.
- H410 Very toxic to aquatic life with long lasting effects.

- **Classification according to Regulation (EC) No 1272/2008**

Skin corrosion/irritation
Hazardous to the aquatic environment - long-term
(chronic) aquatic hazard

Expert judgement

Serious eye damage/eye irritation
Hazardous to the aquatic environment - short-term
(acute) aquatic hazard

The classification of the mixture is generally based on the calculation method using substance data according to Regulation (EC) No 1272/2008.

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· Abbreviations and acronyms:

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
GHS: Globally Harmonised System of Classification and Labelling of Chemicals
EINECS: European Inventory of Existing Commercial Chemical Substances
ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
DNEL: Derived No-Effect Level (REACH)
PNEC: Predicted No-Effect Concentration (REACH)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
SVHC: Substances of Very High Concern
vPvB: very Persistent and very Bioaccumulative
Flam. Liq. 2: Flammable liquids – Category 2
Acute Tox. 3: Acute toxicity – Category 3
Acute Tox. 4: Acute toxicity – Category 4
Skin Corr. 1B: Skin corrosion/irritation – Category 1B
Skin Irrit. 2: Skin corrosion/irritation – Category 2
Eye Dam. 1: Serious eye damage/eye irritation – Category 1
Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3
STOT RE 1: Specific target organ toxicity (repeated exposure) – Category 1
Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1
Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1

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