

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

1.1. Product identifier

Product form : Mixture
Trade name : EDTA

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

1.2.1. Relevant identified uses

Main use category : Professional use
Use of the substance/mixture : Endodontic irrigant used to remove smear layer and to disinfect instrumented canal systems

1.2.2. Uses advised against

Restrictions on use : None known

1.3. Details of the supplier of the safety data sheet

Supplier:

XXXX

Manufacturer:

Inter-Med, Inc. / Vista Dental Products
2200 South Street
Racine, WI 53404
T: (877)-418-4782

1.4. Emergency telephone number

Emergency number : 800-424-9300 (North America) / +1 (703) 527-3887 (International)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Skin corrosion/irritation, Category 2 H315
Serious eye damage/eye irritation, Category 2 H319
Full text of H statements : see section 16

Adverse physicochemical, human health and environmental effects

Causes skin irritation. Causes serious eye irritation.

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP) :



GHS07

Signal word (CLP) :

Warning

Hazard statements (CLP) :

H315 - Causes skin irritation.
H319 - Causes serious eye irritation.

Precautionary statements (CLP) :

P264 - Wash hands thoroughly after handling.
P280 - Wear eye protection, protective gloves.
P337+P313 - If eye irritation persists: Get medical advice/attention.

2.3. Other hazards not contributing to the classification

No additional information available

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

17% EDTA

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Glycine, N,N'-1,2-ethanediylbis[N-(carboxymethyl)-, disodium salt, dihydrate	(CAS-No.) 6381-92-6	15-20	Acute Tox. 4 (Oral), H302 Acute Tox. 4 (Dermal), H312 Acute Tox. 4 (Inhalation), H332 Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335 Aquatic Chronic 3, H412
sodium hydroxide; caustic soda	(CAS-No.) 1310-73-2 (EC-No.) 215-185-5 (EC Index-No.) 011-002-00-6	< 2	Acute Tox. 4 (Oral), H302 Skin Corr. 1A, H314

Specific concentration limits:

Name	Product identifier	Specific concentration limits
sodium hydroxide; caustic soda	(CAS-No.) 1310-73-2 (EC-No.) 215-185-5 (EC Index-No.) 011-002-00-6	(0.5 =<C < 2) Eye Irrit. 2, H319 (0.5 =<C < 2) Skin Irrit. 2, H315 (2 =<C < 5) Skin Corr. 1B, H314 (C >= 5) Skin Corr. 1A, H314

Full text of H-statements: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures after inhalation	: Remove person to fresh air and keep comfortable for breathing. Give artificial respiration if necessary. If you feel unwell, seek medical advice.
First-aid measures after skin contact	: Rinse immediately with plenty of water for 15 minutes. Get medical advice if skin irritation persists.
First-aid measures after eye contact	: Rinse immediately with plenty of water for 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice and attention.
First-aid measures after ingestion	: Rinse mouth. Do not induce vomiting. Get medical advice/attention.

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

Symptoms/effects after inhalation	: Not expected to present a significant inhalation hazard under anticipated conditions of normal use.
Symptoms/effects after skin contact	: Causes skin irritation.
Symptoms/effects after eye contact	: Causes serious eye irritation.
Symptoms/effects after ingestion	: Not expected to present a significant ingestion hazard under anticipated conditions of normal use. On ingestion in large quantities: May cause irritation to the digestive tract.

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

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	: Water spray. Dry powder. Foam. Carbon dioxide.
Unsuitable extinguishing media	: None known.

5.2. Special hazards arising from the substance or mixture

Fire hazard	: On combustion, forms: carbon oxides (CO and CO ₂).
Explosion hazard	: No direct explosion hazard.
Hazardous decomposition products in case of fire	: Toxic fumes may be released.

5.3. Advice for firefighters

Firefighting instructions	: Exercise caution when fighting any chemical fire.
Protective equipment for firefighters	: Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures	: Avoid all unnecessary exposure.
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6.1.1. For non-emergency personnel

Protective equipment	: Use personal protective equipment as required. For further information refer to section 8: "Exposure controls/personal protection".
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17% EDTA

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. In case of inadequate ventilation wear respiratory protection.

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Collect spillage.

Other information : Dispose of materials or solid residues at an authorized site.

6.4. Reference to other sections

For further information refer to section 8: "Exposure controls/personal protection". For disposal of residues refer to section 13: "Disposal considerations".

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Ensure good ventilation of the work station. Avoid contact with eyes. Wear personal protective equipment.

Hygiene measures : Do not eat, drink or smoke when using this product. Always wash hands after handling the product. Wash contaminated clothing before reuse. Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a well-ventilated place. Keep cool.

Incompatible materials : None known.

7.3. Specific end use(s)

See Heading 1.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

sodium hydroxide; caustic soda (1310-73-2)		
Austria	Local name	Natriumhydroxid
Austria	MAK (mg/m ³)	2 mg/m ³
Austria	MAK Short time value (mg/m ³)	4 mg/m ³
Austria	Regulatory reference	BGBl. II Nr. 186/2015
Belgium	Local name	Sodium (hydroxyde de) # Natriumhydroxide
Belgium	Limit value (mg/m ³)	2 mg/m ³
Belgium	Remark (BE)	M: la mention "M" indique que lors d'une exposition supérieure à la valeur limite, des irritations apparaissent ou un danger d'intoxication aiguë existe. Le procédé de travail doit être conçu de telle façon que l'exposition ne dépasse jamais la valeur limite. Lors des mesurages, la période d'échantillonnage doit être aussi courte que possible afin de pouvoir effectuer des mesurages fiables. Le résultat des mesurages est calculé en fonction de la période d'échantillonnage. # M: de vermelding "M" duidt aan dat bij de blootstelling boven de grenswaarde irritatie optreedt of er gevaar bestaat voor acute vergiftiging. Het werkproces moet zo zijn ontworpen dat de blootstelling de grenswaarde nooit overschrijdt. Bij een controle geldt dat de bemonsterde periode zo kort mogelijk moet zijn om een betrouwbare meting te kunnen verrichten. het meetresultaat wordt dan gerelateerd aan de beschouwde periode.
Belgium	Regulatory reference	Koninklijk besluit/Arrêté royal 11/03/2002
Bulgaria	Local name	Натриева основа
Bulgaria	OEL TWA (mg/m ³)	2 mg/m ³ алкални аерозоли
Bulgaria	Regulatory reference	Наредба № 13 от 30.12.2003 г. за защита на работещите от рискове, свързани с експозиция на химични агенти при работа
Croatia	Local name	Natrijev hidroksid; (kaustična soda)
Croatia	KGVI (kratkotrajna granična vrijednost izloženosti) (mg/m ³)	2 mg/m ³
Croatia	Naznake (HR)	C (nagrizajuće)

17% EDTA

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

sodium hydroxide; caustic soda (1310-73-2)		
Croatia	Regulatory reference	Pravilnik o izmjenama i dopunama Pravilnika o graničnim vrijednostima izloženosti opasnim tvarima pri radu i o biološkim graničnim vrijednostima (NN, br. 75/13)
Czech Republic	Local name	Hydroxid sodný
Czech Republic	Expoziční limity (PEL) (mg/m ³)	1 mg/m ³
Czech Republic	Expoziční limity (NPK-P) (mg/m ³)	2 mg/m ³
Czech Republic	Remark (CZ)	I (dráždí sliznice (oči, dýchací cesty) resp. kůži)
Czech Republic	Regulatory reference	Nářízení vlády č. 361/2007 Sb. (zapracovány změny č. 93/2012 Sb., 9/2013 Sb.)
Denmark	Local name	Natriumhydroxid
Denmark	Grænseværdie (ceiling) (mg/m ³)	2 mg/m ³
Denmark	Anmærkninger (DK)	L (markerer, at grænseværdien er en loftværdi, som ikke på noget tidspunkt må overskrides)
Denmark	Regulatory reference	BEK nr 655 af 31/05/2018
Estonia	Local name	Naatriumhüdoksiid
Estonia	OEL TWA (mg/m ³)	1 mg/m ³
Estonia	OEL Ceiling (mg/m ³)	2 mg/m ³
Estonia	Regulatory reference	Vabariigi Valitsuse 18. septembri 2001. a määruse nr 293 (RT I, 30.11.2011, 5)
Finland	Local name	Natriumhydroksidi
Finland	OEL Ceiling (mg/m ³)	2 mg/m ³
Finland	Regulatory reference	HTP-ARVOT 2018 (Sosiaali- ja terveystiete)
France	Local name	Sodium (hydroxyde de)
France	VME (mg/m ³)	2 mg/m ³
France	Note (FR)	Valeurs recommandées/admises
France	Regulatory reference	Circulaire du Ministère du travail (réf.: INRS ED 984, 2016)
Greece	Local name	Υδροξειδίο του νατρίου
Greece	OEL TWA (mg/m ³)	2 mg/m ³
Greece	OEL STEL (mg/m ³)	2 mg/m ³
Greece	Regulatory reference	Π.Δ. 90/1999
Hungary	Local name	NÁTRIUM-HIDROXID
Hungary	AK-érték	2 mg/m ³
Hungary	CK-érték	2 mg/m ³
Hungary	Megjegyzések (HU)	m (maró hatású anyag, amely felmarja a bőrt, nyálkahártyát, szemet vagy mindhármát); l. (HELYILEG IRRITÁLÓ ANYAGOK)
Hungary	Regulatory reference	25/2000. (IX. 30.) EüM–SZCSM együttes rendelet a munkahelyek kémiai biztonságáról
Ireland	Local name	Sodium hydroxide
Ireland	OEL (15 min ref) (mg/m ³)	2 mg/m ³
Ireland	Regulatory reference	Code of Practice for the Chemical Agents Regulations 2018
Latvia	Local name	Nātrija hidroksīds (nātrija sārms, kaustiskā soda)
Latvia	OEL TWA (mg/m ³)	0.5 mg/m ³
Latvia	Regulatory reference	Ministru kabineta 2007.gada 15.maija noteikumiem Nr.325 (Grozījumi Ministru kabineta 2011.gada 1.februārī noteikumiem Nr.92)
Lithuania	Local name	Natrio hidroksidas

17% EDTA

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

sodium hydroxide; caustic soda (1310-73-2)		
Lithuania	NRV (mg/m ³)	2 mg/m ³
Lithuania	Remark (LT)	Ū (ūmus poveikis)
Lithuania	Regulatory reference	LIETUVOS HIGIENOS NORMA HN 23:2011 (Nr. V-695/A1-272, 2018-06-12)
Poland	Local name	Wodorotlenek sodu
Poland	NDS (mg/m ³)	0.5 mg/m ³
Poland	NDSch (mg/m ³)	1 mg/m ³
Poland	Regulatory reference	Dz. U. 2018 poz. 1286
Portugal	Local name	Hidróxido de sódio
Portugal	OEL - Ceilings (ppm)	2 ppm
Portugal	Regulatory reference	Norma Portuguesa NP 1796:2014
Slovakia	Local name	Hydroxid sodný
Slovakia	NPHV (priemerná) (mg/m ³)	2 mg/m ³
Slovakia	Regulatory reference	Nariadenie vlády č. 33/2018 Z.z.
Slovenia	Local name	natrijev hidroksid
Slovenia	OEL TWA (mg/m ³)	2 mg/m ³
Slovenia	KTV factor SL	1
Slovenia	Regulatory reference	Uradni list RS, št. 38/2015 z dne 4.6.2015
Spain	Local name	Hidróxido de sodio
Spain	VLA-EC (mg/m ³)	2 mg/m ³
Spain	Regulatory reference	Límites de Exposición Profesional para Agentes Químicos en España 2018. INSHT
Sweden	Local name	Natriumhydroxid
Sweden	nivågränsvärde (NVG) (mg/m ³)	1 mg/m ³ inhalerbar fraktion
Sweden	kortidsvärde (KTV) (mg/m ³)	2 mg/m ³ inhalerbar fraktion
Sweden	Anmärkning (SE)	3 (Med inhalerbar fraktion menas den mängd partiklar, av totalmängden partiklar i luften, som man inandas genom näsa och mun)
Sweden	Regulatory reference	Hygieniska gränsvärden (AFS 2018:1)
United Kingdom	Local name	Sodium hydroxide
United Kingdom	WEL STEL (mg/m ³)	2 mg/m ³
United Kingdom	Regulatory reference	EH40/2005 (Third edition, 2018). HSE
Iceland	Local name	Natríumhýdroxíð (vítissóti)
Iceland	OEL (15 min ref) (mg/m ³)	2 mg/m ³
Iceland	Regulatory reference	Reglugerð um mengunarmörk og aðgerðir til að draga úr mengun á vinnustöðum (Nr. 390/2009)
Norway	Local name	Natriumhydroksid
Norway	Grenseverdier (Takverdi) (mg/m ³)	2 mg/m ³
Norway	Merknader (NO)	T (Takverdi er en øyeblikksverdi som angir maksimalkonsentrasjon av et kjemikalie i pustesonen som ikke skal overskrides)
Norway	Regulatory reference	FOR-2018-08-21-1255
USA - ACGIH	Local name	Sodium hydroxide
USA - ACGIH	ACGIH Ceiling (mg/m ³)	2 mg/m ³
USA - ACGIH	Remark (ACGIH)	URT, eye, & skin irr
USA - ACGIH	Regulatory reference	ACGIH 2018

17% EDTA

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

8.2. Exposure controls

Appropriate engineering controls:

Ensure good ventilation of the work station. Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure.

Hand protection:

Impermeable protective gloves. EN 374

Eye protection:

Safety glasses with side shields. DIN EN 166

Respiratory protection:

No respiratory protection needed under normal use conditions

Environmental exposure controls:

Avoid release to the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Colour	: Colourless.
Odour	: characteristic.
Odour threshold	: No data available
pH	: 6.8 - 7.5
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: Not applicable
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: Not applicable
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: 1.06
Solubility	: No data available
Log Pow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

Hazardous polymerization will not occur.

10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

10.5. Incompatible materials

None known.

10.6. Hazardous decomposition products

No hazardous decomposition products known at room temperature. On combustion, forms: carbon oxides (CO and CO₂).

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity (oral) : Not classified (Based on available data, the classification criteria are not met)

Acute toxicity (dermal) : Not classified (Based on available data, the classification criteria are not met)

17% EDTA

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

Acute toxicity (inhalation) : Not classified (Based on available data, the classification criteria are not met)

sodium hydroxide; caustic soda (1310-73-2)	
LD50 oral rat	140 - 340 mg/kg
Skin corrosion/irritation	: Causes skin irritation. pH: 6.8 - 7.5
Serious eye damage/irritation	: Causes serious eye irritation. pH: 6.8 - 7.5
Respiratory or skin sensitisation	: Not classified (Based on available data, the classification criteria are not met)
Germ cell mutagenicity	: Not classified (Based on available data, the classification criteria are not met)
Carcinogenicity	: Not classified (Based on available data, the classification criteria are not met)
Reproductive toxicity	: Not classified (Based on available data, the classification criteria are not met)
STOT-single exposure	: Not classified (Based on available data, the classification criteria are not met)
STOT-repeated exposure	: Not classified (Based on available data, the classification criteria are not met)
Aspiration hazard	: Not classified (Based on available data, the classification criteria are not met)
Other information	: Likely routes of exposure: ingestion, inhalation, skin and eye.

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general	: This material has not been tested for environmental effects.
Acute aquatic toxicity	: Not classified (Based on available data, the classification criteria are not met)
Chronic aquatic toxicity	: Not classified (Based on available data, the classification criteria are not met)

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods : Dispose of contents/container in accordance with licensed collector's sorting instructions.

SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

ADR	IMDG	IATA	ADN	RID
14.1. UN number				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.2. UN proper shipping name				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.3. Transport hazard class(es)				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.4. Packing group				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.5. Environmental hazards				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
No supplementary information available				

14.6. Special precautions for user

Overland transport

Not regulated

17% EDTA

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

Transport by sea

Not regulated

Air transport

Not regulated

Inland waterway transport

Not regulated

Rail transport

Not regulated

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

Not applicable

SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

Contains no REACH substances with Annex XVII restrictions

Contains no substance on the REACH candidate list

Contains no REACH Annex XIV substances

15.1.2. National regulations

Germany

Reference to AwSV : Water hazard class (WGK) 3, severe hazard to water (Classification according to AwSV, Annex 1)

WGK remark : Most stringent classification due to insufficient data

12th Ordinance Implementing the Federal Immission Control Act - 12.BImSchV : Is not subject of the 12. BImSchV (Hazardous Incident Ordinance)

Netherlands

SZW-lijst van kankerverwekkende stoffen : None of the components are listed

SZW-lijst van mutagene stoffen : None of the components are listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Borstvoeding : None of the components are listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Vruchtbaarheid : None of the components are listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Ontwikkeling : None of the components are listed

Denmark

Danish National Regulations : Pregnant/breastfeeding women working with the product must not be in direct contact with the product

15.2. Chemical safety assessment

No additional information available

SECTION 16: Other information

Sources of Key data : REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Full text of H- and EUH-statements:	
Acute Tox. 4 (Dermal)	Acute toxicity (dermal), Category 4
Acute Tox. 4 (Inhalation)	Acute toxicity (inhal.), Category 4
Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Aquatic Acute 1	Hazardous to the aquatic environment — Acute Hazard, Category 1
Aquatic Chronic 3	Hazardous to the aquatic environment — Chronic Hazard, Category 3
Eye Dam. 1	Serious eye damage/eye irritation, Category 1
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
Skin Corr. 1A	Skin corrosion/irritation, Category 1A
Skin Irrit. 2	Skin corrosion/irritation, Category 2
STOT SE 3	Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation
H302	Harmful if swallowed.

17% EDTA

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

H312	Harmful in contact with skin.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H332	Harmful if inhaled.
H335	May cause respiratory irritation.
H400	Very toxic to aquatic life.
H412	Harmful to aquatic life with long lasting effects.

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:

Skin Irrit. 2	H315	Calculation method
Eye Irrit. 2	H319	Calculation method

SDS EU (REACH Annex II)

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product