SAFETY DATA SHEETS

This SDS packet was issued with item:

077189004

N/A

Material Safety Data Sheet in Accordance with 2001/58/EC & ANSI 400.1-2003

Date of Issue: June 2011 Supersedes version of: New Page 1 of 2
N.A. = not applicable, N.K. = not known P/N 48130A

Identification of the Substance/Preparation and of the Company/Undertakings Product Details:

Product Details:

Trade Name: Canal Pro EDTA - 17%

Manufacturer:

Coltène/Whaledent Inc. 235 Ascot Parkway Cuyahoga Falls, OH 44223/USA Fax +1 330 916 7077 info@coltenewhaledent.com

Emergency Contact Numbers: USA & Canada: +1 800 535 5053 Main Phone Number: +1 330 916 8800 Authorized EU Representative Coltène/Whaledent GmbH+ Co. KG Raiffeisenstrasse 30

89129 Langenau/Germany Tel. +49 (0) 7345 805 0 Fax +49 (0) 7345 805 201

2. Composition/Information on Ingredients

Chemical Characterization: Non-Ionic Detergent

Hazardous Components:

Chemical NameWeight %OSHA PELSodium EDTA< 20%</td>Not Determined

3. Hazard Identification

Hazard Designation: Not hazardous.

Information Pertaining to Particular Dangers for Man and Environment: None.

Classification is in Line with BC Directive 1999/45/EC: N.A.

4. First-Aid Measures

After Inhalation: Get to fresh air, if irritation persists, consult a physician.

After Skin Contact: Wash thoroughly with water for 15 minutes. If irritation persists, consult a physician.

After Eye Contact: Flush with water for 15 minutes. If irritation persists, consult a physician. After Swallowing: Do not induce vomiting. Drink water to dilute and contact a physician.

5. Fire-Fighting Measures

Flammability: Nonflammable Flash Point: None LEL: Not Established UEL: Not Established

Extinguishing Media: Water, CO₂, dry chemical or foam.

Unsuitable Extinguishing Media: None known.

Protective Equipment: Wear NIOSH approved self-contained breathing respirator in positive pressure mode.

6. Accidental Release Measures

Personal Precautions: Avoid eye contact by wearing safety goggles, avoid skin contact by wearing rubber gloves.

Environmental Precautions: Do not contaminate food or feed with this product. Keep container closed and upright when not in use.

Methods of Cleaning Up: Use absorbent material such as sand or clay, and place in drums for disposal. Small quantities may be diluted with water and flushed down the drain.

7. Handling and Storage

Precautions for Safe Handling: Always wear gloves and eye protection. Keep container closed when not in use. Storage: Keep out of reach of children. Keep container closed.

8. Exposure Controls/Personal Protection

Components with Recommended Limits for the Work Place:

<u>CAS No.</u> <u>Chemical Name</u> <u>Weight %</u> <u>Type/Value</u>

6831-92-6 Sodium EDTA 1% OSHA PEL 400 ppm

Engineering Controls: Local Exhaust Adequate; mechanical ventilation helpful.

Work/Hygienic Protection: Wash hands and equipment after use.

Hand/Skin Protection: Wear Protective Gloves. Respiratory Protection: None Needed. Eye Protection: Wear Safety Goggles. Material Safety Data Sheet in Accordance with 2001/58/EC & ANSI 400.1-2003

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N.A. = not applicable, N.K. = not known Canal Pro EDTA – 17% P/N 48130A

9. Physical and Chemical Properties

Appearance: Clear Liquid Odor: None Solubility: Soluble in water

Boiling Point: 100℃ (212年) Flash Point: N.K. Method: N.A.

Flammability: No Autoflammability: No Density: 1.2 g/cc (25°C)
Vapor Pressure: N.K. Explosive Properties: N.K. Explosive Limits in Air: N.K.

pH: 10 - 12

10. Stability and Reactivity

Chemical Stability: Stable. Conditions to Avoid: Strong oxidizers. Materials to Avoid: None. Hazardous Decomposition Products: CO.

11. Toxicological Information

Acute Toxicity: N.A.

Primary Effects to Skin: Not a primary dermal irritant.

Primary Effects to Eyes: Not an ocular irritant.

Primary Effects to Respiratory System: Not an acute inhalation hazard.

Sensitization: N.A.

Additional Toxicological Info: N.A.

12. Ecological Information

General Information: N.A.

Classification of Water Endangerment: N.A.

13. Disposal Considerations

Product: Not considered a RCRA hazardous waste as identified in Fed. Reg. 40CFR261. If this product cannot be used as directed by the label, contact the local Environmental Control Agency or Agent.

14. Transportation Information

DOT Shipping Name: Not regulated DOT Hazard Class: Not regulated UN-No.: N.A. Sea Transport IMDG/GGV Sea Class: N.A. UN. No.: N.A. UN. No.: N.A. MFGA-No.: N.A. MFGA-No.: N.A.

Air Transport ICAO-Ti and IATA-DGR Class: N.A. UN. No.: N.A.

15. Regulatory Information

TSCA Inventory Status: This product and/or all of its components are included on the TSCA Inventory of Chemical Substances.

SARA 311/312 Hazard Categories: None.

SARA 302 Extremely Hazardous Substances: None.

SARA 313 Toxic Chemicals:

<u>Chemical Name</u> <u>CAS No.</u> <u>Weight %</u>

Classification According to EEC Guidelines: N.A.

Classification According to VBF: N.A.

Canadian Regulations require the inclusion of the following statements under "Regulatory Information";

"This product has been classified in accordance with the hazard criteria of the controlled Products Regulations and the MSDS contains all the information required by the Controlled Products Regulations."

16. Other Information

Revision Summary: 6/8/11 New.

The information and recommendations set forth herein are presented in good faith and are believed to be correct as of the date hereof. Coltène/Whaledent Inc., however, makes no representations as to the completeness of this information and supplies it on the condition that the persons receiving same will make their own determination as to its suitability of their purposes prior to use. In no event will Coltène/Whaledent Inc. be responsible for damages of any nature whatsoever resulting from use of or reliance upon information.

according to Regulation (EC) No 1907/2006

EDTA 17% Solution

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

1.1. Product identifier

EDTA 17% Solution

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

1.3. Details of the supplier of the safety data sheet

Manufacturer

Company name: Magnum Dental AS

 Street:
 Aardla 13

 Place:
 EST-50112 Tartu

 Telephone:
 +372 7371647

Supplier

Company name: COLTENE/Whaledent GmbH & Co. KG

Street: Raiffeisenstraße 30
Place: D-89129 Langenau
Telephone: +49 (7345) 805 0
Telefax: +49 (7345) 805 201
e-mail: info.de@coltene.com
Internet: www.coltene.com

1.4. Emergency telephone Estland 112, Finnland 112, andere +372 7371647

number:

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No. 1272/2008

Hazard categories:

Specific target organ toxicity - repeated exposure: STOT RE 2

Hazard Statements:

May cause damage to organs through prolonged or repeated exposure.

2.2. Label elements

Regulation (EC) No. 1272/2008

Hazard components for labelling EDTA Disodium Salt Dihydrate

Signal word: Warning

Pictograms:



Hazard statements

H373 May cause damage to organs through prolonged or repeated exposure.

Precautionary statements

P260 Do not breathe dust/fume/gas/mist/vapours/spray.
P314 Get medical advice/attention if you feel unwell.
P501 Dispose of waste according to applicable legislation.

2.3. Other hazards

No information available.

according to Regulation (EC) No 1907/2006

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SECTION 3: Composition/information on ingredients

3.2. Mixtures

Hazardous components

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	Classification according to Regulation (EC) No. 1272/2008 [CLP]			
6381-92-6	EDTA Disodium Salt Dihydrate		15 - < 30 %	
	205-358-3		01-2119486775-20	
	Acute Tox. 4, STOT RE 2; H332 H373			

Full text of H and EUH statements: see section 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

After inhalation

Provide fresh air. When in doubt or if symptoms are observed, get medical advice.

After contact with skin

Wash with plenty of soap and water. Take off contaminated clothing and wash it before reuse. In case of skin irritation, consult a physician.

After contact with eyes

In case of contact with eyes flush immediately with plenty of flowing water for 10 to 15 minutes holding eyelids apart and consult an ophthalmologist.

After ingestion

Rinse mouth immediately and drink plenty of water. Never give anything by mouth to an unconscious person or a person with cramps. Do NOT induce vomiting. Immediately call a doctor.

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

No information available.

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

Co-ordinate fire-fighting measures to the fire surroundings.

5.2. Special hazards arising from the substance or mixture

Non-flammable.

Can be released in case of fire: Nitrogen oxides (NOx), Carbon monoxide, Carbon dioxide (CO2), Ammonia (NH3). Gases/vapours, toxic.

5.3. Advice for firefighters

Wear a self-contained breathing apparatus and chemical protective clothing. Full protection suit.

Additional information

Suppress gases/vapours/mists with water spray jet. Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

according to Regulation (EC) No 1907/2006

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Provide adequate ventilation. Do not breathe gas/fumes/vapour/spray. Avoid contact with skin, eyes and clothes. Use personal protection equipment.

6.2. Environmental precautions

Avoid release to the environment. Do not allow to enter into surface water or drains.

6.3. Methods and material for containment and cleaning up

Absorb with liquid-binding material (e.g. sand, diatomaceous earth, acid- or universal binding agents). Collect in closed and suitable containers for disposal. Wash with plenty of water. Dispose of waste according to applicable legislation.

6.4. Reference to other sections

Safe handling: see section 7

Personal protection equipment: see section 8

Disposal: see section 13

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling

Do not breathe gas/fumes/vapour/spray. Avoid contact with eyes and skin.

Advice on protection against fire and explosion

No special fire protection measures are necessary.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Store tightly closed container in a cool, dry and well-ventilated place.

Advice on storage compatibility

Do not store together with: Oxidising agent.

Further information on storage conditions

Protect against direct sunlight.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.2. Exposure controls

Appropriate engineering controls

Use only in well-ventilated areas.

Protective and hygiene measures

Remove contaminated, saturated clothing immediately. Wash hands before breaks and after work. When using do not eat or drink.

Eye/face protection

Tightly sealed safety glasses.

Hand protection

Wear suitable gloves.

When handling with chemical substances, protective gloves must be worn with the CE-label including the four control digits. The quality of the protective gloves resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of hazardous substances. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves.

Skin protection

Wear suitable protective clothing

according to Regulation (EC) No 1907/2006

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Respiratory protection

In case of inadequate ventilation wear respiratory protection.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state: Liquid

Colour: colourless - yellow
Odour: No information available.

Test method

pH-Value: 8 - 9

Changes in the physical state

Melting point: $0\,^{\circ}\mathrm{C}$ Initial boiling point and boiling range: $100\,^{\circ}\mathrm{C}$ Flash point: not determined

Flammability

Solid: not applicable
Gas: not applicable
Lower explosion limits: not determined
Upper explosion limits: not determined
Ignition temperature: not determined

Auto-ignition temperature

Solid: not applicable
Gas: not applicable

Decomposition temperature: not determined

Oxidizing properties

Not oxidising.

Vapour pressure: not determined

Density (at 20 °C): 1,1 - 1,2 g/cm³

Water solubility: completely miscible

Solubility in other solvents

not determined

Partition coefficient:

Viscosity / dynamic:

Viscosity / kinematic:

Vapour density:

Evaporation rate:

not determined

not determined

not determined

not determined

9.2. Other information

Odour threshold: not determined

SECTION 10: Stability and reactivity

10.1. Reactivity

No hazardous reaction when handled and stored according to provisions.

10.2. Chemical stability

The product is stable under storage at normal ambient temperatures.

according to Regulation (EC) No 1907/2006

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10.3. Possibility of hazardous reactions

No known hazardous reactions. Danger of polymerisation: none.

10.4. Conditions to avoid

Protect against: Heat, Frost.

10.5. Incompatible materials

Oxidising agent, strong.

10.6. Hazardous decomposition products

Nitrogen oxides (NOx), Carbon monoxide, Carbon dioxide (CO2), Ammonia (NH3).

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity

Based on available data, the classification criteria are not met.

CAS No	Chemical name					
	Exposure route	Dose		Species	Source	Method
6381-92-6	EDTA Disodium Salt Dihydrate					
	oral	LD50 mg/kg	> 2000	Rat	Manufacturer	
	inhalative vapour	ATE	11 mg/l			
	inhalative aerosol	ATE	1.5 mg/l			

Irritation and corrosivity

Based on available data, the classification criteria are not met.

Sensitising effects

Based on available data, the classification criteria are not met.

Carcinogenic/mutagenic/toxic effects for reproduction

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

May cause damage to organs through prolonged or repeated exposure. (EDTA Disodium Salt Dihydrate)

Aspiration hazard

Based on available data, the classification criteria are not met.

Additional information on tests

The mixture is classified as hazardous according to regulation (EC) No 1272/2008 [CLP].

SECTION 12: Ecological information

12.1. Toxicity

The product is not: Ecotoxic.

12.2. Persistence and degradability

Biodegradable.

12.3. Bioaccumulative potential

The product has not been tested.

12.4. Mobility in soil

The product has not been tested.

12.5. Results of PBT and vPvB assessment

according to Regulation (EC) No 1907/2006

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The product has not been tested.

12.6. Other adverse effects

No information available.

Further information

Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Advice on disposal

Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil. Dispose of waste according to applicable legislation.

Contaminated packaging

Handle contaminated packages in the same way as the substance itself. Dispose of waste according to applicable legislation.

SECTION 14: Transport information

<u>14.1. UN number:</u>	No dangerous good in sense of this transport regulation.
14.2. UN proper shipping name:	No dangerous good in sense of this transport regulation.
14.3. Transport hazard class(es):	No dangerous good in sense of this transport regulation.
14.4. Packing group:	No dangerous good in sense of this transport regulation.

Inland waterways transport (ADN)

14.1. UN number:	No dangerous good in sense of this transport regulation.
14.2. UN proper shipping name:	No dangerous good in sense of this transport regulation.
14.3. Transport hazard class(es):	No dangerous good in sense of this transport regulation.
14.4. Packing group:	No dangerous good in sense of this transport regulation.

Marine transport (IMDG)

14.1. UN number:	No dangerous good in sense of this transport regulation.
14.2. UN proper shipping name:	No dangerous good in sense of this transport regulation.
14.3. Transport hazard class(es):	No dangerous good in sense of this transport regulation.
14.4. Packing group:	No dangerous good in sense of this transport regulation.

Air transport (ICAO-TI/IATA-DGR)

14.1. UN number:	No dangerous good in sense of this transport regulation.
14.2. UN proper shipping name:	No dangerous good in sense of this transport regulation.
14.3. Transport hazard class(es):	No dangerous good in sense of this transport regulation.
14.4. Packing group:	No dangerous good in sense of this transport regulation.

14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS: no

14.6. Special precautions for user

No information available.

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

according to Regulation (EC) No 1907/2006

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EU regulatory information

Information according to 2012/18/EU

(SEVESO III):

Not subject to 2012/18/EU (SEVESO III)

National regulatory information

Employment restrictions: Observe restrictions to employment for juvenils according to the 'juvenile

work protection guideline' (94/33/EC). Observe employment restrictions under the Maternity Protection Directive (92/85/EEC) for expectant or

nursing mothers.

Water contaminating class (D): 2 - clearly water contaminating

15.2. Chemical safety assessment

Chemical safety assessments for substances in this mixture were not carried out.

SECTION 16: Other information

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 Harmonized 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 LC50: Lethal concentration, 50%

LD50: Lethal dose, 50%

Relevant H and EUH statements (number and full text)

H332 Harmful if inhaled.

H373 May cause damage to organs through prolonged or repeated exposure.

Further Information

The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet is not necessarily valid for the new made-up material.

(The data for the hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)