SAFETY DATA SHEETS

This SDS packet was issued with item:

077185028

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

077184245

Material Safety Data Sheet

May be used to comply with OSHA's Hazard Communication Standard, 29 CFR 1910.1200. Standard must be consulted for specific requirements.

U.S. Department of Labor

Occupational Safety and Health Administration (Non-Mandatory Form) Form Approved OMB No. 1218-0072



IDENTITY (As Used on Label and List) BIOSONIC DISINFECTANT Note: Blank spaces are not permitted. If any item is not applicable, or no ULTRASONIC CLEANER CONCENTRATE information is available, the space must be marked to indicate that. Section I Manufacturer's Name **Emergency Telephone Number** WHALEDENT INC. 212 696-8000 Address (Number, Street, City, State, and ZIP Code) Telephone Number for Information 236 FIFTH AVE. 212 696-8000 Date Prepared NEW YORK, NEW YORK 10001 APRIL 4, 1990 Signature of Preparer (optional) Section II — Hazardous Ingredients/Identity Information Other Limits Hazardous Components (Specific Chemical Identity; Common Name(s)) OSHA PEL ACGIH TLV Recommended % (optional) SODIUM ORTHO-BENZYL PARACHLOROPHENATE 4.40 SODIUM ORTHO-PHENYLPHENATE 2.82 SODIUM PARA-TERTIARY AMYLPHENATE 2.49 ISOPROPYL ALCOHOL **400PPM** 7.79 Section III — Physical/Chemical Characteristics **Boiling Point** Specific Gravity (H2O = 1) 100°C. 1.03 Vapor Pressure (mm Hg.) Melting Point N/A N/A Vapor Density (AIR = 1) **Evaporation Rate** N/A N/A (Butyl Acetate = 1) Solubility in Water COMPLETE Appearance and Odor CLEAR DARK AMBER LIQUID - FLORAL ODOR Section IV — Fire and Explosion Hazard Data LEL UEL Flash Point (Method Used) Flammable Limits NONE N/A Extinguishing Media WATER, CARBON DIOXIDE, DRY CHEMICAL OR FOAM Special Fire Fighting Procedures FIREFIGHTERS SHOULD BE MADE AWARE OF PHENO LIC CONTENTS OF THIS MATERIAL SO THEY CAN WEAR APPROPRIATE PROTECTION. Unusual Fire and Explosion Hazards HIGHLY TOXIC GASES (CHLORINE) CAN BE EVOLVED.

Section V -	Reactivity Data					
Stability	Unstable		Conditions to Avoid N/A			
	Stable	х				
Incompatibility (Materials to Avoid)	STRO	ONG ACIDS.		· · · · ·	
Hazardous Decor	nposition or Byprodu	cts	IENOLICS, CAR BON MON	NOXIDE	, CARBON DIC	OXIDE, CHLORINE.
Hazardous Polymerization	May Occur		Conditions to Avoid N/A			
·	Will Not Occur	х				
Section VI -	Health Hazard	Data	·			
Route(s) of Entry	Inha	lation?	ACUTE S	kin? ACl	JTE	Ingestion? ACUTE
Health Hazards (Acute and Chronic) AY CAUSE IRRIT	ATIO	N. EYES - MAY CAUSE	IRRITA	TION.	
INGESTIO	N – HARMFUL	IFING	SESTED.		<u> </u>	
INHALAT	ION - CORROSI	VE TO	LUNGS.			
Carcinogenicity:	N/A	?	IA	ARC Mon	ographs?	OSHA Regulated?
Signs and Symp	toms of Exposure SKIN AND EYE I	RRITA	ATION. INHALATION – L	UNG II	RRITATION. IN	GESTION - DROWSINESS,
	RREGULAR PUI	_SE, L	OSS OF CONSCIOUSNESS	S.		
Medical Condition Generally Aggrav		BREA	THING PROBLEMS.			
	<u>-</u>					
WATER FOR	15 MIN. EYES-	FLUSI O NO	H WITH COPIOUS AMOUNT INDUCE VOMITING DE	ITS OF	WATER. IF IR	CAL ATTENTION. SKIN—FLUSH WITH RITATION PERSISTS GET MEDICAL TIES OF MILK, EGG WHITE, OR
•		_	le Handling and Use			
	en in Case Material I		ased or Spilled ABSORBENT MATERIAL.	PLACE	IN DRUMS FO	OR DISPOSAL
- DINCE WITH	5, 1, 15 511 52, 11 .					
			 			
Waste Disposal I		PROV	ED LANDFILL IN ACCO	RDANC	E WITH LOCAL	., STATE, & FEDERAL REGULATIONS.
December 1 - 0	- 				.,,	
—————	e Taken in Handling	and St	KEEP CONTAINER	CLOSE	STORE AWA	Y FROM STRONG ACIDS.
			STORE IN COOL PLA	ACE.		
Other Precaution	s KEEP OUT OF	REAC	H OF CHILDREN. TRIPLE	RINSE	CONTAINER	BEFORE DISPOSAL.
	DO NOT REUS	E CON	ITAINER.			
Section VIII	- Control Meas	ures				
Respiratory Prote	ection (Specify Type)	N/A		•		
Ventilation	Local Exhaust X				Special	
	Mechanical (Genera	u)	· .		Other	
Protective Gloves	RUBBER OR VII	NYI		Eye Pr	otection SAFETY	GOGGLES OR FACE SHIELD
Other Protective	Clothing or Equipme	nt	BBER OR VINYL APRON	L	JAFELI	GOGGELO ON FACE SHIELD
Work/Hygienic Pr	ractices		FAMINATED CLOTHING.		CLOTHING BEI	ORE RELISE
	TILIVIO V L	COIV	MANUAL ED CEOTHING.	** ^3П	CEOLUING BEI	ONE NEUGE.

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

Date of Issue: November 2010 Supersedes version of: October 2007 Page 1 of 2 P/N 48023G N.A. = not applicable, N.K. = not known

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

Trade Name: BioSonic® Enzymatic Ultrasonic Cleaner Cat. No. UC32

Manufacturer:

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

Raiffeisenstrasse 30 89129 Langenau/Germany Tel. +49 (0) 7345 805 0 Fax +49 (0) 7345 805 201

Authorized EU Representative

Coltène/Whaledent GmbH+ Co. KG

Emergency Contact Numbers: USA & Canada: +1 800 535 5053 Main Phone Number: +1 330 916 8800

2. Composition/Information on Ingredients

Chemical Characterization: Non-ionic detergent.

Hazardous Components

Chemical Name Index, R/S Phrases Weight % F, R11, S7-16 Isopropanol < 1%

Hazard Identification 3.

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.

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: > 200°F 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.

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:

CAS No. Chemical Name Type/Value Weight %

67-63-0 Isopropanol < 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

Date of Issue: November 2010 Coltène/Whaledent Inc. Page 2 of 2
N.A. = not applicable, N.K. = not known BioSonic® Enzymatic Ultrasonic Cleaner Cat. No. UC32 P/N 48023G

9. Physical and Chemical Properties

Appearance: Clear orange liquid

Boiling Point: 100°C (212°F)

Flash Point: < 93.3°C (200°F)

Flammability: Nonflammable

Vapor Pressure: 173 mmHg (25°C)

Additional of the properties of the p

pH: Conc., 6 - 8 Dilute (1:128) 6 - 8 Viscosity: 65 cps Method: Brookfield LVT#1, 30 RPM

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.

Sea Transport IMDG/GGV Sea Class: N.A.

DOT Hazard Class: Not regulated.

UN-No.: N.A.

EmS-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:

 Chemical Name
 CAS-No.
 Weight %

 Isopropanol
 67-63-0
 < 1%</td>

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: 11/29/2010 – Review, no changes. 10/2/07 Review No Changes. 4/28/06 Changed for consistent format. 1/12/06 Bi-annual review, changed to 1999/45/EC in section 3, 91/155/EEC changed to 2001/58/EC. 10/17/05 Bi-annual review. Updated Flammability information to show it is nonflammable instead of combustible. 5/4/05 Added EU Authorized Rep. 10/30/03 Changed to Company Format and Updated Address.

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.

Safety Data Sheet



ANSI Z400.1/Z129.1-2010

Biosonic® Enzymatic Ultrasonic Cleaning Concentrate

Issue Date: September 2014 Internal Document Number: 48232A Page 1 of 6

Section 1: PRODUCT AND COMPANY IDENTIFICATION

Product identifier

Product Name: Biosonic® Enzymatic Ultrasonic Cleaning Concentrate

Product Code(s): UC32, 09648, 09732, 09745, 40002030, 40002030, 50007603, 50007649

Relevant identified uses of the mixture and uses advised against: intended for use in an ultrasonic cleaner for cleaning medical devices. Not intended for the general public. Federal law restricts this device to sale by or on the order

of a physician. Uses advised against: None noted.

Synonyms: UC32, 3022

Manufacturer

Coltène/Whaledent Inc. 235 Ascot Parkway

Cuyahoga Falls, OH 44223 / USA

Phone: 1 330 916 8800 Fax: 1 330 916 7077

info.us@coltene.com

Authorized EC Representative EC REP

Coltène/Whaledent GmbH + Co. KG

Raiffeisenstraße 30 89129 Langenau

Phone: 49 7345 805 0 Fax: 49 7345 805 201 info.de@coltene.com **Emergency Contact Number:**

USA & Canada: 1 800 535 5053

Copies of this SDS can be found at

www.coltene.com

Section 2: HAZARDS IDENTIFICATION

Classification: Reproductive Toxicant / Category 1B, Serious Eye Irritant / Category 2

Appearance: Clear orange liquid, with floral / soapy odor

Contains: Sodium Tetraborate Decahydrate, Alkylpolyglycosides, Ethanolamine **Route(s) of Exposure:** Ingestion, Dermal (skin/eyes), Inhalation (vapors)

Labeling Elements:

Hazard Category Signal Word: Hazard Statements:

DANGER

Reproductive Toxicant /

Category 1B

Serious Eye Irritant /

Category 2

ignai word. Hazard Statements

H360FD: May damage fertility. May damage the unborn child.

H319: Causes serious eye

irritation

Prevention:

P201 P202 P281 Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Use personal protective

equipment as required.

P264 + P280 Wash hands
thoroughly after handling. Wear

eye protection.

Response:

P308 + P313 IF exposed or concerned: Get medical

advice/attention.

P305 + P351 + P338 + P337 + P313 If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. Storage:

P405 Store locked up.

P501 Dispose of contents/container in accordance with federal, state and local regulations

Disposal:





Safety Data Sheet



ANSI Z400.1/Z129.1-2010

Biosonic® Enzymatic Ultrasonic Cleaning Concentrate

Issue Date: September 2014 Internal Document Number: 48232A Page 2 of 6

Note: This product is not required to be classified as a Reproductive Toxicant when sold within the European Union. The borax concentration is below classification thresholds according the Regulation (EC) No 1272/2008. The classification applies for markets where national law has not established a cutoff limit for Borax.

Other hazards which do not result in classification: None noted

Classification in Accordance with 67/548/EEC and 1999/45/EC: Xi – Irritant, R36, S26 (see section 15 for full text)

PBT/vPvB Assessment: This product does not contain persistent, bioaccumulative and toxic chemicals (PBT's) nor does this product contain any very persistent and very bioaccumulative chemicals (vPvB's).

Section 3: COMPOSITION / INFORMATION ON INGREDIENTS

Substances within the mixture contributing to the classification of: Reproductive Toxicant / Category 1B, Serious Eye Irritant / Category 2

Substance (Synonyms)	CAS	EC Number	Index Number	Percent (w/w)
Sodium Tetraborate Decahydrate (Borax)	1303-96-4	215-540-4	005-011-01-1	0.50
Alkylpolyglycosides	68515-73-1	500-220-1	-	6.30
Ethanolamine (2-aminoethanol)	141-43-5	205-483-3	603-030-00-8	0.40

Section 4: FIRST AID MEASURES

Inhalation: If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, (trained personnel should) give oxygen. Get medical attention. (Get medical attention immediately.) (Call a physician.)

Eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

Skin: Wash contacted skin thoroughly after handling. If skin irritation occurs: Get medical advice/attention. Take off contaminated clothing and wash it before reuse.

Ingestion: If swallowed, call a poison control center or physician immediately. Do not induce vomiting unless directed to do so by a physician. Never give anything by mouth to an unconscious person.

Section 5: FIRE FIGHTING MEASURES

Extinguishing Media: In case of fire, use water fog, dry chemical, CO2 or "alcohol resistant" foam. Use foam, carbon dioxide (CO2) or dry chemical to extinguish fire. Caution: CO2 will displace air in confined spaces and may cause an oxygen deficient atmosphere.

Specific Hazards Arising from the Chemical: carbon oxides (CO, CO2) may be released as a result of combustion

Protective Equipment and Precautions for Firefighters: Standard protection for all firefighters stated in this subsection of the SDS text should include self-contained breathing apparatus (SCBA) and full firefighting turn-out gear (Bunker gear).

Section 6: ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment, and Emergency Procedures: Use personal protection recommended in Section 8.

Methods for Containment and Clean-up: Cover with absorbent material. Collect and dispose. Wash residue with soap and water. Do not rinse to drain.

Safety Data Sheet



ANSI Z400.1/Z129.1-2010

Biosonic® Enzymatic Ultrasonic Cleaning Concentrate

Issue Date: September 2014 Internal Document Number: 48232A Page 3 of 6

Other Information: Spills of this material do not need to be reported to the National Response Center.

Section 7: HANDLING AND STORAGE

Precautions for Safe Handling: Wash hands thoroughly after handling. Wear eye protection and impermeable gloves. Wear chemical splash goggles when eye contact is possible due to splashing or spraying of material.

Conditions for Safe Storage, Including Incompatibilities: Store at temperatures above 40°F (4°C) to prevent freezing. Freezing may impact the effectivity of the solution. Keep container closed when not in use. Keep out of reach of children.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Component Exposure Limits:

Component:	Concentration:	NIOSH REL:	OSHA PEL:	IDLH:	8hr TWA	STEL's	Notation
Sodium Tetraborate Decahydrate (also known as Borax, CAS 1303-96-4)	0.50 %w/w	TWA 5 mg/m3	none	none	none	none	none
Ethanolamine (CAS 141-43-5)	0.40 %w/w	TWA 3 ppm (8 mg/m3) ST 6 ppm (15 mg/m3)	TWA 3 ppm (6 mg/m3)	30 ppm	2.5 (mg/m ³)	7.6 (mg/m³)	Skin
Isopropyl Alcohol (CAS 67-63-0)	0.0044 %w/w	TWA 400 ppm (980 mg/m3) ST 500 ppm (1225 mg/m3)	TWA 400 ppm (980 mg/m3)	2000 ppm [10%LEL]	none	none	none

Appropriate Engineering Controls: No specific controls are needed.

Personal Protective Equipment (Eyes and Face): Wear chemical splash goggles when eye contact is possible due to splashing or spraying of material.

Personal Protective Equipment (Skin): It is a good industrial hygiene practice to minimize skin contact. For operations where prolonged or repeated skin contact may occur, impermeable gloves should be worn.

Personal Protective Equipment (Respiratory): It is a good industrial hygiene practice to minimize inhalation of vapors or mists.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Clear Orange Liquid Viscosity: 65 cps

Odor: Floral / Soapy (Brookfield LVT#1, 30 RPM)

Odor Threshold: No data VOC: No data

pH: Conc., 6 - 8 Dilute (1:128) 6 - 8 **Boiling Point:** 100°C (212°F)

Melting Point: Not applicable Solubility (H₂O): Infinitely Soluble

Specific Gravity: 1.03 g/cc (25°C) **Evaporation Rate:** No data Octanol / H₂O Coefficient (log k_{ow}): **Decomposition Temp:** No data No data **Molecular Weight:** No data LFL: No data **Auto Ignition:** No data UFL: No data

Flash Point: > 93.3°C (200°F) Vapor Pressure: 173 mmHg (25°C)

Vapor Density: No data Flammability Class: No data

Safety Data Sheet



ANSI Z400.1/Z129.1-2010

Biosonic® Enzymatic Ultrasonic Cleaning Concentrate

Issue Date: September 2014 Internal Document Number: 48232A Page 4 of 6

Section 10: STABILITY AND REACTIVITY

Chemical Stability: Chemically Stable

Possibility of Hazardous Reactions: This product is not known to be susceptible to chemical reactions that can result in

undesirable effect(s).

Conditions to Avoid: Freezing may impact the effectivity of the solution.

Incompatibility: Chemically-active metals such as potassium, beryllium, powdered aluminum, zinc, calcium, magnesium

& sodium acids should be avoided.

Hazardous Decomposition Products: No data.

Section 11: TOXICOLOGICAL INFORMATION

Likely Routes of Exposure: Ingestion, Dermal (skin/eyes), Inhalation (vapors)

Acute Effects:

Inhalation: All ingredients present in concentrations greater than 1 %w/w have an LC₅₀ greater than 20 mg/L.

Acute effects from vapors are not expected to be hazardous.

Eye Contact: Concentration of ingredients classified as Eye Category 1 or 2 has triggered classification of the

mixtures as hazardous to the eye. Symptoms of exposure are irritation, pain, swelling, lacrimation,

or photophobia.

Skin Contact: Contains 0.4%w/w Ethanolamine, Dermal LD₅₀ - 1025 mg/kg bodyweight. May be slightly irritating to

the skin.

Ingestion: All relevant ingredients present in quantities greater than 1 %w/w have an oral / dermal LD₅₀ greater

than 2000 mg/kg body weight. Acute effects from ingestion are not likely, Observe patients with ingestion carefully for the possible development of esophageal or gastrointestinal tract irritation or burns. If signs or symptoms of esophageal irritation or burns are present, consult a physician.

Sensitization: Propylene Glycol is not expected to cause sensitization by skin contact; however, skin reactions of unknown etiology have been described in some hypersensitive individuals following topical application. Propylene Glycol in cats, two studies of at least 90 days duration show that a species-specific effect of increased Heinz bodies was observed (NOAEL = 80 mg/kg bw/day; LOAEL = 443 mg/kg bw/day), with other hematological effects (decrease in number of erythrocytes and erythrocyte survival) reported at higher doses (6-12% in diet, or 3.7-10.1 g/cat/day).

Protease enzymes have also been known to cause skin sensitization; however, the enzymes are not present in concentrations great enough to warrant classification of Skin Sensitizer.

Carcinogenicity: this product does not contain any substances classified as carcinogens by NTP, ACGIH, IARC or OSHA.

Component Carcinogenicity: not applicable **Mutagenicity:** this product is not a mutagen.

Reproductive Toxicity: this product contains 0.50%w/w Sodium Tetraborate Decahydrate (also known as Borax, CAS 1303-96-4) suspended in solution: There have been limited animal studies which suggest decreased ovulation, fetotoxicity and developmental defects may occur with very high exposure levels. Maternal toxicity was present in some studies.

Specific Target Organ Toxicity - Single Exposure (STOT-SE): not established

Specific Target Organ Toxicity - Repeated or Prolonged Exposure (STOT-RE): skin sensitization may occur.

Safety Data Sheet



ANSI Z400.1/Z129.1-2010

Biosonic® Enzymatic Ultrasonic Cleaning Concentrate

Issue Date: September 2014 Internal Document Number: 48232A Page 5 of 6

Section 12: ECOLOGICAL INFORMATION

Ecotoxicity: Not an acute or chronic ecotoxicant.

PBT/vPvB Assessment: This product does not contain persistent, bioaccumulative and toxic chemicals (PBT's) nor does this product contain any very persistent and very bioaccumulative chemicals (vPvB's).

Persistence / Degradability: degradable

Aquatic Toxicity: all ingredients within this product are not classified as toxic to aquatic organisms. Constituents are either stated by sources as "not toxic to aquatic life" or exhibit toxicities of greater than the endpoints for classification.

Bioaccumulative Potential: low.

Mobility in Soil: highly mobile in soil

Other Adverse Effects: none noted

Section 13: DISPOSAL CONSIDERATIONS

Disposal: dispose of in accordance with federal, state and local regulations.

Additional Disposal Considerations: dispose if shelf-life has been exceeded.

Section 14: TRANSPORT INFORMATION

Emergency Response Guide Number: Not Listed

Department of Transportation: this product is not hazardous for shipment.

UN Proper Shipping Name: Not Applicable

Hazard Class: Not Applicable

Packing Group: Not Applicable

Section 15: REGULATORY INFORMATION

SARA Sections 302 and 304: this product does not contain Extremely Hazardous Substances (EHS) and is not subject to emergency planning requirements.

CERCLA: this product does not contain CERCLA Hazardous Substances and is not subject to reporting requirements.

SARA Section 313: substances within this product are not required to be reported in accordance with SARA 313 or the substances within are exempt by rules for "de minimis concentrations of a toxic chemical in a mixture" §372.38(a).

.The following components appear on one or more of the following state hazardous substances list(s):

Component	CAS	CA	MA	MN	NJ	PA	RI
Triethanolamine	102-71-6	N	N	N	Υ	N	Υ
Ethanolamine (2-aminoethanol)	141-43-5	N	N	N	Υ	N	Υ
propane-1,2-diol (Propylene Glycol)	57-55-6	N	N	N	Υ	N	N
Isopropyl Alcohol	67-63-0	N	N	N	Υ	Υ	Υ

Safety Data Sheet



ANSI Z400.1/Z129.1-2010

Biosonic® Enzymatic Ultrasonic Cleaning Concentrate

Issue Date: September 2014 Internal Document Number: 48232A Page 6 of 6

Sodium Tetraborate Decahydrate (Borax) 1303-96-4 N N N N N Y

California Proposition 65: There are no chemicals within this mixture on the Proposition 65 List.

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.

International Inventories:

US (TSCA): The components within this product are included on the TSCA Inventory of Chemical Substances

Canada (DSL): All ingredients are on the inventory or exempt from listing.

European Union (EINECS): All ingredients conform to the EU requirements.

Japan (ENCS): All other ingredients are on the inventory or exempt from listing.

Philippines (PICCS): All other ingredients are on the inventory or exempt from listing.

South Korea (KECL): All ingredients are on the Inventory or exempt from listing.

Australia (AICS): All ingredients are on the Inventory or exempt from listing.

New Zealand (NZIoC): All ingredients are on the Inventory or exempt from listing.

China (IECSC): All ingredients are on the Inventory or exempt from listing.

Classification in Accordance with 67/548/EEC and 1999/45/EC full text: Xi – Irritant, R36 Irritating to eyes, S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

Section 16: OTHER INFORMATION

National Fire Protection Association (NFPA) Hazardous

Hazardous Material Information System (HMIS®)

NFPA Ratings:

HMIS Ratings:

Health: 1
Fire: 1

Reactivity: 0

Health: 1
Fire: 1

Reactivity: 0

(NFPA and HMIS Hazard Scale: 0 = Minimal 1 = Slight 2 = Moderate 3 = Serious 4 = Severe)

	REVISION HISTORY						
REVISION	DATE	ECN#	CHG BY	APPR BY	DESC. OF CHANGE		
А	09/12/14	14378	SBL	SBL	Updated MSDS to GHS/SDS Format. P/N 48232 Revision A was 48023 Revision H.		

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

UC32 BioSonic Enzymatic Ultrasonic Cleaner

Print date: 15.02.2018 Revision date: 13.05.2016 Page 1 of 6

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

1.1. Product identifier

UC32 BioSonic Enzymatic Ultrasonic Cleaner

Further trade names

Cat. No. UC32

48023

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: COLTENE/Whaledent Inc.

Street: 235 Ascot Parkway Place: Cuyahoga Falls, OH 44223/USA

Telephone: +1 (330) 916 8800 Telefax: +1 (330) 916 7077 e-mail: info.us@coltene.com www.coltene.com Internet:

Authorized Representative

COLTENE/Whaledent GmbH & Co. KG Company name:

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

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No. 1272/2008

Hazard categories:

Serious eye damage/eye irritation: Eye Dam. 1

Hazard Statements:

Causes serious eye damage.

This product is not required to be classified as a Reproductive Toxicant when sold within the European Union . The borax concentration is below classification thresholds according the Regulation (EC) No 1272/2008. The classification H360FD applies for markets where national law has not established a cutoff limit for Borax.

2.2. Label elements

Regulation (EC) No. 1272/2008

Hazard components for labelling

Alkyl Polyglycosides

Signal word: Danger

Pictograms:



Hazard statements

H318 Causes serious eye damage.

Revision No. 2 GB - FN



according to Regulation (EC) No 1907/2006

UC32 BioSonic Enzymatic Ultrasonic Cleaner

Revision date: 13.05.2016 Print date: 15.02.2018 Page 2 of 6

Precautionary statements

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read and understood.

P264 Wash hands thoroughly after handling.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

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 doctor.

P405 Store locked up.

Special labelling of certain mixtures

EUH208 Contains Protease. May produce an allergic reaction.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Hazardous components

CAS No	Chemical name	Chemical name				
	EC No	Index No	REACH No			
	Classification according to Regulation (EC) No. 1272/2008 [CLP]					
68515-73-1	Alkyl Polyglycosides					
	500-220-1					
	Eye Dam. 1, Aquatic Acute 3; H318 H402					
1303-96-4	disodium tetraborate decahydrate; borax decahydrate					
	215-540-4	005-011-01-1				
	Repr. 1B; H360FD					

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.

In all cases of doubt, or when symptoms persist, seek medical advice.

After contact with skin

After contact with skin, wash immediately with: Water and soap.

Change contaminated clothing.

In case of skin irritation, seek medical treatment.

After contact with eyes

After contact with the eyes, rinse with water with the eyelids open for a sufficient length of time, then consult an ophthalmologist immediately.

After ingestion

Do NOT induce vomiting. Let water be drunken in little sips (dilution effect). Seek medical advice.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

Water spray. Foam. Extinguishing powder. Carbon dioxide (CO2). Sand.

Additional information

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



according to Regulation (EC) No 1907/2006

UC32 BioSonic Enzymatic Ultrasonic Cleaner

Revision date: 13.05.2016 Print date: 15.02.2018 Page 3 of 6

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

See protective measures under point 7 and 8.

6.2. Environmental precautions

Do not allow to enter into surface water or drains.

6.3. Methods and material for containment and cleaning up

Wipe up with absorbent material (eg. cloth, fleece). Clear contaminated areas thoroughly.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling

Avoid contact with skin and eyes.

for professional use only Keep out of the reach of children.

Advice on protection against fire and explosion

Keep away from sources of ignition - No smoking.

Further information on handling

Always close containers tightly after the removal of product.

7.2. Conditions for safe storage, including any incompatibilities

Further information on storage conditions

Recommended storage temperature: >0 °C

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Exposure limits (EH40)

CAS No	Substance	ppm	mg/m³	fibres/ml	Category	Origin
1303-96-4	Disodium tetraborate, decahydrate	-	5		TWA (8 h)	WEL
		-	-		STEL (15 min)	WEL

8.2. Exposure controls

Protective and hygiene measures

When using do not eat, drink or smoke.

Eye/face protection

Framed glasses.

Hand protection

Wear suitable gloves.

Skin protection

Lab apron.

Respiratory protection

Provide adequate ventilation.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state: liquid
Colour: orange
Odour: characteristic



according to Regulation (EC) No 1907/2006

UC32 BioSonic Enzymatic Ultrasonic Cleaner

Revision date: 13.05.2016 Print date: 15.02.2018 Page 4 of 6

Test method

pH-Value: 6 - 8

Changes in the physical state

Initial boiling point and boiling range:

Flash point:

Vapour pressure:

No Data

Density (at 25 °C):

Water solubility:

Viscosity / dynamic:

100 °C

No Data

1.03 g/cm³

8 desily soluble.

65 mPa·s

SECTION 10: Stability and reactivity

10.2. Chemical stability

The substance is chemically stable under recommended conditions of storage, use and temperature.

10.4. Conditions to avoid

heat.

10.5. Incompatible materials

Oxidizing agents.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity

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

Irritation and corrosivity

Causes serious eye damage.

Skin corrosion/irritation: Based on available data, the classification criteria are not met.

Sensitisina 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

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

Aspiration hazard

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

Additional information on tests

SECTION 12: Ecological information

12.2. Persistence and degradability

Biodegradable.

12.3. Bioaccumulative potential

Partition coefficient n-octanol/water

CAS No	Chemical name	Log Pow
1303-96-4	disodium tetraborate decahydrate; borax decahydrate	-1,53



according to Regulation (EC) No 1907/2006

UC32 BioSonic Enzymatic Ultrasonic Cleaner

Revision date: 13.05.2016 Print date: 15.02.2018 Page 5 of 6

Further information

According to the criteria of the EC-classification and labelling "dangerous for the environment" (93/21/EEC) the material/product is not to be classified as dangerous to the environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Advice on disposal

Dispose of waste according to applicable legislation.

SECTION 14: Transport information

Land transport (ADR/RID)

<u>14.1. UN number:</u> ---

Marine transport (IMDG)

14.1. UN number: ---

Air transport (ICAO-TI/IATA-DGR)

<u>14.1. UN number:</u> ---

Other applicable information

No dangerous good in sense of these transport regulations.

SECTION 15: Regulatory information

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

EU regulatory information

Authorisations (REACH, annex XIV):

Substances of very high concern, SVHC (REACH, article 59):

disodium tetraborate decahydrate; borax decahydrate

Restrictions on use (REACH, annex XVII):

Entry 30: disodium tetraborate decahydrate; borax decahydrate

Additional information

Safety Data Sheet according to Regulation (EC) No. 1907/2006 (REACH)

National regulatory information

Additional information

Canada WHMIS: This product has been classified according to the hazard criteria of the CPR and the MSDS contains all the information required by the CPR.

SECTION 16: Other information

Relevant H and EUH statements (number and full text)

H318 Causes serious eye damage.

H360FD May damage fertility. May damage the unborn child.

H402 Harmful to aquatic life.

EUH208 Contains Protease. May produce an allergic reaction.

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.



according to Regulation (EC) No 1907/2006

UC32 BioSonic Enzymatic Ultrasonic Cleaner

Revision date: 13.05.2016 Print date: 15.02.2018 Page 6 of 6

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