

Biosonic® Enzymatic Ultrasonic Cleaning Solution

Coltene Inc.

Internal Document Number: 48232B (EU)

Revision Date: October 2020

Section 1 - IDENTIFICATION

Product Names: Biosonic® Enzymatic Ultrasonic Cleaning Solution**Product Codes:** UC32, 40002030, 50007603, 50007649**Recommended Use:** Intended for use in an ultrasonic cleaner for cleaning medical devices.**Restrictions on Use:** Not intended for the general public. Federal law restricts this product to sale to or on the order of a physician.**Manufacturer**

Coltene/Whaledent Inc.
235 Ascot Parkway
Cuyahoga Falls, OH 44223
USA
Phone: 1 330 916 8800
E-mail: info.us@coltene.com
Fax: 1 330 916 7077

Authorized EC Representative

Coltene/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 - HAZARD(S) IDENTIFICATION

Classification in accordance with (EC) No. 1907/2006

Hazard Category, Subcategory: Toxic to Reproduction Category – 1B
Serious Eye Damage / Eye Irritation – Category – 2A

GHS Label Elements:**Symbol(s)****Signal Word:**

Danger

Hazard Statement(s):

Causes serious eye irritation

Precautionary Statement(s):**Prevention:**

Obtain special instructions before use. Do not handle until all safety instructions have been read and understood. Use personal protective equipment as required, safety glasses/goggles and protective gloves. Wash hands thoroughly after handling.

Response:

If exposed or concerned, get medical advice/attention. If in eyes: Rinse cautiously with water with several minutes. Remove contact lenses, if present and it's easy to do so. Continue rinsing for at least 15 minutes. If eye irritation persists, get medical advice/attention.

Storage:

Store locked up. Keep out of reach of children.

Disposal:

Dispose of in accordance with local, state and federal regulations.

Biosonic® Enzymatic Ultrasonic Cleaning Solution

Coltene Inc.

Internal Document Number: 48232B (EU)

Revision Date: October 2020

Statement(s) of Unknown Acute Toxicity:

Zero % of the mixture consists of ingredient(s) of unknown acute toxicity.

Other Hazards which do not result in classification:

This product is not required to be classified as a reproductive toxicant in the European Union since the European Chemical Agency (ECHA) has accepted a Specific Concentration Limit of >6.5% for Disodium Tetraborate Pentahydrate (Borax). A Specific Concentration Limit for Borax in the United States has not been established. Therefore, in the United States, Borax must be classified as a reproductive toxicant in a SDS, if the level exceeds 0.1% of the product.

Section 3 - COMPOSITION / INFORMATION ON INGREDIENTS

Chemical Name	CAS number	Percent (w/w%)
Disodium Tetraborate Pentahydrate	12179-04-3	.50
Alkylpolyglycosides	68515-73-1	6.30
Propylene Glycol	57-55-6	15.00

Section 4 - FIRST AID MEASURES**Description of Necessary Measures:**

Inhalation: Not likely to cause a problem. Contact a physician if you are concerned or feel unwell.

Skin: Not expected to affect skin upon contact however, if exposed wash skin thoroughly with soap and water. If irritation develops and persists contact a physician.

Eyes: Flush eyes with copious amounts of water for at least 15 minutes. Remove contact lenses if present and it's easy to do so. If irritation, pain, swelling, lacrimation or photophobia persist, contact a physician.

Ingestion: If swallowed contact a physician or poison control center. Do not induce vomiting.

Section 5 - FIRE-FIGHTING MEASURES

Extinguishing Media: Water, CO₂, dry chemical or foam are acceptable extinguishing media.

Unsuitable Extinguishing Media: None known

Specific Hazards Arising from the Chemical: Carbon oxides (carbon monoxide, carbon dioxide) may be released as a result of combustion.

Special Protective Equipment and Precautions for Firefighters: Wear protective equipment and self-contained breathing apparatus (SCBA) per fire department's SOP.

Section 6 - ACCIDENTAL RELEASE MEASURES

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

Methods and Materials for Containment and Cleaning Up: Cover with absorbent material. Collect and dispose. Wash residue with soap and water. Do not rinse into drain.

Safety Data Sheet



Biosonic® Enzymatic Ultrasonic Cleaning Solution

Coltene Inc.

Internal Document Number: 48232B (EU)

Revision Date: October 2020

Section 7 - HANDLING AND STORAGE

Precautions for Safe Handling: Wash hands thoroughly after handling. Wear eye protection and protective gloves.

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

Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

Component Exposure Limits:

Component	Concentration	CAS #	OSHA: PEL	ACGIH	NIOSH: REL
Disodium Tetraborate Pentahydrate (Borax)	0.50%w/w	12179-04-3	None	None	5 mg/m ³
Alkylpolyglycosides	6.30%w/w	68515-73-1	None	None	None
Propylene Glycol	15.00%w/w	57-55-6	None	None	None

ACGIH - Threshold Limit Values - Biological Exposure Indices (BEI)

There are no biological limit values for any of this product's components.

Appropriate Engineering Controls:

General ventilation is sufficient.

Individual Protection Measures, such as Personal Protective Equipment (non-molten state):

Eye/Face protection:

Chemical safety goggles or face shield when eye contact is possible due to splashing of material, otherwise, safety glasses are sufficient.

Skin Protection:

Wear protective gloves.

Respiratory Protection:

Not required with adequate ventilation.

Section 9 - PHYSICAL AND CHEMICAL PROPERTIES

Appearance	Clear orange	Physical State	Liquid
Odor	Floral, soapy	Color	Orange tint
Odor Threshold	Not available	pH	Conc. 6-8 Dilute(1:128) 6-8
Melting Point	Not applicable	Flammability class	None
Boiling Point	100°C (212°F)	Freezing point	~ 0°C (32°F)
Evaporation Rate	Not applicable	Molecular Weight	Not available
Autoignition Temperature	Not applicable	Flash Point	Above 93.3°C (200°F)
Lower Explosive Limit	Not applicable	Decomposition temperature	Not available

Safety Data Sheet



Biosonic® Enzymatic Ultrasonic Cleaning Solution

Coltene Inc.

Internal Document Number: 48232B (EU)

Revision Date: October 2020

Upper Explosive Limit	Not applicable	Vapor Pressure	173 mmHg
Vapor Density (air=1)	Not available	Relative Density(water=1)	1.03 g/ml
Water Solubility	Infinitely soluble	Partition coefficient: n-octanol/water	Not available
Viscosity	65 cps	Kinematic viscosity	Not available
Solubility (Other)	Not available	Density	Not available

Section 10 - STABILITY AND REACTIVITY

Chemical Stability:

Chemically Stable

Possibility of Chemical Reactions:

No data available

Incompatible Materials:

Chemically active metals such as potassium, beryllium, aluminum powder, zinc, calcium, magnesium and sodium acids should be avoided.

Hazardous Decomposition Products:

No data available

Section 11 - TOXICOLOGICAL INFORMATION

Information on Routes of Exposure: Skin, eyes, ingestion, inhalation

Skin: May cause irritation with prolonged exposure.

Eye Contact: Irritation, pain, swelling, lacrimation and or photophobia

Ingestion: May cause irritation to the digestive tract.

Inhalation: Acute effects from vapors are not expected to be hazardous.

Sensitization: Propylene Glycol (15%w/w) 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.

Reproductive Toxicity:

This product contains 0.50%w/w Disodium Tetraborate Pentahydrate (commonly known as Borax), 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. Ingestion of this solution in quantities high enough to impact reproduction is not likely.

Section 12 - ECOLOGICAL INFORMATION

Non-Mandatory Section

Ecotoxicity

Component Analysis - Aquatic Toxicity:

Material is not considered harmful to the environment.

Persistence and Degradability:

This material degrades in the environment.

Biosonic® Enzymatic Ultrasonic Cleaning Solution

Coltene Inc.

Internal Document Number: 48232B (EU)

Revision Date: October 2020

Bioaccumulative Potential:

The material will not bioconcentrate in fish and aquatic organisms nor will it absorb to sediment and suspended organic matter.

Mobility in Soil:

High mobility in soil

Other Adverse Effects:

None known

The product does not contain persistent, bioaccumulative and toxic chemicals (PBT) nor does this product contain any very persistent and very bioaccumulative chemicals (vPvB).

Section 13 - DISPOSAL CONSIDERATIONS**Non-Mandatory Section****Disposal Methods:**

Dispose of in accordance with local, state and federal regulations.

Component Waste Numbers:

The U.S. EPA has not published waste numbers for this products components.

Additional Disposal Considerations:

Dispose of is shelf-life is exceeded.

Section 14 - TRANSPORT INFORMATION**Non-Mandatory Section**

Emergency Response Guide Number: Not applicable

ADR, DOT & TDG Information:

Not Regulated

Environmental Hazards:

None

International Bulk Chemical Code

The product does not contain any chemicals required by the IBC Code to be defined as dangerous chemicals in bulk.

IATA & IMDG Information:

Not Regulated

Section 15 - REGULATORY INFORMATION**Non-Mandatory Section****U.S. Federal Regulations**

None of this product's components are listed under SARA Sections 302/304 (40 CFR 355 Appendix A), SARA Section 313 (40 CFR 372.65), CERCLA (40 CFR 302.4), TSCA 12(b), or require an OSHA process safety plan.

SARA Section 311/312 (40 CFR 370 Subparts B and C) reporting categories [Classification according to SARA Section 311/312.]:

Not Classified

U.S. State Regulations

None of this product's components are listed on the state lists from CA, MA, MN, NJ or PA.

Biosonic® Enzymatic Ultrasonic Cleaning Solution

Coltene Inc.

Internal Document Number: 48232B (EU)

Revision Date: October 2020

The following statement(s) are provided under the California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65):
Not listed under California Proposition 65.

Canada Regulations:**CEPA – Priority Substance list**

None of this product's components are on the list.

Ozone Depleting Substances:

None of this product's components are on the list.

Council of Ministers of the Environment – Soil Quality Guidelines

None of this product's components are on the list.

Council of Ministers of the Environment – Water Quality Guidelines

None of this product's components are on the list.

Section 16 - OTHER INFORMATION*HMIS and NFPA Ratings are not required, but are often found in Section 16.***HMIS Rating**

Health: [1] Fire: [1] Reactivity: [0]

Hazard Scale: 0 = Minimal 1 = Slight 2 = Moderate 3 = Serious 4 = Severe * = Chronic hazard

NFPA Ratings

Health: [1] Fire: [1] Reactivity: [0] Other:

Hazard Scale: 0 = Minimal 1 = Slight 2 = Moderate 3 = Serious 4 = Severe

REVISION HISTORY

REVISION	DATE	ECN #	CHG BY	CHK BY	APPR. BY	DESCRIPTION OF CHANGE
A	9/25/14	14378	SBL	SBL	SBL	Updated MSDS to GHS/SDS format. 48232 Revision A supersedes 48023 Revision H
EU	10/20/20		PMc	ES	PMc	Made various changes and updated to (EC) No. 1907/2006 Regulations

Key / Legend:

ACGIH - American Conference of Governmental Industrial Hygienists; ADR - European Road Transport; AU - Australia; BOD - Biochemical Oxygen Demand; C - Celsius; CA - Canada; CA/MA/MN/NJ/PA - California/Massachusetts/Minnesota/New Jersey/Pennsylvania*; CAS - Chemical Abstracts Service; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CFR - Code of Federal Regulations (US); CLP - Classification, Labelling, and Packaging; CN - China; CPR - Controlled Products Regulations; DFG - Deutsche Forschungsgemeinschaft; DOT - Department of Transportation; DSD - Dangerous Substance Directive; DSL - Domestic Substances List; EC - European Commission; EEC - European Economic Community; EIN - European Inventory of (Existing Commercial Chemical Substances); EINECS - European Inventory of Existing Commercial Chemical Substances; ENCS - Japan Existing and New Chemical Substance Inventory; EPA - Environmental Protection Agency; EU - European Union; F - Fahrenheit; F - Background (for Venezuela Biological Exposure Indices); IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; ICAO - International Civil Aviation Organization; IDL - Ingredient Disclosure List; IDLH - Immediately Dangerous to Life and Health; IMDG - International Maritime Dangerous Goods; ISHL - Japan Industrial Safety and Health Law; IUCLID - International Uniform Chemical Information Database; JP - Japan; Kow - Octanol/water partition coefficient; KR KECI Annex 1 - Korea Existing Chemicals Inventory (KECI) / Korea Existing Chemicals List (KECL); KR KECI Annex 2 - Korea Existing Chemicals Inventory (KECI) / Korea Existing Chemicals List (KECL) , KR - Korea; LD50/LC50 - Lethal Dose/ Lethal Concentration; LEL - Lower Explosive Limit; LLV - Level Limit Value; LOLI - List Of Lists™ - ChemADVISOR's Regulatory Database; MAK - Maximum Concentration Value in the Workplace; MEL - Maximum Exposure Limits; MX - Mexico; Ne- Non-specific; NFPA - National Fire Protection Agency; NIOSH - National Institute for Occupational Safety and Health; NJTSR - New Jersey Trade Secret Registry; Nq - Non-quantitative; NSL - Non-Domestic Substance List (Canada); NTP - National Toxicology Program; NZ - New Zealand; OSHA - Occupational Safety and Health Administration; PEL - Permissible Exposure Limit; PH - Philippines; RCRA - Resource Conservation and Recovery Act; REACH- Registration, Evaluation, Authorisation, and restriction of Chemicals; RID - European Rail Transport; SARA - Superfund Amendments and Reauthorization Act; Sc - Semi-quantitative; STEL - Short-term Exposure Limit; TCCA - Korea Toxic Chemicals Control Act; TDG - Transportation of Dangerous Goods; TLV - Threshold Limit Value; TSCA - Toxic Substances Control Act; TW - Taiwan; TWA - Time Weighted Average; UEL - Upper Explosive Limit; UN/NA - United Nations /North American; US - United States; VLE - Exposure Limit Value (Mexico); VN (Draft) - Vietnam (Draft); WHMIS - Workplace Hazardous Materials Information System (Canada).

Biosonic® Enzymatic Ultrasonic Cleaning Solution

Coltene Inc.

Internal Document Number: 48232B (EU)

Revision Date: October 2020

Other Information:

DISCLAIMER: Information included in this Safety Data Sheet was obtained from sources which we believe are accurate and reliable as of the date hereof. HOWEVER, NO REPRESENTATIONS OR WARRANTIES, EITHER EXPRESSED OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR COURSE OF PERFORMANCE OR USAGE OF TRADE. User is responsible for determining whether the product is fit for a particular purpose and suitable for user's method of use or application. Given the variety of factors that can affect the use and application of the product, some of which are uniquely within the user's knowledge and control, it is essential that the user evaluate the product to determine whether it is fit for a particular purpose and suitable for user's method of use or application. Coltene/Whaledent Inc., assumes no risk or responsibility for adverse events which may occur in the use and/or misuse of this product and expressly disclaims liability for loss, damage and/or expense arising out of or in any way connected with the handling, storage, use and/or disposal of this product.