Safety Data Sheet

ANSI Z400.1/Z129.1-2010

Biosonic® General Purpose Ultrasonic Cleaning Solution

Section 1: PRODUCT AND COMPANY IDENTIFICATION

Product identifier

Product Name: Biosonic® General Purpose Ultrasonic Cleaning Solution

Product Code(s): UC30, 09534, 09396, 40001943, 50007498

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: UC30, 3021

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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: Transparent, Blue, with amine/ alcohol odor
Contains: Disodium Tetraborate Pentahydrate, Alkylpolyglycosides
Route(s) of Exposure: Ingestion, Dermal (skin/eyes), Inhalation (vapors)

Labeling Elements:

Hazard Category	Signal Word:	Hazard Statements:
Reproductive Toxicant / Category 1B	DANGER	H360FD: May damage fertility. May damage the unborn child.
Serious Eye Irritant / Category 2		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.

Disposal:

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

~Verified on 2014-10 by Henry Schein to be the most current version of the SDS. To be verified again on 2017-10. ~

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)
Disodium Tetraborate Pentahydrate	12179-04-3	215-540-4	005-011-02-9	0.50
Alkylpolyglycosides	68515-73-1	500-220-1	-	6.30

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.

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 40ºF (4ºC) 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
Disodium Tetraborate Pentahydrate (also known as Borax, CAS 12179-04-3)	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/m^3)	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:	Transparent, Blue Liquid	**Viscosity:**	50 cps
Odor:	Faint Alcohol	(Brookfield LVT#1, 30 RPM)	
Odor Threshold:	No data	**VOC:**	No data
pH:	Conc, 7 - 9 Dilute (1:64) 8 - 9	**Boiling Point:**	100°C (212°F)
Melting Point:	Not applicable	**Solubility (H_2O):**	Infinitely Soluble
Specific Gravity:	1.07 g/cc (25°C)	**Evaporation Rate:**	No data
Octanol / H_2O Coefficient (log k_{ow}):	No data	**Decomposition Temp:**	No data
Molecular Weight:	No data	**LFL:**	No data
Auto Ignition:	No data	**UFL:**	No data
Flash Point:	Above 220ºF (104ºC)	**Vapor Pressure:**	181 mmHg (25°C)
Vapor Density:	No data	**Flammability Class:**	No data

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 LC_{50} 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 LD_{50} - 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 LD_{50} 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).

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 Disodium Tetraborate Pentahydrate; (also known as Borax, CAS 12179-04-3) 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.

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

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

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

UN Number: 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
Propane-1,2-Diol	57-55-6	N	N	N	Y	N	N
Isopropanol	67-63-0	N	N	N	Y	Y	Y
Disodium Tetraborate Pentahydrate; Borax Pentahydrate	12179-04-3	N	N	N	N	N	Y
Ethanolamine	141-43-5	N	N	N	Y	N	Y
benzenemethanaminium, n-ethyl-n-[4-[[4-[ethyl[(3-sulfophenyl)methyl]amino]phenyl](2-sulfophenyl)methylene]-2,5-cyclohexadien-1-ylidene]-3-sulfo-, inner salt, diammonium salt (acid blue 9)	4474-24-2	N	N	N	Y	N	N

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)

NFPA Ratings:

Health: 1
Fire: 1
Reactivity: 0

Hazardous Material Information System (HMIS®)

HMIS Ratings:

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
A	09/12/14	14378	SBL	SBL	Updated MSDS to GHS/SDS Format. P/N 48230 Revision A was 48022 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.

~Verified on 2014-10 by Henry Schein to be the most current version of the SDS. To be verified again on 2017-10. ~