

according to Regulation (EC) No 1907/2006

UC40 BioSonic Universal Ultrasonic Cleaner Concentrate

Revision date: 13.06.2017

Print date: 15.02.2018

Page 1 of 9

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1. Product identifier**

UC40 BioSonic Universal Ultrasonic Cleaner Concentrate

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**

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 number: +49 (0) 6132-84463 GBK GmbH Global Regulatory Compliance (24 h)

SECTION 2: Hazards identification**2.1. Classification of the substance or mixture****Regulation (EC) No. 1272/2008**

Hazard categories:

Acute toxicity: Acute Tox. 4

Serious eye damage/eye irritation: Eye Dam. 1

Hazard Statements:

Harmful if inhaled.

Causes serious eye damage.

2.2. Label elements**Regulation (EC) No. 1272/2008****Hazard components for labelling**

2-butoxyethanol, butyl cellosolve, ethylene glycol monobutyl ether

tetrasodium ethylene diamine tetraacetate

Alcohol, C9-11, Ethoxylated (9EO)

Sodium-N-lauroylsarcosinate

Signal word: Danger**Pictograms:****Hazard statements**

H318 Causes serious eye damage.

H332 Harmful if inhaled.

Precautionary statements

P101 If medical advice is needed, have product container or label at hand.

P102 Keep out of reach of children.

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

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

P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

according to Regulation (EC) No 1907/2006

UC40 BioSonic Universal Ultrasonic Cleaner Concentrate

Revision date: 13.06.2017

Print date: 15.02.2018

Page 2 of 9

2.3. Other hazards

The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII.

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]			
111-76-2	2-butoxyethanol, butyl cellosolve, ethylene glycol monobutyl ether			2 - 6 %
	203-905-0	603-014-00-0		
	Acute Tox. 4, Acute Tox. 4, Acute Tox. 4, Skin Irrit. 2, Eye Irrit. 2; H302 H312 H332 H315 H319			
64-02-8	tetrasodium ethylene diamine tetraacetate			1 - 2 %
	200-573-9	607-428-00-2		
	Acute Tox. 4, Eye Dam. 1; H302 H318			
68439-45-2	Alcohol, C9-11, Ethoxylated (9EO)			1 - 2 %
	Acute Tox. 4, Eye Dam. 1; H302 H318			
137-16-6	Sodium-N-lauroylsarcosinate			<0,45 %
	205-281-5			
	Acute Tox. 1, Skin Irrit. 2, Eye Dam. 1; H330 H315 H318			

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.

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. Do NOT induce vomiting. Seek medical advice immediately.

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

After skin contact: Irritant, erythema (redness).

Following eye contact: Conjunctival redness.

In case of ingestion: erythema (redness), Nausea.

Following inhalation: Irritation to respiratory tract.

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

Treat symptomatically.

SECTION 5: Firefighting measures
5.1. Extinguishing media

according to Regulation (EC) No 1907/2006

UC40 BioSonic Universal Ultrasonic Cleaner Concentrate

Revision date: 13.06.2017

Print date: 15.02.2018

Page 3 of 9

Suitable extinguishing media

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

5.2. Special hazards arising from the substance or mixture

Non-flammable.

In case of fire may be liberated: Gases/vapours, toxic.

5.3. Advice for firefighters

In case of fire: Wear self-contained breathing apparatus. Full protection suit.

Additional information

Suppress gases/vapours/mists with water spray jet. Use water spray jet to protect personnel and to cool endangered containers. 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

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

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). Treat the recovered material as prescribed in the section on waste disposal.

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

Provide adequate ventilation. Do not breathe gas/fumes/vapour/spray. Avoid: Generation/formation of mist.

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

Keep container tightly closed. Keep in a cool, well-ventilated place. Provide adequate ventilation as well as local exhaustion at critical locations.

Advice on storage compatibility

Do not store together with: Strong acid. Oxidising agent, strong.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Exposure limits (EH40)

CAS No	Substance	ppm	mg/m ³	fibres/ml	Category	Origin
111-76-2	2-Butoxyethanol	25	123		TWA (8 h)	WEL
		50	246		STEL (15 min)	WEL

according to Regulation (EC) No 1907/2006

UC40 BioSonic Universal Ultrasonic Cleaner Concentrate

Revision date: 13.06.2017

Print date: 15.02.2018

Page 4 of 9

Biological Monitoring Guidance Values (EH40)

CAS No	Substance	Parameter	Value	Test material	Sampling time
111-76-2	2-Butoxyethanol	butoxyacetic acid	240 mmol/mol	urine	Post shift

DNEL/DMEL values

CAS No	Substance			
DNEL type	Exposure route	Effect	Value	
137-16-6	Sodium-N-lauroylsarcosinate			
Consumer DNEL, acute	inhalation	systemic	5,0 mg/m ³	
Consumer DNEL, acute	oral	systemic	0,15 mg/kg bw/day	

PNEC values

CAS No	Substance		
Environmental compartment	Value		
137-16-6	Sodium-N-lauroylsarcosinate		
Freshwater	0,029 mg/l		
Marine water	0,003 mg/l		

Additional advice on limit values

none

8.2. Exposure controls
Appropriate engineering controls

Provide adequate ventilation as well as local exhaust at critical locations. Do not breathe gas/fumes/vapour/spray.

Protective and hygiene measures

Remove contaminated, saturated clothing immediately. Wash hands and face before breaks and after work and take a shower if necessary. When using do not eat or drink.

Eye/face protection

Wear eye/face protection.

Hand protection

Wear protective gloves.

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.

Respiratory protection

In case of inadequate ventilation wear respiratory protection.

Environmental exposure controls

Avoid release to the environment.

according to Regulation (EC) No 1907/2006

UC40 BioSonic Universal Ultrasonic Cleaner Concentrate

Revision date: 13.06.2017

Print date: 15.02.2018

Page 5 of 9

SECTION 9: Physical and chemical properties
9.1. Information on basic physical and chemical properties

Physical state:	liquid
Colour:	blue
Odour:	characteristic

Test method

pH-Value:	6 - 8
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Changes in the physical state

Melting point:	not determined
Initial boiling point and boiling range:	not determined
Flash point:	not determined

Flammability

Solid:	not applicable
Gas:	not applicable

Explosive properties

not determined

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
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Oxidizing properties

Not oxidising.

Vapour pressure:	not determined
Density:	not determined
Water solubility:	not determined

Solubility in other solvents

not determined

Partition coefficient:	not determined
Viscosity / dynamic:	not determined
Viscosity / kinematic:	not determined
Vapour density:	not determined
Evaporation rate:	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

UC40 BioSonic Universal Ultrasonic Cleaner Concentrate

Revision date: 13.06.2017

Print date: 15.02.2018

Page 6 of 9

10.3. Possibility of hazardous reactions

No known hazardous reactions.

10.4. Conditions to avoid

Heat.

10.5. Incompatible materials

Strong acid. Oxidising agent, strong.

10.6. Hazardous decomposition products

In case of fire may be liberated: Gases/vapours, toxic.

SECTION 11: Toxicological information
11.1. Information on toxicological effects
Acute toxicity

Harmful if inhaled.

ATEmix calculated

ATE (inhalative vapour) 10,70 mg/l; ATE (inhalative aerosol) 1,087 mg/l

CAS No	Chemical name				
	Exposure route	Dose	Species	Source	Method
111-76-2	2-butoxyethanol, butyl cellosolve, ethylene glycol monobutyl ether				
	oral	LD50 mg/kg	470	Rat	Manufacturer
	dermal	ATE mg/kg	1100		
	inhalative vapour	ATE	11 mg/l		
	inhalative aerosol	ATE	1,5 mg/l		
64-02-8	tetrasodium ethylene diamine tetraacetate				
	oral	ATE mg/kg	500		
68439-45-2	Alcohol, C9-11, Ethoxylated (9EO)				
	oral	ATE mg/kg	500		
137-16-6	Sodium-N-lauroylsarcosinate				
	oral	LD50 mg/kg	> 5000	Rat	Manufacturer
	inhalative vapour	ATE	0,05 mg/l		
	inhalative aerosol	ATE mg/l	0,005		

Irritation and corrosivity

Causes serious eye damage.

Skin corrosion/irritation: 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.

according to Regulation (EC) No 1907/2006

UC40 BioSonic Universal Ultrasonic Cleaner Concentrate

Revision date: 13.06.2017

Print date: 15.02.2018

Page 7 of 9

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

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

Practical experience

Other observations

After skin contact: Irritant, erythema (redness).

Following eye contact: Conjunctival redness.

In case of ingestion: erythema (redness), Nausea.

Following inhalation: Irritation to respiratory tract.

SECTION 12: Ecological information

12.1. Toxicity

The product is not: Ecotoxic.

CAS No	Chemical name					
	Aquatic toxicity	Dose	[h] [d]	Species	Source	Method
137-16-6	Sodium-N-lauroylsarcosinate					
	Acute fish toxicity	LC50	107 mg/l	96 h	Brachydanio rerio (zebra-fish)	Manufacturer

12.2. Persistence and degradability

Product is biodegradable.

12.3. Bioaccumulative potential

No indication of bioaccumulation potential.

12.4. Mobility in soil

Yes.

12.5. Results of PBT and vPvB assessment

The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII.

12.6. Other adverse effects

No information available.

Further information

Avoid release to the environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Advice on disposal

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

Contaminated packaging

Dispose of waste according to applicable legislation.

SECTION 14: Transport information

Land transport (ADR/RID)

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.

according to Regulation (EC) No 1907/2006

UC40 BioSonic Universal Ultrasonic Cleaner Concentrate

Revision date: 13.06.2017

Print date: 15.02.2018

Page 8 of 9

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
EU regulatory information

Restrictions on use (REACH, annex XVII):

Entry 3: 2-butoxyethanol, butyl cellosolve, ethylene glycol monobutyl ether

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):

1 - slightly 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

according to Regulation (EC) No 1907/2006

UC40 BioSonic Universal Ultrasonic Cleaner Concentrate

Revision date: 13.06.2017

Print date: 15.02.2018

Page 9 of 9

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)

H302	Harmful if swallowed.
H312	Harmful in contact with skin.
H315	Causes skin irritation.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H330	Fatal if inhaled.
H332	Harmful if inhaled.

Further Information

The information is based on present level of our knowledge. It does not, however, give assurances of product properties and establishes no contract legal rights. The receiver of our product is singularly responsible for adhering to existing laws and regulations.

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