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Safety Data Sheet acc. to OSHA HCS

Printing date 03/15/2019

Version number 2

Reviewed on 03/15/2019

1 Identification

· Product identifier

• Trade name: PrograMill Fluid for One

· Application of the substance / the mixture Coolant/ Cutting solution

Details of the supplier of the safety data sheet
Manufacturer/Supplier: Ivoclar Vivadent Inc.
175 Pineview Drive, Amherst, N.Y. 14228 USA

Tel. +1 800 533 6825 Fax +1 716 691 2285

Ivoclar Vivadent Inc. 1-6600 Dixie Road Mississauga, Ontario L5T 2Y2 Canada Phone: +1 905 670 8499 Fax: +1 905 670 3102

 Information department: Quality Assurance / Regulatory Affairs
 Emergency telephone number: 24 Hour Emergency Assistance: Emergency-Call USA - Infotrac: 1-800-535-5053 Emergency-Call Canada - Canutec: 1-613-996-6666

General SDS Assistance: US: 1-800-533-6825 Canada: 1-800-263-8182

2 Hazard(s) identification

· Classification of the substance or mixture

Skin Irrit. 2H315Causes skin irritation.Eye Irrit. 2AH319Causes serious eye irritation.Repr. 1AH360May damage fertility or the unborn child.

- · Label elements
- *GHS label elements* The product is classified and labeled according to the Globally Harmonized System (GHS).
- · Hazard pictograms



· Signal word Danger

· Hazard-determining components of labeling:

disodium tetraborate

• Hazard statements Causes skin irritation. Causes serious eye irritation. May damage fertility or the unborn child.

(Contd. on page 2)

US

Printing date 03/15/2019

Version number 2

Reviewed on 03/15/2019

Trade name: PrograMill Fluid for One

(Contd. of page 1)

· Precautionary statements Do not breathe dust/fume/gas/mist/vapors/spray. Do not get in eyes, on skin, or on clothing. Wear protective gloves/protective clothing/eye protection/face protection. If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. IF exposed or concerned: Get medical advice/attention. · Classification system: · NFPA ratings (scale 0 - 4) Health = 2

Fire = 0Reactivity = 0

· HMIS-ratings (scale 0 - 4)

HEALTH	1	Health = 1
		Fire = 0
REACTIVITY	0	Reactivity = 0

- · Other hazards
- · Results of PBT and vPvB assessment
- · PBT: Not applicable.
- · vPvB: Not applicable.

3 Composition/information on ingredients

· Chemical characterization: Mixtures

· Description: Mixture of the substances listed below with nonhazardous additions.

· Dangerous components:		
CAS: 56-81-5	glycerol	10-25%
CAS: 82801-62-5	Decanedioic acid, amine salt	10-25%
CAS: 85030-06-4	sebacic acid, compound with 2,2',2"-nitrilotriethanol (1:2)	10-25%
CAS: 10049-36-2	orthoboric acid, compound with 2,2',2"-nitrilotriethanol	10-25%
CAS: 1330-43-4	disodium tetraborate	0.1-<2.5%

4 First-aid measures

- · Description of first aid measures
- After inhalation:
- Supply fresh air or oxygen; call for doctor.
- In case of unconsciousness place patient stably in side position for transportation.
- After skin contact:
- Immediately wash with water and soap and rinse thoroughly.
- If skin irritation continues, consult a doctor.
- After eye contact: Rinse opened eye for several minutes under running water. Then consult a doctor.
- · After swallowing:
- Rinse out mouth and then drink plenty of water.
- Do not induce vomiting; immediately call for medical help.
- Information for doctor:
- Most important symptoms and effects, both acute and delayed No further relevant information available.

(Contd. on page 3) US

Printing date 03/15/2019

Version number 2

Reviewed on 03/15/2019

Trade name: PrograMill Fluid for One

(Contd. of page 2) · Indication of any immediate medical attention and special treatment needed

No further relevant information available.

5 *Fire-fighting measures*

• Extinguishing media

- Suitable extinguishing agents:
- CO2, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam. · For safety reasons unsuitable extinguishing agents: Water with full jet
- Special hazards arising from the substance or mixture

Formation of toxic gases is possible during heating or in case of fire. In case of fire, the following can be released: Carbon monoxide (CO) Nitrogen oxides (NOx)

- Advice for firefighters
- · Protective equipment: Wear self-contained respiratory protective device.

6 Accidental release measures

Wear protective • Environmental p • Methods and ma	tions, protective equipment and emergency procedures equipment. Keep unprotected persons away. precautions: Do not allow to enter sewers/surface or ground water. Iterial for containment and cleaning up: id-binding material (sand, diatomite, acid binders, universal binders, sawdust).	
Ensure adequate		
• Reference to oth See Section 7 for See Section 8 for See Section 13 fo		
CAS: 1330-43-4	disodium tetraborate	6 mg/m3
• PAC-2:		
CAS: 1330-43-4	disodium tetraborate	88 mg/m3
• PAC-3:		
CAS: 1330-43-4	disodium tetraborate	530 mg/m3

CAS: 1330-43-4 disodium tetraborate

7 Handling and storage

· Handling:

· Precautions for safe handling

Only adequately trained personnel should handle this product. Ensure good ventilation/exhaustion at the workplace. Prevent formation of aerosols. For use in dentistry only.

· Information about protection against explosions and fires: No special measures required.

· Conditions for safe storage, including any incompatibilities

· Storage:

• *Requirements to be met by storerooms and receptacles:* Store only in the original receptacle.

• Information about storage in one common storage facility: Do not store together with acids.

(Contd. on page 4)

US

Printing date 03/15/2019

Version number 2

Reviewed on 03/15/2019

Trade name: PrograMill Fluid for One

(Contd. of page 3)

- *Further information about storage conditions:*
- Keep receptacle tightly sealed. Protect from heat and direct sunlight.
- *Specific end use(s)* No further relevant information available.

8 Exposure controls/personal protection

• Additional information about design of technical systems: No further data; see item 7.

- Components with limit values that require monitoring at the workplace: The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit.
- At this time, the other constituents have no known exposure limits.

CAS: 56-81-5 glycerol

- PEL Long-term value: 15* 5** mg/m³ mist; *total dust **respirable fraction
- TLV TLV withdrawn-insufficient data human occup. exp.

CAS: 1330-43-4 disodium tetraborate

REL Long-term value: 1 mg/m³ anhydrous TLV Short-term value: 6* mg/m³ Long-term value: 2* mg/m³ *as inhalable fraction

• *Additional information:* The lists that were valid during the creation were used as basis.

- · Exposure controls
- · Personal protective equipment:
- · General protective and hygienic measures:
- Usual hygienic measures for dental practice and dental laboratories.
- Keep away from foodstuffs, beverages and feed.
- Wash hands before breaks and at the end of work.
- Avoid contact with the eyes and skin.
- Do not inhale gases / fumes / aerosols.
- Breathing equipment: Use suitable respiratory protective device in case of insufficient ventilation.
- · Recommended filter device for short term use: Combination filter A-P2
- Protection of hands:



Protective gloves

After use of gloves apply skin-cleaning agents and skin cosmetics.

- · Material of gloves
- Nitrile rubber, NBR
- Butyl rubber, BR

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

- Penetration time of glove material
- The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

(Contd. on page 5)

US

[·] Control parameters

Printing date 03/15/2019

• Eye protection:

*

Version number 2

Reviewed on 03/15/2019

Trade name: PrograMill Fluid for One

(Contd. of page 4)

Tightly sealed goggles

Information on basis physical and a	homiaal proportion
 Information on basic physical and c General Information 	nemicai properiies
· Appearance:	
Form:	Fluid
Color:	Colorless
· Odor:	Characteristic
· Odor threshold:	Not determined.
• pH-value at 20 •C (68 •F):	8.5
· Change in condition	
Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	>100 °C (>212 °F)
Flash point:	Undetermined.
· Flammability (solid, gaseous):	Not applicable.
Auto igniting:	Product is not selfigniting.
Danger of explosion:	Product does not present an explosion hazard.
Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
· Vapor pressure at 20 •C (68 •F):	<23 hPa (<17.3 mm Hg)
• Density at 20 •C (68 •F):	~1.16 g/cm³ (~9.68 lbs/gal)
Relative density	Not determined.
· Vapor density	Not determined.
• Evaporation rate	Not determined.
Solubility in / Miscibility with	
Water:	Fully miscible.
· Partition coefficient (n-octanol/wate	r): Not determined.
· Viscosity:	
<i>Dynamic at 20 °C (68 °F):</i>	50 mPas
Kinematic:	Not determined.
• Other information	No further relevant information available.

10 Stability and reactivity

· Reactivity No further relevant information available.

- · Chemical stability Stable under normal handling and storage conditions.
- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- **Possibility of hazardous reactions** Reacts with strong acids.

(Contd. on page 6)

US

Printing date 03/15/2019

Version number 2

Reviewed on 03/15/2019

Trade name: PrograMill Fluid for One

(Contd. of page 5)

Exothermic reaction.

Conditions to avoid

Protect from frost.

Keep away from heat and direct sunlight.

• Incompatible materials: No further relevant information available.

· Hazardous decomposition products: None under normal conditions of storage and use.

11 Toxicological information

· Information on toxicological effects

• Acute toxicity:

· LD/LC50 values that are relevant for classification:

CAS: 1330-43-4 disodium tetraborate

Oral LD50 2400 (rat)

· on the skin: Irritant to skin and mucous membranes.

• on the eye: Irritating effect.

• Sensitization: No sensitizing effects known.

· Additional toxicological information:

· Carcinogenic categories

· NTP (National Toxicology Program)

None of the ingredients is listed.

· OSHA-Ca (Occupational Safety & Health Administration)

None of the ingredients is listed.

<u>12 Ecological information</u>

- · Toxicity
- · Aquatic toxicity: No further relevant information available.
- · Persistence and degradability No further relevant information available.
- · Behavior in environmental systems:
- · Bioaccumulative potential No further relevant information available.
- · Mobility in soil No further relevant information available.
- · Additional ecological information:
- General notes:

Water hazard class 1 (Self-assessment): slightly hazardous for water

Do not allow product to reach ground water, water course or sewage system.

- · Results of PBT and vPvB assessment
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- · Other adverse effects No further relevant information available.

13 Disposal considerations

· Waste treatment methods

• Recommendation:

Must not be disposed of together with household garbage. Do not allow product to reach sewage system. Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.

(Contd. on page 7)

Printing date 03/15/2019

Version number 2

Reviewed on 03/15/2019

Trade name: PrograMill Fluid for One

(Contd. of page 6)

· Uncleaned packagings:

• **Recommendation:** Disposal must be made according to official regulations.

UN-Number	
DOT, ADR/RID/ADN, ADN, IMDG, IA	TA Void
UN proper shipping name DOT, ADR/RID/ADN, ADN, IMDG, IA	TA Void
Transport hazard class(es)	
DOT, ADR/RID/ADN, ADN, IMDG, IA	ΤΑ
Class	Void
Packing group DOT, ADR/RID/ADN, IMDG, IATA	Void
Environmental hazards:	Not applicable.
Special precautions for user	Not applicable.
Transport in bulk according to Annex II MARPOL73/78 and the IBC Code	I of Not applicable.
Transport/Additional information:	Product is not classified as a dangerous good for transport (ADR, IMDG, IATA).
UN ''Model Regulation'':	Void

15 Regulatory information

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

· Sara

· Section 355 (extremely hazardous substances):			
None of the ingredients is listed.			
· Section 313 (Specific toxic chemical listings):			
None of the ingrea	None of the ingredients is listed.		
· TSCA (Toxic Sub	• TSCA (Toxic Substances Control Act):		
CAS: 10049-36-2	orthoboric acid, compound with 2,2',2"-nitrilotriethanol		
CAS: 1330-43-4	disodium tetraborate		
· Proposition 65	· Proposition 65		
· Chemicals known to cause cancer:			
None of the ingredients is listed.			
· Chemicals known to cause reproductive toxicity for females:			
None of the ingredients is listed.			
· Chemicals known to cause reproductive toxicity for males:			
None of the ingredients is listed.			
· Chemicals known to cause developmental toxicity:			

None of the ingredients is listed.

(Contd. on page 8)

US

Printing date 03/15/2019

Version number 2

Reviewed on 03/15/2019

Trade name: PrograMill Fluid for One

(Contd. of page 7)

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· Carcinogenic categories

· EPA (Environmental Protection Agency)

CAS: 1330-43-4 disodium tetraborate

• TLV (Threshold Limit Value established by ACGIH)

CAS: 1330-43-4 disodium tetraborate

·NIOSH-Ca (National Institute for Occupational Safety and Health)

None of the ingredients is listed.

· GHS label elements

The product is classified and labeled according to the Globally Harmonized System (GHS). • *Hazard pictograms*



· Signal word Danger

• *Hazard-determining components of labeling: disodium tetraborate*

· Hazard statements

Causes skin irritation. Causes serious eye irritation. May damage fertility or the unborn child.

· Precautionary statements

Do not breathe dust/fume/gas/mist/vapors/spray.

Do not get in eyes, on skin, or on clothing.

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

If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.

If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

IF exposed or concerned: Get medical advice/attention.

· National regulations:

• Other regulations, limitations and prohibitive regulations

This product is classified as a medical device under US and Canadian regulations and has been reviewed by the US Food and Drug Administration and Health Canada.

· Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

Date of preparation / last revision 03/15/2019 / 1
 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
 DOT: US Department of Transportation
 IATA: International Air Transport Association
 ACGIH: American Conference of Governmental Industrial Hygienists
 EINECS: European Inventory of Existing Commercial Chemical Substances
 ELINCS: European List of Notified Chemical Substances
 CAS: Chemical Abstracts Service (division of the American Chemical Society)
 NFPA: National Fire Protection Association (USA)

(Contd. on page 9)

Printing date 03/15/2019

Version number 2

Reviewed on 03/15/2019

Trade name: PrograMill Fluid for One

(Contd. of page 8)

US

LC50: Lethal concentration, 50 percent LD50: Lethal dose, 50 percent PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative NIOSH: National Institute for Occupational Safety OSHA: Occupational Safety & Health TLV: Threshold Limit Value PEL: Permissible Exposure Limit REL: Recommended Exposure Limit Skin Irrit. 2: Skin corrosion/irritation – Category 2 Eye Irrit. 2A: Serious eye damage/eye irritation – Category 2A Repr. 1A: Reproductive toxicity – Category 1A • * Data compared to the previous version altered.