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Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 17.08.2017

Version number 4

Revision: 13.02.2017

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

- · Product identifier
- · Trade name: Essentia LoFlo
- **Relevant identified uses of the substance or mixture and uses advised against** No further relevant information available.
- · Application of the substance / the mixture Auxillary for dental technology
- Details of the supplier of the safety data sheet Henry Schein Shalfoon Ltd 23 William Pickering Drive, Albany Auckland 0632, NEW ZEALAND

PO Box 101140, NSMC Auckland 0745, NEW ZEALAND

Free Phone: 0800 808 855

Further information obtainable from: Regulatory affairs
 Emergency telephone number: 0800 764 766 (National Poisons Centre)

2 Hazards identification

· Classification of the substance or mixture

Acute Tox. 5 H333 May be harmful if inhaled.

Skin Sens. 1 H317 May cause an allergic skin reaction.

· Label elements

· GHS label elements

Exempt from requirements - product regulated as a medical device or an in vitro diagnostic medical device. The product is classified and labelled according to the Globally Harmonised System (GHS).

· Hazard pictograms



· Signal word Warning

Hazard-determining components of labelling: 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate 2-(2H-benzotriazol-2-yl)-p-cresol 2,2'-ethylenedioxydiethyl dimethacrylate 1,3,5-Triazane-2,4,6-triamine, polymer with formaldehyde
Hazard statements May be harmful if inhaled. May cause an allergic skin reaction.
Precautionary statements Avoid breathing dust/fume/gas/mist/vapours/spray. Contaminated work clothing should not be allowed out of the workplace.

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Trade name: Essentia LoFlo

Wear protective gloves.

IF INHALED: Call a POISON CENTER/doctor if you feel unwell.

If skin irritation or rash occurs: Get medical advice/attention.

Dispose of contents/container in accordance with local/regional/national/international regulations.

• Other hazards

· Results of PBT and vPvB assessment

- · **PBT:** Not applicable.
- · vPvB: Not applicable.

3 Composition/information on ingredients

· Chemical characterisation: Mixtures

· Description:

Only substances required to be mentioned according to Annex II of regulation 1907/2006 are listed. Information on the other substances that may be present can be obtained upon request.

· Dangerous compone		10 0 - 0 (
CAS: 72869-86-4	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-	10-<25%
EINECS: 276-957-5	diyl bismethacrylate	
	Skin Sens. 1, H317	
CAS: 41637-38-1	Esterification products of 4,4'-isopropylidenediphenol, ethoxylated and 2-	5-<10%
	methylprop-2-enoic acid.	
	Aquatic Chronic 4, H413	
CAS: 109-16-0	2,2'-ethylenedioxydiethyl dimethacrylate	5-<10%
EINECS: 203-652-6	Skin Sens. 1, H317	
CAS: 2440-22-4	2-(2H-benzotriazol-2-yl)-p-cresol	0.5-<1%
EINECS: 219-470-5	Acute Tox. 2, H330; Skin Sens. 1, H317; Aquatic Chronic 4, H413	
CAS: 75980-60-8	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide	0.5-<1%
EINECS: 278-355-8	Repr. 2, H361	
CAS: 9003-08-1	1,3,5-Triazane-2,4,6-triamine, polymer with formaldehyde	0.2-<0.5%
	Eye Dam. 1, H318; Skin Sens. 1, H317; STOT SE 3, H335	
• Additional informati	ion: For the wording of the listed hazard phrases refer to section 16.	

4 First aid measures

- · Description of first aid measures
- General information:

Immediately remove any clothing soiled by the product.

- If symptoms persist consult doctor.
- After inhalation:

Supply fresh air. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms persist.

Take affected persons into fresh air and keep quiet.

• After skin contact:

Immediately wash with water and soap and rinse thoroughly.

Seek medical treatment.

If skin irritation continues, consult a doctor.

· After eye contact:

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

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• After swallowing:

Rinse out mouth and then drink plenty of water.

If symptoms persist consult doctor.

• Information for doctor:

• Most important symptoms and effects, both acute and delayed Allergic reactions • Indication of any immediate medical attention and special treatment needed No further relevant information available.

5 Firefighting measures

• Extinguishing media

· Suitable extinguishing agents:

CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam. Use fire extinguishing methods suitable to surrounding conditions.

• 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.

· Advice for firefighters

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

• Additional information

Dispose of fire debris and contaminated fire fighting water in accordance with official regulations.

6 Accidental release measures

Personal precautions, protective equipment and emergency procedures Remove persons from danger area. Avoid contact with the eyes and skin. Wear protective clothing.
Environmental precautions: Do not allow product to reach sewage system or any water course. Inform respective authorities in case of seepage into water course or sewage system. Do not allow to penetrate the ground/soil. In case of seepage into the ground inform responsible authorities.
Methods and material for containment and cleaning up: Absorb liquid components with liquid-binding material.

Absorb liquid components with liquid-binding material. Dispose of the material collected according to regulations.

• **Reference to other sections** See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment. See Section 13 for disposal information.

7 Handling and storage

· Handling:

· Precautions for safe handling

Ensure good ventilation/exhaustion at the workplace.

Prevent formation of aerosols.

Avoid contact with the eyes and skin.

• Information about fire - and explosion protection: No special measures required.

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- · Conditions for safe storage, including any incompatibilities
- Storage:
- Requirements to be met by storerooms and receptacles: Store only in unopened original receptacles.
- · Information about storage in one common storage facility: Store away from foodstuffs.
- Further information about storage conditions: None.
- Specific end use(s) No further relevant information available.

8 Exposure controls/personal protection

- Additional information about design of technical facilities: No further data; see item 7.
- · Control parameters
- · Ingredients with limit values that require monitoring at the workplace:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

· DNELs

1879-09-0 6-tert-butyl-2,4-xylenol

Inhalative DNEL inhalation 0.14 mg/m3 (man)

· Additional information: The lists valid during the making were used as basis.

- · Exposure controls
- · Personal protective equipment:
- General protective and hygienic measures:

The usual precautionary measures are to be adhered to when handling chemicals.

Avoid contact with the eyes and skin.

Wash hands before breaks and at the end of work.

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing

- Respiratory protection: Suitable respiratory protective device recommended.
- Protection of hands:



Protective gloves

· Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

· 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.

Eye protection:



Tightly sealed goggles

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Information on basic physical and chen	nical properties
General Information	
Appearance:	
Form:	Pasty
Colour:	According to product specification
Odour:	Odourless
Odour threshold:	Not determined.
pH-value:	Not determined.
Change in condition	
Melting point/freezing point:	Undetermined.
Initial boiling point and boiling range	: Undetermined.
Flash point:	Not applicable.
Flammability (solid, gas):	Not applicable.
Ignition temperature:	Undetermined.
Decomposition temperature:	Not determined.
Auto-ignition temperature:	Product is not selfigniting.
Explosive properties:	Product does not present an explosion hazard.
Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
Vapour pressure:	Not determined.
Density:	Not determined.
Relative density	Not determined.
Vapour density	Not determined.
Evaporation rate	Not determined.
Solubility in / Miscibility with	
water:	Fully miscible.
Partition coefficient: n-octanol/water:	Not determined.
Viscosity:	
Dynamic:	Not determined.
Kinematic:	Not determined.
Solvent content:	
Organic solvents: VOC (EC)	0.0 % 0.0 g/l

10 Stability and reactivity

· Reactivity No further relevant information available.

· Chemical stability

• Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.

· Possibility of hazardous reactions No dangerous reactions known.

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· Conditions to avoid No further relevant information available.

• Incompatible materials: No further relevant information available.

· Hazardous decomposition products: No dangerous decomposition products known.

11 Toxicological information

· Information on toxicological effects

• Acute toxicity

· LD/LC50 values relevant for classification:

72869-86-4 7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate

Oral LD50 > 5000 mg/kg (rat female) (OECD 401)

2440-22-4 2-(2H-benzotriazol-2-yl)-p-cresol

Oral LD50 10000 mg/kg (rat (f+m))

Inhalative LC50/4 h = 0.59 mg/l (rat (f+m))

1879-09-0 6-tert-butyl-2,4-xylenol

Oral	LD50	910 mg/kg (rat (f+m)) (OECD 401)
Dermal	LD50	< 200 mg/kg (rabbit) (OECD 402)

· Primary irritant effect:

· Skin corrosion/irritation No irritant effect.

- · Serious eye damage/irritation No irritating effect.
- Respiratory or skin sensitisation Sensitisation possible through skin contact.
- *Repeated dose toxicity No further relevant information available.*
- CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)
- No further relevant information available.

12 Ecological information

· Toxicity

• Aquatic toxicity:

72869-86-47,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate

EC50/48h (static) > 1.2 mg/l (daphnia magna) (OECD 202)

· Persistence and degradability No further relevant information available.

· Behaviour 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 3 (German Regulation) (Self-assessment): extremely hazardous for water Do not allow product to reach ground water, water course or sewage system, even in small quantities. Danger to drinking water if even extremely small quantities leak into the ground.

· Results of PBT and vPvB assessment

• *PBT:* Not applicable.

• **vPvB:** Not applicable.

• Other adverse effects No further relevant information available.

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13 Disposal considerations

· Waste treatment methods

· Recommendation

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

- · Uncleaned packaging:
- Recommendation: Disposal must be made according to official regulations.
- · Recommended cleansing agents: Water, if necessary together with cleansing agents.

4 Transport information		
· UN-Number · ADR, ADN, IMDG, IATA	not regulated	
· UN proper shipping name · ADR, ADN, IMDG, IATA	not regulated	
· Transport hazard class(es)		
· ADR, ADN, IMDG, IATA · Class	not regulated	
· Packing group · ADR, IMDG, IATA	not regulated	
· Environmental hazards: · Marine pollutant:	No	
Special precautions for user	Not applicable.	
· Transport in bulk according to Annex I and the IBC Code	I of Marpol Not applicable.	
· UN ''Model Regulation'':	not regulated	

15 Regulatory information

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

· New Zealand Inventory of Chemicals		
65997-17-3	Glass, oxide, chemicals	
72869-86-4	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxa-5,12-diazahexadecane-1,16-diyl bismethacrylate	
41637-38-1	<i>Esterification products of 4,4'-isopropylidenediphenol, ethoxylated and 2-methylprop-2-enoic acid.</i>	
2530-85-0	3-trimethoxysilylpropyl methacrylate	
109-16-0	2,2'-ethylenedioxydiethyl dimethacrylate	
112945-52-5	Silicon dioxide	
2440-22-4	2-(2H-benzotriazol-2-yl)-p-cresol	
1879-09-0	6-tert-butyl-2,4-xylenol	
10287-53-3	ethyl 4-dimethylaminobenzoate	
75980-60-8	diphenyl(2,4,6-trimethylbenzoyl)phosphine oxide	
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PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative	 Abbreviations and acronyms: ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning Carriage of Dangerous Goods by Road) IMDG: International Maritime Code for Dangerous Goods IATA: International Air Transport Association 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) VOC: Volatile Organic Compounds (USA, EU) DNEL: Derived No-Effect Level (REACH) LC50: Lethal concentration, 50 percent PBT: Persistent, Bioaccumulative and Toxic 	the International
VPVB: Very Persistent and Very Bioaccumulative (Contd. on page 9) NZ		(Contd. on page 9)

NZ

Safety data sheet according to 1907/2006/EC, Article 31

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(Contd. of page 8) Acute Tox. 2: Acute toxicity – Category 2 Acute Tox. 5: Acute toxicity – Category 5 Eye Dam. 1: Serious eye damage/eye irritation - Category 1 Skin Sens. 1: Skin sensitisation – Category 1 Repr. 2: Reproductive toxicity – Category 2 STOT SE 3: Specific target organ toxicity (single exposure) – Category 3 Aquatic Chronic 4: Hazardous to the aquatic environment - long-term aquatic hazard - Category 4 · Sources • ECHA (http://echa.europa.eu/) • EnviChem (www.echemportal.org) * * Data compared to the previous version altered. This version replaces all previous versions. Disclaimer: The information contained herein is believed to be true and accurate. However, all statements, recommendations or suggestions are made without any guarantee, representation or warranty, express or implied, on our part. Therefore, no warranty is made or to be implied that the information set out in this document is accurate or complete, and we accordingly exclude all liability in connection with the use of this information or the products referred to herein. All such risks are assumed by the purchaser/user. The information contained herein is also subject to change without notice. For the avoidance of doubt, however, nothing in this document excludes or limits our liability for death or personal injury caused by our negligence or for fraudulent misrepresentation.