

Safety Data Sheet according to WHS Regulations

Printing date 17.08.2017

Version number 3

Revision: 23.03.2017

1 Identification

- **Product identifier**
- **Trade name:** *Essentia HiFlo*
- **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**
- **Manufacturer/Supplier:**
*Henry Schein Halas
44 O'Dea Ave
Waterloo NSW 2017
Tel: 1300 65 88 22*
- **Further information obtainable from:** *Regulatory affairs*
- **Emergency telephone number:**
*24 hours Emergency: 13 11 26.
International: +01-813-248-0585 (ChemTel Inc.)*

2 Hazard(s) Identification

- **Classification of the substance or mixture**
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**



GHS07

- **Signal word** *Warning*
- **Hazard-determining components of labelling:**
*7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-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 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.
Wear protective gloves.
IF ON SKIN: Wash with plenty of water.
If skin irritation or rash occurs: Get medical advice/attention.
Dispose of contents/container in accordance with local/regional/national/international regulations.*

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

3 Composition and 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 components:**

72869-86-4	7,7,9(or 7,9,9)-trimethyl-4,13-dioxo-3,14-dioxo-5,12-diazahexadecane-1,16-diyl bismethacrylate Skin Sens. 1, H317	5-<10%
109-16-0	2,2'-ethylenedioxydiethyl dimethacrylate Skin Sens. 1, H317	2.5-<5%
9003-08-1	1,3,5-Triazane-2,4,6-triamine, polymer with formaldehyde Eye Dam. 1, H318; Skin Sens. 1, H317; STOT SE 3, H335	0.2-<0.5%
2440-22-4	2-(2H-benzotriazol-2-yl)-p-cresol Acute Tox. 2, H330; Skin Sens. 1, H317	0.1-<0.2%

- **Additional information:** 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.
- **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.

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5 Fire Fighting 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 formation of dust.
Avoid contact with the eyes and skin.
Wear protective clothing.*
- **Environmental precautions:**
*Do not allow product to reach sewage system or any water course.
Do not allow to penetrate the ground/soil.
Do not allow to enter sewers/ surface or ground water.*
- **Methods and material for containment and cleaning up:**
*Allow to evaporate.
Pick up mechanically.
Prevent formation of dust.
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**
*Prevent formation of dust.
Any unavoidable deposit of dust must be regularly removed.
Avoid contact with the eyes and skin.*
- **Information about fire - and explosion protection:** *Dust can combine with air to form an explosive mixture.*
- **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.*

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· **Specific end use(s)** No further relevant information available.

8 Exposure controls and 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/m ³ (man)
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· **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.

Do not inhale dust / smoke / mist.

Avoid contact with the eyes and skin.

Wash hands before breaks and at the end of work.

Immediately remove all soiled and contaminated clothing

· **Respiratory protection:**

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

Suitable respiratory protective device recommended.

· **Protection of hands:**

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.



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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9 Physical and Chemical Properties

· Information on basic physical and chemical properties	
· General Information	
· Appearance:	
Form:	Pasty
Colour:	According to product specification
· Odour:	Odourless
· Odour threshold:	Not determined.
· pH-value:	Not applicable.
· Change in condition	
Melting point/freezing point:	Undetermined.
Initial boiling point and boiling range:	180 °C (356 °F)
· Flash point:	Not applicable.
· Flammability (solid, gas):	Not determined.
· 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 applicable.
· Density:	Not determined.
· Relative density	Not determined.
· Vapour density	Not applicable.
· Evaporation rate	Not applicable.
· Solubility in / Miscibility with water:	Insoluble.
· Partition coefficient: n-octanol/water:	Not determined.
· Viscosity:	
Dynamic:	Not applicable.
Kinematic:	Not applicable.
· Solvent content:	
Organic solvents:	0.0 %
· Other information	No further relevant information available.

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.
- **Conditions to avoid** No further relevant information available.

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

Oral	LD50	10000 mg/kg (rat (f+m))
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Inhalative	LC50/4 h	0.59 mg/l (rat (f+m))
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1879-09-0 6-tert-butyl-2,4-xylenol

Oral	LD50	910 mg/kg (rat (f+m)) (OECD 401)
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Dermal	LD50	< 200 mg/kg (rabbit) (OECD 402)
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- **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 (carcinogenicity, mutagenicity and toxicity for reproduction)**
No further relevant information available.

12 Ecological Information

- **Toxicity**

- **Aquatic toxicity:**

72869-86-4 7,7,9(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)
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- **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:**
Do not allow undiluted product or large quantities of it 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.

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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.

14 Transport information

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

15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Australian Inventory of Chemical Substances**
All ingredients are listed.
- **Standard for the Uniform Scheduling of Medicines and Poisons**
None of the ingredients is listed.
- **GHS label elements** *The product is classified and labelled according to the Globally Harmonised System (GHS).*
- **Hazard pictograms**



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- **Signal word** *Warning*

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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 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.
Wear protective gloves.
IF ON SKIN: Wash with plenty of water.
If skin irritation or rash occurs: Get medical advice/attention.
Dispose of contents/container in accordance with local/regional/national/international regulations.

- **Directive 2012/18/EU**

- **Named dangerous substances - ANNEX I** None of the ingredients is listed.

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

16 Other information

- **Relevant phrases**

H317 May cause an allergic skin reaction.
H318 Causes serious eye damage.
H330 Fatal if inhaled.
H335 May cause respiratory irritation.

- **Department issuing SDS:** Regulatory affairs

- **Contact:** msds@gceurope.com

- **Abbreviations and acronyms:**

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)
IATA-DGR: Dangerous Goods Regulations by the "International Air Transport Association" (IATA)
ICAO: International Civil Aviation Organisation
ICAO-TI: Technical Instructions by the "International Civil Aviation Organisation" (ICAO)
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
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)
DNEL: Derived No-Effect Level (REACH)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
Acute Tox. 2: Acute toxicity – Category 2
Eye Dam. 1: Serious eye damage/eye irritation – Category 1
Skin Sens. 1: Skin sensitisation – Category 1
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

- **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

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