

Material Safety Data Sheet Cover-Sheet – This page provides additional New Zealand specific information for this product and must be read in conjunction with the Safety Data Sheet (SDS) attached

Product Name:	New Outline Skin Primer
Manufacturer:	Anax Dent GmbH
SDS Expiry:	23 December 2029
Supplier Details:	Henry Schein New Zealand 243-249 Bush Road, Rosedale, Auckland, 0632 PO Box 101 140, North Shore, Auckland 0745 Ph. 0800 808 855 www.henryschein.co.nz
Emergency Contacts:	Poisons/Hazardous Chemical Info Centre – 0800POISON/0800764766 (24 Hours) Phone 111 for Fire, Ambulance or Police
HSNO Class/Category:	3 / 6
HSNO Group Standard:	Dental Products Flammable Group Standard 2020 HSR002556
Statements/Pictograms:	As per attached Safety Data Sheet (SDS)
Date Prepared:	This coversheet was prepared – June 2025

This SDS coversheet has been produced by Henry Schein NZ and has been prepared in accordance with NZ EPA advice on making overseas SDS compliant to HSNO Act. The above information is based on the present state of our knowledge of the product at the time of publication. It is given in good faith, no warranty is implied with respect to the quality or the specifications of the product. Users must satisfy that the product is entirely suitable for their purpose. The SDS and this coversheet may be revised from time to time, please ensure you have a current copy.

# Safety data sheet

according to Regulation (EC) No 1907/2006, Article 31

Printing date 23.12.2024

Version: 2

Revision: 23.12.2024

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

· 1.1 Product identifier

· Trade name: <u>New Outline Skin Primer</u>

• Article number: 16200010

 $\cdot$  1.2 Relevant identified uses of the substance or mixture and uses advised against

No further relevant information available.

· Application of the substance / the mixture Adhering additve

• 1.3 Details of the supplier of the safety data sheet • Manufacturer/Supplier:

anax dent GmbH, Dreifelderstr.5, D-70599 Stuttgart Tel.: 0711/620092-0 Fax: 0711/620092-29 anaxdent.com

• Further information obtainable from: R&D, MANI MEDICAL GERMANY GmbH, Tel:+049 6003/8286-0

· 1.4 Emergency telephone number:

+49 (0) 6003 82 86-0, MANI MEDICAL GERMANY GmbH (8:00 - 17:00) or

+49 (0) 6131 19240 Poison Information Center, University Mainz (24 h)

## **SECTION 2: Hazards identification**

· 2.1 Classification of the substance or mixture

· Classification according to Regulation (EC) No 1272/2008

Flam. Liq. 2 H225 Highly flammable liquid and vapour.

Skin Irrit. 2 H315 Causes skin irritation.

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

STOT SE 3 H335 May cause respiratory irritation.

· 2.2 Label elements

- · Labelling according to Regulation (EC) No 1272/2008
- The product is classified and labelled according to the CLP regulation.

· Hazard pictograms



· Signal word Danger

- Hazard-determining components of labelling: methyl methacrylate
- Hazard statements
- H225 Highly flammable liquid and vapour.
- H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H335 May cause respiratory irritation.

#### · Precautionary statements

P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No
	smoking.

- P241 Use explosion-proof [electrical/ventilating/lighting] equipment.
- P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P303+P361+P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with
	water [or shower].
P405	Store locked up.
P501	Dispose of contents/container in accordance with local/regional/national/international
	regulations.

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#### Trade name: New Outline Skin Primer

Labelling of packages where the contents do not exceed 125 ml
 Hazard pictograms



· Signal word Danger

- *Hazard-determining components of labelling:* methyl methacrylate
- · Hazard statements
- H317 May cause an allergic skin reaction.
- Precautionary statements
- P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

· 2.3 Other hazards

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

## **SECTION 3: Composition/information on ingredients**

· 3.2 Mixtures

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

· Dangerous components:

 CAS: 80-62-6
 methyl methacrylate
 75-100%

 EINECS: 201-297-1
 Flam. Liq. 2, H225; (1) Skin Irrit. 2, H315; Skin Sens. 1, H317; STOT SE
 75-100%

• Additional information For the wording of the listed hazard phrases refer to section 16.

# **SECTION 4: First aid measures**

• 4.1 Description of first aid measures

- General information Immediately remove any clothing soiled by the product.
- After inhalation Take affected persons into fresh air and keep quiet.
- · 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; call for medical help immediately.
- 4.2 Most important symptoms and effects, both acute and delayed No further relevant information available.
- 4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

## **SECTION 5: Firefighting measures**

• 5.1 Extinguishing media

• Suitable extinguishing agents Carbon dioxide Fire-extinguishing powder Foam Water spray

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- · For safety reasons unsuitable extinguishing agents Water with full jet.
- 5.2 Special hazards arising from the substance or mixture No further relevant information available.
- 5.3 Advice for firefighters
- Protective equipment:
- Wear self-contained respiratory protective device. Wear fully protective suit.

#### **SECTION 6:** Accidental release measures

- 6.1 Personal precautions, protective equipment and emergency procedures Ensure adequate ventilation
- *Keep away from ignition sources Wear protective clothing.*
- 6.2 Environmental precautions: Do not allow to enter sewers/ surface or ground water.
- 6.3 Methods and material for containment and cleaning up:

Pick up mechanically.

When pumping out, please ensure grounding.

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust). Dispose of the material collected according to regulations.

• 6.4 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.

#### **SECTION 7: Handling and storage**

- 7.1 Precautions for safe handling Keep receptacles tightly sealed.
  Ensure good ventilation/exhaustion at the workplace.
  Information about fire - and explosion protection: Keep ignition sources away - Do not smoke.
  Protect against electrostatic charges.
- Use explosion-proof apparatus / fittings and spark-proof tools. Fumes can combine with air to form an explosive mixture.
- · 7.2 Conditions for safe storage, including any incompatibilities
- · Storage
- Requirements to be met by storerooms and receptacles: Storage between 10 °C and 25 °C.
- · Information about storage in one common storage facility: -
- Further information about storage conditions: Protect from exposure to the light.
- 7.3 Specific end use(s) No further relevant information available.

## **SECTION 8: Exposure controls/personal protection**

Ingredients with limit values that require monitoring at the workplace: 80-62-6 methyl methacrylate		
OEL (Ireland)	Short-term value: 100 ppm Long-term value: 50 ppm IOELV, Sens	
WEL (Great Britain)	Short-term value: 416 mg/m³, 100 ppm Long-term value: 208 mg/m³, 50 ppm	
PEL (USA)	Long-term value: 410 mg/m³, 100 ppm	

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• Auto-ignition temperature:

· Kinematic viscosity

• pH • Viscosity:

· dynamic:

· Solubility · Water at 20 °C:

• Decomposition temperature:

· Partition coefficient n-octanol/water (log value)

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REL (USA)	Long-term value: 410 mg/m <sup>3</sup> , 100 ppm	(Conta. of pa
TLV (USA)	Short-term value: 100 ppm	
ILV(OSA)	Long-term value: 50 ppm	
	DSEN, A4	
IOELV (European Union)	Short-term value: 100 ppm	
	Long-term value: 50 ppm	
Additional information: 7	he lists valid during the making were used as basis.	
8.2 Exposure controls		
-	controls No further data; see section 7.	
	sures, such as personal protective equipment	
General protective and hy		
Do not inhale gases / fume		
	iled and contaminated clothing	
Store protective clothing s		
Wash hands before breaks	1 2	
Avoid contact with the eye		
Respiratory protection:	<i>unu shin</i> .	
Not necessary if room is w	all vontilated	
	rotective device when high concentrations are present.	
Short term filter device: Filter A		
	1	
Hand protection Protectiv		
Material of gloves Butyl r		
Penetration time of glove	material	
0,1 - 0,2 mm		
Penetration time: 5 min.		
Eye/face protection Safety	glasses	
Body protection:		
D		
Protective work clothing.		
(Only when handling large	e quantities)	
	e quantities)	
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430 °C (DIN 51794)

Not determined. Not determined.

Not determined.

Not determined.

Not determined.

1.6 g/l

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Vapour pressure at 20 °C:	47 hPa	
Density and/or relative density		
Density at 20 °C:	$0.94 \ g/cm^3$	
Relative density	Not determined.	
Vapour density	Not determined.	
9.2 Other information		
Appearance:		
Form:	Fluid	
Important information on protection of heal	th and	
environment, and on safety.		
Ignition temperature:	Product is not selfigniting.	
Explosive properties:	Product is not explosive. However, formation o	
	explosive air/vapour mixtures are possible.	
Change in condition		
Evaporation rate	Not determined.	
Information with regard to physical hazard	classes	
Explosives	Void	
Flammable gases	Void	
Aerosols	Void	
Oxidising gases	Void	
Gases under pressure	Void	
Flammable liquids	Highly flammable liquid and vapour.	
Flammable solids	Void	
Self-reactive substances and mixtures	Void	
Pyrophoric liquids	Void	
Pyrophoric solids	Void	
Self-heating substances and mixtures	Void	
Substances and mixtures, which emit flamm	able	
gases in contact with water	Void	
Oxidising liquids	Void	
Oxidising solids	Void	
Organic peroxides	Void	
Corrosive to metals	Void	
Desensitised explosives	Void	

#### **SECTION 10: Stability and reactivity**

· 10.1 Reactivity No further relevant information available.

· 10.2 Chemical stability

- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- · 10.3 Possibility of hazardous reactions Exothermic polymerization
- 10.4 Conditions to avoid No further relevant information available.
- 10.5 Incompatible materials:

In presence of radical formers (e. g. peroxides), deoxidizing substances, and/or heavy metal ions, polymerization with heat release is possible.

· 10.6 Hazardous decomposition products: -

## **SECTION 11: Toxicological information**

- · 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008
- Acute toxicity Based on available data, the classification criteria are not met.

• Primary irritant effect:

· Skin corrosion/irritation

Causes skin irritation.

· Serious eye damage/irritation Based on available data, the classification criteria are not met.

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## Safety data sheet according to Regulation (EC) No 1907/2006, Article 31

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· Respiratory or skin sensitisation

May cause an allergic skin reaction.

• Germ cell mutagenicity Based on available data, the classification criteria are not met.

• Carcinogenicity Based on available data, the classification criteria are not met.

• *Reproductive toxicity Based on available data, the classification criteria are not met.* 

• STOT-single exposure

May cause respiratory irritation.

• 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.

• 11.2 Information on other hazards

• Endocrine disrupting properties None of the ingredients is listed.

#### **SECTION 12: Ecological information**

· 12.1 Toxicity · Aquatic toxicity: No further relevant information available. • Type of test Effective concentration Method Assessment LC-50: >79 mg/l *Toxicity to fish:* OECD 203 (MMA) NOEC: 40 mg/l ISO 7346 *Time:* 96 h EEC84 Species: Oncorhynchus mykiss Toxicity to Micro- ECO: 100 mg/l starting inhibition Organisms Species: of cell growth (MMA) Pseudomonas putida · 12.2 Persistence and degradability No further relevant information available. · Behaviour in environmental systems: · Components: methyl methacrylate Biodegradability: 30.7% Time: 28 d OECD 301 C Method: Valuation: difficult to decompose · 12.3 Bioaccumulative potential No further relevant information available. · 12.4 Mobility in soil No further relevant information available. · 12.5 Results of PBT and vPvB assessment · PBT: Not applicable. · vPvB: Not applicable. · 12.6 Endocrine disrupting properties The product does not contain substances with endocrine disrupting properties. · 12.7 Other adverse effects • Additional ecological information: · General notes: Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water. Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

## **SECTION 13: Disposal considerations**

## • 13.1 Waste treatment methods

 $\cdot$  **Recommendation** Must be specially treated adhering to official regulations.

## · European waste catalogue

07 01 04\* other organic solvents, washing liquids and mother liquors

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<ul> <li>Uncleaned packaging:</li> <li>Recommendation: Disposal must be made accor</li> </ul>	ding to official regulations.		
SECTION 14: Transport information			
· 14.1 UN number or ID number · ADR, IMDG, IATA	UNI247		
· 14.2 UN proper shipping name · ADR	1247 METHYL METHACRYLATE MONOME	CR,	
· IMDG, IATA	STABILIZED solution METHYL METHACRYLATE MONOMER, STABILIZE solution		
· 14.3 Transport hazard class(es)			
· ADR			
· Class · Label	3 (F1) Flammable liquids. 3		
· IMDG, IATA			
· Class · Label	3 Flammable liquids. 3		
· 14.4 Packing group · ADR, IMDG, IATA	II		
<ul> <li>14.5 Environmental hazards:</li> <li>Marine pollutant:</li> </ul>	No		
14.6 Special precautions for user	Warning: Flammable liquids.		
<ul> <li>Hazard identification number (Kemler code):</li> <li>EMS Number:</li> </ul>	339 F-E,S-D		
· Stowage Category · Stowage Code	B SW2 Clear of living quarters.		
• 14.7 Maritime transport in bulk according to IN instruments			
· Transport/Additional information:	11		
· ADR			
· Limited quantities (LQ)	1L		
· Excepted quantities (EQ)	Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml		
• Transport category • Tunnel restriction code	2 D/E		
· IMDG · Limited quantities (LQ)	IL		
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		(Contd. of page 7)
• Excepted quantities (EQ)		y per inner packaging: 30 ml y per outer packaging: 500 ml
· UN "Model Regulation":	UN 1247 METHYL STABILIZED SOLUI	METHACRYLATE MONOMER, TION, 3, II

## **SECTION 15: Regulatory information**

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

· Directive 2012/18/EU

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

· Seveso category P5c FLAMMABLE LIQUIDS

• Qualifying quantity (tonnes) for the application of lower-tier requirements 5,000 t

• Qualifying quantity (tonnes) for the application of upper-tier requirements 50,000 t

• REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3

• DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II

None of the ingredients is listed.

· REGULATION (EU) 2019/1148

• Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))

None of the ingredients is listed.

· Annex II - REPORTABLE EXPLOSIVES PRECURSORS

None of the ingredients is listed.

· Regulation (EC) No 273/2004 on drug precursors

None of the ingredients is listed.

Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors

None of the ingredients is listed.

· National regulations

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

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

#### **SECTION 16: Other information**

*This Safety Data Sheets is in compliance with Regulation (EC) No 1907/2006, Article 31 as amended by Regulation (EU) 2020/878.* 

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.

· Relevant phrases

H225 Highly flammable liquid and vapour.
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H335 May cause respiratory irritation.

· Department issuing SDS: R&D, MANI MEDICAL GERMANY GmbH

· Contact: Fr. R.Naveenakumar

• Date of previous version: 23.12.2024

• Abbreviations and acronyms: ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road) IMDG: International Maritime Code for Dangerous Goods

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IATA: International Air Transport Association	
GHS: Globally Harmonised System of Classification and Labelling of Chemicals	
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)	
PBT: Persistent, Bioaccumulative and Toxic	
vPvB: very Persistent and very Bioaccumulative	
Flam. Lig. 2: Flammable liquids – Category 2	
Skin Irrit. 2: Skin corrosion/irritation – Category 2	
Skin Sens. 1: Skin sensitisation – Category 1	
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3	
• * Data compared to the previous version altered.	
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