

SAFETY DATA SHEET

Damon® Clear™; Damon® Clear2™

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

1.1 Product identifier

Product name : Damon® Clear™; Damon® Clear2™
Product code : Not available.
Product type : Solid.
Other means of identification : Not available.

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

Product use : Dental product: Orthodontic Appliance
This product, under the normal conditions of use, meets the definition of an "ARTICLE".
Area of application : Professional applications.

1.3 Details of the supplier of the safety data sheet

Supplier/Manufacturer

Ormco Corporation
1332 S. Lone Hill Avenue
Glendora, CA 91740-5339
Telephone no.: 1-800-854-1741

Distributor

ORMCO B.V.
Basicweg 20
3821 BR Amersfoort
Netherlands
Telephone no.: 00800-3032-3032

e-mail address of person responsible for this SDS : customerservice@ormcoeurope.com

1.4 Emergency telephone number

National advisory body/Poison Centre

Telephone number : United Kingdom (UK) National advisory body/Poison Centre: +44 870 600 6266

Supplier

Telephone number : +39-340-1721884
Hours of operation : 08.00-23.00, European time, GMT+1

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Product definition : Mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP/GHS]

Not classified.

The product is not classified as hazardous according to Regulation (EC) 1272/2008 as amended.

Ingredients of unknown toxicity : 89.3 percent of the mixture consists of component(s) of unknown toxicity

Ingredients of unknown ecotoxicity : Contains 16.1 % of components with unknown hazards to the aquatic environment

See Section 11 for more detailed information on health effects and symptoms.

2.2 Label elements

Signal word : No signal word.

Hazard statements : No known significant effects or critical hazards.

Precautionary statements

Prevention : Not applicable.

Response : Not applicable.

Storage : Not applicable.

Disposal : Not applicable.

Supplemental label elements : Contains nickel, Poly(oxy-1,2-ethanediyl), α,α' -[(1-methylethylidene)di-4,1-phenylene] bis[ω -[(2-methyl-1-oxo-2-propen-1-yl)oxy]-, 2-hydroxyethyl methacrylate and 2-diethylaminoethyl methacrylate. May produce an allergic reaction. Safety data sheet available on request.

Annex XVII - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles : Not applicable.

Special packaging requirements

Containers to be fitted with child-resistant fastenings : Not applicable.

Tactile warning of danger : Not applicable.

2.3 Other hazards

Other hazards which do not result in classification : If dust or fumes are generated during processing (e.g., brazing, cutting, grinding, sawing, and welding) hazardous chemicals could be released.

SECTION 3: Composition/information on ingredients

3.2 Mixtures : Mixture

Product/ingredient name	Identifiers	%	Regulation (EC) No. 1272/2008 [CLP]	Type
aluminium oxide	EC: 215-691-6 CAS: 1344-28-1	≥75 - ≤90	Not classified.	[2]
2-hydroxyethyl methacrylate	EC: 212-782-2 CAS: 868-77-9 Index: 607-124-00-X	≤10	Skin Irrit. 2, H315 Eye Irrit. 2, H319 Skin Sens. 1, H317	[1]
zirconium dioxide	EC: 215-227-2 CAS: 1314-23-4	≤5	Not classified.	[2]
Poly(oxy-1,2-ethanediyl), α,α'-[(1-methylethylidene)di-4,1-phenylene] bis[ω-[(2-methyl-1-oxo-2-propen-1-yl)oxy]-	CAS: 41637-38-1	≤3	Skin Irrit. 2, H315 Eye Irrit. 2, H319 Skin Sens. 1A, H317 STOT SE 3, H335 Aquatic Chronic 4, H413 See Section 16 for the full text of the H statements declared above.	[1]

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment, are PBTs, vPvBs or Substances of equivalent concern, or have been assigned a workplace exposure limit and hence require reporting in this section.

Type

[1] Substance classified with a health or environmental hazard

[2] Substance with a workplace exposure limit

[3] Substance meets the criteria for PBT according to Regulation (EC) No. 1907/2006, Annex XIII

[4] Substance meets the criteria for vPvB according to Regulation (EC) No. 1907/2006, Annex XIII

[5] Substance of equivalent concern

Occupational exposure limits, if available, are listed in Section 8.

SECTION 4: First aid measures

4.1 Description of first aid measures

- Eye contact** : No special measures are required. In case of contact with eyes, rinse immediately with plenty of water. Get medical attention if symptoms occur.
- Inhalation** : No special measures required. If inhaled, remove to fresh air. Get medical attention if symptoms occur.
- Skin contact** : No special measures required. In case of contact, immediately flush skin with plenty of water. Get medical attention if symptoms occur.
- Ingestion** : Wash out mouth with water. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. Get medical attention if adverse health effects persist or are severe.
- Protection of first-aiders** : In case of major fire and large quantities: No action shall be taken involving any personal risk or without suitable training.

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SECTION 4: First aid measures

4.2 Most important symptoms and effects, both acute and delayed

Over-exposure signs/symptoms

- Eye contact : No specific data.
- Inhalation : No specific data.
- Skin contact : No specific data.
- Ingestion : No specific data.

4.3 Indication of any immediate medical attention and special treatment needed

- Notes to physician : Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.
- Specific treatments : No specific treatment.

SECTION 5: Firefighting measures

5.1 Extinguishing media

- Suitable extinguishing media : Use an extinguishing agent suitable for the surrounding fire.
- Unsuitable extinguishing media : Do not use water jet.

5.2 Special hazards arising from the substance or mixture

- Hazards from the substance or mixture : No specific fire or explosion hazard.
- Hazardous thermal decomposition products : Decomposition products may include the following materials:
 - carbon dioxide
 - carbon monoxide
 - metal oxide/oxides

5.3 Advice for firefighters

- Special protective actions for fire-fighters : In case of major fire and large quantities: Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.
- Special protective equipment for fire-fighters : Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode. Clothing for fire-fighters (including helmets, protective boots and gloves) conforming to European standard EN 469 will provide a basic level of protection for chemical incidents.

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SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

- For non-emergency personnel** : Low release . For professional use only. Handling of product in very small amounts or in situations where release is highly unlikely
- For emergency responders** : Low release. See also the information in "For non-emergency personnel".

6.2 Environmental precautions : No special measures are required.

6.3 Methods and material for containment and cleaning up

- Small spill** : No special measures required.
- Large spill** : No special measures required.

6.4 Reference to other sections : See Section 1 for emergency contact information.
See Section 8 for information on appropriate personal protective equipment.
See Section 13 for additional waste treatment information.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

- Protective measures** : No special measures are required.
- Advice on general occupational hygiene** : No special measures are required.

7.2 Conditions for safe storage, including any incompatibilities

Store in accordance with local regulations.

Seveso Directive - Reporting thresholds (in tonnes)

Named substances

Name	Notification and MAPP threshold	Safety report threshold
Methanol	500	5000

7.3 Specific end use(s)

- Recommendations** : Not available.
- Industrial sector specific solutions** : Not available.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational exposure limits

Product/ingredient name	Exposure limit values
aluminium oxide	EH40/2005 WELs (United Kingdom (UK), 12/2011). TWA: 10 mg/m ³ 8 hours. Form: inhalable dust
zirconium dioxide	EH40/2005 WELs (United Kingdom (UK), 8/2007). TWA: 4 mg/m ³ 8 hours. Form: Respirable dust EH40/2005 WELs (United Kingdom (UK), 12/2011). STEL: 10 mg/m ³ , (as Zr) 15 minutes. TWA: 5 mg/m ³ , (as Zr) 8 hours.

Recommended monitoring procedures : If this product contains ingredients with exposure limits, personal, workplace atmosphere or biological monitoring may be required to determine the effectiveness of the ventilation or other control measures and/or the necessity to use respiratory protective equipment. Reference should be made to monitoring standards, such as the following: European Standard EN 689 (Workplace atmospheres - Guidance for the assessment of exposure by inhalation to chemical agents for comparison with limit values and measurement strategy) European Standard EN 14042 (Workplace atmospheres - Guide for the application and use of procedures for the assessment of exposure to chemical and biological agents) European Standard EN 482 (Workplace atmospheres - General requirements for the performance of procedures for the measurement of chemical agents) Reference to national guidance documents for methods for the determination of hazardous substances will also be required.

DNELs/DMELs

No DNELs/DMELs available.

PNECs

No PNECs available

8.2 Exposure controls

Appropriate engineering controls : No special measures are required for small quantities under normal and intended conditions of product use.

Individual protection measures

Hygiene measures : No special measures are required for small quantities under normal and intended conditions of product use.

Eye/face protection : No special measures are required for small quantities under normal and intended conditions of product use.

Skin protection

Hand protection : No special protection is required.

Body protection : No special measures are required for small quantities under normal and intended conditions of product use.

Other skin protection : No special measures are required for small quantities under normal and intended conditions of product use.

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SECTION 8: Exposure controls/personal protection

- Respiratory protection** : No special measures are required for small quantities under normal and intended conditions of product use.
- Environmental exposure controls** : No special measures are required for small quantities under normal and intended conditions of product use.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance

- Physical state** : Solid. [Bracket Assembly]
- Colour** : White.
- Odour** : Odourless.
- Odour threshold** : Not applicable.
- pH** : Not applicable.
- Melting point/freezing point** : Not applicable.
- Initial boiling point and boiling range** : Not applicable.
- Flash point** : Not applicable.
- Evaporation rate** : Not applicable.
- Flammability (solid, gas)** : Not available.
- Upper/lower flammability or explosive limits** : Not applicable
- Vapour pressure** : Not applicable.
- Vapour density** : Not applicable.
- Relative density** : Not applicable.
- Solubility(ies)** : Insoluble in the following materials: cold water and hot water.
- Partition coefficient: n-octanol/water** : Not applicable.
- Auto-ignition temperature** : Not applicable.
- Decomposition temperature** : Not applicable.
- Viscosity** : Not applicable.
- Explosive properties** : Not available.
- Oxidising properties** : Not available.

9.2 Other information

- Solubility in water** : Not available.
- Physical/chemical properties comments** : No additional information.

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SECTION 10: Stability and reactivity

- 10.1 Reactivity** : No specific test data related to reactivity available for this product or its ingredients.
- 10.2 Chemical stability** : The product is stable.
- 10.3 Possibility of hazardous reactions** : Under normal conditions of storage and use, hazardous reactions will not occur.
Under normal conditions of storage and use, hazardous polymerisation will not occur.
- 10.4 Conditions to avoid** : No specific data.
- 10.5 Incompatible materials** : No specific data.
- 10.6 Hazardous decomposition products** : Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

Product/ingredient name	Result	Species	Dose	Exposure
2-hydroxyethyl methacrylate	LD50 Oral	Rat	4230 mg/kg	-

Conclusion/Summary : Not available.

Acute toxicity estimates

Not available.

Irritation/Corrosion

Conclusion/Summary : Not available.

Sensitisation

Conclusion/Summary : Not available.

Mutagenicity

Conclusion/Summary : Not available.

Carcinogenicity

Conclusion/Summary : Not available.

Reproductive toxicity

Conclusion/Summary : Not available.

Teratogenicity

Conclusion/Summary : Not available.

Specific target organ toxicity (single exposure)

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SECTION 11: Toxicological information

Product/ingredient name	Category	Route of exposure	Target organs
Poly(oxy-1,2-ethanediyl), α,α' -[[1-methylethylidene]di-4,1-phenylene]bis[ω -[(2-methyl-1-oxo-2-propen-1-yl)oxy]-	Category 3	Not applicable.	Respiratory tract irritation

Specific target organ toxicity (repeated exposure)

Not available.

Aspiration hazard

Not available.

Information on likely routes of exposure : Not available.

Potential acute health effects

- Eye contact** : No known significant effects or critical hazards.
- Inhalation** : No known significant effects or critical hazards.
- Skin contact** : No known significant effects or critical hazards.
- Ingestion** : No known significant effects or critical hazards.

Symptoms related to the physical, chemical and toxicological characteristics

- Eye contact** : No specific data.
- Inhalation** : No specific data.
- Skin contact** : No specific data.
- Ingestion** : No specific data.

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Short term exposure

- Potential immediate effects** : Not available.
- Potential delayed effects** : Not available.

Long term exposure

- Potential immediate effects** : Not available.
- Potential delayed effects** : Not available.

Potential chronic health effects

Not available.

Conclusion/Summary : Not available.

- General** : No known significant effects or critical hazards.
- Carcinogenicity** : No known significant effects or critical hazards.
- Mutagenicity** : No known significant effects or critical hazards.
- Teratogenicity** : No known significant effects or critical hazards.

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SECTION 11: Toxicological information

Developmental effects : No known significant effects or critical hazards.

Fertility effects : No known significant effects or critical hazards.

Other information : Not available.

SECTION 12: Ecological information

12.1 Toxicity

Product/ingredient name	Result	Species	Exposure
2-hydroxyethyl methacrylate	Acute LC50 227000 µg/l Fresh water	Fish - Pimephales promelas - Juvenile (Fledgling, Hatchling, Weanling)	96 hours

Conclusion/Summary : Not available.

12.2 Persistence and degradability

Product/ingredient name	Test	Result	Dose	Inoculum
2-hydroxyethyl methacrylate	OECD 301C Ready Biodegradability - Modified MITI Test (I)	92 to 100 % - 14 days	-	-
Poly(oxy-1,2-ethanediyl), α,α' -[(1-methylethylidene)di-4,1-phenylene]bis[ω-[(2-methyl-1-oxo-2-propen-1-yl)oxy]-	OECD 301D Ready Biodegradability - Closed Bottle Test	24 % - Inherent - 28 days	-	-

Conclusion/Summary : Not available.

Product/ingredient name	Aquatic half-life	Photolysis	Biodegradability
2-hydroxyethyl methacrylate	-	-	Readily
Poly(oxy-1,2-ethanediyl), α,α' -[(1-methylethylidene)di-4,1-phenylene]bis[ω-[(2-methyl-1-oxo-2-propen-1-yl)oxy]-	-	-	Inherent

12.3 Bioaccumulative potential

Product/ingredient name	LogP _{ow}	BCF	Potential
2-hydroxyethyl methacrylate	0.42	-	low
Poly(oxy-1,2-ethanediyl), α,α' -[(1-methylethylidene)di-4,1-phenylene]bis[ω-[(2-methyl-1-oxo-2-propen-1-yl)oxy]-	3.43 to 5.62	-	high

12.4 Mobility in soil

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SECTION 12: Ecological information

Soil/water partition coefficient (K_{oc}) : Not available.

Mobility : Not available.

12.5 Results of PBT and vPvB assessment

PBT : Not applicable.

vPvB : Not applicable.

12.6 Other adverse effects : No known significant effects or critical hazards.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product

Methods of disposal : The generation of waste should be avoided or minimised wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements.

Hazardous waste : Within the present knowledge of the supplier, this product is not regarded as hazardous waste, as defined by EU Directive 2008/98/EC.

Packaging

Methods of disposal : The generation of waste should be avoided or minimised wherever possible. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible.

Special precautions : This material and its container must be disposed of in a safe way. Empty containers or liners may retain some product residues. Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers.

SECTION 14: Transport information

	ADR/RID	ADN	IMDG	IATA
14.1 UN number	Not regulated.	Not regulated.	Not regulated.	Not regulated.
14.2 UN proper shipping name	-	-	-	-
14.3 Transport hazard class(es)	-	-	-	-
14.4 Packing group	-	-	-	-
14.5 Environmental hazards	No.	No.	No.	No.

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SECTION 14: Transport information

Additional information	-	-	-	-
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14.6 Special precautions for user : **Transport within user's premises:** always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code : Not available.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
EU Regulation (EC) No. 1907/2006 (REACH)

Annex XIV - List of substances subject to authorisation

Annex XIV

None of the components are listed.

Substances of very high concern

None of the components are listed.

Annex XVII - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles : Not applicable.

Other EU regulations

Europe inventory : Not determined.

Black List Chemicals (76/464/EEC) : Not listed

Ozone depleting substances (1005/2009/EU)

Not listed.

Prior Informed Consent (PIC) (649/2012/EU)

Not listed.

Seveso Directive

This product is controlled under the Seveso Directive.

Named substances

Name
Methanol

International regulations

Chemical Weapon Convention List Schedules I, II & III Chemicals

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SECTION 15: Regulatory information

Not listed.

Montreal Protocol (Annexes A, B, C, E)

Not listed.

Stockholm Convention on Persistent Organic Pollutants

Not listed.

Rotterdam Convention on Prior Informed Consent (PIC)

Not listed.

UNECE Aarhus Protocol on POPs and Heavy Metals

Not listed.

15.2 Chemical safety assessment : This product contains substances for which Chemical Safety Assessments are still required.

15.3 Registration status : Mixture. Information concerning the substance : Contact local supplier or distributor.

SECTION 16: Other information

✔ Indicates information that has changed from previously issued version.

Abbreviations and acronyms : ATE = Acute Toxicity Estimate
CLP = Classification, Labelling and Packaging Regulation [Regulation (EC) No. 1272/2008]
DMEL = Derived Minimal Effect Level
DNEL = Derived No Effect Level
EUH statement = CLP-specific Hazard statement
PBT = Persistent, Bioaccumulative and Toxic
PNEC = Predicted No Effect Concentration
RRN = REACH Registration Number
vPvB = Very Persistent and Very Bioaccumulative

Key literature references and sources for data : Regulation (EC) No. 1272/2008 [CLP]; European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR), concluded in Geneva on 30 September 1957 plus amendments (Uniform text: Journal of Laws 27/2009 pos. 162 plus amendments); Regulation for the transport of dangerous materials on the Rhine (ADN); Occupational exposure limits; International regulations

Procedure used to derive the classification according to Regulation (EC) No. 1272/2008 [CLP/GHS]

Classification	Justification
Not classified.	

Full text of abbreviated H statements

H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H413	May cause long lasting harmful effects to aquatic life.

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SECTION 16: Other information

[Full text of classifications \[CLP/GHS\]](#)

Aquatic Chronic 4, H413 Eye Irrit. 2, H319 Skin Irrit. 2, H315 Skin Sens. 1, H317 Skin Sens. 1A, H317 STOT SE 3, H335	LONG-TERM (CHRONIC) AQUATIC HAZARD - Category 4 SERIOUS EYE DAMAGE/EYE IRRITATION - Category 2 SKIN CORROSION/IRRITATION - Category 2 SKIN SENSITISATION - Category 1 SKIN SENSITISATION - Category 1A SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE (Respiratory tract irritation) - Category 3
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Training advice : Ensure operatives are trained to minimise exposures. Training staff on good practice.

Date of issue/ Date of revision : 18/04/2017

Date of previous issue : No previous validation

Version : 1

[Notice to reader](#)

To the best of our knowledge, the information contained herein is accurate. However, neither the above-named supplier, nor any of its subsidiaries, assumes any liability whatsoever for the accuracy or completeness of the information contained herein.

Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.