



SAFETY DATA SHEET

Damon™ Q; Damon™ Q2; Damon™ 3MX;
Alias; SnapLink™ Buccal Tubes; Drop-in Hook

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

1.1 Product identifier

Product name : Damon™ Q; Damon™ Q2; Damon™ 3MX; Alias; SnapLink™ Buccal Tubes; Drop-in Hook
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 : +31 (0)0800 3032 3032
Hours of operation : 08.00-23.00, European time, GMT+1

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational exposure limits

Product/ingredient name	Exposure limit values
chromium	EH40/2005 WELs (United Kingdom (UK), 12/2011). TWA: 0.5 mg/m ³ 8 hours.
Nickel	EH40/2005 WELs (United Kingdom (UK), 12/2011). Absorbed through skin. TWA: 0.5 mg/m ³ , (as Ni) 8 hours.
copper	EH40/2005 WELs (United Kingdom (UK), 12/2011). STEL: 2 mg/m ³ , (as Cu) 15 minutes. Form: Dusts and Mists TWA: 1 mg/m ³ , (as Cu) 8 hours. Form: Dusts and Mists TWA: 0.2 mg/m ³ , (as Cu) 8 hours. Form: Fume
manganese	EH40/2005 WELs (United Kingdom (UK), 12/2011). TWA: 0.5 mg/m ³ , (as Mn) 8 hours.
silicon	EH40/2005 WELs (United Kingdom (UK), 12/2011). TWA: 10 mg/m ³ 8 hours. Form: inhalable dust TWA: 4 mg/m ³ 8 hours. Form: respirable dust

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

SECTION 8: Exposure controls/personal 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.
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	: Metallic./Grey.
Odour	: Odourless.
Odour threshold	: Not applicable.
pH	: Not applicable.
Melting point/freezing point	: 1470°C
Initial boiling point and boiling range	: Not available.
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 available.
Viscosity	: Not applicable.
Explosive properties	: Not available.
Oxidising properties	: Not available.

9.2 Other information

Solubility in water	: Not available.
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SECTION 9: Physical and chemical properties

Physical/chemical properties comments : No additional information.

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
manganese	LC50 Inhalation Dusts and mists	Rat	5.14 mg/l	4 hours
	LD50 Oral	Rat	9 g/kg	-
silicon	LD50 Oral	Rat	3160 mg/kg	-

Conclusion/Summary : Not available.

Acute toxicity estimates

Not available.

Irritation/Corrosion

Product/ingredient name	Result	Species	Score	Exposure	Observation
manganese	Eyes - Mild irritant	Rabbit	-	24 hours 500 milligrams	-
	Skin - Mild irritant	Rabbit	-	24 hours 500 milligrams	-
silicon	Eyes - Mild irritant	Rabbit	-	3 milligrams	-

Conclusion/Summary : Not available.

Sensitisation

Conclusion/Summary : Not available.

SECTION 11: Toxicological information

Mutagenicity

Conclusion/Summary : No mutagenic effect.

Carcinogenicity

Conclusion/Summary : Not available.

Reproductive toxicity

Conclusion/Summary : Not available.

Teratogenicity

Conclusion/Summary : Not available.

Not available.

Specific target organ toxicity (repeated exposure)

Product/ingredient name	Category	Route of exposure	Target organs
Nickel	Category 1	Inhalation	respiratory tract

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.

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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.

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	
chromium	Acute EC50 0.2 ppm Marine water	Algae - Bacillariophyta	72 hours	
	Acute EC50 5 ppm Marine water	Algae - Macrocyctis pyrifera - Young	4 days	
	Acute EC50 35000 µg/l Fresh water	Aquatic plants - Lemna minor	4 days	
	Acute LC50 45 µg/l Fresh water	Crustaceans - Ceriodaphnia reticulata	48 hours	
	Acute LC50 22 µg/l Fresh water	Daphnia - Daphnia magna	48 hours	
	Acute LC50 13.9 ppm Fresh water	Fish - Anguilla rostrata	96 hours	
	Chronic NOEC 50 mg/l Marine water	Algae - Glenodinium halli	72 hours	
	Chronic NOEC 0.19 µg/l Fresh water	Fish - Cyprinus carpio	4 weeks	
	Nickel	Acute EC50 2 ppm Marine water	Algae - Macrocyctis pyrifera - Young	4 days
		Acute EC50 450 µg/l Fresh water	Aquatic plants - Lemna minor	4 days
Acute EC50 1000 µg/l Marine water		Daphnia - Daphnia magna	48 hours	
Acute IC50 0.31 mg/l Marine water		Crustaceans - Americamysis bahia - Juvenile (Fledgling, Hatchling, Weanling)	48 hours	
Acute LC50 47.5 ng/L Fresh water		Fish - Heteropneustes fossilis	96 hours	
Chronic NOEC 100 mg/l Marine water		Algae - Glenodinium halli	72 hours	
copper	Chronic NOEC 3.5 µg/l Fresh water	Fish - Cyprinus carpio	4 weeks	
	Acute EC50 1100 µg/l Fresh water	Aquatic plants - Lemna minor	4 days	
	Acute EC50 2.1 µg/l Fresh water	Daphnia - Daphnia longispina - Juvenile (Fledgling, Hatchling, Weanling)	48 hours	
	Acute IC50 13 µg/l Fresh water	Algae - Pseudokirchneriella subcapitata - Exponential growth phase	72 hours	
	Acute IC50 5.4 mg/l Marine water	Aquatic plants - Plantae - Exponential growth phase	72 hours	

SECTION 12: Ecological information

	Acute LC50 0.072 µg/l Marine water	Crustaceans - Amphipoda - Adult	48 hours
	Acute LC50 7.56 µg/l Marine water	Fish - Periophthalmus waltoni - Adult	96 hours
	Chronic NOEC 2.5 µg/l Marine water	Algae - Nitzschia closterium - Exponential growth phase	72 hours
	Chronic NOEC 7 mg/l Fresh water	Aquatic plants - Ceratophyllum demersum	3 days
	Chronic NOEC 0.02 mg/l Fresh water	Crustaceans - Cambarus bartonii - Mature	21 days
	Chronic NOEC 2 µg/l Fresh water Chronic NOEC 0.8 µg/l Fresh water	Daphnia - Daphnia magna Fish - Oreochromis niloticus - Juvenile (Fledgling, Hatchling, Weanling)	21 days 6 weeks
manganese	Acute EC50 31000 µg/l Fresh water	Aquatic plants - Lemna minor	4 days
	Acute LC50 29000 µg/l	Daphnia - Daphnia magna	48 hours
	Acute LC50 28 mg/l Fresh water	Fish - Pimephales promelas	96 hours
	Chronic NOEC 1.7 mg/l Fresh water	Daphnia - Water Flea- Ceriodaphnia dubia	8 days
vanadium	Acute LC50 1550 µg/l	Daphnia - Daphnia magna	48 hours
	Acute LC50 1.8 mg/l Fresh water	Fish - Pimephales promelas	96 hours
	Chronic NOEC 500 mg/l Marine water	Algae - Glenodinium halli	72 hours

Conclusion/Summary : Not available.

12.2 Persistence and degradability

Conclusion/Summary : Not available.

12.3 Bioaccumulative potential

Product/ingredient name	LogP _{ow}	BCF	Potential
silicon	57 to 77	-	high

12.4 Mobility in soil

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.

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 : Not applicable.
**on the manufacture,
placing on the market
and use of certain
dangerous substances,
mixtures and articles**

Other EU regulations

Europe inventory : Not determined.

**Industrial emissions
(integrated pollution
prevention and control) -
Air** : Listed

**Industrial emissions
(integrated pollution
prevention and control) -
Water** : Listed

Ozone depleting substances (1005/2009/EU)

Not listed.

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

Not listed.

Seveso Directive

This product is not controlled under the Seveso Directive.

International regulations

Chemical Weapon Convention List Schedules I, II & III Chemicals

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

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SECTION 15: Regulatory information

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

H228	Flammable solid.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H351	Suspected of causing cancer.
H372 (inhalation)	Causes damage to organs through prolonged or repeated exposure if inhaled.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
H411	Toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.
H413	May cause long lasting harmful effects to aquatic life.

Full text of classifications [CLP/GHS]

SECTION 16: Other information

Aquatic Acute 1, H400	SHORT-TERM (ACUTE) AQUATIC HAZARD - Category 1
Aquatic Chronic 1, H410	LONG-TERM (CHRONIC) AQUATIC HAZARD - Category 1
Aquatic Chronic 2, H411	LONG-TERM (CHRONIC) AQUATIC HAZARD - Category 2
Aquatic Chronic 3, H412	LONG-TERM (CHRONIC) AQUATIC HAZARD - Category 3
Aquatic Chronic 4, H413	LONG-TERM (CHRONIC) AQUATIC HAZARD - Category 4
Carc. 2, H351	CARCINOGENICITY - Category 2
Eye Irrit. 2, H319	SERIOUS EYE DAMAGE/EYE IRRITATION - Category 2
Flam. Sol. 2, H228	FLAMMABLE SOLIDS - Category 2
Skin Sens. 1, H317	SKIN SENSITISATION - Category 1
STOT RE 1, H372 (inhalation)	SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE (inhalation) - Category 1

Training advice : Ensure operatives are trained to minimise exposures. Training staff on good practice.

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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.