

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

### 1.1 Product identifier

<b>Product name</b>	: Damon® Tieback; Generation II Power Chain
<b>Product code</b>	: Not available.
<b>Product type</b>	: Solid.
<b>Other means of identification</b>	: Not available.

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

<b>Product use</b>	: Dental product: Orthodontic Appliance This product, under the normal conditions of use, meets the definition of an "ARTICLE".
<b>Area of application</b>	: 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  
NL 3821 BR AMERSFOORT (HOLLAND)  
00-800-3032-3032

**e-mail address of person responsible for this SDS** : OrmcoCustCare@sybrondental.com

### 1.4 Emergency telephone number

#### National advisory body/Poison Centre

**Telephone number** : CHEMTREC® International (24 hours): +1 (703) 527-3887  
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** : 14.7 percent of the mixture consists of component(s) of unknown toxicity

**Ingredients of unknown ecotoxicity** : Contains 16.4 % 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 isocyanates. Contains 4,4'-methylenediphenyl diisocyanate. 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
4,4'-methylenediphenyl diisocyanate	EC: 202-966-0 CAS: 101-68-8 Index: 615-005-00-9	≤10	Acute Tox. 2, H330 Skin Irrit. 2, H315 Eye Irrit. 2, H319 Resp. Sens. 1, H334 Skin Sens. 1, H317 Carc. 2, H351 STOT SE 3, H335 STOT RE 2, H373  <b>See Section 16 for the full text of the H statements declared above.</b>	[1] [2]

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. Get medical attention if symptoms occur.
- Inhalation** : No special measures required. Get medical attention if symptoms occur.
- Skin contact** : No special measures required. Get medical attention if symptoms occur.
- Ingestion** : If swallowed then seek immediate medical assistance.
- 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.

### 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

## SECTION 4: First aid measures

- Notes to physician** : In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.
- 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  
nitrogen oxides  
Hydrogen cyanide (HCN).

### 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.

## 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.

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## SECTION 6: Accidental release measures

- 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.

### 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
4,4'-methylenediphenyl diisocyanate	<b>EH40/2005 WELs (United Kingdom (UK), 12/2011). Inhalation sensitiser.</b> STEL: 0.07 mg/m <sup>3</sup> , (as NCO) 15 minutes. TWA: 0.02 mg/m <sup>3</sup> , (as NCO) 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

## SECTION 8: Exposure controls/personal protection

### 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.

**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. [Elastic chain]

**Colour** : Various

**Odour** : Odourless.

**Odour threshold** : Not applicable.

**pH** : Not applicable.

**Melting point/freezing point** : 103°C

**Initial boiling point and boiling range** : Not applicable.

**Flash point** : Closed cup: 212°C

**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)** : Not available.

## SECTION 9: Physical and chemical properties

**Partition coefficient: n-octanol/ water** : Not applicable.

**Auto-ignition temperature** : 270°C

**Decomposition temperature** : Not applicable.

**Viscosity** : Not applicable.

**Explosive properties** : Not available.

**Oxidising properties** : Not available.

### 9.2 Other information

**Solubility in water** : 18 g/l

**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
4,4'-methylenediphenyl diisocyanate	LC50 Inhalation Dusts and mists	Rat	380 mg/m <sup>3</sup>	4 hours
	LD50 Oral	Rat	9200 mg/kg	-

**Conclusion/Summary** : Non-cytotoxic.

#### Irritation/Corrosion

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## SECTION 11: Toxicological information

Product/ingredient name	Result	Species	Score	Exposure	Observation
4,4'-methylenediphenyl diisocyanate	Eyes - Moderate irritant	Rabbit	-	100 milligrams	-

**Conclusion/Summary** : Not available.

### Sensitisation

Product/ingredient name	Route of exposure	Species	Result
Damon® Tieback; Generation II Power Chain	skin	Guinea pig	Not sensitizing

**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)

Product/ingredient name	Category	Route of exposure	Target organs
4,4'-methylenediphenyl diisocyanate	Category 3	Not applicable.	Respiratory tract irritation

### Specific target organ toxicity (repeated exposure)

Product/ingredient name	Category	Route of exposure	Target organs
4,4'-methylenediphenyl diisocyanate	Category 2	Not determined	Not determined

### Aspiration hazard

Not available.

**Information on likely routes of exposure** : Routes of entry anticipated: Oral, Dermal, Inhalation.

### 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.



## SECTION 11: Toxicological information

### 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.
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

Conclusion/Summary : Not available.

### 12.2 Persistence and degradability

Product/ingredient name	Test	Result	Dose	Inoculum
4,4'-methylenediphenyl diisocyanate	OECD 302C Inherent Biodegradability: Modified MITI Test (II)	0 % - 28 days	-	-

Conclusion/Summary : Not available.

## SECTION 12: Ecological information

Product/ingredient name	Aquatic half-life	Photolysis	Biodegradability
4,4'-methylenediphenyl diisocyanate	-	-	Not readily

### 12.3 Bioaccumulative potential

Product/ingredient name	LogP <sub>ow</sub>	BCF	Potential
4,4'-methylenediphenyl diisocyanate	4.51	200	low

### 12.4 Mobility in soil

**Soil/water partition coefficient (K<sub>oc</sub>)** : 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.
Additional information	-	-	-	-

**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.

## SECTION 15: Regulatory information

**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

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

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## SECTION 16: Other information

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.
H330	Fatal if inhaled.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H335	May cause respiratory irritation.
H351	Suspected of causing cancer.
H373	May cause damage to organs through prolonged or repeated exposure.

### Full text of classifications [CLP/GHS]

Acute Tox. 2, H330 Carc. 2, H351 Eye Irrit. 2, H319 Resp. Sens. 1, H334 Skin Irrit. 2, H315 Skin Sens. 1, H317 STOT RE 2, H373	ACUTE TOXICITY (inhalation) - Category 2 CARCINOGENICITY - Category 2 SERIOUS EYE DAMAGE/EYE IRRITATION - Category 2 RESPIRATORY SENSITISATION - Category 1 SKIN CORROSION/IRRITATION - Category 2 SKIN SENSITISATION - Category 1 SPECIFIC TARGET ORGAN TOXICITY - REPEATED EXPOSURE - Category 2 SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE (Respiratory tract irritation) - Category 3
STOT SE 3, H335	

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

**Date of issue/ Date of revision** : 27/10/2016

**Date of previous issue** : No previous validation

**Version** : 1

### Notice to reader

## **SECTION 16: Other information**

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.