

Safety Data Sheet

according to Regulation (EC) No 1907/2006

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Revision date: 07.03.2023

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SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1. Product identifier**

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Product code: DBL3-0600 to DBL3-0615**1.2. Relevant identified uses of the substance or mixture and uses advised against****Use of the substance/mixture**

Retainer / Aligner Thermoformed Plastic

1.3. Details of the supplier of the safety data sheet

Company name: DB Orthodontics Ltd
Street: Ryefield Way
Place: Silsden
Telephone: +44 (0) 1535 656999
e-mail: sales@dbortho.com
Internet: www.dbortho.com

1.4. Emergency telephone number:

International +44 (0) 1535 656999

SECTION 2: Hazards identification**2.1. Classification of the substance or mixture****Regulation (EC) No 1272/2008**

This mixture is not classified as hazardous in accordance with Regulation (EC) No 1272/2008.

2.2. Label elements**Additional advice on labelling**

Labelling according to Regulation (EC) No. 1272/2008 [CLP]: not applicable / not relevant
The product is: article

2.3. Other hazards

The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII.

SECTION 3: Composition/information on ingredients**3.2. Mixtures****Chemical characterization**

plastic

Hazardous components

none (according to Regulation (EC) No 1907/2006 (REACH))

SECTION 4: First aid measures**4.1. Description of first aid measures****General information**

In all cases of doubt, or when symptoms persist, seek medical advice.

After inhalation

Exposure route (oral): not applicable

In case of melting: Do not breathe gas/fumes/vapour/spray.

After contact with skin

After contact with molten product, cool skin area rapidly with cold water. Burns caused by molten material must be treated clinically.

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Do not peel solidified product off the skin.

After contact with eyes

Rinse immediately carefully and thoroughly with eye-bath or water. Remove contact lenses, if present and easy to do. Continue rinsing. In case of troubles or persistent symptoms, consult an ophthalmologist.

After ingestion

Call a doctor if you feel unwell.

4.2. Most important symptoms and effects, both acute and delayed

The melted product can cause severe burns.

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures**5.1. Extinguishing media****Suitable extinguishing media**

Co-ordinate fire-fighting measures to the fire surroundings.

5.2. Special hazards arising from the substance or mixture

This material is combustible, but will not ignite readily.

In case of fire may be liberated: Carbon monoxide, Carbon dioxide (CO₂), Pyrolysis products, toxic.

5.3. Advice for firefighters

In case of fire: Wear self-contained breathing apparatus. Full protective suit.

Additional information

Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.

SECTION 6: Accidental release measures**6.1. Personal precautions, protective equipment and emergency procedures****General advice**

Do not breathe gas/fumes/vapour/spray.

For non-emergency personnel

Remove all sources of ignition. Provide adequate ventilation. Use personal protection equipment.

For emergency responders

Use personal protection equipment.

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up**For containment**

Avoid dust formation.

For cleaning up

Take up mechanically.

Other information

Treat the recovered material as prescribed in the section on waste disposal.

6.4. Reference to other sections

Safe handling: see section 7

Personal protection equipment: see section 8

Disposal: see section 13

SECTION 7: Handling and storage**7.1. Precautions for safe handling**

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Advice on safe handling

In case of melting: Provide adequate ventilation as well as local exhaust at critical locations.
Avoid dust formation. Do not breathe dust.

Advice on protection against fire and explosion

Keep away from sources of ignition - No smoking.

Advice on general occupational hygiene

Take off contaminated clothing. Wash hands before breaks and after work. When using do not eat, drink, smoke, sniff.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Keep container tightly closed. Protect from moisture.

Hints on joint storage

Keep away from food, drink and animal feedingstuffs.

Further information on storage conditions

Keep away from heat.

7.3. Specific end use(s)

Plastic articles

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limits

CAS No	Substance	ppm	mg/m ³	fib/cm ³	Category	Origin
-	Dusts non-specific, respirable		4		TWA (8 h)	
-	Dusts non-specific, total inhalable		10		TWA (8 h)	

8.2. Exposure controls



Appropriate engineering controls

Provide adequate ventilation as well as local exhaust at critical locations.

Individual protection measures, such as personal protective equipment

Eye/face protection

In case of melting: Use eye protection according to EN 166.

Hand protection

In case of melting: Wear suitable gloves tested to EN374.

When handling with chemical substances, protective gloves must be worn with the CE-label including the four control digits. The quality of the protective gloves resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of hazardous substances. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves.

Skin protection

Wear suitable protective clothing.

Handling larger quantities ((Generation/formation of dust, Melt): Wear suitable protective clothing.

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Respiratory protection

Usually no personal respirative protection necessary.
In case of inadequate ventilation wear respiratory protection.

Thermal hazards

In case of melting: Incineration.
Protective clothing. (heat-resistant)

Environmental exposure controls

Avoid release to the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state:	solid	
Colour:	colourless	
Odour:	neutral	
Odour threshold:	not determined	
Melting point/freezing point:		not determined
Boiling point or initial boiling point and boiling range:		not determined
Flammability:		not determined
		not applicable
Lower explosion limits:		not applicable
Upper explosion limits:		not applicable
Flash point:		not applicable
Auto-ignition temperature:		not determined
Decomposition temperature:		not applicable
pH-Value:		not applicable
Viscosity / kinematic:		not applicable
Water solubility:		practically insoluble
Solubility in other solvents		
not determined		
Partition coefficient n-octanol/water:		not applicable
Vapour pressure:		not determined
Density:		not determined
Relative vapour density:		not applicable
Particle characteristics:		not applicable

9.2. Other information

Further Information

No information available.

SECTION 10: Stability and reactivity

10.1. Reactivity

No hazardous reaction when handled and stored according to provisions.

10.2. Chemical stability

The product is stable under storage at normal ambient temperatures.

10.3. Possibility of hazardous reactions

No known hazardous reactions.

10.4. Conditions to avoid

Heat. Keep away from sources of ignition - No smoking.

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10.5. Incompatible materials

No information available.

10.6. Hazardous decomposition productsIn case of fire may be liberated: Carbon monoxide, Carbon dioxide (CO₂), Styrene, Pyrolysis products, toxic.**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.

Irritation and corrosivity

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

Sensitising effects

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

Carcinogenic/mutagenic/toxic effects for reproduction

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

STOT-single exposure

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

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.

Information on likely routes of exposure

Skin contact.

particulates and dust: oral, Inhalation, Eye contact.

11.2. Information on other hazards**Endocrine disrupting properties**

No information available.

Further information

The melted product can cause severe burns.

SECTION 12: Ecological information**12.1. Toxicity**

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

The product is not: Ecotoxic.

12.2. Persistence and degradability

Poorly biodegradable.

12.3. Bioaccumulative potential

The product has not been tested.

12.4. Mobility in soil

The product has not been tested.

12.5. Results of PBT and vPvB assessment

The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII.

12.6. Endocrine disrupting properties

This product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms as no components meets the criteria.

12.7. Other adverse effects

No information available.

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Further information

Avoid release to the environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Disposal recommendations

Avoid release to the environment. Dispose of waste according to applicable legislation.

Contaminated packaging

Completely emptied packages can be recycled.

SECTION 14: Transport information

Land transport (ADR/RID)

14.1. UN number or ID number:

No dangerous good in sense of this transport regulation.

14.2. UN proper shipping name:

No dangerous good in sense of this transport regulation.

14.3. Transport hazard class(es):

No dangerous good in sense of this transport regulation.

14.4. Packing group:

No dangerous good in sense of this transport regulation.

Inland waterways transport (ADN)

14.1. UN number or ID number:

No dangerous good in sense of this transport regulation.

14.2. UN proper shipping name:

No dangerous good in sense of this transport regulation.

14.3. Transport hazard class(es):

No dangerous good in sense of this transport regulation.

14.4. Packing group:

No dangerous good in sense of this transport regulation.

Marine transport (IMDG)

14.1. UN number or ID number:

No dangerous good in sense of this transport regulation.

14.2. UN proper shipping name:

No dangerous good in sense of this transport regulation.

14.3. Transport hazard class(es):

No dangerous good in sense of this transport regulation.

14.4. Packing group:

No dangerous good in sense of this transport regulation.

Air transport (ICAO-TI/IATA-DGR)

14.1. UN number or ID number:

No dangerous good in sense of this transport regulation.

14.2. UN proper shipping name:

No dangerous good in sense of this transport regulation.

14.3. Transport hazard class(es):

No dangerous good in sense of this transport regulation.

14.4. Packing group:

No dangerous good in sense of this transport regulation.

14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS: No

14.6. Special precautions for user

No information available.

14.7. Maritime transport in bulk according to IMO instruments

not applicable

SECTION 15: Regulatory information

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

EU regulatory information

Information according to 2012/18/EU (SEVESO III): Not subject to 2012/18/EU (SEVESO III)

National regulatory information

Water hazard class (D): - - non-hazardous to water

15.2. Chemical safety assessment

Chemical safety assessments for substances in this mixture were not carried out.

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SECTION 16: Other information**Abbreviations and acronyms**

CLP: Classification, labelling and Packaging
REACH: Registration, Evaluation and Authorization of Chemicals
GHS: Globally Harmonised System of Classification, Labelling and Packaging of Chemicals
UN: United Nations
CAS: Chemical Abstracts Service
DNEL: Derived No Effect Level
DMEL: Derived Minimal Effect Level
PNEC: Predicted No Effect Concentration
ATE: Acute toxicity estimate
LC50: Lethal concentration, 50%
LD50: Lethal dose, 50%
LL50: Lethal loading, 50%
EL50: Effect loading, 50%
EC50: Effective Concentration 50%
ErC50: Effective Concentration 50%, growth rate
NOEC: No Observed Effect Concentration
BCF: Bio-concentration factor
PBT: persistent, bioaccumulative, toxic
vPvB: very persistent, very bioaccumulative
ADR: Accord européen sur le transport des marchandises dangereuses par Route
(European Agreement concerning the International Carriage of Dangerous Goods by Road)
RID: Regulations concerning the international carriage of dangerous goods by rail
ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
(Accord européen relatif au transport international des marchandises dangereuses par voies de navigation intérieures)
IMDG: International Maritime Code for Dangerous Goods
EmS: Emergency Schedules
MFAG: Medical First Aid Guide
IATA: International Air Transport Association
ICAO: International Civil Aviation Organization
MARPOL: International Convention for the Prevention of Marine Pollution from Ships
IBC: Intermediate Bulk Container
VOC: Volatile Organic Compounds
SVHC: Substance of Very High Concern
For abbreviations and acronyms, see: ECHA Guidance on information requirements and chemical safety assessment, chapter R.20 (Table of terms and abbreviations).

Further Information

The information is based on the present level of our knowledge. It does not, however, give assurance of product properties and establishes no contract legal rights. The receiver of our product is singularly responsible for adhering to existing laws and regulations.

(The data for the hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)