



SAFETY DATA SHEET

Revision Date 15/08/2013

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Product Name ZONE Temporary Cement
Synonyms ZONE Temporary Cement Shade A1, Temporary Cement

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

Recommended Use Dental applications
Uses advised against No information available

1.3 Details of the supplier of the safety data sheet

Dux Dental B.V.
Zonnebaan 14
3542 EC Utrecht
The Netherlands
Tel: +31 (0)30-24 10 924
E-mail: info@dux-dental.com

1.4 Emergency telephone number

National Poisons Information Service (London Centre)
+44 20 7771 5307

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Classification according to EU Directives 67/548/EEC or 1999/45/EC
N; R51/53

2.2 Label elements

This product is a medical device which is regulated under Directive 2007/47/EC (the Medical Device Directive) and complies with ISO 3107:2011. As such it does not present a significant risk to the user or patient when used in accordance with manufacturer's instructions. A Safety Data Sheet is not required for medical devices according to Regulation No 1907/2006 (REACH, Article 2, point 6). This Safety Data Sheet is supplied as an additional service. The product is classified as dangerous according to Directive 1999/45/EC and its amendments.

2.3 Other hazards

None known.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixtures

Chemical Name	EC-No	CAS-No	Weight %	Classification (67/548/EEC)	Classification (1272/2008/EC)	REACH Registration Number
Zinc oxide	215-222-5	1314-13-2	<25	N; R50/53	Aquatic Acute 1 H400 Aquatic Chronic 1 H410	no data available
Magnesium oxide	215-171-9	1309-48-4	15-20	-	-	no data available
Aluminium hydroxide	244-492-7	21645-51-2	5-10	-	-	no data available
Acetic acid	200-580-7	64-19-7	<0.1	R10 C; R35	Flam. Liq. 3 H226 Skin Corr. 1A H314	no data available

For the full text of the R-phrases mentioned in this Section, see Section 16.

For the full text of the H-Statements mentioned in this Section, see Section 16.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General advice	No hazards which require special first aid measures.
Eye contact	Not applicable.
Skin contact	Wash skin with soap and water. Get medical attention if irritation develops and persists.
Ingestion	Get medical attention immediately if symptoms occur.
Inhalation	Not applicable.
Protection of first-aiders	No special protective equipment required.

4.2 Most important symptoms and effects, both acute and delayed

Main symptoms No acute and delayed symptoms and effects are observed.

4.3 Indication of any immediate medical attention and special treatment needed

Notes to physician Treat symptomatically.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media The product itself does not burn. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Extinguishing media which must not be used for safety reasons None known.

5.2 Special hazards arising from the substance or mixture

Special hazard Hazardous decomposition products formed under fire conditions: Metal oxides.

5.3 Advice for firefighters

Special protective equipment for fire-fighters Wear self-contained breathing apparatus and protective suit.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

No special precautions.

6.2 Environmental precautions

Should not be released into the environment.

6.3 Methods and material for containment and cleaning up

Allow to set and remove from surface. Place spilt material in an appropriate container for disposal.

6.4 Reference to other sections

See sections 8 and 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Read attached instructions before use.

7.2 Conditions for safe storage, including any incompatibilities

Store in original container. Keep container tightly closed in a dry and well-ventilated place. Keep away from direct sunlight.

7.3 Specific end use(s)

Exposure Scenario Not available.

Other information Not available.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Chemical Name	European Union	The United Kingdom	France	Spain	Germany
Zinc oxide			VME: 5 mg/m ³ (fume)	VLA-ED: 5 mg/m ³ VLA-EC: 10 mg/m ³	
Magnesium oxide		TWA: 10 mg/m ³ as Mg (inhalable) TWA: 4 mg/m ³ as Mg (respirable)	VME: 10 mg/m ³ (fume)	VLA-ED: 10 mg/m ³	
Aluminium hydroxide					TWA: 4 mg/m ³ inh TWA: 1.5 mg/m ³ alv
Acetic acid	TWA: 25 mg/m ³		VLCT (VLE): 25 mg/m ³	VLA-ED: 25 mg/m ³ VLA-EC: 37 mg/m ³	AGW: 25 mg/m ³

Chemical Name	Italy	Portugal	Netherlands	Denmark	Poland
Zinc oxide				GV: 4 mg/m ³	
Magnesium oxide		VLE-MP: 10 mg/m ³ (inhalable)		GV: 6 mg/m ³ as Mg	NDS: 5 mg/m ³ (fume) NDS: 10 mg/m ³ (dust)
Aluminium hydroxide					NDS: 2.5 mg/m ³ tot as Al NDS: 1.2 mg/m ³ resp as Al
Acetic acid	TWA: 25 mg/m ³	VLE-MP: 10 ppm VLE-CD: 15 ppm		GV: 25 mg/m ³	NDS: 15 mg/m ³ NDSCh: 30 mg/m ³

Chemical Name	Belgium	Sweden	Hungary	Finland	Czech Republic
Zinc oxide	TWA: 5 mg/m ³ (inh) STEL: 10 mg/m ³ (inh)	NGV: 5 mg/m ³	STEL: 20 mg/m ³ TWA: 5 mg/m ³	TWA: 2 mg/m ³ STEL: 10 mg/m ³	Ceiling: 5 mg/m ³ TWA: 2 mg/m ³
Magnesium oxide	TWA: 10 mg/m ³		TWA: 6 mg/m ³ STEL: 24 mg/m ³		Ceiling: 10 mg/m ³ TWA: 5 mg/m ³
Aluminium hydroxide		NGV: 1 mg/m ³ tot as Al			
Acetic acid	TWA: 25 mg/m ³ STEL: 38 mg/m ³	NGV: 13 mg/m ³ KTV: 25 mg/m ³	TWA: 25 mg/m ³ STEL: 25 mg/m ³	TWA: 13 mg/m ³ STEL: 25 mg/m ³	

Derived No Effect Level (DNEL) No information available.

Predicted No Effect Concentration (PNEC) No information available.

8.2 Exposure controls

Appropriate engineering controls Ensure adequate ventilation, especially in confined areas.

Individual protection measures, such as personal protective equipment

Eye protection No special protective equipment required.

Hand protection Protective gloves.

Skin and body protection Long sleeved clothing.

Respiratory protection No special protective equipment required.

Hygiene measures Handle in accordance with good industrial hygiene and safety practice.

Environmental Exposure Controls The product should not be allowed to enter drains, water courses or the soil.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Physical state @20°C	paste / gel
Appearance	A two paste system (yellow base, white catalyst) which sets to a pliable mass
Colour	yellow - white
Odour	None
pH	No information available
Melting/freezing point	No information available
Boiling point/boiling range	No information available
Flash point	No information available
Evaporation rate	No information available
Flammability (solid, gas)	No information available
Flammability Limits in Air	No information available
Vapour pressure	No information available
Vapour density	No information available
Relative density	No information available
Solubility	
Water solubility	Slightly soluble
Partition coefficient (n-octanol/water)	No information available
Autoignition Temperature	No information available
Decomposition temperature	No information available
Viscosity, dynamic	No information available
Explosive properties	No information available
Oxidising Properties	No information available

9.2 Other information

No information available

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

No information available.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous polymerisation does not occur.

10.4 Conditions to avoid

None known.

10.5 Incompatible materials

None in particular.

10.6 Hazardous decomposition products

Metal oxides.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity	
Ingestion	No known effect.
Skin contact	No known effect.
Inhalation	No known effect.

Chemical Name	LD50 Oral	LD50 Dermal	LC50 Inhalation
Zinc oxide	5000 mg/kg (Rat)		
Aluminium hydroxide	> 5000 mg/kg (Rat)		> 2.3 mg/l (Rat)
Acetic acid	3310 mg/kg (Rat)	1060 mg/kg (Rabbit)	11.4 mg/L (Rat) 4 h

Skin corrosion/irritation	No known effect.
Serious eye damage/irritation	No known effect.
Respiratory or skin sensitisation	No known effect.
Germ cell mutagenicity	Not known to cause heritable genetic damage.
Carcinogenicity	Contains no ingredient listed as a carcinogen.
Reproductive toxicity	Not known to cause birth defects or have a deleterious effect on a developing fetus. Not known to adversely affect reproductive functions and organs.
STOT-single exposure	No known effect.
STOT-repeated exposure	No known effect.
Aspiration hazard	No known effect.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Chemical Name	Toxicity to algae	Toxicity to fish	Toxicity to microorganisms	Toxicity to daphnia and other aquatic invertebrates.
Zinc oxide		LC50: 1.1 mg/L Oncorhynchus mykiss 96 h		EC50: >1000 mg/L Daphnia magna 48h
Aluminium hydroxide	EC50: > 100 mg/L Selenastrum capricornutum (OECD TG 201)	LC50: > 100 mg/l Salmo trutta (OECD TG 203)		EC50: > 100 mg/L Daphnia magna (OECD TG 202)
Acetic acid		LC50: 423 mg/L Gold fish LC50: 79 mg/L Pimephales promelas 96 h static LC50: 75 mg/L Lepomis macrochirus 96 h static	EC50: 8.8 mg/L 15 min EC50: 8.8 mg/L 25 min EC50: 8.8 mg/L 5 min	EC50: 47 mg/L Daphnia magna 24 h EC50: 65 mg/L Daphnia magna 48 h Static

12.2 Persistence and degradability

No information available.

12.3 Bioaccumulative potential

Not relevant.

Chemical Name	log Pow
Acetic acid	0

12.4 Mobility in soil

No information available.

12.5 Results of PBT and vPvB assessment

No information available.

12.6 Other adverse effects

No information available.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Waste from residues / unused products

Dispose of as hazardous waste in compliance with local and national regulations.

Contaminated packaging

Empty containers should be taken to an approved waste handling site for recycling or disposal.

SECTION 14: TRANSPORT INFORMATION

According to. ADR, RID, ADN, IMDG, ICAO.

14.1 UN number

3082

14.2 UN proper shipping name

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Zinc oxide)

14.3 Transport hazard class(es)

Hazard Class 9

14.4 Packing group

Packing group III

14.5 Environmental hazards

Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

14.6 Special precautions for user

Not applicable.

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable.

SECTION 15: REGULATORY INFORMATION**15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture****Restrictions on use**

None.

Other regulations

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15.2 Chemical safety assessment

Not required.

SECTION 16: OTHER INFORMATION**Full text of R-phrases referred to under sections 2 and 3**

R10- Flammable

R35 - Causes severe burns

R50/53 - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment

R51/53 - Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment

Full text of H-Statements referred to under sections 2 and 3

H226 - Flammable liquid and vapour

H314 - Causes severe skin burns and eye damage

H400 - Very toxic to aquatic life

H410 - Very toxic to aquatic life with long lasting effects

Revision Note

Format updated in compliance with European REACH and CLP regulations.

This safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006**Disclaimer**

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text