

safety data sheet

to product

Multisil Primer

1. Identification of the substance / preparation and company

Emergency number:

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Company name:

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C NDOR A MHENRY SCHEIN* COMPANY	Condor Dental Research CO Sàrl	Ch. des Cibleries 2, CP 300, 1896 Vouvry Tel. 024 482 61 61, Fax 024 482 61 69
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Smart Dentist Ich kann auch so!	Smart Dentist AG	Verenastrasse 4b, 8832 Wollerau Tel. 044 726 20 20, Fax 044 726 20 25

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

· 1.1 Product identifier

· Trade name: Multisil Primer · Article number: 520 0100 4

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

· Application of the substance / the mixture:

Primer providing perfect bonding between acrylate resins and A-silicones.

1.3 Details of the supplier of the safety data sheet

· Manufacturer/Supplier:

bredent GmbH & Co.KG Weißenhorner Straße 2 89250 Senden

Tel: +49 (0) 7309/872-0 *Fax:* +49 (0) 7309/872-24

· Further information obtainable from:

R & D

e-mail: R.D@bredent.com

· 1.4 Emergency telephone number: (001) 352 323 3500

SECTION 2: Hazards identification

- · 2.1 Classification of the substance or mixture
- · Remark

The device is a medical device pursuant to Council Directive 93/42/EEC of 14 June 1993 concerning medical devices. No safety data sheet is required for the device, so no claim is made to full compliance with the relevant statutory requirements.

· Classification according to Regulation (EC) No 1272/2008



health hazard

Carc. 2 H351 Suspected of causing cancer.

Repr. 2 H361d Suspected of damaging the unborn child.

STOT RE 2 H373 May cause damage to organs through prolonged or repeated exposure.

Asp. Tox. 1 H304 May be fatal if swallowed and enters airways.



Acute Tox. 4 H302 Harmful if swallowed.

Skin Irrit. 2 H315 Causes skin irritation.

- · 2.2 Label elements
- · Labelling according to Regulation (EC) No 1272/2008

Medical products and medical devices within the meaning of Directives 90/385/EEC and 93/42/EEC used in an invasive manner or in direct contact with the body as well as medical products and medical devices falling under Directive 98/79/EC are fully exempt from the provisions of the CLP Regulation and therefore do not need to be classified, packaged or labelled.

The product is classified and labelled according to the CLP regulation.

- · Hazard pictograms GHS07, GHS08
- · Signal word Danger
- · Hazard-determining components of labelling:

dichloromethane

toluene

· Hazard statements

H302 Harmful if swallowed.

H315 Causes skin irritation.

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H351 Suspected of causing cancer.

H361d Suspected of damaging the unborn child.

H373 May cause damage to organs through prolonged or repeated exposure.

H304 May be fatal if swallowed and enters airways.

· Precautionary statements

P201 Obtain special instructions before use.

P260 Do not breathe dust/fume/gas/mist/vapours/spray.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P301+P310 IF SWALLOWED: Immediately call a POISON CENTER/doctor.

P330 Rinse mouth.

P331 Do NOT induce vomiting.

P308+P313 IF exposed or concerned: Get medical advice/attention.

P321 Specific treatment (see on this label).

P362+P364 Take off contaminated clothing and wash it before reuse.

- · 2.3 Other hazards
- · Results of PBT and vPvB assessment
- · **PBT**: Not applicable.
- · vPvB: Not applicable.

SECTION 3: Composition/information on ingredients

- · 3.2 Chemical characterisation: Mixtures
- · **Description:** Mixture of substances listed below with nonhazardous additions.

· Dangerous components:				
	dichloromethane	50-100%		
EINECS: 200-838-9	Carc. 2, H351Acute Tox. 4, H302			
	♦ Acute Tox. 4, H302			
	toluene	10-25%		
EINECS: 203-625-9	◈ Flam. Lig. 2, H225			
	🕉 Repr. 2, H361d; STOT RE 2, H373; Asp. Tox. 1, H304			
	 Flam. Liq. 2, H225 Repr. 2, H361d; STOT RE 2, H373; Asp. Tox. 1, H304 Skin Irrit. 2, H315; STOT SE 3, H336 			

[·] Additional information: For the wording of the listed hazard phrases refer to section 16.

SECTION 4: First aid measures

- 4.1 Description of first aid measures
- · General information: Take affected persons out into the fresh air.
- · After inhalation:

Take affected persons into fresh air and keep quiet.

Seek medical treatment.

- · After skin contact: Seek medical treatment.
- · After eye contact: Rinse opened eye for several minutes under running water.
- · After swallowing: Rinse out mouth and then drink plenty of water.
- · 4.2 Most important symptoms and effects, both acute and delayed No further relevant information available.
- · 4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

SECTION 5: Firefighting measures

- · 5.1 Extinguishing media
- Suitable extinguishing agents:

CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

- · For safety reasons unsuitable extinguishing agents: Water with full jet
- 5.2 Special hazards arising from the substance or mixture

In case of fire, the following can be released:

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Carbon monoxide (CO)

Hydrogen chloride (HCl)

Under certain fire conditions, traces of other toxic gases cannot be excluded.

- · 5.3 Advice for firefighters
- · Protective equipment:

Wear self-contained respiratory protective device.

Wear fully protective suit.

· Additional information

Cool endangered receptacles with water spray.

Dispose of fire debris and contaminated fire fighting water in accordance with official regulations.

SECTION 6: Accidental release measures

· 6.1 Personal precautions, protective equipment and emergency procedures

Particular danger of slipping on leaked/spilled product.

Ensure adequate ventilation

Wear protective clothing.

· 6.2 Environmental precautions:

Prevent from spreading (e.g. by damming-in or oil barriers).

Do not allow to enter sewers/ surface or ground water.

· 6.3 Methods and material for containment and cleaning up:

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).

Dispose contaminated material as waste according to item 13.

Ensure adequate ventilation.

· 6.4 Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Use solvent-proof equipment.

Use only in well ventilated areas.

Avoid splashes or spray in enclosed areas.

Ensure good ventilation/exhaustion at the workplace.

Prevent formation of aerosols.

- · Information about fire and explosion protection: No special measures required.
- · 7.2 Conditions for safe storage, including any incompatibilities
- · Storage:
- · Requirements to be met by storerooms and receptacles:

Provide solvent resistant, sealed floor.

Use only receptacles specifically permitted for this substance/product.

- · Information about storage in one common storage facility: Store away from oxidising agents.
- · Further information about storage conditions: Store receptacle in a well ventilated area.
- · 7.3 Specific end use(s) No further relevant information available.

SECTION 8: Exposure controls/personal protection

- · 8.1 Control parameters
- · Additional information about design of technical facilities: No further data; see item 7.

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Ingredients with limit values that require monitoring at the workplace: 75-09-2 dichloromethane

WEL (Great Britain) Short-term value: 1060 mg/m³, 300 ppm

Long-term value: 350 mg/m³, 100 ppm

BMGV, Sk

108-88-3 toluene

WEL (Great Britain) Short-term value: 384 mg/m³, 100 ppm

Long-term value: 191 mg/m³, 50 ppm

Sk

· Ingredients with biological limit values:

75-09-2 dichloromethane

BMGV (Great Britain) 30 ppm

Medium: end-tidal breath
Sampling time: post shift

Parameter: carbon monoxide

- · Additional information: The lists valid during the making were used as basis.
- · 8.2 Exposure controls
- · Personal protective equipment:
- · General protective and hygienic measures:

Do not eat, drink, smoke or sniff while working.

Use skin protection cream for skin protection.

Be sure to clean skin thoroughly after work and before breaks.

The usual precautionary measures are to be adhered to when handling chemicals.

Keep away from foodstuffs, beverages and feed.

Wash hands before breaks and at the end of work.

· Respiratory protection:

Use suitable respiratory protective device when high concentrations are present.

Short term filter device:

Filter AX

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

Protection of hands:



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

· Material of gloves

Fluorocarbon rubber (Viton)

Recommended thickness of the material: ≥ 0.4 mm

PVA gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

· Penetration time of glove material

The penetration time has to be at least 60 minutes (Permeation according to EN 374 Part 3: Level 3).

The exact break trough time has to be found out by the manufacturer of the protective gloves and has to be observed

· Eye protection: Safety glasses

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· Body protection: Solvent resistant protective clothing

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SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· General Information

· Appearance:

Form: Fluid
Colour: Colourless
Odour: Characteristic
Odour threshold: Not determined.

pH-value: Not determined.

· Change in condition

Melting point/freezing point: Undetermined.

Initial boiling point and boiling range: 40 °C

Flash point: Not applicable.
 Flammability (solid, gas): Not applicable.

· Ignition temperature: 535 °C

· **Decomposition temperature:** Not determined.

· Auto-ignition temperature: Product is not selfigniting.

• Explosive properties: Product does not present an explosion hazard.

· Explosion limits:

 Lower:
 1.2 Vol %

 Upper:
 22.0 Vol %

· Vapour pressure at 20 °C: 453 hPa

Density at 20 °C: 1.27296 g/cm³
 Relative density Not determined.
 Vapour density Not determined.
 Evaporation rate Not determined.

· Solubility in / Miscibility with

vater: Not miscible or difficult to mix.

· Partition coefficient: n-octanol/water: Not determined.

· Viscosity:

Dynamic: Not determined. **Kinematic:** Not determined.

· Solvent content:

 Organic solvents:
 100.0 %

 VOC (EC)
 100.0 %

• 9.2 Other information No further relevant information available.

SECTION 10: Stability and reactivity

- · 10.1 Reactivity No further relevant information available.
- · 10.2 Chemical stability
- · Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- · 10.3 Possibility of hazardous reactions

Reacts with various metals.

Reacts with acids.

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Reacts violently with oxidising agents.

- · 10.4 Conditions to avoid No further relevant information available.
- · 10.5 Incompatible materials: No further relevant information available.
- · 10.6 Hazardous decomposition products: Chlorine compounds

SECTION 11: Toxicological information

- · 11.1 Information on toxicological effects
- · Acute toxicity

Harmful if swallowed.

· LD/LC50 values relevant for classification:				
75-09-2 dichloromethane				
Oral	<i>LD50</i>	1600 mg/kg (rat)		
108-88-3 toluene				
Oral	LD50	5000 mg/kg (rat)		
Dermal	LD50	12124 mg/kg (rabbit)		

- Primary irritant effect:
- · Skin corrosion/irritation

Causes skin irritation.

- · Serious eye damage/irritation Based on available data, the classification criteria are not met.
- · Respiratory or skin sensitisation Based on available data, the classification criteria are not met.
- · Additional toxicological information:
- · CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)
- · Germ cell mutagenicity Based on available data, the classification criteria are not met.
- · Carcinogenicity

Suspected of causing cancer.

· Reproductive toxicity

Suspected of damaging the unborn child.

- · STOT-single exposure Based on available data, the classification criteria are not met.
- · STOT-repeated exposure

May cause damage to organs through prolonged or repeated exposure.

· Aspiration hazard

May be fatal if swallowed and enters airways.

SECTION 12: Ecological information

- · 12.1 Toxicity
- · Aquatic toxicity: No further relevant information available.
- · 12.2 Persistence and degradability No further relevant information available.
- · 12.3 Bioaccumulative potential No further relevant information available.
- · 12.4 Mobility in soil No further relevant information available.
- · Additional ecological information:
- · General notes:

Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water

Do not allow product to reach ground water, water course or sewage system.

Danger to drinking water if even small quantities leak into the ground.

- · 12.5 Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- · vPvB: Not applicable.
- · 12.6 Other adverse effects No further relevant information available.

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SECTION 13: Disposal considerations

- · 13.1 Waste treatment methods
- · Recommendation

Must be specially treated adhering to official regulations.

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

- · Uncleaned packaging:
- · Recommendation: Disposal must be made according to official regulations.

SECTION 14: Transport informa	tion
· 14.1 UN-Number · ADR, ADN, IMDG, IATA	Void
· 14.2 UN proper shipping name · ADR · ADN, IMDG, IATA	1593 DICHLOROMETHANE Void
· 14.3 Transport hazard class(es)	
· ADR, ADN, IMDG, IATA · Class	Void
· 14.4 Packing group · ADR, IMDG, IATA	Void
· 14.5 Environmental hazards: · Marine pollutant:	No
· 14.6 Special precautions for user	Not applicable.
· 14.7 Transport in bulk according to Ann Marpol and the IBC Code	ex II of Not applicable.
· UN "Model Regulation":	UN1593, DICHLOROMETHANE, 6.1, III

SECTION 15: Regulatory information

- 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
- · Labelling according to Regulation (EC) No 1272/2008

The product is classified and labelled according to the CLP regulation.

- · Hazard pictograms GHS07, GHS08
- · Signal word Danger
- · Hazard-determining components of labelling:

dichloromethane

toluene

- · Hazard statements
- H302 Harmful if swallowed.
- H315 Causes skin irritation.
- H351 Suspected of causing cancer.
- H361d Suspected of damaging the unborn child.
- H373 May cause damage to organs through prolonged or repeated exposure.
- H304 May be fatal if swallowed and enters airways.
- · Precautionary statements
- *P201 Obtain special instructions before use.*
- P260 Do not breathe dust/fume/gas/mist/vapours/spray.
- *P280* Wear protective gloves/protective clothing/eye protection/face protection.
- P301+P310 IF SWALLOWED: Immediately call a POISON CENTER/doctor.

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P330 Rinse mouth.

P331 Do NOT induce vomiting.

P308+P313 IF exposed or concerned: Get medical advice/attention.

P321 Specific treatment (see on this label).

P362+P364 Take off contaminated clothing and wash it before reuse.

- · Directive 2012/18/EU
- · Named dangerous substances ANNEX I None of the ingredients is listed.
- · 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· Relevant phrases

H225 Highly flammable liquid and vapour.

H302 Harmful if swallowed.

H304 May be fatal if swallowed and enters airways.

H315 Causes skin irritation.

H336 May cause drowsiness or dizziness.

H351 Suspected of causing cancer.

H361d Suspected of damaging the unborn child.

H373 May cause damage to organs through prolonged or repeated exposure.

Department issuing SDS: R & D

· Contact: R & D

· Abbreviations and acronyms:

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

ICAO: International Civil Aviation Organisation

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

VOC: Volatile Organic Compounds (USA, EU)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

Flam. Liq. 2: Flammable liquids - Category 2

Acute Tox. 4: Acute toxicity – Category 4

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Carc. 2: Carcinogenicity – Category 2

Repr. 2: Reproductive toxicity – Category 2

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

STOT RE 2: Specific target organ toxicity (repeated exposure) – Category 2

Asp. Tox. 1: Aspiration hazard - Category 1

* * Data compared to the previous version altered.

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