

MATERIAL SAFETY DATA SHEET

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

Commercial name: CORE D / CORE D FLOW / AUTOCORE / AUTOCORE MIX

Relevant use of product: Self-etching, dual cure bonding system

Product references: CDD-25, CDD-10, CDB-10, CDF-5, AMB-25, AMB-50, AMD-25, AMD50

Identified use of the mixture: Core build-up material

Information concerning safety data sheet supplier:

G-PHARMA

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SECTION 2 – HAZARDS IDENTIFICATION

2.1 Classification of the mixture

The mixture meets the criteria for classification of Regulation 1272/2008 / EC amending Directives 67/548 / EEC and 1999/ 45 / EC and regulation 1907/2006 / EC (CLP). The mixture requires security sheet according to the requested requirements.

2.1.1 Classification according to regulation (EC) N° 1272/2008 (CLP):

Eyes irrit. 2 : H319, STOT SE 3 : H335; Skin irrit. 2: H315; Skin sens. 1: H317

2.1.2 Classification according to the directive N° 67/548/CEE:

Xi : R36, R37, R38; Skin sens. :R43

2.1.3 Additional Informations

The full text of the classes and categories of danger: hazards H and R phrases are mentioned in Section 16.

2.2 Label elements

Labeling according to Regulation (EC) No 1272/2008 (CLP) and its exemptions from Article 17 (relating to labeling and packaging requirements) provided for products with a capacity of less than 125 ml (Annex I of Regulations section 1.5.2.1)

Pictogram (s)

SGH07



Signal word Warning

H statement H317: May cause an allergic skin reaction.

P statements P261: Avoid breathing dust/fume/gas/mist/vapours/spray.
P272: Contaminated work clothing should not be allowed out of the workplace.
P280: Wear protective gloves/protective clothing/eye protection/face protection.

Additional hazards information: N/A

2.3 Other hazards: the mixtures do not contain PBT or vPvP.

SECTION 3 – COMPOSITION / INFORMATION ON INGREDIENTS

3.1 Products

EC designation : N/A

EEC classification : Class IIa

3.2 Mixture of substances listed below

CE/CAS index	Chemical name	Mass %	Classification according to directive N° 67/548/CEE (DPD)	Classification according to rules (CE) N° 1272/2008 (CLP)	Generic threshold
Index : N/A CAS : 72869-86-4	UDMA Diurethane Dimethacrylate	20-40	Xi eyes irr, skin resp.: R36/37/38 Skin sens. : R43	Skin irrit 2: H315 Eyes irrit 2: H319 STOT SE 3 : H335 Skin sens. : H317	≥ 1 % ≥ 1 % ≥ 1 % ≥ 0,1%
Index : N/A CAS : 65997-13-3	Borosilicate glass	40-60	Irritant eyes, skin XI : R36/37	Eyes irr. 2 : H319 Skin Irr. 2: H315	≥ 1% ≥ 1%

Note: The full text of hazard H and R-phrases is specified in section 16.

SECTION 4 - FIRST AID MEASURES

4.1 Description of first aid measures

General information: Seek medical advice, if symptoms occur, which can be caused by the product

Skin contact: Take off contaminated clothes. Wash skin with plenty of water and soap. In case of an allergic response, seek medical advice.

Inhalation: fresh air

Eye contact: Rinse opened eye for several minutes under running water and consult a doctor

Swallowing: Consult a physician.

4.2 Most important symptoms and effects, both acute and delayed: N/A

4.3 Indication of any immediate medical attention and special treatment needed: see section 4.1

SECTION 5 - FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable Extinguishing media: Non-flammable. Water, sand, chemical foam or dry chemical products are acceptable tools if the fire comes from another source.

There is no particularly measure for a small quantity (less than 1 kg). For large amount, wear an appropriate mask and clothes. Use a water tap to cool off the receptacle

Self-ignition temperature: N/A

Non-suitable Extinguishing media: N/A

Explosion limits in air: N/A

5.2 Special hazards arising from the substance or mixture: High heat can cause a polymerization with a sudden release of energy.

5.3 Instructions for the fire-extinction agent: N/A

SECTION 6 - ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Avoid contact with eyes and skin. Wash with water and soap.

6.2 Environmental precautions:

Large amount: Remove the product following nationals, federals, regionals or locals current laws (by incineration). Remove the content the same way. Small quantity: Polymerized the product before a conventional removal.

6.3 Methods and material for containment and cleaning up:

Absorb with liquid binding material. Clean up affected area.

6.4 Reference to other sections

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

Keep the mixing tips on the cartridge after use.

Avoid eyes and skin contact. For use in dentistry only. Wash hands with water and soap in case of a contact with the product.

7.2 Conditions for safe storage, including any incompatibilities

Store in a cool, dry, place at temperatures between 20°C and 25°C (50° - 77°F).

7.3 Specific end use(s): Dental professional use only.

SECTION 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control parameters

Respiratory and ventilating protection: Work in a well ventilated room.

Personal protective equipment: Gloves and blouse

Specific hygiene measure: Avoid prolonged contact with skin. In case of an eye contact, rinse opened eye for several minutes under running water. Wash hands after use.

SECTION 9 - PHYSICAL & CHEMICAL PROPERTIES

9.1 Information regarding the physicals and chemicals properties

Appearance:

Part A: White opaque paste

Part B: Beige paste

Odour: Ester

Boiling point: gel before boiling

Melting point: Not established

Specific gravity: >1

Flash point: Not established

Inflammability: Not established

Auto flammability: N/A

Explosive properties: N/A

Oxidizing properties: N/A

Vapour pressure (20°): < 1mbar

Solubility in water: Insoluble

Density: ~ 1.75g/cm²

Solubility in water: ~0.1g/l at 21°C

SECTION 10 – STABILITY & REACTIVITY

10.1 Reactivity: N/A.

10.2 Chemical stability: Stable in normal condition of use

10.3 Possibility of hazardous reactions: No dangerous reactions known

10.4 Conditions to avoid: Heat, flammable source, aging; contamination and direct sunlight

10.5 Incompatible materials: Free radicals (peroxides), reducing substances, heavy metal ions..

10.6 Hazardous decomposition products: None in normal condition of use. Acrylic residue after combustion

10.7 Uncontrolled polymerization: Intense heat and light can cause a polymerization. A spontaneous polymerization can appear in presence of free radicals. In this condition, it can be polymerized with heat release

SECTION 11 – TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity for health: Irritation for eyes, skin and mucous membrane. May cause irritation or a skin sensitization if the product is not wash rapidly. .

Chronical toxicit : May be cause a sensitization after a long-term or repeated exposure with skin.

Signes and symptoms of exposure: Irritation of skin or eyes.

11.2 Other Information: N/A

SECTION 12 – ECOLOGICAL INFORMATION

12.1 Toxicity

Slightly toxic for the water. Do not allow the product to enter sewers, surface and ground water

12.2 Persistence and degradability: N/A

12.3 Bioaccumulative potential: N/A

12.4 Mobility in soil: No information available

12.5 Results of PBT and vPvB assessment: N/A

12.6 Other adverse effects: N/A

SECTION 13 - DISPOSAL MEASURES

13.1 Waste treatment methods

Large quantity:

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MSDS

Disposal must be made according to local, state and federal regulations. Do not pour down the drain.

Small quantity:

Polymerize and dispose of normally

SECTION 14 - TRANSPORT INFORMATION

The transportation requirements followed the international transportation requirements.

No restriction for the road, boat or plane transportation. Avoid high temperatures during transportation.

SECTION 15 - REGULATORY INFORMATION**15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture:** Class IIa medical device according to the Directive 93/42 / EEC**15.2 Chemical safety assessment:** N/A**SECTION 16 - OTHER INFORMATION**

N/A : Non applicable

Symbol of potential danger:

STOT SE 3: Specific target organ toxicity - single exposure hazard category 3

Xi: irritating

R phrases

R 36: Irritating to eyes.

R 37: Irritating to respiratory system.

R 38: Irritating to skin.

R 42: May cause respiratory irritation

R 43: May cause a sensitization of the skin

S phrases

S3: Maintain in a well ventilated and fresh area

S9, S14: Avoid extremely high temperature, direct sunlight, flammable and humidity sources

H phrases

Category 1, H334: May cause allergies, asthma or breathing difficulty.

Category 2, H315: Causes skin irritation.

H319: Causes serious eye irritation.

STOT, SE, H335: specific target organ toxicity – Single exposure, Category 3: May cause respiratory irritation.

Category 1: Skin sensitization, H317: May cause skin allergy

P phrases:

P272: Contaminated work clothing should not be allowed out of the workplace

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

P305 + P351 + P338 : IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P302 + P352 : IF ON SKIN: Wash with plenty of soap and water.

P333 + P313 : If skin irritation or rash occurs: Get medical advice/attention.

P363 : Wash contaminated clothing before reuse.

P312: Call a POISON CENTER or doctor/physician if you feel unwell.

Some of the information presented and conclusions drawn herein are from sources other than direct test data on the product itself. The information in this MSDS was obtained from sources that we believe are reliable. However, the information is provided without any warranty, express or implied, regarding its correctness. The conditions or method of handling, storage, use and disposal of the product are beyond our control and may be beyond our knowledge. For this and other reasons, G PHARMA do not assume responsibility and expressly disclaim liability for loss, damage, or expense arising out of or in any way connected with the handling, storage, use or disposal of the product. If the product is used as a component in another product or used in a way other than recommended by the Company, this MSDS information may not be applicable.