

AHL Generic

ZINC PHOSPHATE CEMENT (POWDER/LIQUID)

ISO 9917-1:2007 Glass Polyalkenoate Class 4.2.a

DIRECTIONS FOR USE

FEATURES:

Adhesive to enamel, dentine and non-precious metals. Radiopaque, non-translucent.

INTENDED PURPOSE:

Attach selected dental prostheses.

INTENDED PATIENT POPULATION:

From child to geriatrics

INTENDED USER:

This product has been formulated for use in dentistry and is intended for use by dental professionals only.

CLINICAL BENEFIT:

To restore the function of the teeth and help maintain the integrity of the remaining tooth structure.

INDICATIONS FOR USE:

Cementation of crowns, bridges, inlays and onlays. Cementation of orthodontic bands.

CONTRA-INDICATIONS:

Pulp capping

CONTENTS OF PACK:

087XPL - powder 90g, liquid 30ml, instructions for use 087X1 – powder 90g, instructions for use 006X3 - liquid 30ml

PRECAUTIONS AND WARNINGS:

Liquid contains Phosphoric Acid.

- CORROSIVE.
- Causes burns
- In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
- In case of accident or if you feel unwell, seek medical advice immediately (show label where possible).
- Do not expose patients or users known to be allergic to this type of material.

PROCEDURE

- (1) PREPARATION:
- Clean the preparation and restoration with oil-free prophypaste, water and air dry.

(2) MIX RATIO:

The powder: liquid ratio is 1.8:1 (m:m) or 3.0:1 (m:v)

(2) MIXING:

- Dispense powder and liquid onto clean, dry glass slab PAPER PADS AND PLASTIC BLOCKS ARE NOT SUITABLE.
- Divide powder into six parts.
- Add one part to the liquid and spatulate thoroughly for 15 seconds using a stainless steel spatula.
- Repeat procedure for remaining portions.
- Total mixing time 11/2 minutes.
- Using excess powder or rapid mixing without dissipating heat by spreading cement over slab, will shorten the working and setting time.
- A smooth creamy consistency should be obtained.

Total mixing time: 1 minute 30 seconds.

Working time: 45 seconds from end of mixing at 23°C. Setting time: 7 minutes from end of mixing.

For test purposes, the ratio of powder 1.80g to liquid 1.00g tested at 23±1°C & RH 50±10%

ISO 9917-1 net setting time: 2 to 8 minutes from start of mix at 36-38°C & RH 90-100%.

(3) PLACEMENT:

- Apply cement to restoration band or bracket and seat in place as quickly as possible.
- Optimum properties are obtained by maintaining compression while the cement is settina.
- Remove excess only after cement has set.

STORAGE:

- Store in a cool, dry place (5-25°C).
 - Always replace cap immediately after use

EXPIRY:

The expiry date is shown in year, month format. Do not use the product after this date

DISPOSAL:

Dispose of the contents and containers in accordance with relevant local and national requirements.

POSSIBLE SIDE EFFECTS / RESIDUAL RISKS:

This product contains substances that may cause and allergic reaction.

- CORROSIVE
- Causes burns. •

BATCH CODE:

The batch code gives an open date of manufacture in month, year, day format LOT with a numerical suffix to uniquely identify the batch of material. Please quote this batch number in all correspondence.

DEVICE CODES:

087XPL REF 087X1

90g Powder / 30ml Liquid 90g Powder

30ml Liquid

COMPOSITION:

006X3

Composition	% by weight
Zinc Oxide	50 – 70
Magnesium Oxide	5 – 15
Phosphoric acid	20 - 30
Deionised Water	5 – 15

AHL operate a policy of continuing surveillance & monitoring of our products. If you experience any incidents relating to the use of this product, please immediately contact us at the below address stating the batch number shown on the packaging. If you experience any serious incident relating to the use of this product, please immediately contact AHL at the below address and the competent authority of the territory you are in

A summary of safety & clinical performance (SSCP) is available via the EUDAMED database. https://ec.europa.eu/tools/eudamed

Caution: U.S. Federal Law restricts this device to sale by or on the order of a dental professional.



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