



Technical Information

- ADSEAL-

Head Office) 270, Osongsaengmyeong1-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, Korea
Tel : +82-43-216-0433 Fax : +82-43--217-1988 METABIOMED.CO.,LTD

1. Scope

Product name: Root Canal Sealer

Brand name: ADSEAL

2. General Product Introductions

2.1 Product's intended use

ADSEAL is used for permanent sealing material of the root canal.

This material is intended for use by properly trained dental professionals only.

2.2 Product's classification and regulation conformity

a) FDA Classification – Class II, Regulation Number: 872.3820

b) CE Classification – Class IIa, According to MDD93/42/EEC (AnnexII Rule 8)

2.3 Description and Performance

ADSEAL is able to fill easily root canal obturation and economize a time.

- a) Easy to mix by paste: paste
- b) Hermetic sealing ability
- c) Nonstaining to the teeth
- d) Insoluble in tissue fluids
- e) Excellent biocompatibility
- f) Good radio-opacity
- g) Working time of 35minutes at 23°C(73°F)
- h) Setting time of 45minutes at 37°C(99°F)

2.4 Mechanism Principle

This product is a root canal filler sealer that is completely mixed with a root canal filling resin sealer used for dental treatment and is used together with a sealing point (gertera differential) to permanently fill the root canal. Base and Catalyst And it is chemically polymerized by the reaction between the epoxy group of the base and the amine component of the catalyst. Bismuth subcarbonate and zirconium oxide were added as fillers to improve the barrier properties. Calcium phosphate and calcium oxide were added to improve biocompatibility.

2.5 Size



Technical Information

- ADSEAL-

Head Office) 270, Osongsaengmyeong1-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, Korea
 Tel : +82-43-216-0433 Fax : +82-43--217-1988 METABIOMED.CO.,LTD

a) Available Sizes

Product name	Size	Weight
Dual Syringe	Height: 37mm	Base: 9g
	Inside diameter: Body A: 9.9mm, Body B: 6.8mm	Catalyst: 4.5g
Mixing Pad	Width: 60mm, Depth: 50mm	70sheets

3. Composition/information on ingredients

Name	Raw Material	Standard
Base	Poly(Bisphenol A-co-epichlorohydrin), Glycidyl end-capped	FDA(21 CFR 177,2280)
	Ethylene glycol monosalicylate	FDA(21 CFR 310.545(10)(V))
	Calcium phosphate	K.P
	Bismuth subcarbonate	USP
	Zirconium oxide	FDA(21CFR310.545(10)(VI))
Catalyst	Poly(1,4-butanediol) bis(4-aminobenzoate)	USP polymer
	Triethanolamine	K.P
	Calcium phosphate	K.P
	Bismuth Subcarbonate	USP
	Zirconium oxide	FDA(21CFR10,545(10)(VI))
	Calcium oxide	K.P



Technical Information

- ADSEAL-

Head Office) 270, Osongsaengmyeong1-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, Korea
Tel : +82-43-216-0433 Fax : +82-43--217-1988 METABIOMED.CO.,LTD

4. Labeling Description

4.1 LOT No.

①②③ ④⑤ ⑥⑦ ⑧⑨ ⑩

①②③: Product Code

Brand Name	Code
ADSEAL	ADS

④⑤: Manufacture year (00~99)

⑥⑦: Manufacture month (0~12)

⑧⑨: Manufacturing date (1~31)

⑩: Production number (1~9)



Technical Information

- ADSEAL-

Head Office) 270, Osongsaengmyeong1-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, Korea
 Tel : +82-43-216-0433 Fax : +82-43--217-1988 METABIOMED.CO.,LTD

5. Packing Characteristics

5.1 Product package



Items	Notes
Weigh (g)	<ul style="list-style-type: none"> ● ADSEAL <ul style="list-style-type: none"> -Base 9g -Catalyst 4.5g -Total 13.5g
	<ul style="list-style-type: none"> ● ADSEAL 4.5 <ul style="list-style-type: none"> -Base 3g -Catalyst 1.5g -Total 4.5g
Quantity (ea)	<ul style="list-style-type: none"> ● ADSEAL <ul style="list-style-type: none"> -Base(Epoxy resin, Calcium phosphate) 1 -Catalyst(Amines, Bismuth subcarbonate) 1 -Spatula 1 -Mixing pad(50 x 50mm) 50




Technical Information

- ADSEAL-

Head Office) 270, Osongsaengmyeong1-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, Korea
 Tel : +82-43-216-0433 Fax : +82-43--217-1988 METABIOMED.CO.,LTD

Items	Notes
	<ul style="list-style-type: none"> ADSEAL 4.5 <ul style="list-style-type: none"> -Base(Epoxy resin, Calcium phosphate) 1 -Catalyst(Amines, Bismuth subcarbonate) 1 -Spatula 1 -Mixing pad(50 x 50mm) 50
Material Type	Paper coated polyethylene, Polyoxymethylene copolymer

5.2 Shipping package

	Items	Notes
	Dimension (mm)	520(W) x 440(D) x 345(H)
	Gross weight (kg)	15.3
Material Type	Double-wall Corrugated Fiberboard Box	



Technical Information

- ADSEAL-

Head Office) 270, Osongsaengmyeong1-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, Korea
 Tel : +82-43-216-0433 Fax : +82-43--217-1988 METABIOMED.CO.,LTD

6. Physical and Biological Characteristics

6.1 Physical evaluation

Test Item	Test Standard	Test Criteria	Result	Pass/Fail
Flow	ISO 6876	More than 20min in diameter	44.08mm	Pass
Working time	ISO 6876	Inner 35min±10%	10%: 21.0mm 20%: 35.0min	Pass
Setting time	ISO 6876	Inner 50min±10%	45.33min/4.6%	Pass
Film thickness	ISO 6876	Should not more than 50 μ m	3.3	Pass
Radio-opacity	ISO 6876	Should not less than 3mm of aluminium	5.44mm	Pass
Solubility and Disintegration	ISO 6876	Should be not exceed 3% by mass	0.0324%	Pass
Character	Manufacturer standard	Should be free from extraneous matter	Free from extraneous	Pass
Volume	Manufacturer standard	Error Range: below 1%	27.9987g/0.1%	Pass
Figure	Manufacturer standard	Should be no colour and translucent	0%, 0ppm(very safe)	Pass
pH	-	pH difference \leq 1.5	0.96 dis	Pass
K·Mn Consumption	-	K·Mn Consumption range \leq 1ml	83.7ml over	Pass
Heavy metal	-	Mild	0 ppm	Pass



Technical Information

- ADSEAL-

Head Office) 270, Osongsaengmyeong1-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, Korea
 Tel : +82-43-216-0433 Fax : +82-43--217-1988 METABIOMED.CO.,LTD

6.2 Biological evaluation

Test Item	Test Standard	Test Criteria	Result	Pass/Fail
Cytotoxicity (Agar overlay method)	ISO 10993-5	Should not more than 1 and 0 of Zone index and lysis index	Grade 0 (None)	Pass
Oral Mucosa Irritation	ISO 10993-10	Should be no abnormal or death	No abnormal	Pass
Sensitization	ISO 10993-10	1.6 ≤ SI	No clinical signs	Pass
Pyrogen	ISO 10993-11	Should not more than 0.5°C or more above the baseline temperature	No clinical signs	Pass
Genotoxicity (Bacterial Reverse Mutation)	ISO 10993-3	Should be no abnormal	No abnormal signs	Pass
Genotoxicity (Micronucleus)	ISO 10993-3	Should be no abnormal	No abnormal signs	Pass
Acute Systemic Toxicity (Acute oral route application)	ISO 10993-11	Should be no abnormal	No abnormal signs	Pass
Subcutaneous Tissue Implantation	ISO 10993-6	Should be no clinical signs	No clinical signs	Pass



Technical Information

- ADSEAL-

Head Office) 270, Osongsaengmyeong1-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, Korea
Tel : +82-43-216-0433 Fax : +82-43--217-1988 METABIOMED.CO.,LTD

7. Directions for Use

- ① Canal walls must be dry. ADSEAL should be carried to the canal with either lentulo spiral or obturation point (gutta-percha, silver or titanium root canal points).
- ② To avoid the formation of air bubbles in the material and overfilling of the canal.
- ③ Advance the lentulo spiral slowly to the apex running at very low speed.
- ④ Dip the disinfected and dry master point into ADSEAL and with pumping motions slowly push it into the canals.
- ⑤ ADSEAL is the endodontic product for every dental practice.
- ⑥ It can be used for all established and more recent root canal sealing techniques.
- ⑦ It is suitable for the single –point method, thermoplasticize method and all condensation techniques

8. Environmental Limitation

8.1 Shelf Life

Use within 2 years from the manufacturing date.

8.2 Store

Keep syringe cap tight closed

Store at 18°C~24°C(64°F~75°F)

Store protected from UV light

HISTORY

- Date of creation	: 2016.03.02
- Revision number and Revision date	
* Revision number	: 6
* Date of last revision	: 2021.10.12
- Prepared by	: METABIOMED CO., LTD.