Sealing Solutions

COMPOUND DATA SHEET
FM257/1 Red

General description
FM257/1 is a bromobutyl compound with silicate filler. Unconventionally cured, free from MBT.

Identification as per Ph.Eur. 3.2.9., method A
A typical ATR-FTIR spectrum of a clean, cut surface of FM257/1 is enclosed on page 3.

Physical properties

Hardness *ISO 48-4 (1s indentation; measured after min.1h)*	**52 ± 5 °Shore A**
Density *ISO 2781*	**1.350 ± 0.025 g/cm³**
Ash content *EP 2.4.16*	**46.0 ± 2.0 %**
Compression set *ISO 815-1, (typical value)*	**15 %**
Modulus 100 *Internal method. 100mm/min, (typical value)*	**2.2 N/mm²**
Modulus 300 *Internal method. 100mm/min, (typical value)*	**4.4 N/mm²**
Elongation @ Break *Internal method. 200mm/min, ISO 37 Dumb-bell 2, (typical value)*	**460 %**
Tensile Strength @ Break *Internal method. 200mm/min, ISO 37 Dumb-bell 2, (typical value)*	**7.6 N/mm²**
Water Vapor Transmission Rate *ASTM F-1249, 38°C, 100%RH (typical value)*	**0.04 [g-mm]/m².24h**
Oxygen Transmission Rate *ASTM D-3985, 38°C, 85%RH, 100% O_2 (typical value)*	**67 [cc-mm]/m².24h**

Compound ingredient declarations

Latex	FM257/1 is not made with natural rubber latex.
Nitrosamines	FM257/1 is not made with chemicals that are associated with nitrosamine formation as per the ASTM F1313-90 list.
BSE/TSE	For the raw materials of FM257/1, certification confirming that such products are either of vegetable origin or are manufactured in severe process conditions for inactivation of prions as described in the EMA/410/01-rev.3 and in the European Pharmacopoeia 5.2.8. “Minimizing the risk of transmitting Animal Spongiform Encephalopathy Agents” is available.
MBT	FM257/1 is not made with 2-mercapto-benzothiazole (MCBT, also named MBT), or any of its derivatives.

Further compound declarations can be found in file MD0035.

For detailed extractables information, please contact your Datwyler representative.

Chemical properties

Ph.Eur.3.2.9. : FM257/1 meets the chemical requirements for
ISO 8871-1 Type I closures specified in Ph.Eur. 3.2.9, USP
USP <381> <381> and ISO 8871-1. Typical results are given in the table on page 2. A typical UV spectrum is enclosed on page 3.

Ph.Jap.7.03. : FM257/1 meets the chemical requirements specified in Ph.Jap. 7.03. Typical results are given in the table on page 2. A typical UV spectrum is enclosed on page 3.

Note : Chemical testing is performed on non-post-treated standard test plates or products, prepared using representative process conditions.

Elemental impurities
An overview of the elemental impurities is given on page 2.

Biocompatibility
USP <87><88>: FM257/1 is non-cytotoxic and meets the
ISO 10993-5 requirements of the Elution Test as described in
Ph.Jap.7.03. USP <87>,”Biological Reactivity Tests, in vitro“ and the ISO 10993-5 "in vitro cytotoxicity". A typical test certificate is enclosed on page 4.
ISO 10993-5 cytotoxicity testing is considered equivalent with Pharm. Jap. 7.03 cytotoxicity testing.

Note : “FMxxx” refers to the type of compound, the extension “/x” refers to the color of the said compound. Differently colored compounds might be used for testing throughout this document. It is generally accepted that the color is irrelevant for the properties discussed, except Ash content and Density which are different per color.

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Typical results of chemical properties as per Ph.Eur.3.2.9., USP <381> and ISO 8871-1 for FM257/1:

Characteristic		Limits	FM257/1
Appearance of solution	Turbidity	Type I: ≤ 6 NTU (*) Type II: ≤ 18 NTU (*)	**0.6**
	Color	Solution S is not more intensely colored than reference	**Pass**
Acidity or alkalinity (NA : Not applicable)		≤ 0.8 ml 0.01M HCl	**NA**
		≤ 0.3 ml 0.01M NaOH	**0.0**
UV Absorbance (max 220-360 nm)		Type I: ≤ 0.2 Type II: ≤ 4.0	**0.0**
Reducing substances		Type I: ≤ 3.0 ml 0.01M $Na_2S_2O_3$ Type II: ≤ 7.0 ml 0.01M $Na_2S_2O_3$	**0.2**
Extractable heavy metals		≤ 2 ppm Pb^{2+}	**Pass**
Extractable zinc		≤ 5.0 ppm Zn^{2+}	**0.0**
Ammonium		≤ 2 ppm NH_4^+	**Pass**
Residue on evaporation (only for EP)		Type I: ≤ 2.0 mg Type II: ≤ 4.0 mg	**0.1**
Volatile sulphides		Any black stain on the paper is not more intense than that produced by a control solution	**Pass**

(*) By definition corresponding with reference suspensions II and III (for Ph.Eur.) or B and C (for USP) respectively

Typical results of chemical properties as per Ph.Jap.7.03:

Characteristic		Limits	FM257/1
Appearance	%T at 430nm	≥ 99.0%	**99.8**
	%T at 650nm	≥ 99.0%	**99.9**
pH (difference with blank)		-1.0 ≥ ≤ 1.0	**0.1**
Zinc		≤ 1 ppm Zn^{2+}	**0.0**
Reducing substances		≤ 2.0ml 0.002 M $KMnO_4$	**0.3**
Residue on evaporation		≤ 2.0mg	**0.1**
UV absorbance (Max. Abs. 220-350nm)		≤ 0.20	**0.01**
Cadmium*		≤ 5 ppm	**0.0**
Lead*		≤ 5 ppm	**0.7**

(*) measured directly on the rubber

Elemental impurities for FM257/1:

Elemental Impurity		ICH Q3D Class Reference	Result (µg/g)*
Arsenic	As	1	**<0.05**
Cadmium	Cd	1	**<0.05**
Mercury	Hg	1	**<0.05**
Lead	Pb	1	**<0.05**
Vanadium	V	2A	**<0.05**
Cobalt	Co	2A	**<0.05**
Nickel	Ni	2A	**<0.05**
Lithium	Li	3	**<0.05**
Copper	Cu	3	**<0.05**
Antimony	Sb	3	**<0.05**
Zinc	Zn	-	**0.23**

The elemental impurities are extracted with a 0.2N HNO_3, 0.05N HCl and 200 ppb gold solution in a 1g rubber/2.5mL ratio. The containers are sealed and heated to 70°C for 24h, after which they are allowed to cool and measured within 48h. The results are an average of 3 replicates, measured via ICP-OES according to Elemental Impurities – Procedures USP ‹233›.

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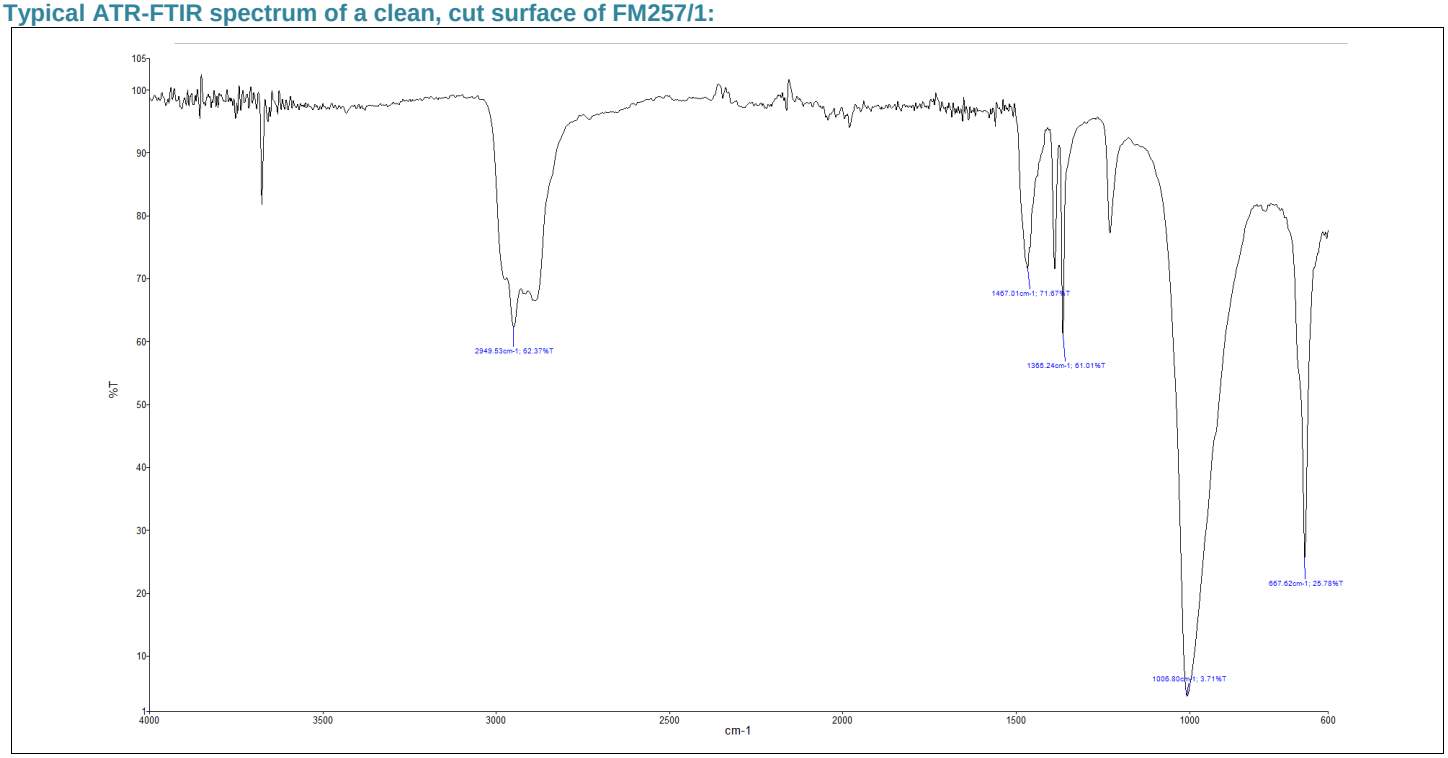
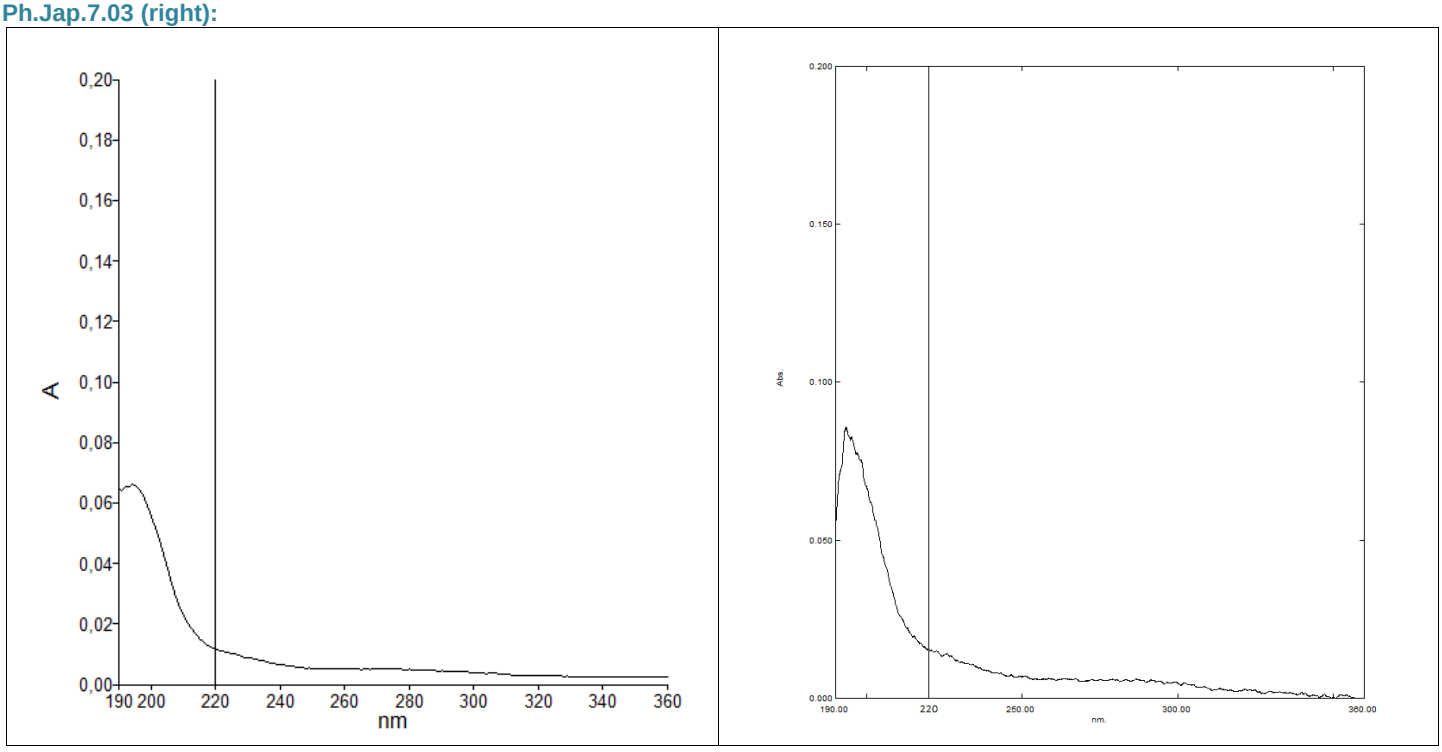
Typical ATR-FTIR spectrum of a clean, cut surface of FM257/1:



Typical UV spectrum of the Solution S extract of FM257/1, measured as per Ph.Eur. 3.2.9., USP <381> and ISO8871-1 (left) and Ph.Jap.7.03 (right):



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USP<87> Elution Test certificate for FM257/1:

TOXIKON
Leaders in Life Science and Technology

TEST RESULT REPORT

BELAC

Project Number:	**TE 09968**	**Study Number:**	**09-B2506-N1**
Sponsor:	**Helvoet Pharma Belgium NV**	**Report Date:**	**24/12/2009**
Contact:	*Mrs. Nadia Nouri*		
Address:	Industrieterrein Kolmen 1519 3570 Alken, Belgium	Date Sample Arrival: Technical Initiation: Technical Completion:	18/12/2009 21/12/2009 24/12/2009
PO.Number:	PB0904230		

Study	**Elution Test - ISO**	Temp/Time	37°C/24 hours
Test Item	FM257/2 V9250 SAF1	Ratio	25cm²/20mL
Lot	30171994	Vehicle	MEM-Complete

REFERENCE: According to "ISO 10993-5, 2009: Biological Evaluation of Medical Devices- Part 5:Tests for In Vitro Cytotoxicity." and "USP 32-NF 27, 2009: <87> Biological reactivity test, in vitro." Toxikon Reference: SOP 3.1.2.3, rev. 08

PROCEDURE: The biological reactivity of a mammalian monolayer, L929 mouse fibroblast cell culture, in response to the test item extract was determined. The samples and control articles were autoclaved prior to the preparation of the extracts. Extracts were prepared at 37±1°C for 24 hours in a humidified atmosphere containing 5±1% carbon dioxide (static). Positive (natural rubber) and negative (silicone) control articles were prepared to verify the proper functioning of the test system. The maintenance medium on the cell cultures is replaced by the extracts of the test item or control article in triplicate and the cultures are subsequently incubated for 48 hours, at 37±1°C, in a humidified atmosphere containing 5±1% carbon dioxide. Biological reactivity was rated on the following scale: Grade 0 (No reactivity); Grade 1 (Slight reactivity), Grade 2 (Mild reactivity), Grade 3 (Moderate reactivity) and Grade 4 (Severe reactivity). The test item is considered non-cytotoxic if none of the cultures exposed to the test item shows greater than mild reactivity (Grade 2).

RESULTS: No reactivity (Grade 0) was exhibited by the cell cultures exposed to the test item at the 48 hours observation. Severe reactivity (Grade 4) was observed for the positive control article. The negative control article showed no signs of reactivity (Grade 0).

CONCLUSION: Based on the evaluation criteria mentioned above, the test item is considered non-cytotoxic.

RECORD STORAGE: All raw data generated in this study will be archived at Toxikon Europe, according to SOP 4.2.8.

AUTHORIZED PERSONNEL

ir. Peter Cornelis *Study Director*	Vanessa Ruymen *Quality Assurance*

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