Sealing Solutions

COMPOUND DATA SHEET
FM257/2 Dark Grey

General description
FM257/2 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 FM257/2 is enclosed on page 3.

Physical properties

Hardness *ISO 7619-1 (1sec Indentation)*	**52 ± 5 °Shore A**
Density *ISO 2781*	**1.355 ± 0.025 g/cm³**
Ash content *Internal method. Calc.4h@700°C*	**46.0 ± 2.0 %**
Compression set *ISO 815, (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 *Internal method. 200mm/min, ISO 37 Dumb-bell 2, (typical value)*	**7.6 N/mm²**
Water Vapor Transmission Rate *Mocon, 38°C,100%RH, 1.33 mm thickness, (typical value)*	**0.03 g/m².24h**
Oxygen Transmission Rate *Mocon, 38°C, 85%RH, 100% O2, 1.39 mm thickness, (typical value)*	**48 cc/m².24h**

Compound ingredient declarations

Latex	FM257/2 is not made with natural rubber latex.
Nitrosamines	FM257/2 is not made with chemicals that are associated with nitrosamine formation as per the ASTM F1313-90 list.
Phthalates	FM257/2 is not made using Di(2-EthylHexyl) Phthalate (DEHP) or other phthalates.
BSE/TSE	For the raw materials of FM257/2, 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	FM257/2 is not made with 2-mercapto-benzothiazole (MCBT, also named MBT), or any of its derivatives.
Heavy Metals	FM257/2 fulfills the EC Guideline 94/62/EC for heavy metals in packaging materials and the CONEG regulation on reduction of toxics in Packaging Law: “packaging components shall not contain more than 100 ppm of Pb, Cd, Hg, and Cr(VI)“.

Chemical properties

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

Ph.Jap.7.03. : FM257/2 meets the chemical requirements specified in Ph.Jap. 7.03.
Typical results are given in the table on page 2.

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

Biocompatibility

USP <87><88>:
ISO 10993-5
Ph.Jap.7.03. FM257/2 is non-cytotoxic and meets the requirements of the Elution Test as described in 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.

Team Leader R&D lab	Senior Manager Material Development	Manager Global Quality & Regulatory Affairs
Date : 25 Nov 2014	Date : 27 Nov 2014	Date : 01 Dec 2014

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Typical results of chemical properties as per the Ph.Eur.3.2.9., ISO 8871-1 and the USP <381> for FM257/2:

Characteristic		Limits		FM257/2
Appearance of solution	Turbidity	Type I: ≤ 6 NTU (*) Type II: ≤ 18 NTU (*)		**1**
	Color	Solution S is not more intensely colored than reference		**Pass**
Acidity or alkalinity (NA : Not applicable)		≤ 0.8 ml 0.01M HCl	EP	**NA**
			USP**	**NA**
		≤ 0.3 ml 0.01M NaOH	EP	**0.0**
			USP**	**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+}	EP	**Pass**
			USP***	**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
(**) Corrected with blank
(***) Measured as per USP <231>; USP <231> will become obsolete by Dec 1, 2015

Typical results of chemical properties as per the Ph.Jap.7.03 for FM257/2:

Characteristic		Limits	FM257/2
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+}	**<0.01**
Reducing substances		≤ 2.0ml 0.002 M KMNO4	**0.3**
Residue on evaporation		≤ 2.0mg	**0.1**
UV absorbance (Max. Abs. 220-350nm)		≤ 0.20	**0.01**
Cadmium*		≤ 5 ppm	**<0.05**
Lead*		≤ 5 ppm	**0.69**

(*) measured directly on the rubber

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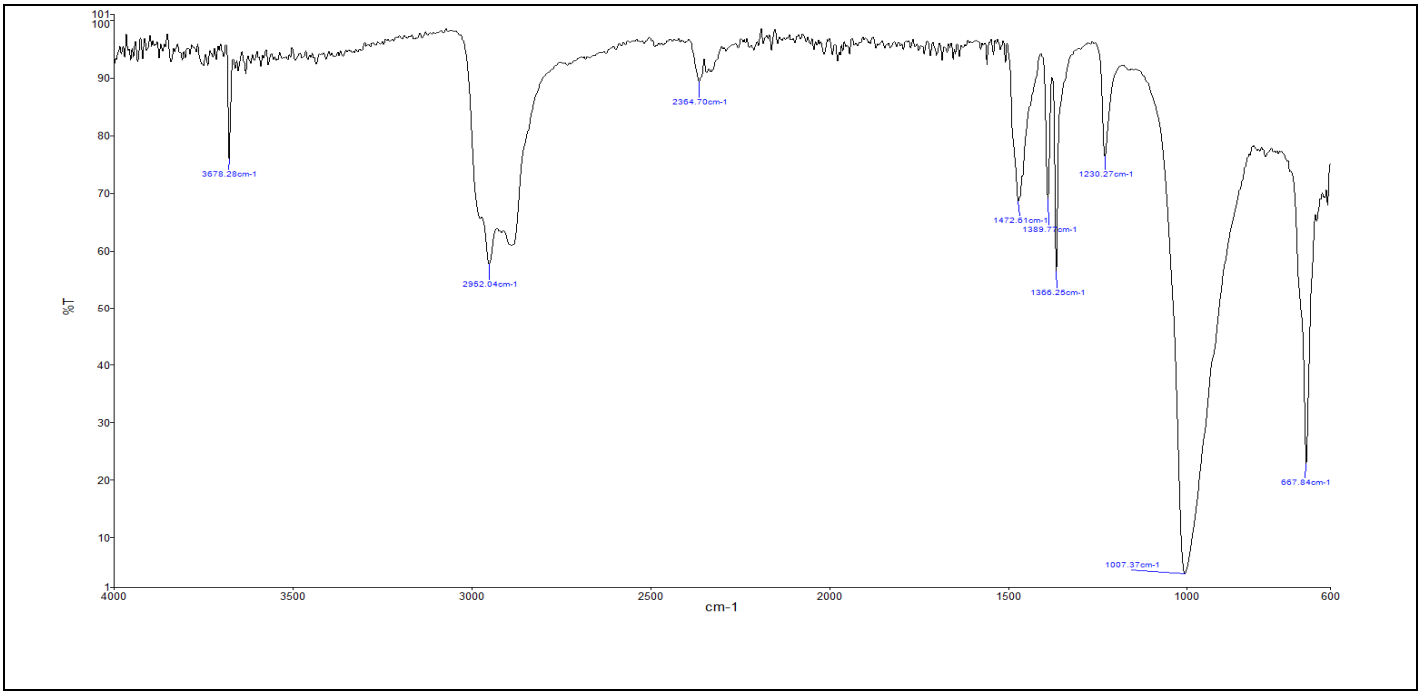
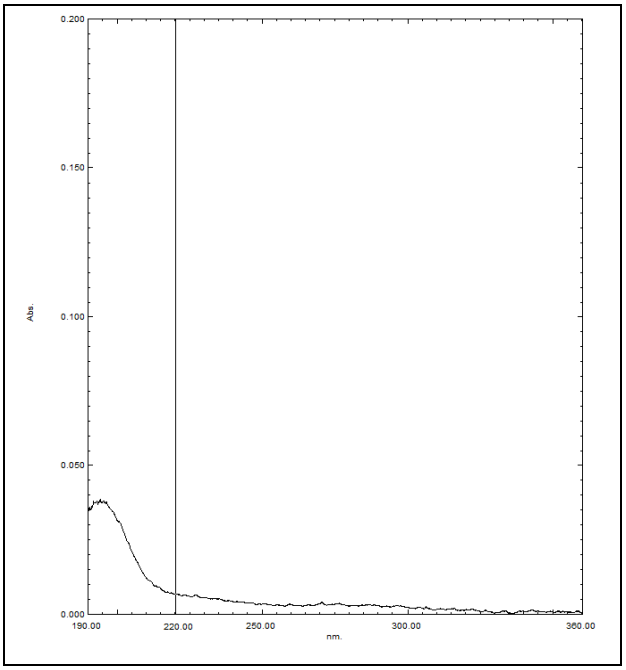
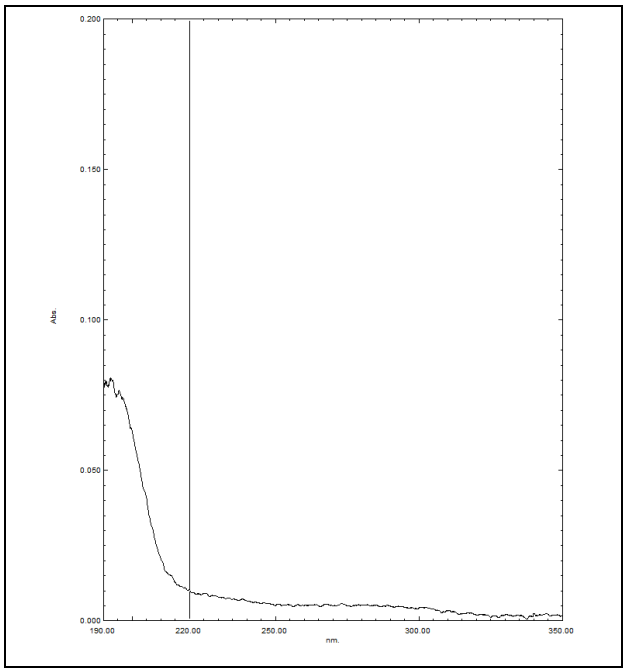
Typical ATR-FTIR spectrum of a clean, cut surface of FM257/2:



Typical UV spectrum of the Solution S extract of FM257/2, measured as per the Ph.Eur. 3.2.9., ISO8871-1 and USP <381> (left) and Ph.Jap.7.03 (right):





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USP<87> Elution Test certificate for FM257/2:

TOXIKON
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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:	18/12/2009 21/12/2009
PO.Number:	PB0904230	Technical Completion:	24/12/2009

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

for ir. Peter Cornelis
Study Director

Vanessa Ruymen
Quality Assurance

The test results on the enclosed report are only referring to the tested articles. Partly reproduction of this report can only be allowed after written permission of Toxikon. Toxikon guarantees that all results are acquired by testing according to officially accepted scientific methodology.

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