Sealing Solutions

COMPOUND DATA SHEET
FM153/0 Red Brown

General description
FM153/0 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 FM153/0 is enclosed on page 2.

Physical properties

Hardness *ISO 7619-1(1sec Indentation). Avg of 3 measurements*	**44 ± 5 °Shore A**
Density *ISO 2781*	**1.293 ± 0.025 g/cm³**
Ash content *Internal method. Calc.4h@700°C*	**43 ± 2.0 %**
Compression set *ISO 815, (typical value)*	**20 %**
Modulus 100 *Internal method. 100mm/min,ISO 37 Dumb-bell 2, (typical value)*	**1.1 N/mm²**
Modulus 300 *Internal method. 100mm/min,ISO 37 Dumb-bell 2, (typical value)*	**2.3 N/mm²**
Elongation @ Break *Internal method. 200mm/min, ISO 37 Dumb-bell 2, (typical value)*	**740 %**
Tensile Strength *Internal method. 200mm/min, ISO 37 Dumb-bell 2, (typical value)*	**11 N/mm²**
Water Vapor Transmission Rate *Not available*	**NA g/m².24h**
Oxygen Transmission Rate *Not available*	**NA cc/m².24h**

Compound ingredient declarations

Latex FM153/0 is not made with natural rubber latex.

Nitrosamines FM153/0 is not made with chemicals that are associated with nitrosamine formation as per the ASTM F1313-90 list.

Phthalates FM153/0 is not made using Di(2-EthylHexyl) Phthalate (DEHP) or other phthalates.

BSE/TSE For the raw materials of FM153/0, 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 FM153/0 is not made with 2-mercapto-benzothiazole (MCBT, also named MBT), or any of its derivatives.

Heavy Metals FM153/0 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)".

Biocompatibility
FM153/0 is non-cytotoxic and meets the requirements of the Elution Test as described in General Chapter <87>,"Biological Reactivity Tests, in vitro" of the USP. A typical USP<87> Elution Test certificate is enclosed on page 3.

Chemical properties
FM153/0 meets the chemical requirements for Type I closures specified in Ph.Eur. 3.2.9 and in USP <381>.
Typical results are given in the table below.
A typical UV spectrum is enclosed on page 2.

Characteristic		Limits		FM153/0
Appearance of solution	*Turbidity*	*Type I: 6 NTU (*) Type II: 18 NTU (*)*		***0***
	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+}*		***0.3***
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
Note : Chemical testing is performed on non-post-treated standard test plates or products, prepared using representative process conditions.

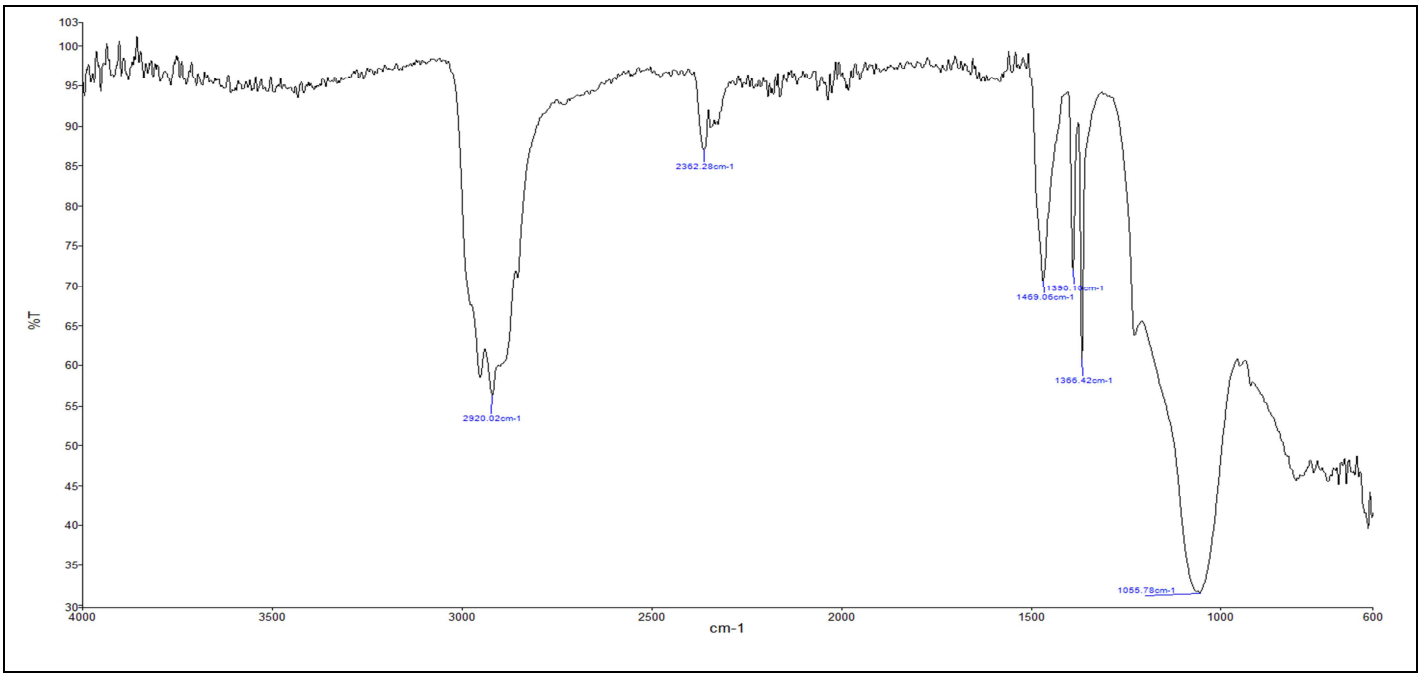
Note : "FMxxx" refers to the type of compound, the extension "/x" refers to the color of the said compound. Differently colored compounds might be used for testing throughout this document. It is generally accepted that the color is irrelevant for the properties discussed, except Ash content and Density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

Team Leader R&D lab	Senior Manager Material Development	Manager Global Quality & Regulatory Affairs
Date : 24 Jan 2014	Date : 03 Feb 2014	Date : 05 Feb 2014

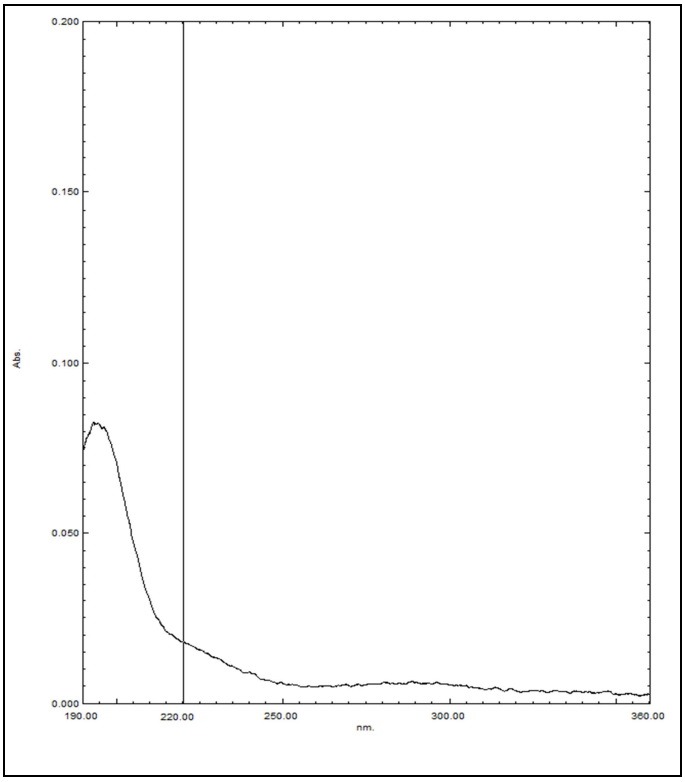
Datwyler Pharma Packaging International NV, Industrieterrein Kolmen 1519, BE-3570 Alken, Belgium
T +32 11 590 811, F +32 11 314 086, pharma@datwyler.com, www.datwyler.com

COMPOUND DATA SHEET
FM153/0 Red Brown

Typical ATR-FTIR spectrum of a clean, cut surface of FM153/0:



Typical UV spectrum of the Solution S extract of FM153/0, measured as per the USP <381> / Ph.Eur. 3.2.9.:



Datwyler Pharma Packaging International NV, Industrieterrein Kolmen 1519, BE-3570 Alken, Belgium
T +32 11 590 811, F +32 11 314 086, pharma@datwyler.com, www.datwyler.com

COMPOUND DATA SHEET
FM153/0 Red Brown

Select certificate for FM153/0:

TOXIKON

225 Wildwood Ave., Woburn, MA 01801
Telephone: (617) 933-6903
Fax: (617) 933-9196

TEST RESULT CERTIFICATE

Client: Helvoet Pharma Belgium NV
Address: Industriepark, B-3570 Alken, Belgie

Technical Initiation: 04/05/94
Technical Completion: 04/07/94
Final Report: 04/07/94
P.O. #: PB944190T

Contact: Mr. Deschaetzen

Project #: 94-1301.9

TEST ARTICLE: V9074 FM153/0

LOT #: 405537

NAME OF STUDY: Elution Test

REFERENCE: This study was based on the method described in USP XXII, Pp. 1495-1497, 1990, and Supplement 9, 1993.

GENERAL PROCEDURE: The biological reactivity of a mammalian monolayer, L929 mouse fibroblast cell culture, in response to the test article was determined. The test article was extracted in cell culture medium, at a ratio of 25 cm^2 per 20 mL. Extracts were prepared at 37±1°C, in a humidified atmosphere containing 5±1% carbon dioxide, for 24 hours. Positive (natural rubber) and negative (silicone) control articles were prepared to verify the proper functioning of the test system. The controls were incubated similar to the test article extracts, for 48 hours. Biological reactivity (cellular degeneration and malformation) was rated on a scale from Grade 0 (No Reactivity) to Grade 4 (Severe Reactivity). The test article met the requirements of the test if none of the cultures exposed to the test article showed greater than a Mild Reactivity, Grade 2.

RESULTS: No signs of reactivity (Grade 0) were exhibited by the cell cultures exposed to the test article or the negative control article at the 48 hour observation. Severe reactivity (Grade 4) was observed for the positive control article.

CONCLUSION: The test article is considered non-cytotoxic and meets the requirements of the Elution Test, USP XXII.

AUTHORIZED PERSONNEL:

Mark Turner, B.S.
Study Director

Katherine O'Kelly, B.S.
Quality Assurance

Environmental Sciences and Toxicology

Datwyler Pharma Packaging International NV, Industrieterrein Kolmen 1519, BE-3570 Alken, Belgium
T +32 11 590 811, F +32 11 314 086, pharma@datwyler.com, www.datwyler.com