

# COMPOUND DATA SHEET – ADDENDUM 01

## FM257/2 Dark Grey

### General description

FM257/2 is a bromobutyl compound with silicate filler. Unconventionally cured, free from MBT.

### FM257/2 has been tested for Elemental Impurities according to the upcoming revision of USP General Chapter 381 – Elastomeric Components Used in Injectable Pharmaceutical Packaging/Delivery Systems (Extractable Elements).

The new USP<381> specifies analyses for antimony (Sb), arsenic (As), cadmium (Cd), cobalt (Co), copper (Cu), lead (Pb), lithium (Li), mercury (Hg), nickel (Ni), vanadium (V), and zinc (Zn) – with quantitative reporting of actual values measured, based upon a method with detection sensitivity to 0.05µg per gram elastomer. It is scheduled to be issued in the course of 2018.

Typical values obtained are:

Elemental Impurity		ICH Q3D Class Reference	Result (µg/g)*	Analytical Method Used	Comments regarding source of information
Arsenic	As	1	<0.05	ICP-OES	Result is the average of 3 replicates
Cadmium	Cd	1	<0.05	ICP-OES	Result is the average of 3 replicates
Mercury	Hg	1	<0.05	ICP-OES	Result is the average of 3 replicates
Lead	Pb	1	<0.05	ICP-OES	Result is the average of 3 replicates
Vanadium	V	2A	<0.05	ICP-OES	Result is the average of 3 replicates
Cobalt	Co	2A	<0.05	ICP-OES	Result is the average of 3 replicates
Nickel	Ni	2A	<0.05	ICP-OES	Result is the average of 3 replicates
Lithium	Li	3	<0.05	ICP-OES	Result is the average of 3 replicates
Copper	Cu	3	<0.05	ICP-OES	Result is the average of 3 replicates
Antimony	Sb	3	<0.05	ICP-OES	Result is the average of 3 replicates
Zinc	Zn	-	0.23	ICP-OES	Result is the average of 3 replicates

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

\* Numbers preceded by < are below the reporting limit

Manager R&D Lab	Senior Manager Material Development	Head of Regulatory Affairs and Chemical Compliance
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