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November 18, 2015

COMPLIANCE STATEMENT
Garlock Gylon® Style 3504

This is to certify the following;

Garlock Gylon® Style 3504 conforms to both the Ingredient and Extract requirements of Food and Drug Administration Regulation 21 CFR 177.1550, "**Perfluorocarbon Resins - Substances for Use as Basic Components of Single and Repeated Use Food Contact Surfaces**". The filler is listed in the Food Chemicals Codex (FCC 3rd Edition) and is considered GRAS (generally recognized as safe per of Food and Drug Administration Regulation 21 CFR 170.30, "**Eligibility for Classification as Generally Recognized as Safe (GRAS)**." The pigment is approved for use in contact with food under 21 CFR 178.3297.

No Animal Derived Ingredients (ADI's) are used in the composition or in the process of manufacturing Garlock Gylon® Style 3504. We can therefore state that Garlock Gylon® Style 3504 is Transmissible Spongiform Encephalopathy (TSE) Free.

Garlock Gylon® Style 3504 has been tested by the Moog Medical Device Group per the United States Pharmacopeia (USP) testing protocols <87> and <88>. The material was found to meet the requirements of USP <87> Biological Reactivity Tests, In Vitro; Elution Test, in accordance with USP-32 – NF 27 through Second Supplement, Official December 1, 2009 to May 1, 2010. The material was also found to meet the requirements of USP 27-NF 22, General Chapter <88> for Class VI designation at a temperature extraction of 121°C for one hour. Garlock Gylon® Style 3504 has also been tested by NASMSA and was found to meet the Physicochemical Test Limits for Plastics (2008) as specified in United States Pharmacopeia 31, National Formulary 26 (USP), General Chapter <661>.

No Phthalates are intentionally added to Garlock Gylon® Style 3504 nor are disclosed as contaminants in any of the raw materials. Testing at ALS Environmental on the as manufactured sheet found no evidence of the following Phthalates at a detection level of 49 µg/Kg; Dimethylphthalate, Diethylphthalate, Di-n-butylphthalate, Bis(2-ethylhexyl)phthalate, Diisobutyl phthalate.

Michael P. McNally
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