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September 25, 2023

This **RESIDUAL SOLVENT STATEMENT** is being provided to confirm residual solvents for the material listed below based on guidance relating to residual solvents in medicinal products and their components (commonly referred to as Q3C) in accordance with The International Conference on Harmonization (ICH).

Product Name: Pre-Hydrated® Ticaloid® 5415 Powder

Product Number (New): 38514915CA

Pre-Hydrated® Ticaloid® 5415 Powder is a blend of Cellulose Gum and Xanthan Gum.

Cellulose Gum

- No Class 1 solvents have been used, nor do we believe they are produced in the manufacturing process for CMC.
- The Class 2 solvent Methyl alcohol (methanol or MeOH) is used as a solvent diluent in the manufacturing process for CMC. This product contains less than 3000 ppm (< 0.3 %) methanol.
- The Class 3 solvent Isopropyl alcohol (2-propanol or IPA) is used as a solvent diluent in the manufacturing process for CMC. This product contains less than 5000 ppm (0.5%) IPA.
- No other solvents are likely to be present, nor do we suspect they would be produced in the manufacturing process for CMC.

Xanthan Gum

Xanthan gum contains Isopropyl alcohol or ethyl alcohol, which are considered Class 3 solvents in accordance with USP. No class one, two or other solvents are used during the manufacture of this product. The maximum concentration of isopropyl alcohol or ethyl alcohol meets the FCC specification of 750 ppm (0.0750%) singly or combined.

Thank you for your continued interest in our products.

North America Quality Assurance
Ingredion Incorporated
Westchester, IL 60154

Next Review Date:
September 25, 2026