

April 23, 2022

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:** Ticaloid® ULTRASMOOTH Powder

**Ingredion Pin Code:** 38514908

Ticaloid® ULTRASMOOTH Powder is a blend of Cellulose Gum, Xanthan Gum, AND Carrageenan.

### **Cellulose Gum**

Methyl alcohol is used as a processing aid during the manufacture of this ingredient. Methyl alcohol is considered a Class 2 solvent in accordance with USP<467>. This product contains less than 3000 ppm (< 0.3 %) of methanol. Isopropyl alcohol is used as a processing aid during the manufacture of this ingredient. Isopropyl alcohol is considered a Class 3 solvent in accordance with USP<467>. The maximum concentration of isopropyl alcohol meets the FCC specification of no more than 750 ppm. No class one or other solvents are used during the manufacture of this ingredient.

### **Xanthan Gum**

Isopropyl alcohol is used as a processing aid during the manufacture of this ingredient. Isopropyl alcohol is considered a Class 3 solvent in accordance with USP<467>. No class one, two or other solvents are used during the manufacture of this ingredient. The maximum concentration of isopropyl alcohol meets the FCC specification of no more than 750 ppm.

## **Carrageenan**

Isopropyl alcohol is used as a processing aid during the manufacture of this ingredient.

Isopropyl alcohol is considered a Class 3 solvent in accordance with USP<467>. No class one, two or other solvents are used during the manufacture of this ingredient. The maximum concentration of isopropyl alcohol meets the FCC specification of no more than 750 ppm.

Thank you for your continued interest in our products.

*North America Quality Assurance*

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