

# PRODUCT INFORMATION



Document No.: PRD-02

## GELLAN GUM

in accordance with US and international test standards. If animal testing is required, it is conducted in accordance with these test standards. An OECD approved alternative to animal testing will be evaluated.

In accordance with and pursuant to Article 11, 2. (e) and Article 18 of EU Regulation 1223/2009 on cosmetic products, the most recent safety study using gellan gum test articles analogous to the CP Kelco gellan gum commercial product was conducted prior to 2001.

Please note that this information does not apply to all products. Please see Animal Testing Policy Letter, available upon request.

### 35. Residual Solvents/ Organic Volatile Impurities (OVI)

With the exception of IPA (2-propanol, iso-propanol, isopropyl alcohol) organic volatile chemicals (solvents) are not used in our manufacture, handling or storage of gellan gum.

Subsequently CP Kelco does not test for the presence of other solvents. The NF monograph for gellan gum lists an isopropyl alcohol requirement of not more than 750 mg/kg (ppm). This solvent is listed under Class 3 in the ICH guidelines and the current USP/NF Residual Solvents Section <467>. CP Kelco uses isopropyl alcohol (2-propanol, IPA) in the manufacture of gellan gum that it tested to comply with the purity criteria of the NF. No other Class 3 solvent and no solvents from Class 1, Class 2, or "other" solvents from Table 4 are used in the production of these gellan gum products.

### 36. Irradiation

CP Kelco gellan gum products do not undergo irradiation unless otherwise stated on the product data sheet and labeled.

### 37. Pesticide Residue Analysis

Pesticide use in CPKelco manufacturing plants is restricted to the external grounds. Pesticides are not stored on site and are applied by external certified pest control providers. For additional confirmation, CPKelco performs a Multi-Residue Analysis (Organohalides, Organonitrogen, Organophosphates and N-methyl Carbamates) on an annual basis. Results are included in the report for annual skip-lot testing results.

### 38. Aflatoxin Screening

Aflatoxin screening (B1, B2, G1 and G2) is conducted on an annual basis. Results are included in the report for annual skip-lot testing results.

### 39. FDA Continuing Guarantee

**[For food, pharmaceutical, and cosmetic uses]**

Available upon request

### 40. REACH Status

Available upon request