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#### List of Subjects

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: July 7, 2003.

**Peter Caulkins,**

*Acting Director, Registration Division, Office of Pesticide Programs.*

#### Summary of Petition

The petitioner's summary of the pesticide petition is printed below as required by FFDCA section 408(d)(3). The summary of the petition was prepared by the petitioner and represents the view of the petitioner. The summary may have been edited by EPA if the terminology used was unclear, the summary contained extraneous material, or the summary unintentionally made the reader conclude that the findings reflected EPA's position and not the position of the petitioner. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

#### CP Kelco

PP 3E6567

EPA has received a pesticide petition (PP 3E6567) from CP Kelco, 8355 Aero Drive, San Diego, CA 92123, proposing pursuant to section 408(d) of the FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR part 180 to establish an exemption from the requirement of a tolerance for gellan gum (CAS Reg. No. 71010-52-1) in or on all raw agricultural commodities (RAC) when used as a sticker/thickener in seed treatment and pesticide formulations. EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

#### A. Residue Chemistry

1. *Plant metabolism.* As a polysaccharide polymer, gellan gum is non-systemic and therefore no metabolism of gellan gum in raw

agricultural commodities or processed commodities is expected.

2. *Analytical method.* Analytical methods for determination of the polysaccharide polymer, gellan gum are available. Gellan gum is determined by the dissolution of gellan gum containing gels by heating and cooling in the presence of a dilute sequestrant solution (e.g. 0.1% w/v sodium hexametaphosphate). The gellan gum assay is based upon the presence of the 6-deoxyhexose rhamnose which can be determined using the cysteine-sulfuric acid procedure, originally developed by Dische and Shettles and modified by Graham.

3. *Magnitude of residues.* Gellan gum is applied as a minor component of pesticidal formulations. Gellan gum degrades into simple non-toxic sugars and their salts.

#### B. Toxicological Profile

1. *Acute toxicity.* The acute toxicity of gellan gum was studied using male and female rats via the oral and inhalation routes. In the acute oral toxicity study, the lethal dose (LD)<sub>50</sub> for both males and females was established at >5,000 milligrams/kilogram body weight (mg/kg bwt). For the acute inhalation toxicity study, the LD<sub>50</sub> for both males and females was established at >5.09 milligrams/Liter (mg/L). Gellan gum is practically non-toxic to rats when administered as a single large dose (5 g/kg bwt) in diet or via gavage.

2. *Genotoxicity.* Gellan gum was shown to be non-genotoxic in a battery of standard short-term tests. The Ames test, involving *S. typhimurium* at 10, 30, 100, 300, and 1,000 µg/plate resulted in a negative response. A deoxyribonucleic acid (DNA) repair test using the rat hepatocyte as a test subject at 3, 5, 10, and 20 milligrams/liter (mg/L) resulted in a negative response. For the V-79/hypoxanthine guanine phosphoribosyl transferase/(HGPRT) study, involving the Chinese hamster lung fibroblasts, doses at 3, 5, 10, and 20 mg/mL resulted in a negative response.

3. *Reproductive and developmental toxicity.* Groups of 26 male and female CD (Sprague-Dawley) rats were administered gellan gum in their diets at doses of 0, 2.5, 3.8, or 5.0%. Males were treated for 70 days prior to mating and for 3 weeks after mating. Females were treated for 14 days prior to mating and throughout mating, gestation, and lactation. Selection was made for the pups (F<sub>1</sub>) of this mating and they were allowed to mature and were mated to form the F<sub>2</sub> generation. There was no treatment-related effect of mating or fertility index, conception rate, length of gestation, length or parturition, number

of live pups, number of dead pups, post-implantation loss index, survival index on day 4, 7, 14, or 21 or lactation index for any of the generations.

For teratology studies, gellan gum was fed to groups of 25 pregnant female Sprague-Dawley rats at dietary levels of 0, 2.5, 3.8, or 5.0% during days 6–15 of gestation. Gellan gum has no fetotoxic or teratogenic effects on rats when ingested in the diet at levels up to 5.0%. In the reproduction and teratogenic studies in rats in which gellan gum was given at doses up to 50 g/kg in the diet, there was no evidence of interference with the reproductive process, and no embryotoxic or developmental effects were observed.

4. *Subchronic toxicity.* For short-term studies, male and female Sprague-Dawley rats (20/sex/group) were fed dietary levels of gellan gum ranging from 0–6% for 13 weeks. Although the animals on this study experienced symptoms of a sialodacryoadenitis viral infection, all animals survived treatment and there were no adverse effects associated with the feeding of gellan gum at levels up to 60 gram/kilogram (g/kg). Also, prepubertal rhesus monkeys (2/sex/group) were dosed by oral gavage with gellan gum at levels of 0, 1, 2, or 3 g/kg/day for 28 days. There were no overt signs of toxicity reported at levels up to 50 g/kg in the diet.

5. *Chronic toxicity.* Groups of 50 male and female Swiss Crl mice were fed gellan gum admixed in the diet at 0, 1.0, 2.0, and 3.0% for 96 and 98 weeks for males and females, respectively. All animals were examined twice daily for mortality and morbidity. Physical examination for the presence of palpable masses was initiated on a weekly basis starting in week 26. Body weights and food consumption were measured for 7–day periods on a weekly basis for the first 26 weeks of treatment and every 2 weeks thereafter. At necropsy, a complete gross pathological examination was performed on the animals from the control and 3.0% groups. Only the liver, kidneys, ovaries, testes, adrenals, pituitary, lungs, and heart were examined for animals of the 1.0 and 2.0% groups. There were no effects attributable to the feeding of gellan gum on either body weight gain or food consumption. There were no neoplastic or non-neoplastic changes which were associated with the feeding of gellan gum.

For the rat, groups of 50 F<sub>1</sub> generation Sprague-Dawley rats of each sex were exposed to gellan gum *in utero* and continued on gellan gum diets for approximately 104 weeks. The dietary levels of gellan gum were 0, 2.5, 3.8, and 5.0%. The rats were observed daily for