Evaluation Summary of Guar Gum for Use as a Cigarette Ingredient

Guar gum is approved for use as a food additive by U. S. Food and Drug Administration (FDA) and is on the list of substances "Generally Recognized As Safe" (GRAS) (21 CFR § 184.1339), and is approved by the Flavor and Extract Manufacturers Association (FEMA No. 2537) as GRAS for use in foods.[1] The Joint FAO/WHO Expert Committee on Food Additives (JECFA) as well as the Council of Europe (CoE No. 166) have approved the use of guar gum as a food additive.[2,3] Guar gum is included in the FDA Inactive Ingredients Guide for use as: oral suspensions, syrups, powder for reconstitution and tables (film coated and sustained action) tablets; topical lotion; buccal/sublingual tablet; and vaginal tablet.[4]

Guar gum has a low order of acute toxicity and has no chronic toxic, teratologic, genotoxic and mutagenic effects. Acute toxicity studies by oral routes in different animal species show the LD50 of guar gum is above 6 g/kg.[5-7] In chicks, short term feeding of guar gum at the 2% level decreased weight gain in studies by, while another study reported gain in body weight.[8,9] Several short-term feeding studies in the rat, mouse, dog, and monkey did not find any evidence of tissue damage or organ toxicity.[10-12] In one study, feeding of guar gum at ≥1% (500 mg/kg/day) resulted in decreased body weight gain in female rats,[6] while in males, decreased body weight was observed at high levels, ≥7.5% (3.75 g/kg/day).

In National Toxicology Program's (NTP) chronic feeding studies, no compound related clinical signs, or adverse effects on survival were noted in rats and mice given 5% guar gum.[10,13,14] The rodents might have tolerated higher doses, but 5% of diet is the upper limit for chronic feeding studies in the Bioassay Program, and this level represented the maximum tolerated dose (MTD) for females of both species in the NTP studies.[15] Interestingly, in these studies, incidence of hepatocellular carcinoma in male mice fed guar gum was lower than control animals. The authors of this bioassay concluded that guar gum is not carcinogenic in rats and mice of either sex.[10,13,14]

Administration of guar gum up to 900 mg/kg to rats (highest dose) and 600 mg/kg to hamster (highest dose) did not have any teratogenic effects.[16] In mice, administration of 170 mg/kg of guar gum had no clearly discernible effect on nidation or maternal or fetal survival, while 800 mg/kg resulted in a significant number of maternal deaths.[16] Guar gum was found non-mutagenic in the host-mediated assay, cytogenetic assay, and dominant lethal gene assay.[17] Exposure of *Saccharomyces cerevisiae* to guar gum at 1 and 5% was quite toxic and increased mitotic recombination frequency.[17] In an *in vitro* cytogenetic assay, guar gum resulted in adverse effects on human embryonic lung cells in anaphase.[17]

Occupational sensitization with rhinitis or asthma from guar gum has been reported in isolated cases.[18] However, the potential of guar gum or guar gum-containing products as important allergens remains unclear.[19]

The primary use of guar gum in modern cigarettes occurs in the reconstituted tobacco sheet material where guar gum acts as a binder for the ground tobacco. Guar gum is also frequently used as a binder in paper processes, and may be found in the various papers used to make cigarettes. Guar gum may also be used as a binder in the tobacco mat material used in modern electrically heated cigarette products. Guar gum is currently used worldwide at levels below

0.80% (8000 ppm, total weight of tobacco) in selected cigarette brands manufactured and/or distributed by Philip Morris USA Inc. (PM USA) and/or Philip Morris Products SA (PMP SA).

As suggested by the purge and trap studies conducted by PM USA, guar gum applied to tobacco (or sheet material) would not be expected to extensively distill at 100 °C.[20] At the higher temperatures used in the pyrolysis studies, the results of the analysis are consistent with chemicals expected from the pyrolytic decomposition of polysaccharides and suggest that guar gum would be pyrolyzed extensively.[21] Of the potential pyrolysis products identified in this test method, only formaldehyde has been recognized as a potential carcinogen by a regulatory body. Formaldehyde is a natural constituent of tobacco smoke and the potential for a small contribution to the overall formaldehyde concentration already present in tobacco smoke by guar gum is probably negligible.

Philip Morris USA Inc. (PM USA) has conducted two separate investigations involving the addition of guar gum to cigarette tobacco. For these studies, guar gum was a component of the reconstituted tobacco sheet used in the filler tobacco. Guar gum concentrations ranged from 4.5 to 9.0% of the sheet material, thus giving about 1.3 to 2.5% of the total tobacco weight in the cigarettes tested. While the design of the first study was complicated by the lack of a representative control cigarette containing reconstituted tobacco sheet material processed concurrently with the test cigarettes, a three-way ANOVA was used to analyze the data for effect of sheet making process plus guar gum, tobacco feedstock type, and propylene glycol concentration. There were not any dose dependent increases for any smoke constituents with the addition of guar gum.[22]

The second study involved a more traditional investigation with test and control cigarettes prepared concurrently. In the second study, smoke chemistry analysis indicated that aldehydes were increased with increased guar gum concentration.[23] However, measurement of smoke aldehyde concentrations during a 90-day smoke inhalation study using these same cigarettes did not indicate guar gum dependent increases in aldehyde concentrations.[24] The inconsistency of the smoke chemistry findings between the various investigations precludes development of a firm conclusion regarding the potential for guar gum to contribute to aldehyde formation during tobacco pyrolysis.

Evaluations of the mutagenic potential of the smoke condensate, and the cytotoxic potential of the particulate and gas vapor phases did not indicate any significant difference between the control and test cigarettes containing guar gum.[25-28] The biological effects of inhaling smoke from guar gum treated cigarettes was assessed in Sprague-Dawley rats exposed nose-only to smoke for 6 hrs/day, 7 days/week for 13 weeks. The results of the smoke inhalation studies indicated that guar gum addition to reconstituted tobacco sheet used in the filler tobacco at levels up to 2.5% of the total tobacco weight did not discernibly alter the biological effects normally associated with smoke exposure in rodents.[24]

The results of this evaluation of guar gum involving a review of published information and internal studies, suggests that addition of guar gum as a cigarette ingredient at the current use levels does not discernibly alter the biological effects normally associated with cigarette smoke.

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