WILLY BENECKE
NATURAL GUMS

Hamburg, 16-Dec-19

To whom it may concern

Subject: Nitrosamine

On September 19th, 2019, European Medicines Agency (EMA) published a new requirement that Marketing Authorization Holders (MAHs) for human medicines containing chemically synthesized active substances review their medicines for the possible presence of nitrosamines.
Information on nitrosamines for marketing authorization holders (EMA/189634/2019)[1]
Questions and answers on "Information on nitrosamines for marketing authorization holders" (EMA/CHMP/428592/2019 Rev. 1)[2]

Other authorities started an equivalent approach, e.g. Health Canada[3], TGA (Australia), Swissmedic[4].

Please note this refers only to human medicine containing chemically synthesized active substances. Other active ingredients and also excipients are not listed.

We supply our products (e.g. Gum Arabic, Guar Gum, Locust Bean Gum, Tragacanth, and Xanthan) as a food grade excipient and are not affected by this.

Kind regards
WILLY BENECKE GmbH

i.A. Vera Strakosch

[1] Information on nitrosamines for marketing authorization holders. EMA/189634/2019: https://www.ema.europa.eu/en/documents/referral/nitrosamines-emea-h-a53-1490-information-nitrosamines-marketing-authorisation-holders_en.pdf
[2] Questions and answers on "Information on nitrosamines for marketing authorization holders". EMA/CHMP/428592/2019 Rev. 1. https://www.ema.europa.eu/en/documents/referral/nitrosamines-emea-h-a53-1490-questions-answers-information-nitrosamines-marketing-authorisation_en.pdf
[3] Health Canada: Information to Marketing Authorization Holders (MAHs) of Human Pharmaceutical Products Regarding Nitrosamine Impurities. October 2, 2019
[4] https://www.swissmedic.ch/swissmedic/en/home/news/mitteilungen/aufforderung-zlinhaberinnen-ham.html