

Food Standards Australia New Zealand
PO Box 5423
Kingston, ACT
Australia

Electronic Submission, Application A1129

Monk Fruit Extract (Lo Han Guo)

Tate & Lyle is a manufacturer and distributor of monk fruit extract and is making this submission to assist Food Standards Australia New Zealand, FSANZ, in the assessment of this low calorie sweetener. Tate & Lyle is requesting that monk fruit extract be permitted as a general purpose sweetener to be used at Good Manufacturing Practice (GMP) levels.

This proposal is consistent with FSANZ risk assessment that concluded that an ADI of “not specified” is appropriate for monk fruit extract and this would allow manufactures to use this sweetener in foods and beverages that were not specifically included in the Saraya Co, Ltd. submission.

This approach would also be consistent with the four GRAS Notifications submitted to FDA and cited by FSANZ in their risk assessment. GRAS notification numbers 301,359,522, 556, 627, and 706 all contained similar exposure calculations based on general use at GMP levels. They all received letters of no questions and are incorporated by reference into this submission. Further, as noted by FSANZ, China and Japan permit the use of monk fruit extract (lo han guo) in foods and beverages with no maximum limits. Monk fruit extract is used in these countries according to GMP in many food categories, e.g. non-alcoholic beverage, fermented milk products- yoghurts, flavored milk, ice cream, and sports foods and beverages.

FSANZ has specified that all monk fruit extract must meet the requirements in USP/NF (10th Edition) and the labeling requirements in the draft standard.

Tate & Lyle is therefore requesting that the draft standard be revised to eliminate the categories of use and permit monk fruit extract to be used at GMP levels.



GRAS Notification References:

https://www.accessdata.fda.gov/scripts/fdcc/?set=GRASNotices&id=301&sort=GRN_No&order=DESC&startrow=1&type=basic&search=luo%20han%20guo

https://www.accessdata.fda.gov/scripts/fdcc/?set=GRASNotices&id=359&sort=GRN_No&order=DESC&startrow=1&type=basic&search=luo%20han%20guo

https://www.accessdata.fda.gov/scripts/fdcc/?set=GRASNotices&id=522&sort=GRN_No&order=DESC&startrow=1&type=basic&search=luo%20han%20guo

https://www.accessdata.fda.gov/scripts/fdcc/?set=GRASNotices&id=556&sort=GRN_No&order=DESC&startrow=1&type=basic&search=Monk%20Fruit

https://www.accessdata.fda.gov/scripts/fdcc/?set=GRASNotices&id=627&sort=GRN_No&order=DESC&startrow=1&type=basic&search=luo%20han%20guo

https://www.accessdata.fda.gov/scripts/fdcc/?set=GRASNotices&id=706&sort=GRN_No&order=DESC&startrow=1&type=basic&search=luo%20han%20guo