Chengdu PNP Biotech Co., Ltd.

No. 13, South Section 1, Second Ring Road
Suite 709, Wuhou District, Chengdu
Sichuan 610041, P.R. China
info@pnpbiotech.com
www.pnpbiotech.com

REGULATORY STATUS STATEMENT

Monk Fruit Extract 50% Mogroside V

This statement summarises the regulatory position of Monk Fruit Extract 50% Mogroside V in the principal markets as of the document date and supports the customer's own compliance assessment of its finished product. It is provided for general guidance and does not constitute legal advice.

1. Regulatory status in major markets

Market / jurisdiction	Regulatory framework	Status / classification	Basis / documentation	Remarks
United States (FDA)	FD&C Act; 21 CFR Part 111	Monk fruit extract is used in the United States as a natural sweetener and flavouring and has GRAS status through industry notices. No GRAS notice and no new-dietary-ingredient notification has been filed by us.	FD&C Act; 21 CFR Part 111	Finished-product use, dosage and label claims: customer to confirm.
European Union (EFSA / European Commission)	Reg. (EU) 2015/2283; Reg. (EU) 1169/2011; Reg. (EC) 1924/2006	*Siraitia grosvenorii* fruit has no history of consumption in the Union before 15 May 1997 and is listed as a novel food in the EU Novel Food Catalogue, so this preparation requires an authorisation under Regulation (EU) 2015/2283. EFSA has authorised no health claim.	2015/2283; 1169/2011; 1924/2006	Current novel-food authorisation covering this grade: customer to verify before placing on the EU market.
China (SAMR / NHC)	New Food Raw Material Safety Review Measures; GB 7718; GB 2760	Luo han guo (*Siraitia grosvenorii*) is listed in the national food-and-medicine catalogue, and mogrosides are permitted as a sweetener in specified food categories under the national food-additive standard. No health-food registration is held by us.	Food-and-medicine catalogue; GB 7718; GB 2760	Permitted categories and use levels in the finished product: customer to determine.
Codex Alimentarius (FAO / WHO)	Codex GSFA; Codex labelling standards	No Codex commodity standard exists for this extract and JECFA has established no specification for mogrosides; the additive provisions of the destination market apply.	Codex GSFA	Customer to confirm.
Canada (Health Canada / NNHPD)	Food and Drug Regulations; Natural Health Products Regulations	Recognised as a natural-health-product medicinal ingredient and used as a sweetener in foods subject to the applicable listings. No product licence or NPN is held by us.	FDR; NHP Regulations	Customer to confirm permitted-use conditions.
Australia / New Zealand (TGA / FSANZ)	Food Standards Code; Therapeutic Goods Act	Novel-food status of the extract must be confirmed with FSANZ before sale as a food. No ARTG listing is held by us.	FSANZ Food Standards Code; TGA	Customer to determine the regulatory route.
Other markets	National food and food-supplement law	Classification depends on the intended use and the jurisdiction.	Applicable national law	Customer to determine.

2. Other

- The article is a water-extracted, resin-purified extract of luo han guo fruit, standardised to not less than 50.0% mogroside V by HPLC; no carrier, excipient or additive is present.
- Mogrosides are intensely sweet triterpene glycosides. The product is a concentrated sweetener, not a table-top preparation: dosing and sweetness equivalence in the finished product are the manufacturer's responsibility.
- Not listed on the WADA Prohibited List; not a controlled substance in major sports jurisdictions.

Classification applies to the ingredient as supplied; finished-product and supplement status remain the customer's responsibility.

Prepared by: Mia Yu Approved by: Charlie Wang Date: Nov. 18, 2026