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REGULATORY STATUS STATEMENT

Niacinamide 99%

This statement summarises the regulatory position of Niacinamide 99% 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)	21 CFR 184.1535 (GRAS); DSHEA 1994; FCC; USP monograph	Niacinamide (nicotinamide, CAS 98-92-0) is affirmed GRAS as a direct human food ingredient used as a nutrient supplement under 21 CFR 184.1535 and is marketed as a dietary ingredient under DSHEA; FCC and USP monographs define the article. No GRAS notice or NDI notification has been filed by us.	21 CFR 184.1535; DSHEA 1994; FCC; USP	Use level and label claims: customer to confirm.
European Union (EFSA / European Commission)	Reg. (EC) 1925/2006; Dir. 2002/46/EC; Reg. (EU) 1169/2011	Niacinamide is a permitted source of vitamin B3 for food fortification under Regulation (EC) No 1925/2006 and for use in food supplements under Directive 2002/46/EC. The reference intake for niacin is 16 mg NE/day under Regulation (EU) No 1169/2011. No EU novel-food authorisation is claimed by us.	1925/2006; 2002/46/EC; 1169/2011	Member State implementing rules differ: customer to confirm.
China (NHC / SAMR)	GB 14880 (nutrition fortifier); GB 1903 series; Chinese Pharmacopoeia	Niacinamide is a permitted vitamin-B3 nutrition fortifier under GB 14880 and is an article of the Chinese Pharmacopoeia. The GB 14757-2010 additive standard covers nicotinic acid (niacin), not niacinamide, and is therefore not cited as the identity standard for this salt-free amide.	GB 14880; Chinese Pharmacopoeia	Fortification category and level: customer to apply.
Codex Alimentarius (FAO / WHO)	Codex GSFA; Codex nutrition labelling; JECFA	Vitamin B3 is a nutrient rather than a technological additive, so it has no GSFA technological-function listing; Codex labelling provisions for vitamins apply where relevant.	Codex GSFA; Codex labelling	Customer to confirm against the destination standard.
Canada (Health Canada / NNHPD)	NHP Ingredients Database; Food and Drug Regulations	Niacinamide is listed as a permitted medicinal ingredient in the Natural Health Products Ingredients Database and is permitted as a food ingredient. No product licence or NPN is held by us.	NHP Ingredients Database; FDR	Customer to confirm permitted-use conditions.
Australia / New Zealand (FSANZ)	Food Standards Code, Standard 1.3.1; Standard 2.9.1	Permitted as a vitamin under Standard 1.3.1 and in infant formula under Standard 2.9.1. No ARTG listing is held by us.	Standard 1.3.1; Standard 2.9.1	Customer to determine.
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 niacinamide (nicotinamide, CAS 98-92-0; C6H6N2O; MW 122.12), the amide of nicotinic acid and a form of vitamin B3, produced by chemical synthesis and crystallised to 99.0-101.0% on the dried basis; no carrier, excipient or additive is present.
- As a water-soluble vitamin it carries no fat, no digestible carbohydrate, no protein and no significant energy; vitamin B3 is declared as niacinamide, the supplied moiety.
- 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: Oct. 27, 2026