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REGULATORY STATUS STATEMENT

Vegan Vitamin D3 100,000 IU/g Powder

This statement summarises the regulatory position of Vegan Vitamin D3 100,000 IU/g Powder 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 184.1950 (GRAS); DSHEA 1994	Cholecalciferol (vitamin D3) is affirmed as generally recognised as safe for direct addition to food under 21 CFR 184.1950 and is used as a nutrient in dietary supplements under DSHEA. Not an FDA-approved drug.	21 CFR 184.1950; DSHEA 1994	Finished-product use, dosage and label claims: customer to confirm.
European Union (EFSA / European Commission)	Reg. (EC) 1925/2006; Dir. 2002/46/EC; Reg. (EU) 1169/2011	Vitamin D is listed in Annex I to Regulation (EC) No 1925/2006 (addition of vitamins to foods) and in Annex I to Directive 2002/46/EC (food supplements). The nutrient reference value is 5 micrograms per day (Regulation (EU) No 1169/2011, Annex XIII).	1925/2006 Annex I; 2002/46/EC Annex I; 1169/2011 Annex XIII	Conditions of use, NRV declaration and claims: customer to confirm.
China (SAMR / NHC)	GB 14880	Vitamin D, including cholecalciferol, is listed as a permitted food nutrition fortifier in GB 14880, subject to the permitted food categories and addition levels of that standard.	GB 14880	Other food categories are subject to the applicable approvals.
Canada (Health Canada / NNHPD)	Natural Health Products Regulations	Cholecalciferol is a permitted medicinal ingredient for natural health products. No product licence or Natural Product Number is held by us for this material.	NHP Regulations	Customer to confirm permitted-use conditions.
Australia / New Zealand (TGA / FSANZ)	Therapeutic Goods Act; Food Standards Code	No Australian Register of Therapeutic Goods listing is held by us; vitamin D as a permitted nutritive substance is governed by the applicable Food Standards Code provisions.	TGA; FSANZ Food Standards Code	Customer to determine.
Japan (MHLW)	Food Sanitation Act	Cholecalciferol is listed as an existing food additive in Japan; no Japanese approval is claimed by us for a specific use.	MHLW food-additive standards	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

- Cholecalciferol (CAS 67-97-0; C27H44O; MW 384.6) is vitamin D3; 1 microgram of cholecalciferol is equivalent to 40 IU, so 100,000 IU/g corresponds to 0.25% cholecalciferol.
- Cholecalciferol is included in the Codex advisory list of vitamin compounds for use in foods for special dietary uses (CAC/GL 10-1979).
- Not listed on the WADA Prohibited List; not a controlled substance in major sports jurisdictions.
- The substance is listed in the U.S. TSCA inventory and is subject to EU REACH where applicable.

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. 17, 2026