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REGULATORY STATUS STATEMENT

Vitamin K2 (MK-7)

This statement summarises the regulatory position of Vitamin K2 (MK-7) 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)	DSHEA 1994; 21 CFR 170/180 (GRAS); GRN 887	Fermentation-derived menaquinone-7 is the subject of GRAS notice GRN 887 (use as a nutrient in nutritional beverages for ages 1-13 at 4 g per serving) and is marketed as a dietary-supplement ingredient under DSHEA. Not an FDA-approved drug.	GRN 887; 21 CFR 170.3(o)(20); DSHEA 1994	Finished-product use and label claims: customer to confirm.
European Union (EFSA / European Commission)	Reg. (EC) 1170/2009; Dec. 2009/345/EC; Reg. (EU) 432/2012	Menaquinone (MK-7) from *Bacillus subtilis* subsp. natto is authorised as a novel-food ingredient (Decision 2009/345/EC) and listed as a permitted vitamin K source for food supplements and fortified foods (Reg. (EC) 1170/2009). Vitamin K health claims are governed by Reg. (EU) 432/2012.	2009/345/EC; (EC) 1170/2009; (EU) 432/2012	Conditions of use, NRV declaration and claims: customer to confirm.
China (SAMR / NHC)	GB 14880; NHC Announcement No. 8 of 2016	Fermentation-derived vitamin K2 was approved as a food nutrition fortifier in 2016 (NHC Announcement No. 8) for use in formulated milk powder for children and for pregnant and lactating women (GB 14880).	NHC Announcement No. 8 (2016); GB 14880	Other food categories are subject to the applicable approvals.
Canada (Health Canada / NNHPD)	Natural Health Products Regulations	No Natural Product Number or product licence 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 K2 use in food is governed by the applicable Food Standards Code provisions.	TGA; FSANZ Food Standards Code	Customer to determine.
Japan (MHLW)	Food Sanitation Act	Natto-derived menaquinone-7 has a long history of dietary use in Japan; no Japanese food-additive designation is claimed by us.	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

- Menaquinone-7 (CAS 2124-57-4; C46H64O2; MW 649.0) is the vitamin K2 form; the vitamin K nutrient reference value is 75 micrograms (EU) and the US Daily Value is 120 micrograms.
- 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. 16, 2026