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REGULATORY STATUS STATEMENT

Magnesium Citrate Anhydrous 15% Magnesium

This statement summarises the regulatory position of Magnesium Citrate Anhydrous 15% Magnesium 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 184.1434 (GRAS); 21 CFR 184.1; FCC monograph; DSHEA 1994	Magnesium citrate is affirmed as GRAS for direct addition to food under 21 CFR 184.1434 and is used as a magnesium nutrient supplement; a Food Chemicals Codex monograph defines the article. No GRAS notice or NDI notification has been filed by us.	21 CFR 184.1434; FCC; DSHEA 1994	Use level in the finished product: customer to confirm.
European Union (EFSA / European Commission)	Directive 2002/46/EC Annex II; Reg. (EC) 1925/2006 Annex II; INS E345	Magnesium citrate is a permitted source of magnesium in food supplements (Annex II of Directive 2002/46/EC) and in foods with added nutrients (Annex II of Regulation (EC) 1925/2006), with INS/E number E345. EFSA has authorised no health claim specific to the salt.	2002/46/EC; 1925/2006; E345	Finished-product nutrient declaration and claims: customer to apply.
China (NHC / SAMR)	GB 1903.38 (food nutrient fortifier magnesium citrate); GB 14880	GB 1903.38 is the national food-safety standard for the nutrient fortifier magnesium citrate and the article is a permitted magnesium source under GB 14880 for the categories and levels set out there. No health-food registration is held by us.	GB 1903.38; GB 14880	Fortification category and use level: customer to apply.
Codex Alimentarius (FAO / WHO)	Codex GSFA (INS 345)	Magnesium citrate appears in the Codex General Standard for Food Additives as INS 345 for the categories and levels set out there.	Codex GSFA, INS 345	Customer to confirm the category and level.
Canada (Health Canada / NNHPD)	Food and Drug Regulations; Natural Health Products Regulations	Permitted as a magnesium source in foods and accepted as a medicinal ingredient for natural health products; the finished product needs a product licence and NPN. None is held by us.	FDR; NHP Regulations; NHPID	Permitted conditions and claims: customer to determine.
Australia / New Zealand (TGA / FSANZ)	Food Standards Code (Schedule 15 / Schedule 29); Therapeutic Goods Act	Permitted as a mineral source in formulated supplements and as a food additive; no ARTG listing is held by us.	Food Standards Code; Therapeutic Goods Act	Customer to determine the food or listed-medicine route.
Other markets	National food, supplement and medicine law	Classification depends on the intended use and the jurisdiction.	Applicable national law	Customer to determine.

2. Other

- The article is the anhydrous magnesium salt of citric acid, obtained by neutralisation of citric acid with a magnesium source in purified water, controlled to not less than 15.0% magnesium on the dried basis; no carrier, excipient or additive is present.
- Magnesium citrate is not classified as hazardous under GHS/CLP. Fine dust is a mechanical irritant; bulk handling is confined to trained personnel with local exhaust ventilation.
- Magnesium is a permitted nutrient in sports nutrition products and the salt is not listed on the WADA Prohibited List.

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: Sep. 07, 2026