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REGULATORY STATUS STATEMENT

Creatine Monohydrate 99%

This statement summarises the regulatory position of Creatine Monohydrate 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)	Dietary Supplement Health and Education Act (DSHEA) 1994; FD&C Act	Marketed as a dietary-supplement ingredient; not an FDA-approved drug. No New Dietary Ingredient notification or GRAS notice has been submitted by us for this material.	DSHEA 1994; FD&C Act 413; 21 CFR 190.6	Customer to confirm NDI status for its finished product.
European Union (EFSA / European Commission)	Regulation (EU) 2015/2283 (Novel Food)	Novel-food status depends on documented history of food use before 15 May 1997; we do not claim any EU novel-food authorisation.	Reg. (EU) 2015/2283	Customer to confirm before placing a food supplement on the market.
United Kingdom (FSA)	UK Novel Food framework	Novel-food status to be confirmed against the UK register; no UK authorisation is claimed by us.	UK Novel Food regime	Customer to confirm.
Canada (Health Canada / NNHPD)	Natural Health Products Regulations	We do not hold a Natural Product Number or product licence 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.	TGA; FSANZ	Customer to determine.
China (SAMR / NMPA)	GB 24154 (sports nutrition foods); QB/T 2834 (creatine monohydrate); not in GB 2760 / GB 14880	Creatine monohydrate is a designated ingredient for sports nutrition foods under GB 24154 (speed-and-strength category, typical intake 1-3 g per day) and has the product standard QB/T 2834. It is not listed in GB 2760 or GB 14880 and may not be used as an ordinary food ingredient in China. The customer is responsible for confirming the permitted product category and intake for the intended market.	GB 24154 (sports nutrition foods); QB/T 2834 (creatine monohydrate); not in GB 2760 / GB 14880	Food category and use level: customer to determine.

2. Other

• 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: Sep. 14, 2026