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REGULATORY STATUS STATEMENT

Dihydroberberine 98%

This statement summarises the regulatory position of Dihydroberberine 98% 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)	Dietary-supplement ingredient; not listed in GB 2760 / GB 14880	Dihydroberberine is the reduced derivative of berberine, an isoquinoline alkaloid. Neither dihydroberberine nor berberine is listed as a food additive or fortificant in GB 2760 or GB 14880 in China. The article is supplied as a dietary-supplement ingredient for export and for uses where the customer holds the applicable registration. The customer is responsible for determining the legal status of the intended food category and use level.	Dietary-supplement ingredient; not listed 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. 30, 2026