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REGULATORY STATUS STATEMENT

Lion Mane Extract 30% Beta-Glucan

This statement summarises the regulatory position of Lion Mane Extract 30% Beta-Glucan 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 Part 111	The fruiting body and its water extract are marketed as dietary ingredients under DSHEA. No GRAS notice and no NDI notification has been filed by us.	DSHEA 1994; 21 CFR Part 111	Finished-product use, dosage and label claims: customer to confirm.
European Union (EFSA / European Commission)	Reg. (EU) 2015/2283; Reg. (EC) 1924/2006	The fruiting body is a traditional food in Asia. For the EU the customer should verify the entry for *Hericium erinaceus* in the EU Novel Food Catalogue before the extract is placed on the market, because several mushroom species and their extracts are treated as novel. EFSA has authorised no health claim.	2015/2283; 1924/2006	Novel-food status and claims: customer to verify.
China (NHC / SAMR)	Food Safety Law; health-food rules	*Hericium erinaceus* is a cultivated edible fungus with a long history of consumption in China, and the dried fruiting body is a conventional food. The purified extract is not itself listed as a new food raw material; the species is included in the list of fungal species permitted for use in health foods, and a health-food product needs registration. No health-food registration is held by us.	Food Safety Law; health-food registration rules	Finished-product registration or filing: customer to determine.
Codex Alimentarius (FAO / WHO)	Codex labelling standards	No Codex commodity standard exists for the extract and JECFA has established no specification for the article.	Codex	Customer to confirm.
Canada (Health Canada / NNHPD)	Food and Drug Regulations; Natural Health Products Regulations	*Hericium erinaceus* is used as a medicinal ingredient in 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; Therapeutic Goods Act	FSANZ has assessed *Hericium erinaceus* as a novel food for Australia and New Zealand, there being no history of consumption there, so a novel-food application or a record of acceptable use is required before sale as food. No ARTG listing is held by us.	FSANZ Food Standards Code; TGA	Customer to determine the food or listed-medicine route.
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

- The article is a hot-water extract of the fruiting body of *Hericium erinaceus*, standardised to not less than 30.0% beta-glucan by AOAC 995.16 and not less than 50.0% polysaccharides by UV; no carrier, excipient or additive is present. Food-grade ethanol is used as the precipitation solvent and is removed to residual levels during drying.
- Beta-glucan is a cell-wall polysaccharide and is not an allergen in its own right, but the article is a mushroom preparation: people with a known allergy to edible fungi should avoid it, and the finished-product label should carry the mushroom allergen statement where the destination market requires one.
- Not listed on the WADA Prohibited List; not a controlled substance in major sports jurisdictions.

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. 18, 2026