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REGULATORY STATUS STATEMENT

Hyaluronic Acid 95%

This statement summarises the regulatory position of Hyaluronic Acid 95% 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; TSCA inventory	Sodium hyaluronate is marketed in the United States as a dietary ingredient under DSHEA and the substance is listed on the TSCA inventory. No GRAS notice and no NDI notification has been filed by us.	DSHEA 1994; 21 CFR Part 111; TSCA	Finished-product use, dosage and label claims: customer to confirm.
European Union (EFSA / European Commission)	Reg. (EU) 2015/2283; Commission Implementing Decision 2013/705/EU; Cosmetics Reg. (EC) 1223/2009	Hyaluronic acid from rooster comb has been authorised as a novel-food ingredient in the EU under Decision 2013/705/EU for specified categories and levels; the fermented sodium salt must be checked against the EU Novel Food Catalogue for its own status. The ingredient is listed in the EU cosmetic-ingredient database (CosIng). No EFSA health claim is authorised.	2015/2283; 2013/705/EU; 1223/2009	Novel-food status of this fermented grade: customer to determine.
China (NHC / SAMR)	2021 NHC announcement on three-new-foods (sodium hyaluronate); 2008 new-resource-food approval	Sodium hyaluronate produced by fermentation with *Streptococcus equi* subsp. zooepidemicus was approved as a new food ingredient for ordinary food use by the 2021 NHC announcement (following the 2008 health-food approval), for the categories and maximum levels set out there. The announcement requires a recommended intake of not more than 200 mg/day and labels to state that infants, pregnant and lactating women should not consume it. No health-food registration is held by us.	2021 NHC three-new-foods announcement; 2008 approval	Food category, level and label warnings: customer to apply.
Codex Alimentarius (FAO / WHO)	Codex GSFA; Codex labelling standards	No Codex standard exists for hyaluronic acid / sodium hyaluronate and it is not listed as an additive in the Codex GSFA.	Codex GSFA	Customer to confirm.
Canada (Health Canada / NNHPD)	Natural Health Products Regulations; Food and Drug Regulations	Sodium hyaluronate is used in natural health products; a finished product requires a product licence and NPN. None is held by us.	NHP Regulations; FDR	Customer to confirm permitted-use conditions.
Australia / New Zealand (TGA / FSANZ)	Food Standards Code; Therapeutic Goods Act	Classification depends on whether the article is supplied as a food, a cosmetic ingredient or a therapeutic good; no ARTG listing is held by us.	FSANZ Food Standards Code; TGA	Customer to determine.
Other markets	National food and food-supplement law	Use in foods or supplements is approved in Japan, Korea, the United States, the European Union, Australia, New Zealand and Brazil; the exact conditions depend on the jurisdiction.	Applicable national law	Customer to determine.

2. Other

- The article is sodium hyaluronate, the sodium salt of a high-molecular-weight glycosaminoglycan produced by microbial fermentation and purified by ethanol precipitation, standardised to not less than 95.0% on the dried basis by HPLC; no carrier, excipient or additive is present.
- The polymer consists of D-glucuronic acid and N-acetyl-D-glucosamine disaccharide units and is not a protein, fat or digestible macronutrient; it is declared as sodium hyaluronate in the nutritional panel.
- 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: Aug. 31, 2026