

INCI Name: Water, Sodium Hyaluronate

CAS#: 9067-32-7

EINECS#: N/A

Appearance: Clear Liquid

Suggested Use Level: 1 – 5%

Suggested Applications:

- Hair Care: Gels, Serums, Anti-aging formulations
- Skin Care: Creams, Lotions, Anti-aging formulations

Formulating suggestions: It is not recommended to expose material to temperatures above 75°C. However, if heat is required, it is recommended to add during the cooling phase after emulsion has formed.

Solubility: Water soluble

Optimum pH Range: 4.0-8.0

Thermostability: We do not recommend heating past 75°C.

Preservative System: Phenoxyethanol

Shelf Life: 24 months from date of manufacture, provided the ingredient is stored under proper conditions and not exposed to extreme temperatures or moisture.

Storage Conditions: Store under dry, ambient conditions in tightly closed containers away from light. Avoid bacterial contamination.

Packaging Type: HDPE containers

Natural Origin Index: 0.995

Information Regarding Origin

INCI	Source	Origin
Sodium Hyaluronate	Fermentation	China

Country of Manufacture: United States

Composition

INCI Name	CAS	Percent Range	Function
Water	7732-18-5	98.5%	Solvent
Sodium Hyaluronate	9067-32-7	1.0%	Active Ingredient
Phenoxyethanol (<i>preservative</i>)	122-99-6	0.5%	Preservative

Listings in Substance Inventories

EU EINECS/ELINCS/NLP:	Listed
Canada DSL:	Listed
US TSCA	Not applicable
Korea KECI:	Not Listed
China IECSC/IECIC	Listed
Japan ENCS:	Listed
Australia AICS:	Listed
Philippine PICCS:	Not Listed
New Zealand (NZIoC):	Listed

REACH Status

Sodium Hyaluronate Powder is exempt from REACH registration. According to Article 2(9) of Regulation (EC) 1907/2006, polymers are exempt from the provisions on registration of Title II of REACH. Sodium Hyaluronate meets the criteria set for a polymer defined in Article 3(5) and the monomer for this polymer can be considered as non-isolated intermediates, for which REACH regulation is not applicable according to Article 2(1).

Based on the available data, the requirements for exemption from the obligation to register are met for Sodium Hyaluronate (CAS: 9067-32-7).

OVI (Organic Volatile Impurities)

The manufacturing process for this product does not use residual solvents listed in ICH Class I, II or III, USP 35 <467>, or California Prop 65.

Residual Solvents, Impurities:

Solvents other than water are not used during the manufacturing process. The substances listed in Annex II of EC Regulation 1223/2009 are not used as raw materials during the manufacturing process.

Nanomaterials (EC) 1223/2009

HyaClear® Solution is completely water soluble and therefore does not contain any nanoparticles as defined by (EC) 1223/2009. According to Article 16 of EU Cosmetic Regulation (EC) 1223/2009, 'nanomaterial' means an insoluble or biopersistent and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm.

CMR

No substances classified as Carcinogenic, Mutagenic or Toxic to Reproduction (CMR) category 1, 2, 3 under the Directive 67/548/EEC (Dangerous Substances Directive) or CMR 1A, 1B, 2 under the Regulation (EC) 1272/2008 (Classification, Labelling and packaging) are contained or used during the manufacturing process.

Substances of Very High Concern (SVHC)

This product is not manufactured or formulated with any of the Substances of Very High Concern (SVHC) as per the candidate list as defined in Article 57 of Regulation (EC) No 1907/2006 – REACH that was current as of the effective date of this document.

Heavy Metals

Due to the nature of the raw materials and the manufacturing process of HyaClear® Solution it is not expected to find levels of heavy metals above the limits outlined by the FDA and Health Canada.

Lead	< 10 ppm
Arsenic	< 3 ppm
Mercury	< 1 ppm
Cadmium	< 3 ppm
Antimony	< 5 ppm
Chromium	< 3 ppm

Regulation EC 1223/2009

HyaClear® Solution is in compliance with the regulation on cosmetics (1223/2009) (EC).

Pesticides

The raw materials used in the manufacturing of HyaClear® Solution should meet the pesticide regulations set by FDA, Health Canada and/or EU Regulations. As a result, we have tested Aquatic testing was not conducted for HyaClear® Solution to determine Limit of Qualification (LOQ) levels of all types of pesticides (300+ Compounds), and results are negative. Spices - Botanicals - and other Specialty Samples were Below LOQ levels.

Natural & Organic Standard Compliance

HyaClear® Solution does not have any natural or organic certifications.

California Safer Consumer Products Act

HyaClear® Solution does not contain any chemicals listed on the “Informational ‘Initial’ List of Candidate Chemicals and Chemical Groups”.

California Safe Cosmetics Program

HyaClear® Solution does not contain any chemicals known or suspected to cause cancer or reproductive toxicity as defined by the California Department of Public Health (CDPH). This includes chemicals listed on Prop 65, NTP, and IARC.

Animal Testing

HyaClear® Solution has never been tested on animals in accordance with Article 18 of regulation (EC) n.1223/2009.

BSE/TSE Statement

HyaClear® Solution is derived from non-animal sources and therefore does not pose concerns for Bovine Spongiform Encephalopathy (BSE) or other Transmissible Spongiform Encephalopathies (TSE).

GMO Statement

HyaClear® Solution has not been obtained from genetically modified raw materials.

Gluten Statement

HyaClear® Solution does not contain gluten.

Vegan Compliance

HyaClear® Solution does not contain any animal by-products, ingredients of animal origin, and is cruelty free.

Irradiation

HyaClear® Solution has not been irradiated at any point during the manufacturing and packaging process.

Parabens

HyaClear® Solution does not contain parabens.

Allergens Statement (EC) 1223/2009

HyaClear® Solution does not contain any of the 26 fragrance allergens listed in Annex III of the Cosmetics Directive 76/768/EEC, respectively Regulation (EC) No 1223/2009.

Food Allergens statement

The following food allergens are not used during the manufacturing process, and therefore are not anticipated to be present in HyaClear® Solution:

- Cereals containing gluten and products of these (wheat, rye, barley, oats)
- Celery or derivatives
- Crustaceans and bi-valves (e.g. shellfish such as shrimp, lobster, crab & clams)
- Eggs or albumin derivatives
- Fish or derivatives
- Lupin
- Dairy products (e.g. whey, lactose, casein, milk or cream)
- Mustard or derivatives
- Tree nuts or derivatives (including almonds, Brazil nuts, cashews, chestnuts, hazelnuts, pecans, pine nuts, pistachio nuts, macadamia nuts and walnuts)
- Peanuts or derivatives
- Sesame seeds

DRC 3TG Conflict-Free Policy

HyaClear® Solution is not produced using gold, tin, tantalum and tungsten, the derivatives of cassiterite, columbite-tantalite or wolframite. In addition, no raw materials used are sourced from the eastern portion of the Democratic Republic of the Congo (DRC) and surrounding countries. Therefore, HyaClear® Solution is DRC 3TG conflict-free.

Phthalates

HyaClear® Solution does not contain phthalates.

CITES of Wild Fauna and Flora

This product does not contain substances regulated under CITES appendices I, II or III.

Sewer Sludge

This product is not manufactured from ingredients grown in sewer sludge.

Aquatic Testing

Aquatic testing was not conducted for HyaClear® Solution.

Biodegradability

Biodegradability studies were not conducted for HyaClear® Solution.

Safety Testing

Please see Cosmetic Ingredients Review (CIR) report "Final Report of the Safety Assessment of Hyaluronic Acid, Potassium Hyaluronate, and Sodium Hyaluronate" published in International Journal of Toxicology Volume 28 Number 4S on July/August 2009.

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