

Soliance

Raw Material Information Profile



Trade name: PRIMALHYAL 10
 INCI name : Hydrolyzed hyaluronic acid
 Commercial reference: SO_PRIM10
 Harmonized tariff code: 3913900088
 Supplier name: SOLIANCE
 Country of origin: FRANCE

1. Regulatory status

a. Chemical regulations compliance

Composition

Chemical name	CAS #	EC #	FDA %
HYALURONIC ACID	9004-61-9	232-678-0	A

FDA Standards : A > 50%, B: 25 - 50%, C: 10 - 24,99%, D: 5 - 9,99%, E: 1 - 4,99%, F:0,1 - 0,99%, G < 0,1%

Additives (intentionally added to maintain quality or stability...)

Chemical name	CAS #	EC #	%
<i>none</i>			

By-products and impurities

Based on our actual knowledge of our production process, raw materials and equipment used, we expect that the material contains:

	Not expected	Yes	Nature & Max in ppm
Residual solvents	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Bioethanol < 1%
Phthalates	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Free Ethylene Oxide	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Polycyclic Aromatic Hydrocarbon	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Glycol Ether	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Dioxane	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Nitrosamines	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Diethylene glycol	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Volatile Organic Compounds mentioned in the Swiss list RD814.018 - Ordinance on the incentive tax	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Dioxin	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Other impurities	<input type="checkbox"/>	<input type="checkbox"/>	

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Global Inventories Status

COUNTRY	INVENTORY	YES	NO	Additional information
USA	TSCA listed	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Cosmetic Use exempted
CANADA	DSL listed	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
	NDSL listed	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
	Low volume exemption*	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
EUROPE	EINECS listed	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
	ELINCS listed	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
	REACH Compliance	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Exempted (Polymer)
AUSTRALIA	AICS listed	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
	low volume chemical permit /Low volume exemption*	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
PHILIPPINES	PICCS listed **	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Cosmetic End Product exempted
	Small Quantity Importation*	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
CHINA	IECSC listed **	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Cosmetic End Product exempted
JAPAN	ENCS listed **			Cosmetic use exempted
	ISHL listed **	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Cosmetic End Product exempted
	Low volume exemption*			Cosmetic use exempted
KOREA	ECL listed **	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Cosmetic End Product exempted
TAIWAN	Taiwan inventory listed	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
NEW ZEALAND	NZ listed **	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Cosmetic End Product exempted

* Low volume exemption or Low volume chemical permit is only based on the assumption that the ingredient is imported by Givaudan.

** Exemption in case of importation of the cosmetic finished product

b. Cosmetic Regulations compliance

COUNTRY	Regulation	YES	NO	% restricted or comment
USA	California Safe Cosmetic Act	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Canada	Canada Cosmetic Law	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Europe	EU Cosmetic Regulation 1223/2009	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Presence of ingredients listed in annexes:
China	IECIC	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Japan	Cosmetic Standards	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
	Quasi-drugs	<input type="checkbox"/>	<input checked="" type="checkbox"/>	
Korea	Korean Cosmetic Law	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Mexico	Mexico Cosmetic Directive	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
MERCOSUR	Mercosur Cosmetics	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Taiwan	Taiwan Cosmetic Regulation	<input checked="" type="checkbox"/>	<input type="checkbox"/>	

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2. Product specification

- Refer to attached Specifications sheet

3. Manufacturing and ingredients

Production process

- Refer to attached Flow chart
- ISO certification

Origin

Ingredient	Origin*	Country of origin
Hydrolyzed hyaluronic acid	Natural : Biotechnology (Vegetal Raw Materials)	France

*Natural or Synthetic

Natural raw material of vegetal, animal, mineral or microbiological origin, as such, obtained by physical, enzymatic or microbiological processes, or obtained by traditional preparation processes (e.g. extraction, distillation, heating, torrefaction, fermentation)

- We hereby confirm that we do not use CITES regulated vegetal species as intentional components of the raw material.

GMO

- We hereby confirm that the raw material is not obtained from Genetically Modified Raw Materials (G.M.O.) and does not contain Genetically Modified Organisms (G.M.O.).
- The used microorganism is non genetically modified.
- The components of culture medium are non genetically modified.

BSE

- We hereby confirm that the raw material does not contain any ingredient of animal origin and is never in contact, during its manufacturing process, with raw materials of animal origin. Consequently, the product is not exposed, nor concerned by the risk of Bovine Spongiform Encephalopathy (BSE/TSE).

Heavy metals

- We hereby confirm that the total sum of results of heavy metals contained in the raw material is lower than 20 p.p.m. (mg/kg).
- Refer to attached statement

Pesticides

- Based on information concerning the raw materials, production process, and equipment used, we hereby confirm that pesticides are not likely to be present.
- Refer to attached statement

Palm oil

- We hereby confirm that the raw material does not contain palm oil or derived.

Nanomaterials

- We hereby confirm that the raw material is not a Nanomaterial as defined by the Cosmetic EU Regulation N°1223/2009, the French Decree N°2012-232 and the European Commission Recommendation N°2011/696.

4. Safety and Environment

Toxicological information

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We hereby confirm that the raw material is in compliance with the requirement of the EU Cosmetic Regulation (EC) N°1223/2009 regarding the ban on animal testing and with regards to the marketing in the EU of cosmetic products.

Refer to Toxicological summary

Ecotoxicological information

Refer to Safety Data Sheet

5. Certifications

	Yes	No	Not checked
Halal	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Kosher	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Ecocert approved	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Cosmos approved	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

6. List of attached documents

- Flow chart
- ISO certificate
- TDS
- Heavy metals certificate
- Pesticides certificate
- Toxicological summary
- SDS
- SVHC certificate
- CMR certificate
- Prop65 certificate
- Allergens certificate
- Ecocert approval attestation
- Cosmos approval attestation
- Halal certificate
- Kosher certificate

Pomacle, December 4, 2015,

Amélie Sanhaji
Deputy for Regulatory Affairs

This document completes the product technical and safety data sheet. Information contained in this notice are based on our current knowledge and relate to the product in the state in which it is delivered. This certificate does not exempt or prevent the user to test under its own responsibility the material described in the document.

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Givaudan