

Regulatory Product Information Sheet

REG-LYSL001-REV9

1. Product name	Product Code
Lysofix™ Liquid	LYSL001

2. Composition

Raw material INCI (PCPC/Cosing)	% (W/W)	CAS No.	EC No.
Glycerin / Glycerin	66.00 - 84.00	56-81-5	200-289-5
Glycine Soja (Soybean) Seed Extract / Glycine Soja (Soybean) Seed Extract	16.00 - 34.00	1448790-48-4	---

3. Process and origin

Raw material INCI (PCPC/Cosing)	Process	Origin	Country of Origin
Glycerin / Glycerin	Chemical	Palm oil and/or Palm Kernel oil (<i>Elaeis guineensis</i>)	Malaysia
Glycine Soja (Soybean) Seed Extract / Glycine Soja (Soybean) Seed Extract	Extraction from soybean / Enzymatic hydrolysis	Plant (<i>Glycine Soja</i>)	Ukraine

4. Manufacturing Country

USA

5. Manufacturing flow chart

See Annex 1

6. Palm-oil / Palm-oil Derivative

- The product is RSPO Certified _____
- The product does not contain Palm-oil / Palm-oil Derivative
- The product contains Palm-oil / Palm-oil Derivative Glycerin
- The Palm-oil / Palm-oil Derivative is RSPO Certified Mass Balance

Lucas Meyer Cosmetics Canada Inc. Place de la Cité, Tour Belle Cour, 2590 boul. Laurier, #650 Québec (Québec) G1V 4M6 Canada
 T: +1 418 653-6888 - F: +1 418 653-6005
 www.lucasmeyercosmetics.com

Information and suggestions that may be provided by us, including with respect to the composition or use of our ingredients, are provided in good faith, based on the state of our current technical and scientific knowledge, but without any warranty as to their relevance, accuracy, completeness, presentation, use or otherwise. No express or implied license on patents or other intellectual property rights shall be deemed given as a result of such information or suggestions being provided. No warranty is given that the use of our ingredients, alone or in combination with other products, or the information and suggestions that we are providing respect the intellectual property rights of third parties. Any person relying on the information and suggestions that we are providing shall do so at his own risk and we will therefore accept no liability whatsoever with respect thereto. Any person using our ingredients in the formulation of his finished products is solely responsible for ensuring that the use made of our ingredients, the finished products that he is placing on the market as well as their packaging, labelling and advertising materials and the claims he makes with respect to his finished products and the ingredients they contain comply with applicable laws and regulations. We hereby disclaim any warranty of suitability of our ingredients for any purpose. Any user of our ingredients shall himself determine the suitability of our ingredients for his intended use and, as the case may be, obtain the required regulatory approvals for the commercialization of his finished products. Any information or suggestion that may be provided by us shall in no manner be interpreted as a legal or regulatory advice. Any person receiving same shall consult his own legal or regulatory advisors for legal or regulatory advices.

7. Stabilization of the product

The following substances are added during manufacture of the above-mentioned product:

Additive/Processing aid	Function	Origin	%
Not Applicable	---	---	---

8. Raw material status

To the best of our knowledge, based on the evaluation of the raw materials and the manufacturing process involved, the above-mentioned product does not contain:

- BSE TSE (animal origin materials)
 - CMR (carcinogenic, mutagenic, reprotoxic) substances as defined by CLP Reg (EC) 1272/2008
 - Contaminants listed on Prop 65
 - Ethylene glycol
 - Food allergens Eggs, Milk and milk products, Peanuts, Tree nuts, Fish, Crustacean shellfish
 - Formaldehyde
 - Genetically modified organisms (GMOs) Non GMO IP Soya Lecithin
 - Nanomaterials
 - Volatile Organic Compound (VOC)
 - Residual solvents*
 - Gluten
 - Nitrosamines
 - Phtalates
 - Paraben
 - Substances on the list of Substances of Very High Concern (SVHC)
- *Could contain technically unavoidable methanol (≤ 6 ppm) that comes from the Glycine Soja (Soybean) Seed Extract manufacturing process

9. Allergens

The above-mentioned product, contains the following fragrance allergens as listed in Annex III of EU Regulation 1223/2009:

- None
- Allergen name : _____

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10. Animal Testing

- Never tested
 Not tested after September 11, 2004
 Last testing date : _____

11. International Regulatory Status

The above-mentioned product is listed on the following international registries:

Country	Japan	Canada	Australia	China	New Zealand	Korea	Philippines
Registry	ENCS	DSL	AICS	IECIC	NZIoC	KECI	PICCS
Glycerin / Glycerin	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Glycine Soja (Soybean) Seed Extract / Glycine Soja (Soybean) Seed Extract	<input checked="" type="checkbox"/>	^b <input type="checkbox"/>	^b <input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	Not listed

Exemptions: ^a unmodified naturally occurring chemical; ^b exemption for new substances notification; ^c non-hazardous chemical

12. REACH

We hereby confirm that the above-mentioned product and raw materials are compliant with European Union's Chemicals Legislation (REACH) Regulation (EC) 1907/2006

Substance (INCI)	Status
Glycerin / Glycerin	Exempted (Annex V, paragraph 9 amended by Regulation (EC) 987/2008)
Glycine Soja (Soybean) Seed Extract / Glycine Soja (Soybean) Seed Extract	Exempted (< 1 ton/year)

13. Certification by a Third-Party (Certificate available upon request)

- COSMOS approved
 Organic COSMOS Certified
 Halal certified

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14. Compliance status

To the best of our knowledge, based on the evaluation of the raw materials and the manufacturing process involved, the above-mentioned product is compliant with the following requirements:

**Refer to "Vegan Information Statement"*

- Kosher Halal Vegan*

15. Heavy metals

- Tested Not tested

Based on the evaluation of the raw materials and the manufacturing process involved, the above-mentioned product contains less than 10ppm of total heavy metals, as detailed below:

Heavy Metals	Testing Results (ppm)
Lead	< 2
Cadmium	< 2
Mercury	< 2
Arsenic	< 2
Chromium	< 2

16. Pesticides

- Testing conducted and pesticides not detected above the concentration limits of the European Pharmacopoeia, Section 2.8.13
- Based on supplier information on raw materials and production processes, pesticide residues are expected to conform with concentration limits of the European Pharmacopoeia, Section 2.8.13

17. Environmental status

- The active ingredient is sourced from sustainable production
- The product is wild harvested
- The product is free from plant material classified under the CITES convention

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18. Toxicology

Ecotoxicological data available? No Yes SDS available on request
Toxicology data available? No Yes Toxfile available on request

Date of issue: October 25, 2019



Issued by: _____

Marie-Claude Gingras
Quality Assurance and Regulatory Affairs Manager

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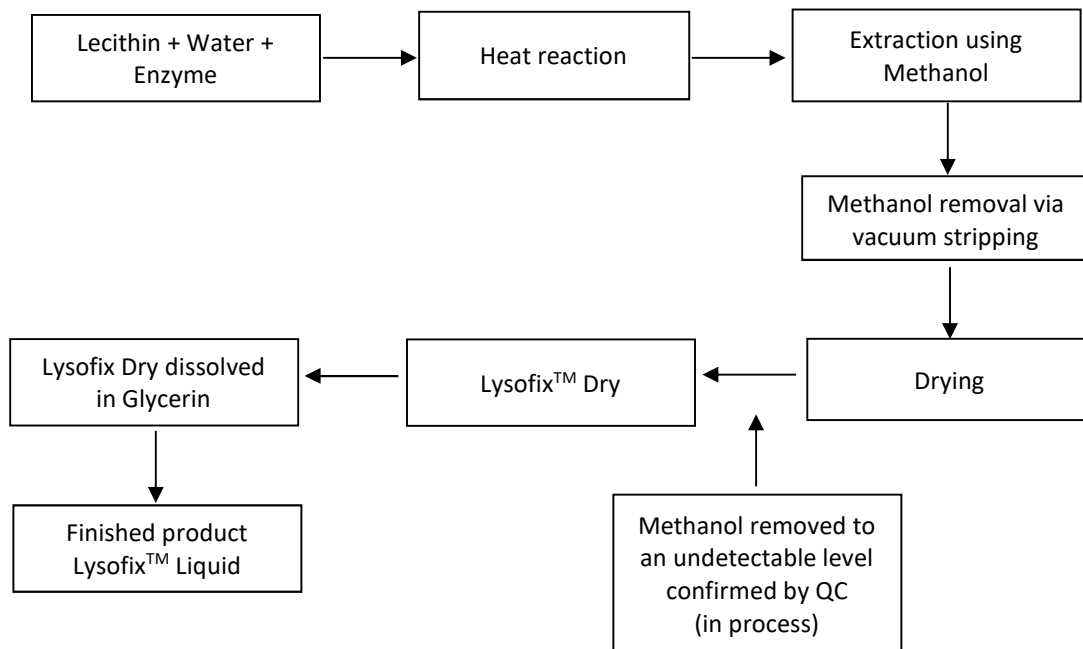
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ANNEX 1

Lysofix™ Liquid

Manufacturing Flow Chart



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Document Control

Date	Rev	Reason
2019-01-28	1	Document created considering all technical information available
2019-03-01	2	Addition of Vegan Compliance Status (p.3)
2019-03-05	3	Addition of food allergens (p.2)
2019-03-19	4	Addition of RSPO Grade (p.1), Addition of IP Status of soya lecithin (p.2)
2019-04-04	5	Precision on the residual solvents (p2)
2019-05-08	6	Correction of the REACH Status of Glycine Soja (Soybean) Seed Extract
2019-05-30	7	Addition of EG, Formaldehyde, Nitrosamines, Phtalates, SVHC
2019-06-20	8	Removal of the mention *INCI name under revision with PCPC.
2019-09-30	9	Modification of Corporate Logo, Modification of the Country of origin for Glycine Soja (Soybean) Seed Extract (Section 3), Addition of the category "The product is RSPO Certified" to the template (Section 6), Addition of the absence of Paraben (Section 8), Addition of a note about "Vegan" to the template (Section 14).

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