

Eco Lips, Inc.

Disclosure Report Date Submitted: June 12th, 2025

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Disclosure Materials

Certified B Corporations must complete a Disclosure Questionnaire to identify potentially sensitive issues related to the company (e.g. historical fines, sanctions, material litigation, or sensitive industry practices).

This component does not affect the company's score on the B Impact Assessment. If the company answers affirmatively to any items in the Disclosure Questionnaire that B Lab deems relevant for public stakeholders, then, as a condition of their certification, the company must:

- Be transparent about details of the disclosure issues identified on the company's public B Impact Report
- 2) Describe how the company has addressed this issue
- 3) Demonstrate that management practices are in place to avoid similar issues from arising in the future, when necessary.

In all cases, the Standards Advisory council reserves the right to refuse certification if the company is ultimately deemed not to uphold the spirit and integrity of the community.

In addition to the voluntary indication of sensitive issues in the Disclosure Questionnaire, companies pursuing Certification also are subject to a background check by B Lab staff. Background checks include a review of public records, news sources, and search engines for company names, brands, executives/founders, and other relevant topics.

Sensitive issues identified through background checks may or may not be within the scope of questions in the Disclosure Questionnaire, but undergo the same review process and are subject to the same possible review by the Standards Advisory Council, including ineligibility for B Corp Certification, required remediation, or disclosure.

This document contains a copy of the company's completed Disclosure Questionnaire and related disclosure documentation provided by the company



Disclosure Questionnaire

Industries and Products

Yes No Please indicate if the company is involved in production of or trade in any of the following. Select Yes for all options that **Animal Products or Services** $\boxed{}$ **Biodiversity Impacts** \square Chemicals $\boxed{}$ **Disclosure Alcohol** \square **Disclosure Firearms Weapons** $\boxed{}$ **Disclosure Mining** $\boxed{}$ **Disclosure Pornography** $\boxed{}$ **Disclosure Tobacco** $\boxed{}$ **Energy and Emissions Intensive** $\boxed{}$ Industries Gambling \square **Genetically Modified Organisms** \square Illegal Products or Subject to \square **Phase Out** Industries at Risk of Human $\overline{\mathbf{A}}$ **Rights Violations Monoculture Agriculture Nuclear Power or Hazardous** \square **Materials** Payday, Short Term, or High $\overline{\mathbf{A}}$ **Interest Lending** Water Intensive Industries \square **Tax Advisory Services** \square

Outcomes & Penalties

	Yes	No	
Please indicate if the company has had any formal complaint to a regulatory agency or been assessed any fine or sanction in the past five years for any of the following practices or policies. Check all that apply.			
Anti-Competitive Behavior		\checkmark	
Breaches of Confidential Information		N.	
Bribery, Fraud, or Corruption		N.	
Company has filed for bankruptcy		\triangleright	
Consumer Protection		V	
Financial Reporting, Taxes, Investments, or Loans		\searrow	
Hazardous Discharges Into Air/Land/Water (Past 5 Yrs)		\searrow	
Labor Issues			
Large Scale Land Conversion, Acquisition, or Relocation		K	
Litigation or Arbitration			
On-Site Fatality		\searrow	
Penalties Assessed For Environmental Issues		V	
Political Contributions or International Affairs		\searrow	
Recalls	V		
Significant Layoffs		V	
Violation of Indigenous Peoples Rights		Y	
Other		N	



Practices

	Yes	No
Please indicate if the following statements are true regarding whether or not the company engages in the following practices. Check all that apply. If the statement is true, select "Yes." If false, select "No."		
Animal Testing		\checkmark
Company/Suppliers Employ Under Age 15 (Or Other ILO Minimum Age)		\checkmark
Company prohibits freedom of association/collective bargaining		\checkmark
Company workers are prisoners		\checkmark
Conduct Business in Conflict Zones		\checkmark
Confirmation of Right to Work		\checkmark
Does not transparently report corporate financials to government		\vee
Employs Individuals on Zero-Hour Contracts		\vee
Facilities located in sensitive ecosystems		V
ID Cards Withheld or Penalties for Resignation		V
No formal Registration Under Domestic Regulations		\vee
No signed employment contracts for all workers		V
Overtime For Hourly Workers Is Compulsory		V
Payslips not provided to show wage calculation and deductions		\vee

	Yes	No
Sale of Data		V
Tax Reduction Through Corporate Shells		N
Workers cannot leave site during non-working hours		N
Workers not Provided Clean Drinking Water or Toilets		N
Workers paid below minimum wage		\searrow
Workers Under Bond		\checkmark
Other	\checkmark	

Supply Chain Disclosures

	Yes	No
Please indicate if any of the following statements are true regarding your company's significant suppliers.		
Business in Conflict Zones		\vee
Child or Forced Labor		V
Negative Environmental Impact		\vee
Negative Social Impact		V
Other		✓



Disclosure Questionnaire Statement

Disclosure Questionnaire Category: Recalls

Eco Lips, Inc. reported conducting two voluntary recalls in the past five years, representing less than 0.2% of the company's products for the same period. When a product is recalled, various stakeholders such as customers, suppliers, investors, commercial partners, and local communities may face negative impacts, including health and safety risks, financial losses, loss of trust, damage to credibility, and other inconveniences. Certified B Corps must make their recalls transparent under their B Corp Profile.



Disclosure Questionnaire Statement

Disclosure Questionnaire Category: Other disclosures

Issue Date	2019-2024
Topic	The U.S. Food and Drug Administration (FDA) issues warning due to violations of Current Good Manufacturing Practice (CGMP) regulations for finished pharmaceuticals
Summary of Issue	Eco Lips was first inspected by the FDA in 2019 resulting in several formal 483 Observations and annual follow-up inspections for the next 4 years. Deficiencies identified in the 483 observations culminated in a warning letter (WL 631629) on 9/20/2022. The corrective/preventive actions for the 483's included voluntary recall of two OTC products in 2022 due to one product having an incorrect ingredient listed on the label, and the other was Out-of-Specification for its active ingredient content.
Size/Scope of Issue (e.g. \$ financial implication, # of individuals affected)	The recalls in the past five years due to FDA's observations represents 0.2% of the company's total products for the same period.
Impact on Stakeholder(s)	Potential risk of negatively impacting people's health.
Implemented Management Practices	Corrective Actions also included replacing the quality department leadership in July of 2022, and an overhaul of the Eco Lips quality program under the new leadership. The FDA last inspected Eco Lips in July 2024 and issued a resolution letter on 8/22/2024 indicating that the corrective/preventive actions have adequately addressed all previous violations noted in the warning letter.
	Additionally, the most recent 3rd party Good Manufacturing Practices (GMP) audit in June 2024 (UL Audit ID 1015078 for ISO 22716:2007) reported acceptable results with a passing "Limited Risk" designation following 3 minor observations that have been resolved (corrective/preventive action plan reviewed and approved by UL on 7/11/2024). This audit signifies that the audited facility is compliant with the requirements of ISO 22716:2007, the international standard for GMP in the cosmetics sector.
	Eco Lips continues to prioritize continuous quality improvement



(CQI) initiatives, as is required by GMP and FDA regulations to prevent future non-compliance while continuously raising the bar with regards to process control, quality, and safety for both employees and products produced. Some of the past initiatives include implementing a more robust Quality Management System (QMS) used for carrying out document control/retention, quality event reporting (non-conformance, deviations, change controls, risk assessments, complaint tracking, corrective/preventive actions, etc.), internal/external audits, master manufacturing records, etc. Per FDA/GMP requirements, Eco Lips conducts internal audits (at least 6 per year), annual quality systems management reviews, and annual product reviews, which are all geared at identifying potential/actual safety or quality issues and opportunities for improvement. Eco Lips is in the process of building out and implementing a new Enterprise Resource Planning (ERP) system as one of these CQI initiatives to further improve process control and workflows. Notably, our most recent 3rd party GMP audit for compliance to ISO 22716, FDA Cosmetic <u>Guidance</u>, and <u>ANSI 455-3</u> standards confirmed effectiveness and closure of past CAPA's, and had no new additional non-conformances/observations. Report **FDA Resolution Letter**

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