Certified B Corporation
bcorporation.net

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 and B Lab deems them to be material, the company must:

1) Be transparent about 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 systems are in place to avoid similar issues from arising in the future.

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

In addition to the voluntary indication of sensitive issues in the Disclosure Questionnaire, companies pursuing Certification also are subject to background checks 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.

Certified B Corporation
bcorporation.net

DISCLOSURE QUESTIONNAIRE

Company Name: Weleda
Date Submitted: 09/16/2021

Industries & Products	Yes	No
Please indicate if the company is involved in production of or trade in any the following. Select Yes for all options that apply.		
Animal Products or Services	√ More Details >>	
Biodiversity Impacts		√
Chemicals		√
Company Explanation Of Disclosure Item Flags		√
Disclosure Alcohol		√
Disclosure Firearms Weapons		√
Disclosure Mining		√
Disclosure Pornography		√
Disclosure Tobacco		√
Energy and Emissions Intensive Industries		√
Fossil fuels		√
Gambling		√
Genetically Modified Organisms		√
Illegal Products or Subject to Phase Out		√
Industries at Risk of Human Rights Violations		√
Monoculture Agriculture		√
Nuclear Power or Hazardous Materials		√
Payday, Short Term, or High Interest Lending		√
Water Intensive Industries		√
Tax Advisory Services		√

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		√
Child or Forced Labor		√
Negative Environmental Impact		√
Negative Social Impact		√
Other		√

Outcomes & Penalties	True	False
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		√
Breaches of Confidential Information		√
Bribery, Fraud, or Corruption		√
Company Explanation Of Disclosure Item Flags		√
Company has filed for bankruptcy		√
Consumer Protection		√
Financial Reporting, Taxes, Investments, or Loans		√
Hazardous Discharges Into Air/Land/Water (Past 5 Yrs)		√
Labor Issues		√
Large Scale Land Conversion, Acquisition, or Relocation		√
Litigation or Arbitration		√
On-Site Fatality		√
Penalties Assessed For Environmental Issues		√
Political Contributions or International Affairs		√
Recalls		√
Significant Layoffs		√
Violation of Indigenous Peoples Rights		√
Other		√

Practices	True	False
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		√
Company/Suppliers Employ Under Age 15 (Or Other ILO Minimum Age)		√
Company Explanation Of Disclosure Item Flags		√
Company prohibits freedom of association/collective bargaining		√
Company workers are prisoners		√
Conduct Business in Conflict Zones		√
Confirmation of Right to Work		√
Does not transparently report corporate financials to government		√
Employs Individuals on Zero-Hour Contracts		√
Facilities located in sensitive ecosystems		√
ID Cards Withheld or Penalties for Resignation		√
No formal Registration Under Domestic Regulations		√
No signed employment contracts for all workers		√
Overtime For Hourly Workers Is Compulsory		√
Payslips not provided to show wage calculation and deductions		√
Sale of Data		√
Tax Reduction Through Corporate Shells		√
Workers cannot leave site during non-working hours		√
Workers not Provided Clean Drinking Water or Toilets		√
Workers paid below minimum wage		√
Workers Under Bond		√
Other		√

B Corp Certification - Disclosure Questionnaire Documentation

PROVIDED BY: Weleda UPDATED AS OF: 09/16/2021

DISCLOSURE QUESTIONNAIRE CATEGORY	Animal Testing
TOPIC	Weleda is required to carry out animal testing by regulatory authorities on some of their products in their anthroposophic pharmaceutical medicines in line with national safety legislation. In addition to regulatory / approval requirements, they conduct animal studies in individual cases in order to be able to provide and communicate recognized proof of efficacy to stakeholders such as physicians.
SUMMARY OF ISSUE	Weleda are required to carry out animal testing via a third party on some of their products for drug safety requirements and for pharmacodynamics, in order to prove efficacy for regulatory applications. Weleda performs clinical studies as well as non-clinical studies. The vast majority of the non-clinical studies are performed in vitro or even cell-free. As anthroposophy is a holistic therapeutic approach there are hardly any alternative in vitro systems available that would be appropriate to reflect the in vivo situation. In these cases, they occasionally perform animal experiments to generate evidence for existing products to support anthroposophic therapies.
SIZE/SCOPE OF ISSUE (e.g. $ financial implication, # of individuals affected)	About 2.5% of the products as a percentage of the total annual revenue underwent animal testing at some point in their product development and life cycle process. Most likely this percentage rises slightly as new products will be developed as part of a newly defined pharma strategy..
IMPACT ON STAKEHOLDERS	The use of animals is a general concern within society, and consumers are therefore (to a certain extent) interested to know if animal research was involved. It is important to note that approx. 70% of the experiments in the EU are categorized as causing mild discomfort, and that strict guidelines and standards are in place to minimize discomfort and weigh the discomfort versus the aim of the study and future (health) benefit of the results.
IMPLEMENTED MGT PRACTICES	Where Weleda is required to order animal tests for the assessment of efficacy and safety and no appropriate non-animal alternative recognized by regulatory authorities is available, the company commissions specialised contract research organisations. These third parties are required to provide statements that animal testing will be carried out in compliance with national and international standards (e.g. ICH or ISO 10993/GLP/animal welfare) and legislation (e.g. European Directive 2010/63/EU). In order to formalise this process a policy will be developed ensuring that scientific projects, involving necessary animal testing complies with the 3Rs principles (Replacement, Reduction and Refinement) and general guidance for animal welfare. Weleda aims to have such a policy and related process in place by the end of this year. Whenever possible the company try to avoid animal testing and use alternative methods instead. However, alternative tests for e.g. safety issues need to be accepted by the authorities. This is only true for assays that has been validated by institutions such as the European Centre for the Validation of Alternative Methods (ECVAM).

Certified B Corporation bcorporation.net

B Corp Certification - Disclosure Questionnaire Documentation

PROVIDED BY: Weleda UPDATED AS OF: 09/16/2021

IMPLEMENTED MGT PRACTICES CONT'D	In addition to the above-mentioned animal welfare requirements the selection of professional contract research organisations is based on their expertise in the field of research. During the preparation of the study plan, i.e. the obliging framework of the individual study, their internal scientists work closely together with the third-party professionals in order to set up a study design that is in accordance with the 3Rs principles.The service agreements with specialised and professional contract research organisations contain statements that animal testing will be carried out in compliance with national or international standards (e.g. ICH or ISO 10993/GLP/animal welfare) and legislation (e.g. European Directive 2010/63/EU). The company also requests that all major procedures and handling steps are defined by SOPs. Usually an inspection of the SOP will be performed by the company before any study is ordered. The company always reserve the right to perform onsite inspections of study-related facilities. Despite the fact that pharmaceutical products are rather strictly regulated regarding animal testing, concerns, feedback and engagement of animal testing-related stakeholders are taken seriously. Weleda usually answers all questions in a constructive and open manner.Weleda is a supporter of the Center for Alternative to Animal Testing in Europe (CAAT-Europe) and has a strong relationship to the department of in vitro toxicology and biomedicine at the University of Konstanz (inaugurated by the Doerenkamp-Zbinden foundation). Weleda always strives to act according to the highest ethical standards and is aware of its responsibility. The company is convinced that animals are sentient creatures and their welfare must be respected. Therefore, the company does not order animal studies from companies that do not come from a regulated market or that do not have established animal welfare measures in place.
REPORT	Centre for Alternative to Animal Testing in Europe (CAAT-Europe) : https://www.biologie.uni-konstanz.de/leist/caat-europe/ EMA Guideline on the topic of 3Rs: https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-principles-regulatory-acceptance-3rs-replacement-reduction-refinement-testing-approaches_en.pdf