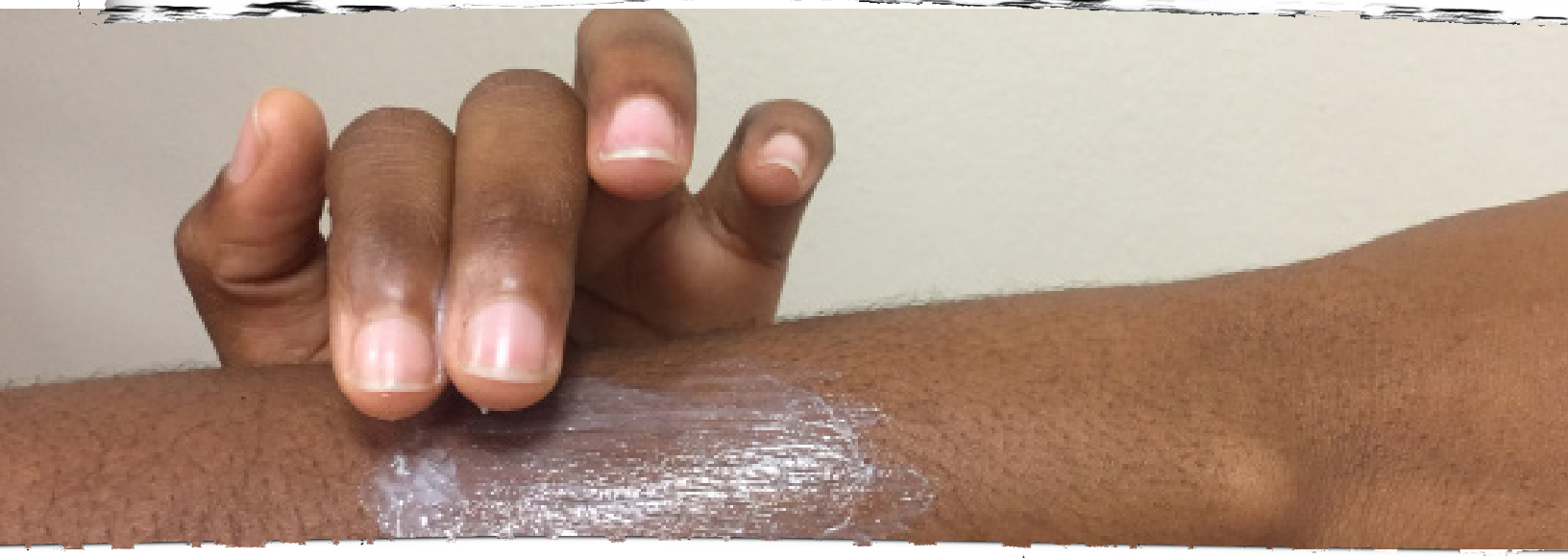
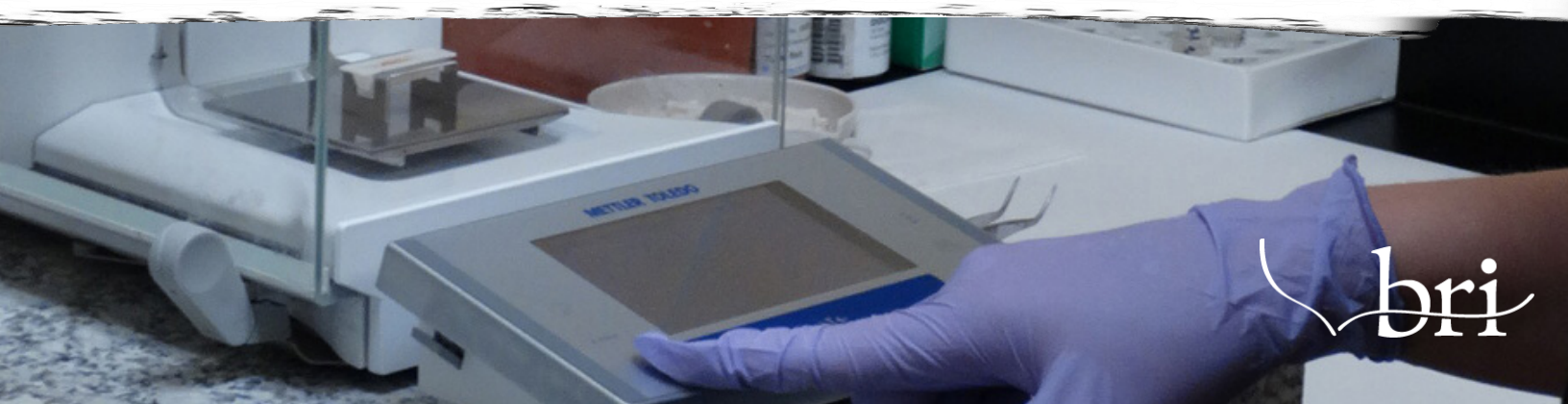
Cosmetic Sampling Methods



Collection of Products for Mercury Analysis

September 2023



COSMETICS SAMPLING METHODS

Protocol for Sampling and Analyzing Skin Lightening Products for Mercury

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Biodiversity Research Institute (BRI) is a 501(c)3 nonprofit organization located in Portland, Maine, USA. Founded in 1998, BRI is dedicated toward supporting global health through collaborative ecological research, assessment of ecosystem health, improving environmental awareness, and informing science-based decision making. The following sampling protocol is based on over 400 skin lightening products analyzed since 2016.

September 2023

Suggested Citation: Evers DC, M. Taylor, and M. Burton. 2023. Protocol for sampling and analyzing skin lightening products for mercury. Report BRI 2023-03, Biodiversity Research Institute, Portland, Maine, USA.

Contents

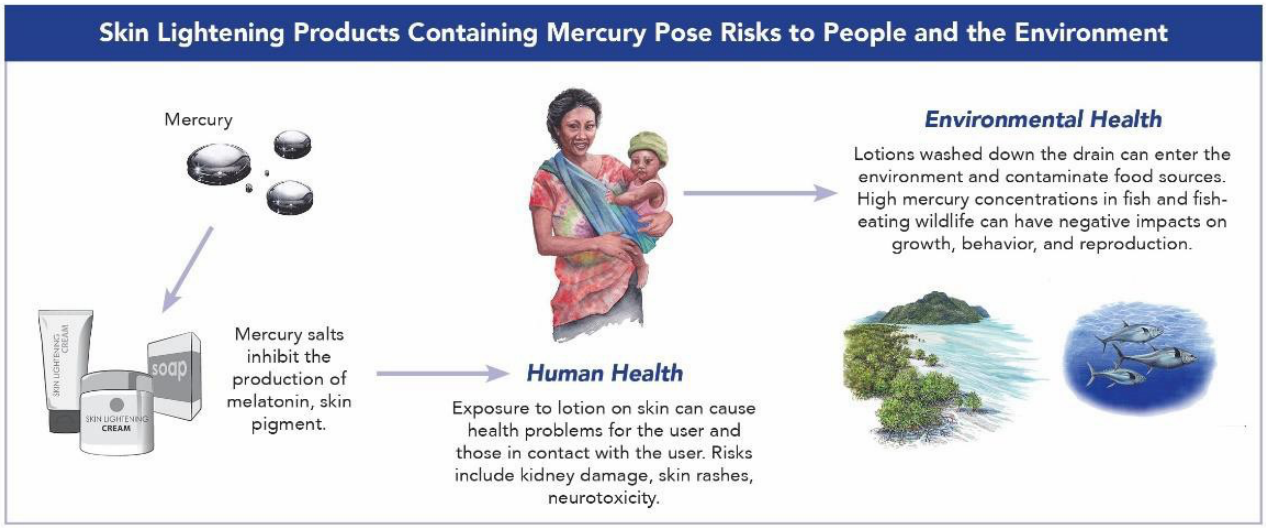
1.0 – General Overview

Mercury is a pollutant of global importance. This naturally occurring element is toxic to humans and biota. Exposure to mercury may cause serious health problems especially in sensitive populations, such as pregnant women and children. Exposure can come from indirect (e.g., diet) or direct pathways. Topical applications of skin lightening products with mercury is widespread in some communities (Eagles-Smith et al. 2018). As a result, Article 4 of the Minamata Convention on Mercury obligates Parties to ban the manufacture, import, and export of skin lightening products with mercury concentrations above 1 ppm (µg/g) by 2020 (Parties that join the Minamata Convention after 2020 are expected to implement Article 4 upon ratification).

Mercury found in cosmetics can exist in two forms: inorganic and organic (Ladizinski et al. 2011; WHO 2007). Organic mercury compounds such as ethylmercury, methylmercury, and phenyl mercuric salts may be used preservatives. Trace amounts of mercury are legally added to some cosmetics, such as mascara, for its properties in preventing the growth of microorganisms. Inorganic mercury salts, including mercurous chloride (or calomel), mercuric chloride, mercurous oxide, and ammoniated mercury are added to lightening products to interfere with melanin production (melanin is the pigment that produces a dark color in skin and hair). Both organic and inorganic forms can be hidden in the ingredient list (e.g., "*calomel*" instead of mercurous chloride) or omitted completely. Lightening products may also include other highly toxic ingredients including hydroquinone, corticosteroids, and trace amounts of harmful elements (e.g., arsenic).

Although there are some legitimate uses of lightening products to treat dermatological disorders (e.g., hyperpigmentation), medically prescribed lightening products do not use mercury as an active ingredient (Hamann et al. 2014). However, historically, skin lightening products have been used for centuries in response to harmful cultural practices that associate lighter skin tones with higher societal benefits including, but not limited to, improving the likelihood for marriage, greater professional opportunities, and status. Today, these products are still marketed for lightening overall skin complexions and removing age spots and freckles.

Exposure to mercury from skin lightening products can result in a number of health problems, ranging from skin irritations and allergic reactions to kidney damage and neurotoxicity. Symptoms include numbness in hands, feet and mouth, tremors, changes in vision or hearing, depression, and memory loss. Additionally, the potential maternal transfer of mercury to a fetus has implications for neurological development (Bastiansz et al. 2022). In addition to human health, environmental health is also at risk. Through skin washing, mercury is eventually released into wastewater and, under certain environmental conditions, can be converted to methylmercury and absorbed into the food web exposing fish, wildlife and eventually humans to potential mercury contamination.



The Minamata Convention on Mercury requires that cosmetics with mercury content above 1 ppm, including skin lightening soaps and creams, be banned after 2020 (including manufacture, import or export).

2.0– Protocol Overview

The Minamata Convention requires each Party to ban the manufacture, import and export of cosmetics containing over 1 ppm of mercury. This sampling and testing protocol is designed as a guide for the collection, shipping, and analysis of skin lightening products for the measurement of total mercury. Use of this methodology by all collaborators will ensure consistency in sampling in all locations and that data generated will be scientifically sound. Proper sample collection and analysis ensures suitability of the results for comparison with other global monitoring results.

Purchased skin lightening products (SLPs) can be shipped to either Biodiversity Research Institute (BRI)'s Mercury Laboratory or another partner laboratory. BRI's laboratory methods follow U.S. Environmental Protection Agency standards.

3.0– Skin Lightening Products Sampling Methodology

3.1Sampling Strategy

The sampling strategy will strive to represent the overall market for SLPs in each country and allow estimates of the:

(1) percent of SLPs with mercury over 1ppm and

(2) amount and variability of mercury in SLPs for each country

The sampling strategy will involve two phases. Phase 1 will generate a baseline assessment of products with mercury above 1ppm (# = estimated number of SLP to test) and inform Phase 2, which will then target brands likely to have high mercury concentrations.

Phase 1 (Screening):

Each participating team will work to identify brands for SLPs available within the country—in both commercial and informal markets (informal referring to SLPs that are created within the country and not recorded through Customs). Once identified, these products should be purchased and collected for testing. It is assumed that there is a limited number of commercially available brands (~20-30) per country.

Informal market SLPs will likely have fewer creams, so a sample of 5 – 10 creams should be collected if available. The variation in mercury concentrations is assumed to be larger in SLPs from the informal sector compared to commercial markets.

Following the analysis of the samples identified (as detailed in Section 3.0 of this Protocol), an assessment of the findings will be made to verify the number of SLPs that contain mercury within the sample size and inform Phase 2.

Phase 2 (Targeted Sampling):

Based on the findings of Phase 1, SLPs that are over 1 ppm will be identified for a more targeted round of sampling to better understand the variation in mercury concentrations for each brand. Variation of mercury within targeted SLPs will be determined through multiple sampling of different containers/batches of the same product from different stores/sources (i.e., 5–10 samples from each brand). This sampling strategy will strive to better understand the extent and variation of mercury concentrations in SLPs that are over 1 ppm.

3.2 Equipment Needed for Sampling

Materials for SLPs collection are listed below.

Item	Purpose
Phone/ camera	To take a picture of the skin lightening product. Be sure to take multiple photos of relevant information on all packaging, including brand and product names, country of manufacture, and ingredient lists.
Sample log	To be completed after collection of samples to serve as an inventory for the testing lab
Labels	For labeling products sampled with the labeling format detailed in Section 3.3
Permanent marker or ball point pen	For labeling sample log and data sheets

3.3 Duplicate Sampling Requirements

In the event that each of the skin lightening products collected is to be analyzed by more than one laboratory (for example, an identified national laboratory in addition to BRI's laboratory), aliquots or splits for each product should be done.
Materials for splitting of samples are listed below.

Item	Purpose
0.5 – 1 ounce plastic containers (preferably with a secure screw top)	To contain each split sample
Rubbing alcohol	To sterilize containers and sampling area/equipment after each sample is prepared.
Plastic spatulas/ spoons/ droppers	For transferring products to sample containers.
Paper towels and cotton pads	For sanitizing sampling area
Labels and permanent marker or ball point pen	For labelling samples according to sample log
Gloves	To prevent cross-contamination amongst samples.

For each product that is to be split:

1. Obtain a sample container and sanitize by wiping with rubbing alcohol on a clean paper towel or cotton pad.
2. Label the sample container(s) according to the labeling format described in Section 1.3.
3. Prior to splitting the sample, ensure that the skin lightening product is homogenous by securely shaking or stirring with a sanitized stirrer/spoon.
4. Wearing gloves, use a clean spatula/spoon/dropper to place product in its labelled sample container. Secure cap/cover.
5. To prevent cross-contamination of samples during this process, ensure that sampling area and equipment are sanitized with rubbing alcohol after each sample is split. Change gloves as needed.

3.4 Sample Labeling Format

Skin lightening products will be analyzed from several countries. It is important that all sample labels are written legibly and clearly. In addition, it is imperative that all samples have a unique sample label ID. Each country is assigned a unique three-letter code, following the country codes developed by the International Organization for Standardization (ISO). The full list of country codes is available online at:

https://www.iso.org/obp/ui/#search/code/

When labeling each cosmetic sample, please use the following convention:

Record your 3-letter country code, a number corresponding to the sampling site (for example, label sample site 1, 2, or 3) followed by the word SLP, and the two-digit, sequential number of the sample (e.g., from 01 to 35). Below the label, please record the date the sample was collected, using the format of DD-MM-YYYY.

As an example, the first cosmetic sample collected from the first community in Vanuatu (VUT) on May 4, 2021, would be labeled as follows:

VUT-1-SLP-01
04-05-2021

NOTE: The Sample Label will serve as the primary identification marker.

Each SLP should be assigned a unique sample number, entered into a log and photographed along with its list of ingredients if available. Please be sure to link photo file names with the corresponding SLPs unique identifier. The following information should be recorded:

- name of the product
- country of purchase
- manufacturing company and country
- distributor
- batch number if provided on the label

3.5 Skin Lightening Product Shipment

SLP samples are to be stored at ambient temperature until shipment. For SLPs shipped to the BRI Lab, the following protocol should be followed:

1. Email a copy of your Sample Data Sheet to BRI (mark.burton@briwildlife.org) and/or a partner lab and await further instructions about shipping. BRI will assist with the development of a “Commercial Invoice” to accompany the shipment. Once BRI receives this information and you are ready to ship, BRI will arrange the shipment online with DHL or FedEx. If DHL or FedEx is not in your area, BRI will arrange shipping through another courier. BRI will pay for the shipping costs and track the shipment (once under a verified project or collaboration agreement). Further details will be provided by BRI.
2. Prior to shipment, contact your local shipping service (FedEx or DHL or other agreed upon courier) to confirm whether any requirements are needed for shipping “cosmetic creams for laboratory analysis”. For example, in some cases, shipments must be sent via a shipping service location that is equipped with a working scanner.
3. Ensure products are securely sealed but easily accessible for potential inspection by shipping agents or Customs.
4. Print a copy of the Sample Data Sheet and Commercial Invoice to place with the shipment.
5. Place the SLP and Sample Data Sheet in a DHL or shipping envelope obtained from the shipping provider. Please use a padded envelope to prevent breakage during shipment (Figure 1), or if using a box, ensure that products are secure with packing material.
6. Once shipment is processed, please notify BRI representative via email.

Figure 1: Example of a DHL envelope

4.0 Skin Lightening Products Testing Methods

4.1 Testing Strategy

The testing for mercury concentrations in SLPs requires a two-step approach.

Step 1 (Screening):

To prevent saturation of the lab's mercury analyzer, a portable hand-held analyzer such as Olympus™ XRF, Jerome® J405, or Lumex™ to detect general mercury concentrations in the SLP should be used to initially screen the first batch of samples. The limit of detection (LOD) for many portable analyzers is higher than 1 ppm and usually is ~5–10 ppm. Consequently, SLPs with mercury less than 10 ppm will read as "< LOD," while the actual concentration could range between 0–10 ppm. Therefore, we will follow Step 1 with either Step 2a (analyses with a Direct Mercury Analyzer; DMA) or Step 2b (analyses with another lab instrument that would be approved or provided by BRI).

Countries with in-house analytical abilities will be encouraged to use their labs and instruments. To help build country and laboratory capacity, a percentage of samples will have a split analyses (i.e., analyzed at the country lab as well as an outside lab—either at BRI or another approved

laboratory). The split analyses are a common method to calibrate laboratories and contributes to a quality assurance and quality control (QA/QC) process.

Step 2 (Analyses):

Lab analysis will include each of the samples collected. The method for analyzing each is described in Table 2. The number of samples representing both the screening (Phase 1) and targeted (Phase 2) sampling effort will vary by country.

a. To determine the mercury concentration of each SLP that is below 10 ppm, we will analyze each SLP using a DMA. Each country's analytical strategy will be customized for this process as described briefly below.
b. To determine the mercury concentration of each SLP that is above 10 ppm we will ship all SLPs to another lab with the capacity to analyze highly elevated mercury concentrations that cannot be analyzed with a DMA (i.e., >1,000 ppm).

Table 1. Example country-level lab analysis strategy for SLPs in Phase 1 and Phase 2 (# = estimated number of SLPs).*

Country	Phase 1 (Universe Sampling)			Phase 2 (Targeted Sampling)		
Lab	Step 1	Step 2a <10 ppm	Step 2b >10 ppm	Step 1	Step 2a <10 ppm	Step 2b >10 ppm
In-country or regional lab	25-40**	~15-25		60-80	~30-40	
BRI Lab		~10-20			~10-15	
Partner Lab			~5			~15

*The actual numbers of samples tested may vary according to in-country availability of relevant SLPs and decisions by in-country labs.

**We estimate 20-30 commercially available brands and 5-10 from informal markets per country.

c. As part of a QA/QC process, samples will be analyzed at two or more labs. A total of 30- 50% of samples will be analyzed at BRI for Phase 1 (Step 2a), but only 30% for Phase 2 (Step 2a) – assuming lab calibration is good based on Phase 1. The in-country lab will analyze all samples below 10 ppm, while the partner lab will analyze samples above 10 ppm for both phases (i.e., Step 2b).

4.2 Information Dissemination

All cosmetic mercury concentrations will be entered into a centralized database that will be provided to each country's Ministry of Health and/or other designated government ministry. A list of SLPs found with mercury > 1ppm will be generated and provided to each country after analysis.

5.0 Literature Cited

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