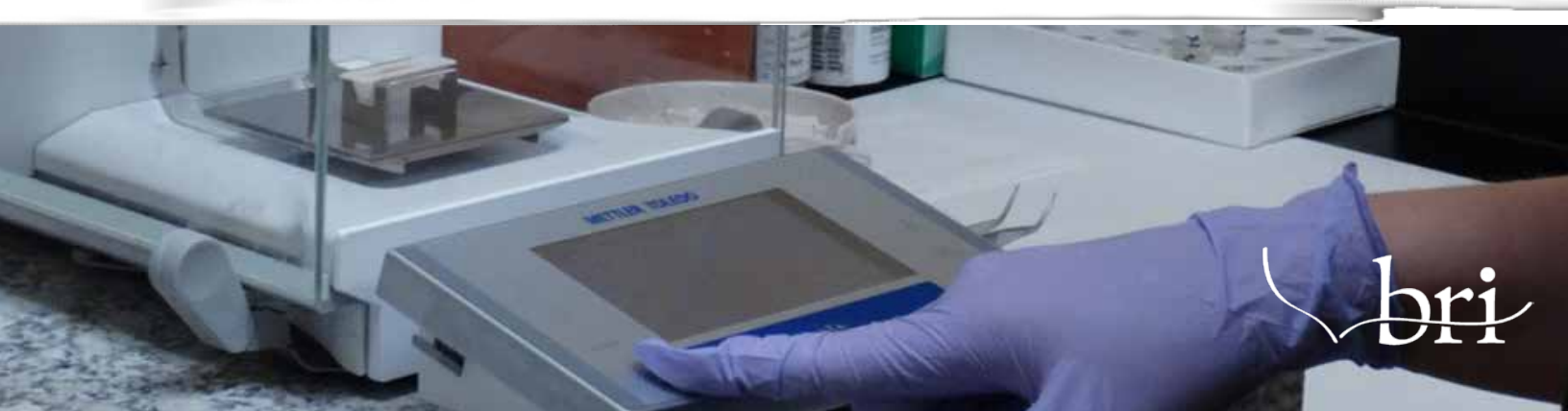
Cosmetic Sampling Methods

Collection of Products for Mercury Analysis



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.

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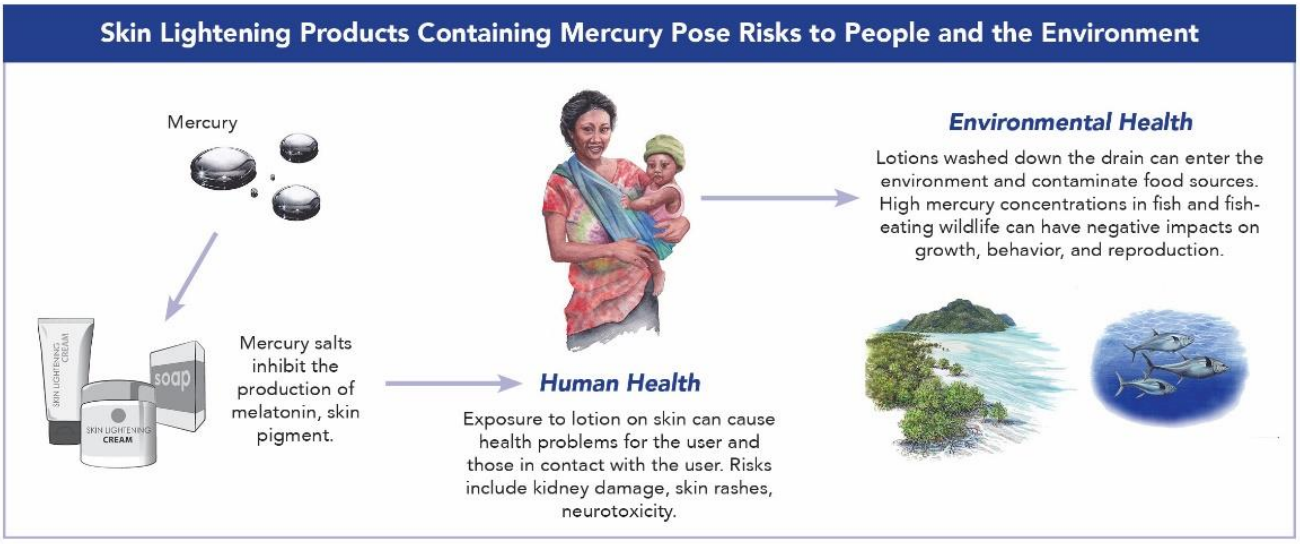
1.0 General Overview

Mercury is a pollutant of global importance. It is a naturally occurring element but toxic to humans and biota. Exposure to mercury may cause serious health problems especially in sensitive populations such as pregnant women and children. Mercury in cosmetics exists in two forms: inorganic and organic (Ladizinski et al. 2011; WHO 2007). Mercury in cosmetics is used in the form of mercurous chloride and can be hidden in the ingredient list as "*calomel*" or omitted completely. This compound readily decomposes into metallic mercury and highly toxic mercuric chloride on exposure to sunlight. Trace amounts of mercury are also legally added to some cosmetics, such as mascara, for its properties as a preservative in preventing the growth of microorganisms.

Mercury is used in some skin lightening or anti-aging soaps and creams because mercury salts inhibit the formation of melanin, the pigment that gives human skin a dark color. Such products may also include other harmful ingredients, including hydroquinone, which is highly toxic. Skin lightening products are used throughout the world among dark-skinned populations for many



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).

cultural reasons, including but not limited to, improving social status, but they are also marketed as treatments to remove age spots and freckles.

Exposure to mercury from the skin lightening products can result in a number of health problems, including allergic reactions, skin irritation, kidney damage and neurotoxicity. Symptoms include numbness in hands, feet and mouth, tremors, changes in vision or hearing, and memory loss. In addition to human health, the environment is also at risk. Through washing, mercury is eventually released into wastewater and, under favorable environmental conditions, can be converted to methylmercury and absorbed into the food web, exposing fish, wildlife and eventually humans to potential mercury contamination.

1.0 Protocol Overview

The Minamata Convention requires each Party to ban the manufacture, import and export of cosmetics containing over 1ppm of mercury by the end of 2020. 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, the Antigua and Barbuda Laboratory, or another partner laboratory. BRI's laboratory methods follow U.S. Environmental Protection Agency standards.

2.0 Skin Lightening Products Testing Methodology

2.1 Sampling Strategy

The sampling strategy will strive to represent the universe of SLPs in each country so an appropriate estimate of the (1) percent of SLPs with mercury over 1ppm and (2) amount of

mercury in SLPs can be calculated for each country. The sampling strategy will involve two phases.

Each participating team will work to identify brands for SLPs available within the country- in both commercial and informal markets (SLPs that are created within the country and not recorded through Customs). Once identified, these creams should be purchased and collected for testing. We assume 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. We believe the variation in mercury concentrations will be larger in SLPs from the informal vs the commercial market. Note that brands manufactured in the United States or Europe should not be collected for testing as they are considered to be mercury-free.

There is a two-part process for sampling (Table 1). Phase 1 will generate a baseline assessment of products with mercury above 1ppm (# = estimated number of SLP to test), while Phase 2 will target brands likely to have high mercury concentrations.

Table 1. Overview of SLP sampling strategy.*

Country	Phase 1 (Universe Sampling)	Phase 2 (Targeted Sampling)	Goal (Information dissemination)
	# of SLPs	*# of SLPs*	*# of SLPs*
Caribbean Region per country	20-30; plus ~10 from informal markets	10-20 SLPs deemed >1ppm	Create a list of creams with mercury >1 ppm for the Caribbean Region and outreach materials
Total for Analyses			**Combine all countries to create a list of toxic cosmetics in the Caribbean Region**

*The total number of SLPs in Phase 2 will depend on the total number of SLPs analyzed in Phase 1. The total number of samples per SLP in Phase 2 by country will depend on the total number of SLP brands identified as having mercury concentrations over 1 ppm.

Once the Phase 1 sampling and analyses process is completed, an assessment of the findings will be made. Thereafter, 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 from different stores/sources within the same brand (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.

2.2 Equipment Needed for Sampling

Materials for SLPs collection are listed below.

Item	Purpose
Phone/camera	To take a picture of the skin lightening product
Sample log	To be completed after collection of samples to serve as an inventory for the BRI Lab
Permanent marker or ball point pen	For labeling sample log and data sheets

2.3 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 (as there could be multiple sites in one country, label sample 1, 2, or 3) followed by the word SLP, and the two-digit, sequential number of the sample (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-MAY-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. The following information should be recorded:

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

2.4 Skin Lightening Product Shipment

Skin lightening products samples are to be stored at ambient temperature until shipment. For SLPs shipped to the BRI Lab or the Antigua and Barbuda Lab, the following protocol should be followed:

1. 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).

Figure 1: Example of a DHL envelope

2. Email a copy of your Sample Data Sheet to either BRI (mark.burton@briloon.org) or another to-be-determined lab and await further instructions about shipping. Once BRI receives this information and you are ready to ship, BRI will arrange the shipment online with DHL. You will receive instructions from DHL via email to complete the shipments. If DHL is not in your area, BRI will arrange shipping through another courier, such as UPS or FedEx. BRI will pay for the shipping costs and track the shipment.

3.0 Skin Lightening Products Testing Methods

3.1 Testing Strategy

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

Step 1 (Screening):

In order to prevent saturation of the lab's mercury analyzer, a portable hand-held analyzer such as Jerome J405, Lumex, or Niton XRF 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 the Antigua and Barbuda lab). 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 in Table 1. How they are analyzed 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 (possibly the IAEA Lab in Jamaica). The IAEA lab has the capacity to analyze highly elevated mercury concentrations that cannot be analyzed with a DMA (i.e., >1,000 ppm).

Table 2. Proposed/tentative 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
Antigua and Barbuda lab	70-80	50-70		120-130	60-70	
BRI Lab		~30			~20	
IAEA Lab			10-15			20-30

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

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 Year 1/Phase 1. The Antigua and Barbuda lab will analyze all samples below 10 ppm, while the IAEA lab will analyze 30-50% of the samples above 10 ppm for both Years/Phases (i.e., Step 2b).

3.2 Information Dissemination

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

4.0 Literature Cited

Ladizinski B, Mistry N, Kundu RV (2011). Widespread use of toxic skin-lightening compounds: medical and psychological aspects. Dermatologic Clinics, 29:111-123.