Incident Report Review

Report Number: 20230826-A8518-2147345548

Who you are: Public Safety Entity

Step 1: What Happened

What Happened:

Pura Stainless knowingly sold Lead-contaminated children's products through at least 2018. There was no recall. These products are still in use in homes today. Summary / Overview: In 2017 and 2018 - and possibly later - Pura Stainless continued to sell high-Lead-content insulated stainless steel Pura Kiki baby bottles after learning of the following issue with their product: multiple documented instances of product failure resulting in child-accessible Lead at very high levels (as much as 800,000 ppm) in one component — far in excess of the CPSIA Lead-content ban for Lead in children's products (limiting Lead in substrates to 100 ppm.) Pura's sales of Lead-contaminated children's product on store shelves (virtual and brick and mortar) and distribution from warehouse inventory continued after the company stated (in writing to customers - see below) that they had begun to manufacture a Lead-free version of the product. Lead-contaminated versions of this product continued to be sold through at least 2018, and may have been sold as late as 2019 (possibly even later, until Lead-contaminated inventory was exhausted). These unsafe and illegal Lead-contaminated baby bottles are still in use in homes across the United States today in 2023, as no voluntary recall was ever announced by the manufacturer. Separately, Made Safe dot org knowingly continued to allow their certification to be used on the packaging of (and marketing for) these products – after learning that the products were in violation of the CPSIA due to unsafe levels of Lead. See attached PDF for full report which your website did not accept in text form.

When it happened:

8/9/2023

This is an estimate

Where it Happened:

The address where it happened:

Step 2: Tell Us About the Product

Describe the product

ONE) Product Name: Pura Brand - Pura Kiki model - insulated stainless steel baby bottle [this issue does not pertain to the non-insulated version of this bottle.] TWO) Dates Manufactured: All years prior to and including through mid-2018, & possibly later dates (a date through which the product continued to be manufactured with high levels of Lead would need to be determined via a CPSC audit of the manufacturing processes of the manufacturer). THREE) Dates Sold: As no recall was done at the time we first made the manufacturer aware of this concern in 2016/2017 (the product was not pulled from store shelves, nor was it pulled from distribution centers - as clearly indicated from the communications from the manufacturer, images attached), and as our inquires determined that the company's statements explicitly indicated that they were continuing to distribute and sell the Lead-contaminated product until the Lead-contaminated inventory was exhausted — with our sources indicating likely tens of thousands of units warehoused at that time, it is possible that units of the Lead-contaminated (illegal and unsafe)

version of the insulated stainless steel Pura Kiki baby bottles was sold online and through retail outlets through 2019 and possibly later. We have published correspondence from Pura Kiki dated July 7, 2018 where they admit that they are continuing to sell their (older) Lead-contaminated stock (see website) despite having been directly made aware of the Lead issue in 2017. FOUR) Compounding Factor: Product Durability / Intended Duration of Use: A primary compounding factor with this product is that it was marketed and sold as an item that can be used throughout a child's entire early childhood. As a result, if a parent bought this Lead-contaminated bottle to use for their newborn in 2018 or 2019 (or even in earlier years) the intention - by design, and in confirmed practice) was that the child would still be using the product - continuously - when they were four or five or six years old. We have found this to be the case - see point number nine below. Their slogan, "Baby Grows...Bottle Evolves" underscores this concern [see attached image with their marketing language relevant to this product]. In support of any investigation you may undertake in this matter, we have a full timeline indicating the company's knowledge of the issue - and the fact that they continued to sell Lead-contaminated bottles, in spite of this knowledge - on our website (LeadSafeMama.com) FIVE) Compounding Factor: Fraudulent / Misleading Packaging with Made Safe Certification Language: The company used and continues to use language including the following phrases (which would indicate to the consumer that the product is Lead-free): "Made Safe Certified"; "Eco-progressive"; "Toxin-Free"; "Kids Safety and Sustainability First"... SIX) Date Issue First Reported by Lead Safe Mama, LLC: April / May 2017 SEVEN) Dates of Documented (saved) Communication Thread with CPSC about this product: We have several saved communications with the CPSC about this product specifically and this issue in general from July 2018 (see our website for full communication thread). There were also earlier communications about this issue but we did not save copies. After this exchange from July of 2018, we never received a response or determination of next steps. These communications were with the following parties: Stephanee Synnott PhD, Jonathan Midgett PhD and DeWane Ray. We were told on July 30, 2018 that Dr. John Boja would get back to us. We never heard back from anyone after this communication about this issue. EIGHT) Date of Follow Up Letter to CPSC (sent to CPSC through former CPSC official as we had not received any response to our previous communications): December 2021 (see our website for full communication). NINE) 2023 Issue With This Product: Lead Safe Mama, LLC is a small business that does in-home visits with families of Lead-poisoned children around the country. This year (in the first 7 months of 2023) we have worked with several families who had a confirmed Lead-contaminated version of this product still in use in their home. There have been two common scenarios: #1) a child who had the bottle as an infant is now using the bottle at 4, 5 or 6 years old; and #2) the family has had a second or third child since they purchased this bottle 4 or 5 or 6 years ago, and they are now using the bottle (again) for their youngest infant. There is also a concern for these bottles (due to the promised durability of the product) to be handed down from one family to another. Each of these scenarios creates the opportunity for these bottles to poison children for years into the future, which is why we are demanding an investigation and recall of these bottles now, even though the company states that the current version of their products no longer use Lead to create their vacuum seal [they claim this is true for versions manufactured since mid-2018 (in a written response when pressed on the subject by a customer who also happened to be a reader of our posts, and forwarded that communication to us)].

Brand name: Pura Stainless

Manufacturer/ Importer/ Private Labeler Name: Pura Stainless

Please provide Model Name or Number: Pura Kiki Insulated Stainless Steel Baby Bottle

Serial Number:

SKU#:

UPC Code:

Date Manufactured: 7/1/2018

Manufacturer Date Code:

Upload photos or documents related to the product, damage, or injuries

- Lead-in-Pura-Kiki-Baby-Bottles.png, , 987.94KB
- Pura-2023-language.png, , 66.31KB
- Pura-2023-Ad.png,, 375.278KB
- Full-Response-to-Erika-From-Pura.png, , 106.666KB
- Pura-Bottle-Cap-Came-Off-Again.png, , 115.514KB
- Full Report LSM_04_2023.pdf, , 7044.959KB

Address on the product

office@purastainless.com

Website On Product:

https://www.purastainless.com

Telephone Number on the product:

805 • 884 • 0313

Still have the product:

Yes

Product was damaged or modified:

No

Explanation of damage/modification:

Recent recalls of comparable products set precedents for a CPSC recall of this product (Green Sprouts Lead-contaminated stainless baby bottle - November 2022, Nuk Lead-painted baby bottle - July 2022, & Cupkin Lead-contaminated stainless children's cup.)

Contacted the manufacturer:

Yes

Step 3: Tell Us Who Was Involved

Person #1

Injury Information:

Seen by Medical Professional

Relationship to me:

Years:

2

Months:

0

Date of Death:

First Name:

Last Name:	
Email:	
Phone Number:	
Gender:	
Races:	
Hispanic/Latino:	
Address:	

Step 3.5: Tell Us the Case Details

What is the case number:

LSM_04_2023

Case Documents/Photos:

File Name Description Size

Lead-in-Pura-Kiki-Baby-Bottles.png 987.94KB

Pura-2023-language.png 66.31KB

Pura-2023-Ad.png 375.278KB

Full-Response-to-Erika-From-Pura.png 106.666KB

Pura-Bottle-Cap-Came-Off-Again.png 115.514KB

Full Report LSM_04_2023.pdf 7044.959KB

Who are the Principal Investigator(s) of the case you are reporting:

Tamara Elise Rubin, Owner - Lead Safe Mama, LLC

Step 4: Tell Us How to Contact You

First Name:

Tamara

Last Name:

Rubin

Organization / Agency:

Lead Safe Mama, LLC

Email Address: TamaraRubin@mac.com

Phone Number: 4156093182

Address:

7933 SE 15th Ave

Portland

Oregon

97202-6601

May we release your name and contact information to the product manufacturer / importer / private labeler?

Yes