Heavy metals in diaper creams

HEAVY METAL INDEX · SYNTHESIS REPORT

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Abstract

The only finished-product measurements on file for diaper creams are four single-unit grey-literature laboratory reports on zinc oxide products. Across those four units lead runs from 1244.1 to 4657.1 ppb and cadmium from 45.26 to 509.5 ppb, each detected in all four, while arsenic and mercury fall below the reporting value. No non-zinc-oxide cream has been measured, and no United States rule sets a heavy-metal limit for the finished product.

1 | Product anatomy

A diaper cream is a topical barrier product applied to the diaper area to prevent or treat diaper dermatitis. The dominant active class is zinc oxide, formulated as a cream, an ointment or a stiffer paste, usually at 10 to 40 percent by weight. Zinc oxide is the element source that the pathway evidence below is about: it is the ingredient present in bulk, and its principal element is zinc.

A second class of products uses no zinc oxide. Plain petrolatum and plant-based preventatives, described on the non-zinc-oxide product page (diaper-cream-non-zno), occupy this row. They are relevant to a synthesis of metals in diaper creams for one reason and with one caveat: they are the natural comparison group for any claim that zinc oxide carries a metal load, and no metal measurement of any non-zinc-oxide diaper cream is on file. The comparison cannot be made from data. It can only be named as a gap.

The finished product is what a caregiver applies, and it is the basis on which the four measurements were made. It is not the same object as the zinc oxide raw material, which carries its own ingredient specification, and it is not a daily dose. Keeping those three bases apart, finished product, ingredient, and daily exposure, is what the rest of this page depends on.

2 | Measured evidence

Four finished-product datasets were opened, and they are all the same kind of document: a single retail unit of one product, relabelled with an internal lot number by a consumer-advocacy business, sent to a commercial laboratory, and analysed by ICP-MS for lead, cadmium, arsenic and mercury. The report image is appended to a blog article. The matrix is the finished zinc oxide cream, ointment or paste, as received. The results are total-element concentrations in the finished product, in ppb, where 1 ppm equals 1,000 ppb equals 1 mg/kg. Arsenic is total arsenic and mercury is total mercury; neither is speciated. These are grey literature, evidence tier C, and they are excluded from the certification pipeline by design.

The four reports are single units, so they are listed, not pooled. A single unit is a point, not a distribution, and four points chosen by an advocate are not a sample of the category.

REPORT	PRODUCT FORM (NEUTRAL)	LEAD (PPB)	CADMIUM (PPB)	ARSENIC (PPB)	MERCURY (PPB)
Report A	40% zinc oxide ointment	3303.8	55.50	< 10.00	< 5.00
Report B	40% zinc oxide paste	1401.0	509.5	< 10.00	< 5.00
Report C	40% zinc oxide maximum-strength paste	4657.1	473.1	< 10.00	< 5.00
Report D	13% zinc oxide cream	1244.1	45.26	< 10.00	< 5.00

Across the four units, lead ran from 1244.1 to 4657.1 ppb and cadmium from 45.26 to 509.5 ppb. Lead was above the reporting value in four of four units and cadmium in four of four. Arsenic was below the 10.00 ppb reporting value and mercury below the 5.00 ppb reporting value in every unit. The lowest lead result was in the 13 percent product and one of the two highest was also a 40 percent product, so within these four units lead did not order itself by zinc oxide percentage. Four points cannot establish that relationship or rule it out.

The same advocate later published a comparison chart of eleven diaper products, one unit each. Four of the eleven charted values match the four laboratory reports above, rounded. The other seven have no laboratory report on file, the chart's cadmium and lead figures for those seven are not verifiable against a report, and for several of them the chart does not state whether zinc oxide is present. The chart is therefore not used here for any concentration, range, detection rate or comparison, and it charts no product without zinc oxide, so it cannot compare zinc-oxide and non-zinc-oxide products either. The four verified units are the whole of the measured evidence.

The limitations are the same for all four reports and are load-bearing. Each figure is one unit from one lot. The unit was selected and shipped by an advocate, which is a purposive rather than a random sampling frame. None of the reports prints a sample mass, a digestion procedure, a calibration, a recovery, a detection limit beyond the bare reporting value, or a laboratory accreditation. The "less than" entries are left-censored reporting values, not measurements of zero. A single non-detect on total arsenic or total mercury does not establish that either metal is absent below the reporting value, and four detects of lead and cadmium in four purposively chosen units do not establish a category detection rate. Read as what they are, the reports show that lead and cadmium were present, at the printed concentrations, in these four specific units.

3 | Zinc dermal pathway evidence

None of the pathway studies on file measures lead or cadmium. They measure zinc, the principal element of the zinc oxide active. They bear on a narrower question than the one a caregiver asks: whether a zinc oxide vehicle on skin delivers its element into or through skin, and whether barrier damage changes that. They do not answer whether lead or cadmium in a diaper cream reaches or crosses infant skin, because none of them measures lead or cadmium, and none of them uses a diaper cream on infant diaper-area skin.

On intact adult skin the delivered fraction is small. Ågren ([6]) applied occlusive zinc oxide dressings to the forearms of five adults for 48 hours and measured epidermal zinc of 49 µg/g dry weight under a hydrocolloid vehicle and 127 µg/g under a gum-rosin vehicle, with blister-fluid zinc of 0.29 and 0.68 µg/mL. Khabir and colleagues ([7]) dosed excised human abdominal skin with a 20 percent zinc oxide nanoparticle formulation for 48 hours and found exogenous zinc in the viable epidermis of 3.1 µg/g dry weight, against an endogenous 13 µg/g, with the dermis indistinguishable from blank and the particles themselves retained in the stratum corneum; zinc entered as ions, not particles. The European Scientific Committee on Consumer Safety ([10]), reviewing nano zinc oxide as a sunscreen ingredient, adopted a dermal-absorption fraction of 0.03 percent of the applied dose from its in vitro human-skin data. All three describe intact adult skin and a sunscreen or dressing vehicle, not a diaper cream on an infant.

Barrier damage is where the sources disagree, and the disagreement is left standing rather than resolved. Ågren's rat model showed much greater systemic zinc uptake through full-thickness back wounds than through intact skin: serum zinc rose to 4.06 µg/mL under one vehicle against 0.95 µg/mL in controls, and the vehicle ranking that held on intact skin reversed on wounds. A single-case neonatal report ([9]) followed a preterm infant with eroded diaper dermatitis whose serum zinc reached 427 µg/dL during concurrent zinc oxide ointment and oral zinc, then fell to 52 µg/dL after both were stopped, with a Naranjo causality score of 9; the infant's damaged skin and the concurrent oral dose both bear on that reading. In a hairless-mouse model, UVB injury increased skin zinc uptake from topical zinc oxide nanoparticles ([8]), though the numeric values sit only in a supplementary figure not on file. Against these, the Scientific Committee reported no significant difference between damaged and intact skin, and no enhancement of zinc penetration on UVB-damaged skin, in the pig and human models it reviewed. These results are about zinc, in wounds, erosion, UVB injury and intact skin, in rats, mice, adults and one infant. They are a reason to measure the dermal route for the metals that were actually found in the creams. They are not a measured fraction for lead or cadmium, and this synthesis does not treat them as one.

A narrative review of the infant skin barrier ([11]) supplies the background that makes the diaper area a plausible place to ask the question: the infant barrier approaches adult properties at about two years, the diaper area is occluded and over-hydrated, and an infant's skin surface area is large relative to body weight. The review also notes that data on the effectiveness of zinc oxide ointment in preventing diaper dermatitis are limited. It reports no metal concentration and no dermal-absorption fraction for any metal.

4 | Toxicology

Toxicology here is the hazard each measured metal is known for, and what, if anything, is known about that metal on infant skin from a diaper cream. A reference dose or a classification derived from ingestion or inhalation is not a dermal dose from a cream, and none of the four reports measured absorption, blood levels or any biological endpoint. The reports are concentrations in a product.

Lead is a developmental neurotoxicant, and the endpoint that dominates infant and child assessment is the developing nervous system. Lead was the metal found at the highest concentrations in the four units, from

1244.1 to 4657.1 ppb. What is not on file is the step from that concentration to a dose: no measurement of how much cream is applied, how much lead leaves the vehicle, or what fraction crosses intact or dermatitic infant skin. Cadmium's long-term dietary endpoint is kidney tubular dysfunction, on an oral, cumulative record; it was detected in all four units, from 45.26 to 509.5 ppb, and again with no dermal-transfer measurement on file. Arsenic's regulated hazard is carried by the inorganic species, and mercury's neurodevelopmental hazard by methylmercury; the reports measured total arsenic and total mercury, both below the reporting value in all four units, so neither a speciated result nor a detected total is available to carry forward. A non-detect on a total method is not proof of absence below the reporting value, and it is not a speciation result.

The exposure surface deserves its own sentence, without a number. The diaper area is occluded, often wet, and often already inflamed, and the infant barrier is immature in early infancy; those are reasons the dermal route could matter more here than for an adult cosmetic. They are not a measured absorbed fraction. No study on file reports the share of lead or cadmium that crosses infant skin from a diaper cream.

5 | Exposure framing

A dermal exposure from a diaper cream has at least four inputs: how much metal is in the product, how much product is applied, how long it stays on the skin, and what fraction is absorbed. The four reports supply the first input for two metals, in four units. They supply none of the other three. No document opened for this work provides, together, an applied mass, a use frequency, a contact time and a dermal-absorption fraction for lead or cadmium from a diaper cream.

Because those inputs are missing, no illustrative dose is offered. Multiplying a concentration by an assumed application and an assumed absorption would produce a number that looked like a dose and was not one. The measured concentrations are concentrations. The honest statement for a caregiver is that lead and cadmium were present in four specific units at the printed levels, that the amount reaching a child from those or any other units has not been measured, and that stopping or continuing a product is a decision this page does not make.

6 | Regulatory landscape

A diaper cream is not one legal object, and which instrument applies depends on how the product is marketed. The limits below are cited in their own unit and on their own basis. None of them is placed beside the measured ppb results as a score, because none of them is a finished-product total-metal limit on the same basis as those results, and several are on hold in the evidence register pending a separate impact review.

In the United States a zinc oxide diaper-rash product is an over-the-counter skin-protectant drug. The codified skin-protectant monograph ([12]) lists zinc oxide as a permitted active at 1 to 25 percent of the finished product and sets no heavy-metal limit for the finished product. A 1990 proposed rule for diaper-rash products ([13]) would have allowed zinc oxide above 25 to 40 percent in an ointment dosage form, again with no metal limit; it is a proposal, and the operative post-2020 text was not obtained. The result that matters for this synthesis is the absence: the United States skin-protectant framework on file sets no finished-product heavy-metal limit for a diaper cream. Two lead figures that a consumer advocate cited against the products, a Washington State cosmetics figure and a general cosmetics figure, are characterised inconsistently within the advocate's own pages and their applicability to a product that is a drug is not established, so they are not used here.

The limits that do exist attach to something other than the finished drug product. The United States colour-additive specification for zinc oxide ([14]) limits the zinc oxide ingredient, when used as a colour, to cadmium 15, mercury 1, arsenic 3 and lead 20 ppm, with purity not less than 99 percent; it governs the ingredient,

not the drug active, and it is an ingredient specification, not a measurement of any product. In Canada, licensed zinc oxide diaper-rash products are natural health products under the 2024 Diaper Rash Products Monograph ([15]), whose finished-product specifications follow the Quality of Natural Health Products Guide ([16]); the Guide's topical limits are arsenic 3, cadmium 3, lead 10, total mercury 1 and antimony 5 ppm of the finished product. A product marketed as a cosmetic falls under the cosmetic guidance instead: Health Canada's cosmetic-impurity guidance ([17]) treats lead above 10, arsenic above 3, cadmium above 3, mercury above 1 and antimony above 5 ppm of the finished product as technically avoidable, and the German orientation values ([18]) are lead 2.0, cadmium 0.1, mercury 0.1, arsenic 0.5 and antimony 0.5 mg/kg for cosmetics in general. The European zinc oxide active-substance monograph, as recorded in the pharmacopoeial knowledge database ([20]), retains lead and cadmium tests at limits that were not obtained, adds a thallium test at 5 ppm, and deletes the arsenic test; those are ingredient-grade tests, and the updated lead and cadmium values are not on file.

A cutaneous drug-product guideline, the International Council for Harmonisation Q3D(R2) ([19]), sets permitted daily exposures for elemental impurities in cutaneous drug products on a µg/day basis, with a dose-dependent concentration column. Those values, and a topical chromium figure that appears in one Canadian appendix table, are recorded on the source pages but are held in the evidence register pending a separate review of how they would interact with the certification pipeline. They are named here for completeness and are not applied to the measured results. Converting any of these limits onto the ppb finished-product basis of the four reports would require an assumed zinc oxide fraction or an assumed daily applied mass, and the reports do not supply either; any such conversion would be a derived figure, not a measurement, and none is made on this page.

7 | Implications

For parents

Four specific units of zinc oxide diaper cream, ointment or paste were tested, one unit each, and lead and cadmium were found in all four, with lead the higher of the two, from about 1.2 to 4.7 ppm, and cadmium from about 0.045 to 0.51 ppm. Arsenic and mercury were below the tests' reporting values in every unit. These are four units chosen by an advocate, not a survey of the shelf, and each was tested once with no published quality control, so they cannot say how common these levels are or how a given product on the shelf compares.

The statement not to take from this page is a risk verdict. No study on file follows lead or cadmium from a diaper cream across a child's skin and into the body, so the amount, if any, that reaches a child is unmeasured. Whether to use, change or stop a product is a caregiving decision this page does not make.

For manufacturers

The finished product and the zinc oxide raw material need separate numbers. The ingredient specifications on file constrain the zinc oxide raw material; they are not a measurement of the finished cream, and a compliant ingredient does not by itself establish a finished-product concentration. A brand that wants to speak to metals in its finished diaper cream has to measure the finished product, on the finished-product basis, across lots rather than in a single unit.

The zinc oxide percentage is not a proxy for the metal load. In the four units on file the lowest lead result was in the lowest-strength product and one of the highest was a 40 percent product, so lead did not track zinc oxide content in this small set. Whether lead and cadmium enter through the zinc oxide ingredient, through another ingredient, or through both is not settled by four units, and the platform attribution used in the certification taxonomy is a program framing, not a finding of these sources.

For regulators

The gap is the finding. The United States skin-protectant framework on file sets no finished-product heavy-metal limit for a diaper cream, and the limits that exist elsewhere are on different objects and different bases: an ingredient specification in ppm of the zinc oxide raw material, a cutaneous drug dose in µg/day, and cosmetic guidance in ppm of a finished cosmetic. A number written for one of those objects should not be read as a finished-product drug limit, and the measured ppb results should not be scored against it. Where a government has no finished-product number for metals in this product, the gap should stay visible rather than be filled by borrowing a limit from an adjacent basis.

Speciation rules that exist for food should not be relaxed because the matrix is a cream. Total arsenic is not inorganic arsenic and total mercury is not methylmercury; the four reports measured totals, both below the reporting value, and that is all they can support.

For researchers

The next useful study is specific. Measure lead, cadmium, arsenic and mercury in the finished diaper cream on the finished-product basis, across multiple lots and multiple products rather than one unit each, with sample mass, digestion, calibration, recovery, detection limits and accreditation reported. Include the non-zinc-oxide products, because the clean comparison group has never been measured and the whole clean-versus--contaminated question rests on it. Speciate arsenic and mercury where a total is detected. Then, and separately, measure the dermal step: how much lead or cadmium leaves the vehicle and crosses intact and compromised infant-relevant skin, so that a concentration can become an exposure. Until that dermal step is measured, a concentration in a diaper cream is a concentration in a diaper cream.

8 | Data gaps and research agenda

No peer-reviewed survey of metals in finished diaper creams is on file. No non-zinc-oxide diaper cream has been measured for metals, so the clean baseline of the product pair has no measured evidence. No study on file measures lead or cadmium absorption from a diaper cream, and no dermal-absorption fraction for any metal from a diaper cream was opened. Inorganic arsenic and methylmercury in a diaper cream: no data found, and the total-arsenic and total-mercury results that exist are non-detects. A market detection rate cannot be calculated from four purposively selected units or from an eleven-item advocacy chart whose unverified values are not used here. The primary texts that would settle several regulatory questions, including the operative United States over-the-counter skin-protectant monograph and the ingredient-grade lead and cadmium limits behind the pharmacopoeial requirement, were not obtained and are logged for retrieval.

The research agenda follows those gaps, in order. First, finished-product content in mg/kg for lead, cadmium, arsenic and mercury, across lots and products, with full method reporting, including non-zinc-oxide products. Second, speciation of arsenic and mercury wherever a total is detected. Third, a dermal-transfer measurement for lead and cadmium on intact and compromised skin. Fourth, a sampling frame that is not built from advocate-selected units.

9 | How to cite

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STATUS AND LICENCE

Editorially reviewed in-house; no external peer review has been completed on this finding. Published as an institutional technical report with its review state tracked on the article page.

COMPETING INTERESTS

The Heavy Metal Index reports what the peer-reviewed and regulatory literature supports. It is operated separately from any certification program, does not evaluate or endorse brands, and does not use certification thresholds as evidence for the statements made here.

DATA AVAILABILITY

Every source behind this finding is listed with its own extraction record at https://heavymetalindex.com/synthesis/heavy-metals-in-diaper-creams/sources, each linking to the ingest receipt, the extracted values, and the file hash of the document it was built from.

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