

The Mucosal Gap

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THE CLAIM

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Menstrual and intimate-care products contact the vaginal mucosa, the body's most absorptive surface, for hours at a time. A 2024 study measured lead and cadmium in all 60 tampon samples it tested, and arsenic in 57 of 60, and no government sets a per-metal numeric content limit for the metals these products contain. HMTc tests for them, certifies to the limit the exposure route demands, and certifies heavy-metal safety — nothing else.

Abstract

Menstrual and intimate-care products contact the vulvovaginal mucosa, one of the body's most permeable surfaces, and the internal ones stay there for hours at a time. That surface absorbs more readily than skin and drains part of what crosses it into the bloodstream without the liver's first pass. A 2024 peer-reviewed study measured lead and cadmium in all 60 tampon samples it tested, and arsenic in 57 of 60. No government sets a per-metal numeric content limit for a menstrual product.

HMTc closes that gap without inventing a number. For device forms, where no government sets a per-metal numeric content limit, it reads a ceiling across by analogy from the strictest health-based limit a government has drawn for an article in comparable prolonged mucosal contact, and enforces it every lot by mass-spectrometry testing of the full analyte panel, sampled component by component with the tampon applicator tested distinctly. For cosmetic forms it reads across the strictest sovereign contaminant limit, adopting the mucosal-contact tier for lead because the vaginal mucosa is more permeable than the oral mucosa that tier was written for. The mark certifies heavy-metal safety only, and states the presence-versus-dose evidence honestly rather than as alarm.

The vaginal mucosa is not skin

Contaminant regulation treats the body as either a gut or a skin. Food limits assume the metal is swallowed, buffered by stomach acid, and subject to the fractional absorption of the gastrointestinal tract; cosmetic limits assume the metal sits on intact skin, whose outer keratin layer is a genuine barrier that most metals

cross slowly and incompletely. The vulvovaginal mucosa is neither. It is a thin, non-keratinised, richly vascularised epithelium kept moist and, during menstruation, in continuous contact with an absorbent or collecting device. Clinical medicine uses the vaginal route for systemic drug delivery for precisely this reason: it is highly permeable, and a portion of what is absorbed reaches the bloodstream without the first-pass hepatic metabolism that would clear an equivalent oral dose ^[4]. A limit calibrated to skin contact, or to a fraction of a swallowed dose, does not describe what this surface does with a metal held against it for four to eight hours.

The exposure geometry compounds the point. An internal device is not an incidental touch; it is an occlusive, prolonged, mucosal contact repeated for several days every month across decades of a person's life. A mechanistic model of lead released from a worn tampon has been published, and it is careful to show that only a small fraction of the lead released reaches tissue in its baseline scenario ^[3]. That honesty cuts both ways: it establishes that a real, quantifiable pathway from product to tissue exists, while showing that the magnitude depends on release rate, permeability, and wear time rather than on product content alone. The route is real. What crosses it is the open question the evidence has only begun to measure.

What the 2024 tampon study found, and what it did not

The anchor evidence is Shearston and colleagues, published in *Environment International* in 2024 ^[1]. The study digested thirty tampons spanning fourteen brands and eighteen product lines bought in the United States, the European Union, and the United Kingdom, and measured sixteen metals and metalloids by mass spectrometry. Lead was present in every one of the sixty subsamples, at a median of one hundred seventy-three micrograms per kilogram and a maximum of four hundred sixty-eight. Cadmium was present in every subsample; total arsenic in all but three. The authors found higher lead in non-organic than in organic tampons and higher cadmium, cobalt, and lead in products bought in the United States than in Europe, and reported that no product category was consistently lower across all metals. A systematic review prepared for the United States Food and Drug Administration's device centre in the same year reached the same qualitative conclusion across the wider literature ^[2].

What that evidence establishes is presence: these metals are in these products, measurably, across brands and markets, not as an outlier but as the ordinary case. What it does not establish is dose. The Shearston figures are total content per unit mass of the product, obtained by dissolving the whole tampon; they are not a measurement of how much metal leaves the product during use, crosses the mucosa, and reaches a body. The study did not speciate arsenic or mercury, so the reported arsenic is total arsenic rather than the more toxic inorganic fraction, and chromium and mercury were below the detection limit in most samples. The honest reading is neither dismissal nor alarm. Presence is established and the absorptive route is established; the exposure that results is not yet quantified, and a certification program has to be built to be correct under both the optimistic and the pessimistic reading of that uncertainty.

A rulebook that never measured content

The reason no number exists to look up is structural, not accidental. Tampons, pads, cups, and discs are regulated as medical devices: in the United States under 21 CFR Part 884 as Class II obstetrical and gynecological devices ^[5], and in the European Union under the Medical Devices Regulation 2017/745 ^[6]. Device law asks whether a material is biocompatible, and it answers that question through the ISO 10993 series, which evaluates a device for biological reactivity, sensitisation, and the release of constituents under

simulated-use extraction ^[7]. Biocompatibility testing can, in principle, flag a leachable metal. It is not, and was never intended to be, a numeric ceiling on how much lead or cadmium a finished tampon may contain. A product can pass its biocompatibility file and still carry the lead the 2024 study measured, because the file was never asked that question.

The cosmetic side of the category has the opposite problem. [Feminine wipes](#), [deodorants](#), [douches](#), and [intimate washes](#) are cosmetics, and several governments do set trace-metal limits for cosmetics. But those limits were written for skin. The one place a government has drawn a stricter cosmetic line for a mucosal-contact product is oral care: Germany's technically-avoidable-contaminant guidance sets lead in toothpaste at five hundred micrograms per kilogram against two thousand for general cosmetics, because toothpaste meets mucosa and is partly swallowed ^[8]. No regulator has extended that logic to the vaginal mucosa, which is more permeable than the oral. The result across the whole category is a single gap with two shapes: for devices, no government sets a per-metal numeric content limit; for cosmetics, it borrows a rulebook written for a less absorptive surface.

What HMTc requires

HMTc closes the gap in the two ways the two product families allow, and it never invents a number of its own to paper over the difference. For the device forms, [tampons](#), [pads](#), [cups](#), [discs](#), and [period underwear](#), no government sets a per-metal numeric content limit for the finished menstrual product, so rather than leave those cells blank the standard reads a ceiling across by analogy: for each metal it adopts the strictest health-based limit a government has set for an article in comparable prolonged mucosal contact. Every certified lot is still tested for the full analyte panel by mass spectrometry, sampled component by component, with the tampon applicator tested as a distinct component, so that read-across ceiling is enforced against measured content for every metal the literature has actually measured in these products, lead, cadmium, arsenic, mercury, [nickel](#), chromium, and, from the broadest published screen, [aluminium](#) and [tin](#) ^[10]. [Antimony](#), which leaches from the polyester used in some applicators and cups, is monitored on those components even though it sits outside the certified panel. The posture is deliberate: where the science shows a metal is present and no per-metal numeric content limit exists, the defensible act is to hold the product every lot to the strictest health-based limit a government has drawn for a comparable contact, disclosed as a read-across, rather than to invent a threshold of the program's own.

For the cosmetic forms, a sovereign limit does exist, and the standard reads across to it, choosing the stricter mucosal-contact value wherever a government has drawn one. Lead is held at the mucosal-contact tier, five hundred micrograms per kilogram, rather than the general-cosmetic two thousand, on the explicit ground that the vaginal mucosa is more permeable than the oral mucosa that tier was written for ^[8]. Cadmium, arsenic, and mercury are held at the strictest general-cosmetic sovereign values, and nickel at the only cosmetic nickel content limit any government publishes ^[9]. Inorganic arsenic and hexavalent chromium are enforced by reflex speciation on any elevated total result. The one determination the program makes in the other direction is methylmercury, which has no formation pathway in a fibre, polymer, or aqueous product and is bounded by the total-mercury control; it is recorded as not material, and that determination is tested against the evidence every time the standard is rebuilt, so it cannot quietly become an excuse.

Safety, and only safety

It is worth stating plainly what the mark does and does not assert, because a category this sensitive is easy to overclaim in either direction. The Heavy Metal Tested and Certified mark certifies heavy-metal safety, and nothing else. It is not a statement that a product performs well, that it is healthy, that it is free of every other chemical of concern, or that products without the mark are dangerous. It is a statement that the product's metal content was measured against the strictest limit the exposure route can be shown to warrant, and met it. The framing is harm reduction, not fear. The evidence does not support telling anyone that menstrual products are unsafe; it supports the more modest and more useful claim that the metals are present, the route is real, no government sets a per-metal numeric content limit, and a person is entitled to choose a product whose metal content was actually checked by someone with no incentive to find it clean.

Why a brand certifies

For a brand, the gap is a liability that testing converts into a differentiator. This is a category with unusually high public salience, a peer-reviewed study that reached national coverage, and no regulatory floor to point to when a customer, a retailer, or a plaintiff's expert asks what a product contains. A certificate that rests on per-lot mass-spectrometry testing against a published, exposure-appropriate standard is the record that answers that question before it is asked, and it is a record the brand controls rather than one assembled adversarially after a headline. Certifying does not require conceding that a product was ever unsafe. It requires only measuring what no regulator has required the brand to measure, in the one category where the exposure route makes that measurement most worth having.

Common questions

▼ Does the HMTc mark mean a menstrual or intimate-care product is free of heavy metals?

No. No analytical method can certify the absence of an element, and the program does not claim to. The mark means the product was tested, lot by lot, and that every metal was either below the strictest limit its exposure route warrants or, where no lawful limit exists, held under a mandatory control that measures it every lot and drives it down. It is a statement about testing and limits, not about zero.

▼ Does this briefing say tampons are dangerous?

No. It says that lead, cadmium, and arsenic have been measured in tampons across brands and markets, that the vaginal mucosa is an unusually absorptive route, and that no government sets a per-metal numeric content limit for these products. Presence measured in a product is not the same as an absorbed dose that causes harm, and the published exposure model is explicit that only a fraction of released lead reaches tissue in its baseline case ^[3]. The case for testing rests on the combination of established presence, a real absorptive pathway, and no per-metal numeric content limit, not on a claim of demonstrated harm.

▼ Why certify against a standard when there is no per-metal numeric content limit to meet?

Because there is no per-metal numeric content limit to meet. In a category a government already sets one, a certificate that merely restates that floor adds little. Here that numeric content floor is absent for menstrual products, and the cosmetic limits that do exist are borrowed from skin, so a program that tests every lot against an exposure-appropriate standard is supplying that measurement rather than duplicating a regulator's.

▼ Is the vaginal route really more absorptive than skin?

Yes, and it is established enough that medicine relies on it. The vaginal mucosa is used clinically to deliver drugs systemically precisely because it is thin, non-keratinised, richly vascularised, and drains partly around the liver's first-pass metabolism ^[4]. Intact skin, by contrast, is a keratinised barrier most metals cross slowly. A limit calibrated to skin understates what the mucosal route can do with the same metal.

References

Works cited in this briefing's text, in first-appearance order. This is not the full evidence base for the underlying standard; it is only what the prose above draws on. Every range in the briefing is a model built on one of these published anchors. Where a work carries a DOI or a public URL, its title and domain link to it; primary legal documents and published standards are named but not linked to a corpus record.

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- [5] **21 CFR Part 884 — Obstetrical and Gynecological Devices** [↗](#) REGULATION
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- [7] **ISO 10993-1 — Biological evaluation of medical devices, Part 1** STANDARD
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