Mouthwash/oral rinse: HMTc Standard

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CORRESPONDENCE

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KEYWORDS

heavy metals, food safety, dietary exposure

PUBLICATION HISTORY

This revision 2026-08.

Abstract

The Heavy Metal Tested & Certified heavy-metal-safety standard for mouthwash/oral rinse in Oral Care, evaluated on finished oral-care product as placed on market — total heavy-metal content per unit mass of product as sold (ug/kg). Not a dietary maximum level and not a migration/leachate value.. 5 of 11 panel analytes publish a numeric limit taken from the strictest applicable government maximum; the remainder are held under mandatory control or a substantiated not-material determination.

1 | How every number on this standard is set

HMTc Method v2.0 (government-limit default), Category 20 Oral Care: a formulated oral product takes the strictest applicable sovereign finished-cosmetic contaminant maximum in its as-sold basis, with the Germany BVL 2017 toothpaste tier read across to non-toothpaste oral-mucosal forms where it is stricter; an oral-care article takes the Canadian mouth-contact accessible-part lead ceiling and is otherwise held under component-level control. Species never replace totals, no ingredient purity specification anchors a finished-product cell, no migration value anchors a content cell, and no cell is occurrence-derived.

2 | Master limit table

All values in ppb (µg/kg), as sold basis. A brand meeting every value qualifies for the mark.

ANALYTE	HMTC LIMIT	BASIS
Lead (Pb)	500	read-across (DE)

Cadmium (Cd)	100	government maximum level (DE)
Total arsenic (tAs)	500	government maximum level (DE)
Inorganic arsenic (iAs)	≤ tAs	bounded by tAs (reflex speciation)
Mercury, total (tHg)	100	government maximum level (DE)
Methylmercury (MeHg)	≤ tHg	bounded by tHg (reflex speciation)
Nickel (Ni)	10,000	read-across (South Korea)
Tin (Sn)	control	measured every lot; no human-food maximum
Aluminium (Al)	560,000	read-across (European Union)
Total chromium (Cr)	50	read-across (AU)
Hexavalent chromium (Cr-VI)	5	read-across (European Union)

3 | Derivation — where each number comes from

Every cell traces to one named sovereign maximum level (the strictest for the nearest analog), or to an explicit control, not-material, or species-bounded determination. No occurrence statistic selects a certification value.

ANALYTE	HMTC	SOVEREIGN ANALOG / DETERMINATION
Lead (Pb)	500	read-across (DE); toothpaste
Cadmium (Cd)	100	government maximum level (DE)
Total arsenic (tAs)	500	government maximum level (DE)
Inorganic arsenic (iAs)	≤ tAs	bounded by tAs (reflex speciation)
Mercury, total (tHg)	100	government maximum level (DE)
Methylmercury (MeHg)	≤ tHg	bounded by tHg (reflex speciation)
Nickel (Ni)	10,000	read-across (South Korea); cosmetic products other than eye makeup or color makeup products

Tin (Sn)	control	No jurisdiction sets a tin content limit for any oral-care or cosmetic product; the sovereign tin maximum levels in the register are canned-food and food-contact values written for tinplate migration into food and are a different basis entirely. Tin is additionally not a pure impurity in this category: stannous fluoride and stannous chloride are authorised anticaries and antigingivitis actives in dentifrices and mouthrinses, so a finished-product tin ceiling would be exceeded by design in a compliant stannous formulation and would be meaningless as a contaminant control. The cell is held under mandatory analytical control with a declaration reconciliation rather than declared not-material, because tin is unambiguously present at material levels in this category and an absence claim would be contradicted on its face.
Aluminium (Al)	560,000	read-across (European Union); toys (accessible toy material); pacifiers/soothers reached via the EN 1400 soother standard (excluded from the TSD itself, Annex I item 16); EN 71-3 test basis
Total chromium (Cr)	50	read-across (AU); drinking water
Hexavalent chromium (Cr-VI)	5	read-across (European Union); toys (accessible toy material); pacifiers/soothers reached via the EN 1400 soother standard (excluded from the TSD itself, Annex I item 16); EN 71-3 test basis

4 | Cite this standard

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References

[1] DE
Binds Pb, Cd, tAs, tHg. toothpaste.
MAXIMUM LEVEL

[2] South Korea

Binds Ni. cosmetic products other than eye makeup or color makeup products.

READ-ACROSS

[3] AU

Binds Cr. drinking water.

READ-ACROSS

[4] European Union

Binds Cr-VI, Al. toys (accessible toy material); pacifiers/soothers reached via the EN 1400 soother standard (excluded from the TSD itself, Annex I item 16); EN 71-3 test basis.

READ-ACROSS

STATUS AND LICENCE

A normative certification standard, editorially reviewed and version-controlled in-house; every value traces to a named sovereign maximum level, disclosed in the derivation. © 2026 Institute of Contaminant Standards / Heavy Metal Certified. All rights reserved.

COMPETING INTERESTS

This standard is published by the Heavy Metal Tested & Certified (HMTc) program, operated by the Institute of Contaminant Standards. Its statements about government regulations, toxicology, and occurrence are sourced to the cited primary and expert-body records and to the independently maintained Heavy Metal Index; the program's own certification thresholds are not used as evidence for any factual claim made here.

DATA AVAILABILITY

The works this standard draws on are listed in full in the references above and on the standard page at https://heavymetalcertified.com/standards/mouthwash-oral-rinse. Primary legal instruments and expert-body assessments are named with their public identifiers; the underlying occurrence and toxicology corpus is maintained on the Heavy Metal Index.

PUBLICATION HISTORY

This revision 2026-08. The full dated record is maintained at https://heavymetalcertified.com/standards/mouthwash-oral-rinse.