

Oral solids: softgels/gelcaps: HMTc Standard

Karen Pendergrass ·  · Heavy Metal Tested & Certified, Institute of Contaminant Standards

CITE AS

Pendergrass, K. (2026). Oral solids: softgels/gelcaps: HMTc Standard (Standard No. 10.83138/hmtc.std.16.supplements-oral-solids-softgels). Institute of Contaminant Standards.
<https://doi.org/10.83138/hmtc.std.16.supplements-oral-solids-softgels>
© 2026 Institute of Contaminant Standards / Heavy Metal Certified. All rights reserved.

KEYWORDS

heavy metals, food safety, dietary exposure

PUBLICATION HISTORY

This revision 2026-08.

CORRESPONDENCE

Corrections are logged publicly on the article page, each with its date, the affected value, and the source that resolved it.

Abstract

The Heavy Metal Tested & Certified standard for Oral solids: softgels/gelcaps (Dietary Supplements (Human)), stated as sold. Every limit is read across from the strictest sovereign infant-and-child-food maximum level for the analyte and applied to all supplements as a voluntary child-protective over-compliance; the laxer adult supplement floor (sovereign supplement MLs, USP <2232>, Prop 65) is disclosed and never selected.

1 | How every number on this standard is set

HMTc Method v2.0 — child-protective over-compliance: strictest sovereign infant-and-child-food ML by lookup, applied to all supplements; adult floor (supplement ML / USP <2232> / Prop 65 MADL) disclosed, never selected

2 | Master limit table

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

ANALYTE	TIER	HMTc LIMIT	BASIS
Lead (Pb)	Tier 1	10	human-grade read-across (Australia / New Zealand)
Cadmium (Cd)	Tier 1	5	human-grade read-across (European Union)

Total arsenic (tAs)	Tier 2	50	human-grade read-across (India)
Inorganic arsenic (iAs)	Tier 1	10	human-grade read-across (European Union)
Mercury, total (tHg)	Tier 1	4	human-grade read-across (Israel)
Methylmercury (MeHg)	Tier 1	≤ tHg	bounded by tHg (reflex speciation)
Nickel (Ni)	Tier 2	100	human-grade read-across (European Union)
Tin (Sn)	Tier 2	5,000	human-grade read-across (India)
Aluminium (Al)	Tier 2	500	human-grade read-across (Australia / New Zealand)
Total chromium (Cr)	Tier 2	1,000	human-grade read-across (China)
Hexavalent chromium (Cr-VI)	Tier 2	≤ Cr	bounded by Cr (reflex speciation)

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)	10	Australia / New Zealand — infant formula products
Cadmium (Cd)	5	European Union — infant formulae, follow-on formulae, food for special medical purposes intended for infants and young children, and young-child formulae placed on the market as liquid and manufactured from cow's milk proteins or cow's milk protein hydrolysates
Total arsenic (tAs)	50	India — Infant Milk substitute and Infant foods

Inorganic arsenic (iAs)	10	European Union — infant formulae, follow-on formulae, food for special medical purposes intended for infants and young children, and young-child formulae placed on the market as liquid
Mercury, total (tHg)	4	Israel — Infant and toddler formulas, ready-to-eat
Methylmercury (MeHg)	≤ tHg	MeHg carries no product-specific sovereign cell; it is a component of and bounded by its parent total tHg (MeHg ≤ tHg), an enforceable ceiling via reflex speciation rather than an empty cell.
Nickel (Ni)	100	European Union — infant/young-child formula, liquid
Tin (Sn)	5,000	India — Infant Milk substitute and Infant foods
Aluminium (Al)	500	Australia / New Zealand — infant formula, follow-on formula, and special medical purpose product for infants other than preterm-infant products
Total chromium (Cr)	1,000	China — human-food analog
Hexavalent chromium (Cr-VI)	≤ Cr	Cr-VI carries no product-specific sovereign cell; it is a component of and bounded by its parent total Cr (Cr-VI ≤ Cr), an enforceable ceiling via reflex speciation rather than an empty cell.

4 | Cite this standard

Pendergrass, K. (2026). *Oral solids: softgels/gelcaps: HMTc standard* (Standard No. 10.83138/hmtc.std.16.supplements-oral-solids-softgels). Institute of Contaminant Standards. <https://doi.org/10.83138/hmtc.std.16.supplements-oral-solids-softgels>

© 2026 Institute of Contaminant Standards / Heavy Metal Certified. All rights reserved.

References

- [1] Australia / New Zealand — human-food maximum levels
Binds Pb, Al. Strictest applicable human-food sovereign maximum for the nearest analog.
MAXIMUM LEVEL
- [2] China — human-food maximum levels
Binds Cr. Strictest applicable human-food sovereign maximum for the nearest analog.
MAXIMUM LEVEL

- [3] European Union — human-food maximum levels
Binds Cd, iAs, Ni. Strictest applicable human-food sovereign maximum for the nearest analog.
MAXIMUM LEVEL
- [4] Israel — human-food maximum levels
Binds tHg. Strictest applicable human-food sovereign maximum for the nearest analog.
MAXIMUM LEVEL
- [5] India — human-food maximum levels
Binds tAs, Sn. Strictest applicable human-food sovereign maximum for the nearest analog.
MAXIMUM LEVEL
-

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.

DATA AVAILABILITY

The works this reference draws on are listed in full in the references above and on the briefing page at <https://heavymetalcertified.com/standards/supplements-oral-solids-softgels>. 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.

COMPETING INTERESTS

This briefing 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.

PUBLICATION HISTORY

This revision 2026-08. The full dated record is maintained at <https://heavymetalcertified.com/standards/supplements-oral-solids-softgels>.