Oral solids: softgels/gelcaps: HMTc Standard

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CORRESPONDENCE

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

KEYWORDS

heavy metals, food safety, dietary exposure

PUBLICATION HISTORY

This revision 2026-08.

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	HMTC LIMIT	BASIS
Lead (Pb)	10	read-across (Australia / New Zealand)
Cadmium (Cd)	5	read-across (EU 2023/915)
Total arsenic (tAs)	50	read-across (India)

Inorganic arsenic (iAs)	10	read-across (EU 2023/915)
Mercury, total (tHg)	4	read-across (Israel)
Methylmercury (MeHg)	≤ tHg	bounded by tHg (reflex speciation)
Nickel (Ni)	100	read-across (EU 2024/1987)
Tin (Sn)	5,000	read-across (India)
Aluminium (Al)	500	read-across (Australia / New Zealand)
Total chromium (Cr)	1,000	read-across (GB 2762)
Hexavalent chromium (Cr-VI)	≤ 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	read-across (Australia / New Zealand); infant formula products
Cadmium (Cd)	5	read-across (EU 2023/915); 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	read-across (India); Infant Milk substitute and Infant foods
Inorganic arsenic (iAs)	10	read-across (EU 2023/915); 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	read-across (Israel); Infant and toddler formulas, ready-to-eat
Methylmercury (MeHg)	≤ tHg	bounded by tHg (reflex speciation)
Nickel (Ni)	100	read-across (EU 2024/1987); infant/young-child formula, liquid

Tin (Sn)	5,000	read-across (India); Infant Milk substitute and Infant foods
Aluminium (Al)	500	read-across (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	read-across (GB 2762); grains and grain products including cereals and milled grain products
Hexavalent chromium (Cr-VI)	≤ Cr	bounded by Cr (reflex speciation)

4 | Cite this standard

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References

[1] Australia / New Zealand
Binds Pb, Al.
READ-ACROSS

[2] EU 2023/915
Binds Cd, iAs.
READ-ACROSS

[3] India
Binds tAs, Sn.
READ-ACROSS

[4] Israel
Binds tHg.
READ-ACROSS

[5] EU 2024/1987
Binds Ni.
READ-ACROSS

[6] GB 2762
Binds Cr. grains and grain products including cereals and milled grain products.
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

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

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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/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.

PUBLICATION HISTORY

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