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HEALTH RISK ASSESSMENT:

HEAVY METALS IN AYURVEDIC MEDICINES

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ABBREVIATIONS

ATSDR	Agency for Toxic Substances and Disease Registry
AvMs	Ayurvedic medicines
BLL	Blood lead level
BMD	Benchmark dose
BMDL	Benchmark dose level
bw	Body weight
CAS RN	Chemical Abstract Service Registry Number
CDI	Chronic daily intake
CMR	Carcinogenic, mutagenic or toxic to reproduction
DL	Detection limit
ECHA	European Chemicals Agency
EFSA	European Food Safety Authority
EU	European Union
HBGV	Health-based guidance value
HNZ	Health New Zealand – Te Whatu Ora
JECFA	Joint FAO/WHO Expert Committee on Food Additives
HAS	Health Sciences Authority
IARC	International Agency for Research on Cancer
LD_{50}	Median lethal dose (causes death in 50% of animals)
LOAEL	Lowest observed adverse effect level
LOD	Limit of detection
MN	Membranous nephropathy

MOE	Margin of exposure
NOAEL	No observed adverse effect level
NPC	National Poisons Centre
NZTDS	New Zealand total diet study
OTC	Over the counter
POD	Point of departure
PTMI	Provisional tolerable monthly intake
PTWI	Provisional tolerable weekly intake
RQ	Risk quotient
SCCS	Scientific Committee on Consumer Safety
SLP	Skin-lightening product
SUSMP	Standard for the Uniform Scheduling of Medicines and Poisons
TDI	Tolerable daily intake
TWI	Tolerable weekly intake
UF	Uncertainty factor
UK	United Kingdom
USA	United States of America
US EPA	United States Environmental Protection Agency
US FDA	United States Food and Drug Administration
WHO	World Health Organization

1. EXECUTIVE SUMMARY

Ayurveda is an ancient Indian traditional system of medicine where 'Ayu' is life and 'Veda' is science or knowledge. Ayurveda incorporates all aspects of life whether physical, psychological, spiritual or social. Ayurvedic medicines (AvMs) generally contain minerals, medicinal herbs and herbal preparations. They can be mono- or polyherbal. There are currently no AvMs approved as medicines in New Zealand. AvMs available in New Zealand generally do not contain restricted or pharmacy-only medicinal ingredients and are easily available as over-the-counter (OTC) products as no prescription is required. Therefore, they can be considered as similar to dietary supplements or herbal remedies.

Following reports of increases in lead absorption notifications (n=19) due to the use of contaminated AvMs in 2023, a survey funded by Health New Zealand (HNZ) was conducted in 2024-2025 to determine the prevalence and concentrations of detectable heavy metals. Samples that were found to have detectable levels of at least one of arsenic (n=34), cadmium (n=32), lead (n=45) and/or mercury (n=15) in the survey were considered for the current risk assessment.

Chronic dietary intake (CDI) was estimated for AvMs containing detectable levels of arsenic, cadmium, mercury and lead following best international practices. Health-based guidance values (HBGV) and toxicological points of departure established by the Joint FAO/WHO Expert Committee on Food Additives were utilised in the risk assessment for heavy metals.

A margin of exposure (MOE) approach was used to characterise the oral exposure risk for arsenic and lead in AvMs, as there are no safe exposure levels for either heavy metal. The benchmark dose levels for arsenic are derived from human cancer data. Therefore, an MOE of low health concern could not be determined. For cadmium and mercury, risk quotients (RQ) were calculated as HBGVs were available for both heavy metals. To provide context, the mean CDI of heavy metals from use of AvMs was also compared to the mean dietary exposure for each heavy metal for young adult males as estimated in the New Zealand total diet study 2016.

The chronic oral exposure for total arsenic from AvM consumption ranged from 0.001 to 210 µg/kg bw/day. An adjusted mean chronic oral exposure was also estimated by excluding the extremely high arsenic concentration from a single AvM sample, to identify the contribution of this unexpected result made to overall intake. The mean CDI (11 µg/kg bw/day) of arsenic from AvMs was higher than the mean dietary exposure (0.14 µg/kg bw/day) of inorganic arsenic through different food sources. However, after excluding the unexpected total arsenic result in one AvM sample, the adjusted mean chronic oral exposure (0.01 µg/kg bw/day) was 7% of dietary exposure to arsenic. Similarly, the mean estimate of chronic oral exposure for cadmium in AvMs was lower than the mean dietary exposure. However, the mean estimates of chronic oral exposure of lead and mercury from AvMs were higher than the mean dietary exposure of these heavy metals. Therefore, the mean CDI of lead and mercury from AvMs and mean dietary exposure of both heavy metals were combined to estimate overall risks.

Arsenic is a genotoxic carcinogen and for such chemicals an MOE greater than 10,000 is considered to be of low concern. However, the points of departure (PODs) for arsenic are derived from human cancer data. According to The European Food Safety Authority (EFSA), there are no precedents in identification of an MOE of low concern using PODs derived from

human cancer data. Consequently, an MOE of low health concern could not be specified. The MOE for arsenic from AvMs ranged from 0.001 to 190. There is no safe level of arsenic, therefore exposure to lead should be kept as low as reasonably achievable. For chemicals other than genotoxic carcinogens an MOE of greater than 100 is generally considered to represent a low cause for concern.

The combined mean estimates of lead exposure from AvMs and dietary exposure was 0.17 µg/kg bw/day and the MOE was 8. The MOEs for lead in AvMs ranged from 0.4 to 1,000. There were only two AvMs for which the margin of exposure (4 and 0.4) was less than 10, which raises health concerns for consumers. Even though the concentration of lead in one AvM (6 mg/kg) was not very high, the MOE was less than one due to the very high recommended dose (10 to 20 g twice a day) of the AvM. All other Ayurvedic medicines if taken according to the label instructions and within recommended doses did not raise any health concerns, as the MOEs were more than 10. Nevertheless, there is no safe level of lead and lead exposure, therefore exposure to lead should be kept as low as reasonably achievable.

None of the AvMs raised any health concerns due to the presence of cadmium when taken within the recommended dose. The RQs were less than one for all the products.

The combined mean estimates of mercury exposure from AvMs and dietary exposure was 0.66 µg/kg bw/day and the RQ was 1.10. Four AvMs with high levels of mercury raised health concerns as the RQ was greater than one. For all other AvMs, the RQs ranged from 0.0003 to 0.78 with no appreciable health risks if taken according to the label instructions and recommended dose.

The MOE and RQ indicate that most of the AvMs did not raise any health concerns if they are taken according to the label instructions and within the recommended dose. However, high levels of heavy metals in some AvMs suggest that efforts to decrease heavy metals concentrations in these products should be supported.

2. INTRODUCTION

Ayurvedic medicines (AvMs) are a subgroup of herbal and mineral medicines originating from the Indian subcontinent. The purpose of this report is to summarise generic health risk assessment data for exposure to heavy metals from the consumption of AvMs that are available over the counter and online to consumers in New Zealand. This report will only consider oral exposure to AvMs contaminated with arsenic, cadmium, lead and mercury.

Products classified as medicines that are available through a doctor's prescription are outside the scope of this report.

2.1 PRODUCT DESCRIPTION – AYURVEDIC MEDICINES

Herbal products are widely used around the world for their therapeutic and cosmetic properties. They are perceived as safe because they contain substances of natural origin such as from plants, minerals and animals. The World Health Organization (WHO) has estimated that more than 80% of the world's population in over 170 of WHO's 194 Member States currently use some form of traditional medicine (WHO, 2023). Interest in herbal therapeutic products has also grown in the western world, where these types of natural products may be consumed as dietary supplements. In a recent survey, more than half of 329 respondents in a New Zealand survey reported that they take supplements or natural remedies every day, with a further 25% taking them a few times a week (ConsumerNZ, 2022).

One such form of supplement available in the New Zealand market is AvMs or Ayurvedic products. Ayurveda is an ancient Indian traditional system of medicine where 'Ayu' means life and 'Veda' is science or knowledge. AvMs generally contain minerals, medicinal plants, herbs and herbal preparations. They can be mono- or polyherbal. Ayurveda incorporates all aspects of life whether physical, psychological, spiritual or social. AvMs are available in many dosage forms (Tiwari et al., 2018):

1. Solid: *Vati* or *Gutika* (tablets or pills);
2. Semi-solid: *Ghritas* (ghee), *Lepa* (herbal paste);
3. Liquid: *Asava* and *Arista* (fermented formulation), Arka, *tailas (*oil*)*; and
4. Powder: *Churna* (fine powder), *Ksaras* (ashes of herbs), *Bhasma* (calcinations of metals, minerals).

There are currently no AvMs approved as medicines in New Zealand (Medsafe, 2024a). AvMs available in New Zealand generally do not contain restricted or pharmacy-only medicinal ingredients and are easily available as over-the-counter (OTC) products (no prescription is required). Therefore, they may be considered to be dietary supplements or herbal remedies. There are no quality standards specified for herbal preparations/remedies or AvMs in New Zealand as they do not need pre-market approval and are sold without regulatory oversight.

AvMs have been found to occasionally contain high levels of heavy metals in multiple studies, which can present health risks to consumers (Bhalla and Pannu, 2022; Deswal *et al.*, 2019; Giacomino *et al.*, 2015; Saper *et al.*, 2004; Saper *et al.*, 2008). Note that all the studies report concentrations of total arsenic and total mercury in AvMs. It is likely that

inorganic forms of arsenic and mercury are predominantly found in plants and herbs. In the context of this report, the risk assessment of AvMs was performed for inorganic arsenic and mercury. In New Zealand, lead is the only heavy metal specifically included in the 'List of diseases notifiable by health practitioners and laboratories to the Medical Officer of Health', with lead absorption levels equal to or in excess of 5 µg/dL being notifiable. Traditional medicines or cosmetics were the fifth most commonly identified non-occupational sources of lead exposure, resulting in 25 notifications from 2014 to 2022 (EHINZ, 2023). The median blood lead level (BLL) in notified cases from the use of traditional medicines or cosmetics was 35.23 µg/dL (range 11.81–90.71 µg/dL). During October 2023, the National Public Health Service and the New Zealand National Poisons Centre noted an increase in lead absorption notifications (n=19) due to the use of AvMs. The median BLL for these 19 cases was 92.00 µg/dL (range 5.40–220 µg/dL). Therefore, there is a growing concern regarding the safety of AvMs after many reports of high BLLs due to the use of contaminated Ayurvedic products by New Zealand consumers.

Contamination of AvMs can be due to many reasons. The herbs and minerals used in the AvMs can be contaminated with heavy metals due to natural (igneous and sedimentary) or anthropogenic factors (manufacturing, agriculture, pollution, mining and industrial processes). In addition to the contaminated herbs, accidental cross-contamination in the manufacturing facility or by transfer from the packaging used in the product may also contaminate the AvMs (Mustatea *et al.*, 2021).

2.2 HEAVY METALS IN AYURVEDIC MEDICINES

There are many studies in literature that have quantified heavy metals in AvMs. A summary of some of these studies is presented in Table 1.

Table 1: Concentration of heavy metals in different Ayurvedic medicines

Reference	Country	Sample size	Detection method	Median (range) (ppm) or (mg/kg)
(Bhalla and Pannu, 2022)	India	42	ICP-MS	As: <DL (<DL–1,038.83) Cd: <DL Pb: 1.40 (<DL–57.10) Hg: 13.52 (<DL–61,095)
(Mikulski *et al.*, 2017)	India	252	ICP-MS	As: 8.4 (0.46–44,800) Cd: (4.70) Pb: 5 (0.46–43,200) Hg: 53 (0.80– 279,000)
(Martena *et al.*, 2010)	Netherlands	242	ICP-MS	As: 7.60 (0.2–89,800) Pb: 13 (0.5–60,000) Hg: 50 (0.20–171,000)
(Rai *et al.*, 2007)	India	24	ICP-MS	As: 3.35 (0.38–5.00) Cd: 0.14 (0.03–0.22)
(Abollino *et al.*, 2018)	Italy	9	ICP-OES	As: 32.50 (1.10–479,000) Pb: 3.20 (0.50–373) Hg: 117 (1.0–15,600)
(Deswal *et al.*, 2019)	India	10	AAS	Cd: 1 (0.65–2.00) Pb: 3.25 (3–10)
(Deswal *et al.*, 2022)	India	9	AAS	Cd: 1.60 (0.60–2) Pb: 6.42 (3–10)
(Giacomino *et al.*, 2011)	Italy	4	ICP-OES	As: 8.07 (0.04–771) Cd: 0.07 (0.01–0.26) Pb: 6.41 (3.00–76.00) Hg: 25260 (13,500–28,500)
(Giacomino *et al.*, 2015)	India	7	ICP-OES	As: 6.84 (<1.30–421,000) Pb: 110 (0.41–135,000) Hg: 157 (3.64–49,000)
	Italy	5		As: <1.3 (<1.30–2.02) Pb: 1.33 (0.71–3.24)
(Jayawardene *et al.*, 2010)	USA	5	ICP-MS	As: <DL (<DL–304) Cd: <DL (<DL–14.40) Pb: 331 (1.9–36,000) Hg: 37 (<DL–10,000)
(Rai *et al.*, 2007)	India	3	ICP-OES	Cd: 0.14 (0.03–0.22) Pb: 3.35 (0.38–5)
(Nath *et al.*, 2020)	India	54	GFAAS	Cd: 0.23 (0.13–1.80) Pb: 1.21 (1.09–4.70)
(Kamat and Suryawanshi, 2015)	India	5	ICP-MS	As: 0.0007 (0.0005–0.003) Cd: 0.0003 (0.0001–0.0005) Pb: 0.02 (0.0064–1) Hg: not detected
(Saper *et al.*, 2004)	USA	70	XRF	As: 430 (37.00–8130) Pb: 40 (5–37,500) Hg: 20225 (28–104,000)
(Saper *et al.*, 2008)	USA	115	XRF	As: 2 (10.50–27.50) Pb: 7.50 (3–20.50) Hg: 25.50 (24.50–34.50)
	India	77		Pb: 11 (2.50–25,950) Hg: 13050 (47.50–28,200)

As: Arsenic, Cd: Cadmium, Pb: Lead, Hg: Mercury, ICP-MS: Inductively coupled plasma mass spectrometry, ICP-OES: Inductively coupled plasma atomic emission spectroscopy, USA: United States of America, AAS: Atomic absorption spectroscopy, GFAAS: Graphite furnace atomic absorption spectroscopy, DL: Detection limit, XRF: X-ray fluorescence spectroscopy

The majority of the studies summarised in Table 1 were carried out in India, as the Ayurvedic system of medicine originates from the subcontinent and is widely practiced there. In general, the extremely high concentration of heavy metals in some studies were found in rasa shastra medicine, an ancient practice of deliberately combining herbs with metals (e.g., mercury, lead, iron, zinc), minerals (e.g., mica), and gems (e.g., pearl). There were two

studies that allow comparison between AvMs manufactured in India and those manufactured in other countries (Italy and the United States) (Giacomino *et al.*, 2015; Saper *et al.*, 2008). Both the studies show that Indian manufactured AvMs have higher median concentrations of arsenic, lead and mercury than the AvMs manufactured in Italy and the United States. This may be due to stricter quality regulations and surveillance programmes in these countries.

2.3 NEW ZEALAND SURVEYS OF HEAVY METALS IN AYURVEDIC MEDICINES

A survey funded by HNZ was conducted in 2024–2025 to determine the prevalence and concentrations of detectable arsenic, cadmium, lead and mercury in AvMs (Gautam, 2025). Samples (n=75) were purchased from Indian ethnic retail stores in Auckland and Christchurch and online stores based in New Zealand. Samples were analysed by inductively coupled plasma mass spectrometry (ICP-MS). The details of AvMs sampled and the concentrations of arsenic, cadmium, lead and mercury for each sample are presented in Appendix A. An overview of the results of the survey is presented in Table 2.

Table 2: Concentration of heavy metals in the 75 Ayurvedic medicines available in New Zealand

Heavy metal	LOD (mg/kg)	Number of samples at or above LOD	Median (range)*, mg/kg	Mean
Total Arsenic	0.01–1	26	0.23 (0.12–9,800)	338
Cadmium	0.004–0.04	33	0.04 (0.004–0.74)	0.09
Lead	0.02–0.20	50	0.40 (0.02–6.30)	0.74
Total mercury	0.002–0.01	17	3.20 (0.02–166)	30

*Calculated for samples detected above the limit of detection

An unpublished report by Health New Zealand –Te Whatu Ora included the results of analyses of AvMs associated with notified cases of lead absorption (HNZ, 2025). All the AvMs taken by the notified cases were purchased overseas, mainly in India, and when analysed were also shown to contain high levels of arsenic, lead or mercury. The concentration of arsenic, cadmium, lead and mercury in the samples are presented in Table 3.

Table 3: Concentrations (mg/kg or ppm) of heavy metals in Ayurvedic medicine samples collected by Health New Zealand – Te Whatu Ora from individuals in October 2023 to December 2024

Sample no.	Arsenic	Cadmium	Lead	Mercury
PHA24205/1	6.35	NA	6,000	9,130
PHA24111/1	2.91	0.50	32	64.20
PHA24111/2	3.71	0.10	210	21.20
PHA24111/3	1.01	0.06	2	0.50
PHA24185/1	9.22	0.14	218	13,800
PHA24185/2	2,010	0.28	1.40×10^5	60,600
PHA24185/3	5	0.20	110	16,800
PHA24264/1	2.77	NA	66.40	143
PHA24258/1	4,740	NA	3,530	13,300
LJB 237 ITIS TABLETS	180.20	NA	7,670	24,200
LJB 242 ITIS OINTMENT	20.3	NA	30,400	15,800
LJB 244 HALBO TABLET	NA	NA	142	NA
LJB 245 PAXID TABLET	NA	NA	13.50	NA
JCH115C	120	< LOD	93,500	NA

*NA: Not available, LOD: Limit of detection

2.4 REGULATION OF AYURVEDIC MEDICINES IN NEW ZEALAND

The regulatory framework for AvMs or herbal remedies is highly fragmented across countries. They can be either treated as dietary supplements or herbal medicines.

In New Zealand, dietary supplements are regulated under the Dietary Supplements Regulations 1985, which fall under the Food Act 2014. Medsafe is responsible for administering the Dietary Supplement Regulations and the Ministry for Primary Industries (MPI) administers the Food Act. Dietary supplements do not require pre-approval and it remains the responsibility of the sponsor (the person legally responsible for placing the product on the market) to ensure the product is made to an acceptable quality, is safe to use and complies with the law.

Herbal medicines are viewed as a legitimate alternative to conventional western medicines by many cultures and practices. Under New Zealand's Medicines Act 1981, a herbal remedy is defined as:

> a medicine (not being or containing a prescription medicine, or a restricted medicine, or a pharmacy-only medicine) consisting of—
>
> (a) any substance produced by subjecting a plant to drying, crushing, or any other similar process; or
>
> (b) a mixture comprising 2 or more such substances only; or
>
> (c) a mixture comprising 1 or more such substances with water or ethyl alcohol or any inert substance.
>
> (Medicines Act 1981, Section 2)

Herbal remedies, including AvMs, are exempt from the requirements of the Medicines Act 1981 provided a therapeutic purpose is not intended or claimed for them through either advertising or labelling and provided they do not contain a substance classified as a medicine under the Act. AvMs are readily available as over-the-counter products as no prescription is required. There are no quality standards for herbal preparations/remedies in New Zealand as they do not need pre-market approval and are sold with minimal regulatory oversight.

2.5 HEAVY METAL LIMITS FOR HERBAL REMEDIES

Although there are no regulatory quality standards for heavy metals in AvMs in New Zealand, WHO and various pharmacopoeias recommend maximum permissible limits of toxic metals in herbal preparations, as summarised in Table 4.

Table 4: Permissible limits of heavy metals in herbal or traditional medicines and medicinal herbs from different jurisdictions

Reference	Regulatory document	Permissible concentrations (mg/kg)			
		Pb	Cd	Hg	As
Steinhoff (2019)	European pharmacopoeia	5	1	0.1	-
Vinogradova *et al.* (2023)	United States pharmacopeia	0.5	0.5	3	1.5
WHO (2007)	World Health Organization	10	0.3	-	-
Vinogradova *et al.* (2023)	Ayurvedic pharmacopoeia	10	0.3	1	3
HSA (2025)	Singapore Health Sciences Authority	10	0.3	0.5	5

2.6 AYURVEDIC PRODUCT RECALLS DUE TO THE PRESENCE OF HEAVY METALS

High levels of arsenic, lead, and mercury have been reported in AvMs, which has led to their recall from markets in several countries. There is no database which records the recall of AvMs from the market. However, some regulatory agencies such as the United States Food and Drug Administration (US FDA), Medsafe (New Zealand), Health Sciences Authority (HAS, Singapore) and Health Canada have issued warnings and recalled AvMs due to excessive levels of heavy metals. Some of the recent product recalls are summarised below.

1. A survey funded by HNZ was conducted in 2024–2025 to determine the prevalence and concentrations of detectable arsenic, cadmium, lead and mercury in AvMs (Gautam, 2025). AvMs (n=6) that were found to contain high levels of arsenic and mercury were recalled from the market by Medsafe (Medsafe, 2025).

2. Singapore's HSA issued a recall notice for an Ayurvedic product Planet Ayurveda Water-EX tablets (HSA, 2024). This product was tested under HSA's product quality surveillance programme and was found to contain mercury exceeding the national legislative limit. The concentration of mercury was not reported.

3. The US FDA in association with a wholesale group announced a recall of various products of Zaarah Herbals in March 2025 due to the presence of elevated levels of lead and arsenic (US FDA, 2025). These products were rasayan churan, gurmar powder, vasaka powder and bhringraj powder. It is worth noting that the active ingredient in gurmar powder, vasaka powder, and bhringraj powder is one of the ingredients in some of the AvMs included the New Zealand's survey of AvMs.

4. Health Canada issued safety information to the general public regarding three Ayurvedic products: brain tab tablets, mucuna powder and yograj guggul capsules (Health Canada, 2019). These products were found to be contaminated with high levels of lead and mercury. The testing of these products was prompted by a local health authority in British Columbia due to a case of lead poisoning of a patient who had been using these Ayurvedic products. The concentrations of lead and mercury were not reported.

5. Eleven Ayurvedic supplements were found to contain high levels of mercury. These products were voluntarily recalled by a New York company (Food Safety News, 2015). The recall was prompted by the New York City Department of Health laboratory and the US FDA. The concentrations of mercury were not reported.

3. HAZARD IDENTIFICATION

3.1 PREVIOUS ASSESSMENTS

No previous health impact assessments that characterised the risks of heavy metals from the use of AvMs were found for New Zealand.

3.2 HEALTH EFFECTS – INCIDENT SURVEILLANCE AND CASE REPORTS

3.2.1 INCIDENT SURVEILLANCE – NEW ZEALAND

The National Poisons Centre (NPC) provided a summary of cases exposed to heavy metals associated with traditional, herbal, and supplemental products from the year 2018 to 2025. There were 59 cases about 36 unique exposure scenarios meeting inclusion criteria in the investigated time frame. The yearly exposures are summarised in Table 5.

Table 5: Unique reported exposure cases to heavy metals associated with products of interest in contacts with NPC, 2018–2025

Heavy metal	2018	2019	2020	2021	2022	2023	2024	2025*	Total
Lead	0	1	2	0	1	2	11	2	19
Arsenic	0	0	0	0	0	0	0	1	1
Mercury	3	0	0	1	6	2	3	1	16
Cadmium	0	0	0	0	0	0	0	0	0
Total	3	1	2	1	7	4	14	4	36

* Data presented are until 30 April 2025

Overall, 35 of 36 contacts were exposures reported by adults aged 20 or older. Of the 19 cases about lead exposures, 18 originated from health professionals. Six of 16 cases about mercury exposures originated from health professionals. Of the 16 contacts about mercury exposures, 12 were associated with products used topically. The information provided by the NPC revealed that mercury exposures were due to the topical use of skin-lightening creams. Therefore, these are excluded from the summary of unique exposures compiled below. Details of the remaining exposure incidents are given in Table 6. Although not under the scope of this report, exposures from other forms of traditional medicines (e.g. traditional Chinese medicine) are also presented in Table 6 as they may contain herbal or medicinal plants.

Table 6: Summary of unique cases contacting the National Poisons Centre associated with traditional, herbal, and supplemental products, 2018–2025

S.no	Suspected source	Age group	Metal of concern	Reported signs and symptoms
1	Supplement from India (self-tested for mercury)	20+ adult	Mercury	self-reported vision disturbances, tremor, twitching, insomnia
2	Supplement from India (self-tested for mercury)	20+ adult	Mercury	self-reported vision disturbances, tremor, twitching, insomnia
4	Ayurvedic products (not verified for lead)	20+ adult	Lead	Elevated BLL, nausea and vomiting, anaemia, basophilic stippling. No neurological symptoms reported
5	Ayurvedic products (not verified for lead)	20+ adult	Lead	Elevated BLL, fatigue, anaemia
6	Ayurvedic products (not verified for lead)	20+ adult	Lead	Elevated BLL, anaemia, basophilic stippling, abdominal pain, constipation, myalgias in arms and legs, fatigue
7	Chinese herbal supplement (reported by healthcare provider to contain lead)	20+ adult	Lead	Elevated BLL, abnormal liver function tests, anaemia, basophilic stippling, chronic abdominal pain, neurocognitive decline
8	Chinese herbal supplement (reportedly contains mercury sulphide)	20+ adult	Mercury	self-reported lower abdomen “not feeling good”, burning while urinating
9	Traditional medicine cream (not verified for lead)	20+ adult	Lead (topical product)	Elevated BLL, vague symptoms
10	Kamini (lists lead as ingredient)	20+ adult	Lead	Elevated BLL, ‘lead lines’ on gums and nails, chronic abdominal pain
11	Ayurvedic products (not verified for lead)	20+ adult	Lead	Elevated BLL, anaemia, basophilic stippling, abdominal pain, fatigue, weakness
12	Kamini (lists lead as ingredient)	20+ adult	Lead	Elevated BLL, anaemia, basophilic stippling, hyponatraemia, abnormal liver function tests, abdominal pain, constipation, nausea and vomiting, weight loss
13	Kamini (lists lead as ingredient)	20+ adult	Lead	Elevated BLL, anaemia, basophilic stippling, hyponatraemia, hypertension, abnormal LFT, abdominal pain, constipation, colitis, nausea and vomiting, confusion
14	Ayurvedic products (not verified for lead)	20+ adult	Lead	self-reported 'cardiac event', dementia, increasing confusion
15	Ayurvedic products (not verified for mercury)	20+ adult	Mercury	Elevated blood mercury. Lower limb pain, muscle weakness,

S.no	Suspected source	Age group	Metal of concern	Reported signs and symptoms
				tingling, acrodynia, generalised fatigue
16	Home-made libido enhancer supplement from India (not verified for lead)	20+ adult	Lead	Elevated BLL, anaemia, basophilic stippling, uncontrollable abdominal pain, agitation, mild tachycardia and hypertension
17	Ayurvedic products (reportedly verified for lead content)	20+ adult	Lead	Elevated BLL, no symptoms
18	Ayurvedic products (not verified for lead)	20+ adult	Lead	Elevated BLL, fatigue, nausea, mild confusion
19	Ayurvedic products (not verified for lead)	20+ adult	Lead	Elevated BLL, anaemia, basophilic stippling, abdominal pain, fatigue
20	Ayurvedic products (not verified for lead)	20+ adult	Lead	Microcytic anaemia, low iron stores
21	Ayurvedic products (not verified for lead)	20+ adult	Lead	Elevated BLL, abnormal liver function tests, back pain
22	Ayurvedic products (not verified for lead)	20+ adult	Lead	Elevated BLL, basophilic stippling, fatigue, lethargy, headache, persistent nausea, abdominal cramping, erratic bowel movements, malaise
23	Ayurvedic products (not verified for lead)	20+ adult	Lead	Elevated BLL, anaemia, basophilic stippling, abdominal pain, fatigue, myalgias
24	'Indian opioids' (not verified for lead)	20+ adult	Lead	Elevated BLL, no symptoms
25	Homeopathic product allegedly containing arsenic trioxide	10–19 year	Arsenic	No symptoms

S.no: Serial number, BLL: Blood lead level, LFT: Abnormal liver function test

3.2.2 CASE REPORTS – HEAVY METAL POISING DUE TO AVMS

Consumption of AvMs contaminated with high levels of heavy metals can have deleterious adverse health effects. There are many clinical reports of heavy metal poisoning due to consumption of contaminated AvMs in many countries, including New Zealand. Some of the recent cases are summarised below.

1. An unpublished report by HNZ reported high blood lead levels in a population cluster in Auckland due to the use of unlabelled AvMs. Since mid-October 2023, the National Public Health Service and the New Zealand National Poisons Centre have noted an increase in lead absorption notifications (n=19) due to the use of AvMs. The median BLL for these 19 cases was 92.00 µg/dL (range 5.40–220 µg/dL). All cases were symptomatic and most required hospital treatment with a number of cases requiring chelation therapy. All the AvMs taken by the notified cases were purchased overseas, mainly in India, and when analysed were also shown to contain extremely high levels of arsenic, lead or mercury.

2. In New Zealand, Medicines and Medical Devices Safety Authority (Medsafe) issued a safety alert on 4 March 2024 due to several cases of lead poisoning with AvMs (Medsafe, 2024b). There were eight notified cases of lead poisoning in people taking AvMs. Some of these people were very unwell, presenting with symptoms such as nausea, vomiting, abdominal pain and constipation. Medsafe was able to retrieve samples of some of the products identified in the cases of lead poisoning. Laboratory testing identified very toxic levels of lead.

3. A severe case of lead and arsenic poisoning was reported in Auckland in a 28-year-old man with end-stage kidney disease on chronic haemodialysis (Hsiao et al., 2019). The man presented with progressive global motor weakness, tremor and hallucinations which was preceded by eight months of polyarthralgia, constipation, abdominal pain, nausea and vomiting, and one month of severe neuropathic pain in all limbs, nightmares and involuntary vocalisation. Physical examination revealed high blood pressure and low heart rate. Alopecia was also noted with no abnormalities on skin or nails. Haematological investigations revealed normocytic normochromic anaemia. Further investigation disclosed the use of AvMs over a long but unquantifiable duration. The BLL was found to be significantly elevated at 130 µg/dL, but his blood mercury level was very low. Hair samples were also found to contain arsenic at 1.21 mg/kg, indicating ongoing exposure in the two to three months prior to hospital admission. The Ayurvedic products recovered from the patient contained high levels of arsenic (50–290 mg/kg), lead (28–12,000 mg/kg) and mercury (5–75,000 mg/kg).

4. A 40-year-old Indian male residing in New Zealand was reported to have high BLL of 3.5 µmol/L or 72.5 µg/dL, possibly due to the consumption of AvMs for the past eight years (Tsutsui *et al.*, 2013). He presented lethargy, malaise, myalgia and arthralgia in the previous two months. Other symptoms noted by the spouse were pallor, intermittent memory loss and personality changes. The patient also suffered from diabetes, hypertension, dyslipidaemia, gout and oesophageal reflux and was taking combination of medicines regularly for all the conditions. Haematological investigations revealed anaemia (97 g/L from 147 g/L a year ago). Liver function tests revealed no signs of hepatoxicity. ‘Lead lines’ or blue-purplish lines on the gums of the patient was also clearly visible which is one of the indications of lead toxicity. Three AvMs were suspected to be the source of the lead exposure. The concentrations of lead in three AvMs were 2.7, 4.4 and 14.8 mg/kg. Coincidentally, one of the three AvMs of same brand and active ingredients was included in the 2024–2025 New Zealand AvM survey (Gautam, 2025). The AvM in the survey was in tablet and syrup form. The concentration of lead in both the formulations in the New Zealand survey was <LOD and 1.7 mg/kg, which is less than that reported in the case report (Tsutsui *et al.*, 2013).

5. Arsenic poisoning was reported in a 14-year old girl with the history of epilepsy in Kerala, India (Philips *et al.*, 2022). The girl was admitted to hospital with jaundice, grade 2 ascites with firm hepatomegaly, and splenomegaly. Histopathological investigation of the liver suggested severe alcoholic hepatitis with additional findings of dense fibrosis localised mostly in the portal regions. Haemtological investigations revealed anaemia, thrombocytopenia, an aspartate aminotransferase to alanine aminotransferase ratio >2, hypoalbuminemia and hyponatraemia with raised prothrombin time. Clinical evaluation revealed the use of multiple AvMs for seizures from the age of nine years. Nail and hair clippings of family members and the girl were also analysed for arsenic content. Clippings of the family members had very low arsenic concentrations (<0.1 mg/kg) but

concentrations ranged from 2.8 to 4.8 mg/kg in the girl's nail and hair clippings, respectively, suggestive of systemic toxicity. Mutation analysis also ruled out any genetic causes for liver disease. After ceasing the use of AvMs for six months and with suitable treatment, alcoholic hepatitis was resolved but the classical features of hepato-portal sclerosis or non-cirrhotic portal hypertension persisted. The AvMs were retrieved from the family of the patient and analysed for potential contaminants. The concentration of arsenic in nine AvMs ranged from 0.43 to 246 mg/kg. Cadmium and nickel were also found in very low concentrations.

6. Gitelman *et al.* (2023) recently reported a case of lead poisoning in a 39-year old woman from Ontario, Canada who had been in the hospital three times in over six weeks. She presented with abdominal pain, constipation, nausea and vomiting, and had a medical history of hypothyroidism and infertility. Her haemoglobin level was 67 g/L (normal 115–155 g/L). A bone marrow biopsy to investigate the anaemia showed a moderate-to-marked increase in iron storage. Eventually the patient's abdominal pain improved and her haemoglobin remained higher than 70 g/L after transfusions but the cause of anaemia was unknown. At follow-up after two weeks, she was still experiencing ongoing fatigue, shortness of breath, headaches and tinnitus. Urine analysis showed elevated levels of coproporphyrin III and δ-aminolevulinic acid, markers of lead poisoning. Other tests were normal. Clinical evaluation revealed the use of AvMs daily to treat infertility for more than a year, which she stopped before her admission to the hospital but had resumed after discharge. Her BLL was 55 µg/dL. Other potential sources of lead exposure such as occupational and environmental were ruled out through the patient's history. After receiving suitable treatment, the BLL had decreased to 12.1 µg/dL after 1 year. AvM pills (n=17) and two incense samples were retrieved from the patient and submitted for elemental analysis. Of these, 11 pills contained lead levels greater than the detection limit and one pill contained 129,000 mg/kg of lead (about 13% lead by weight), strongly suggesting that the pills were the source of the lead toxicity. Four additional pills contained 7,900 to 33,000 mg/kg of mercury.

7. Mercury-induced membranous nephropathy (MN) was reported in two male patients from the southern state of Tamil Nadu in India (aged: 48 and 70 years) (Doshi *et al.*, 2019). The patients presented with fever, arthralgia and foamy urination. The patients were known to have diabetes mellitus for four years (first patient only) and both had hypertension. Renal biopsy in both patients showed 28 glomeruli, with features typical of MN. Clinical evaluation revealed that the patients had been consuming an AvM for bronchial asthma during the past two months. Blood examination revealed elevated blood mercury level at 24 µg/L (normal <11 µg/L) in the first patient while it was markedly elevated in the second patient (levels not provided). After stopping consuming AvM and with suitable treatment, the renal function returned to normal.

8. Ciocan *et al*. (2021) reported lead poisoning in Genoa, Italy in an Indian sailor with microcytic anaemia (Hb 9.9 mg/dL), persistent abdominal pain, emesis, dark stool, hyperchromic urine, latent jaundice and asthenia. He had the history of treatment with topical AvMs for lower back pain. He was also prescribed an oral AvM formulation by an Ayurvedic practitioner in his last appointment. Blood tests at the time of admission showed signs of anaemia with haemoglobin 9.9 g/dL (normal 13.8 to 18 g/dL), total bilirubin 3.5 mg/dL (normal 0.1 to 1.2 mg/dL), SGOT 90 mg/dL and SGPT 160 mg/dL. A screening for lead poisoning showed a BLL of 102 µg/dL. Following chelation treatment, the patient's symptoms gradually disappeared and his BLL dropped (42.2 µg/dL) but was

still elevated at the time of discharge. Lead exposures from other sources in the ship were ruled out after testing 150 products, which were found to be lead-free. The blood and urinary lead levels of other crew members were also in the normal range. Four AvMs were retrieved from the sailor and submitted for elemental analysis. Concentrations of arsenic, lead and mercury were in the range 0.35 to 135 mg/kg, 2.31 to 21,500 mg/kg and 0.50 to 145,710 mg/kg, respectively. Despite extremely high levels of mercury in the AvMs, no symptoms of poisoning were observed. This may be due to the low oral absorption of elemental mercury.

Many other reports of intoxication from the use of AvMs are available in the literature (Breeher *et al.*, 2013; Breeher *et al.*, 2015; Dargan *et al.*, 2008; Fernández *et al.*, 2015; Gunturu *et al.*, 2011; Kales *et al.*, 2007; Mathee *et al.*, 2015; Pinto *et al.*, 2014; Spriewald *et al.*, 1999; Van der Sluis and Sutherland, 2025). In general, lead intoxication is most common, followed by arsenic and mercury poisoning from the consumption of contaminated AvMs.

3.3 TOXICOLOGY

The toxicology of heavy metals has been extensively reviewed by several authorities, such as the International Agency for Research on Cancer (IARC), Agency for Toxic Substances and Disease Registry (ATSDR), United States Environmental Protection Agency (US EPA), European Food Safety Authority (EFSA) and European Chemicals Agency (ECHA). Hence, the toxicology of heavy metals is only briefly summarised below based on information provided in reports.

3.3.1 ARSENIC

Most of the toxicology data available on arsenic are for industrial workers and from exposure from drinking water (ATSDR, 2007). Arsenic is acutely toxic in humans and ingestion of large doses leads to gastrointestinal symptoms, disturbances of cardiovascular and central nervous system functions, multiorgan failure and eventually death (ATSDR, 2007). The minimum lethal dose of arsenic in humans is approximately 2 mg/kg bw. Acute oral exposure to lower levels of arsenic has resulted in effects on the digestive tract (constriction of the throat, dysphagia, nausea, vomiting, watery diarrhoea), respiratory tract (respiratory distress, haemorrhagic bronchitis), central nervous system (encephalopathy, weakness, delirium), cardiovascular system (hypotension, shock), liver (increased enzymes and size) and blood (anaemia, leukopenia).

Arsenic occurs in a range of inorganic and organic forms, with the organic forms generally being less toxic. Chronic oral exposure in humans to elevated levels of inorganic arsenic has been associated with effects on the gastrointestinal system, blood, skin, eyes, lungs, heart, central nervous system, liver and kidneys. Such effects include anaemia, peripheral neuropathy, skin lesions, hyperpigmentation, gangrene of the extremities, vascular lesions and liver or kidney damage.

Inorganic arsenic is a genotoxic carcinogen but does not interact directly with DNA (EFSA, 2024). It induces DNA base oxidation, DNA single and double strand breaks and clastogenic and aneugenic events both *in vitro* and *in vivo* via generation of oxidative stress. It is a weak inducer of gene mutations and has an extraordinary ability to inhibit DNA repair at very low concentrations *in vitro* and at low exposure levels in human studies, as inferred from the elevated levels of DNA damage. The inhibition of DNA repair can potentially worsen the genotoxic effects not only of exogeneous DNA damage but also of endogenously induced

DNA damage that is an important source of genomic instability in cancer. This detrimental combination makes arsenic a 'special' indirect genotoxin (EFSA, 2024).

There are many epidemiological studies that provide sufficient evidence for an association between low to moderate exposure to inorganic arsenic (in drinking water) and both basal cell carcinoma and squamous cell carcinomas of the skin, bladder cancer and lung cancer (EFSA, 2024)

IARC has determined that inorganic arsenic is carcinogenic to humans (Group 1), and the US EPA has also classified inorganic arsenic as a human carcinogen (Group A) via the inhalation and oral routes (ATSDR, 2007; IRIS, 1991). This classification is based on the inhalation of arsenic-containing particulates by workers in occupational settings (smelters, coal-fired power plants, battery assembly, glass manufacturing and the electronics industry). IARC estimated that approximately 25% of daily dietary arsenic intake is from inorganic sources.

3.3.2 CADMIUM

Acute toxicity data for cadmium in humans are very scarce and there are no reliable human studies following acute-duration oral exposure. The no-observed-effect level (NOEL) of a single oral dose of cadmium is estimated to be 3 mg elemental cadmium/person, and the lethal doses range from 350 to 8,900 mg (EFSA, 2009b). Acute exposure to high doses of cadmium in laboratory animals results in a variety of effects, including altered haematological parameters, focal necrosis and degeneration of the liver, focal necrosis in renal tubular epithelium, necrosis and ulceration in the stomach and intestines, decreased motor activity, and testicular atrophy and necrosis (EFSA, 2009b).

Cadmium is primarily toxic to the kidneys and bones after repeated exposure in animals and humans (EFSA, 2009b). Chronic exposure to cadmium via the oral or inhalation routes has produced proximal tubule cell damage, proteinuria, glycosuria, amino aciduria, polyuria, decreased absorption of phosphate and enzymuria in humans and a number of laboratory animal species. The renal damage caused by cadmium is often cumulative and has been related to the lifetime cadmium dose; episodic exposures at any age contribute to a person's lifetime accumulated cadmium exposure and therefore risk.

IARC has classified cadmium as a human carcinogen (Group 1) based on animal and occupational studies and concluded that "there is sufficient evidence in humans for the carcinogenicity of cadmium and cadmium compounds" (IARC, 1993). Cadmium and cadmium compounds cause cancer of the lung and have also been associated with cancer of the kidney and prostate. However, the studies supporting this conclusion relate to occupational exposure by the respiratory route and it is uncertain whether this conclusion is relevant to oral exposure.

3.3.3 LEAD

Studies of lead exposure in humans as well as laboratory animals have reported effects on the nervous, cardiovascular, renal, immune, haematological and reproductive systems, developmental effects, and an increased incidence of cancer (EFSA, 2010; JECFA, 2011a). There are no HBGVs for lead as there is no evidence of thresholds for a number of critical health effects (developmental neurotoxicity in young children and cardiovascular effects and nephrotoxicity in adults). Hence, there is no level of exposure that is considered safe.

The acute toxicity of lead is low, but the ingestion of large amounts of lead can produce gastrointestinal symptoms, including colic, constipation, abdominal pain, anorexia and vomiting (JECFA, 2011a).

The critical effects that occur as a result of exposure to lead include developmental neurotoxicity in young children and cardiovascular and kidney effects in adults, with changes in the systolic blood pressure and the prevalence of chronic kidney disease being the critical endpoints in adults.

Exposure to lead during pregnancy has been associated with toxic effects on the human foetus, including an increased risk of preterm delivery, low birth weight and impaired mental development, such as decreased IQ scores (ATSDR, 2020).

Human studies are inconclusive regarding the association between lead exposure and other birth defects, but animal studies have shown a relationship between high lead exposure and birth defects (CDC, 2012).

Human studies are also inconclusive regarding the relationship between lead exposure and cancer risk. However, animal studies have reported kidney tumours in rats and mice exposed to lead via the oral route. Consequently, IARC has classified inorganic lead compounds as probably carcinogenic to humans (IARC, 2006).

3.3.4 MERCURY

The toxicity of mercury salts depends on their solubility. Mercury salts are corrosive, which enhances gastrointestinal permeability and absorption. Acute exposure to mercuric salts at high doses primarily causes burning chest pain, darkened discoloration of the oral mucous membrane and severe gastrointestinal symptoms due to extensive corrosive damage to the gastrointestinal tract (Park and Zheng, 2012). Following acute inorganic mercury poisoning, impaired renal function and damage have been reported. This is also supported by studies in animals where there is consistent evidence of dose- and duration-dependent increases in severity of renal toxicity, including damage to proximal tubules, distal tubules and glomerular membranes, loss of brush border membranes and necrosis (ATSDR, 1999).

The lethal dose of inorganic mercury following acute oral exposure has been estimated to be 29–50 mg/kg, with death attributed to renal failure, cardiovascular collapse and severe gastrointestinal damage

The kidney is the target organ for inorganic mercury, mainly the proximal convoluted tubules. Neurological and renal toxicity have been consistently observed in animals after oral exposure to inorganic mercury salts (ATSDR, 1999). Clinical symptoms and signs of inorganic mercury poisoning include polyuria and proteinuria (especially low molecular proteinuria), which can develop into nephritic syndrome in severe cases, with haematuria and anuria. Inorganic mercury salts generally do not cross the blood-brain barrier to induce neurotoxicity or cross the blood-placenta barrier to cause developmental toxicity as they are not lipid-soluble (Park and Zheng, 2012).

Mercuric chloride induced forestomach and thyroid tumours in male rats in carcinogenicity studies. There is limited evidence of renal tumours in male rats exposed to phenylmercuric acetate. IARC concluded that inorganic mercury compounds are not classifiable as to their carcinogenicity to humans (Group 3), based on inadequate evidence in humans for mercury and mercury compounds and limited evidence for carcinogenicity of mercuric chloride in experimental animals (forestomach tumours in rats) (ATSDR, 1999). The US EPA concluded that mercuric chloride is a possible human carcinogen (Group C) based on no human data

and limited evidence of carcinogenicity in animals (forestomach and thyroid tumours in male rats) (IRIS, 2012).

4. DOSE–RESPONSE INFORMATION

A point of departure (POD) is defined as the point on a toxicological dose–response curve established from experimental data or observational data generally corresponding to an estimated low effect level or no effect level. It marks the beginning of extrapolation to health-based guidance values (HBGVs) such as reference dose (RfD) or reference concentration (RfC), tolerable daily intake (TDI), tolerable weekly intake (TWI), provisional tolerable monthly intake (PTMI) or provisional tolerable weekly intake (PTWI). The most common PODs used are the no-observed-adverse-effect level (NOAEL), the lowest-observed-adverse-effect level (LOAEL), or the statistical benchmark dose (BMD).

The BMD approach has distinct advantages over the NOAEL approach in that the modelled BMD (BMD_{05}, BMD_{10} or other) reflects the shape of the dose–response curve and is less affected by the choice of experimental concentrations. However, the BMD approach requires a robust dataset and additional knowledge of statistical modelling. When no BMD can be calculated or is available, usually NOAEL or LOAEL values are applied.

4.1 ARSENIC

Many epidemiological studies show that the chronic intake of inorganic arsenic through diet or drinking water is associated with increased risk of cancers of the skin, bladder and lung. In 2009, the Panel on Contaminants in the Food Chain (CONTAM) of EFSA chose a benchmark response of 1% additional risk after modelling the dose–response data from key epidemiological studies for inorganic arsenic (EFSA, 2009a). For lung, skin, and bladder malignancies as well as skin lesions, a range of benchmark dose lower confidence limit ($BMDL_{01}$) values between 0.3 and 8 µg/kg bw/day were derived. Recently, CONTAM established a lower reference point of 0.06 µg/kg bw/day based on a case-control study on skin cancer (squamous cell carcinoma) (EFSA, 2024). The panel used the benchmark dose (lower confidence limit) (BMDL) based on a benchmark response (BMR) of 5% (relative increase of the background incidence after adjustment for confounders, $BMDL_{05}$). This is a conservative estimate of the lowest dose that could be associated with increased induction of skin cancer after exposure to inorganic arsenic. The reference point or $BMDL_{05}$ is also considered to be sufficiently low to cover lung cancer, bladder cancer, skin lesions, ischaemic heart disease, chronic kidney disease, respiratory disease, spontaneous abortion, stillbirth, infant mortality and neurodevelopmental effects, which are associated with higher exposure levels.

The Joint FAO / WHO Expert Committee on Food Additives (JECFA) also established a BMDL for a 0.5% increased incidence of lung cancer (JECFA, 2011a). The $BMDL_{0.5}$ was determined by using a range of assumptions to estimate exposure to inorganic arsenic from drinking water and food in the pivotal epidemiological study. The $BMDL_{0.5}$ for inorganic arsenic was estimated to be 3.0 µg/kg bw/day (2.0–7.0 µg/kg bw/day based on the range of estimated total dietary exposure). It should be noted that this range is higher than EFSA's recently derived $BMDL_{05}$. It should be noted that JECFA will reevaluate arsenic during October 2025. JECFA noted that the previously derived PTWI of 15 µg/kg bw (2.1 µg/kg bw/day) is in the region of the $BMDL_{0.5}$, therefore was no longer appropriate and was withdrawn.

Recently, FAO evaluated the safety of inorganic and organic arsenic at its 101th expert committee meeting and derived a range of new $BMDL_{0.5}$ values (0.3–0.34 µg/kg bw/day)

from three key human studies on ischemic heart disease (IHD) (JECFA, 2026). The Committee selected a $BMDL_{0.5}$ of 0.3 µg/kg bw/day for IHD as a POD and noted that the POD for IHD of 0.3 µg/kg bw/day is lower than the lowest benchmark dose lower confidence interval for a 0.1% increased incidence ($BMDL_{0.1}$) for cancer (lung) of 1 µg/kg bw/day. Consequently, a $BMDL_{0.5}$ of 0.3 µg/kg bw/day is used in characterising risks in this study as this value is more health-protective (JECFA, 2026).

PODs for inorganic arsenic are summarised in Table 7.

Table 7: Point of departures and reference dose for inorganic arsenic

Study / key effect	Point of departure (POD)	Uncertainty Factor (UF)	HBGV	Reference
Epidemiological studies / Incidences of lung and bladder cancer and for dermal lesions	$BMDL_{01}$ 0.3 to 8 µg/kg bw/day	-	-	(EFSA, 2009a)
Epidemiological studies / Incidences of lung cancer	$BMDL_{0.5}$ 3 µg/kg bw/day	-	-	(JECFA, 2011a)
Epidemiological studies / Incidences of skin cancer	$BMDL_{05}$ 0.03 µg/kg bw/day	-	-	(EFSA, 2024)
Epidemiological studies / ischemic heart disease	$BMDL_{01}$ 0.3 µg/kg bw/day			(JECFA, 2026)

HBGV: Health-based guidance value; bw: body weight; RfD: Reference dose; NOAEL: No-observed-adverse-effect level.
(Subscript denotes benchmark response of exposure dose associated with 1% extra risk)

4.2 CADMIUM

EFSA considered cadmium in 2009. The Panel did not consider the dose–response data for cancer as a sufficient basis for quantitative risk assessment and based their assessment on kidney effects (EFSA, 2009b). A meta-analysis was conducted on the relationship between urinary cadmium (a measure of cadmium body burden) and urinary β-2-microglobulin (B2M; a biomarker of renal tubular damage). A urinary reference point of 1 µg cadmium/g creatinine was derived, equating to a TWI of 2.5 µg/kg bw per week. Creatinine enters urine at a fairly constant rate and is used to standardise biomarker measurements.

JECFA published an addendum to their evaluation of cadmium in 2011 (JECFA, 2011a). JECFA followed a similar approach to EFSA but concluded that for those aged 50 years or older (a point at which cadmium in the body would have achieved a steady state) there was no evidence of increased B2M urinary excretion at urinary cadmium concentrations less than 5.24 µg/g creatinine. This equates to a PTMI of 25 µg/kg bw per month, equivalent to 5.8 µg/kg bw per week. The JECFA's HBGV is more than twice the EFSA value, when considered at the same timeframe.

EFSA subsequently reviewed the approach and assumptions used in deriving the TWI and compared them to the approach and assumptions employed by JECFA (EFSA, 2011a; b). Although there are some commonalities in both the EFSA's and JECFA's approach to deriving HBGV, there were some key differences that led to different HBGVs. The differences were seen in parameters selected as reference points to derive HBGV, the statistical approach to account for the variability and uncertainty of the marker of exposure (urinary cadmium concentration), the marker of response (B_2M) in the concentration-effect model and the methodology for transforming urinary cadmium concentrations into dietary intake values (EFSA, 2011b).

HBGVs for cadmium are summarised in Table 8.

Table 8: Health-based guidance values for cadmium

Study / key effect	Point of departure (POD)	Uncertainty factor (UF)	HBGV	Reference
Human studies-meta-analysis / urinary cadmium levels and beta-2-microglobulin	1 µg cadmium/g creatinine	Not required	TWI: 0.0025 mg/kg bw (2.5 µg/kg bw, equivalent to 0.36 µg/kg bw/day)	(EFSA, 2009b)
Human studies-meta-analysis / urinary cadmium levels and beta-2-microglobulin	-	-	PTMI: 0.025 mg/kg bw (25 µg/kg bw per month, equivalent to 0.82 µg/kg bw/day)	(JECFA, 2011a)

HBGV: Health-based guidance value; NOAEL: No-observed-adverse-effect level; RfD: Reference dose; bw: body weight; TWI: tolerable weekly intake; PTMI: provisional tolerable monthly intake

4.3 LEAD

According to the US EPA, the degree of uncertainty regarding the health effects of lead is very low. The critical effects that occur as a result of exposure to lead (changes in levels of certain blood enzymes, elevation of blood pressure and neurobehavioral deficits in children) occur at exposure levels (measured as blood lead) so low as to be essentially without a threshold. Therefore, the USEPA's RfD Work Group considered it inappropriate to develop an RfD for inorganic lead (US EPA, 2004). This is consistent with the conclusions of other evaluations (EFSA, 2010; JECFA, 2011a). Consequently, exposure to lead should be kept as low as reasonably achievable. In New Zealand, the health advice is that there is no safe level of lead and lead exposure needs to be avoided as much as possible (Ministry of Health, 2021).

For non-threshold effects, BMDs for selected benchmark response, typically 1–10% extra risk of the critical effect, have been derived. Developmental neurotoxicity was identified as a critical effect in young children. In adults, cardiovascular risk related to elevation of blood pressure was identified as the critical effect (JECFA, 2011a). The respective BMDLs derived from blood lead levels in µg/L (corresponding dietary intake values in µg/kg bw/day) were developmental neurotoxicity $BMDL_{01}$, 12 (0.5); and effects on systolic blood pressure $BMDL_{01}$, 36 (1.3 to 1.5) (EFSA, 2010; JECFA, 2011a; MPI, 2018). The current risk assessment does not consider products consumed by young children, the age group at risk of developmental neurotoxicity. Consequently, the BMDLs, based on effects on prevalence of increased blood pressure was used in the risk assessment.

PODs for lead are summarised in Table 9.

Table 9: Point of departures for lead

Study / key effect	Point of departure (POD)	Uncertainty factor (UF)	HBGV	Reference
Long-term exposure in workers / increased systolic blood pressure	$BMLD_{01}$: 1.5 µg/kg bw/day	-	-	(EFSA, 2010; JECFA, 2011a; MPI, 2018)

Long-term exposure in workers / developmental toxicity	$BMLD_{10}$: 0.5 µg/kg bw/day	-	-	(EFSA, 2010)

4.4 MERCURY

As methylmercury mainly occurs in foods of marine origin, mercury present in AvMs is almost certainly inorganic. JECFA derived a PTWI for inorganic mercury of 4 µg/kg bw, based on a BMD for subchronic toxicity in rats (JECFA, 2011a). Following oral exposure to mercuric chloride in a subchronic toxicity study in rats, increased relative kidney weight in male and female rats was considered as the critical effect for establishing a PTWI. The PTWI was derived from the $BMDL_{10}$ (lower 95th percentile confidence limit for a benchmark dose giving a 10% change in response over baseline) of 0.11 mg/kg bw/d as mercuric chloride for kidney weight changes in male rats. This corresponds to 0.06 mg/kg bw/d as Hg, adjusted from a five days/week dosing schedule to an average daily dose and for the percent contribution of inorganic mercury to an Hg (II) chloride dose µg/kg bw. The PTWI for inorganic mercury is considered applicable to dietary exposure to total mercury from foods other than fish and shellfish. The CONTAM Panel of EFSA also agreed with the rationale of JECFA in setting a PTWI using kidney weight changes in male rats as the critical effect (EFSA, 2012).

The HBGV of mercury is summarised in Table 10.

Table 10: Health-based guidance value for inorganic mercury

Study / key effect	Point of departure (POD)	Uncertainty factor (UF)	Reference dose (RfD)	Reference
Rats, 6-month drinking water study / No effects observed	$BMLD_{10}$: 0.112 mg/kg bw/day corresponding to 0.06 mg/kg bw/day	100	PTWI: 0.004 mg/kg bw (4 µg/kg bw equivalent to 0.57 µg/kg bw/day)	(EFSA, 2012; JECFA, 2011a)

HBGV: Health-based guidance value; bw: body weight; BMDL: = 95% lower confidence limit on the BMD; PTMI: provisional tolerable weekly intake. (subscript denotes benchmark response of exposure dose associated with 10% extra risk)

4.5 SUMMARY

JEFCA and EFSA have established HBGVs for cadmium and inorganic mercury only. For inorganic arsenic and lead, PODs will be utilised in the risk assessment. Given that the HBGVs and PODs established by JECFA and EFSA differ in some cases, the JECFA-established HBGVs and PODs will be used in the current risk assessment, as these have an international scope, while those established by EFSA are primarily established for the European population.

5. EXPOSURE ASSESSMENT

As previously discussed, consumers in New Zealand can purchase AvMs without prescription from both physical and virtual retailers. The New Zealand survey described in section 2.3 of this report sampled AvMs that were intended solely for adult consumption by the oral route (Gautam, 2025). The majority of AvM labels and manufacturer's websites make claims for their products for preserving general health and wellbeing. Other positive effects asserted for the AvMs include adaptogenic and stress-relieving qualities, immunomodulatory and antioxidant properties, enhancement of stamina and energy, supportive functions in microbial balance and general bodily harmony, improvement of vigour, increase in strength, assistance in muscle growth and athletic performance, and support for intellect, focus, and the nervous system. Consequently, prolonged use of AvMs is anticipated, as users look to achieve these health-supportive effects.

The oral risks of AvMs containing heavy metals were evaluated by estimating chronic daily intake (CDI) (US EPA, 1989; 2001). The CDI (mg/kg bw/day) depends on the metal concentration in the AvMs, the daily AvMs intake and the body weight of adult users, and is calculated by the below equation. CDIs for specific heavy metals and individual AvMs are included in APPENDIX B: and are calculated as:

$$\mathrm{CDI} = \frac{\mathrm{C} \times \mathrm{IR}}{\mathrm{BW}}$$

where C is the concentration (mg/kg) of inorganic arsenic, cadmium, lead or mercury in an AvM. Samples that were found to have detectable levels of at least one of arsenic (n=34), cadmium (n=32), lead (n=45), and mercury (n=15) were considered for the risk assessment.

IR ($kg \cdot day^{-1}$) is the daily ingestion rate and was calculated based on the recommended dose from the label for each AvM and is presented in APPENDIX A:.

BW is the user's body weight. For the current risk assessment, the 25th percentile body weight for New Zealand adults, 66.8 kg, rounded off to 70 kg, was selected to provide a conservative estimate of oral exposure.

CDI was calculated for each AvM in which the heavy metals were found above the detection limit.

6. RISK CHARACTERISATION

Risk characterisation is the final step of the risk assessment process that integrates hazard identification, hazard characterisation and exposure assessment to estimate the likelihood of adverse effects in a given population.

Inorganic arsenic is a known human carcinogen and there is no safe level for lead exposure; therefore, these metals are considered to have no dose threshold for their adverse effects. Hence, there is no HBGV available to directly characterise the exposure risk associated with oral exposure of inorganic arsenic and lead. Therefore, in both the cases the Margin of Exposure (MOE) approach has been used to characterise the oral exposure risk (JECFA, 2009). The MOE is calculated by dividing the toxicological point of departure (BMDL or NOAEL) by the estimated oral exposure of the specific chemical:

$$\mathrm{MOE} = \frac{\mathrm{BMDL}}{\mathrm{CDI}}$$

For a genotoxic carcinogen like arsenic, an MOE of 10,000 or greater has been proposed as indicating low concern for public health if it is based on the benchmark-dose lower bound (BMDL) from an animal study (EFSA, 2005). However, the BMDLs for arsenic are derived from human cancer data (see Table 7). According to EFSA, there are no precedents in identification of an MOE of low concern using BMDL derived from human cancer data (EFSA, 2024). Consequently, an MOE of low health concern was not specified in the current study.

According to EFSA, for lead, an MOE of 10 or greater would be sufficient to ensure that there was no appreciable risk of a clinically significant effect on systolic blood pressure. EFSA also reported that even at MOEs between 1 and 10 the risk would be very low (EFSA, 2010).

Some recent publications have used an oral reference dose or PTWI in the risk characterisation of inorganic arsenic and lead. However, these HBGVs were withdrawn more than a decade ago by the respective evaluation bodies (EFSA, 2010; JECFA, 2011b; US EPA, 2004). The use of withdrawn HBGVs does not align with the best practices for conducting a risk assessment. There are no HBGVs for lead and arsenic as there is no safe level of exposure.

For heavy metals that have a HBGV (cadmium and inorganic mercury), the estimated oral exposure to a specific heavy metal is compared to the established HBGV (TDI, TWI or PTMI) and a risk quotient (RQ) is calculated using the equation:

$$\mathrm{RQ} = \frac{\mathrm{CDI}}{\mathrm{HBGV}}$$

Where CDI is the chronic dietary (oral) intake. RQs>1 represent a cause for concern while RQs<1 represent a low or acceptable level of health concerns.

Diet is often the predominant route of human exposure to toxicants. To provide additional context to the current risk assessment, CDIs of heavy metals from the use of AvMs were compared to the mid-bound mean dietary exposure for each heavy metal for young adult males (19 to 24 years) from the New Zealand total diet study 2016 (NZTDS) (MPI, 2018) to provide further context.

7. RESULTS

7.1 CHRONIC DAILY INTAKES AND COMPARISONS TO DIETARY EXPOSURE

For the current risk assessment, the daily consumption of the tested AvMs was taken into account, at the maximum doses indicated on the label of each product (APPENDIX A:).

The results of the oral exposure assessment for the heavy metals present in AvMs for individual products are presented in APPENDIX B:. The mean, median and range of CDIs of each heavy metal from consuming AvMs are summarised in Table 11.

Table 11: Chronic daily intake values (µg/kg bw/day) of heavy metals in adults through the consumption of tested AvMs

Heavy metal	Median (range)	Mean
Arsenic	0.01 (0.001 to 210)	11 (adjusted: 0.01)[a]
Cadmium	0.0005 (8.57E-05 to 0.003)	0.001
Lead	0.014 (1.57E-06 to 0.0036)	0.10
Mercury	0.07 (1.71E-04 to 4.60)	0.62

[a] One sample contained a very high concentration of arsenic (presumed to be inorganic). The adjusted mean is the mean calculated after exclusion of this sample.

One AvM sample was found to have extremely high levels (9,800 mg/kg) of total arsenic. The impact of this sample on the summary statistics in Table 11 is apparent, with the mean CDI much greater than the median. Therefore, an adjusted CDI (0.01 µg/kg bw/day) was estimated by excluding the extremely high arsenic concentration from a single AvM sample. The CDI for total arsenic ranged from 0.001 to 210 µg/kg bw/day. The highest CDI of arsenic was from the AvM that had high arsenic concentration. Comparing heavy metal exposure resulting from AvM ingestion to dietary background exposures is helpful in providing context to exposure from various sources. In the 2016 NZTDS, the mid-bound mean dietary exposure of inorganic arsenic was reported to be 0.14 µg/kg bw/day (MPI, 2018). The unadjusted mean CDI (11 µg/kg bw/day) of arsenic from use of AvMs is substantially higher than the mid-bound mean dietary exposure. However, upon excluding the unexpected total arsenic result in one AvM sample the adjusted mean CDI was 0.01 µg/kg bw/day, which is approximately 7% of the mid-bound mean dietary exposure of inorganic arsenic (0.14 µg/kg bw/day). Therefore, diet is a much greater contributor to inorganic arsenic exposure than 'typical' AvMs.

The CDIs for cadmium from intake of AvMs ranged from 8.57E-05 to 0.03 µg/kg bw/day. The mean CDI (0.001 µg/kg bw/day) of cadmium from AvMs was less than 1% of the mid-bound mean adult dietary exposure of cadmium (0.21 µg/kg bw/day) (MPI, 2018). Therefore, diet is a much greater contributor to cadmium exposure than typical AvMs and is a greater contributor to cadmium exposure than any individual AvM.

The CDIs for lead ranged from 0.001 to 3.6 µg/kg bw/day. The mean CDI (0.1 µg/kg bw/day) of lead from AvMs was 1.25 times higher than the mid-bound mean dietary exposure of lead (0.08 µg/kg bw/day) through different food sources. Therefore, long-term consumption of AvMs can increase the overall exposure to lead. As mentioned previously, there is no safe level of lead and lead exposure, therefore exposure to lead should be kept as low as reasonably achievable.

The CDIs for total mercury ranged from 1.71E-04 to 4.60 µg/kg bw/day. As previously mentioned, mercury in AvMs is almost certainly inorganic mercury. The mean CDI (0.62 µg/kg bw/day) of mercury from AvMs was 15 times higher than the mean dietary exposure of mercury (0.05 µg/kg bw/day) through different food sources. Therefore, long-term consumption of AvMs is expected to markedly increase the overall exposure to mercury.

7.2 RISK CHARACTERISATION

The MOE was used to characterise the oral exposure risk due to the consumption of AvMs contaminated with arsenic and lead. For cadmium and mercury, RQ was determined. Calculated MOE and RQ from consumption of individual AvMs are reported in APPENDIX C:.

The MOEs for arsenic in individual AvMs ranged from 0.001 to 190. The lowest MOE was from an AvM that was found to have extremely high levels (9,800 mg/kg) of arsenic. For all the other AvMs, the MOE ranged from 4.6 to 190. There is no safe level of arsenic as it is a genotoxic carcinogen and exposure to arsenic should be kept as low as reasonably achievable. While no 'acceptable' level for MOEs derived from PODs from human studies has been proposed, MOEs of greater than 100 and exposures from AvMs that are substantially less than mean dietary exposures suggest that arsenic exposure from most AvMs will not be the main determinant of overall arsenic exposure risk.

The mean CDI of lead from AvMs was higher than the mid-bound mean dietary exposure from different food sources. The mean oral exposure of lead from AvMs and food were combined to estimate overall risks. The combined mean CDI of lead was 0.17 µg/kg bw/day and the MOE was 8. The MOE for individual AvMs containing lead ranged from 0.4 to 1,000. There were only two AvMs for which the MOE (4 and 0.4) was less than 10, which raise a concern for human health risk. Even though the concentration of lead in one AvM (6 mg/kg) was not very high, the MOE was less than one due to the very high recommended dose (10 to 20 g twice a day) of the AvM. The consumption of other AvMs do not raise a concern for human health risk as the MOEs are more than 10. Nevertheless, there is no safe level of lead and lead exposure, therefore exposure to lead should be kept as low as reasonably achievable and efforts should be made to ensure the lead content of AvMs is as low as possible.

None of the AvMs raised any health concerns due to the presence of cadmium as the RQs (0.0001 to 0.040) were less than one for all the products. Even after considering the combined cadmium exposure from the diet and use of AvMs, RQs remain of low concern.

The mean CDI of mercury was higher than the mid-bound mean dietary exposure from different food sources. Mean mercury exposures from AvMs alone exceed the PTWI for inorganic mercury. Consideration of combined dietary and AvMs exposure will further increase the risk. The combined mean CDI was 0.66 µg/kg bw/day and the RQ was 1.10, slightly >1. This shows that long-term consumption of AvMs containing mercury may increase overall exposure to mercury and raise health concerns. However, for most of the individual AvMs, the RQs ranged from 0.0003 to 0.80 with no appreciable health risks if taken according to the label instructions and recommended dose. There were four AvMs with high levels of mercury for which the RQs were more than one which may raise a concern for human health risks. This suggests that efforts should be made to decrease the mercury content of AvMs.

8. CONCLUSIONS

The present risk assessment was conducted to evaluate the human health risks associated with consuming AvMs contaminated with heavy metals. CDIs were estimated only for AvMs that were found to have detectable levels of arsenic, cadmium, mercury and lead in a survey (2024-2025) funded by Health New Zealand.

The results of this risk assessment show that long-term consumption of some AvMs with high level of heavy metals (arsenic, lead and/or mercury) can present human health risks of concern. Consumption of AvMs for long periods with high levels of mercury and lead can contribute to increases in overall exposure to these heavy metals to undesirable levels. Heavy metals present in low levels can also be of concern when the daily recommended dose of AvM is very high. There is also no safe level for lead and arsenic exposure, therefore exposure to lead and arsenic should be kept as low as reasonably achievable.

The MOE and RQ indicate that most of the AvMs did not raise any health concerns if they are taken according to the label instructions and within the recommended dose. However, high levels of heavy metals in some AvMs suggest that efforts to decrease heavy metals concentrations in these products should be supported.

9. REFERENCES

Abollino O, Giacomino A, Paparella G, Magi E, Conca E, Malandrino M. (2018) Potentially toxic elements in ayurvedic formulations: total and bioaccessible content. Microchemical Journal; 136: 236-243.

ATSDR. (1999) Toxicological profile for mercury (update). USA: Agency for Toxic Substances and Disease Registry.

ATSDR. (2007) Toxicological profile for arsenic. USA: Agency for Toxic Substances and Disease Registry.

ATSDR. (2020) Toxicological profile for lead. USA: Agency for Toxic Substances and Disease Registry.

Bhalla A, Pannu A. (2022) Are Ayurvedic medications store house of heavy metals? Toxicology Research; 11(1): 179-183.

Breeher L, Gerr F, Fuortes L. (2013) A case report of adult lead toxicity following use of ayurvedic herbal medication. Journal of Occupational Medicine and Toxicology; 8: 1-5.

Breeher L, Mikulski MA, Czeczok T, Leinenkugel K, Fuortes LJ. (2015) A cluster of lead poisoning among consumers of ayurvedic medicine. International Journal of Occupational and Environmental Health; 21(4): 303-307.

CDC. (2012) CDC updates guidelines for children's lead exposure. Environmental Health Perspectives; 120(7): 1-a268.

Ciocan C, Mansour I, Beneduce A, Loia RC, Milanesio N, Declementi M, Godono A, Garzaro G, Pira E. (2021) Lead poisoning from ayurvedic treatment: a further case. La Medicina del Lavoro; 112(2): 162.

ConsumerNZ. (2022) Why are natural health products so popular? Accessed at: https://www.consumer.org.nz/articles/why-are-natural-health-products-so-popular. Accessed: 17 June 2024.

Dargan PI, Gawarammana IB, Archer JR, House IM, Shaw D, Wood D. (2008) Heavy metal poisoning from ayurvedic traditional medicines: an emerging problem? International Journal of Environment and Health; 2(3-4): 463-474.

Deswal M, Deswal P, Laura J. (2019) Risk assessment of some herbal powders and herbal formulations contaminated with heavy metals. International Journal of Pharma Sciences and Research; 10(1): 393.

Deswal M, Deswal P, Laura J. (2022) Study on heavy metals in some ayurvedic herbal products and risk assessment of their calculated average daily dose intake in humans. Journal of Herbal Medicine; 34: 100569.

Doshi M, Annigeri RA, Kowdle PC, Subba Rao B, Varman M. (2019) Membranous nephropathy due to chronic mercury poisoning from traditional Indian medicines: report of five cases. Clinical Kidney Journal; 12(2): 239-244.

EFSA. (2005) Opinion of the Scientific Committee on a request from EFSA related to a harmonised approach for risk assessment of substances which are both genotoxic and carcinogenic. EFSA Journal; 3(10): 282.

EFSA. (2009a) Scientific opinion on arsenic in food. EFSA Journal; 7(10): 1351.

EFSA. (2009b) Cadmium in food-Scientific opinion of the panel on contaminants in the food chain. EFSA Journal: 1-139.

EFSA. (2010) Scientific opinion on lead in food EFSA panel on contaminants in the food chain (CONTAM). EFSA Journal; 8(4): 1-151.

EFSA. (2011a) Statement on tolerable weekly intake for cadmium. EFSA Journal; 9(2): 1975.

EFSA. (2011b) Comparison of the approaches taken by EFSA and JECFA to establish a HBGV for Cadmium. EFSA Journal; 9(2): 2006.

EFSA. (2012) Scientific opinion on the risk for public health related to the presence of mercury and methylmercury in food. EFSA Journal; 10(12): 2985.

EFSA. (2024) Update of the risk assessment of inorganic arsenic in food. EFSA Journal; 22(1): e8488.

EHINZ. (2023) Non-occupational/unknown source of lead absorption notifications. Accessed at: https://www.ehinz.ac.nz/indicators/hazardous-substances/non-occupationalunknown-source-of-lead-absorption-notifications/. Accessed: 12 November 2025.

Fernández S, Pollio G-A, Domínguez V, Nogué S, Torra M, Cardellach F. (2015) Outbreak of lead poisoning associated with ayurvedic medicine. Medicina Clínica (English Edition); 144(4): 166-169.

Food Safety News. (2015) Imported dietary supplements recalled for elevated lead and mercury levels. Accessed at: https://www.foodsafetynews.com/2015/09/imported-dietary-supplements-recalled-for-elevated-lead-and-mercury-levels/. Accessed: 7 July 2025.

Gautam A. (2025) Survey report on heavy metals in ayurvedic medicines available in New Zealand Christchurch: ESR.

Giacomino A, Abollino O, Malandrino M, Karthik M, Murugesan V. (2011) Determination and assessment of the contents of essential and potentially toxic elements in ayurvedic medicine formulations by inductively coupled plasma-optical emission spectrometry. Microchemical Journal; 99(1): 2-6.

Giacomino A, Abollino O, Casanova C, La Gioia C, Magi E, Malandrino M. (2015) Determination of the total and bioaccessible contents of essential and potentially toxic elements in ayurvedic formulations purchased from different commercial channels. Microchemical Journal; 120: 6-17.

Gitelman J, An H, Spilchuk V, Kim J. (2023) Lead toxicity from ayurvedic medicines. Canadian Medical Association Journal; 195(30): E1010-E1012.

Gunturu KS, Nagarajan P, McPhedran P, Goodman TR, Hodsdon ME, Strout MP. (2011) Ayurvedic herbal medicine and lead poisoning. Journal of Hematology & Oncology; 4: 1-6.

Health Canada. (2019) Public advisory_Health Canada warns that products sold by Dutta Health Centre-Ayurvedic Clinic in Surrey, B.C., may pose health risks. Accessed at: https://recalls-rappels.canada.ca/en/alert-recall/health-canada-warns-products-sold-dutta-health-centre-ayurvedic-clinic-surrey-bc-may. Accessed: 7 July 2025.

HNZ. (2025). Elevated Blood Lead Levels from traditional medicine – Cluster Summary (unpublished), unpublished.

HSA. (2024) Planet ayurveda water-ex tablets. Accessed at: https://www.hsa.gov.sg/announcements/product-recall/planet-ayurveda-water-ex-tablets. Accessed: 4 July 2025.

HSA. (2025) Regulatory overview of traditional medicines. Understand the requirements to import, manufacture or sell traditional medicines in Singapore. Accessed at: https://www.hsa.gov.sg/traditional-medicines/overview. Accessed: 8 July 2025.

Hsiao C-Y, Gresham C, Marshall MR. (2019) Treatment of lead and arsenic poisoning in anuric patients–a case report and narrative review of the literature. BMC nephrology; 20: 1-13.

IARC. (1993) Cadmium and cadmium compounds. In: (eds). Beryllium, cadmium, mercury, and exposures in the glass manufacturing industry. International Agency for Research on Cancer.

IARC. (2006) IARC monographs on the evaluation of carcinogenic risks to humans: Inorganic and organic lead compounds. Accessed at: https://publications.iarc.who.int/Book-And-Report-Series/Iarc-Monographs-On-The-Identification-Of-Carcinogenic-Hazards-To-Humans/Inorganic-And-Organic-Lead-Compounds-2006. Accessed: 27 October 2026.

IRIS. (1991) Arsenic, inorganic; CASRN 7440-38-2_chemical assessment summary. Accessed at: https://iris.epa.gov/ChemicalLanding/&substance_nmbr=278. Accessed: 18 August 2023.

IRIS. (2012) Mercuric chloride (HgCl2); CASRN 7487-94-7. Accessed at: https://cfpub.epa.gov/ncea/iris/iris_documents/documents/subst/0692_summary.pdf. Accessed: 1 August 2023.

Jayawardene I, Saper R, Lupoli N, Sehgal A, Wright RO, Amarasiriwardena C. (2010) Determination of in vitro bioaccessibility of Pb, As, Cd and Hg in selected traditional Indian medicines. Journal of Analytical Atomic Spectrometry; 25(8): 1275-1282.

JECFA. (2009) Principles and methods for the risk assessment of chemicals in food. Geneva: Food and Agriculture Organization of the United Nations and the World Health Organization.

JECFA. (2011a) Safety evaluation of certain food additives and contaminants / prepared by the seventy-third meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA). WHO Food Additives Series, No. 64. Geneva: World Health Organization and Food and Agriculture Organization of the United Nations.

JECFA. (2011b) Safety evaluation of certain food additives and contaminants: Prepared by the Seventy-third meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA). WHO Food Additives Series, No. 64. Geneva: World Health Organization and Food and Agriculture Organization of the United Nations.

JECFA. (2026) Evaluation of certain contaminants in food: one-hundred-and-first report of the Joint FAO/WHO Expert Committee on Food Additives WHO Technical Report Series, No. 1061. Geneva: World Health Organization and Food and Agriculture Organization of the United Nations.

Kales SN, Christophi CA, Saper RB. (2007) Hematopoietic toxicity from lead-containing Ayurvedic medications. Medical Science Monitor: International Medical Journal of Experimental and Clinical Research; 13(7): CR295.

Kamat SS, Suryawanshi R. (2015) Quantitative analysis of toxic elements by ICP-MS in herbal tablets. Journal of Academia and Industrial Research 3(9): 445.

Martena MJ, van Der Wielen JC, Rietjens IM, Klerx WN, De Groot HN, Konings EJ. (2010) Monitoring of mercury, arsenic, and lead in traditional Asian herbal preparations on the Dutch market and estimation of associated risks. Food Additives and Contaminants; 27(2): 190-205.

Mathee A, Naicker N, Teare J. (2015) Retrospective investigation of a lead poisoning outbreak from the consumption of an ayurvedic medicine: Durban, South Africa. International Journal of Environmental Research and Public Health; 12(7): 7804-7813.

Medsafe. (2024a) Recent cases of lead poisoning with ayurvedic medicines. Accessed at: https://www.medsafe.govt.nz/safety/Alerts/Ayurvedic_Medicines_Lead_Poisioning.asp. Accessed: 12 June 2025.

Medsafe. (2024b) Ayurvedic medicines: cases of lead poisoning in New Zealand. Accessed at: https://www.medsafe.govt.nz/safety/Alerts/Ayurvedic_Medicines_Lead_Poisioning.asp. Accessed: 7 July 2025.

Medsafe. (2025) Safety information_alert communication_ayurvedic medicines update. Accessed at: https://www.medsafe.govt.nz/safety/Alerts/Ayurvedic-medicines-update.asp. Accessed: 4 August 2025.

Mikulski MA, Wichman MD, Simmons DL, Pham AN, Clottey V, Fuortes LJ. (2017) Toxic metals in ayurvedic preparations from a public health lead poisoning cluster investigation. International Journal of Occupational and Environmental Health; 23(3): 187-192.

MPI. (2018) 2016 New Zealand total diet study. Accessed at: https://www.mpi.govt.nz/dmsdocument/43177-2016-NZ-Total-Diet-Study-with-Appendices-report-. Accessed: 30 July 2026.

Mustatea G, Ungureanu E, Iorga S, Ciotea D, Popa M. (2021) Risk assessment of lead and cadmium in some food supplements available on the Romanian market. Foods; 10: 581.

Nath A, Chakraborty D, Das S. (2020) Assessment of lead and cadmium in fifty-four Indian herbal medicine: tribal and marketed varieties. Environmental Science and Pollution Research; 27: 4127-4136.

Park J-D, Zheng W. (2012) Human exposure and health effects of inorganic and elemental mercury. Journal of Preventive Medicine and Public Health; 45(6): 344.

Philips CA, Ahamed R, Abduljaleel JK, Rajesh S, Theruvath AH, Raveendran R, Augustine P. (2022) Ayurvedic treatment induced severe alcoholic hepatitis and non-cirrhotic portal hypertension in a 14-year-old girl. Oxford Medical Case Reports; 2022(10): 113.

Pinto B, Goyal P, Flora S, Gill K, Singh S. (2014) Chronic arsenic poisoning following ayurvedic medication. Journal of Medical Toxicology; 10: 395-398.

Rai V, Kakkar P, Misra C, Ojha S, Srivastava N, Mehrotra S. (2007) Metals and organochlorine pesticide residues in some herbal ayurvedic formulations. Bulletin of Environmental Contamination and Toxicology; 79: 269-272.

Saper RB, Kales SN, Paquin J, Burns MJ, Eisenberg DM, Davis RB, Phillips RS. (2004) Heavy metal content of ayurvedic herbal medicine products. Jama; 292(23): 2868-2873.

Saper RB, Phillips RS, Sehgal A, Khouri N, Davis RB, Paquin J, Thuppil V, Kales SN. (2008) Lead, mercury, and arsenic in US-and Indian-manufactured ayurvedic medicines sold via the Internet. Jama; 300(8): 915-923.

Spriewald B, Rascu A, Schaller K, Angerer J, Kalden J, Harrer T. (1999) Lead induced anaemia due to traditional Indian medicine: a case report. Occupational and Environmental Medicine; 56(4): 282.

Steinhoff B. (2019) Quality of herbal medicinal products: State of the art of purity assessment. Phytomedicine; 60: 153003.

Tiwari AK, Tripathi MK, Dwivedi N, Tiwari A, Tripathi SP, Dwivedi N, Ahirwar PK, Pathak J. (2018) Standardization of dhanyapanchaka kvatha ghana vati-an ayurvedic formulation. Indian Journal of Traditional Knowledge 17: 386-390.

Tsutsui RS, Van Schalkwyk J, Spriggs D. (2013) Lead poisoning from ayurvedic medicines. New Zealand Medical Journal; 126(1374): 80-83.

US EPA. (1989) Risk-assessment guidance for superfund. Volume 1. Human health evaluation manual. Part A. Interim report (Final). Accessed at: https://semspub.epa.gov/work/HQ/191.pdf. Accessed: 5 July 2025.

US EPA. (2001) Risk Assessment guidance for superfund: volume III-part a. Accessed at: https://semspub.epa.gov/work/HQ/134487.pdf. Accessed: 5 July 2025.

US EPA. (2004) Integrated risk information system (IRIS)_chemical assessment summary_lead and compounds (inorganic); CASRN 7439-92-1. Accessed at: https://iris.epa.gov/ChemicalLanding/&substance_nmbr=277. Accessed: 22 July 2025.

US FDA. (2025) New York wholesale group recalls zaarah herbals rasayan churan, zaarah herbals gurmar powder, zaarah herbals vasaka powder and zaarah herbals bhringraj powder because of possible health risk. Accessed at: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/new-york-wholesale-group-recalls-zaarah-herbals-rasayan-churan-zaarah-herbals-gurmar-powder-zaarah. Accessed: 7 July 2025.

Van der Sluis A, Sutherland K. (2025) Lead pencil: a case of intractable abdominal pain secondary to lead poisoning. The New Zealand Medical Journal (Online); 138(1610): 112-115.

Vinogradova N, Glukhov A, Chaplygin V, Kumar P, Mandzhieva S, Minkina T, Rajput VD. (2023) The content of heavy metals in medicinal plants in various environmental conditions: A review. Horticulturae; 9(2): 239.

WHO. (2007) WHO guidelines for assessing quality of herbal medicines with reference to contaminants and residues. 1-89.

WHO. (2023) Integrating traditional medicine in health care. Accessed at: https://www.who.int/southeastasia/news/feature-stories/detail/integrating-traditional-medicine. Accessed: 9 July 2025.

APPENDIX A: DESCRIPTION OF AYURVEDIC MEDICINES AND RESULTS OF HEAVY METAL ANALYSIS

Table 12: Description and ingestion rate of Ayurvedic medicines

Sample code	Dosage form	Active ingredients	Therapeutic uses	Direction for use	IR (kg/d)
24Ayur-001	Tablets	Giloy (*Tinospora cordifolia*)	Immunity booster, aiding digestion, purifying blood, general debility and different types of fever	1 tablet (580 mg) twice daily	0.0010
24Ayur-002	Tablets	Gokshura (*Tribulus terrestris*) fruit extract	Improves vigour, boosts strength and stamina. Also enhances penile erection	1–2 tablets (250 mg) twice daily	0.0010
24Ayur-004	Tablets	Extracts of Svarnapatri (*Cassia angustifolia* Vahl.), Haritaki (*Terminalia chebula* Retz.), Yasti (*Glycyrrhiza glabra* Linn.), Triphala (*Emblica officinalis* Geartn, *Terminalia chebula*, *Terminalia belerica*.). Powders of Misreya (*Foeniculum vulgare* Mill.), Sanchal, Sarjika Kshara, Oil of Eranda (*Ricinus communis* Linn)	Immunomodulator and antioxidant, respiratory protection from pollutants	1–2 tablets to be taken with water at bedtime or as advised by physician	0.0010
24Ayur-006	Capsule	Ashwagandha (*Withania somnifera*)	Weakness and fatigue	1–2 capsules (451 mg) twice daily	0.0015
24Ayur-008	Tablets	*Emblica officinalis, Swertia chirata, Terminalia chebula, Piper nigrum, Curcuma zedoaria*	Antipyretic, respiratory infections, dyspepsia and loss of appetite	2 tablets (250 mg) thrice a day	0.0015

Sample code	Dosage form	Active ingredients	Therapeutic uses	Direction for use	IR (kg/d)
24Ayur-009	Tablets	Daru Haldi (*Berberis aristata*), Karanj (*Caesalpinia bonducella*), Haldi (*Curcuma longa*), Neem (*Azadirachta indica*), Manjishta *(Rubbia cordifolia*), Kali jiri (*Centratherum anthelminticum*), Chandan swet (*Santalum album*), Amla (*Emblica officinalis*),	Detoxifies blood and caters to skin ailments like acne and serious skin problems like eczema, scabies, leprosy, and leukoderma	1–2 tablets (250 mg) twice daily	0.0015
24Ayur-010	Wet extract (20 gm)	Shilajeet, Triphala Kwath	Helps maintain overall health and wellbeing, boosts stamina and energy levels	1–2 drops with milk in the morning and evening	0.0003
24Ayur-011	Tablets	Vayavidanga (*Embelia ribes*) Sonth (*Zingiber officinale*) Pippali (*Piper longum*) Harad (*Terminalia chebula*)	Beneficial in chronic fever, cough, cold, respiratory tract infections and other viral infections	1–2 tablets (250 mg) twice daily or as directed by the physician	0.001
24Ayur-012	Tablets	Arjuna Bark, Ashwagandha Root, Vidarikand, Amalaki, Licorice Root, Cardamom, and other herbal extracts	For cardiovascular problems. It helps regulate bad cholesterol in the blood and helps prevent plaque formation in heart arteries	1–2 tablets (500 mg) twice daily empty stomach with water or as directed by the physician	0.002
24Ayur-013	Capsule	Ashvagandha, Shilajit	Helps maintain overall health and wellbeing boosts stamina and energy levels	1–2 capsules (450 mg) twice daily	0.002
24Ayur-015	Capsule	Shilajit, Amla Rasayan	Helps maintain overall health and well-being, boosts stamina and energy levels	1–2 capsules (450 mg) twice daily	0.002

Sample code	Dosage form	Active ingredients	Therapeutic uses	Direction for use	IR (kg/d)
24Ayur-017	Capsule	*Nigella sativa* (Black Seed), Ginger, Garlic	General health and immunity booster, beneficial properties, including antioxidant activity, as well as its supportive roles in microbial balance and overall bodily harmony	1 capsule (500 mg) once or twice daily	0.001
24Ayur-018	Capsule	Akarakarabha, Ashwangandha, *Dioscorea bulbifera* Rz, Gokshura, Karpuram, Kunkuma (*Crocus sativus* Linn.), Lavang (*Syzygium aromaticum*), Mucuna Prurita, Musali, *Myristica fragrans*, Jatiphala, Rajat Bhasma, Sudh Shilajeet (Black Bitumen Purified), Swarna Bhasma, Tvak (*Cinnamomum zeylanicam*), Vidari, Yasad Bhasma	Helps maintain overall health and well-being Boosts stamina and energy levels	1–2 capsules (500 mg) twice daily	0.002
24Ayur-019	Capsule	Shilajit	Maintain overall health and wellbeing	1–2 capsules (500 mg) twice daily	0.002
24Ayur-020	Granules	Ashwagandha and other ingredients	Impotency, male sexual problems such as erectile dysfunction, premature ejaculation, etc. It enhances spermatogenesis and improves the quality of sperm	10 to 20 grams twice daily with milk/warm water	0.004
24Ayur-022	Capsule	*Withania somnifera, Mucuna pruriens, Curculigo orchioides, Piper nigrum*- 5 mg*, Tribulus terrestris, Myristica fragrans, Asparagus racemosus, Bacopa monnieri*	Support hormone levels, increases energy levels and increases stamina	2 capsules (500 mg) twice daily	0.001

Sample code	Dosage form	Active ingredients	Therapeutic uses	Direction for use	IR (kg/d)
24Ayur-023	Capsule	Shilajit (Asphaltum) extract	Helps maintain overall health and wellbeing, boosts stamina and energy levels	1–2 capsules (500 mg) twice daily	0.002
24Ayur-024	Capsule	*Chlorophytum borivilianum*	Improves power and performance, reduce anxiety and improves digestion	1 capsule (500 mg) twice daily	0.001
24Ayur-025	Capsule	*Gymnema sylvestre*	Overall wellbeing. Supports the natural functioning of the pancreas and liver	1 or 2 (500 mg) capsules a day	0.002
24Ayur-026	Capsule	100% Natural Gymnema Extract (*Gymnema sylvestre*) and Vegetable Cellulose (capsules)	Liver health in normal metabolism and digestion. It also helps in alcohol induced liver discomfort	1-2 capsules (500 mg) twice daily	0.002
24Ayur-027	Capsule	100% Tongkat ali powder (*Eurycoma longifolia*), Vegetable Cellulose	Adaptogenic, stress-relieving properties and may encourage enhanced drive and enthusiasm	1–2 capsules (500 mg) twice daily	0.002
24Ayur-028	Capsule	100% Natural Ecdysterone Extract (*Serratula tinctoria*), Vegetable Cellulose	Support muscle growth and athletic performance	1 or 2 capsules once or twice a day with water	0.002
24Ayur-029	Tablets	Shatavari (*Asparagus racemosus*), Organic Gum Acacia, DM Water	Help support female hormone health, libido and reproductive health	1–2 tablets a day with meals	0.001
24Ayur-030	Tablets	Organic Gotu Kola (*Centella asiatica*), Organic Gum Acacia, DM Water	Support the intellect, focus, and nervous system	1–2 tablets a day with meals	0.001
24Ayur-031	Tablets	Organic Safed Musli (*Chlorophytum borivilianum*), Organic Gum Acacia, DM Water	Holistic support for blood sugar levels, stress and libido. general overall health in both men and women	1–2 tablets a day with meals	0.001

Sample code	Dosage form	Active ingredients	Therapeutic uses	Direction for use	IR (kg/d)
24Ayur-032	Tablets	Brahmi (*Bacopa monnieri*), Organic Gum Acacia, DM Water	Brain tonic, mental clarity and overall wellness	1–2 tablets a day with meals	0.001
24Ayur-034	Resin	100% Natural Shilajit Extract Powder (Asphaltum)	Support energy, brain health and normal immune function. Supports body building and sports performance in post-workout recovery	Pea-size portion (100–150 mg) with milk twice a day	0.0003
24Ayur-037	Capsule	100% Natural Shilajit	Support energy, brain health and normal immune function	1 or 2 capsules (500 mg) once or twice a day	0.06
24Ayur-038	Tonic	*Iron oxide, Zingiber officinale, Piper nigrum, Piper longum, Terminalia chebula, Terminalia bellirica, Emblica officinalis, Trachyspermum ammi, Embelia ribes, Cyperus rotundus, Plumbago zeylanica, Woodfordia fruticose,* Water, Jaggery.	Anaemia and liver disorders	15 ml mixed with an equal amount of water, taken after each meal	0.045
24Ayur-039	Tonic	*Boerhavia diffusa, Sida cordifolia, Linum usitatissimum, Cissampelos pareira, Adhatoda vasica, Tinospora cordifolia, Plumbago zeylanicum, Solanum surattense,* Jaggery*, Mesua ferrea, Cinnamomum zeylanicum, Amomum subulatum, Piper nigrum, Vetiveria zizanioides, Cinnamomum tamala*	Sluggish liver, oedema	15 ml mixed with an equal amount of water, taken after each meal	0.045
24Ayur-040	Tonic	*Tecomella undulata,* Jaggery*, Woodfordia fruticose, Piper longum, Piper cubeba, Plumbago zeylanica, Zingiber officinale, Cinnamomum zeylanicum, Amomum subulatum, Cinnamomum tamala, Terminalia chebula, Terminalia bellirica, Emblica officinalis*	Sluggish liver, liver enlargement, hepatitis, jaundice	15 ml mixed with an equal amount of water, taken after each meal	0.045

Sample code	Dosage form	Active ingredients	Therapeutic uses	Direction for use	IR (kg/d)
24Ayur-041	Tonic	*Cuminum cyminum, Jaggery, Woodfordia fruticose, Zingiber officinale, Myristica fragrans, Cyperus rotundus, Cinnamomum zeylanicum, Elettaria cardamomum, Cinnamomum tamala, Mesua ferrea, Trachyspermum ammi, Piper cubeba, Syzygium aromaticum*	Bloating, flatulence, poor appetite, post-partum care	15 ml mixed with an equal amount of water, taken after each meal	0.045
24Ayur-042	Paste	*Adhatoda vasica, Asparagus racemosa, Tinospora cordifolia, Emblica officinalis, Eclipta alba* - each 10 mg, *Terminalia chebula, Terminalia bellirica, Emblica officinalis, Piper longum, Vitis vinifera, Terminalia chebula*	Support for eye health, dry eyes, conjunctivitis, glaucoma, cataracts	0.5 teaspoon (3 grams) twice daily (before breakfast and before bed) with warm water	0.012
24Ayur-044	Capsule	*Asparagus racemosus*, *Rubia cordifolia*, *Aloe vera*, Zinc oxide	Irregular periods, infertility, PMS, pre- and post-menopause, hormonal imbalances, leucorrhoea	take one capsule (500 mg), twice daily with water	0.002
24Ayur-045	Capsule	*Andrographis paniculata, Cyperus rotundus, Aphanamixis rohituka, Boerhavia diffusa, Terminalia arjuna, Tinospora cordifolia, Eclipta alba,* Navayas Lauh, Arogyavardhini Ras	Supports liver health, promotes appetite, supports anorexia and malnutrition	Take one capsule (500 mg) twice daily with water after meals	0.002
24Ayur-046	Granules	*Asparagus adscendens,* Ghee, *Zingiber officinale, Piper nigrum, Piper longum, Elettaria cardamomum, Amomum subulatum, Cinnamomum zeylanicum, Cinnamomum tamala, Asparagus racemosa, Plumbago zeylanica, Tribulus terrestris, Withania somnifera, Terminalia chebula, Syzygium aromaticum, Myristica fragrans, Asteracantha longifolia, Mucuna pruriens, Nelumbo speciosus, Bambusa arundinacea, Anacyclus pyrethrum*	Aphrodisiac and antioxidant properties may help aid the treatment of ailments such as erectile dysfunction, male infertility and lack of libido	5 g mixed with 1 cup of warm boiled milk, twice a day	< LOD

Sample code	Dosage form	Active ingredients	Therapeutic uses	Direction for use	IR (kg/d)
24Ayur-047	Capsule	*Adhatoda vasica, Tinospora cordifolia* Miers*, Emblica officinalis,* Triphala*,* Trikatu*, Aegle marmelos*	Strengthens the immune response to illness and infection	2 capsules (500 mg) once daily after food	0.001
24Ayur-048	Capsule	*Tinospora cordifolia*	Improve liver function, purify the blood and for healthy digestion	2 capsules (500 mg) once daily after food	0.001
24Ayur-052	Tablets	Himsra (*Capparis spinosa*), Kasani (*Cichorium intybus*), Mandur bhasma, Kakamachi (*Solanum nigrum*), Arjuna (*Terminalia arjuna*), Kasamarda (*Cassia occidentalis*), Biranjasipha (*Achillea millefolium*), Jhavuka (*Tamarix gallica*)	Protects the liver against various hepatotoxins. Corrects liver dysfunction and damage. Promotes appetite and growth	2 tablets (250 mg) twice daily	0.001
24Ayur-053	Syrup	Sunthi (ginger), Pippali (long pepper), Mulethi (licorice), Dalchini (cinnamon), Tulsi (holy basil), Kali Mirch (black pepper), Arjuna, and ashwagandha are some of the main constituents of Patanjali Divya Swasari Pravahi	Cough, cold, rhinitis, sinusitis	5–10 ml dosage 2-3 times a day	0.033
24Ayur-056	Tablets	*Argyreia speciosa, Tribulus terrestris, Withania somnifera, Asteracantha longifolia, Lactuca serrio*	Used in male infertility due to oligozoospermia, spermatorrhoea	2 tablets (500 mg) twice a day	0.001
24Ayur-057	Syrup	Pasanabheda, Small Caltrops	Prevents kidney stones, supports urinary tract health, has diuretic action	1–2 teaspoons twice daily	0.033
24Ayur-058	Syrup	Chicory, Caper Bush	Promotes appetite and growth, corrects liver dysfunction and damage protects the liver against various hepatotoxins	1 teaspoon (5 ml) twice daily	0.01

Sample code	Dosage form	Active ingredients	Therapeutic uses	Direction for use	IR (kg/d)
24Ayur-059	Tablets	Ashvagandha (*Withania somnifera*), Kokilaksha (*Asteracantha longifolia*), Vriddhadaru (*Argyreia speciosa*), Gokshura (*Tribulus terrestris*), Jeevanti (*Leptadenia reticulata*)	Reduces anxiety, improves performance, and increases confidence	1 tablet (500 mg) twice daily	0.001
24Ayur-060	Capsule	Gokshura (*Tribulus terrestris*), Kokilaksha (*Asteracantha longifolia*), Vathada (*Prunus amygdalus*), Sunishannaka (*Blepharis edulis*), Kumkuma (*Crocus sativus*)	Promote general health, aphrodisiac, improve blood circulation in the body	2 capsules (500 mg) daily	0.001
24Ayur-063	Tablets	Ashvagandha (*Withania somnifera*) root extract	Anti-stress and adaptogenic actions, thereby increasing endurance and energy and counteracting anxiety and stress	2 tablet (250 mg) twice daily	0.001
24Ayur-064	Tonic	*Tinospora cordifolia, Tecomella undulata, Phyllanthus niruri, Terminalia chebula*	Potent hepatoprotective, helps rejuvenate and protects the liver from damage due to toxins, harmful drugs, and viruses	2 teaspoons (10 ml) 2–3 times a day before a meal	0.012
24Ayur-065	Tablets	Indian Bdellium, Licorice, Tinospora Gulancha	Immunomodulator, management of upper and lower respiratory tract infections, allergic disorders of the upper respiratory tract, skin and soft tissue infections, dental and periodontal infections, ocular infections, bone and joint infections and urinary tract infections	1 tablet (500 mg) twice daily	0.001

Sample code	Dosage form	Active ingredients	Therapeutic uses	Direction for use	IR (kg/d)
24Ayur-066	Tablets	Sonth / Sunthi (*Zingiber officinale*) Harada (*Terminalia chebula*) Vayevidanga (*Embelia ribes*) Giloy / Guduchi (*Tinospora cordifolia*) Bilawa (*Semecarpus anacardium*) Peepali (*Piper longum*) Baheda (*Terminalia bellirica*) Vacha (*Acorus calamus*) Amla (*Emblica officinalis*)	Chronic fever, cough, cold, respiratory tract infections	1–2 tablets (500 mg) twice with lukewarm water thrice daily	0.002
24Ayur-069	Tonic	*Eclipta alba, Terminalia chebula, Piper longum*	Hair growth	4 teaspoons (20 ml) 2 times a day	0.04
24Ayur-071	Powder	Senna leaves, Ajwain, and Yashtimadhu	Daily wellness routines, complement a balanced lifestyle and support overall digestive regularity	0.5 to 2 teaspoons (10,000 mg) as per requirement before bedtime with drinking water	0.01
24Ayur-083	Tablets	Triphala, *Curcuma longa*, *Berberis aristata*, *Solanum indicum*, *Solanum surattense*, *Curcuma zedoaria*, *Zingiber officinale*, *Piper nigrum*, *Piper longum*	Acute and chronic fever, and supports heart health	2 tablets (250 mg) thrice a day	0.0015

Table 13: Concentrations (mg/kg or ppm) of heavy metals in Ayurvedic medicine samples analysed in this survey

Sample no.	Antimony	Arsenic	Bismuth	Cadmium	Copper	Lead	Mercury	Silver	Tin
24Ayur-001[a]	< LOD	0.39	< LOD	0.023	4.35	0.11	3.10	0.07	0.15
24Ayur-002	< LOD	0.51	< LOD	0.14	2.10	0.14	< LOD	< LOD	< LOD
24Ayur-003	< LOD	0.45	< LOD	0.02	13.6	0.28	< LOD	< LOD	< LOD
24Ayur-004	< LOD	0.11	< LOD	0.02	5.80	0.96	< LOD	< LOD	< LOD
24Ayur-005	< LOD	0.10	< LOD	0.01	3.50	0.85	< LOD	< LOD	< LOD
24Ayur-006[a]	< LOD	< LOD	< LOD	0.02	5.55	0.15	0.12	0.63	0.16
24Ayur-007	< LOD	< LOD	< LOD	< LOD	< LOD	0.11	< LOD	< LOD	< LOD
24Ayur-008[a]	< LOD	0.85	0.06	0.11	20.00	2.55	20.85	0.07	0.67
24Ayur-009[a]	25.50	9,800	< LOD	0.15	5,200	1.15	64.0	< LOD	4.15
24Ayur-010	< LOD	6.2	< LOD	0.04	3.00	0.37	< LOD	< LOD	< LOD
24Ayur-011[a]	< LOD	0.73	< LOD	0.038	10.35	0.66	160	0.05	1.11
24Ayur-012[a]	< LOD	2.25	0.01	0.09	14.45	1.70	20.50	0.10	6.0
24Ayur-013[a]	< LOD	0.73	< LOD	0.50	4.20	1.67	7.40	3.25	2.30
24Ayur-015	< LOD	< LOD	< LOD	< LOD	3.50	0.30	0.47	< LOD	< LOD
24Ayur-016	< LOD	< LOD	< LOD	< LOD	1.20	0.60	< LOD	< LOD	< LOD
24Ayur-017	< LOD	< LOD	< LOD	0.006	0.42	0.11	< LOD	< LOD	< LOD
24Ayur-018[a]	< LOD	0.55	< LOD	0.042	13.15	0.50	0.06	67	< LOD
24Ayur-019	< LOD	0.12	< LOD	0.015	1.00	0.08	< LOD	27	< LOD
24Ayur-020	0.11	< LOD	< LOD	0.007	0.013	6.30	< LOD	< LOD	3.50
24Ayur-021	< LOD	< LOD	< LOD	0.013	3.40	0.18	0.065	0.017	0.27
24Ayur-022	< LOD	0.23	< LOD	0.033	7.40	0.15	< LOD	0.70	0.12
24Ayur-023	< LOD	0.62	< LOD	0.062	5.10	0.44	< LOD	0.12	< LOD
24Ayur-024	< LOD	< LOD	< LOD	< LOD	2.20	0.16	< LOD	< LOD	< LOD
24Ayur-025	< LOD	< LOD	< LOD	< LOD	3.80	0.20	< LOD	< LOD	< LOD
24Ayur-026	< LOD	< LOD	< LOD	< LOD	6.10	0.20	< LOD	< LOD	< LOD
24Ayur-027	< LOD	< LOD	< LOD	0.13	2.00	0.70	< LOD	< LOD	< LOD
24Ayur-028[a]	< LOD	< LOD	< LOD	< LOD	4.00	< LOD	< LOD	< LOD	< LOD
24Ayur-029	< LOD	< LOD	< LOD	< LOD	5.20	0.60	< LOD	< LOD	< LOD
24Ayur-030[a]	< LOD	< LOD	< LOD	0.75	8.10	1.10	< LOD	< LOD	< LOD

Sample no.	Antimony	Arsenic	Bismuth	Cadmium	Copper	Lead	Mercury	Silver	Tin
24Ayur-031	< LOD	< LOD	< LOD	< LOD	3.60	< LOD	< LOD	< LOD	< LOD
24Ayur-032	< LOD	< LOD	< LOD	0.10	14.60	2.40	< LOD	< LOD	< LOD
24Ayur-033	< LOD	< LOD	< LOD	< LOD	4.30	< LOD	< LOD	< LOD	< LOD
24Ayur-034	< LOD	0.37	< LOD	0.082	4.20	0.76	< LOD	< LOD	< LOD
24Ayur-035	< LOD	< LOD	< LOD	< LOD	5.00	< LOD	< LOD	< LOD	< LOD
24Ayur-036	< LOD	< LOD	< LOD	< LOD	1.80	< LOD	< LOD	< LOD	< LOD
24Ayur-037	< LOD	< LOD	< LOD	0.04	3.00	0.40	< LOD	< LOD	< LOD
24Ayur-038[a]	< LOD	0.042	< LOD	0.007	0.15	0.28	< LOD	< LOD	< LOD
24Ayur-039	< LOD	0.018	< LOD	0.006	0.21	0.03	< LOD	< LOD	< LOD
24Ayur-040	< LOD	0.012	< LOD	< LOD	0.30	< LOD	< LOD	< LOD	< LOD
24Ayur-041	< LOD	0.017	< LOD	0.005	0.50	0.02	< LOD	< LOD	< LOD
24Ayur-042	< LOD	< LOD	< LOD	< LOD	0.12	0.02	0.002	< LOD	< LOD
24Ayur-043	< LOD	< LOD	< LOD	< LOD	5.40	< LOD	< LOD	< LOD	< LOD
24Ayur-044	< LOD	< LOD	< LOD	< LOD	2.40	0.30	< LOD	< LOD	< LOD
24Ayur-045	< LOD	< LOD	< LOD	0.15	7.00	2.00	0.11	< LOD	< LOD
24Ayur-046	< LOD	< LOD	< LOD	< LOD	1.50	< LOD	< LOD	< LOD	< LOD
24Ayur-047	< LOD	< LOD	< LOD	< LOD	4.00	0.20	< LOD	< LOD	< LOD
24Ayur-048	< LOD	< LOD	< LOD	< LOD	4.50	0.20	< LOD	< LOD	< LOD
24Ayur-049[a]	< LOD	< LOD	< LOD	< LOD	6.70	< LOD	< LOD	< LOD	< LOD
24Ayur-050	< LOD	< LOD	< LOD	< LOD	2.40	< LOD	< LOD	< LOD	< LOD
24Ayur-051	< LOD	< LOD	< LOD	< LOD	0.06	< LOD	< LOD	< LOD	0.17
24Ayur-052	< LOD	< LOD	< LOD	0.18	10.80	1.70	< LOD	< LOD	< LOD
24Ayur-053	< LOD	0.010	< LOD	< LOD	0.23	< LOD	< LOD	< LOD	< LOD
24Ayur-054	< LOD	< LOD	< LOD	< LOD	< LOD	< LOD	< LOD	< LOD	< LOD
24Ayur-055	< LOD	< LOD	< LOD	< LOD	4.30	< LOD	< LOD	< LOD	< LOD
24Ayur-056	< LOD	< LOD	< LOD	0.07	11.00	1.40	< LOD	< LOD	< LOD
24Ayur-057	< LOD	0.018	< LOD	< LOD	0.08	< LOD	< LOD	< LOD	< LOD
24Ayur-058[a]	< LOD	0.042	< LOD	0.05	5.63	< LOD	< LOD	< LOD	< LOD
24Ayur-059[a]	< LOD	< LOD	< LOD	< LOD	10.40	0.70	< LOD	< LOD	< LOD
24Ayur-060	< LOD	< LOD	< LOD	0.14	14.00	1.50	< LOD	< LOD	< LOD
24Ayur-061	< LOD	< LOD	< LOD	< LOD	0.50	< LOD	< LOD	< LOD	< LOD

Sample no.	Antimony	Arsenic	Bismuth	Cadmium	Copper	Lead	Mercury	Silver	Tin
24Ayur-062	< LOD	< LOD	< LOD	< LOD	2.10	< LOD	< LOD	< LOD	< LOD
24Ayur-063	< LOD	< LOD	< LOD	< LOD	4.00	0.20	< LOD	< LOD	< LOD
24Ayur-064	< LOD	0.012	< LOD	< LOD	< LOD	< LOD	< LOD	< LOD	< LOD
24Ayur-065	< LOD	< LOD	< LOD	< LOD	7.0	0.70	< LOD	< LOD	< LOD
24Ayur-066[a]	< LOD	< LOD	< LOD	< LOD	10.10	0.65	163	< LOD	1.20
24Ayur-067	< LOD	< LOD	< LOD	< LOD	< LOD	< LOD	< LOD	< LOD	< LOD
24Ayur-068[a]	< LOD	< LOD	< LOD	< LOD	0.26	< LOD	< LOD	< LOD	< LOD
24Ayur-069	< LOD	0.02	< LOD	0.005	0.30	0.02	< LOD	< LOD	< LOD
24Ayur-070	< LOD	< LOD	< LOD	< LOD	0.05	< LOD	< LOD	< LOD	< LOD
24Ayur-071[a]	< LOD	< LOD	< LOD	< LOD	5.15	0.35	< LOD	< LOD	< LOD
24Ayur-072	< LOD	0.016	< LOD	< LOD	< LOD	< LOD	< LOD	< LOD	< LOD
24Ayur-083	< LOD	< LOD	< LOD	0.10	25.0	3.20	3.30	0.37	< LOD
24Ayur-084	< LOD	< LOD	< LOD	< LOD	3.60	< LOD	5.60	10.60	< LOD
24Ayur-085	< LOD	< LOD	< LOD	< LOD	3.30	< LOD	1.17	1.03	< LOD
Minimum	0.11	0.12	0.013	0.005	0.01	0.02	0.02	0.01	0.12
Maximum	26.00	0.37	0.110	0.75	5,200	2.40	166	675	1.10

LOD: limit of detection

a: Mean of two values. If one of the two analysis results was < LOD, the LOD was substituted to calculate the mean value. If both analysis results were < LOD, the mean value was reported as < LOD.

APPENDIX B: CHRONIC DAILY INTAKE OF AVMS

Table 14: Chronic daily intake (µg/kg bw/day) of Ayurvedic medicine samples in adult population

Sample no	Arsenic	Cadmium	Lead	Mercury
24Ayur-001	0.01	0.0004	0.001	0.05
24Ayur-002	0.01	0.002	0.002	–
24Ayur-004	0.001	0.0003	0.01	–
24Ayur-006	–	0.0004	0.003	0.003
24Ayur-008	0.02	0.002	0.05	0.45
24Ayur-009	210	0.002	0.02	1
24Ayur-010	0.03	0.0002	0.00	–
24Ayur-011	0.01	0.0005	0.01	2.30
24Ayur-012	0.06	0.002	0.05	0.60
24Ayur-013	0.02	0.01	0.04	0.11
24Ayur-014	0.01	0.0005	0.01	–
24Ayur-015	–	–	0.01	0.01
24Ayur-017	–	8.57E-05	0.001	–
24Ayur-018	0.01	0.001	0.01	0.002
24Ayur-019	0.003	0.0004	0.002	–
24Ayur-020	–	0.004	3.60	–
24Ayur-022	0.003	0.0005	0.004	–
24Ayur-023	0.02	0.002	0.01	–
24Ayur-024	–	–	0.002	–
24Ayur-025	–	–	0.01	–
24Ayur-026	–	–	0.01	–
24Ayur-027	–	0.004	0.02	–
24Ayur-029	–	–	0.01	–
24Ayur-030	–	0.014	0.02	–

Sample no	Arsenic	Cadmium	Lead	Mercury
24Ayur-032	–	0.0014	0.04	–
24Ayur-034	0.001	0.0003	0.003	–
24Ayur-037	–	0.03	0.34	–
24Ayur-038	0.01	0.001	0.06	–
24Ayur-039	0.004	0.001	0.01	–
24Ayur-040	0.002	–	–	–
24Ayur-041	0.003	0.001	0.004	–
24Ayur-042	–	–	0.003	1.71E-04
24Ayur-044	–	–	0.01	
24Ayur-045	–	0.002	0.06	0.001
24Ayur-047	–	–	0.003	–
24Ayur-048	–	–	0.003	–
24Ayur-052	–	0.002	0.02	–
24Ayur-053	0.004	–	–	–
24Ayur-056	–	0.001	0.002	–
24Ayur-057	0.01	–	–	–
24Ayur-058	0.01	0.001	–	–
24Ayur-059	–	–	0.01	–
24Ayur-060	–	0.002	0.02	–
24Ayur-063	–	–	0.003	–
24Ayur-064	0.002	–	–	–
24Ayur-065	–	–	0.01	–
24Ayur-066	–	–	0.02	4.66
24Ayur-069	0.001	0.001	0.01	–
24Ayur-071	–	–	0.01	–
24Ayur-072	–	–	–	–
24Ayur-083	–	0.001	–	0.07

"-" CDI was not estimated as the concentration of respective heavy metal in the AvM was below the limit of detection

APPENDIX C: MARGIN OF EXPOSURE AND RISK QUOTIENT OF AYURVEDIC MEDICINES

Table 15: Margin of exposure and risk quotient of Ayurvedic medicine samples in adult population

Sample no	Margin of exposure		Risk quotient	
	Arsenic	Lead	Cadmium	Mercury
24Ayur-001	30	867	0.0004	0.10
24Ayur-002	41	750	0.002	-
24Ayur-004	190	110	0.0003	-
24Ayur-006	-	466	0.0005	0.005
24Ayur-008	16	27	0.002	0.78
24Ayur-009	0.001	61	0.002	1.6
24Ayur-010	11	945	0.0002	-
24Ayur-011	28	160	0.0006	4.01
24Ayur-012	4.6	30	0.003	1.03
24Ayur-013	16	35	0.015	0.20
24Ayur-014	46	1047	0.0006	-
24Ayur-015	-	194	-	0.01
24Ayur-017	-	945	0.0001	-
24Ayur-018	21	105	0.001	0.003
24Ayur-019	-	656	0.0005	-
24Ayur-020	-	0.42	0.004	-
24Ayur-022	91	350	0.0005	-
24Ayur-023	17	120	0.002	-
24Ayur-024	-	656	-	-
24Ayur-025	-	262	-	-

Sample no	Margin of exposure		Risk quotient	
	Arsenic	Lead	Cadmium	Mercury
24Ayur-026	-	262	-	-
24Ayur-027	-	75	0.004	-
24Ayur-029	-	145	-	-
24Ayur-030	-	80	0.015	-
24Ayur-032	-	36	0.002	-
24Ayur-034	190	460	0.0004	-
24Ayur-037	-	4.40	0.04	-
24Ayur-038	11	25	0.005	-
24Ayur-039	16	233	0.004	-
24Ayur-040	38	-	-	-
24Ayur-041	27	350	0.004	-
24Ayur-042	-	437	-	0.0003
24Ayur-044	-	175	-	
24Ayur-045	-	26	0.002	0.002
24Ayur-047	-	525	-	-
24Ayur-048	-	525	-	-
24Ayur-052	-	61	0.003	-
24Ayur-053	70	-	-	-
24Ayur-056	-	75	0.0012	-
24Ayur-057	35	-	-	-
24Ayur-058	50	-	0.008	-
24Ayur-059	-	150	-	-
24Ayur-060	-	70	0.002	-
24Ayur-063	-	525	-	-
24Ayur-064	58	-	-	-
24Ayur-065	-	150	-	-

Sample no	Margin of exposure		Risk quotient	
	Arsenic	Lead	Cadmium	Mercury
24Ayur-066	-	80	-	8.17
24Ayur-069	26	131	0.003	-
24Ayur-071	-	30		-
24Ayur-072	-	-		-
24Ayur-083	-	21	0.002	0.12
24Ayur-084	-	-	-	0.14
24Ayur-085	-	-	-	0.03

'–'Margin of exposure and risk quotient was not estimated as the concentration of respective heavy metal in the AvM was below the limit of detection

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