USP Advisory Panel on Metal Impurities
Draft Metals and Limits Table: For Discussion Purposes Only

Revised April 22, 2009

No.	Metal	Advisory Panel Recommendations (based on 50 kg person) oral mcg/day	Oral PDE (mcg/day for 50 kg)	Oral PDE (mcg/g)	Parenteral, mcg/g (1/10 of Oral)	Advisory Panel Comments Based on 50 kg/person, 10g/day
1	**Antimony**	20	20	2	0.2	Found in API screens. Found in phosphoric acid.
2	**Arsenic** (Inorganic)	15	15	1.5	0.15	EPA 25 mcg/day, JECFA and FDA roughly 130 mcg/day for 60kg person. ASTDR 18 mcg/day—60 kg person. California Prop 65 10 mcg/day. Speciation above this level.
3	**Boron**	2500	2500	250	25	WHO is 1 mg per day. Used in API synthesis. **Aligns with EMEA Class 2.**
4	**Cadmium**	25	25	2.5	0.25	Health Canada 5 mcg/day; USFDA 55 mcg/day; ATSDR is 12 mcg/day; California Prop 65 4.1 mcg/day.
	Chromium III	250	250	25	2.5	**Consistent with EMEA.**
5b	**Chromium VI**	20	20	2	0.2	Chromium 6 is a carcinogen. Canada 15-20 mcg/day; ANSI 20 mcg/day; 250 mcg/day total. EPA 150 total; 250 EMEA; daily; Chrom 6 orally reduces to Chrom 3. See 2003 NSF document. 20 mcg/day set by EPA for Chromium 6 and not Chromium 3.
6	**Cobalt**	1000	1000	100	10	EPA total daily intake 1000 (provisional) for pharmaceuticals, foods, and dietary supplements.
7	**Copper**	2500	2500	250	25	**Consistent with EMEA**. FDA recommends 500 maximum total daily intake; 2500 EMEA.
8	**Lead**	10	10	1	0.1	EU 210 mcg/day; JECFA 210 mcg/day; FDA 75-25-6 mcg/day; Health Canada: 17mcg/day; ANSI 20mcg/day; California 15 mcg/day(for carcinogen; 0.5 for reproduction).
9	**Manganese**	2500	2500	250	25	**Consistent with EMEA.**
10a	**Total Mercury** (as Methyl Mercury)	2	2	0.2	0.02	FDA for seafood 200 mcg/week; JECFA: 14 mcg/day; ATSDR: 18; (10% of daily intake). Primary application is dietary supplements.
10b	**Mercury** (Mercuric)	15	15	1.5	0.15	Mercuric form is the form that would most likely be found in pharmaceuticals. Consistent with the current EPA limit. Further consideration of exposure sources such as diets, dental supplies needed.
11	**Molybdenum**	250	250	25	2.5	**Consistent with EMEA.**
12	**Nickel**	250	250	25	2.5	**Consistent with EMEA.**
13	**Osmium**	100 (combination not to exceed)	100 (combination not to exceed)	10 (combination not to exceed)	1 (combination not to exceed)	**Consistent with EMEA.**
14	**Rhodium**					
15	**Ruthhenium**					
16	**Iridium**					
17	**Palladium**	100	100	10	1	**Consistent with EMEA.**
18	**Platinum**	100	100	10	1	**Consistent with EMEA.**
19	**Tin**	2500	2500	250	25	**Organic form toxic. Aligns with EMEA Class 2.**
20	**Tungsten**	100	100	10	1	**Aligns with EMEA Class 1A.**
21	**Vanadium**	250	250	25	2.5	**Consistent with EMEA.**

High Toxicity **Medium Toxicity** **Low Toxicity**

PDE = Permissible Daily Exposure