

Potassium

Function

Potassium is an essential element critical to a large number of electrolyte and osmolar regulations (Oh and Uribarri 1999). Deficiency is more likely to be brought on by impaired renal function than by decreased intake (McLaren 1999). Manifestations of potassium deficiency include muscle weakness, respiratory inadequacy, hypotension, and electrocardiographic abnormalities.

Safety Evidence

Potassium toxicity is more likely to result from renal insufficiency (due to decreased kidney function or decreased water intake) than from excess consumption (McLaren 1999). Serious cardiac toxicity develops when serum potassium levels become too high (>6.5 mEq per L), but the amounts of potassium associated with such hyperkalemic states depend heavily on water consumption and kidney function. Because of the impact of these factors as well as of other electrolytes (principally sodium and chloride), the evidence for potassium safety or toxicity at a particular intake level must be judged cautiously.

Supplementation trials have found no adverse effects of potassium chloride at daily potassium doses of 1,900 mg (Siani et al. 1991) or 2,340 mg (Fotherby and Potter 1992). The evaluations for possible adverse effects were not specified.

A meta-analysis of clinical trials on potassium (mostly potassium chloride) for possible lowering of blood pressure indicated that this mineral “appeared to be well tolerated in all studies included” (Whelton et al. 1997). The potassium dosages in those clinical trials ranged from 1,876 to 7,820 mg per day. The dietary potassium levels were not identified.

Potassium doses of 1,250 mg administered three times per day (for a daily total of 3,750 mg) produced only minor and infrequent adverse effects as revealed by endoscopy (McMahon et al. 1982). In a follow-up study, the wax-matrix formulation was administered in dosages ranging from 900 to 3,700 mg per day (McMahon et al. 1984). Endoscopically evident erosions of the upper GI tract were evident in a few subjects supplemented with 1,560 to 3,120 mg of potassium per day for twenty-one months. Gastrointestinal symptoms were mild and did not correlate with lesions shown by endoscopic evaluation.

Published Official Reviews of Potassium Safety

The FNB has reviewed potassium, the other electrolytes, and water to establish new Dietary Reference Intakes (DRI). The FNB concluded that large amounts of supplemental potassium can cause acute or chronic toxicity, but that there was not enough appropriate data to support a UL (Food and Nutrition Board 2004).

The UK EVM concluded that the evidence was not sufficient to set an SUL, but could support a GL (Expert Group on Vitamins and Minerals 2003). From the clinical trial evidence judged to be most relevant (McMahon et al. 1982; McMahon et al. 1984; Grimm et al. 1988, 1990), UK EVM concluded that “supplemental doses of up to 3,700 mg potassium per day appear to be without overt adverse effects, but may be associated with gastrointestinal lesions diagnosed by endoscopy.” Based on this conclusion (with no correction for uncertainty), UK EVM set 3,700 mg as the GL for potassium. It was not specified whether this GL applied to supplemental potassium or total intake from all sources. The UK EVM recognized that the Recommended Nutrient Intake (RNI) in the UK for potassium was 3,500 mg for adults over eighteen years of age, but did not identify any estimate of average potassium intake by the population as a whole.

The FDA (Food and Drug Administration 1975) requires labeling on oral drug products containing 100 mg or more of potassium, warning that “there have been several reports, published and unpublished, concerning non specific small-bowel lesions” related to use of such products. The FDA did not provide any dose-response evaluation that would justify such a finding, but concluded that “coated potassium tables should be used only when adequate dietary supplementation is not practicable.”

CRN ULS for Potassium

The clinical trial data on potassium chloride, together with the epidemiology supporting the safety of larger amounts of potassium from fruits and vegetables, indicate that this nutrient has a wide margin of safety. Clinical trials collectively show no pattern of adverse effects for supplemental potassium of 1,500 mg, with the potassium from foods being unspecified. Larger quantities of potassium as potassium chloride can produce gastrointestinal effects, and these seem more likely if the daily total is ingested all at once, especially on an empty stomach. The UK EVM established guidance indicating that 3,700 mg of potassium was safe, but did not specify the amounts for foods and supplements. The evidence that was used, however, related to supplemental potassium. Considering clinical trial evidence and the apparent safety of potassium intakes as high as 8 to 11 g per day from fruits and vegetables, CRN sets its ULS for potassium at 1,500 mg per day, with the provision that it should be divided into doses no larger than

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500 mg each. There is no discernable scientific justification for the FDA threshold of
100 mg of potassium for regulation of such products as drugs.

<u>Comparison of Safety Values for Potassium</u>	
CRN ULS	1,500 mg (no more than 500 mg per dose)
US FNB UL	Reviewed but not established
EC SCF UL	Not reviewed (as of May 2004)
EC supplement maximum	Not established (as of May 2004)
UK EVM GL, supplement	3,700 mg, with minor adverse effects

References

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