Biotin

Introduction

Biotin is a B vitamin and a coenzyme for carboxylase enzymes, involved in the synthesis of fatty acids and amino acids and in gluconeogenesis. It supports the health of the skin, nerves, digestive tract, and lungs. Clinical deficiency of biotin is rare. Functional deficiency of biotin has occurred through genetic defects in the enzymes that depend on it and, more rarely, through long-term consumption of large quantities of raw egg white, which contains the biotin-binding protein avidin. Impaired biotin function has serious consequences because of the resulting damage to the enzyme systems associated with respiration (Dakshinamurti 1994).

Safety Considerations

No toxic effects of oral biotin have been reported in humans. Infants have been given injections of up to 10 mg for 6 months (Miller and Hayes 1982), and oral intakes of up to 10 mg (Select Committee on GRAS Substances [SCOGS] 1978) have not produced adverse effects, demonstrating that biotin must have an extremely low order of toxicity. Acute doses of 200 mg or intravenous doses of 20 mg have not produced adverse effects (Mock 1996).

Only marginal adverse effects are produced in animals as a result of biotin doses in the hundreds of milligrams per kilogram of body weight (Institute of Medicine [IOM] 1998; European Commission's Scientific Committee on Food [EC SCF] 2001; Expert Group on Vitamins and Minerals [EVM] 2003). In view of the absence of adverse effects in humans at even extremely high doses, these effects in animals are not relevant to the safety of supplemental biotin.

Official Reviews

IOM (1998). The IOM set an acceptable intake (AI) of biotin at 30 μg. The IOM concluded that the data on adverse effects of biotin were insufficient for a risk assessment and that an UL value could not be derived.

EC SCF (2001). The EC SCF concurred that there were no data to support a risk assessment and therefore did not set an UL value.

EVM (2003). Similarly, the UK's EVM concluded that the data from studies on humans and animals were not sufficient for the establishment of a SUL. In the absence of established toxicity at any observed intake level, the EVM identified a clinical trial (Maebashi et al. 1993) that involved oral administration of 9 mg per day of supplemental biotin without adverse effects. Given the low number of individuals studied, the EVM applied an UF of 10 to conclude that biotin supplements of 0.9 mg per day should be considered safe. Considering the likely intake from food, the EVM set a guidance level for consumption from all sources at 0.97 mg per day.

CRN Recommendations

CRN concurs with the IOM, the SCF, and the EVM that a properly defined UL cannot be set because of the absence of known adverse effects at any observed level of intake. A CRN upper limit for supplements (ULS) may be identified as the highest level of intake for which there are sufficient data to support a conclusion of safety. In the U.S., biotin supplements of 5 mg and 7.5 mg are quite common. The FDA has never given public notice of receipt of any reports of adverse effects associated with biotin. The absence of adverse effect at 9 mg of biotin per day (Maebashi et al. 1993) suggests that biotin supplements with lower amounts are likely to be safe. It also suggests that the UF of 10 by the EVM is unnecessarily restrictive.

Based on (1) the absence of adverse effects at 9 mg of supplemental biotin (recognizing that the study size was small) and (2) the absence of any adverse effect reports for biotin, even though 2.5 mg and higher products are quite common in the U.S., the CRN identifies 2.5 mg as its supplement UL.

Quantitative Summary for Biotin

CRN UL, supplemental intake	2.5 mg (2,500 µg)/day
IOM UL, total intake	Not determined
EC SCF UL, total intake	Not determined
EC supplement maximum	Not determined
EVM, guidance level, supplemental intake	9 mg (900 µg)/day

References

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