

Consumer Fact Sheet—Kava

The California Department of Public Health (CDPH) Food and Drug Branch (FDB) is providing this information to make consumers aware of the potential risk of injury associated with the use of kava and kava-containing foods/dietary supplements.

Kava (also known as kava, awa, ava, kawa, ava pepper, ava root, yati, and yaqona) usually refers to the plant *Piper methysticum*, which is a member of the pepper family. The name "kava" is also commonly attributed to the beverage or herbal products derived or extracted from the rhizomes and root of the species *Piper methysticum* (National Institute of Health: National Center for Complementary and Integrative Health, 2016; Teschke and Schulze, 2010; Codex Alimentarius Commission, 2012; Food and Agriculture Organization of the United Nations and World Health Organization, 2016).

Traditionally, kava root has been used in the Pacific Islands to make recreational and ceremonial beverages. In addition, kava root's active ingredient, kavalactones, has sedative and psychoactive properties. Dietary supplements containing kavalactones are marketed to relieve anxiety, improve insomnia, etc. throughout the world, including the United States.

Kava and Public Health Safety

Reports of adverse effects from chronic and heavy consumption of kava-containing products have triggered world-wide public health concerns. These adverse effects include:

- Hepatotoxicity (liver injury)
- Vision impairment
- Rashes or dermatitis
- Nausea
- Seizures

In response, public health agencies, including the United States Food and Drug Administration (FDA), Centers for Disease Control and Prevention (CDC), and the National Institute of Health (NIH) published information notifying the public about the risks associated with the consumption of kava-containing products:

- FDA issued a <u>consumer advisory</u> about the potential risk of severe liver injury associated with the use of kava-containing dietary supplements, citing over 25 adverse events reported in other countries due to liver injuries from kava use (FDA, 2002). Additionally, FDA published a <u>memorandum</u> which concluded that sufficient toxicological data demonstrates that kava is not safe for human consumption and cannot be considered generally recognized as safe (GRAS; FDA, 2020).
- CDC issued a <u>report</u> on the toxicity of kava-containing products (CDC, 2002).
- NIH reported on potential adverse health effects including increased risk of liver damage due to combining kava with alcohol; heart problems and eye irritation due to heavy consumption of kava; and dry, scaly skin or yellowing of the skin due to long term use of high doses of kava (NIH, 2016).

Regulation of Kava

Kava and kava-based preparations may be regulated as food, dietary supplements, or drugs. California adopts many federal food safety regulations including food additives.¹

Kava as a food additive:

Under federal law, kava is not considered generally recognized as safe or GRAS.² The federal Food and Drug Administration has deemed kava an unapproved food additive and prohibits its addition in conventional food.^{3, 4}

Kava as a dietary supplement:

Kava used as a dietary ingredient in a dietary supplement, or kava marketed as a dietary supplement is not currently prohibited in the U.S., as long as all the related federal and state requirements have been met. Under the Dietary Supplement Health and Education Act (DSHEA), a firm is responsible for determining that the dietary supplements it manufactures or distributes are safe and that any representations or claims made about them are substantiated by adequate evidence to show that they are not false or misleading. Furthermore, manufacturers of kava-containing dietary supplements must follow the dietary supplement Current Good Manufacturing Practices (cGMPs) including labeling. Additional details can be located on the FDA website specific to Questions and Answers on Dietary Supplements.

Kava as a drug:

California adopts federal law regarding new drug applications.⁵ Currently, kava-containing products have not been approved as a drug in the U.S. Therefore, kava products are not considered drugs and cannot make health claims.

Summary

Reports of adverse effects from chronic and heavy consumption of kava-containing products present a public health concern. However, there are currently no regulatory limitations regarding the use of kava as a dietary supplement.

Key References

National Institutes of Health: National Center for Complementary and Integrative Health. 2016. Kava. Available at: https://www.nccih.nih.gov/health/kava. Accessed September 20, 2023.

Teschke, R. and J. Schulze. 2010. Risk of Kava hepatotoxicity and the FDA consumer advisory. *JAMA* 304:2174-2175.

¹ See CA Health & Safety Code sections 110085, 110095, 110105, 110110, 110111.

² See Title 21 CFR sections 170.30(a)-(c), 170.3(f)-(i),

³ See FDA Warning Letter dated March 11, 2016, Herbal Junction (Warning Letter SEA 16-09).

⁴ See FDA Memorandum dated August 11, 2020, Review of the published literature pertaining to the safety of Kava for use in conventional foods.

⁵ See CA Health & Safety Code section 110110.

- Codex Alimentarius Commission. 2012. Discussion paper on the development of a standard for Kava. In Proceedings of the Joint Food and Agriculture Organization of the United Nations / World Health Organization Food Standards Programme, Twelfth Session, Madang, Papua New Guinea. Available at:

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