

# **The Use of an Alternate Name for Potassium Chloride in Food Labeling: Guidance for Industry**

## ***Draft Guidance***

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For questions regarding this draft document contact the Center for Food Safety and Applied Nutrition (CFSAN) at 240-402-2371.

**U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Food Safety and Applied Nutrition**

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# **The Use of an Alternate Name for Potassium Chloride in Food Labeling: Guidance for Industry<sup>1</sup>**

This draft guidance, if finalized, will represent the current thinking of the Food and Drug Administration (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

## **I. Introduction**

The purpose of this draft guidance is to advise food manufacturers of our intent to exercise enforcement discretion for declaration of the name “potassium chloride salt” in the ingredient statement on food labels as an alternative to the common or usual name “potassium chloride.”

FDA intends to exercise this enforcement discretion to provide industry with greater flexibility when labeling their food products, including those that are formulated to reduce sodium content. This enforcement discretion may result in manufacturers using potassium chloride as a substitute ingredient for sodium chloride and lead to increased consumer understanding of the use of potassium chloride as a replacement for sodium chloride (i.e., salt).

This draft guidance is consistent with FDA’s Nutrition Innovation Strategy to reduce the burden of chronic disease in the United States through improved nutrition, by empowering consumers with information, and supporting and fostering industry innovation in developing and promoting healthfulness of food options.<sup>2,3,4</sup> This draft guidance is also consistent with FDA’s previous activities to encourage manufacturers to reduce the sodium levels in food products in the interest of public health.<sup>5</sup>

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<sup>1</sup> This guidance has been prepared by the Office of Nutrition and Food Labeling in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

<sup>2</sup> FDA Nutrition Innovation Strategy. March 2018. <https://www.fda.gov/food/food-labeling-nutrition/fda-nutrition-innovation-strategy>.

<sup>3</sup> Healthy Innovation, Safer Families: FDA’s 2018 Strategic Policy Roadmap: <https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/UCM592001.pdf> (pg. 15).

<sup>4</sup> Reducing the Burden of Chronic Disease, Remarks by Scott Gottlieb, M.D., FDA Commissioner of Food and Drugs. <https://www.fda.gov/news-events/speeches-fda-officials/reducing-burden-chronic-disease-03292018>.

<sup>5</sup> Draft Guidance: Voluntary Sodium Reduction Goals: Target Mean and Upper Bound Concentrations for Sodium in Commercially Processed, Packaged, and Prepared Foods: Guidance for Industry. June, 2016.

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FDA's guidance documents, including this draft guidance, do not establish legally enforceable responsibilities. Instead, guidances describe our current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in FDA guidances means that something is suggested or recommended, but not required.

## **II. Background**

Under section 403(i)(2) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), the label of food fabricated from two or more ingredients must bear the common or usual name of each ingredient.<sup>6</sup> A common or usual name is the name by which an article is known to the American public. Common or usual names are generally established by common usage, though in some cases they may be established by regulation pursuant to sections 403(a)(1), 403(i), and 701(a) of the FD&C Act. See 21 CFR 102.5(d).<sup>7</sup>

“Salt” is the common or usual name of sodium chloride. See 21 CFR 101.22(h)(4). Salt is defined as “a usually whitish crystalline solid, chiefly sodium chloride, used extensively in ground or granulated form as a food seasoning and preservative.”<sup>8</sup> Thus, in the context of food, the name “salt” specifically refers to sodium chloride. Salt is also defined as “an ionic chemical compound formed by replacing all or part of the hydrogen ions of an acid with metal ions or other cations.”<sup>9</sup> Both sodium chloride and potassium chloride, in addition to other potassium- and sodium-containing food ingredients (e.g. potassium citrate, sodium lactate), are salts within this definition. Although potassium chloride is a type of salt, the common or usual name for this ingredient is “potassium chloride,” as established by longstanding common usage.

Americans consume on average 3,400 milligrams (mg) of sodium per day, nearly 50 percent more than the 2,300 mg/day limit recommended by Federal guidelines (Ref. 1). Excess sodium intake increases risk for hypertension (Refs. 2, 3, 4, 5), a leading cause of heart disease and stroke, which are the first and fifth leading causes of mortality in the United States, respectively (Ref. 6).

Over 70 percent of sodium consumed comes from processed and prepared foods (Ref. 7). Food manufacturers wishing to reduce sodium chloride in their products sometimes use substitute ingredients that provide similar taste and other technical functions of sodium chloride in foods. One such substitute ingredient that is often used is potassium chloride. Potassium chloride is generally recognized as safe (GRAS) as a food ingredient when used under the conditions specified in 21 CFR 184.1622. These conditions include use as a flavor enhancer, flavoring

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<https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM503798.pdf>. When finalized, this guidance will represent FDA’s current thinking on this topic.

<sup>6</sup> See also 21 CFR 101.4(a)(1).

<sup>7</sup> When establishing a common or usual name by regulation, FDA considers the principles under 21 CFR 102.5(a)-(c).

<sup>8</sup> The American Heritage Dictionary definition for “salt.” Available online:

<https://www.ahdictionary.com/word/search.html?q=salt>

<sup>9</sup> *Id.*

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agent, nutrient supplement, pH control agent, stabilizer, and thickener. From a food technology perspective, sodium chloride and potassium chloride to a certain extent have similar taste and functions (e.g. preservation, moisture retention) (Ref. 8). In most instances, potassium chloride is used as a partial substitute for sodium chloride.

From a nutrition or public health perspective, the substitution of potassium chloride for sodium chloride is advantageous due to the over-consumption of sodium and under-consumption of potassium at the population level compared to federal recommendations.<sup>10</sup> Increased potassium intake is associated with improved blood pressure control (Ref. 10). The 2015-2020 *Dietary Guidelines for Americans* states that potassium is a “nutrient of public health concern” (Ref. 1). The average daily potassium intake in the U.S. is approximately 3,000 mg/day for men and 2,300 mg/day for women (Ref. 9), but the Adequate Intake of potassium is 3,400 mg/day for men and 2,600 mg/day for women (Ref. 2). Potassium is therefore under-consumed in the U.S.

### **III. Guidance**

Potassium chloride, in some instances, can be used as a partial substitute for sodium chloride in food processing and manufacturing, and this use may help to reduce sodium in food. FDA has considered whether declaration of alternate names for potassium chloride, such as “potassium chloride salt,” may signal to consumers that potassium chloride has been used as a substitute for sodium chloride in food. Such information may help facilitate consumers’ choices to decrease their sodium consumption.

As noted, sodium chloride and potassium chloride can have similar functions in food and can substitute for each other in some applications. Addition of the term “salt” to the common or usual name “potassium chloride” may help consumers to better understand the similarities between potassium chloride and sodium chloride with respect to taste and function. Because “potassium chloride salt” includes the entire common or usual name of the ingredient, FDA considers it unlikely that consumers would confuse it with sodium chloride or other potassium-containing salts.

Thus, we consider it appropriate to exercise enforcement discretion for the declaration “potassium chloride salt” in the place of “potassium chloride” in the ingredient statement of food labels when potassium chloride is used as an ingredient in the food.

### **IV. References**

The following references marked with an asterisk (\*) are on display at the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at <https://www.regulations.gov>. References without

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<sup>10</sup> Information regarding the potassium content of a product is available to consumers via the ingredient listing on food packages. In addition, the updated Nutrition Facts label final rule issued by FDA in 2016 (81 FR 33742) and required on most food packages by January 2020, requires a declaration of potassium on the Nutrition Facts label – both the absolute amount per serving as well as the percent Daily Value.

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asterisks are not on public display at <https://www.regulations.gov> because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. FDA has verified the website addresses, as of May 1, 2019, but websites are subject to change over time.

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