

Unilever

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Date August 23, 2016

VIA ELECTRONIC SUBMISSION

Division of Dockets Management (HFA-305) Food and Drug Administration 5630 Fishers Lane, Room 1061 Rockville, Maryland 20852

Re: Docket No. FDA-2016-P-1826: Request FDA Issue Guidance Recognizing "Potassium Salt" as an Additional Common or Usual Name for Potassium Chloride

## Dear Sir or Madam:

Unilever submits these comments in support of the citizen petition filed by NuTek Food Science, LLC (NuTek) (Docket No. FDA-2016-P-1826).

Unilever is one of the world's largest consumer product companies with \$70 billion in global sales. Our foods, home and personal care brands have been trusted the world over since 1890. Our food and beverage products include many leading brands in the United States, such as Hellmann's® mayonnaise; Ben & Jerry's®, Breyers® and Klondike® ice cream; I Can't Believe It's Not Butter®, Promise® and Country Crock® spreads; Lipton® tea and Knorr® savory foods.

The NuTek citizen petition requests that the Commissioner of Food and Drugs issue guidance recognizing "potassium salt" as an additional common or usual name for potassium chloride, the ingredient defined in 21 C.F.R. § 184.1622. Unilever fully supports this petition. Recognizing "potassium salt" as an alternate common or usual name would improve consumer understanding and promote clear food labeling.

Potassium chloride has been safely used as a food ingredient in the U.S. for decades. In 1983, FDA approved potassium chloride as Generally Recognized as Safe (GRAS). In affirming the GRAS status of potassium chloride, FDA permitted use in foods for several different technical purposes. As a practical matter, potassium chloride is a salt substitute, used to facilitate the improvement of the nutritional profile of food. Potassium as a mineral is also well-known to have beneficial effects on the cardiovascular system. <sup>2,3,4</sup>

NuTek presented consumer study data showing consumers lack familiarity with the term potassium chloride. Indeed, Unilever has generated its own consumer data leading to similar conclusions. Unilever study results showed that consumer perception of "potassium salt" was significantly better than potassium chloride. Unilever considers "potassium salt" as an appropriate descriptive name to be used for labelling of potassium chloride.

In conclusion, we support the citizen petition submitted by NuTek and ask FDA grant the request in light of increased benefits to consumers and to help both the FDA and the food industry in our combined efforts to enhance the nutritional profiles of food.

Sincerely,

Patrizia Barone, Ph.D.

Regional Regulatory Affairs Vice President

North American Region and Global Foods & Refreshment

<sup>&</sup>lt;sup>1</sup> 48 FR 51614 (Nov. 10, 1983)

<sup>&</sup>lt;sup>2</sup> U.S. Department of Health and Human Services (HHS) and U.S. Department of Agriculture (USDA), 2015-2020 Dietary Guidelines for Americans, 8th Ed., Dec. 2015, available at http://health.gov/dietaryguidelines/2015/resources/2015-2020\_Dietary\_Guidelines.pdf.

<sup>&</sup>lt;sup>3</sup> Whelton PK, He J, Cutler JA et al. Effects of oral potassium on blood pressure. Meta-analysis of randomized controlled clinical trials. *Journal of the American Medical Association*, 1997, 277(20):1624–1632 (http://www.ncbi.nlm.nih.gov/pubmed/9168293).

<sup>&</sup>lt;sup>4</sup> WHO. Prevention of recurrent heart attacks and strokes in low and middle income populations: Evidence-based recommendations for policy makers and health professionals. Geneva, World Health Organization (WHO), 2003 (http://www.who.int/cardiovascular\_diseases/resources/pub0402/en/)