

PETITION

Use of Aspartame as a Flavor Enhancer in Beer Containing Less than 3% Alcohol by Volume

SUMMARY

Pursuant to 21 C.F.R. § 172.804, aspartame already is an approved sweetener in many foods, including fruit wine and "malt coolers" with ethanol contents below 7% by volume. This petition by The Stroh Brewery Company ("Stroh") covers the use of much lower amounts of aspartame in beer containing less than 3% alcohol by volume (hereinafter "weak beer") for the purpose of enhancing flavor. The estimated aspartame consumption resulting from this proposed use is minuscule at only 21 mg/month for the average beer consumer. Consequently, the proposed use of aspartame is well within the scope of presently approved uses and will not alter previous safety evaluations.

PRODUCT CATEGORY

The Stroh Brewery Company holds U.S. Patent No. 4,816,280: "Malt beverages with improved flavor and method of making same" (Appendix I), and corresponding patents world wide, covering the use of Aspartame, preferably in concentrations between 4 and 20 ppm, for the purpose of

improving the fullness and flavor balance of certain malt beverages even below the threshold for sweetness, for example, of those beer types which are low in calories (so-called "Light Beers") and also of beer types which are low in alcohol, i.e., of malt beverages which have a degree of attenuation either higher or lower than that of regular beer or ale.

Stroh now proposes that 21 C.F.R. § 172.804 be amended to provide for the use of aspartame in amounts up to 20 ppm as a flavor enhancer in weak beer.

FUNCTIONALITY AND TEST DATA

Reference is made to U.S. Patent 4,816,280, and especially to Examples 1, 2, and 3 thereof, which demonstrate that the addition of low concentrations of aspartame as described confers on the product certain defined sensory characteristics.

Specifically, the product:

- (a) has less of an aged or oxidized taste to thereby improve the stability of the flavor of the final product during aging after packaging,
- (b) is smoother,
- (c) is less astringent,
- (d) has more body or "mouthfeel," and/or
- (e) has less "afterbitter." (See Patent No. 4,816,280).

The stability of aspartame in beverages as a function of time and temperature of storage is governed mainly by the pH of the beverage, as described in Petition No.

FAP2A3661 for carbonated beverages, dated August 13, 1982. The following experiment was conducted to determine the stability of aspartame in a typical weak beer of pH 4.3 and ethanol content of 2.7 percent by volume and containing 0, 12 and 20 ppm aspartame at the time of packaging:

Method of Analysis: Aspartame (APM) and its breakdown product diketopiperzaine (DKP) were determined in the laboratories of The NutraSweet Co. by the methods described in Appendix II.

Storage of the Experimental Beverage: The beverage was packaged in standard glass beverage bottles containing 12 fl. oz. of beverage (355 ml) and 25 ml of carbon dioxide headspace. The bottles were stored at 41° F for two months and then placed in a stability study comprising **typical unrefrigerated** storage conditions of 71° F and **typical refrigerated storage conditions** of 41° F. Samples were withdrawn for analysis on the initial day of the study and after 30, 60 and 90 days. The results are as follows:

Code	Identity	Stored at	Aspartame, ppm				Diketopiperazine, ppm			
			Initial	30d	60d	90d	Initial	30d	60d	90d
79-1	Ultra-A 12 ppm A.	41°F	11	12	11	12	nd ¹	nd	nd	nd
		71°F	—	12	11	11	—	nd	<1	<1
79-1B	Ultra-A 20 ppm A.	41°F	16	20	19	19	nd	nd	nd	<1
		71°F	—	19	18	18	—	nd	<1	1
81-1A	Ultra-B 12 ppm A.	41°F	11	12	11	12	nd	nd	<1	nd
		71°F	—	12	11	11	—	nd	<1	<1
81-1B	Ultra-B 20 ppm A.	41°F	18	20	19	20	nd	nd	<1	nd
		71°F	—	20	18	18	—	nd	<1	1

¹nd * none detected

As the above results show, aspartame at low levels in weak beer is considerably more stable than is aspartame in carbonated beverages (see petition 6A3942). The rate of aspartame decrease in weak beer is no more than 1-2 ppm or approximately 0.8% per week. Based on Stroh marketing data, the average consumption time is 8 weeks after bottling, resulting in total loss at that time of approximately 7%. In only two samples (79-1B and 81-1B) did the level of diketopiperazine reach a detectable level of 1 ppm. It follows that stability of aspartame is not a technical problem in the application proposed by Stroh.