

FDA has calculated exposure estimates to aspartame under the assumption that the sweetener would be used in food with no limits other than CGMP. Having considered the results of these exposure estimates, which were made using extremely conservative assumptions (such as, that aspartame would replace all sugars added to food), the agency concludes that the use of aspartame as a general purpose sweetener will not cause the ADI for aspartame to be exceeded. The agency has estimated exposure to DKP (the major decomposition product of aspartame) and concludes that the ADI for DKP will also not be exceeded by its use as a general purpose sweetener. Based on these evaluations, the agency further concludes that the use of aspartame as a general purpose sweetener, subject only to CGMP conditions of use (including a specific CGMP level of use of 0.5 percent in baked goods and baking mixes), is safe and that the regulation for aspartame should be amended in § 172.804(c) as set forth below. In addition, § 172.804(b) is amended to conform to the requirement of providing three addresses for methods that are incorporated by reference, one where the method may be obtained and two where it may be examined by the public.