

Appendix VIII

Environmental Assessment

02F-0220

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ENVIRONMENTAL ASSESSMENT

1. Date: January 31, 2002
2. Name of petitioner: Nutrinova, Inc.
3. Post Office Address: 285 Davidson Ave.  
Suite 102  
Somerset, NJ 08873  
Phone: (732) 271-7220

4. Description of the proposed action:

a. Requested approval:

The proposed action involves Acesulfame potassium (ACK). Nutrinova, Inc. proposes to amend the food additive regulation for ACK to permit its use as a general-purpose sweetener and flavor enhancer in accordance with Good Manufacturing Practice.

As provided in section 21 CFR § 172.800, ACK is currently approved for 15 food and beverage categories. This petition provides data in support of extending the current approved uses of ACK to its use as a general-purpose sweetener and flavor enhancer, with the elimination of the individual categories identified in the current regulation.

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b. Need for action:

ACK is intended for use as a non-nutritive sweetener. Its safety, stability, taste performance and blending advantages with other sweeteners make it a superior non-caloric sweetener for full or partial sugar replacement in beverages and foods.

c. Locations of use:

ACK will be sold to food and beverage manufacturers, in whose manufacturing facilities ACK will be incorporated into finished products. ACK will also be sold to other manufacturers including pharmaceutical, dietary supplements, medical foods and food services, including restaurants, for use in preparing a variety of finished products. It is expected that ACK will be consumed as a component of the human diet in patterns corresponding to national population density.

d. Locations of disposal:

ACK is not metabolized. Following consumption disposal into the environment is expected to occur nationwide, with the substance largely unchanged, entering publicly owned treatment works (POTWs) or septic tanks.

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5. Identification of the substance that is the subject of the proposed action:

Common or Usual Name: ACESULFAME POTASSIUM  
ACESULFAME K

Chemical Name(s):

6-Methyl-1,2,3-Oxathiazine-4(3H)-one-2,2-Dioxide,  
Potassium Salt

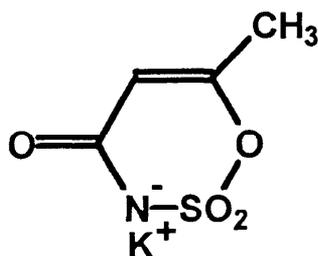
3,4-Dihydro-6-methyl-1,2,3-oxathiazine-4(3H)-one-2,2-  
dioxide, Potassium salt

CAS Registry No: 55589-62-3

Molecular Weight: 201.2

Molecular Formula:  $C_4H_4NO_4KS$

Structural Formula:



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Physical Description: White crystalline powder,  
odorless, intensely sweet and  
highly water-soluble.

6. Introduction of substances into the environment:

- a. Introduction of substances into the environment as  
a result of manufacture.

No extraordinary circumstances apply to the  
manufacture of ACK. By reference we incorporate the  
EA provided to the Agency in Appendix III in FAP #  
OA4212 and updated on June 10, 1998. An updated  
Environmental Assessment is provided in this general-  
purpose petition.

ACK is manufactured by Nutrinova Nutrition  
Specialties & Food Ingredients, GmbH the parent  
company in Frankfurt, Germany. The facilities are  
operated in compliance with all applicable  
environmental and occupational exposure requirements.

- b. Introduction of substances into the environment as  
a result of use:

There will be little or no introduction of ACK into  
the environment as a result of its direct use because it is  
incorporated into food and beverages. Since ACK is not  
metabolized it will enter the environment almost  
exclusively after consumption through excretion.

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ACK will enter the environment in highly diluted form through release into sewage systems and on into POTWs for further dilution, treatment and final discharge into the environment. It is expected that there will be virtually little or no ACK found in the environment. Accumulation of ACK in the environment is highly unlikely.

The quantities calculated here for environmental release as a result of this general-purpose petition will be significantly reduced from that presented in the previously approved FAP OA4212 for ACK. This is a result of the fact that this petition calculates environmental release on the basis of plant production/capacity. Environmental release was formerly presented to the Agency based upon a calculated theoretical maximum dietary intake from an MRCA study. This latter approach results in a greatly exaggerated value of ACK release since the quantity actually exceeds plant capacity by a significant multiple of 3.4.

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c. Introduction of substances into the environment as a result of disposal:

i. Calculating the EICs for ACK in the aquatic environment:

Based upon the assumptions provided in 1990 in FAP OA4212 the Petitioner concluded at that time that the maximum total concentration of ACK expected in POTW effluent would be about 0.12 ppm. This was derived from the assumption of 10.2 million pounds entering POTWs each year for those categories for which approval was being sought. The concentration of ACK in receiving environments would be substantially lower as a result of further dilution.

The plant capacity for ACK is 4,000 metric tons per year. This corresponds to approximately 8.8 million pounds per year or  $4.0 \times 10^6$  kg/year. The calculation of EIC based upon the attached FDA draft guidance document (Appendix X-b) "Guidance for Preparing an Environmental Assessment for Acesulfame K" is as follows:

$$\text{EIC-Aquatic (ppm)} = A \times B \times C \times D$$

A = kg/year production volume of the substance

A = 8.8 million pounds (maximum import)

$$= 4.0 \times 10^6 \text{ kg}$$

B = 1/liters per day entering POTW's

$$B = 8.97 \times 10^{-12}$$

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C = year/365 days

D =  $10^6$  mg/kg (conversion factor)

EIC-Aquatic = 0.098 ppm

This number reflects a lower and more realistic (though still exaggerated) value of environmental release than the 1990 value of 0.12 ppm. Since the Agency found the earlier 1990 assessment acceptable we believe that the new lower estimate provides further confidence that ACK will have no impact on the environment as a result of extending the current approvals.

The EIC-Aquatic value assumes that the production facility is operating at full capacity and furthermore that all production volume is dedicated to the US market. In fact neither assumption is true. The plant does not operate at full capacity and the plant supplies the entire global market. Thus using plant capacity as a measure for US environmental release is a gross over exaggeration of the real situation.

ii. Calculating the EICs for ACK in the terrestrial environment:

Again utilizing the FDA guidance document for the Environmental Assessment we have the following:

EIC-Terrestrial (ppm) = A x B x C x D

A = kg/year production volume of the substance

A = 8.8 million pounds (maximum import)

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$$= 4.0 \times 10^6 \text{ kg}$$

$$B = 1/6.4 \times 10^9 \text{ kg sewage sludge/year} = 1.56 \times 10^{-10}$$

$$C = .33$$

$$D = 10^6 \text{ mg/kg (conversion factor)}$$

$$\text{EIC-Terrestrial} = 200 \text{ ppm}$$

7. Fate of Substances Released into the Environment:

The fate of ACK in the environment is discussed in the Environmental Assessment for FAP's 3A4391 and OA4212. The information set forth therein is incorporated herein by reference.

8. Environmental Effects of Released Substances:

Based upon the manufacturing and processing conditions of ACK, its physical state, low volatility and high water solubility as well as the normal methods, by which it will enter the environment, very low levels of environmental exposure are expected. Data have been presented in previous petitions for the sweetener, including data relating to potential toxicity to organisms in the environmental assessments submitted in FAPs 2A3659 and OA4212. The studies demonstrate that ACK is not acutely toxic to Daphnia, two species of freshwater fish (zebra fish and golden orfe), or microorganisms. The high

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water/n-octanol partition coefficient of 225 will exclude any substantial accumulation in aquatic organisms.

Based upon these data, together with information submitted regarding levels of introduction of ACK to the environment, subsequent dilution of the sweetener in marine systems, and its fate therein, no adverse environmental effects are expected.

9. Use of Resources and Energy:

The use of resources and energy has been evaluated in previous submissions regarding ACK, including FAP OA4212; this information is incorporate herein.

10. Mitigation Measures:

Mitigation measures taken at the manufacturing site for ACK have been described in previous petitions and updated here. Considering the lack of any anticipated adverse environmental effects from the production and use of ACK in the proposed application, Petitioner concludes that no additional mitigation procedures are required.

11. Alternative to the Proposed Action:

No potential adverse environmental impacts have been identified for the proposed action. Therefore, no alternatives are presented in this document.

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12. List of Preparers:

- a. Dr. Richard Barndt, Head, Innovation, Regulatory & Scientific Affairs, Nutrinova, Inc., Ph.D. Food Science
  
- b. Dr. Gert-Wolfhard von Rymon Lipinski, Corporate Director of Scientific & Regulatory Affairs, Nutrinova Nutrition Specialties and Food Ingredients, GmbH
  
- c. Dr. Jon Simplicio, Consultant, Formerly Director of Scientific and Regulatory Affairs to Nutrinova, Inc., Ph.D. Chemistry

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13. Certification:

"The undersigned official certifies that the information presented is true, accurate, and complete to the best of knowledge of Nutrinova, Incorporated."

Date: February 25, 2002

Responsible  
Official:



Name & Title,  
Responsible  
Official:

Richard L. Barndt, Ph.D.  
Head, Innovation, Regulatory &  
Scientific Affairs

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