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October 16, 1997

Conf 97-192



HAND DELIVERED

Ms. Donna R. Koehnke
Secretary
United States International
Trade Commission
500 E Street, S.W.
Washington, D.C. 20436

Re: Certain Acesulfame Potassium and Blends and
and Products Containing Same, Inv. No. 337-TA- _

Dear Secretary Koehnke:

Pursuant to Section 337 of the Tariff Act of 1930, enclosed for filing on behalf of Nutrinova Nutrition Specialties and Food Ingredients GmbH and Nutrinova Inc. please find the following:

- 1) an original and fourteen (14) copies of the confidential version of the verified Complaint with the confidential exhibits (Ex. Nos. 5, 6, 11, 16-18, 22-26) segregated from the non-confidential exhibits (Ex. Nos. 1-4, 7-10, 12-15, 19-21) as required by Commission Rule 201.6(c) (original and one copy unbound, without tabs);
- 2) fourteen (14) copies of a public version of the verified Complaint and non-confidential versions of the exhibits (two copies unbound, without tabs);
- 3) four (4) additional copies of the public and confidential versions of the Complaint and accompanying exhibits, one each for service upon proposed respondents and one additional public version of the Complaint and exhibits for service on the government of the Peoples Republic of China;

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OFC. OF THE SECRETARY
U.S. INT'L TRADE COMMISSION
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A MEMBER OF GLOBALEX WITH MEMBER OFFICES IN BERLIN, BRUSSELS, DRESDEN, FRANKFURT, LONDON, PARIS, SINGAPORE, STUTTGART AND TAIPEI

Ms. Donna Koehnke
Secretary
Page 2

4) certified copies of United States Patent Nos. 4,695,629 and 4,158,068 (which have been included with the original Complaint as Exhibits 8 and 12 and legible copies which are included with all copies of the Complaint);

5) one certified copy and three additional copies of the prosecution history for U.S. Patent No. 4,695,629. The rivet in the certified copy was inadvertently broken during photocopying. A new copy with the rivet intact will be filed as soon as it can be obtained.

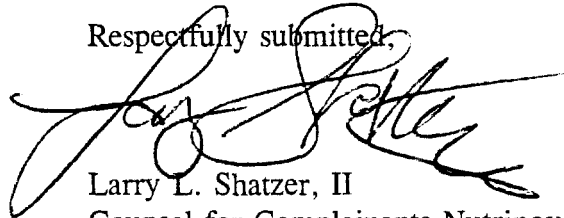
6) four copies of the prosecution history of U.S. Patent No. 4,158,068. Nutrinova requested a certified copy of the prosecution history of this patent from the U.S. Patent and Trademark Office ("PTO") on September 9, 1997. As indicated in the attached letter from Andrea Jones of the Certification Division of the PTO, Nutrinova's receipt of a certified copy of this prosecution history has been delayed due to the inability of the PTO to locate the file at this time. Accordingly, a certified copy and three additional copies will be filed as soon as it becomes available.

7) four copies of each reference document mentioned in the prosecution history for U.S. Patent Nos. 4,695,629 and 4,158,068.

The declaration attached as Confidential Exhibit 17 contains a facsimile signature as the original was unavailable at the time the Complaint was being prepared for filing. The original signed copy of Confidential Exhibit 17 will be filed within the next few days.

Accompanying this filing is a declaration pursuant to Rule 201.6 requesting confidential treatment of the confidential business information contained in the Complaint and Confidential Exhibit Nos. 5, 6, 11, 16-18, 22-26.

Respectfully submitted,



Larry L. Shatzer, II
Counsel for Complainants Nutrinova
Nutrition Specialties and Food
Ingredients GmbH and Nutrinova Inc.



**UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office**

ASSISTANT SECRETARY AND COMMISSIONER
OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

October 15, 1997



ROBERT N. BLACKMON
ORDER 67127167
2101 CRYSTAL PLAZA ARCADE #289
ARLINGTON, VA 22202

RE: Serial Nbr: 05/808,987 Patent Nbr: 4,158,068

Dear Sir/Madam:

This is in reference to your order for Patent File Wrapper and Content
which we are unable to complete due to the following reason(s):

The file cannot be located at this time to complete your order. An official search is being made
and as soon as the application file is found, copies will be furnished to you.

If you have any questions concerning this notice, please contact the Status Unit at (703)308-9726
or by FAX at (703)308-9759 and reference control number C -0900052.

Andrea S. Jans
Certification Division



UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, D.C.

In the Matter of)	
)	Investigation No.
CERTAIN ACESULFAME POTASSIUM)	
AND BLENDS AND PRODUCTS)	
CONTAINING SAME)	337-TA-
)	

DECLARATION SUPPORTING CONFIDENTIALITY

1) I am a member of the Bars of the District of Columbia and the State of Tennessee, and an attorney with the law firm of Foley & Lardner, 3000 K Street, N.W., Washington D.C. 20007. I am an attorney for Complainants Nutrinova Nutrition Specialties and Food Ingredients GmbH and Nutrinova Inc.

2) Pursuant to Commission Rule 201.6, Complainants request confidential treatment of certain proprietary business information in the Complaint and Exhibits 5, 6, 11, 16, 17, 18, 22-26.

3) The information for which confidential treatment is requested is as follows:

A) Information on confidential investigative means used to obtain information on Respondents and their infringing conduct.

(Complaint ¶¶ 6.2, 6.3, 6.12, 6.14-6.17, Exhibits 5, 16, 17, and 18);

B) Information on the trade secret process utilized by Nutrinova GmbH to manufacture acesulfame K (Complaint ¶ 7.14, Exhibits 11, 25, and 26); and

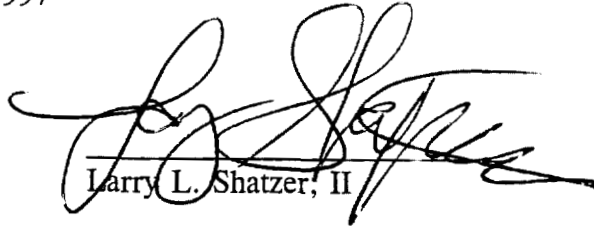
C) Information on Complainants' investment in the domestic industry and proprietary information obtained from its customers (Complaint ¶¶ 4.3, 6.6-6.9, 7.2-7.12, Exhibits 6, 22-24).

4) Based upon my information, knowledge and belief, disclosure of the information set forth in paragraph 3 would reveal "confidential business information" as defined in Commission Rule 201.6(a), and would cause substantial harm to the competitive position of Complainants.

5) Based upon my information, knowledge and belief, information substantially identical to that identified as confidential business information is not available to the public.

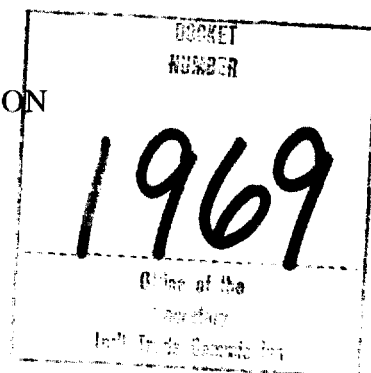
I declare under penalty of perjury that the foregoing is true and correct.

Executed this 15th day of October, 1997


Larry L. Shatzer, II

PUBLIC VERSION

**UNITED STATES INTERNATIONAL TRADE COMMISSION
WASHINGTON, D.C.**



In the Matter of)
)
CERTAIN ACESULFAME POTASSIUM) Investigation No.
AND BLENDS AND PRODUCTS)
CONTAINING SAME) 337-TA-
)

**COMPLAINT UNDER SECTION 337 OF
THE TARIFF ACT OF 1930, AS AMENDED**

Complainants:

Nutrinova Nutrition Specialties
and Food Ingredients GmbH
D - 65 926
Frankfurt am Main
Federal Republic of Germany

Nutrinova Inc.
25 Worlds Fair Drive
Somerset, New Jersey 08873

Counsel for Complainants:

Colin G. Sandercock
Charles F. Schill
Larry L. Shatzer, II
Melinda F. Levitt
Mary Atchley Jester
Todd J. Burns
Susan Shaw McBee

FOLEY & LARDNER
3000 K Street, N.W., Suite 500
Washington, D.C. 20007
Tel: (202) 672-5300

Proposed Respondents:

Hangzhou Sanhe Food
Company Ltd.
258 Qiutao Road
Hangzhou, Zheijiang
People's Republic of China

JRS International, Inc.
141 Lanza Avenue, Bldg. 12
Garfield, New Jersey 07026

Dingsheng, Inc.
5323 Tyler Avenue
Temple City, Calif. 91780

WYZ Tech, Inc.
4570 Eucalyptus Ave. #B
Chino, California 91710

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LIST OF EXHIBITS

1. Hoechst AG 1996 Annual Report
2. Sanhe Promotional Materials
3. JRS Trade Show Promotional Materials
4. Dingsheng Promotional Materials
5. WYZ Tech Promotional Materials (Confidential)
6. Declaration of Dr. Lisa Y. Hanger (Confidential)
7. The Sunett Multi-Sweetener Concept Brochure
8. Certified Copy of U.S. Patent No. 4,695,629
9. Certified Copies of Assignments of U.S. Patent No. 4,695,629
10. List of Foreign Applications and Status for U.S. Patent No. 4,695,629
11. Reaction Sequence Diagram (Confidential)
12. Certified Copy of U.S. Patent No. 4,158,068
13. Certified Copies of Assignments of U.S. Patent No. 4,158,068
14. Patent Term Extension for U.S. Patent No. 4,158,068
15. List of Foreign Applications and Status for U.S. Patent No. 4,158,068
16. Declaration of Dr. Christian Klug (Confidential)
17. Declaration of Dr. Udo Dettmeier (Confidential)
18. Claim Chart Re: Infringement of U.S. Patent No. 4,695,629 (Confidential)
19. Sanhe Promotional Materials
20. 1997 IFT Annual Meeting Program, Food Expo and Exhibit Directory

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21. JRS Promotional Materials
22. Floor Plan of Somerset, N.J. facility (Confidential)
23. Letter regarding license under U.S. Patent No. 4,158,068 (Confidential)
24. List of Customers/Licensees for U.S. Patent No. 4,158,068 (Confidential)
25. Claim Chart Re: Nutrinova Practice of U.S. Patent No. 4,695,629 (Confidential)
26. Claim Chart Re: Nutrinova Practice of U.S. Patent No. 4,158,068 (Confidential)

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I. INTRODUCTION

1.1 This complaint is filed by Nutrinova Nutrition Specialties and Food Ingredients GmbH ("Nutrinova GmbH") and Nutrinova Inc. pursuant to Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, to remedy the unlawful importation into the United States, the sale for importation, or the sale within the United States after importation by the owner, importer or consignee, of acesulfame potassium manufactured abroad by a process covered by the valid claims of U.S. Patent No. 4,695,629 ("the '629 patent") as well as acesulfame potassium that infringes or is utilized to induce infringement of U.S. Patent No. 4,158,068 ("the '068 patent"). The '629 and '068 patents are valid and enforceable United States patents owned by Nutrinova GmbH.

II. COMPLAINANTS

2.1 Nutrinova GmbH is a corporation organized under the laws of the Federal Republic of Germany and has its principal place of business at D-65-926, Frankfurt am Main, Federal Republic of Germany.

2.2 On September 1, 1997, the Food Ingredients Business Unit of Hoechst AG became Nutrinova GmbH, a separately incorporated, but wholly owned, subsidiary of Hoechst AG, a German corporation. Hoechst AG is the holding company for a number of companies that manufacture food ingredients, basic chemicals, pharmaceuticals, technical polymers, polyester products, industrial gases, paints and coatings, diagnostics products, crop protection products and animal health products. Nutrinova GmbH manufactures sweetening and food preservation products that are sold worldwide. A copy of Hoechst AG's 1996 Annual Report is attached hereto as Exhibit 1.

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2.3 Nutrinova Inc. is a corporation organized under the laws of the state of Delaware and has its principal place of business at 25 Worlds Fair Drive, Somerset, New Jersey 08873.

2.4 On September 12, 1997, the Food Ingredients Division of Hoechst Celanese Corporation, became Nutrinova Inc. a separately incorporated, but wholly owned, subsidiary of Nutrinova GmbH. The employees of Nutrinova Inc. however, will continue to be paid by Hoechst Celanese Corporation and on loan to Nutrinova Inc. until December 31, 1997. At that time they will become employees of Nutrinova Inc. Nutrinova Inc. undertakes research and development, sales and marketing, customer service, warehousing and distribution operations at its New Jersey facility for acesulfame potassium sold by Complainants in the United States. Nutrinova Inc. also works with customers in developing the appropriate formulations or blends of acesulfame potassium for use in the customers' food products.

III. RESPONDENTS

3.1 Upon information and belief, Respondent Hangzhou Sanhe Food Co. Ltd. ("Sanhe") is a corporation organized under the laws of the People's Republic of China and has its principal place of business at 258 Qiutao Road, Hangzhou, Zhejiang, People's Republic of China.

3.2 According to Sanhe's promotional material, Sanhe is a manufacturer of "food auxiliary and additives." Its main products are said to be acesulfame potassium, polypeptide protein hydrolytic, hydrolytic plant protein, and the food preservative potassium sorbate.

3.3 Sanhe claims that its facilities occupy a land area of 20,000 square meters and a "construction area" of 12,000 square meters. It further claims that it has fixed assets of 21

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million yuan. A copy of Sanhe's promotional material is attached hereto as Exhibit 2.

3.4 Upon information and belief, Respondent JRS International, Inc. ("JRS") is a Delaware corporation with its principal place of business at 141 Lanza Avenue, Building #12, Garfield, New Jersey 07026. According to JRS's promotional materials, JRS is a subsidiary of Sanhe and a distributor in the United States of acesulfame potassium manufactured by Sanhe. A copy of JRS's promotional material is attached as Exhibit 3.

3.5 Upon information and belief, Respondent Dingsheng, Inc. ("Dingsheng") is a California corporation with its principal place of business at 5323 Tyler Avenue, Temple City, California 91780. According to Dingsheng's promotional materials, Dingsheng is a subsidiary of Sanhe and a distributor in the United States of acesulfame potassium manufactured by Sanhe. A copy of Dingsheng's promotional material is attached as Exhibit 4.

3.6 Upon information and belief, Respondent WYZ Tech, Inc. ("WYZ Tech") is a California corporation with its principal place of business at 4570 Eucalyptus Ave. #B, Chino, California 91710. According to information distributed by WYZ Tech, the company is a subsidiary of Sanhe and a distributor in the United States of acesulfame potassium manufactured by Sanhe. A copy of promotional letter from WYZ Tech is attached as Confidential Exhibit 5.

IV. THE PRODUCT AT ISSUE

4.1 The product at issue, acesulfame potassium, or "acesulfame K" as it is more commonly known, is a non-nutritive sweetener that is nearly 200 times sweeter than sucrose, *i.e.*, table sugar. Acesulfame K is manufactured by Nutrinova GmbH at its plant in Frankfurt am Main, Germany and is sold worldwide as an ingredient to food manufacturers under the

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brand name Sunett® Brand Sweetener.

4.2 Acesulfame K was discovered in 1967 by a scientist at Hoechst AG. After many years and a substantial investment in testing and obtaining regulatory approval for use as a food ingredient, Hoechst AG first sold acesulfame K in Europe in 1983 and in the United States in 1988. Currently approved for use in over 80 countries and used in no less than 3,000 products, acesulfame K is one of the world's most widely used sweeteners.

4.3 Because acesulfame K has been found to act synergistically when blended with other sweeteners, its most common use is in such blends. Blends of acesulfame K with other sweeteners taste more like sucrose than other synthetic sweeteners, either alone or in mixtures. Indeed, as set forth in the Declaration of Dr. Lisa Y. Hanger attached as Confidential Exhibit 6, approximately [] of the use of acesulfame K by Complainants' customers is in blends. At least [] of the work performed by Nutrinova Inc.'s [] person research and development staff in the company's three research and development laboratories in the Somerset, New Jersey facility relates to developing appropriate blend formulations for Nutrinova's customers to use in specific product formulations. The use of acesulfame K in blends is explained in more detail in the brochure attached as Exhibit 7.

4.4 The United States Food and Drug Administration (FDA) has approved the use of acesulfame K in tabletop sweeteners, chewing gum, dry beverage bases, dry dessert bases, dry dairy product analog bases, confections, hard and soft candies, baked goods, yogurts, refrigerated and frozen desserts, spoon-for-spoon sugar replacement products, table syrups, sweet sauces and toppings, and alcoholic beverages. Approval for liquid beverages, the largest

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potential market, has been obtained in other countries and is expected imminently in the United States.

V. THE PATENTS AT ISSUE

A. The '629 Patent

5.1 The '629 patent is based on United States application Serial No. 870,078, filed June 3, 1986, as a division of Serial No. 714,177, filed on Mar. 20, 1985, now Patent No. 4,607,100. A certified copy of the '629 patent is attached as Exhibit 8. The '629 patent claims priority under 35 U.S.C. § 119 to Federal Republic of Germany application Serial No. 3410439 filed March 22, 1984. The '629 patent expires on March 20, 2005, as calculated twenty years from the filing date of parent application Serial No. 714,177. Inventors Karl Clauss, Adolf Linkies, and Dieter Reuschling assigned all right, title and interest in the '629 patent (by the assignment in the parent application) to Hoechst AG. On September 1, 1997, Hoechst AG assigned all right, title and interest in the '629 patent to Nutrinova GmbH. Certified copies of the assignments are attached as Exhibit 9. Also filed with the Complaint is a certified copy and three additional copies of the prosecution history of the '629 patent, as well as four copies of each patent and the applicable pages from each reference cited in the prosecution history.

5.2 The '629 patent discloses and claims a process for the preparation of 6-methyl-3,4-dihydro-1,2,3-oxathiazin-4-one 2,2-dioxide and its non-toxic salts, such as acesulfame K.

5.3 A list of all foreign patents and each foreign patent application (not already issued as a patent) corresponding to the '629 patent, including an indication of its status, is attached

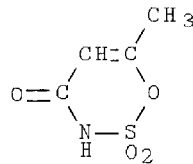
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to this Complaint as Exhibit 10.

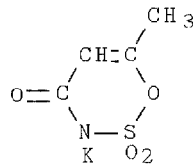
5.4 The '629 patent has 5 claims. It is believed that claim 1, the only independent claim, and claims 2-5, the dependent claims, are infringed by the Respondents' importation, use, or sale of acesulfame K into the United States. Claim 1 of the '629 patent reads as follows:

A process for the preparation of 6-methyl-3,4-dihydro-1,2,3-oxathiazin-4-one 2,2-dioxide and its non-toxic salts by ring closure of an acetoacetamide derivative, which comprises using as the acetoacetamide derivative acetoacetamide-N-sulfonic acid or its salts, and carrying out the ring closure by the action of at least the approximately equimolar amount of SO₃, where appropriate in an inert inorganic or organic solvent, and then, where appropriate, also neutralizing with a base the 6-methyl-3,4-dihydro-1,2,3-oxathiazin-4-one 2,2-dioxide which is produced in the form of the acid in this reaction.

5.5 The invention disclosed and claimed in the '629 patent relates to a novel method for the preparation of acesulfame (or as it is known by its chemical name 6-methyl 3,4-dihydro-1,2,3-oxathiazin-4-one 2,2-dioxide) or its salts, one of which is acesulfame K. The chemical structure of 6-methyl-3,4-dihydro-1,2,3-oxathiazin-4-one 2,2-dioxide is shown below:



Acesulfame K that results after the neutralization of 6-methyl-3,4-dihydro-1,2,3-oxathiazin-4-one 2,2-dioxide with a base is shown below:



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5.6 The process of the '629 patent relates generally to a two- and optionally three-part reaction; namely,

- (a) acetoacetylating a sulfamic acid derivative to form an intermediate;
- (b) ring closure of the intermediate with sulfur trioxide;
- (c) followed by an optional neutralization with a base.

5.7 The reaction sequence used by Nutrinova GmbH is attached as Confidential Exhibit 11 (with diketene as the acetoacetylating agent). As Confidential Exhibit 11 shows, a major by-product of the '629 patent is sulfate (SO_4) which results when the sulfur trioxide combines with water.

5.8 The advantages of the processes covered by the '629 patent over the prior art include:

- (1) the use of starting materials that are readily available at a relatively low cost and pose minimal health risks, as compared to the starting materials of the other known processes;
- (2) relative ease and mild conditions under which the reaction is conducted; and
- (3) high yields which are between about 65% to 95% of theory for the overall process.

5.9 The claims of the '629 patent are actually directed to a sub-portion of the

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complete reaction description set forth in the '629 specification; namely, the claims cover ring closure step (b) and, optionally, the neutralization step (c) of the reaction sequence depicted in Confidential Exhibit 11. As claim 1 indicates, the intermediate acetoacetamide-N-sulfonic acid and/or its salts undergo ring closure by the action of at least an approximately equimolar amount of SO₃, where appropriate in an inert inorganic or organic solvent, to form the acid form of acesulfame. The acid form of acesulfame K is then optionally neutralized with a base.¹

B. The '068 Patent

5.10 On June 12, 1979, the U.S. Patent and Trademark Office duly, properly and legally issued U.S. Patent No. 4,158,068, entitled "Sweetener Mixture," to Hoechst AG, as the assignee of inventors Gert-Wolfhard von Rymon Lipinski and Erich Lueck. A certified copy of the '068 patent is attached as Exhibit 12. Inventors Gert-Wolfhard von Rymon Lipinski and Erich Lueck assigned all right, title and interest in the '068 patent to Hoechst AG. On September 1, 1997, Hoechst AG assigned all right, title and interest in the '068 patent to Nutrinova GmbH. Certified copies of these assignments are attached as Exhibit 13.

5.11 The '068 patent issued from U.S. Patent Application No. 808,987 filed June 22, 1977, claiming priority under 35 U.S.C. § 119 from German Application No. 2628294 filed June 24, 1976. A certified copy of the U.S. Patent and Trademark Office prosecution history for the '068 patent and three additional copies as well as four copies of each patent and the

¹ Complainants own additional patents covering aspects of the process for making acesulfame K. One or more of these patents may be asserted against the Respondents once discovery is conducted in the investigation.

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applicable pages of each reference cited therein are being submitted with the Complaint.

5.12 On July 3, 1989, the Commissioner of Patents extended the term of the '068 by a period of two years pursuant to 35 U.S.C. § 156, thereby extending the expiration date of the '068 patent to June 22, 1999. A copy of the duly awarded patent term extension for the '068 patent, as it appears in the certified copy of the prosecution history, is attached hereto as Exhibit 14.

5.13 A list of foreign patents and patent applications corresponding to the '068 patent, including an indication of status, is attached hereto as Exhibit 15.

5.14 The '068 patent describes and claims sweetener mixtures that include acesulfame K. The inventors of the '068 patent discovered through their research that they could better approximate the taste of natural sugar by mixing acesulfame K with at least one additional sweetener in a particular range of ratios. The additional sweetener may be one of four different synthetic sweeteners:

- (i) aspartyl phenyl alanine methyl ester (aspartame);
- (ii) the sodium salt of cyclohexyl sulfamic acid (a cyclamate sweetener);
- (iii) the sodium salt of saccharin; or
- (iv) neohesperidin-dihydrochalcone.

5.15 A synthetic sweetener that mimics the taste of natural sugar is highly desirable. At the time of the invention of the '068 patent, it was completely unpredictable how a mixture of two or more synthetic sweeteners would affect the sweetness intensity and/or the taste quality

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of the resultant blend.

5.16 Like many synthetic sweeteners, acesulfame K produces an aftertaste in high concentrations. The inventors of the '068 patent discovered that the taste of acesulfame K evolves very rapidly and fades slowly. By providing acesulfame K in a mixture with at least one of the synthetic sweeteners mentioned above, the resulting mixture exhibits an unexpectedly and markedly improved taste.

VI. INFRINGEMENT, IMPORTATION, AND OFFERS FOR SALE

A. The '629 Patent

6.1 Upon information and belief claims 1-5 of the '629 patent are infringed by the process used by Respondents' in the manufacture of acesulfame K and by the importation, use, and sale of acesulfame K in the United States. More specifically, on information and belief, Respondents' infringing process includes the ring closure of an acetoacetamide-N-sulfonate or acetoacetamide-N-sulfonic acid by at least an approximately equimolar amount of sulfur trioxide, followed by neutralization of the resulting product to form acesulfame K.

6.2 As Dr. Christian Klug explains in his declaration attached as Confidential Exhibit 16, Nutrinova GmbH has found that acesulfame K samples obtained from Respondents JRS, Dingsheng, and WYZ Tech, and manufactured by Sanhe [

]. As Confidential Exhibit 11 and paragraph 5.9 supra, indicate, [

] As Dr. Udo Dettmeier

explains in his declaration attached as Confidential Exhibit 17, he knows of no other commercially viable processes [] that do not use

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technology covered by the '629 patent. A exemplary claim chart showing how Respondents' process to produce acesulfame K infringes the '629 patent is attached as Confidential Exhibit 18.

6.3 At an Institute of Food Technologists ("IFT") trade show on June 16, 1997, a representative of Sanhe who identified herself as Jane Wu of WYZ Tech, informed [] of Complainants that the acesulfame K being offered for sale by Sanhe was manufactured at two production plants in China "using the same technology as Hoechst."

6.4 In view of the analysis of Respondents' acesulfame K, the declarations of Dr. Klug and Dr. Dettmeier, and the statements of Respondents, Complainants believe that Respondents infringe the '629 patent. At a minimum, Complainants believe that they have met the requirements of 35 U.S.C. § 295, as they have made reasonable efforts to determine that an infringing process was actually used including obtaining samples of and testing Respondents' product. These tests have established that a substantial likelihood exists that Respondents' acesulfame K imported into the United States was made by a process covered by claims 1-5 of the '629 patent.

B. Inducement to Infringe the '068 Patent

6.5 The blend ratios found in claims 1 and 2 of the '068 patent are broad enough to encompass a substantial majority of blended uses of acesulfame K. See Confidential Ex. 6. Upon information and belief, as alleged in paragraphs 6.11 to 6.15, infra, Respondents have specifically and repeatedly encouraged their customers to infringe claims 1 and 2 of the '068 patent, inter alia, by their sales literature and marketing techniques that teach and encourage blending of acesulfame K with a further sweetener, particularly aspartame, in violation of 35

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U.S.C. § 271(b).

6.6 Upon information and belief, [] have directly infringed the '068 patent at least by [] within the ranges of claims 1 and 2 of the patent. Complainants know that Respondents actively distributed samples of acesulfame K with a suggestion to blend. See ¶¶ 6.11, 6.14, infra. One Respondent, JRS, has represented [] As indicated previously, about [] of acesulfame K sold in the United States is used in blends the substantial majority of which fall within the broad ranges of the claims of the '068 patent. See Confidential Ex. 6.

6.7 Complainants have learned that one or more of the Respondents []

6.8 Complainants have also learned that one or more of the Respondents []

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].

6.9 In light of the sensitive and proprietary nature of this information that is exclusively in the hands of third parties i.e., [] or Respondents and their customers, it is not possible to obtain any additional or more specific information at this time. Nevertheless, in light of the foregoing, Complainants believe that their allegation of induced infringement is likely to have further evidentiary support after a reasonable opportunity for further investigation or discovery.

C. Importation and Offers for Sale

6.10 In April 1997, Andreas Lotz, at that time Director of Sales and Marketing of the Hoechst Celanese Food Ingredients Business Unit attended an Institute of Food Technologists ("IFT") trade show in Edison, New Jersey. At that trade show, Mr. Lotz obtained an approximately 25 gram sample of acesulfame K from a booth operated by JRS. The individual in the booth provided Mr. Lotz with a business card that identified her as Jane Xu, General Manager of JRS. As noted above, Complainants tested the samples provided by Ms. Xu and determined that the acesulfame was made by a process that, upon information and belief, infringes the '629 patent. See Confidential Exhibit 16.

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6.11 At the same trade show Mr. Lotz also obtained promotional material from JRS indicating that the company was a subsidiary of Sanhe. See Exhibit 3. These promotional materials also specifically suggest the use of acesulfame K in blends with other sweeteners to obtain synergistic effect.

6.12 On June 16, 1997, at an IFT trade show in Orlando, Florida, [] visited a booth operated by Sanhe. A representative of Sanhe, who identified herself as Jane Hu, of WYZ Tech provided [] two samples of acesulfame K. One sample was approximately 25 grams and the second was approximately 1 kilogram. Ms. Hu stated that the acesulfame K was manufactured at two production plants in China "using the same technology as Hoechst." Ms. Hu quoted prices to [] and indicated that Sanhe had the capacity to supply the United States with 12.5 metric tons per month. [] was also provided with the promotional material referring to Dingsheng that is attached as Exhibit 4, as well as additional promotional material that is attached as Exhibit 19. A copy of Sanhe's entry in the IFT Food Expo Exhibit Directory is attached as Exhibit 20.

6.13 Complainant tested the samples provided by Ms. Hu, but the results were inconclusive as to whether the acesulfame K was manufactured by a process that infringes the '629 patent. See Confidential Exhibit 16. Some of the promotional materials provided at the Orlando trade show were the same as those distributed at the New Jersey show attended by Mr. Lotz. A crude attempt, however, was made to tape over the reference in the materials referring to the synergistic effects of using acesulfame K in a blend with other sweeteners. See Exhibit 19.

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6.14 On [

] Among the statements that Ms. Xu made [] was that acesulfame K had the best flavor when blended with sugar or aspartame and that acesulfame K could be blended with other sweeteners to reduce costs, because less acesulfame K achieves the same sweetness intensity.

6.15 [

] from JRS. The sample was independently tested and, upon information and belief, was manufactured by a process that infringes the '629 patent. See Confidential Exhibit 16. A copy of the promotional materials received are attached as Confidential Exhibit 21.

6.16 [

]

6.17 [

] The materials, however, bore the name WYZ Tech. The sample was independently tested and, upon information and belief, was manufactured by a process that infringes the '629 patent. See Confidential Exhibit 16. A copy of the promotional materials received are attached as Confidential Exhibit 5.

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6.18 The item number, from the harmonized Tariff Schedules of the United States, of the articles being imported unlawfully and in violation of Nutrinova GmbH's patent rights is 2934.90.90.00.

VII. THE DOMESTIC INDUSTRY

A. Economic Prong

7.1 A domestic industry exists with respect to the patents at issue by virtue of the activities of Nutrinova Inc. and its predecessor-in-interest Hoechst Celanese Corporation, which have made significant investment in plant and capital equipment and have employed a significant amount of labor in research and development, sales and marketing, distribution and in obtaining regulatory approval for Sunett® Brand Sweetener. In addition, Complainants have engaged in substantial licensing of the '068 patent to domestic customers.

7.2 The Somerset, New Jersey facility of Nutrinova Inc. is almost wholly dedicated to Sunett® Brand Sweetener. The only non-Sunett® Brand Sweetener activity conducted at the facility is customer service and marketing for sorbate products. The Somerset facility has approximately [] square feet of space. Approximately [] square feet of that space is devoted to three research and development laboratories, another [] square feet is devoted to offices and conference facilities, [] square feet is used for warehouse, shipping and receiving needs and the remaining [] square feet is dedicated to common areas. A floor plan diagram of the Somerset facility is attached as Confidential Exhibit 22.

7.3 Nutrinova Inc. employs a total of [] people, [] of whom are dedicated to Sunett® Brand Sweetener. These [] employees are principally involved in the following

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activities [] technical, [] regulatory, [] sales, [] marketing, [] customer service, [1] secretarial, [] computer systems, and [] administration. Nutrinova Inc. invested a total of approximately [] in wages and benefits for these employees in 1996.

7.4 Nutrinova Inc. carries out extensive research and development at its Somerset facility. This research and development is critical to Complainants' ability to sell acesulfame K in the United States. Specifically, the research and development staff in the New Jersey facility devotes most of its time [] to working with specific customers to formulate blends and products using Sunett® Brand Sweetener. The research and development staff also does some general research and competitive analysis []. As noted, the vast majority of Complainants' U.S. customers use acesulfame in blends. See Confidential Ex. 6. Many of these customers, however, could not do so without first obtaining the assistance of Nutrinova Inc.'s research and development staff.

7.5 [] full time employees work in research and development on Sunett® Brand Sweetener. [] of these employees have advanced degrees, including [] with PhDs and [] with a Masters degree in the areas of food science and technology. The research and development staff works with customers to create blend recipes or formulas for each customers' products. Because each product has its own unique taste profile and sweetening requirements, considerable testing and research is necessary to find the best formulation. This work is done either in Nutrinova Inc.'s three research and development laboratories or the research and development staff travels to the customers' facilities to work with the customers' technicians to create the appropriate blend formulations.

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7.6 One of Nutrinova Inc.'s three research and development laboratories is a sensory laboratory. In this laboratory, Nutrinova Inc. employs a trained panel of expert consumers who are assembled two to three times per week to test and evaluate products containing acesulfame K. Nutrinova Inc. has extensively trained these expert consumers over a period of six months to evaluate different aspects of taste. This training included the use of a consultant at a cost of []. Results of testing in the sensory laboratory are utilized in creating blend formulas tailored to the specific needs of customers. The sensory laboratory cost [] to construct. Equipment in the sensory lab includes [] computerized booths. Each computer contains specially designed software for taste evaluation. Nutrinova Inc. has invested over [] in equipment and software for the sensory lab and pays a license fee of [] per year on the software. Nutrinova Inc. pays its panel of expert consumers [] per hour and in 1996 paid over [] to its expert consumers.

7.7 In its formulation laboratory Nutrinova Inc. researchers perform basic blend and product formulations and testing using a wide array of sophisticated equipment. The formulation laboratory cost [] to construct and Nutrinova Inc. has invested over [] in equipment for the formulation laboratory.

7.8 The Somerset facility also contains a pilot plant laboratory containing large equipment necessary to prepare a number of different types of products that can contain acesulfame K, including chewing gum, hard candy, baked goods, frozen foods and beverages. The pilot plant cost [] to construct. Equipment in this laboratory includes industrial ovens, tempering cabinets, an industrial freezer and a carbonator. Nutrinova Inc. has invested

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over [] in equipment for the pilot plant laboratory.

7.9 [] full-time employees at the Somerset facility are devoted to regulatory affairs. The responsibilities of these employees include developing information and filing petitions to the FDA in support of approval for Sunett® Brand Sweetener, directing the efforts of numerous external technical, legal, regulatory and public relations consultants, providing assistance to customers on health-related questions from consumers and to provide regulatory guidance to customers on the appropriate use of Sunett® Brand Sweetener.

7.10 In obtaining FDA approval for Sunett® Brand Sweetener Nutrinova Inc. has invested approximately [] over the last [] years. These expenses include testing costs, technical support costs, travel expenses, and expert and legal consulting fees. Without this approval Complainants could not sell acesulfame K in the United States.

7.11 [] full-time employees, [] at the Somerset facility and [] at other locations in the United States, are devoted to sales and marketing of Sunett® Brand Sweetener. Their responsibilities include meeting with customers to evaluate needs, locating potential new customers for Sunett® Brand Sweetener, advertising and promotion, and negotiating terms of sale and customer contracts including global sales contracts.

7.12 [] full-time employees are devoted to customer service. Their responsibilities include providing the primary contact for key customers, taking orders, handling routine inquires, claims, credits and refunds, shipping and warehousing. These employees spend [] of their time with matters relating to Sunett® Brand Sweetener and [] of their time with matters relating to sorbates.

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7.13 Complainants also engage in extensive licensing of the '068 patent. Each sale of Sunett® Brand Sweetener is accompanied by an implied license to blend the product with other sweeteners pursuant to the claims of the '068 patent. On occasion, this implicit license has been made explicit as reflected in Confidential Exhibit 23. A list of licensees/customers is attached hereto as Confidential Exhibit 24.

B. Technical Prong

7.14 Nutrinova GmbH has developed a commercial process covered by the '629 patent and uses that process to manufacture acesulfame K. [

] A chart illustrating the correspondence between claim 1 of the '629 patent and Nutrinova GmbH's method for manufacturing acesulfame K is attached hereto as Confidential Exhibit 25.

7.15 A substantial majority of Complainants' U.S. customers blend the acesulfame K in ratios within the scope of claims 1 and 2 of the '068 patent under an implied license. Moreover, as set forth in the exemplary claim chart attached as Confidential Exhibit 26,

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Nutrinova Inc. regularly blends acesulfame K in its research and development laboratories in ratios within the scope of claims 1 and 2 of the '068 patent in creating various formulations for its customers.

7.16 All the activities of Nutrinova Inc. in the United States, described above, constitute a domestic industry devoted to the exploitation of the '629 and '068 patents.

VIII. RELATED LITIGATION

8.1 The U.S. patents have not been the subject of previous or current litigation. The foreign patents have not been the subject of previous or current litigation except for the United Kingdom counterpart to the '068 patent that was the subject of an infringement action instituted by Hoechst AG in 1995. That action was subsequently settled.

IX. RELIEF

WHEREFORE, Complainants request that the Commission:

- a. Institute an investigation pursuant to Section 337 of the Tariff Act of 1930, as amended, into unfair methods of competition and unfair acts in the importation of certain acesulfame potassium and blends and products containing same into the United States, or in their sale, which acesulfame potassium is made by a process that infringes claims 1-5 of United States Patent No. 4,695,629, and any acesulfame potassium and blends and products containing same that infringe claims 1 and 2 of United States Patent No. 4,158,068;
- b. Schedule and conduct a hearing on said unlawful acts and, following, said hearing;
- c. Issue a permanent exclusion order pursuant to Section 337(d) of the Tariff Action of 1930, as amended, excluding entry into and sales within the United States of any

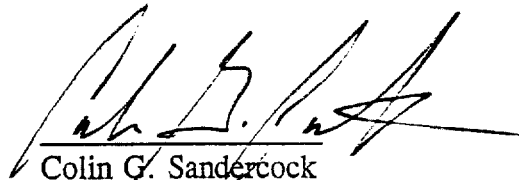
PUBLIC INSPECTION

acesulfame potassium and blends and products containing same that infringe the claims at issue herein in United States Patent Nos. 4,695,629, and 4,158,068;

d. Issue a permanent cease and desist order pursuant to Section 337(f) of the Tariff Act of 1930, as amended, directing Respondents to cease and desist from engaging in the unfair methods or acts relating to the importation into and sale within the United States of certain acesulfame potassium and blends and products containing same which infringe the claims at issue herein in United States Patent Nos. 4,695,629, and 4,158,068 or the blending of such acesulfame potassium that infringes the claims of U.S. Patent No. 4,158,068; and

e. Grant such other and further relief as it finds appropriate under the law, based upon the facts complained of herein and under the authority of the Commission.

Respectfully submitted,



Colin G. Sanderclock
Charles F. Schill
Larry L. Shatzer, II
Melinda F. Levitt
Mary Atchley Jester
Todd J. Burns
Susan Shaw McBee

Dated: October 16, 1997

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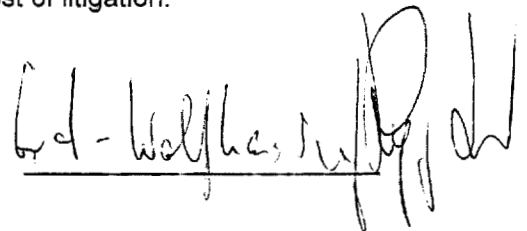
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VERIFICATION OF COMPLAINT

I, Gert-Wolfhard von Rymon Lipinski, declare, in accordance with 19 C.F.R. §§ 210.4 and 210.12(a), under penalty of perjury under the laws of the United States that the following statements are true and correct:

1. I am Director of Regulatory Services and Management System of complainant Nutrinova Nutrition Specialties & Food Ingredients GmbH and am duly authorized to sign this Complaint on behalf of Complainants;
2. I have read the foregoing Complaint;
3. To the best of my knowledge, information, and belief, based upon reasonable inquiry, the foregoing Complaint is well-founded in fact and is warranted by existing law or by a non-frivolous argument for the extension, modification, or reversal of existing law or the establishment of new law;
4. The allegations and other factual contentions have evidentiary support or are likely to have evidentiary support after a reasonable opportunity for further investigation or discovery; and
5. The foregoing Complaint is not being filed for an improper purpose, such as to harass or to cause unnecessary delay or needless increase in the cost of litigation.

Executed this 14 of October, 1997



Gert-Wolfhard von Rymon Lipinski

Hoechst 

Nutrinova · Industriepark Höchst · D-65926 Frankfurt am Main

To whom it may concern

**Regulatory Services &
Management System**

Nutrinova
Nutrition Specialties &
Food Ingredients GmbH
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Datum: 13.10.97
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Vollmacht - Power of Attorney

Hiermit bevollmächtigen wir Herrn Dr. Gert-Wolfhard von Rymon Lipinski, Director Regulatory Services and Management Systems, der Nutrinova Nutrition Specialties & Food Ingredients GmbH, in unserem Namen Schriftstücke für Klagen auf Patentverletzung in den USA mit Einzelunterschrift zu unterzeichnen.

We hereby authorize Dr. Gert-Wolfhard von Rymon Lipinski, Director Regulatory Services and Management Systems, Nutrinova Nutrition Specialties & Food Ingredients GmbH, to sign letters and declarations on patent litigation in the USA on our behalf by single signature.

Nutrinova Nutrition Specialties & Food Ingredients GmbH


Dr. Steinmetz
Chief Executive Officer


Arnold
Financial Officer

Hoechst 