

**Appendix 4**



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Specialty Grain Products Company

As members of the expert panel convened by ConAgra Specialty Grain Products Company to review Oatrim for self affirmation as Generally Recognized as Safe (GRAS), we are in agreement with the following statements:

- o Oatrim is best characterized as "hydrolyzed oat flour" or "hydrolyzed oat bran" for USDA and FDA regulated applications and "oat flour, modified" or "oat bran, modified" for all other applications.
- o The process for making Oatrim uses GRAS ingredients
  - Oat flour or oat bran
  - Hydrochloric Acid (HCl), Food Chemicals Codex, 1981, Monographs, pages 144-145
  - Sodium Hydroxide solution, Food Chemicals Codex, 1981, Monographs, pages 287-288
  - Alpha-amylase, a GRAS enzyme
  - Calcium salts, such as calcium chloride solution, Food Chemicals Codex, 1981, Monographs, page 49
- o Oat flour or oat bran is pre-gelatinized and enzyme thinned to facilitate separation and recovery of the water-soluble fraction.
- o All processing equipment is in compliance with Good Manufacturing Practices (GMP).
- o Oatrim is derived from a wet process that refines oat flour or oat bran by removing insoluble residues (fiber, some proteins, fat, minerals) while retaining maximum of the soluble fiber natural in oat flour or oat bran.
- o Oat flour or oat bran is pre-gelatinized and enzyme thinned to facilitate separation and recovery of the soluble fraction.
- o Oatrim will function as a grain based humectant and texture modifier in a wide variety of foods without negatively impacting the color and flavor of the finished product.
- o Oatrim is similar to other existing cereal adjuncts such as pre-cooked flours, pre-cooked bran and starches, and to the best of our knowledge will not adversely impact the health and nutrition of the public.

Therefore, in our opinion, Oatrim is GRAS for all applications.

<u>Dr. Rosemary Newman</u>	Date
<u>Dr. Paul Seib</u>	3/22/91
<u>Dr. Peter Wood</u>	3/22/91
<u>Dr. George Inglett</u>	3/28/91
<u>Mr. Paul Smith</u>	3/22/91
Mr. Paul Smith	Date

## OATRIM

### Identity:

Oatrim is a starch product (Attachment 1) produced by the hydrolysis of oat flour or oat bran by an  $\alpha$ -amylase, Takalite<sup>®</sup>, a food grade  $\alpha$  amylase from *B. licheniformis* (Attachment 2).

### Manufacturing Process:

Milled products of oats, such as oat bran and oat flour, are hydrolyzed with  $\alpha$ -amylase. The solubilized starch product is separated from the insoluble fibers and is dried or concentrated. The patent for the manufacture of Oatrim is attached (Attachment 3).

### Regulatory status:

GRAS self-affirmation statement attached (Attachment 4).

### Attachments:

1. Oatrim composition.
2. Takalite<sup>®</sup>, An improved thermal stable bacterial alpha-amylase for starch liquifaction.
3. U.S. Patent No. 4,996,063. Method for making a soluble dietary fiber composition from oats.
4. ConAgra GRAS Expert Panel statement, March 22, 1991.

### OATRIM Composition

Component	OATRIM-1 %, db	OATRIM-5 %, db	OATRIM-10 %, db
Fat (Crude)	0.3	1.4	0.6
Protein (Nitrogen x 6.25)	1.9	5.0	4.0
Minerals (Ash)	1.4	3.1	4.2
Beta-Glucan	1.6	5.8	10.2
Pentosans	1.0	2.0	3.0
Amylodextrins (by difference)	93.8	82.7	78.0