

Polydextrose Food Additive Petition – 2005

Section H - Environmental Assessment

Introduction

As requested by the Agency, a new updated Environmental Assessment is hereby provided. This EA was prepared following the CFSAN/OFAS guidance document (20). We incorporate by reference into this section the data from the previous PDX environmental assessments provided to the agency by Pfizer Inc. and Cultor Food Science in the previous food additive petitions listed below.

<u>FAP #</u>	<u>Date Filed</u>	<u>Filing Notice</u>	<u>Approval Notice</u>	<u>EA Pages</u>
9A3441	12/14/78	44 FR 22816 - 4/17/79	46 FR 30080 - 6/5/81	01092-98
8A4068	2/1/88	53 FR 19046 - 5/25/88	59 FR 37419 - 7/22/94	000062
9A4126	12/22/88	54 FR 10727 - 3/15/89	59 FR 37419 - 7/22/94	000069
2A4332	6/22/92	57 FR 38311 - 8/24/92	65 FR 64604 - 10/20/00	000063
5A4478	7/31/95	60 FR 48716 - 9/20/95	65 FR 79718 - 12/20/00	057*
7A4556	2/18/97	62 FR 50387 - 9/25/97	63 FR 57596 - 10/28/98	11

*On December 5, 1995, FDA requested Pfizer Inc. (21) to provide a Revised Master Environmental Assessment for polydextrose as part of FAP 5A4478. This document (22) was submitted to FDA on June 26, 1996, and we incorporate it by reference.

1. **Date:** October 10, 2005
2. **Name of petitioner:** Danisco USA Inc.
3. **Address:** 440 Saw Mill River Road
Ardsley, NY 10502

4. **Description of the Proposed Action:**

a. Requested approval:

The proposed action involves polydextrose (PDX). Danisco Sweeteners proposes to amend the food additive regulation for PDX (21 CFR 172.841) to permit its use as a general purpose bulking agent, humectant and texturizer in foods at levels in accordance with good manufacturing practice (GMP). Use levels corresponding to GMP for each food category are given in Table 1, Appendix 1. Use of PDX in foods at levels exceeding the maxima listed therein is not GMP because it exceeds the amount necessary to achieve the desired effect and results in functional defects or excessive cost.

As provided in section 21 CFR 172.841, PDX is currently approved for use in 13 food categories. This petition provides data in support of extending the currently approved uses of PDX to its use as a general purpose bulking agent, humectant and texturizer, with the elimination of the individual food categories identified in the current regulation. The proposed amended regulation is given in Section G.

b. Need for action:

PDX was developed for use as a low calorie bulking agent to replace the bulk of sugars when a high intensity sweetener is used to provide sweetness with reduced caloric content. PDX is water soluble and provides only 1 kcal/g vs 4 kcal/g for sugars and starches. It has no sweetness or flavor of its own, which makes it an ideal companion to currently used intense sweeteners. It has been used in food safely all over the world for over 24 years, but its approved uses in the US are limited to the 13 categories listed in under 21 CFR 172.841.

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This action is needed because there is a growing incidence of obesity and diabetes in this country and broader use of PDX will make available a greater variety of reduced sugar and reduced calorie foods to enable consumers to better manage their weight and improve nutrition. Many people would like to enjoy the benefits of PDX use that approval of this petition would permit.

c. Locations of use:

PDX will be sold to food and beverage manufacturers in whose food processing facilities PDX would be incorporated into finished products.

d. Locations of disposal:

PDX is only partially metabolized in the human GI tract, with about 33% (1) to 54% (3) of the ingested amount being excreted intact. Following consumption, the amount excreted would enter largely unchanged into publicly owned treatment works (POTWs) or domestic septic systems.

5. **Identification of substances that are the subject of the proposed action:**

Common or Usual Name: Polydextrose

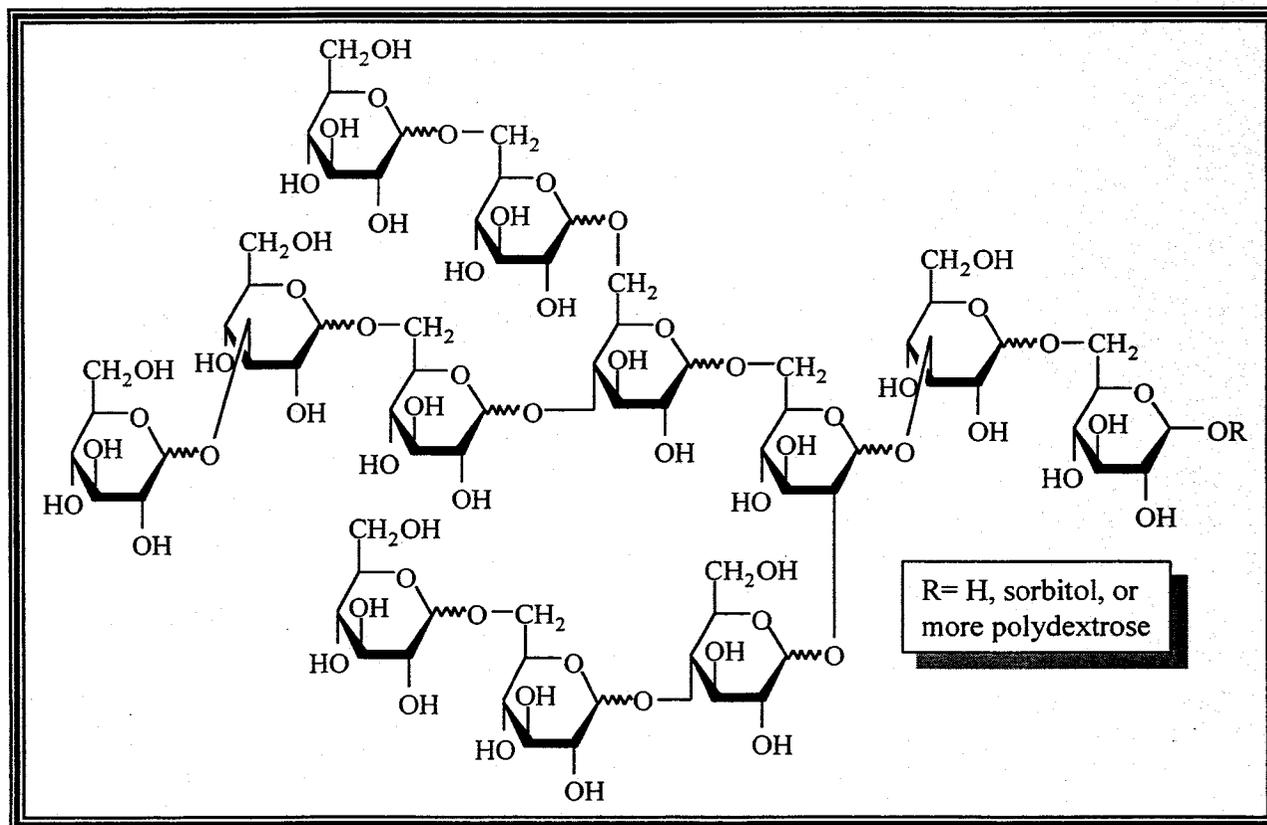
Chemical Name: Polydextrose

CAS Registry Number: 68424-04-4

Molecular Weight: Average MW ~2000

Molecular formula: $(C_6H_{10}O_5)_n$ where n averages 12

Structural Formula:



Physical Description: polysaccharide; white to light tan powder or granules; soluble in water up to ~80% solids.

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Additional information is given in Section A.

6. Introduction of substances into the environment:

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

PDX is manufactured by Danisco Sweeteners, Inc., Terre Haute, IN, a division of the parent company Danisco A/S in Copenhagen, Denmark. The facilities are operated in compliance with all applicable environmental and occupational exposure requirements. No extraordinary circumstances apply to the manufacture of PDX. Spills of product are minimal and disposed of in on-site dedicated treatment works. Further details of the production facility are given in the 1996 Revised Master Environmental Assessment for FAP 5A4478 (22).

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

There will be little or no direct introduction of PDX into the environment as a result of its use because it is incorporated into food and beverages. However, since PDX is poorly metabolized, it will enter the environment almost exclusively after consumption through excretion. As noted above, about 33-54% of ingested PDX is excreted intact.

PDX 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 PDX found in the environment. PDX has been demonstrated to be biodegradable (6), hence accumulation of PDX in the environment is highly unlikely.

Confidential calculations of EICs for PDX in the aquatic and terrestrial environments. See item 3 in Volume 2.

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

Accidental spills of polydextrose will be collected and disposed of as waste into on-site dedicated treatment works. Assuming 0.5% wastage (22) from spillage, equipment washings and disposal of off-spec food products, this amount is insignificant and not likely to enter the environment. Concentrations in treatment plant effluents are expected to be minimal as PDX is biodegradable.

7. Fate of Substances Released into the Environment:

The fate of PDX in the environment is discussed in the Revised Master Environmental Assessment for FAP 5A4478 (22). Polydextrose is extremely water-soluble (80 g of PDX is soluble in 20 g of water) and rapidly biodegradable (see below).

8. Environmental Effects of Released Substances:

Data have been presented in previous petitions for PDX, including data relating to potential toxicity to organisms in the environmental assessments submitted in FAPs 9A3441 and 5A4478. The studies demonstrated that

- PDX is not acutely toxic to freshwater fish (bluegill *Lepomis macrochirus*). The NOEL was 20,000 mg/L, or over 100,000 times the level expected to be found in aqueous ecosystems (0.184 ppm), and is unlikely to have any adverse effects on other aquatic organisms.
- PDX is readily biodegradable: BOD₅ = 280,000 ppm; BOD₂₀ = 485,000 ppm (41% of theoretical)

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Based upon the manufacturing and processing conditions of PDX, 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 with no adverse environmental effects are expected. Twenty years of full-scale production of PDX have not revealed any environmental concerns.

9. Use of Resources and Energy:

The use of resources and energy has been evaluated in previous PDX submissions, including the 1996 Revised Master Environmental Assessment for FAP 5A4478 (22). *Confidential production facility information; see Item 4 Volume 2.* Thus there will be no alteration of existing land use from the subject action. All raw materials used in PDX manufacture (glucose, sorbitol and citric acid) are derived from renewable resources (cornstarch).

10. Mitigation Measures:

Mitigation measures taken at the manufacturing site for PDX have been described in previous petitions. Considering the lack of any anticipated adverse environmental effects from the production and use of PDX in the proposed application, we conclude 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.

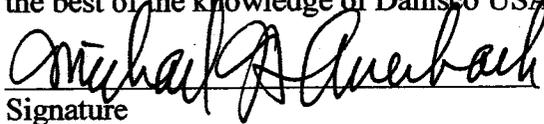
12. List of Preparers:

Michael H. Auerbach, Senior Science Advisor, Regulatory Affairs, Danisco USA Inc.
- Education: S.B. in chemistry - Massachusetts Institute of Technology, 1961-1964;
Ph.D. in analytical chemistry - Cornell University, 1964-1970;
- Experience: Monsanto Polymers and Petrochemicals Co, Springfield, MA - 1969-1976
Pfizer Central Research, Groton, CT - 1976-1996
Cultor Food Science, Inc., Groton, CT; Ardsley, NY - 1996-1999
Danisco USA, Inc., Ardsley, NY - 1999-present

18 years experience in analytical techniques and industrial chemical product R&D;
16 years experience in the food industry; and
12 years experience in worldwide food regulatory affairs, including compliance with
FDA and EPA regulations.

13. Certification

The undersigned official certifies that the information presented herein is true, accurate and complete to the best of the knowledge of Danisco USA Inc.


Signature

12/6/05
Date

Michael H. Auerbach, Senior Science Advisor, Regulatory Affairs
Printed Name and Title

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