



ENVIRONMENTAL ASSESSMENT REPORT

1. **Date:** April 3, 2001
2. **Name of Sponsor:** Basell Polyolefins N.V.
The Netherlands
3. **Address:** 2801 Centerville Road
Wilmington, Delaware 19808-1652

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

The purpose of this notification is to expand upon the clearance for certain polymers of butene-1 currently set forth in 21 C.F.R. § 177.1570. The notification would allow for the use of polymers that comply with the specifications of Section 177.1570(b)(1) in contact with all food types, under Conditions of Use A-H, as described in 21 C.F.R. § 176.170(c), Table 2, subject to no thickness limitation, provided that representative test specimens meet proposed maximum extractives limitations in 95% ethanol. In addition, polymers subject to a broader range of viscosity and melt index than currently specified would be permitted for use under Conditions of Use B-H, as described in 21 C.F.R. § 176.170(c), Table 2.

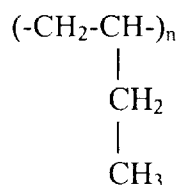
5. **Identification of Substances that are the Subject of the Proposed Action:**

1. **Chemical Names/CAS No./Common Names:**
Butene-1-polymer
(Chemical Abstracts Service Registry No. 9003-28-5)
Poly-1-butene polymer or butene polymer

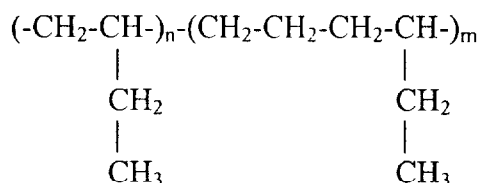
Butene-1-ethylene copolymer
(Chemical Abstracts Service Registry No. 25087-34-7)
Butene/ethylene copolymer or ethylene/butene copolymer
2. **Brand Names:**

Product grades are designated as _____ (polybutylene) or
(developmental product) followed by a four digit code. The code indicates
whether the polymer is a homopolymer or copolymer and describes the melt index
and specific additive package for a given grade.
3. **Structural Formulas:**
The structural formulas for the polymers are as follows:

000004



for the butene-1 polymers and



for the butene/ethylene copolymers.

6. Introduction of Substances into the Environment:

a. Production of the food-contact substance:

We have determined that no extraordinary circumstances apply to the manufacture of the food-contact substance. Therefore, information regarding the production of the food-contact substance is not provided.

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

There will be little or no introduction of substances into the environment as a result of the use of polybutene-1 and butene-ethylene copolymers because these substances are almost completely incorporated into food-packaging materials and, essentially, are expected to remain with this packaging throughout use of the product.

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

i. Landfilling: Based on the migration studies on food-packaging materials made from polybutene-1 and butene-ethylene copolymers, which were performed to demonstrate the safety of these substances, only very low levels of substances are expected to leach from these materials in landfills. Landfills are regulated by the U.S. Environmental Protection Agency. This agency's regulations require new municipal solid waste landfill units and lateral expansions of existing units to have composite liners and leachate collection systems to prevent leachate from entering ground and surface water and to have groundwater monitoring systems. Although owners and operators of existing active municipal solid waste landfills that were constructed before October 9, 1993, are not required to retrofit liners and leachate collection systems, they are required to monitor groundwater and to take corrective action as appropriate. Thus, we expect only small quantities, if any, of substances to be introduced into the environment in landfill leachate.

ii. Combustion: Polybutene-1 and butene-ethylene copolymers are composed of carbon and hydrogen, elements commonly found in municipal solid waste.¹ The complete combustion of these substances will produce only carbon dioxide and water. Because the market volume² of the subject polymers is a small fraction of the municipal solid waste generated and disposed in the United States and these substances will be replacing similar materials, adding these substances to waste that is combusted will not alter significantly the emissions from municipal waste combustors.

7. Fate of Substances Released into the Environment:

No information need be provided on the fate of substances released into the environment as the result of use and/or disposal of polybutene-1 and butene-ethylene copolymers, because, as discussed under Format Item 6, only small quantities, if any, of substances will be introduced into the environment as a result of use and/or disposal of these polymers.

8. Environmental Effects of Released Substances:

No information need be provided on the environmental effects of substances released into the environment as a result of use and/or disposal of polybutene-1 and butene-ethylene copolymers, because, as discussed under Format Item 6, only small quantities, if any, of substances will be introduced into the environment as a result of such use and/or disposal. Therefore, the use and disposal of the food additive are not expected to threaten a violation of applicable laws and regulations, *e.g.*, the Environmental Protection Agency's regulations in 40 C.F.R. Parts 60 and 258.

9. Use of Resources:

a. Market volume:

We estimate sales of the subject polymers will increase by about
per year over the next five years.

b. Types of food contact articles and food applications:

The subject polymers are expected to be used in a variety of food-contact applications. Information on some currently anticipated applications for the

¹ *Municipal Waste Combustors - Background Information for Proposed Guidelines for Existing Facilities*, EPA-450/3-89-27e, United States Environmental Protection Agency, Office of Air Quality Planning and Standards, Research Triangle Park, NC 27711; August 1989; Table 2.2-1.

² See the market volume provided under format item 9.

polymer is set forth in the following table. Please note that this information is intended for illustrative purposes only, and is not intended to represent an exhaustive list of the possible applications for the polymers.

Description of some food-contact articles and food applications affected by the proposed action		
Articles to be made with packaging containing the food contact substance	Types of food packaging applications	Type of packaging materials currently used for these applications
-films -lidding stock -heat seal coatings -household wrapping film -liners for dry cereal -heat seal coatings for retortable foods or microwaveable foods in trays	-meat -produce -cheeses -snack food (<i>i.e.</i> , potato chips/pretzels) -condiments and single portion products such as coffee creme	-polypropylene and ethylene copolymers -ethylene vinyl acetate (EVA) copolymer -polyvinyl chloride (PVC) film

c. Disposal patterns:

Polybutene-1 and butene-ethylene copolymers will be incorporated into food-packaging materials at production plants located throughout the United States. Food-packaging materials are expected to be used by consumers in patterns corresponding to national population density and to be widely distributed across the country. Disposal of the subject food-packaging materials is expected to occur nationwide with the materials ultimately being deposited in municipal solid waste landfills or combusted. We predict that there will be very limited, if any, recovery from waste for recycling of the articles made with the subject polymers. This conclusion is based on the following: 1) the negligible recycling rates of articles currently used in the expected applications of the subject packaging,³ 2) the unacceptableness of certain food contact articles, *e.g.*, films, in recycling streams, because of the variety of resins used to make films and because of the contamination of food contact films with foods.^{4 & 5}

³ *Characterization of Municipal Solid Waste in the United States: 1998 Update*, EPA530-R-99-021, U.S. Environmental Protection Agency (5305W), Washington, DC 20460, September 1999, Table 7.

⁴ J.A. Goff, "Plastic Film Recycling: A New Beginning," *Waste Age*, Vol. 26, No. 2, February 1995, page 69.

d. **Resource use impacts related to solid waste management strategies:**

The potential for FDA's action on this notification to have adverse effects on resource use related to the solid waste management strategies of source reduction, recycling, and landfilling impact can be assessed by comparing articles expected to be made with the subject copolymers to articles that they will compete with and replace. As noted above, the subject copolymers are expected to be used in the production of films, sheet, and coatings intended for contact with food. Typical materials produced from the polymers may include food packaging films, lidding stock, heat seal coatings, and the like. These new articles are expected to compete with and replace other currently regulated food-packaging materials such as those noted above. Articles made with the subject copolymers will be essentially the same in weight and volume as articles made with competing materials because the competing polymeric materials are very similar to the subject copolymers in composition. Thus, use of the subject copolymers will neither reduce nor increase the amount of packaging needed for the projected applications.

Because the articles made with the subject copolymers are so similar to the articles they will be competing with and replacing, there is little if any potential for FDA's action on this notification to have any impact on resource use related to the solid waste management strategy of source reduction or on the resources involved with landfill volumes.

In addition, FDA's action is expected to have little, if any, impact on resource use related to the solid waste management strategy of recycling, based on the following. As noted above, there is currently negligible recycling of the articles the subject copolymers are expected to compete with and replace. Further, future recycling of food contact films and containers to be used in the expected applications is not likely because of the difficulty of cleaning articles that have residual food adhering to the films and containers and because these articles are currently made from a diversity of materials. These circumstances make recycling of articles of the type noted above difficult to the point of not being feasible. We believe that the FDA's action on this Notification is very unlikely to disrupt current recycling streams or to affect future recycling efforts because 1) articles made with the subject copolymers are expected to be very similar to the articles being replaced, 2) there is essentially no recycling of these currently used articles, and 3) articles made with the subject copolymers are also not expected to be recycled.

⁵ S. Apotheker, "Film at 11: A picture of curbside recovery efforts for plastic bags," *Resource Recycling*, Vol. XIV, No. 5, May 1995, page 35.

e. **Potential for impacts on energy use:**

Analysis of potential impact on energy that could result from FDA's action on this Notification is not needed because 1) the packaging materials currently used in the expected applications, identified above, are very similar to the subject copolymers and 2) the recycling of food packaging materials will not change as a result of FDA's approval of the subject copolymers because currently regulated materials for the proposed uses are not now recycled nor are articles made with the subject copolymers expected to be recycled, as discussed above.

10. Alternatives to the Proposed Action:

Alternatives to the proposed action need not be considered, because no potential adverse effects have been identified.

11. List of Preparers:

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12. Certification:

The undersigned certifies that the information presented is true, accurate, and complete to the best knowledge of the firm or agency responsible for preparation of the environmental assessment.

Date: April 3, 2001



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