

## Environmental Assessment

1. **Date** May 23, 2007
2. **Name of Applicant/Notifier** The Dow Chemical Company
3. **Address** All communications on this matter are to be sent to Mr. Garry M. Wiltshire, The Dow Chemical Company, 1803 Building #416, Midland, Michigan 48674.  
Telephone: (986) 638-1557
4. **Description of the Proposed Action**

The action requested in this Notification is the establishment of a clearance to permit the use of ethylene/hexene copolymers, containing up to 25 weight percent hexene, in the manufacture of articles for contact with all types of food under Conditions of Use A through H, as set forth in Table 2 of 21 C.F.R. § 176.170(c).

The subject copolymers offer similar technical properties to other Linear Low Density Polyethylene (LLDPE) copolymers made from ethylene and other comonomers that make them useful in a variety of food-contact applications. For purposes of this Environmental Assessment, subject materials will be designated as E/H copolymers.

While the petitioned for polymers are intended to compete with other alpha-olefin-based copolymer films, coatings, and molded articles, it is expected that these E/H polymers will primarily replace other LLDPE copolymers.

The Notifier does not intend to produce finished food packaging materials from the subject polymers. Rather, the polymers will be sold to manufacturers engaged in the production of food-contact materials. Food-contact materials produced with the use of the polymers will be utilized in patterns corresponding to the national population density and will be widely distributed across the country. Therefore, it is anticipated that disposal will occur nationwide, with about 80% of the materials being deposited in land disposal sites, and about 20% combusted.<sup>1</sup>

The types of environments present at and adjacent to these disposal locations are the same as for the disposal of any other food-contact material in current use. Consequently,

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U. S. EPA *Municipal Solid Waste Generation, Recycling, and Disposal in the United States: Facts and Figures for 2003*, EPA530-F-05-003; 2005.

there are no special circumstances regarding the environment surrounding either the use or disposal of food-contact materials prepared the subject copolymers.

## **5. Identification of Substance that Is the Subject of the Proposed Action**

The additives that are the subject of this Notification are copolymers of ethylene and hexene. Specifically, the subject of the FCN is copolymers produced by the polymerization of the two monomers such that the finished copolymers will contain up to 25 weight percent hexene units.

## **6. Introduction of Substances into the Environment**

Under 21 C.F.R. § 25.40(a), an environmental assessment ordinarily should focus on relevant environmental issues relating to the use and disposal from use, rather than the production, of FDA-regulated articles. Moreover, information available to the Notifier does not suggest that there are any extraordinary circumstances in this case indicative of any adverse environmental impact as a result of the manufacture of E/H copolymers. Consequently, information on the manufacturing site and compliance with relevant emissions requirements is not provided here.

No environmental release is expected upon the use of the subject polymers to fabricate food-contact materials. In these applications, the polymers will be entirely incorporated into the finished food package. Any waste materials generated in this process, *e.g.*, plant scraps, are expected to be disposed of as part of the packaging manufacturer's overall nonhazardous solid waste in accordance with established procedures.

Disposal by the ultimate consumer of food-contact materials produced by the subject copolymers will be by conventional rubbish disposal and, hence, primarily by sanitary landfill or incineration. The subject copolymers consist of carbon and hydrogen, elements that are commonly found in municipal solid waste. The proposed use of the FCS and the market volume (available in a confidential attachment to the FCN) show that 1) the FCS will make up a very small portion of the total municipal solid waste currently combusted (estimated to be 33 million tons or 14% of 236 million tons in 2003)<sup>1</sup> 2) the FCS will not significantly alter the emissions from properly operating municipal solid waste combustors<sup>2</sup>, and 3) incineration of the FCS will not cause municipal solid waste combustors to threaten a violation of applicable emissions laws and regulations (40 CFR part 60 and/or relevant state and local laws).

Only extremely small amounts, if any, of the copolymer constituents are expected to enter the environment as a result of the landfill disposal of food-contact articles, in light of the Environmental Protection Agency's (EPA) regulations governing municipal solid waste landfills. EPA'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 ground-water monitoring systems. 40 C.F.R. Part 258. Although owners and operators of existing active

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<sup>2</sup> Paul M. Sullivan; William H. Hallenbeck; Gary R. Brenniman, *Municipal Solid Waste Combustion*; University of Illinois at Chicago: Chicago, IL, 1993.

municipal solid waste landfills that were constructed before October 9, 1993 are not required to retrofit liners and leachate collections systems, they are required to monitor groundwater and to take corrective action as appropriate. The lack of any leaching is especially true considering that the subject substances are high molecular weight polymers that contain only minute levels of extractable material even under conditions that greatly exaggerate environmental exposure conditions.<sup>3</sup> Even if a very small amount of substances leach from the landfilled food-packaging material into the landfill, we expect only extremely small amounts of substances, if any, to migrate from landfill leachate into the environment; this conclusion is based on EPA's regulations in 40 C.F.R. Part 258.

## **7. Fate of Emitted Substances in the Environment**

No significant effect on the concentrations of and exposures to any substances in the atmosphere are anticipated due to the proposed use of E/H copolymers. The polymers are of high molecular weight and do not volatilize. Thus, no significant quantities of any substances will be released upon the use and disposal of food-contact articles manufactured with these polymers.

No significant introductions of substances into the environment as a result of the proposed use of the FCS were identified as discussed under Format Item 6. Consequently, evaluation of the environmental fate of the FCS or its combustion products is not required.

No significant effects on the concentrations of and exposures to any substances in fresh water, estuarine, or marine ecosystems are anticipated due to the proposed use of the subject copolymers. No significant introductions of substances into the aqueous environment is anticipated as a result of the proposed use of the FCS as discussed in Format Item 6.

Considering the factors discussed above, no significant effects on the concentrations of and exposures to any substances in terrestrial ecosystems are anticipated as a result of the proposed use of the subject copolymers. Thus, there is no expectation of any meaningful exposure of terrestrial organisms to these substances as a result of the proposed use of the copolymers.

Considering the foregoing, we respectfully submit that there is no reasonable expectation of a significant impact on the concentration of any substance in the environment due to the proposed use of E/H copolymers in the manufacture of articles intended for use in contact with food.

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<sup>3</sup> This expectation is confirmed by the results of extraction studies described in "Migration\_Study\_of\_Oligomers\_from\_Ethylene-hexene\_Copolymers.pdf.". As shown there, when 20 mil thick test plaques were extracted with either 10% ethanol or 95% ethanol at 121 °C for 2 hours followed by 40 °C for 10 days, minute levels of components of the subject substances were found in the extracts at levels ranging from less than 110 parts per billion (ppb) to 1.36 parts per million (ppm). Thus, the quantity of E/H copolymer constituents in leachate of solid waste deposited in landfills will be extremely small.

## **8. Environmental Effects of Released Substances**

No significant introductions of substances into the environment as a result of the proposed use of the FCS were identified under Format Item 6. Consequently, evaluation of the environmental effects of the proposed use of the FCS is not required.

## **9. Use of Resources and Energy**

As is the case with other food packaging materials, the production, use and disposal of E/H copolymers involves the use of natural resources such as petroleum products, coal, and the like. However, the use of the subject copolymers in the fabrication of food-contact materials is not expected to result in a net increase in the use of energy and resources, since the copolymers are intended to be used in place of similar polymers now on the market for use in food packaging applications.

The replacement of these types of materials by E/H copolymers is not expected to have any adverse impact on the use of energy and resources. Manufacture of the copolymers and conversion to finished food packaging materials will consume energy and resources in amounts comparable to the manufacture of other similar polyolefins. Moreover, E/H copolymers will replace food-contact articles that are not currently recovered for recycling to a significant extent but are disposed of by means of sanitary landfill and incineration.

These copolymers will be used for single and repeat use food-contact articles such as finished food-packaging films and rigid containers that could contact all types of food. While the E/H copolymers are suitable for contact with all food types, there are cost and technical limitations that will limit the types of food-packaging applications. While the copolymers might find limited use in beverage bottling, they will be limited in that application both by cost and function. These copolymers will have a negative cost basis versus high density polyethylene used in milk bottles and they do not have the high gas barrier property of polyethylene terephthalate used in carbonated beverage bottles. Thus, we would not expect any impact on current or future recycling programs as a result of the use of these copolymers.

## **10. Mitigation Measures**

As shown above, no significant adverse environmental impacts are expected to result from the use and disposal of food-contact materials fabricated from the subject polymers. This is primarily due to the minute levels of leaching of potential migrants from the finished article; the insignificant impact on environmental concentrations of combustion products of the polymers; and the similarity of the subject copolymers to the materials they are intended to replace. Thus, the use of the copolymers as proposed is not reasonably expected to result in any new environmental problem requiring mitigation measures of any kind.

## **11. Alternatives to the Proposed Action**

No potential adverse environmental effects are identified herein which would necessitate alternative actions to that proposed in this Notification. The alternative of not clearing the action proposed herein would simply result in the continued use of the materials, which the subject copolymers would otherwise replace; such action would have no environmental impact. In view of the excellent qualities of the subject ethylene/hexene copolymers for use in food-contact applications, the fact that the polymer constituents are not expected to enter the environment in more than minute quantities upon the use and disposal of finished food-contact articles, and the absence of any significant environmental impact which would result from their use, the clearance of the use of the use of the subject copolymers as described herein by allowing this Notification to become effective is environmentally safe in every respect.

## **12. List of Preparers**

Garry M. Wiltshire, Product Regulatory Technical Leader, The Dow Chemical Company,  
1803 Building #416, Midland, MI 48674,

## **13. Certification**

The undersigned official certifies that the information provided herein is true, accurate, and complete to the best of her knowledge.

Date: May 23, 2007

Garry M. Wiltshire