

## Attachment 7 - Environmental Assessment

1. **Date** May 27, 2003
2. **Name of Applicant/Notifier** Eastman Chemical Company
3. **Address** All communications on this matter are to be sent in care of Counsel for Notifier, Joan Sylvain Baughan, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, D.C. 20001. Telephone: (202) 434-4147.

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

The action requested in this Notification is the establishment of a clearance to permit the use of petroleum hydrocarbon resin (cyclopentadiene-type), hydrogenated (CAS Reg. No. 68132-00-3) as an adjuvant substance at levels up to 15% in blends with high density polyethylene (HDPE) used in films having a maximum thickness of 4 mils (0.004 inch) for use in contact with (1) Food Types I, II, IV-B, VI-A, VI-B, VII-B, and VIII as described in Table 1 of 21 C.F.R. § 176.170(c), under Conditions of Use C-G as described in Table 2 of 21 C.F.R. § 176.170(c), and (2) Food Types III, IV-A, V, VI-C, VII-A, and IX as described in Table 1 of 21 C.F.R. § 176.170(c), under Conditions of Use D-G as described in Table 2 of 21 C.F.R. § 176.170(c)."

The subject hydrocarbon resin offers technical properties that makes it useful in HDPE films used in food-contact applications. In particular, the intended technical effect of this resin is to enhance the moisture vapor barrier properties of the HDPE films in which it will be used. This property is of particular importance in applications involving the packaging of dry food that requires exclusion of moisture in the packaged food.

The Notifier does not intend to produce finished food packaging materials from the subject hydrocarbon resin. Rather, the hydrocarbon resin will be sold to manufacturers engaged in the production of food-contact materials. Food-contact films produced with the use of the hydrocarbon resin 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 76% of the materials being deposited in land disposal sites, and about 24% combusted.<sup>1</sup>

000118

<sup>1</sup> *Characterization of Municipal Solid Waste in the United States: 1997 Update*, EPA 530-R-98-007, U.S. Environmental Protection Agency (5305W), Washington DC, 20460, May 1998.

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, there are no special circumstances regarding the environment surrounding either the use or disposal of food-contact films prepared using the hydrocarbon resin.

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

The food-contact substance that is the subject of this Notification is petroleum hydrocarbon resin (cyclopentadiene-type), hydrogenated (CAS Reg. No. 68132-00-3). As dealt with by the Notifier, the hydrocarbon resin is hydrogenated PDCPD resin and is referred to herein as such. A confidential description of the hydrocarbon resin appears in Section II-B of this Notification.

#### **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 the hydrogenated PDCPD resin. 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 hydrocarbon resin to fabricate packaging materials. In these applications, the hydrocarbon resin 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 films produced by the subject hydrocarbon resin will be by conventional rubbish disposal and, hence, primarily by sanitary landfill or incineration. The subject hydrocarbon resin consists of carbon and hydrogen. No toxic combustion products are expected as a result of the proper incineration of the hydrocarbon resin.

**000119**

Only extremely small amounts, if any, of the hydrocarbon resin 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



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 resins that contribute only minute levels of extractable material even under conditions that greatly exaggerate environmental exposure conditions.<sup>2</sup>

## 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 the hydrocarbon resin. The hydrocarbon resin is of a high molecular weight such that it does not volatilize. Thus, no significant quantities of any substances will be released upon the use and disposal of food-contact articles manufactured with the hydrocarbon resin.

The products of complete combustion of the hydrocarbon resin would be carbon dioxide and water; the concentrations of these substances in the environment will not be significantly altered by the proper incineration of the hydrocarbon resin in the amounts utilized for food packaging applications.


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 hydrocarbon resin. No significant quantities of any substance will be added to these water systems upon the proper incineration of the hydrocarbon resin, nor upon its disposal in landfills due to the low levels of aqueous migration of the hydrocarbon resin.

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 hydrocarbon resin. In particular, the extremely low levels of migration of components of the hydrocarbon resin, even at 100°C, demonstrated by the extraction studies, indicate that virtually no leaching of these substances may be expected to occur under normal environmental conditions when finished food-contact materials are disposed of. Furthermore, the very low production of the hydrocarbon resin for use in food-

000120

---

<sup>2</sup> This expectation is confirmed by the extraction data described in Section II-F of the Notification. As shown there, the hydrocarbon resin is identical to the hydrocarbon resin that is currently permitted under 21 C.F.R. § 177.1520(b) for use in polypropylene films. Test data in the food additive petitions leading to this clearance (Food Additive Petition Numbers 1B4267 and 4B4411) demonstrate that after extraction with 8% ethanol at 100°C for 30 minutes followed by 49°C for 10 days, or 95% ethanol at 66°C for 30 minutes followed by 49°C for 10 days, only minute levels of components of the subject substances were found in the extracts at levels ranging from 3 parts per million (ppm) to 38.6 ppm. Thus, the quantity of the hydrocarbon resin in solid waste deposited in landfills will be extremely small.



contact applications, as indicated in confidential Attachment 8 of this Notification. Thus, there is no expectation of any meaningful exposure of terrestrial organisms to these substances as a result of the proposed use of the hydrocarbon resin.

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 the hydrocarbon resin in the manufacture of films intended for use in contact with food.


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

As discussed previously, the only substances that may be expected to be released to the environment upon the use and disposal of food packaging materials fabricated with the use of the subject hydrocarbon resin consist of extremely small quantities of combustion products and extractables. As discussed in Section III of the Notification, none of the potential migrating components of the hydrocarbon resin present any toxicological concern at the minute levels at which they could be extracted upon use and disposal. Based on these considerations, no adverse effect on organisms in the environment is expected as a result of the disposal of articles containing the hydrocarbon resin. In addition, the use and disposal of the hydrocarbon resin 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. part 60 that pertain to municipal solid waste combustors and part 258 that pertain to landfills.

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

As is the case with other food packaging materials, the production, use and disposal of these hydrocarbon resin involves the use of natural resources such as petroleum products, coal, and the like. However, the use of the subject hydrocarbon resin in the fabrication of food-contact films is not expected to result in a net increase in the use of energy and resources, since HDPE films containing the hydrocarbon resin are intended to be used in place of HDPE films without hydrocarbon resins. In some cases, the use of the hydrocarbon resin could potentially reduce the net amount of packaging material required due to improved performance characteristics, which may allow the use of thinner HDPE films and, thus, lead to a net decrease in the amount of natural resources used. **000121**

The replacement of HDPE films with HDPE films containing the hydrocarbon resin is not expected to have any adverse impact on the use of energy and resources. Manufacture of the finished food-contact films containing the hydrocarbon resin will consume energy and resources in amounts comparable to the manufacture and use of HDPE films (*i.e.*, without the hydrocarbon resin). Moreover, the hydrocarbon resin will be used to manufacture films; consequently, the hydrocarbon resin will not be used in bottles, including those used for packaging milk or soda or any beverage. Packaging for other types of food, particularly films, is not recovered for recycling to a significant extent, but is disposed of by means of sanitary



landfill and incineration. HDPE films produced using the hydrocarbon resin are expected to be disposed of according to the same patterns when they are used in place of the current HDPE films. Thus, there will be no impact on current or future recycling programs.

#### **10. Mitigation Measures**

As shown above, no significant adverse environmental impacts are expected to result from the use and disposal of food-contact films fabricated using the subject hydrocarbon resin. This is primarily due to the minute levels of leaching of potential migrants from films containing the hydrocarbon resin, the insignificant impact on environmental concentrations of combustion products of the hydrocarbon resin, and the close similarity of the HDPE films containing the subject hydrocarbon resin to the HDPE films they are intended to replace. Thus, the use of the hydrocarbon resin 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 approving the action proposed herein would simply result in the continued use of the films that would otherwise be replaced by the use of the hydrocarbon resin; such action would have no environmental impact. In view of the excellent qualities of the hydrocarbon resin for use in HDPE food-contact film applications, the fact that components of the hydrocarbon resin are not expected to enter the environment in more than minute quantities upon the use and disposal of finished food-contact films, and the absence of any significant environmental impact which would result from its use, the clearance of the use of the hydrocarbon resin as described herein by allowing this Notification to become effective is environmentally safe in every respect.

#### **12. List of Preparers**

Lester Borodinsky, Staff Scientist, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, D.C. 20001.

000122



**13. Certification**

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

Date: May 27, 2003

[Redacted Signature Box]

Joan Sylvain Baughan

Counsel for Eastman Chemical Company

000123

~~CONFIDENTIAL~~