

## Environmental Assessment

1. **Date:** April 30, 2007
2. **Name of Applicant/Notifier:** BASF Corporation
3. **Address:** 26 Davis Drive  
Research Park Triangle, NC 27709-3528

All communications on this matter are to be sent in care of Counsel for Notifier:

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

The action requested in this Food-Contact Notification (FCN) is to establish the clearance of the food-contact substance (FCS), vinylidene chloride/vinyl chloride/methyl acrylate copolymer, for use as a component of coatings applied to fruits and vegetables with inedible peels, excluding citrus fruits. The finished product contains approximately 30% of the FCS polymer as an aqueous dispersion. The intended technical effect of the coating is to extend the shelf-life of fruits and vegetables by maintaining the fruits and vegetables in marketable condition for an extended period of time. This effect is accomplished by slowing the rate of oxygen uptake and carbon dioxide release by the fruit. The slower respiration rate inhibits metabolism within the fruit and thereby increases shelf life. The FCS is intended to remain with food up to the point of ingestion, where it will be discarded as part of the inedible peel.

The FCS 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 of the FCS will occur nationwide, with the material being land disposed or combusted; as a component of

coatings applied to fruits and vegetables with inedible peels (excluding citrus fruits), it is not anticipated that the FCS will be used in applications that will compete with or displace food-contact articles that are currently being recycled. According to the U.S. Environmental Protection Agency's (EPA) 2005 update regarding municipal solid waste in the United States, 54.3% of municipal solid waste generally was land disposed, 13.6% was combusted, and 32.1% was recovered for recycling and composting.<sup>1</sup> There are no special circumstances regarding the environment surrounding either the use or disposal of coatings prepared from the subject polymer.

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

The FCS that is the subject of this Notification is vinylidene chloride/vinyl chloride/methyl acrylate copolymer. The Chemical Abstracts Service (CAS) Registry No. for the polymer is 28572-91-0.

#### **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 subject polymer. Consequently, information on the manufacturing site and compliance with relevant emissions requirements is not provided here.

In the process whereby the FCS is coated onto fruits and vegetables, most of the coating adheres to the fruits and vegetables, and a small amount drips off as waste. Specifically, the fruits

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<sup>1</sup> *Municipal Solid Waste in the United States: 2005 Facts and Figures*, EPA530-R-06-011, U.S. Environmental Protection Agency (5305W), Washington DC, 20460, October 2006.

and vegetables move on a conveyer belt through a spray area. The FCS is sprayed onto the fruits and vegetables; as the fruits and vegetables move further on the conveyer to the packing area, the spray dries and forms a coating. A small amount (no more than 1%) of the spray does not deposit on the fruit and instead deposits on the conveyer belt, where it rapidly dries. This dried material is physically removed (scraped, brushed etc.) from the conveyer belt at the end of the packing run and is treated as a non-hazardous solid waste and disposed in conventional waste treatment facilities. Thus, the concentration of the FCS that will be introduced into the environment at use sites is likely to be low because almost all of it adheres to fruits and vegetables.

Disposal by the ultimate consumer of the coating produced by the subject polymer will be by conventional rubbish disposal and, hence, primarily by sanitary landfill or incineration. Only extremely small amounts, if any, of the polymer's constituents are expected to enter the environment as a result of the landfill disposal of peels containing the coating, in light of EPA's 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 groundwater 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 collection 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 substance is a high molecular weight polymer that contains only minute levels of extractable material even under conditions that greatly exaggerate environmental exposure conditions.

With regard to incineration, the FCS consists primarily of carbon, hydrogen, oxygen, and chlorine. With regard to carbon, hydrogen, and oxygen, these are elements that are commonly found in municipal solid waste. With regard to chlorine, this element could potentially form combustion products that could be toxic at levels much higher than could be present from combustion of this FCS. Based on the proposed use of the food-contact substance, the anticipated market volume (available in a confidential attachment to the FCN), and calculations regarding the maximum introduced levels of chlorine containing combustion products (available in a confidential attachment to the FCN), we have concluded that the food-contact substance will make up a very small portion of the total municipal solid waste currently combusted, the food-contact substance will not significantly alter the emissions from properly operating municipal solid waste combustors, and incineration of the food-contact substance will not cause municipal waste combustors to threaten a violation of applicable emissions laws and regulations (40 C.F.R. Part 60 and/or relevant state and local laws).

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

### **(a) Air**

No significant effects on the concentrations of and exposures to any substances in the atmosphere are anticipated due to the proposed use of the subject polymer. The polymer is of high molecular weight and does not volatilize. Thus, no significant quantities of any substances will be released upon the use and disposal of coatings manufactured with the polymer.

As indicated above in item 6, the food-contact substance will make up a very small portion of the total municipal solid waste currently combusted, the food-contact substance will not significantly alter the emissions from properly operating municipal solid waste combustors,

and incineration of the food-contact substance will not cause municipal waste combustors to threaten a violation of applicable emissions laws and regulations.

**(b) Water**

No significant effects on the concentrations of and exposures to any substances in freshwater, estuarine, or marine ecosystems are anticipated due to the proposed use of the subject polymer. No significant quantities of any substance will be added to these water systems upon the proper incineration of the polymer, nor upon its disposal in landfills, because no significant introductions of substances into the environment were identified in Format Item 6.

**(c) Land**

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 polymer. In particular, the extremely low potential levels of maximum migration of components of the polymer indicate that virtually no leaching of this substance may be expected to occur under normal environmental conditions when the coating is disposed. Furthermore, the very low production of the polymer for use in coatings precludes any substantial release to the environment of its components. Thus, there is no expectation of any meaningful exposure of terrestrial organisms to the subject polymer as a result of its proposed use.

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 subject polymer, vinylidene chloride/vinyl chloride/methyl acrylate copolymer, as a component of coatings applied to fruits and vegetables with inedible peels, excluding citrus fruits.

## **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 coatings fabricated with the subject polymer consist of extremely small quantities of combustion products and extractables. The low levels expected in the human diet from the proposed use of the subject polymer may be considered safe.

Based on these considerations, no adverse effect on organisms in the environment is expected as a result of the disposal of peels containing the polymer. In addition, the use and disposal of the polymer are not expected to threaten a violation of applicable laws and regulations, *e.g.*, EPA'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 polymers, the production, use, and disposal of the subject polymer involves the use of natural resources such as petroleum products, coal, and the like. However, the use of the subject polymer in the fabrication of coatings is not expected to result in a net increase in the use of energy and resources, since the polymer is intended to be used in materials that will be used in place of similar materials now on the market. Polymers currently used in such applications include polyvinyl alcohol resins that are currently permitted for this use.

The partial replacement of these types of materials by the subject polymer is not expected to have any adverse impact on the use of energy and resources. Manufacture of the polymer, and its conversion to finished coatings, will consume energy and resources in amounts comparable to the manufacture and use of other polymers. Moreover, the applications that are the subject of this Notification are not recovered for recycling, but are disposed by means of landfill and

incineration. Coatings produced from the subject polymer are expected to be disposed according to the same patterns when used in place of current materials.

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

As shown above, no significant adverse environmental impacts are expected to result from the use and disposal of coatings fabricated from the subject polymer. This is primarily due to the minute levels of leaching of potential migrants; the insignificant impact on environmental concentrations of combustion products of the polymer; and the close similarity of the subject polymer to the materials it is intended to replace. Thus, the use of the polymer 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 materials which the subject polymer would otherwise replace; such action would have no environmental impact. In view of the excellent qualities of the subject polymer for use in the intended application, the fact that the polymer constituents are not expected to enter the environment in more than minute quantities upon the use and disposal, and the absence of any significant environmental impact which would result from its use, the establishment of an effective FCN to permit the use of the subject polymer as described herein is environmentally safe in every respect.

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

Lester Borodinsky, Ph.D., Staff Scientist, Keller and Heckman LLP

Melvin S. Drozen, Partner, Keller and Heckman LLP

**13. Certification**

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

Date: 4/30/07



Melvin S. Drozen  
Counsel for BASF Corporation