

ENVIRONMENTAL ASSESSMENT

Environmental Assessment

1. **Date** September 22, 2004
2. **Name of Applicant/Notifier** The Dow Chemical Company
3. **Address** All communications on this matter are to be sent to Ms. Sandra Kupperblatt, The Dow Chemical Company, 1803 Building, Midland, Michigan 48674. Telephone: (986) 638-6231
4. **Description of the Proposed Action**

The action requested in this Notification is the establishment of a clearance to permit the use of vinylidene chloride/butyl acrylate copolymers in the manufacture of articles or components 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 principal use of the proposed copolymer will be in the production of film for packaging food products such as fresh red meat, sliced luncheon meats, poultry and cheese, dry products requiring protection from moisture and/or oxygen, and as a barrier component of multilayer constructions.

The subject copolymers offer several technical properties that make them useful in a variety of food-contact applications. In particular, the polymers impart good toughness and excellent gas barrier properties.

The petitioned for polymers are intended to replace currently produced copolymers consisting of vinylidene chloride copolymerized with vinyl chloride.

The vinylidene chloride-butyl acrylate copolymer will be incorporated into food-packaging materials at production plants located throughout the United States. 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 79.1% of the materials being deposited in land disposal sites and about 20.9% combusted.¹

¹ *Municipal Solid Waste in the United States: 2001 Facts and Figures*, EPA 530-R-02-001, U.S. Environmental Protection Agency (5305W), Washington DC, 20460.

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 materials prepared from the subject copolymers.

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

The food contact substance (FCS) which is the subject of this Notification is a copolymer of vinylidene chloride and butyl acrylate (CAS # 9011-09-0). 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 10 weight percent butyl acrylate units. The weight average molecular weight for these copolymers is in the range of 70,000 to 200,000. For purposes of this Environmental Assessment, the subject materials will be designated as VDC/BA copolymers.

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 VDC/BA copolymers. Consequently, information on the manufacturing site and compliance with relevant emissions requirements is not provided here.

Little or no introduction of VDC/BA copolymer into the environment will result from its use because it is almost completely incorporated into food-packaging materials, and essentially all of it is expected to remain with this packaging throughout use of the product.

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, hydrogen, oxygen and chlorine. The products of complete combustion of the polymer would be hydrogen chloride, carbon dioxide and water; the concentrations of these substances in the environment will not be significantly altered by the proper incineration of the polymers in the amounts utilized for food packaging applications. When copolymers of VDC/BA are burned in an incinerator using current best available technology and operating conditions, there should be no increase in dioxins emitted from the incinerator. It is widely recognized that the emission of dioxins is related to the design and operation of incinerators. The use and disposal of the VDC/BA copolymers is not expected to threaten a violation of the Environmental Protection Agency's regulations in 40 C.F.R. part 60 that pertain to

municipal solid waste combustors. If the VDC/BA copolymer (4-10% BA) replaces vinylidene chloride/vinyl chloride (VDC/VC) copolymer (10-20% VC) on a pound for pound basis, the average reduction in HCL generated on complete combustion would be 4%.

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 in 40 C.F.R. Part 258.² The lack of any leaching is especially true considering that the subject substances are high molecular weight polymers that contain only minute levels of residuals.³ In addition, the introduction of these substances into the environment will not threaten a violation of the Environmental Protection Agency's regulations in 40 C.F.R. part 258 that pertain to landfills.

7. Fate of Emitted Substances in the Environment

No information need be provided on the fate of substances released into the environment as the results of use and/or disposal of the VDC/BA copolymer, because, as discussed under Format Item 6, only a very small quantity of the FCS or its decomposition products, if any, will be introduced into the environment as a result of its use and disposal.

8. Environmental Effects of Released Substances

No information need be provided on the fate of substances released into the environment as the results of use and/or disposal of the VDC/BA copolymer, because, as discussed under Format Item 6, only a very small quantity of the FCS or its decomposition products, if any, will be introduced into the environment as a result of its use and disposal.

9. Use of Resources and Energy

The FCS will be used as a food-packaging film and is expected to replace the currently regulated food-packaging VDC/VC films. There is currently very limited, if any, recycling of food-contact films. Further, future recycling of food-contact films is not likely because of the difficulty of cleaning films that have residual food adhering to them and because

² 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. 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.

³ This expectation is confirmed by the results of migration calculations described in Part II, Section F of the Notification. As shown there, minute levels of components of the subject substances were calculated to be present at an exaggerated worst-case level (assuming 100% migration of oligomer residuals) of 730 ppm. Thus, the quantity of VDC/BA copolymer constituents in solid waste deposited in landfills will be extremely small.

food-contact films are made from diverse materials that are not specifically identified on the finished packaging material. Thus, the agency's decision not to object to the introduction into commerce of the VDC/BA copolymer in contact with food has no potential to significantly affect existing recycling programs.

As stated above, VDC/BA copolymers are expected to replace VDC/VC copolymers. Therefore, it is not anticipated that there will be a significant impact on landfill volume requirements. Also, it is not likely that the FCS is compostable.

As is the case with other food packaging materials, the production, use and disposal of VDC/BA 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 currently in the market of food packaging applications. Polymers currently used in the applications in which VDC/BA copolymers are anticipated to be used include VDC/VC 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 close 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 vinylidene chloride/butyl acrylate 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 subject copolymers as described herein by allowing this Notification to become effective is environmentally safe in every respect.

12. List of Preparers

Sandra Kupperblatt, Product Regulatory Technical Manager, The Dow Chemical Company, 1803 Building, 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: October 28, 2004

Sandra A. Kupperblatt