

**ENVIRONMENTAL ASSESSMENT
EVONIK RÖHM SERVICES
FOOD CONTACT NOTIFICATION**

1. **Date:** June 30, 2008
2. **Name of Applicant/Notifier:** Evonik Röhm GmbH
SABIC Petrochemical B.V.
3. **Address:** 64293 Darmstadt
Kirschenallee, Germany
Telephone: +49 6151 18-4016
Facsimile: +49 6151 18-844016
E-mail: Mario.funk@evonik.com

All communications on this matter are to be sent in care of Counsel for Notifier:
Catherine R. Nielsen, Partner
Keller and Heckman LLP
1001 G Street, N.W., Suite 500 West
Washington, D.C. 20001
Telephone: (202) 434-4140
Facsimile: (202) 434-4646
E-mail: nielsen@khllaw.com

4. **Description of the Proposed Action**

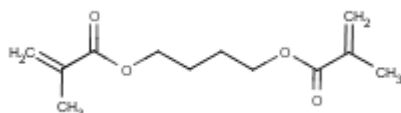
The action requested in this notification is to permit the use of 1,4-butanediol dimethacrylate (CAS Reg. No. 2082-81-7) (1,4-BDDMA) as a co-monomer in the manufacture of low density polyethylene (LDPE). 1,4-BDDMA is intended to be used in the polymerization of LDPE at a level not to exceed 0.10 mol% as incorporated into the LDPE. The subject food-contact substance changes the rheological properties of LDPE when used as a coating on articles intended to contact food.

The Notifier does not intend to produce finished food-contact articles from the subject food-contact substance. Rather, the food-contact substance that is the subject of this Notification will be sold to manufacturers engaged in the production of LDPE, which ultimately will be used in the production of food-contact articles. Food-contact articles produced with the food-contact substance 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 subject food-contact substance will occur nationwide, with the material being land disposed, combusted, or recycled. According to the U.S. Environmental Protection Agency's 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.¹

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 food-contact substance.

5. **Identification of Substance that is the Subject of the Proposed Action**

The food-contact substance that is the subject of this Notification is: 1,4-butanediol dimethacrylate (CAS Reg. No. 2082-81-7) (1,4-BDDMA).



¹ *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.

MW of 1,4-BDDMA = 226.26892 g/mol
Chemical formula of 1,4-BDMMA = C₁₂H₁₈O₄

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 food-contact substance. 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 food-contact substance to fabricate food-contact materials. In these applications, the food-contact substance is expected to be used in the polymerization of LDPE that will then be used as a coating to fabricate all forms of LDPE-coated food-contact articles, and the food-contact substance will be entirely incorporated into the finished food-contact article. Any waste materials generated in this process (*e.g.*, plant scraps) are expected to be disposed of as part of the food-contact article manufacturer's overall nonhazardous solid waste in accordance with established procedures.

Disposal by the ultimate consumer of food-contact articles produced with the subject food-contact substance will be by conventional rubbish disposal and, hence, primarily by sanitary landfill or incineration. The food-contact substance is composed of carbon, oxygen and hydrogen, elements that are commonly found in municipal solid waste. The proposed use of the food-contact substance and the market volume (available in a confidential attachment to the FCN) show that 1) the food-contact substance will make up a very small portion of the total municipal solid waste currently combusted (estimated to be 33.4 million tons or 13.6% of 245.7 million tons in 2005),² 2) the food-contact substance will not significantly alter the emissions from properly operating municipal solid waste combustors,³ and, therefore, 3) incineration of the food-contact substance will not cause municipal solid waste combustors to threaten a violation of applicable emissions laws and regulations (40 C.F.R. Part 60 under/or relevant state and local laws).

Only extremely small amounts, if any, of the FCS 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

² *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.

³ Paul M. Sullivan; Hallenbeck, W.H.; Brenniman, G.R. *Municipal Solid Waste Combustion*; University of Illinois at Chicago: Chicago, IL, 1993.

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 comonomer intended to be incorporated into LDPE, samples of which have been shown to contain no detectable extractable material, even under conditions that greatly exaggerate environmental exposure conditions.⁴

7. Fate of Emitted Substances in the Environment

(a) Air

No significant effect on the concentrations of and exposures to any substances in the atmosphere are anticipated due to the proposed use of the food-contact substance. The food-contact substance is incorporated into a polymer, and does not readily volatilize. Thus, no significant quantities of any substances will be released upon the use and disposal of food-contact articles manufactured with the food-contact substance.

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,

⁴ This conclusion is confirmed by the results of migration studies described in the subject FCN. For this FCN, LDPE containing the food-contact substance at its maximum proposed use level was extracted with either 10% ethanol or 95% ethanol at 66°C for 2 hours followed by 40°C for 10 days. In all cases, there was no detectable 1,4-BDDMA in analyses employing an LOD of 0.50 µg/in². Thus, the quantity of leachate from the food-contact substance in solid waste deposited in landfills will be extremely small and, furthermore, no greater than from LDPE currently used and disposed.

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 fresh water, estuarine, or marine ecosystems are anticipated due to the proposed use of the subject food-contact substance. The fate of the food-contact substance in the aqueous environment does not need to be addressed because no significant introductions of substances into the environment were identified in 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 food-contact substance. In particular, the polymeric, hydrocarbon nature of the LDPE into which the food-contact substance will be incorporated is expected to result in virtually no leaching of the food-contact substance under normal environmental conditions when finished food-contact materials are disposed of. Furthermore, the very low production of the food-contact substance for use in food-contact applications precludes any substantial release to the environment of their components. Thus, there is no expectation of any meaningful exposure of terrestrial organisms to this substance as a result of the proposed use of the food-contact substance.

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 food-contact substance in the manufacture of articles intended for use in contact with food. Therefore, the environmental fate of substances does not need to be addressed due to the fact that no significant introduction of substances into the environment as a result of the proposed use of the food-contact substance were identified as discussed under Item 6.

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 subject food-contact substance consist of extremely small quantities of combustion products and leachables, if any. Thus, no adverse effect on organisms in the environment is expected as a result of the disposal of articles containing the food-contact substance. In conclusion, no information needs to be provided on the environmental effects of substances released into the environment as a result of use and/or disposal of the food-contact substance because, as discussed under Item 6, only extremely small quantities, if any, of substances will be introduced into the environment as a result of use and/or disposal of the food-contact substance. Therefore, the use and disposal of the food-contact substance 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 and Energy

As is the case with other food packaging materials, the production, use and disposal of the food-contact substance involves the use of natural resources such as petroleum products, coal, and the like. However, the use of the subject food-contact substance 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 food-contact substance is intended to be used in food-contact articles which will be used in place of similar polymers now on the market for use in food-contact applications. Substances currently used in the applications in which the subject food-contact substance is anticipated to be used include those that are permitted under 21 C.F.R. § 177.1520 (“Olefin polymers”).

The partial replacement of these types of materials by the subject food-contact substance is not expected to have any adverse impact on the use of energy and resources. Manufacture of the food-contact substance, and its use in the manufacture of finished food-contact materials, will consume energy and resources in amounts comparable to the manufacture and use of the other food-contact substances. Furthermore, the use proposed in this Notification for the subject food-contact substance, which is a co-monomer used in the polymerization of LDPE, is as a replacement for the same uses of LDPE without the subject food-contact substance incorporated (*i.e.*, other low density polyethylene articles, that are not currently recovered for recycling). Food-contact materials produced using the subject food-contact substance are expected to be disposed of according to the same patterns when they are used in place of the current materials. 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 materials fabricated using the subject food-contact substance. This is primarily due to the minute levels, if any, of leaching of components of the food-contact substance from finished articles employing the food-contact substance, the insignificant impact on environmental concentrations of combustion products of the food-contact substance, and the similarity of the LDPE into which the subject food-contact substance will be incorporated to the materials it is intended to replace. Thus, the use of the food-contact substance as proposed is not reasonably expected to result in any new environmental problems requiring mitigation measures of any kind.

11. Alternatives to the Proposed Action

No potential adverse environmental effects are identified herein that would necessitate alternative actions to those proposed in this Notification. The alternative of not approving the action proposed herein would simply result in the continued use of the materials that the subject food-contact substance would otherwise replace; such action would have no environmental impact. In view of the fact that the food-contact substance constituents are not expected to enter the environment upon the use and disposal of finished food-contact articles, and the absence of any significant environmental impact which would result from its use, the establishment of an

effective Food Contact Notification to permit the use of the subject food-contact substance as described herein is environmentally safe in every respect.

12. List of Preparers

Donna J. Robie, Ph.D., Staff Scientist, Keller and Heckman LLP, 1001 G Street, N.W.,
Suite 500 West, Washington, D.C. 20001.

Catherine R Nielsen, Partner, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500
West, Washington, D.C. 20001.

13. Certification

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

Date: _____

Catherine R. Nielsen, Partner
Counsel for Evonik Röhm Services