

**ENVIRONMENTAL ASSESSMENT
BASF AKTIENGESELLSCHAFT
FOOD CONTACT NOTIFICATION**

- 1 Date: April 26, 2007
2. Name of Applicant: BASF Aktiengesellschaft
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Germany

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4. Description of the Proposed Action

The action requested in this notification is to permit the use of polymers made from 2-propenoic acid, 4-(((4-benzoylphenoxy)-carbonyl)oxy)-butyl ester (CAS No.: 131513-00-3) which has the function of a photo initiator, and one or more of the following monomers

acrylic acid	CAS No : 79-10-7
n-butyl acrylate	CAS No.: 141-32-2
2-ethylhexyl acrylate	CAS No.. 103-11-7
methylacrylate	CAS No.: 96-33-3
methylmethacrylate	CAS No.: 80-62-6

Examples for polymers are

2-Propenoic acid, polymer with butyl 2-propenoate, 2-ethylhexyl 2-propenoate and methyl 2-propenoate:	CAS No.: 98060-25-4
2-Propenoic acid, 2-methyl-, methyl ester, polymer with 2-ethylhexyl 2-propenoate	CAS No.. 25265-15-0
2-Propenoic acid, polymer with butyl 2-propenoate	CAS No.. 25119-83-9

(Please note that the photo initiator does not appear in the name of the polymers, because it is present in the copolymer below 2 % by weight.

The action is needed to provide for an improved food-contact material for pressure sensitive adhesive applications. The polymers that are subject of this Notification allow pressure-sensitive adhesive formulations in which the food-contact substance will be used to be applied over a

broader range of temperatures than similar pressure-sensitive adhesive systems formulated with normally liquid or solid resins or processing oils.

The notifier does not intend to produce finished food-contact articles from the subject substance. Rather, the food-contact substance that is the subject of this Notification will be sold to formulators engaged in the production of adhesives formulation who will, in turn, supply the adhesive to fabricators of materials employing the adhesive to suitable substrates. In this final stage the polymer of the adhesive film will be crosslinked by UV-irradiation, in order to obtain the pressure-sensitive tack suitable for use in contact with food. 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 the disposal will occur nationwide, with about 76 % of the materials being deposited in land disposal sites, and about 24 % combusted.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 FCS that is subject of this Notification is polymers of 2-propenoic acid, 4-(((4-benzoylphenoxy)-carbonyl)oxy)-butyl ester (CAS No.: 131513-00-3), which has the function of a photo initiator, and one or more of the following monomers:

acrylic acid	CAS No 79-10-7
n-butyl acrylate	CAS No.: 141-32-2
2-ethylhexyl acrylate	CAS No : 103-11-7
methylacrylate	CAS No : 96-33-3
methylmethacrylate	CAS No 80-62-6

6. Introduction of Substances into the Environment

Under 21 CFR § 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 provided in form of a report: "The environmental Management System of BASF Aktiengesellschaft at the Ludwigshafen Site", see Annex 27 a.

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 to fabricate articles that employ pressure-sensitive adhesives, and 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 non-hazardous solid waste in accordance with established procedures.

Disposal by the ultimate consumer of food-contact articles produced by the subject food-contact substance will be by conventional rubbish disposal and, hence, primarily by sanitary landfill or incineration. The food-contact substance consists of carbon and hydrogen. Thus, no toxic combustion products are expected as a result of the proper incineration of the copolymer.

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

Only extremely small amounts, if any, of the food-contact substance 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 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 food-contact substances are polymeric materials that are hydrocarbons and, therefore, unlikely to be extractable by aqueous media.

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 polymeric and does not readily volatilize. The content of volatile impurities is typically below 0.1 %. 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.

The products of complete combustion of the food-contact substance 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 food-contact substance in the amounts utilized for food-contact applications.

(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. No significant quantities of any substance will be added to these water systems upon the proper incineration of food packaging employing the food-contact substance, nor upon its disposal in landfills due to the extremely low levels of aqueous leaching of food-contact substance components anticipated.

(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 food-contact substance is expected to result in virtually no leaching of the components 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 substances 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 these substances 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.

8. Environmental Effects of Released Substances

As discussed previously, the only substances that might be expected to be released to the environment upon the use and disposal of food packaging materials fabricated with the subject copolymer 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 addition, the use and disposal of food-contact articles containing 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. 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 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 pressure-sensitive adhesive materials now on the market for use in pressure-sensitive adhesive 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 0 175 125 ("Pressure-sensitive adhesives")

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. Instead the manufacture of the finished food-contact materials, will consume much less energy and resources, because there is no energy needed to for transporting organic solvents or water. Furthermore in the manufacture of the finished food-contact materials less energy is consumed compared to adhesives formulated with polymer solutions or dispersions, because no drying is necessary.

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 subject food-contact substance 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 problem requiring mitigation measures of any kind.

11. Alternatives to the Proposed Action

The UV-acrylics fulfill the highest standards of safety in terms of ecology and toxicology. They are free of solvents and they contain a minimum of substances that are capable of migration. The most important advantages of UV-acrylics are summarized below

- No organic solvents are emitted.
- They are compact, and no energy needs to be expended on transporting organic solvents or water.
- Less energy is consumed compared to adhesives formulated with polymer solutions or dispersions, because no drying is necessary.
- They contain a minimum of substances that are capable of migration
- They do not cause any irritation to the skin when tested according to OECD Method 404
- They are not toxic to cells according to ISO 10993-5.

Consequently 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 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 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

Dr. Gisbert Schleier, KS/KS – E 100, BASF Aktiengesellschaft, D-67056 Ludwigshafen, Germany.

12. Certification

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

Date April 26, 2007



Dr. Gisbert Schleier
Manager Product Safety and Regulatory Affairs