

Environmental Assessment

1. **Date** August 28, 2008
2. **Name of Applicant/Notifier** Zeon Corporation
Tokyo, Japan
3. **Address** All communications on this matter are to be sent in care of Counsel for Notifier, George G. Misko, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, D.C. 20001.
Telephone: (202) 434-4170.
4. **Description of the Proposed Action**

The action requested in this Notification is to establish the clearance of the food-contact substance (FCS), 1,3-Butadiene, 2-methyl-, homopolymer, of *cis*-1,4-configuration, cyclized (CAS Reg. No. 68441-13-4) optionally containing 2,2'-methylenebis(4,6-di-*tert*-butylphenyl) octylphosphite (CAS Reg. No. 126050-54-2) at a level not to exceed 0.05 percent by weight. The FCS is intended for use as a modifier in food contact materials made from ethylene-vinyl acetate-vinyl alcohol (EVOH) copolymers complying with 21 C.F.R. § 177.1360(a)(3) at a level not to exceed 35 weight-percent of the polymer blend. The EVOH/FCS blend may also contain optional adjuvant substances permitted for such use by regulation in 21 CFR Parts 170 through 179. Food contact materials containing the FCS will not exceed 2 mils in thickness and may be used in contact with Food Types I, II, IV-B, VI-A, VI-B, VI-C, and VII-B, under conditions of use C through G, as described in Tables 1 and 2 of FDA's "Definitions of Food Types and Conditions of Use for Food Contact Substances," available at <http://www.cfsan.fda.gov/~rdb/opa-fcn3.html>.

The subject polymer offers several technical properties when used as a modifier for EVOH. While EVOH is a good oxygen barrier material in low humidity, its barrier qualities are less effective at high humidity and temperatures. Blending EVOH with the FCS significantly improves the oxygen-barrier properties of EVOH at high humidity and elevated temperatures; this is because the FCS absorbs small amounts of fugitive oxygen that migrates through the EVOH matrix of the EVOH/QIR layer.

The Notifier does not intend to produce finished food packaging articles with the subject copolymer. Rather, the FCS will be sold to manufacturers engaged in the production of food-contact articles. Food-contact articles produced with the polymer will be utilized in patterns corresponding to the national population density and will be widely distributed across the

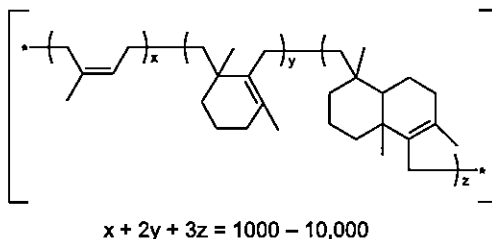
country. Therefore, it is anticipated that disposal will occur nationwide, with about 79% of the materials being deposited in land disposal sites, and about 21% combusted.¹

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 with respect to the environment surrounding either the use or disposal of food-contact materials prepared from the FCS.

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

The substance that is the subject of this Notification is 1,3-Butadiene, 2-methyl-, homopolymer, of *cis*-1,4-configuration, cyclized. Its CAS Reg. No. is 68441-13-4. The FCS may optionally contain 2,2'-methylenebis(4,6-di-*tert*-butylphenyl) octylphosphite (CAS Reg. No. 126050-54-2) at a level not to exceed 0.05 percent by weight.

The chemical formula for the FCS is $(C_5H_8)_n$ where $n = 1,000-10,000$. The chemical structure for the FCS cannot be depicted by a single figure because the compound has several kinds of micro units (*i.e.*, isoprene monomer units, monocyclic units, and dicyclic units). The typical structure, including major components of micro units, is illustrated by the figure shown below.



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 that would suggest any adverse environmental impact as a result of the manufacture of the subject 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 substance to fabricate packaging materials. Any waste materials generated in this process, *e.g.*, plant scraps, are

¹ *Characterization of Municipal Solid Waste in the United States: 2001 Update*, EPA 530-R-03-011, U.S. Environmental Protection Agency, Washington DC, 20460, October 2003.

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 materials containing the subject substance will be primarily by sanitary landfill or incineration. The FCS consists of carbon, hydrogen, and oxygen. These are elements that are commonly found in municipal solid waste. Based on the proposed use of the FCS, we have concluded that the FCS will make up a very small portion of the total municipal solid waste currently combusted, the FCS will not significantly alter the emissions from properly operating municipal solid waste combustors, and incineration of the FCS 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).

In light of EPA's regulations governing municipal solid waste landfills, only extremely small amounts, if any, of the subject substance are expected to enter the environment as a result of the landfill disposal of food-contact articles. Any leaching to the environment is not anticipated considering the low solubility of the FCS in water. 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.

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 subject substance. Further, no significant quantities of any substances will be released upon the use and disposal of food-contact articles manufactured with the subject substance.

The products of complete combustion of the subject substance are carbon dioxide and water; the concentrations of these substances in the environment will not be significantly altered by the proper incineration of the subject substance in the amounts utilized for food packaging 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 substance. No significant quantities of any substance will be added to these water systems upon the proper incineration of food packaging employing the subject substance, nor upon its disposal in landfills due to the anticipated extremely low levels of aqueous extraction of the subject substance, as the substance contains or includes an organic ester that has a low solubility in water (0.4 µg/L (or 0.4 parts per billion)).

(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 substance. In particular, because of its low solubility in water, extremely low levels of aqueous extraction of the subject substance are expected to occur under normal environmental conditions when finished food-contact materials are disposed of. Thus, there is no expectation of any meaningful exposure of terrestrial organisms to this substance 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 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 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 substance consist of extremely small quantities of combustion products and extractables. Thus, no adverse effect on organisms in the environment is expected as a result of the disposal of articles containing the subject substance. In addition, the use and disposal of food-contact articles containing the subject substance are not expected to threaten a violation of applicable laws and regulations, *e.g.*, the 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 food packaging materials, the production, use and disposal of the subject substance involves the use of natural resources such as petroleum products, coal, and the like. However, the use of the subject 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 subject substance is intended to be used in packaging which will be used as a substitute for some of the EVOH blends now on the market for use in the same food packaging applications; this is the

case where better oxygen scavenging is desired under high humidity and high temperature conditions and the subject substance will lead to improved oxygen barrier properties in films prepared from EVOH.

The partial replacement of these EVOH blended products by the subject substance is not expected to have any adverse impact on the use of energy and resources. Manufacture of the subject substance, and its use in the conversion to finished food packaging materials, will consume energy and resources in amounts comparable to the manufacture and use of other EVOH blends. Furthermore, the FCS will not be used in applications that may be replacements for polyethylene terephthalate (PET) soda bottles or high density polyethylene (HDPE) milk bottles. As PET and HDPE bottles are the predominant food packaging articles recovered for recycling, and as the subject substance will not be used in such applications, articles fabricated from the subject substance will be disposed of by means of sanitary landfill and incineration. Packaging materials produced using the subject substance are expected to be disposed of according to the same patterns when they are used in place of the currently used plasticizers in the applications for which clearance of the subject substance is being sought in this Notification. 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 substance. This is primarily due to the minute levels of leaching of potential migrants expected from finished articles employing the subject substance and the insignificant impact on environmental concentrations of combustion products of the subject substance. Thus, the use of the subject 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

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 EVOH blends that the subject substance would otherwise replace; such action would have no environmental impact. In view of the fact that the subject substance is 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 substance as described herein is environmentally safe in every respect.

12. List of Preparers

Mitzi L. Ng, Associate, 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.

August 28, 2008

Date

George G. Misko
Counsel for Zeon Corporation