

**G. Environmental Assessment**

- 1. Date** December 27, 2001
  
- 2. Name of Applicant/Notifier** Chevron Phillips Chemical Company LP
  
- 3. Address** All communications on this matter are to be sent in care of Counsel for Notifier, Joan Sylvain Baughan, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, D.C. 20001.  
Telephone: (202) 434-4147.
  
- 4. Description of the Proposed Action**

The action requested in this notification is to broaden the existing clearance of poly(ethylene-methyl acrylate-cyclohexenylmethyl acrylate), optionally with benzoylated triphenylbenzene, for use as components of non-food-contact layers of multilayer food-contact articles. These substances are currently permitted for use in multilayer food-contact articles when separated from all types of food, except dry food containing no surface free fat or oil, by one or more layers of polymer(s) having a total thickness no less than 0.25 mils (0.00025 inch). More specifically, the subject copolymer, with the optional use of benzoylated triphenylbenzene, is currently cleared for use in direct contact with dry food containing no surface fat or oil (*i.e.*, Food Type VIII described in § 176.170(c), Table 1) under Conditions of Use A through H, as

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described in Table 2 of § 176.170(c). Alternatively, multilayer food-contact articles, where the subject copolymer is separated from direct contact with food, is permitted for use in applications involving aqueous, acidic and low alcohol-content food (*i.e.*, Food Type I, II, IV-B, VIA, VIB, and VIIB described in § 176.170(c), Table 1) under Conditions of Use C through G, as described in Table 2 of § 176.170(c), and involving fatty and high alcohol-content food (Food Type III, IV-A, V, VI-C, VIIA, and IX described in § 176.170(c), Table 1) under Conditions of Use E through G, as described in Table 2 of § 176.170(c). The permitted multi-layer articles are flexible films, rigid polypropylene containers, or containers made of paper or paperboard.

The purpose of the current Notification is to modify the part of the limitations noted above such that the multi-layer articles shall be flexible films, containers made of paper or paperboard, or rigid containers except for bottles consisting primarily of polyethylene phthalate polymers complying with 21 C.F.R. § 177.1630, § 177.1315, or effective food-contact notifications, or bottles consisting primarily of polyethylene complying with 21 C.F.R. § 177.1520 having a density greater than 0.94 grams per cubic centimeter. All other limitations will remain the same. In essence, the only change will be that the subject substances will be used in the non-food-contact layers of *all* rigid containers -- except for bottles consisting primarily of polyethylene phthalate polymers complying with 21 C.F.R. § 177.1630, § 177.1315, or effective food-contact notifications, or bottles consisting primarily of polyethylene complying with 21 C.F.R. § 177.1520 having a density greater than 0.94 grams per cubic centimeter -- rather than in the non-food-contact layers only of polypropylene containers.

The subject poly(ethylene-methyl acrylate-cyclohexenylmethyl acrylate) copolymer offers several technical properties that makes it useful in a variety of food, pharmaceutical, and medical device applications. In particular, when used in conjunction with substances identified confidentially elsewhere in the notification, the copolymer imparts the ability to absorb oxygen from the interior space of packaged food that requires "oxygen free" environments.

The uses for the polymer at issue in this notification are foods that are packaged in rigid containers with the exception of bottles consisting primarily of polyethylene phthalate polymers complying with 21 C.F.R. § 177.1630, § 177.1315, or effective food-contact notifications, or bottles consisting primarily of polyethylene complying with 21 C.F.R. § 177.1520 having a density greater than 0.94 grams per cubic centimeter. Thus, for the applications covered in this notification, the copolymer is expected to be used to produce containers except for bottles consisting primarily of polyethylene phthalate polymers or polyethylene as described above that are used to hold foods where the oxygen barrier properties of the containers will be of greatest value.

The Notifier does not intend to produce finished food packaging materials from the subject poly(ethylene-methyl acrylate-cyclohexenylmethyl acrylate) copolymer. Rather, the copolymer will be sold to manufacturers engaged in the production of food-contact materials. Food-contact materials produced with the use of the copolymer 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 76% of the materials being deposited in land disposal sites, and about 24% combusted.<sup>11</sup>

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 poly(ethylene-methyl acrylate-cyclohexenylmethyl acrylate) copolymer.

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

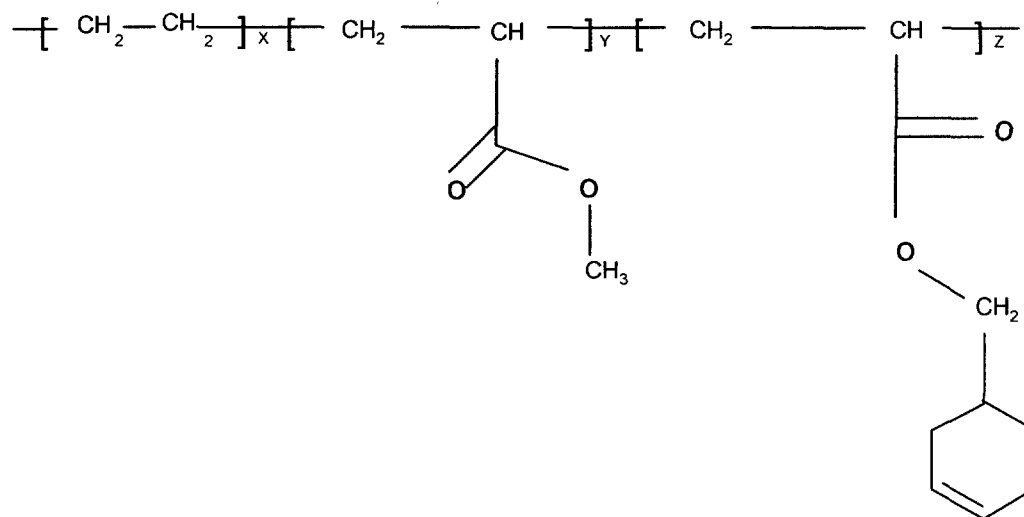
The additives that are the subject of this Notification are poly(ethylene-methyl acrylate-cyclohexenylmethyl acrylate) copolymer containing a minimum of 65 weight percent ethylene, no more than 28 weight percent cyclohexenylmethyl acrylate, and the remainder being methyl acrylate units, and the optional substance benzoylated triphenylbenzene.

Poly(ethylene-methyl acrylate-cyclohexenylmethyl acrylate) is manufactured by the reaction of poly(ethylene-methylacrylate), complying with 21 C.F.R. § 177.1340 with 3-cyclohexenyl methanol (Chemical Abstracts Service (CAS) Registry Number 1679-51-2). The CAS Reg. No. for poly(ethylene-methyl acrylate-cyclohexenylmethyl acrylate) is 223503-47-7. The CAS nomenclature is 2-propenoic acid, methyl ester, polymer with ethene,

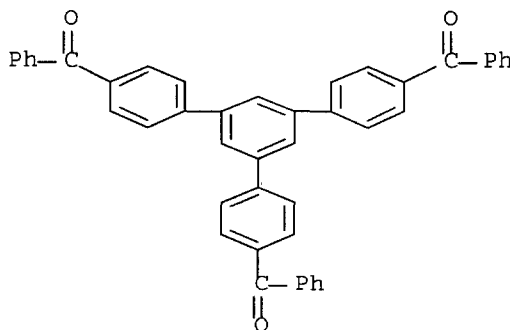
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<sup>11</sup> *Characterization of Municipal Solid Waste in the United States: 1997 Update*, EPA 530-R-98-007, U.S. Environmental Protection Agency (5305W), Washington DC, 20460, May 1998.

3-cyclohexen-1-ylmethyl ester. The structure of poly(ethylene-methyl acrylate-cyclohexenylmethyl acrylate) is depicted below:



The Chemical Abstracts Service (CAS) Registry Number for benzoyleated triphenylbenzene is 227099-60-7. The CAS nomenclature is methanone, [5'-(4-benzoylphenyl)(1,1':3',1''-terphenyl)-4,4''-diyl]bis(phenyl-). The structure of the substance is depicted below.



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**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 poly(ethylene-methyl acrylate-cyclohexenylmethyl acrylate) copolymer or benzoylated triphenylbenzene. 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 copolymer, either with or without the optional benzoylated triphenylbenzene, to fabricate packaging materials. In these applications, the polymer is expected largely to be used in film form, in paper and paperboard containers, or in rigid containers except for bottles consisting primarily of polyethylene phthalate polymers complying with 21 C.F.R. § 177.1630, § 177.1315, or effective food-contact notifications, or bottles consisting primarily of polyethylene complying with 21 C.F.R. § 177.1520 having a density greater than 0.94 grams per cubic centimeter, and will be entirely incorporated into the finished food package. Any waste materials generated in this process, *e.g.*, plant scraps, are 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 produced by the subject copolymer, along with the optional benzoylated triphenylbenzene, will be by conventional rubbish disposal and, hence, primarily by sanitary landfill or incineration. The subject poly(ethylene-methyl acrylate-cyclohexenylmethyl acrylate) copolymer consists of carbon, hydrogen, and oxygen, while benzoylated triphenylbenzene also consists of carbon, hydrogen, and oxygen. Thus, no toxic combustion products are expected as a result of the proper incineration of the copolymer or its optional adjuvant.

Only extremely small amounts, if any, of poly(ethylene-methyl acrylate-cyclohexenylmethyl acrylate) copolymer constituents or of benzoylated triphenyl benzene 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 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 substances are high molecular weight polymers that contain only minute levels of extractable material even under conditions that greatly exaggerate environmental exposure conditions.<sup>12</sup>

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<sup>12</sup> This expectation is confirmed by the results of extraction studies described in Section E of the notification. As shown there, when multilayer films were extracted with 10% ethanol at 66°C for 2 hours followed by 40°C for 10 days and with 95% ethanol at 40°C for 10 days, minute levels of components of the subject substances were found in the extracts at levels ranging from non-detected at 50 parts per billion (ppb) to a maximum of 2.36 parts per

**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 poly(ethylene-methyl acrylate-cyclohexenylmethyl acrylate) copolymer or the proposed optional use of benzoylated triphenylbenzene. The polymer is of high molecular weight and does not volatilize; likewise, benzoylated triphenylbenzene 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 these copolymers.

The products of complete combustion of the polymer and optional benzoylated triphenylbenzene 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 polymer in the amounts utilized for food packaging applications.

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million (ppm). Thus, the quantity of poly(ethylene-methyl acrylate-cyclohexenylmethyl acrylate) copolymer or benzoylated triphenylbenzene in solid waste deposited in landfills will be extremely small.



**(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 copolymer and optional adjuvant. 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 due to the extremely low levels of aqueous migration of polymer components.

**(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 poly(ethylene-methyl acrylate-cyclohexenylmethyl acrylate) copolymer and optional benzoylated triphenylbenzene. In particular, the extremely low levels of maximum migration of components of poly(ethylene-methyl acrylate-cyclohexenylmethyl acrylate) or benzoylated triphenylbenzene, demonstrated by the extraction studies, indicate that virtually no leaching of these substances may be expected to occur under normal environmental conditions when finished food-contact materials are disposed of. Furthermore, the very low production of poly(ethylene-methyl acrylate-cyclohexenylmethyl acrylate) copolymer and benzoylated triphenylbenzene 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 copolymer and optional benzoylated triphenylbenzene.

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 poly(ethylene-methyl acrylate-cyclohexenylmethyl acrylate) copolymer, optionally with benzoylated triphenylbenzene, 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 copolymer and optional benzoylated triphenylbenzene consist of extremely small quantities of combustion products and extractables. As discussed in Section F of the notification, the acute oral lethal dose (LD<sub>50</sub>) of extracts of either poly(ethylene-methyl acrylate-cyclohexenylmethyl acrylate) or oxidized poly(ethylene-methyl acrylate-cyclohexenylmethyl acrylate) was found to be greater than 2500 mg/kg b.w. in male and female rats.

The oral LD<sub>50</sub> value for the monomer cyclohexenyl methanol has been determined to be greater than 2000 mg/kg body weight. In addition, cyclohexenyl methanol has been tested in genetic toxicity screening assays, specifically, the Reverse Mutation Assay (Ames Test) using *Salmonella Typhimurium*, an *in vitro* chromosome aberration assay in human lymphocytes, an *in vitro* mouse lymphoma L5178Y TK<sup>+/+</sup> forward mutation assay, and an *in vivo/in vitro* assay of unscheduled DNA synthesis in rat primary hepatocyte cultures. All of these assays produced

negative results, with the exception of an *in vitro* mouse lymphoma L5178Y TK<sup>+/-</sup> forward mutation assay in the presence of metabolic activation where it was considered to be weakly mutagenic. Cyclohexenyl methanol is not intended to be present as a component of the finished food-contact material; rather, to the extent there is any cyclohexenyl methanol remaining in the final polymer, it is only at trace levels as an unavoidable residual reactant, determined to be not detected in the polymer using a method with a limit of detection of 10 parts per million (ppm) by weight of the polymer. In addition to having a molecular structure that is not associated with untoward toxicity, the substance has been found to be inactive in two of three standard genotoxicity testing systems, as well as being inactive in the UDS assay. Of the studies that have been conducted on the compound, it is our understanding that the Ames mutagenicity assay, in which the compound gave a clear negative result, is the study that gives the most reliable indication of whether a test substance is likely to have carcinogenic potential; the negative result obtained in the chromosome aberration study and UDS assay further ameliorate any concern as to genotoxicity. The data confirms that the compound tested only weakly positive in the mouse lymphoma assay, a test system that is generally considered highly sensitive and of less predictive value than the Ames test, and that doses associated with severe cell toxicity were required to produce the positive result.

Furthermore, the LD<sub>50</sub> of benzoylated triphenylbenzene was determined to be greater than 5000 mg/kg body weight; and was considered to be negative (a) in studies on the Reverse Mutation Assay (Ames Test) using *Salmonella Typhimurium* and *Escherichia coli*, (b) for inducing forward mutations at the TK locus in L5178Y mouse lymphoma cells under both nonactivation and activation conditions in the *in vitro* L5178Y +/- Mouse Lymphoma Forward

Mutation Assay, and (c) for inducing chromosomal aberrations with and without exogenous metabolic activation in cultured human peripheral blood lymphocytes in the *in vitro* Chromosome Aberration Test in Human Lymphocytes.

Based on these considerations, no adverse effect on organisms in the environment is expected as a result of the disposal of articles containing the copolymers. In addition, the use and disposal of the copolymer and benzoylated triphenylbenzene 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 poly(ethylene-methyl acrylate-cyclohexenylmethyl acrylate) copolymer, optionally containing benzoylated triphenylbenzene, involves the use of natural resources such as petroleum products, coal, and the like. However, the use of the subject copolymer or optional benzoylated triphenylbenzene 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 copolymer is intended to be used in packaging which will be used in place of similar materials now on the market for use as food packaging. Specifically, as discussed in Item 4 above, the proposed use in this Notification for the subject copolymer is as a component of non-food-contact layers in rigid containers, except for bottles consisting primarily of polyethylene phthalate polymers complying with 21 C.F.R. §

177.1630, § 177.1315, or effective food-contact notifications, or bottles consisting primarily of polyethylene complying with 21 C.F.R. § 177.1520 having a density greater than 0.94 grams per cubic centimeter) that are used to hold food. Its function in these containers is to serve as an oxygen limiting material. Polymers currently used in such applications include nylon resins, ethylene-vinyl alcohol copolymers (EVOH), and polyvinylidene chloride (PVDC).

The partial replacement of these types of materials by poly(ethylene-methyl acrylate-cyclohexenylmethyl acrylate) is not expected to have any adverse impact on the use of energy and resources. Manufacture of the copolymer and benzoylated triphenylbenzene, and their conversion to finished food packaging materials, will consume energy and resources in amounts comparable to the manufacture and use of other polymers. Moreover, the rigid containers that are the subject of this Notification currently in use for food packaging are not recovered for recycling to a significant extent but are disposed of by means of sanitary landfill and incineration; bottles consisting primarily of the noted polyethylene phthalate polymers or high density polyethylene, the types of containers that are recovered for recycling to a significant extent, are not of interest to the Notifier at this juncture. Packaging materials produced from poly(ethylene-methyl acrylate-cyclohexenylmethyl acrylate) copolymer 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 from the subject copolymer, optionally containing benzoylated triphenylbenzene. 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 copolymer to the materials they are intended to replace. Thus, the use of the copolymer 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 copolymer would otherwise replace; such action would have no environmental impact. In view of the excellent qualities of the poly(ethylene-methyl acrylate-cyclohexenylmethyl acrylate) copolymer for use in food-contact applications, the fact that the copolymer 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 poly(ethylene-methyl acrylate-cyclohexenylmethyl acrylate) copolymer as described herein is environmentally safe in every respect.

**12. List of Preparers**

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

Date: December 28, 2001



*J*  
Joan Sylvain Baughan

Counsel for Chevron Phillips Chemical Company LP