

Attachment 2 - Environmental Assessment

1. **Date** September 5, 2003
2. **Name of Applicant/Notifier** Arakawa Chemical Industries, Ltd.
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, NW, Suite 500 West, Washington, DC 20001. Telephone: 202-434-4170.

4. **Description of the Proposed Action**

The action requested in this Notification is for FDA to concur in the safety of a hydrogenated petroleum hydrocarbon resin for use as a component of ethylene-vinyl acetate (EVA) polymer blends films and coatings intended for use in contact with fatty food types. The resin is identified herein as RESIN A.

RESIN A is currently cleared under 21 C.F.R. § 177.1520 for use in blends with polypropylene in contact with all food types, and under food-contact notification (FCN 166) for use in polymer blends generally that are used in contact with aqueous, acidic, and alcoholic food types. The resin's use in EVA polymer blend films and coatings intended for contact with non-fatty foods is covered under FCN No. 166; the instant notification seeks only to extend this clearance to cover the use of the films and coatings with fatty food types. The use of RESIN A in polymer blends provides improvements in various physical properties of the film or coating, including moisture resistance, permeability to oxygen, clarity, and mechanical properties.

The current clearances were promulgated in response to a series of Food Additive Petitions, the last of which was converted to a food contact notification, submitted by the instant

Notifier.¹ The relevant information set forth in the previous petitions is incorporated herein; for the ready reference of the Environmental Impact review staff, the necessary information with regard to the environmental impact of the use and disposal of RESIN A is reproduced herein, revised and updated as appropriate.

Food-contact materials produced with the use of 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 76% of the materials being deposited in land disposal sites, and about 24% combusted.²

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 polymer.

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

The subject resin is hydrogenated aromatic petroleum hydrocarbon resin produced by the catalytic polymerization of substituted aromatic olefins from low-boiling distillates of cracked petroleum stocks having a maximum boiling point of 220°C (428°F), followed by catalytic reduction of the resulting aromatic hydrocarbon resin. The Chemical Abstracts Service (CAS) Registry Number is 88526-47-0. The product is referred to herein as RESIN A. This resin is also known by its trade name _____, and is sometimes referred to in this Petition as _____.

¹ The resin also is cleared under 21 C.F.R. § 176.170, "Components of paper and paperboard in contact with aqueous and fatty foods," for use in wax-polymer blend coatings on paper and paperboard. The clearance under Section 176.170 resulted from FAP Nos. 8B4072 and 2B4315; the clearance in Section 177.1520 resulted from FAP No. 2B4338.

² 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.

P-115, which is the RESIN A grade of lowest molecular weight intended for use in EVA polymer blends.

Since RESIN A is produced by the hydrogenation of aromatic starting materials, a small fraction of the resin remains unsaturated. The degree of aromaticity in the finished resin is monitored and strictly limited by a specification for the aniline point.

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 significant environmental release is expected upon the use of the subject polymer to fabricate packaging materials. In these applications, the polymer is expected to be used in polymer blends in the form of films or coatings applied to other food contact articles. Thus, the food contact substance 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 resin will be by conventional rubbish disposal and, hence, primarily by sanitary landfill or incineration. The subject polymer consists of carbon and hydrogen. The combustion products

are expected to be carbon dioxide and water. Thus, no toxic combustion products are expected as a result of the proper incineration of the copolymer.

Only extremely small amounts, if any, of components of the resin 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.³ The lack of any leaching is confirmed by the absence of detectable migration of resin components from film specimens under exaggerated exposure conditions relative to environmental conditions.⁴

7. Fate of Emitted Substances in the Environment

(a) Air

No significant effects on the concentrations of and exposures to any substances in the atmosphere are anticipated due to the proposed use of RESIN A. As the resin is not volatile, no significant quantities of any substances will be released upon the use and disposal of food-contact articles manufactured with the resin.

The products of complete combustion of the resin 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 resin in the amounts utilized for food packaging applications.

³ 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 collections systems, they are required to monitor groundwater and to take corrective action as appropriate.

⁴ As indicated by data presented in FAP No. 9B4653 (later converted to FCN No. 166), when LDPE/RESIN A blend films were extracted with 10% ethanol for 2 hours at 100°C followed by 10 days at 40°C, there was no detectable migration of the resin.

(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 resin. No significant quantities of any substance will be added to these water systems upon the proper incineration of the resin, nor upon its disposal in landfills due to the extremely low levels of aqueous migration of resin 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 FCS, a hydrogenated aromatic petroleum hydrocarbon resin. In particular, the extremely low levels of migration of resin components 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. Thus, there is no expectation of any meaningful exposure of terrestrial organisms to these substances as a result of the proposed use of the resin.

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 hydrogenated aromatic petroleum hydrocarbon resin 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 resin consist of extremely small quantities of combustion products and extractables. No

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adverse effect on organisms in the environment is expected as a result of the disposal of articles containing the resin. In addition, the use and disposal of the resin are not expected to threaten a violation of applicable laws and regulations, *e.g.*, 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 hydrogenated aromatic petroleum hydrocarbon resin involves the use of natural resources such as petroleum products, coal, and the like. However, the use of the subject resin as a component of films and coatings is not expected to result in a net increase in the use of energy and resources, since the resin is intended to be used in place of a portion of the other polymers (*e.g.*, EVA, LDPE) that make up the films and coatings in which the resin will be employed.

The partial replacement of these types of materials by hydrogenated aromatic petroleum hydrocarbon resin is not expected to have any adverse impact on the use of energy and resources. Manufacture of the resin, and its conversion to finished film food packaging materials, will consume energy and resources in amounts comparable to the manufacture and use of other polymers that it is intended to replace. Moreover, similar polymers currently in use for film food packaging materials are not recovered for recycling to a significant extent but are disposed of by means of sanitary landfill and incineration. Packaging materials produced with hydrogenated aromatic petroleum hydrocarbon resin 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.

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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 resin. This is primarily due to the minute levels of leaching of potential migrants from the finished article and the insignificant impact on environmental concentrations of combustion products of the resin. Thus, the use of the resin 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 resin would otherwise replace; such action would have no environmental impact. In view of the excellent qualities of hydrogenated aromatic petroleum hydrocarbon resin for use in food-contact applications, the fact that the resin 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 hydrogenated aromatic petroleum hydrocarbon resin as described herein is environmentally safe in every respect.

12. List of Preparers

Holly Foley, Staff Scientist, Keller and Heckman LLP, 1001 G Street, NW, Suite 500 West, Washington, DC 20001.

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

Date: September 5, 2003

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George G. Misko

Counsel for Arakawa Chemical Industries, Ltd.

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