ENVIRONMENTAL ASSESSMENT

1.	**Date:**	March 1, 1999
2.	**Name of Applicant/Petitioner:**	Arakawa Chemical Industries, Ltd.
3.	**Address:**	All communications on this matter are to be sent in care of Counsel for Petitioner, 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

This petition requests promulgation of a new Food Additive Regulation to permit the safe use of a currently cleared hydrogenated petroleum hydrocarbon resin as a component of polymer blends intended for use in contact with non-fatty food types. If the requested action is taken, a material with excellent physical properties will be made available to compete with, and to some degree replace, other closely related materials that are currently permitted for this use.

We note that, while FDA promulgated regulations, effective August 29, 1997, amending its requirements for environmental assessments, the Agency has not yet made available guidance documents for preparing EA's under the new regulations. Consequently, the EA presented here has been prepared in accordance with the format requirements that previously appeared at 21 C.F.R. § 25.31a, modified as appropriate to focus on the impact of use and disposal of the subject resins, in keeping with the new regulations. Since the

requirements set forth under new Section 25.40 are less extensive than the former requirements, we understand that an EA prepared in accordance with the previous formats will be accepted.

The subject resin, hydrogenated aromatic petroleum hydrocarbon resin, is an aromatic hydrocarbon resin that is hydrogenated to yield an essentially paraffinic resin containing a low degree of unsaturation. The product is identified herein as RESIN A or by its trade name ARKON resin. RESIN A is listed 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 at levels not to exceed 50% by weight of the coating solids. RESIN A is also listed at 21 C.F.R. § 177.1520 for use in blends with polypropylene complying with 21 C.F.R. § 177.1520. The current clearances were promulgated in response to a series of Food Additive Petitions submitted by the instant Petitioner.[1/] The relevant information set forth in the previous petitions is incorporated herein by reference.

The instant petition is intended in essence to broaden the existing clearance for RESIN A in blends with polypropylene so that the resin may be employed similarly in blends with other polymers. This use of RESIN A in polymer blends provides improvements in various physical properties of the film or sheet, including moisture resistance, permeability to oxygen gas, clarity, and mechanical properties (*i.e.*, Young modulus). The polymers with which the resin is particularly expected to be employed include low-density polyethylene (LDPE) and other olefin polymers complying with 21 C.F.R. § 177.1520, ethylene-vinyl acetate

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[1/] The clearance under Section 176.170 resulted from FAP Nos. 8B4072 and 2B4315; the clearance in Section 177.1520 resulted from FAP No. 2B4338.

copolymers (EVA) complying with 21 C.F.R. § 177.1350, and ionomeric resins complying with 21 C.F.R. § 177.1330. These polymers are employed in food-contact applications almost exclusively in film or sheet form; thus, RESIN A is not expected to be used in the fabrication of rigid food containers such as bottles and cans.

We also note that several similar types of resins are currently permitted for use in blends with other polymers to achieve similar technical results. These include *alpha*-methylstyrene-vinyl toluene resins, hydrogenated, cleared under 21 C.F.R. § 178.3610; and terpene resins, listed under 21 C.F.R. § 178.3930. Polymer blends with RESIN A are expected to compete with, and to some degree replace, blends prepared with these resins and with films produced from the base polymers alone. Since chemically related materials are already permitted that provide the polymer with properties similar to those achieved by the use of RESIN A, the use of RESIN A as proposed is not expected to alter the applications for which the finished food-contact articles are suited or the method of their disposal.

The Petitioner produces the subject resin at its manufacturing facilities located in Okayama, Japan. The resin will be incorporated into blends with other polymers and fabricated into finished food-contact materials at various locations across the country. The resulting food-contact articles will be used in patterns corresponding to national population density, and will be widely distributed throughout the country. Consequently, it is expected that disposal will occur nationwide, with the majority of the containers ultimately being deposited in land disposal sites, or to some small extent being recycled, and with the remainder being incinerated.

The types of environments present at and adjacent to these disposal locations are the same as for the disposal of any other retail food packaging material in current use. Therefore, there are no special considerations regarding the environment surrounding the disposal of packaging materials made from polymer blends containing hydrogenated aromatic petroleum hydrocarbon resin when the same is used as proposed herein.

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

The additive that is the subject of this Petition is aromatic petroleum hydrocarbon resin, hydrogenated. The Chemical Abstracts Service (CAS) Registry Number is 88526-47-0. The polymer typically has a weight-average molecular weight (M_w) near 1,000. The product is referred to herein as RESIN A. This resin is also known by its trade name ARKON, and is sometimes referred to in this Petition as ARKON P-115, which is the RESIN A grade of lowest molecular weight intended for use in blends with other polymers.

RESIN A is produced by the catalytic polymerization of substituted aromatic olefins from low-boiling distillates of cracked petroleum stocks, followed by catalytic reduction of the resulting aromatic hydrocarbon resin. The starting fraction has a maximum boiling point of 220°C (428°F).

The structure of RESIN A is represented schematically in Section A of this Petition, page 6. Because the structural diagram reveals confidential details of the starting materials from which the resin is produced, the structure is not reproduced here.

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 as shown in Section A of this Petition.

6. Introduction of Substances into the Environment

FDA's environmental assessment regulations no longer routinely require information on the introduction of substances to the environment resulting from the production of food-contact substances. No extraordinary circumstances apply to the manufacture of RESIN A by the Petitioner. Consequently, the site of production of the subject resin is not addressed here.

Little or no introduction of the resin into the environment will occur as a result of its use because it is intended to be completely incorporated into polymer blends used in the manufacture of food-contact materials and all of the substance is expected to remain in the package throughout use of the final product.

With respect to the introduction of substances into the environment upon the disposal of the product, disposal by the ultimate consumer of food packaging materials fabricated with the use of hydrogenated petroleum hydrocarbon resins will be by conventional rubbish disposal and, hence, generally by sanitary landfill or incineration. While it is possible that some portion of these materials will be recycled, post-consumer recycling programs for the polymers with which the resin are expected to be employed are not currently widespread.

Hydrogenated petroleum hydrocarbon resins are prepared only from carbon and hydrogen containing materials. No toxic combustion products are expected as a result of the proper incineration of this resin.

When food packaging materials containing hydrogenated petroleum hydrocarbon resin are placed in sanitary landfills, no significant amount of leaching of any substance from these materials into the environment is anticipated. This conclusion is based on the extremely low levels of migration of resin components under exaggerated exposure conditions (from an environmental condition standpoint) as shown in Section B of this Petition. The lack of significant leaching is further supported by the Environmental Protection Agency's regulations pertaining to landfills set forth at 40 C.F.R. Part 258.

7. Fate of Emitted Substances in the Environment

No information need be provided on the fate of substances released into the environment as the result of use and/or disposal of hydrogenated petroleum hydrocarbon resins because, as discussed under Item 6 above, only small quantities, if any, of substances will be introduced into the environment as a result of using and/or disposing of food packaging materials containing the resin. Therefore, the use and disposal of the food additive will not lead to releases that will significantly alter the concentration of any substance in the environment.

8. Environmental Effects of Released Substances

Hydrogenated petroleum hydrocarbon resin is of a low order of toxicity. Data provided in FAP 8B4072 demonstrate that the polymer is not mutagenic and has an oral LD_{50} of greater than 16,000 mg/kg. Additional data provided in Food Additive Master File No. 509 include the results of subchronic (13-week) feeding studies in rats with an *in utero* phase and in dogs. These studies demonstrated no toxic effects in rats administered the resin in the feed at levels up to 36,000 ppm, or in dogs receiving 300 milligrams resin per kilogram body weight per day.

For these reasons, and given the absence of any significant environmental introductions, no adverse toxicological effects are expected as a result of the proposed use and subsequent disposal of food packaging materials made with the use of hydrogenated petroleum hydrocarbon resin.

9. Use of Resources and Energy

As is the case with other food-packaging materials, the production, use and disposal of hydrogenated petroleum hydrocarbon resin involves the use of natural resources such as petroleum products, coal, and the like. However, the manufacture of the subject polymer will not result in an increase in the use of such natural resources since the product is intended to compete with and replace other hydrocarbon-derived products currently on the market for use in food-contact materials, including *alpha*-methylstyrene-vinyl toluene resins, hydrogenated, and terpene resins, which are cleared for use in contact with food under 21 C.F.R.

§§ 178.3610 and 178.3930, respectively. The energy required to produce the subject resin will be similar to that needed to produce the competing materials.

As shown in Section C of this Petition, the use of hydrogenated aromatic petroleum hydrocarbon resins in blends with other polymers provides improvements in various physical properties of the film or sheet, including moisture resistance, permeability to oxygen gas, clarity, and mechanical properties (*i.e.*, Young modulus). In addition to polypropylene, with which the resin is currently permitted for use, the polymers with which the resin is particularly expected to be employed include low-density polyethylene (LDPE) and other olefin polymers complying with 21 C.F.R. § 177.1520, ethylene-vinyl acetate copolymers (EVA) complying with 21 C.F.R. § 177.1350, and ionomeric resins complying with 21 C.F.R. § 177.1330. These polymers are employed in food-contact applications almost exclusively in film or sheet form; thus, RESIN A is not expected to be used in the fabrication of rigid food containers such as bottles and cans.

The food-contact applications in which polymer blends containing RESIN A are employed will be the same as those in which polymer blends made with the similar types of resins identified above (*e.g.*, *alpha*-methylstyrene/vinyl toluene and terpene resins), or materials made from the base polymer alone, are now used. This is because, rather than providing significant new properties which make new types of applications possible, the use of the hydrogenated petroleum hydrocarbon resin results in improvements in the existing desirable properties of the base polymer.

The use of RESIN A in blends with other polymers will not result in any change in post-consumer disposal patterns for finished food-contact articles due to the close similarity of such materials to the polymer blends that will be replaced. Food-contact materials produced from the cleared polymers are currently disposed of by means of sanitary landfill or incineration; if there is any collection of such post-consumer food-contact articles for purposes of recycling, it is believed to be limited to mixed-polymer recycling streams. The same is expected to be true of materials manufactured from blends of RESIN A with other polymers. Consequently, the proposed use of the resin is expected to have no adverse impact on current or future recycling programs for food packaging materials.

10. Mitigation Measures

No adverse environmental impacts have been identified in connection with the proposed use of hydrogenated aromatic petroleum hydrocarbon resins. Consequently, mitigation measures are not addressed here.

11. Alternatives to the Proposed Action

No potential adverse environmental effects are identified herein which would necessitate alternative actions to that proposed in this Petition. Consequently, alternatives to the proposed action are not discussed here.

12. List of Preparers

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b. Holly H. Foley, Staff Scientist, 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: 3-1-99

George G. Misko

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