ENVIRONMENTAL ASSESSMENT

1.	**Date**	May 19, 2000
2.	**Name of Applicant/Notifier**	Schenectady International, Inc.
3.	**Address**	All communications on this matter are to be sent in care of Counsel for Notifier, Ralph A. Simmons, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, D.C. 20001. Telephone: (202) 434-4120.

4. Description of the Proposed Action

The action requested in this Notification is the establishment of a clearance to permit the use of 2,6-di-*tert*-butyl-4-*sec*-butylphenol for use as an antioxidant at a maximum level of 0.06% (600 parts per million (ppm)) in plasticized vinyl chloride homo- and copolymers (PVC) used in contact with all types of food under Conditions of Use C through G as set forth in 21 C.F.R. § 176.170(c), Table 2. The antioxidant that is the subject of this notification is marketed under the name

The antioxidant is used in plasticized PVC to retard oxidation of the polymer. The plasticized PVC containing the subject antioxidant will be used in a variety of food, pharmaceutical, and medical device applications.

5. Environmental Consequences of the Proposed Action

a. *Production of the food-contact substance:* There are no extraordinary circumstances that apply to the manufacture of the food-contact substance that would present a significant environmental effect from the proposed action.

b. *Use and disposal of the food-contact substance:* This action involves a food-contact substance that is a minor component of finished food-packaging materials present at levels up to and including 0.06 percent-by-weight of the finished packaging material and remains with the packaging through its use by consumers. Consequently, the food-contact substance remains with the packaging through its use by consumers. The principal routes of potential environmental introduction of the food-contact substance will result from its disposal in municipal solid waste combustors or in landfills. These disposal routes are governed by Environmental Protection Agency (EPA) regulations at 40 C.F.R. Part 60 (for combustors) and Part 258 (for landfills). Furthermore, only very low levels of the substance will leach from the finished packaging material,[1/] and there will be a limited market volume for the substance (an estimate of the market

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1/ This expectation is supported by the results of extraction studies described in Section II-D of the Notification. As shown there, when laboratory samples of plasticized PVC containing up to 0.06% 2,6-di-*tert*-butyl-4-*sec*-butylphenol were tested to determine the extent to which the subject polymer could transfer to the food, the maximum level of migration to 10% ethanol was less than 0.44 parts per billion (ppb); testing with an edible oil showed a maximum level of migration of 1.78 parts per million (ppm). Thus, the quantity of 2,6-di-*tert*-butyl-4-*sec*-butylphenol leachate from plasticized PVC in solid waste deposited in landfills will be extremely small.

volume of 2,6-di-*tert*-butyl-4-*sec*-butylphenol is provided separately in a confidential section of the Notification). Thus, based on the extremely low levels of the substance, if any, that could be expected to enter the environment as a result of use and disposal of these coated food-contact articles, introduction of combustion products or introductions at landfill sites are not environmentally significant. Therefore, we do not expect that any limited increase in environmental introductions resulting from the proposed action will violate EPA regulations governing combustors and landfills or have any other adverse environmental effect.

As is the case with other food packaging materials, the use and disposal of 2,6-di-*tert*-butyl-4-*sec*-butylphenol involves the use of natural resources such as petroleum products, coal, and the like. However, the use of the subject antioxidant in plasticized PVC food-contact materials is not expected to result in a net increase in the use of energy and resources, since the antioxidant is intended to be used in place of antioxidants now on the market for use in plasticized PVC. The partial replacement of these antioxidants by 2,6-di-*tert*-butyl-4-*sec*-butylphenol is not expected to have any adverse impact on the use of energy and resources, as the use in finished plasticized PVC food packaging materials will consume energy and resources in amounts comparable to the use of other antioxidants. In addition, the partial replacement of the currently used antioxidants by 2,6-di-*tert*-butyl-4-*sec*-butylphenol is not expected to increase the volume of plasticized PVC used as food-contact articles. Moreover, plasticized PVC currently in use for food packaging is not recovered for recycling to a

significant extent but instead is disposed of by means of sanitary landfill and incineration. Thus, there will be no impact on current or future recycling programs.

6. Alternatives to the Proposed Action

Alternatives to the proposed action need not be considered because no potential adverse effects have been identified.

7. List of Preparers

a. Lester Borodinsky, Staff Scientist, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, D.C. 20001; Ph.D. in Chemistry.

b. Ralph A. Simmons, Partner, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, D.C. 20001; Attorney at Law

8. Certification

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

Date: May 19, 2000

Ralph A. Simmons

Counsel for Schenectady International, Inc.