



**Part IV — ENVIRONMENTAL IMPACT OF
FOOD CONTACT SUBSTANCE**

1. **Date:** July 5, 2000

2. **Notifying Party:** Mr. Nicholas Wright
Shell Chemical Company
One Shell Plaza
P.O. Box 4320
Houston, TX 77210
Telephone: (713) 241-3122
Facsimile: (713) 241-1308
E-mail: nwright@shellus.com

3. **Authorized Agent:** Ralph A. Simmons, Partner
Keller and Heckman LLP
1001 G Street, N.W.
Washington, D.C. 20001.
Telephone: (202) 434-4120
Facsimile: (202) 434-4646
E-mail: simmons@khlaw.com

4. **Description of the Proposed Action**

This notification is submitted with respect to _____, vinyl neodecanoate, CAS Reg. No. 51000-52-3, which is intended for use to make a homopolymer or as a reactant with monomers listed in 21 C.F.R. § 175.105, as a component of adhesives, and for polymerization alone or with the various monomers listed in 21 C.F.R. § 176.180 to form coatings intended for use on paper and paperboard intended to contact dry food.

000027

4. Environmental consequences of the proposed action

a. Production of the food-contact substance

The Food and Drug Administration has advised that environmental assessments no longer must routinely provide information on the introduction of substances to the environment resulting from the manufacture of food-contact substances unless extraordinary circumstances exist. As the manufacture of _____ in the European Union does not involve any extraordinary circumstances that are not addressed by general emission requirements of The Netherlands or the European Union, no data are submitted.

b. Use and disposal of the food-contact substance

_____ is intended to be used as a component of adhesives formulations for finished food-packaging materials and to manufacture coatings used in contact with dry food. Consequently, _____ remains a component of food-packaging material throughout the lifetime of the food-packaging material, including the food-packaging material's use and disposal. The principal routes of potential environmental introduction of the food-contact substance will result from its disposal in municipal solid waste combustors (*see* 40 C.F.R. Part 60 ("Standards of Performance for New Stationary Sources")) or in landfills. *See* 40 C.F.R. Part 258 ("Criteria for Municipal Solid Waste Landfills"). As discussed more fully below,

introductions of combustion products of _____ or introductions of _____ at
landfill sites are not expected to be environmentally significant.

Only very low levels of substances will leach into landfills from the adhesive uses due to the presence of a functional barrier between the adhesive and the environment and the minimal exposure of ground-water to the adhesive from any contact that may occur at the edges and seams. Additionally, the use as a component of a coating on a finished food-packaging material will result in only extremely low levels of substances, if any, entering the environment as a result of the disposal of the food-contact substance. Further, as described in Appendix IX, there will be a limited market volume for _____ *See confidential*
Appendix IX.

When food packaging materials incorporating _____ are added to sanitary landfills, no significant amount of leaching of _____ or products made from it into the environment is anticipated. This conclusion is based on the structure of the compound itself and the results of biodegradation studies confirming the stability of the compound. Disposal in sanitary landfills is expected to produce virtually no _____ due to the highly stable structure of _____ monomer and its ability to protect against chemical and biological degradation. The stability of _____ is the result of the branched Versatic structure. This structural feature of _____ protects the ester bonds of _____ and adjacent monomers against hydrolysis and provides alkali resistance, water resistance, and resistance to other polar materials.

Additional proof of stability may be found in a report entitled "Group Research Report, SBGR.91.273" prepared by Shell Research Ltd., Sittingbourne Research Centre, Kent, UK, in November 1992. The report investigates the inherent biodegradability of Versatic-10 acid, VeoVa-10TM and four other esters that are not the subject of this FCN. The study was conducted in accordance with OECD Test Guidance 302C.

The results are reported as percent biodegradation values for the test and reference substances in terms of net oxygen demand. Specifically, the data from the study indicate a very low order of biodegradability for . The authors of the study attribute the lack of biodegradability to two major factors. First, the presence of the quaternary carbon atoms block normal metabolic pathways of *beta*-oxidation of the alkyl chain. Second, the high degree of branching of the results in steric interference with biodegradative enzymes. See Appendix III.

is prepared only from carbon and hydrogen containing materials. The products of complete combustion of in a properly operated incinerator are carbon dioxide and water. Thus, no toxic combustion products are expected as a result of this product in a properly operated incinerator.

Based on the above analysis and the chemical stability of , the introduction of combustion products or leachate at landfill sites will be virtually nil and not environmentally significant.

Little, if any, change in the use of energy and natural resources will occur because the proposed food-contact substance will be replacing other currently regulated substances. See §§ 175.105(c)(5) and 176.180(b)(2). Further the use of _____ will not affect either the uses of the packaging material to which the subject food-contact substance will be added or the disposal technologies used for these materials.

The manufacturer's MSDS for _____ giving additional general information is enclosed as Appendix X.

6. Projected Market

See confidential Appendix IX.

7. Fate of Emitted Substances in the Environment

(a) Air

No significant effect on the concentrations and exposures to any substances in the atmosphere are anticipated due to the proposed use of

_____ is a highly stable material and in the polymerized state, the highly branched structure of _____ protects itself and its comonomers from degradation. Also,

the combustion products of _____ in a properly operated incinerator are carbon dioxide and water. The concentration of these substances would not be significantly altered by the proper incineration of _____ in the amounts used for food packaging.

(b) Water

No significant effects on the concentrations and exposures to any substances in fresh water, estuarine, or marine ecosystems are anticipated due to the propose use of _____. No significant quantities of any substance will be added to these water systems upon the proper incineration of _____ or upon its disposal in landfills due to extremely low levels of migration projected from these limited uses.

(c) Land

Because of the factors cited above, no significant effects on the concentrations and exposures to any substances in the terrestrial ecosystems are anticipated as a result of the proposed uses of _____. In particular, the low level of expected migration and the resistance to biodegradation would indicate that virtually no leaching of _____ will take place when finished food-contact materials are placed in sanitary landfills.

8. Alternatives to the proposed action:

No potential adverse environmental effects are identified that would necessitate alternative actions to those proposed in this FCN. The alternative of not approving the action proposed in this FCN would result in continued use of competing products, and therefore would have no environmental impact. However, the excellent properties of [redacted] in food-contact adhesives and coatings and the very low probability of migration of [redacted] from food- contact articles, as well as the absence of significant environmental impact from its use, argue favorably for its approval for use as a component of adhesives and coatings intended for use on paper and paperboard in contact with dry food.

8. List of Preparers

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

Thomas C. Brown, Staff Scientist, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, D.C. 20001. Qualifications: B.S., Chemistry, with 22 years of experience in evaluation of food additive petitions with the U.S. Food and Drug Administration and 4 years involved in preparing and submitting food additive petitions and FCNs.

9. Certification

The undersigned certifies that the information provided in this Environmental Assessment is true, accurate, and complete to the best of his knowledge

Date: July 5, 2000



✓
Ralph A. Simmons
Counsel for Shell Chemical Company

Part V — CERTIFICATION

The undersigned counsel for the Notifier hereby certifies that the information provided herein is accurate and complete to the best of his knowledge.

Respectfully submitted,

Shell Chemical Company

Date: July 5, 2000

By



/
Ralph A. Simmons
Keller and Heckman LLP

Counsel for Shell Chemical Company