Environmental Assessment

1.	**Date**	October 6, 2005
2.	**Name of Applicants/Notifiers**	Johnson Polymer LLC Sturtevant, Wisconsin NatureWorks, LLC Minnetonka, Minnesota
3.	**Address**	All communications on this matter are to be sent in care of Counsel for Notifiers, 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 styrene, methyl methacrylate, and glycidyl methacrylate copolymer as a polymer chain extender at a maximum level of 0.2% by weight of polylactide polymers (PLA) complying with FCNs 178 and 475. PLA employing the subject copolymer is intended for use as a component of PLA food-contact articles in contact with all types of food (except food containing more than 15% alcohol) under Conditions of Use E through G as defined at 21 C.F.R. Section 176.170(c), Table 2.

PLA employing the subject copolymer is an alternate grade of the polylactide polymers cleared by FCNs 178 and 475. Similar to PLA permitted in FCNs 178 and 475, the subject polymers offer several technical properties that make them useful in a variety of food-contact applications. In particular, the moisture and oxygen barrier properties of the polymers make them useful in flexible food packaging and in certain rigid packaging applications. The polymers also offer good contact clarity.

The Notifiers do not intend to produce finished food packaging materials from PLA employing the subject copolymer. Primarily, PLA employing the copolymer will be sold to manufacturers engaged in the production of food-contact materials. Food-contact materials produced with the use of the polymers 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 79% of the materials being deposited in land disposal sites, and about 21% combusted.[1]

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 PLA employing the copolymer.

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

The substance that is the subject of this Notification is a copolymer of styrene (CASRN 100-42-5), methyl methacrylate (CASRN 80-62-6), and glycidyl methacrylate (CASRN 106-91-2).

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 Notifiers 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 subject styrene/methyl methacrylate/glycidyl methacrylate copolymer. 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 with PLA, or with the PLA employing the copolymer used to fabricate packaging materials. In these applications, the polymers 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 using PLA employing the subject copolymer will be by conventional rubbish disposal and, hence, primarily by sanitary landfill or incineration. The subject copolymer, as well as PLA itself, consists of carbon, oxygen, and hydrogen. No toxic combustion products are expected as a result of the proper incineration of the polymers.

With regard to combustion, the EPA reports that the amount of municipal solid waste (MSW) generated in the United States in the year 2001 was 229.2 million tons. After materials recovery, the total amount of MSW disposed of in 2001 was 161.2 million tons. Of this amount,

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[1] *Characterization of Municipal Solid Waste in the United States: 2001 Update*, EPA 530-R-03-011, U.S. Environmental Protection Agency, Washington DC, 20460, October 2003.

33.6 million tons were combusted.[2] The subject copolymer is composed of carbon, hydrogen, and oxygen, elements commonly found in municipal solid waste (MSW). The complete combustion of the subject copolymers will produce carbon dioxide and water. Because the market volume estimate of the subject copolymers to manufacture food-contact articles is a small fraction of the total MSW generated and disposed of in the United States and because the subject copolymers will replace and compete with similar materials (see Item 9 below), adding to the waste that is combusted will not alter significantly the emissions from municipal waste combustors. Because of the low levels of combustion products compared to the amounts currently generated by municipal waste combustors, we do not expect that the combustion of the subject copolymers will cause municipal waste combustors to threaten a violation of applicable emissions laws and regulations, *i.e.*, 40 C.F.R. Part 60.

Only extremely small amounts, if any, of constituents of the subject copolymer 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 copolymer, as well as the PLA with which it will be used, are high molecular weight polymers that contain only minute levels of extractable material even under conditions that greatly exaggerate environmental exposure conditions.[3]

The lack of any significant introduction of substances into the environment also is supported by data showing the compostability of articles made with the food-contact substance. These data are confidential to the submitter and are contained in an appendix to the cover letter filed with this EA.

7. Fate of Emitted Substances in the Environment

No significant effect on the concentrations of and exposures to any substances in the atmosphere are anticipated due to the proposed use of the subject copolymer in PLA. The copolymer is of relatively high molecular weight and does not volatilize. Thus, no significant

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[2] *Municipal Solid Waste in the United States: 2001 Facts and Figures*, EPA530-S-03-001, United States Environmental Protection Agency (5305W), Washington DC, 20460, October 2003.

[3] This expectation is confirmed by the results of extraction studies described elsewhere in the Notification. As shown there, when a representative sample of PLA employing the copolymer was extracted with 10% ethanol, heptane , or Miglyol (a fractionated coconut oil) at 40°C for 10 days, only minute levels of components of the subject copolymer were found in the extracts, at a maximum level of 98.75 parts per billion (ppb). Thus, the quantity of leachate from the subject copolymer in solid waste deposited in landfills will be extremely small.

quantities of any substances will be released upon the use and disposal of food-contact articles manufactured with PLA employing the copolymer.

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

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. No significant quantities of any substance will be added to these water systems upon the proper incineration of PLA employing the copolymer, nor upon its disposal in landfills due to the extremely low levels of aqueous migration of polymer components.

As noted above in Section 6 of this Environmental Assessment, data showing the compostability of articles made with the food-contact substance are contained in a separate confidential appendix. The compost generated showed no ecotoxicity.

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 copolymer. In particular, the low production of the subject copolymer for use in PLA used in food-contact applications, as indicated in confidential sections of this Notification, is not expected to result in significant introductions of landfill leachate. Finally, the presence of PLA employing the subject copolymer in controlled commercial composting sites is not anticipated to result in introductions of adverse substances into terrestrial ecosystems. Thus, there is no expectation of any meaningful exposure of terrestrial organisms to these substances as a result of the proposed use of the subject copolymer.

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 the subject copolymer in PLA used in the manufacture of articles intended for 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 PLA employing the subject copolymer consist of extremely small quantities of combustion products, extractables, and the products of commercial composting. As discussed in Section III.A of the Notification, none of the potential migrating components of the polymers present any toxicological concern at the minute levels at which they could be extracted upon use and disposal. Based on these considerations, no adverse effect on organisms in the environment is expected as a result of the disposal of articles containing PLA employing the subject copolymer. In addition, the use and disposal of PLA employing the subject copolymer 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. Finally, PLA employing the subject copolymer exhibited complete disintegration under controlled commercial composting conditions and the compost generated indicated no adverse ecotoxicity.

9. Use of Resources and Energy

As is the case with other food packaging materials, the production, use, and disposal of PLA employing the subject copolymer involves the use of natural resources such as petroleum products, coal, and the like. However, the use of the subject copolymer in PLA used in the fabrication of food-contact materials is not expected to result in a net increase in the use of energy and resources, since PLA employing the copolymer is intended to be used in place of similar polymers now on the market for use in food packaging applications. (See Attachment A. Life Cycle)

Polymers currently used in the applications in which PLA is anticipated to be used include polystyrene for rigid containers, and polyethylene terephthalate (PET) and cellophane for use in film applications.

The replacement of these types of materials by PLA is not expected to have any adverse impact on the use of energy and resources. Manufacture of the copolymer, its use in PLA, and subsequent conversion of PLA employing the subject copolymer to finished food packaging materials will consume energy and resources in amounts comparable to the manufacture and use of PET, cellophane, and polystyrene. Moreover, PLA employing the subject copolymer will be used to manufacture rigid articles composed of polystyrene, a polymer that is not currently being recycled to a significant extent, and films, which also are not currently recycled to a significant extent. Consequently, the use of PLA employing the subject copolymer will not have an impact on current or future recycling programs.

One important facet regarding PLA, including PLA employing up to 0.2% of the subject copolymer, that is different than most other polymers is that PLA is not manufactured from petroleum derived substances as the basic raw material. Rather, the lactic acid from which PLA is manufactured is derived solely from grain derived sugars that are fermented and distilled; currently, the lactic acid is derived from corn, although future alternatives sources may be other grains, such as wheat, sugar beets, and rice. Thus, PLA *per se* is manufactured from a renewable resource; with the use of up to 0.2% of the subject copolymer, the product contains at least 99.8% PLA. According to Section 101(b)(6) of the National Environmental Policy Act (NEPA) (42 U.S.C. Section 4331(b)(6)),

> (b) In order to carry out the policy set forth in [NEPA], it is the continuing responsibility of the Federal Government to use all practicable means, consistent with other essential considerations of national policy, to improve and coordinate Federal plans, functions, programs, and resources to the end that the Nation may...(6) *enhance the quality of renewable resources* and approach the maximum attainable recycling of depletable resources. [*emphasis added*]

Thus, as PLA employing the subject copolymer is manufactured from raw materials that predominantly (at least 99.8%) are derived from a renewable resource, the replacement of other polymers by PLA employing the subject copolymer will have a net effect of reduction of the use of depletable resources. NatureWorks, LLC had radiocarbon dating conducted on its product by an independent third party (Beta Analytics Inc.).

Sample Identification	Mean Biobased Result	Apparent Biobased Content
NatureWorks® PLA	100%	97-100%

The application of radiocarbon dating to derive "biobased content" is built upon the same concepts as determining a radiocarbon age, but without use of the age equations. It is done by deriving a ratio of the amount of radiocarbon (C) in an unknown sample to that of a modern reference standard. If the material being analyzed is a mixture of present day radiocarbon and fossil carbon (containing no radiocarbon), then the values obtained correlates directly to the amount of biobased material present in the sample. (See Attachment B. Calculation of Biobased Content)

Therefore, for all of the foregoing reasons, the use of PLA employing the subject copolymer as described in this Notification will not have an adverse impact on energy and resources.

10. Mitigation Measures

As shown above, no significant adverse environmental impacts are expected to result from the use and disposal of PLA food-contact materials fabricated using the subject copolymer. 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 use of renewable resources for the manufacture of PLA employing the subject copolymer. Thus, the use of the subject copolymer in PLA 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 PLA employing the subject copolymer would otherwise replace; such action would have no environmental impact. In view of the excellent qualities of PLA employing the subject copolymer for use in food-contact applications, the fact that the polymer 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 their use, the clearance of the use of the subject copolymer in PLA as described herein by allowing this Notification to become effective is environmentally safe in every respect.

12. List of Preparers

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13. Attachments

A. Life Cycle
B. Calculation of Biobased Content

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

Date: October 6, 2005

Ralph A. Simmons

Counsel for Johnson Polymer LLC
and Natureworks LLC