APPENDIX VI

ENVIRONMENTAL ASSESSMENT

1.	**Date:**	June 18, 1998
2.	**Name of Applicant/ Petitioner:**	Mitsubishi Gas Chemical Company, Inc.
3.	**Address:**	All communications on this matter are to be sent in care of Counsel for Petitioner, Jerome H. Heckman, Keller and Heckman, 1001 G Street, N.W., Washington, D.C. 20001. Telephone: (202) 434-4110.

4. Description of the Proposed Action

This petition requests promulgation of a Food Additive Regulation to permit the safe use of Nylon MXD-6, a polyamide produced by the condensation of adipic acid and 1,3-benzene-dimethanamine, as a basic polymer in certain food packaging applications. More specifically, the instant Petition seeks amendment of 21 C.F.R. §§ 177.1500 and 177.1390 of the Food Additive Regulations to permit the safe use of Nylon MXD-6 as a non-food contact layer of multilayer films and rigid plastic containers with polypropylene food-contact layers. It is anticipated that the subject resin will be utilized as a gas-barrier layer in conjunction with polypropylene food-contact and exterior layers. The use of the polymer in this way

provides a significant decrease in the permeability of the finished package to gases such as oxygen and carbon dioxide, thus extending the shelf-life of the food product.

The Petitioner anticipates that the major market for Nylon MXD-6 will be in laminate films and containers for packaging oxygen-sensitive, heat sterilized, shelf-stable foods. The foods to be packaged in these containers are expected to consist primarily of specialty food products such as condiments, (including ketchup, barbecue sauce, jellies, salad dressings,) as well as a small number of shelf-stable meals intended for microwave reheating, such as stews and soups; no other applications are known to the Petitioner at this time. These foods are currently packaged in multilayer barrier-type containers. As noted above, the Nylon gas-barrier layer is expected to be surrounded by polypropylene layers; the polypropylene and Nylon materials will be fused with a suitable adhesive interlayer.

Nylon MXD-6 complying with the specifications set forth in Item 10.1 of Section 177.1500(b) is currently permitted for use as a film not exceeding 40 microns (1.6 mil) in thickness in direct contact with dry and fatty foods. The purpose of this Petition is to slightly expand the uses for which MXD-6 is

cleared so that the polymer may be employed in applications involving aqueous as well as fatty food types, albeit not in direct contact with the food. Table 1, below, lists typical laminate containers, their volume, mass and applications. No new manufacturing technologies which might pose new environmental concerns are involved in the production of these containers.

As mentioned above, the subject polymer is particularly well-suited for use in improving the gas barrier properties of polymers such as polypropylene because of its excellent gas impermeability and other desirable technical properties. A number of other resins with good gas barrier properties are currently available and permitted for use in food packaging applications. These include, e.g., polyvinylidene chloride (PVDC) and ethylene/vinyl acetate/vinyl alcohol copolymer (EVOH). Multilayer articles containing an inside layer prepared from MXD-6 are intended to compete with, and to some extent replace, multilayer laminates prepared with these other, cleared barrier resins. However, nylon MXD-6 does not offer sufficient barrier properties to compete with non-polymeric packaging, such as glass or aluminum. Thus, approval of the proposed amendment will not affect recycling of these materials. Apart from a general improvement in the barrier properties of the resulting food-contact articles, thus extending the shelf-life of the food product, the use of the polymer in containers of this type will not alter the technical properties of the articles or, consequently, the applications for which the structures are suited. For this reason, multilayer constructions containing an MXD-6 barrier layer are not expected to find wholly new markets, but will be used in applications in which similar laminates

containing a polyolefin food-contact layer with an interior gas-barrier layer are currently employed.

The Petitioner manufactures the subject resin at its production facilities located in Niigata City, Japan. The resin will subsequently be employed in the production of food-contact articles by other manufacturers at various locations across the United States.

Food-contact articles fabricated with the subject resin 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 about 80% of the containers being deposited in land disposal sites or, to some extent, being recycled, and with about 20% being incinerated, according to current Environmental Protection Agency (EPA) projections.[1/] The types of environments present at and adjacent to the expected 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 containers

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1/ U.S. Environmental Protection Agency, Characterization of Municipal Solid Waste in the United States: 1996 Update(EPA Report No. 530-R-97-015), Table 48.

made from the subject polyamide resin when the same is used as proposed herein.

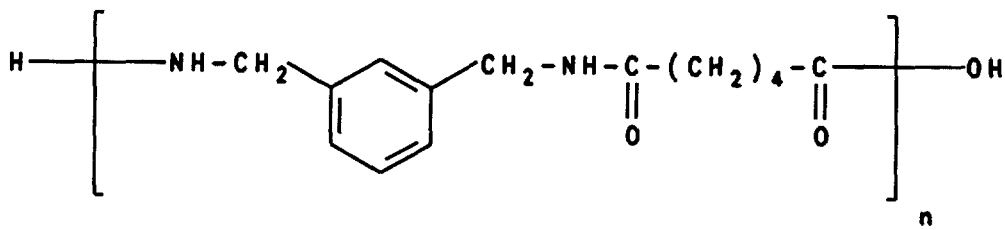
The use of Nylon MXD-6 resin as proposed will not affect the method of disposal for the finished article, whether it is disposed of via sanitary landfill, incineration, or by recycling. As discussed under Item 6 below, only minute quantities of MXD-6 components may be expected to leach from articles placed in land-disposal facilities, and no significant quantities of toxic combustion products will be produced upon incineration of the polymer. See Format Item 9 for a discussion of the extent to which the proposed action might impact polypropylene recycling programs.

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

The subject of this Petition is a polyamide resin produced by the polycondensation of adipic acid and 1,3-benzene-dimethanamine. The polymer is commonly known as Nylon MXD-6.

When named in terms of the starting monomers from which it is produced, the Chemical Abstracts Service (CAS) Registry No. for Nylon MXD-6 is 25718-70-1, and the CAS nomenclature is Hexanedioic acid, polymer with 1,3-benzenedimethanamine. When named in terms of the structure of the finished polymer, the CAS Registry No. for Nylon MXD-6 is 25805-74-7, and the CAS nomenclature is Poly(iminomethylene-1,3-phenylenemethylene-imino-(1,6-dioxo-1,6-hexanediyl)). The empirical formula for the polymer is $HO-[(C_6H_8O_2)(C_8H_{10}N_2)]_n-H$.

Nylon MXD-6 has the following structural formula:



The melting point for MXD-6 is in the range of 455°F to 470°F. As produced by the Petitioner, the polymer has a minimum number-average molecular weight of 10,000.

6. Introduction of Substances into the Environment

The Petitioner has reviewed its manufacturing procedures and has concluded that no extraordinary circumstances as defined by FDA (62 Fed. Reg. 40570, July 29, 1997)exist in the manufacture of Nylon MXD-6.

With regard to the market size for the subject polymer, the Petitioner anticipates that the use of the polymer in multilayer constructions will be limited to use in a number of specialty applications, primarily involving containers for packaging oxygen-sensitive, heat sterilized shelf-stable food. These applications are discussed further under Item 9 below. The Petitioner's estimates of the total U.S. market for the resin in applications of this type in the years following promulgation of a regulation responsive to this Petition are set forth under Appendix VII, Confidential Environmental Information.

With respect to the introduction of substances into the environment upon the use of the product, only small quantities of waste, in the form of plant scrap, are expected to be formed at the site of production of food packaging laminates. As is typical of gas barrier resins, the polymer will be formed into a layer that will be surrounded by adhesive interlayers and

polyolefin exterior layers. Thus, the resin will be fully incorporated into the finished laminate. Scrap material resulting from the fabrication of food packages may be re-worked into interior layers of subsequent laminate production batches or otherwise disposed of as nonhazardous solid waste.

Disposal by the ultimate consumer of food packaging materials fabricated with the use of the subject polymer will be by conventional rubbish disposal and, hence, by sanitary landfill, incineration, and possibly, to some extent, recycling, as discussed in Item 4 above.

Incineration of Nylon MXD-6 in correctly operating incinerators will not generate toxic combustion products. Sample calculations showing the worst-case quantity of NO_x that may be produced by incineration of MXD-6 are presented in Appendix VII.

The value calculated in Appendix VII may be placed in perspective by comparison to the total quantity of nitrogen oxides emitted annually. According to an Environmental Protection Agency technical report titled "Anthropogenic Emissions Data for the 1985 National Acid Precipitation Assessment Program Inventory," nitrogen oxide emissions for the 48 contiguous states in 1985 totaled 20.6 million tons. The figure calculated in

Appendix VII is orders of magnitude below the total annual NO_x emission rate. Clearly, the possible release of nitrogen compounds from incineration of food-contact materials containing Nylon MXD-6 is of no concern at these levels. Moreover, it should be noted that the estimated worst-case amount of NO_x that may be produced, as small as it is, does not represent a net increase in potential toxic combustion products since MXD-6 will largely be utilized in place of other polymers (e.g., polyvinylidene chloride) that may also contribute small quantities of similar species to the environment upon incineration.

Further, a portion of the Nylon MXD-6 used as a result of the proposed regulation will replace polyvinylidene dichloride (PVDC) in high temperature laminates. While the Petitioner does not know how much PVDC will be replaced by the nylon, it is estimated that at least 10% of all MXD-6 will be used in these applications. As shown in the Confidential Appendix, this quantity of PVDC may generate 1.3×10^5 kg per year of chlorine when the laminates are incinerated. Assuming that 20% of all packaging materials are disposed of through incineration, the use of Nylon MXD-6 in the petitioned applications could result in a reduction of atmospheric chlorine.

When food packaging materials containing the subject polyamide resin are added to sanitary landfills, no significant amount of leaching of any substance from this polymer into the environment is anticipated. This conclusion is based on the fact that the polymer will be employed in an interior (buried) layer of multilayer articles and will not be directly exposed to the environment. The lack of leaching of MXD-6 components in any meaningful quantities is further confirmed by the extraction data developed under grossly exaggerative exposure conditions (from an environmental conditions standpoint) as shown in Section B of this Petition.

To summarize these data, when containers made from a polypropylene/Nylon MXD-6 laminate were extracted with 8% aqueous ethanol at 250°F for two hours, allowed to cool to 120°F, and were maintained at this temperature for 10 days, total nonvolatile extractives from the test containers averaged 0.032 milligram per square inch (mg/in^2). The specific levels of Nylon MXD-6 species *per se* migrating from the test containers were as follows: the cyclic "monomer" of adipic acid with *m*-xylylenediamine, the major oligomeric component of the resin, was found at an average level of 0.275 microgram per square inch ($\mu g/in^2$), while MXDA and adipic acid monomers were not detected in the extracts.

These values may be converted to corresponding percentages of the amount of polymer in the test samples as follows. The containers were a total of 1000 microns (0.04 inch) in thickness; the Nylon MXD-6 layer of the test containers was 85 microns in thickness, or 8.5% of the total. Thus, assuming a laminate density of 1 g/cm^3, the containers weighed approximately 0.65 gram per square inch, of which total the MXD-6 layer comprised about 0.055 gram per square inch.

Based on these figures, the nonvolatile residue of 0.032 mg/in^2 represents 0.005% of the weight of the total container. A migration level of 0.275 $\mu g/in^2$ for the cyclic monomer is equivalent to 0.0005% of the MXD-6 portion of the laminate.

Moreover, even if very small amounts of the subject additive, its monomers, and nonvolatile extractives migrate from the food packaging in landfills, we expect extremely low quantities to actually enter the environment. This finding is based on the Environmental Protection Agency's (EPA) regulations governing municipal solid waste landfills.

Using these percentage-migration levels and the maximum food-contact market for MXD-6 set forth in Appendix VII, the

total quantities of nonvolatile extractives and of the MXD-6 cyclic monomer in particular that may leach from finished articles placed in land disposal sites may be calculated by assuming that a maximum of 80% of products containing the polymer will be disposed of by landfilling. These calculations are set forth in Appendix VII. The actual quantity of leaching of laminate constituents under environmental conditions is expected to be far lower than indicated by these calculations in light of the grossly exaggerative conditions of the extraction studies.

7. Fate of Emitted Substances in the Environment

(a) Air

Except for the potential reduction in harmful chlorine compounds as a result of reduced use of PVDC, no significant effect on the concentrations of and exposures to any substances in the atmosphere are anticipated due to the proposed use of Nylon MXD-6. As indicated in Item 6 above, no significant quantities of volatile substances used in the production of the nylon MXD-6 is released to the atmosphere at the site of manufacture. Moreover, the polymer per se is of high molecular weight and does not volatilize.

With regard to the products of combustion of the polymer, 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, as indicated by the calculations set forth in Item 6 above.

(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 polymers. Information provided in Item 6 of this Environmental Assessment demonstrates that no substance will be emitted to aqueous compartments of the environment at levels that could cause any adverse environmental impact. More specifically, there is no significant aqueous release of substances involved in the manufacture of MXD-6 at the site of production or use of the polymer. No significant quantities of any substance will be added to these water systems upon the proper incineration of the polymer, nor upon its disposal in landfills due to the extremely low levels of migration of resin components, as demonstrated in Section B of this Petition and as discussed in Item 6, above.

(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 Nylon MXD-6. In particular, the extremely low levels of migration of polymer constituents, even at greatly

elevated temperature, demonstrated by the extraction studies indicate that virtually no leaching of these substances may be expected to occur under normal environmental conditions, either when small quantities of plant scrap or larger amounts of finished food-contact materials are disposed of. Thus, there is no expectation of any meaningful exposure of terrestrial organisms to these substances as a result of the proposed use of the polymer.

As detailed earlier, Nylon MXD-6 will be used in place of PVDC in the proposed applications. Since PVDC is expected to degrade and release a small quantity of chlorine compounds when disposed of in landfill applications, the use of the nylon polymer in these applications will reduce potential leaching of chlorine into groundwater.

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 use as proposed of Nylon MXD-6 as an interior layer of multilayer constructions 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 containing a non-food contact layer produced from the subject nylon resin consist of extremely small quantities of the combustion products listed in Item 6 and of Nylon MXD-6 oligomers, primarily the cyclic "monomer" of MXDA with adipic acid. As shown above, incineration of the resin will not result in a meaningful increase in environmental levels of the combustion products; moreover, since the resin will largely be employed in place of other polymeric materials that are expected to yield similar combustion products, the use and disposal of Nylon MXD-6 is not expected to lead to any net increase in the formation of these substances. Consequently, no effect on organisms in the environment is expected as a result of the disposal of articles containing MXD-6 by means of incineration.

As demonstrated by the extraction studies described in Section B of this Petition, Nylon MXD-6 oligomers are not expected to leach at more than trace levels from finished food-contact materials deposited in landfill sites. Toxicological data presented in Appendix V of this Petition demonstrate an

acute oral LD_{50} value in rats of greater than 5,000 mg/kg for the MXD-6 oligomers. Since these substances are not expected to leach from packaging materials deposited in landfill sites in more than the minute quantities calculated under Item 6 above, and since they are of such a low order of toxicity, the Petitioner respectfully submits that no adverse environmental impact can reasonably be anticipated from substances produced and/or released as a result of the proposed use and subsequent disposal of the subject polymer by any anticipated means.

9. Use of Resources and Energy

As is the case with other food-packaging materials, the production, use and disposal of Nylon MXD-6 involves the use of natural resources such as petroleum products, coal, and the like. However, the use of MXD-6 as a gas-barrier layer in laminated constructions in place of other barrier polymers is not expected to result in a significant increase in the use of energy and resources. This is because the manufacture and use of the subject polymer involves the consumption of raw materials in quantities comparable to the production of the polymers with which it is expected to compete.

The use of Nylon MXD-6 in laminated films is not expected to have an impact on established PP recycling programs because there is currently limited, if any, recycling of food-contact films. Furthermore, the future recycling of food-contact films is not likely because of the difficulty of cleaning films that have residual food adhering to them and because food-contact films are made from diverse materials that are not specifically identified on the finished packaging material.

We do not expect the use of Nylon MXD-6 with polypropylene rigid constructions to adversely affect polypropylene recycling. We anticipate that only a very small

fraction of food-packaging material using Nylon MXD-6 will be recycled after use by consumers. Currently, post-consumer polypropylene-based food-contact materials are not widely collected for purposes of recycling;[2/] to the extent such recycling occurs, the polypropylene is usually included in a general-plastics stream for use in non-food applications that permit the use of mixed polymers. The recycled end products would be items such as furniture, pallets, bird feeders and carpet.[3/]

[2/] Id at Table 7.

[3/] Robert A. Bennett, (1992) "Recycling Plastics, Product Applications and Potential," page 35, and Andrews and Subramanian, Eds., *Emerging Technology in Plastics Recycling*, ACS Symposium Series 513, American Chemical Society, Washington, DC 20036.

10. Mitigation Measures

Measures taken in the plant to recover or safely dispose of excess raw materials and by-products from the manufacture of Nylon MXD-6 are described in Item 6 above.

The only other potential adverse environmental impacts would be those resulting from the use and disposal of articles containing the subject polymer. As shown above, no significant effects on the environment are anticipated; this is primarily due to the low toxicity of the polymer and that of the extractable fraction thereof; the minute levels of leaching of potential migrants from the finished laminated article; the insignificant impact on environmental concentrations of combustion products of MXD-6; and the suitability of the laminated construction for inclusion in mixed-plastics. 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 Petition. The alternative of not approving the action proposed herein would simply result in the continued use of currently cleared resins with which Nylon MXD-6 would otherwise compete; such action would have no environmental impact. As discussed previously, MXD-6 is expected to be used in place of other resins that are currently employed as inner layers of multilayer constructions; these polymers include EVOH, and PVDC. In view of the excellent qualities of the polymer for use in food packaging materials, the fact that resin components 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 promulgation of a Food Additive Regulation to permit the safe use of Nylon MXD-6 as a non-food contact layer of multilayer articles intended for use with food is environmentally safe in every respect.

12. List of Preparers

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c. Mark L. Itzkoff, J.D., Attorney, Keller and Heckman, 1001 G Street, N.W., 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: June 18, 1998

Mark L. Itzkoff

Counsel for Mitsubishi Gas Chemical Company, Inc.

14. References

All data referenced in this Environmental Assessment are included in this Petition.

15. Appendices

The following materials are attached as appendices to the Environmental Assessment:

A. Environmental Protection Regulations of Niigata City, Japan.

B. Reports of studies on recyclability of polypropylene/Nylon MXD-6 multilayer construction.

C. Material Safety Data Sheets for Substances Used in the Production of Nylon MXD-6.

C.1 Adipic Acid
C.2 M-Xylenediamne
C.3 Sodium Hypophosphite
C.4 Sodium Acetate, anhydrous