

Food Additive Petition for Modification of the Regulation, 21 CFR 177.1630,
Polyethylene Terephthalate Polymer (e)(4)(v) Modifier:
Hexanedioic acid polymer with 1,3-benzenedimethanamine

Section H, Environmental Assessment

Format following
21 CFR 25.31a
April 26, 1985

1. Date: December 18, 1989
2. Name of applicant/petitioner: Toyobo Company Limited
3. Address: Toyobo Research Center
1-1, 2-Chome Katata
Otsu, Shiga 520-02
JAPAN

c/o Center For Regulatory Services
2347 Paddock Lane
Reston, VA 22091
4. Description of Proposed Action:

This petition is to amend the regulation for safe use of polyethylene terephthalate polymer modified with hexanedioic acid polymer with 1,3-benzenedimethanamine to permit the following:

Increase the temperature to permit the hot filling of all currently regulated uses of the additive with the exception of foods containing free fats or oils at temperatures of 95°C.

To remove the limitation with respect to foods containing ethanol at a maximum of 80% and for foods containing over 8% ethanol to permit hot filling at temperatures of 160°F (71°C). Also in the case of ethanol, at levels greater than 8%, it will be proposed that the modifier used in the polyethylene terephthalate equal a level not to exceed 10% weight of the polyethylene terephthalate.

Modified PET article containing Nylon MXD-6 has excellent oxygen gas impermeability. Consequently, this article could be used to protect the foods which are liable to deteriorate by oxygen.

In these applications, this article could be a replacement for aluminum can, steel can or glass bottle, which consume more energy in their production.

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5. Identification of the Chemical Substances:

Polyethylene terephthalate

- (a) Common or Usual Name: Polyethylene terephthalate base polymer
- (b) Chemical Name: Poly (oxy-1,2-ethanedioyl carbonyl-1,4-phenylene carbonyl)
- (c) Chemical Abstract Service (CAS) Registry Number: 25038-59-9
- (d) Regulatory Description: 21 CFR 177.1630(e)(4)(ii)

Hexanedioic polymer with 1,3-benzenedimthamine

- (a) Common or Usual Name: Nylon MXD-6
- (b) Chemical Name: Hexanedioic polymer with 1,3-benzenedimethanamine
- (c) Chemical Abstract Service (CAS) Registry Number: 25718-70-1
- (d) Regulatory Description: 21 CFR 177.1500(a)(10)(ii) Nylon MXD-6. Resins manufactured by the condensation of adipic acid and 1,3-benzenedimethanamine.

Nylon MXD-6 Modified Polyethylene Terephthalate

Regulatory Description: 21 CFR 177.1630(e)(4)(v)

6. Introduction of Substances into the Environment:

Synthesis:

Synthesis of hexanedioic polymer with 1,3-benzenedimthamine. An environmental impact analysis report dated February 1, 1983, was submitted as part of Food Additive Petition 3B3752, resulting in the regulation published in the Federal Register, September 19, 1986 (51 FR 33248). A review of that environmental impact analysis report resulted in a finding of no significant impact in May 1985, prepared by Katherine M. Hart and approved by Dr. Buzz L. Hoffmann, Environmental Impact Section (copy enclosed).

The use of the modifier in PET was the subject of a Food Additive Petition, FAP 4B3818, and an environmental impact analysis report dated July 1, 1984 was part of that food additive petition. The petition was approved and the regulation printed in the Federal Register of July 24, 1985, a review of the environmental impact analysis report resulted in finding of no significant impact in February 14, 1985 (copy enclosed).

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Process:

The raw materials of Nylon MXD-6 are introduced into a closed vessel (autoclave) and polymerized in the presence of water under heat and high pressure followed by polymerization under atmospheric pressure.

During this process, water and a very little amount of metaxylylenediamine are distilled off. The amount of metaxylylenediamine involved in the distillate is approximately 0.5 wt% of total metaxylylenediamine introduced into a vessel. This distillate is treated by the activated sludge process in the same way as the distillate in the polymerization of Nylon 6 is treated, so that the distillate does not cause any environmental problems. Further, no volatile products are discharged to the atmosphere in the polymerization process. Nylon MXD-6 is now manufactured only in Japan in the amount of approximately 50 tons per year.

The air and water emission from the polymerization process complies with the current Japanese regulations (Exhibit H1).

There is no adverse environmental effects in the United States that can not be avoided, because the modified PET articles are manufactured only in Japan. In the future, if manufacturing of the Nylon MXD-6 and the modified PET article should be manufactured in the United States, there would be no adverse environmental effects that can not be avoided.

Use:

PET articles containing the modifier will be used in patterns corresponding to population density, and it is expected that the disposal will occur nationwide.

Major disposal will be at land disposal sites, with some disposal by incineration. It is also possible to recycle PET after use of the modifier.

7. Fate of Emitted Substances in the Environment:

(a) Air

Table 1 shows the composition of the combustion products of Nylon MXD-6. This combustion products are similar to the combustion products of Nylon 6 and Nylon 66.

Table 1 - Composition of Combustion Products

	Combustion Product (mg/g sample)							
	CO ₂	CO	CH ₄	C ₂ H ₄	C ₂ H ₂	C ₆ H ₆	HCN	NO _x
Nylon MXD-6	910	230	3.0	8.1	4.5	0.6	23.4	1.6
Nylon 6	915	220	9.9	60.3	12.0	---	48.4	1.0
Nylon 66	940	270	14.2	61.8	18.9	---	50.9	0.5

Condition of Combustion: Furnace Temperature 700°C
Air Flow Rate: 500 ml/minute

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The quantitative consumption of Nylon MXD-6 is now very small (about 50 T/year) in Japan, compared with all other plastics (about $7,500 \times 10^3$ T/year). Therefore, there are no significant potential adverse environmental effects by the use, consumption, and disposal of this article.

(b) Fresh water, estuarine and marine ecosystems (water emissions)

No Pollution expected.

(c) Terrestrial ecosystems

No effects expected.

8. Effects of Released Substances:

None Expected

9. Use of Resources in Energy:

The consumption of raw materials in the manufacture of Nylon MXD-6 would be an irreversible commitment of resources. These could be partially recovered as fuel if the modified PET article or Nylon MXD-6 would be disposed by incineration. However, in Japan the raw material consumed in the manufacture of Nylon MXD-6 is insignificant compared to that in the manufacture of all other polymers. Even though raw material consumption for Nylon MXD-6 is an irreversible commitment, this proposed action would have a net positive effect on the environment because the manufacture of replacing materials such as aluminum or glass requires a much greater commitment of resources than Nylon MXD-6.

10. Mitigation Measures:

The only 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, due to the low toxicity of the polymer and that of the extractable fraction thereof, the low levels of migration of polymer constituents, and the fact that the polymer is intended to compete with and replace alternative materials which are currently in use and which are closely related to the subject copolymer in composition and manufacture. 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.

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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 products which the subject copolymer would otherwise replace; such action would have no environmental impact. However, the view of the excellent qualities of the polymer for food packaging, the minute levels in which resin components migrate from the finished container into food or into land in which the containers are disposed, and the absence of any significant environmental impact which would result from its use, the promulgation of a food additive regulation to permit the safer use of the subject copolymer in contact with food is environmentally safe in every respect.

As the substantial adverse environmental effects are not identified for this proposed action, the evaluation of alternatives is considered to be unnecessary.

As described above, the use of resources for the manufacture of Nylon MXD-6 would be infinitesimal compared to these overall total consumption in Japan. The amount of waste from Nylon MXD-6 is also infinitesimal compared to that of total plastic waste in Japan.

The amount of resources consumption and the waste load would be much less than the products replaced. We believe that the economic, technical, and health benefits to the public of the proposed action would outweigh the action's potential risks to the environment.

12. List of Preparers:

Those persons preparing the assessment together with their qualifications.

Dr. William A. Olson
Center for Regulatory Services
Biochemistry, Toxicology & Regulatory Consultant

Mr. Masao Murano,
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13. Certification

The undersigned official certifies that the information presented is true, accurate, and complete to the best of the knowledge of the firm or agency responsible for preparation of the environmental assessment.

(Date)

Dec. 25, 1989

(Signature of Responsible Official)

[Redacted Signature Box]

(Title)

Chief Scientist
Katata Research Center
TOYOBO CO. LTD.

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14. References:	
Environmental Impact Analysis Report - February 1, 1983 submitted as part of Food Additive Petition 3B3752	043
Approval of Food Additive Petition 3B3752 - September 19, 1986 (51 FR 33248)	049
Finding of No Significant Impact - FAP 3B3752 - May 24, 1985	053
Environmental Impact Analysis Report - July 1, 1984 Date of Filing of Food Additive Petition 4B3818	056
Approval of Food Additive Petition 4B3818 - July 24, 1985	075
Finding of No Significant Impact - FAP 4B3818 - February 14, 1985	077

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H. Environmental Impact Analysis Report

A. Data : Feb. 1, 1983

B. Name of Petitioner : Toyobo Co., Ltd.

C. Address : 2-2-8, Dojima-Hama, Kita-ku, Osaka 530, Japan

D. Environmental information.

1. Description of Proposed Action

Toyobo Co., Ltd., has petitioned the Food and Drug Administration for a regulation on the use of Nylon MXD-6 films. Nylon MXD-6 film is intended for use in packaging, transporting or holding foods, types V and IX described in Table 1 of §176.170(C) under conditions of use C, D, E and H described in Table 2 of §176.170(C).

Nylon MXD-6 film has the many excellent properties, including outstanding strength, superior pinhole and abrasion resistance, good gas impermeability, and good oil resistance, which are very important as the food packaging film.

2. Discussion of the Problem Impact of Proposed Action on the Environment

(1) Probable Adverse and Beneficial Environment Effects of the Use, Consumption and Disposal of the Article.

Nylon MXD-6 film has the superior physical properties, such as the pliability and the impact resistance at low temperature, and an excellent oxygen gas impermeability. Consequently, this film could be used to protect the foods

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which are liable to deteriorate by oxygen and also used to package the frozen and refrigerated food products.

In these applications, this film could be a replacement for aluminum can, steel can or glass bottle, which consume more energy in their production.

This nylon MXD-6 film will be disposed of in the same way by incineration open dumping or sanitary landfill as most other plastics are treated. Table 1 shows the composition of the combustion products of Nylon MXD-6. This composition is approximately the same in case of Nylon 6 and Nylon 66. We believe that the products of combustion of Nylon MXD-6 will be less dangerous or cause less pollution than Nylon 6 and Nylon 66.

The amount of consumption of Nylon MXD-6 is now very small (about 50 T/year) in Japan, compared with all other plastics (about $7,500 \times 10^3$ T/year). Therefore, there is no substantial adverse environmental effects by the use, consumption and disposal of this film.

Table 1. Composition of Combustion Products

	combustion product (mg/g sample)							
	CO ₂	CO	CH ₄	C ₂ H ₄	C ₂ H ₂	C ₆ H ₆	HCN	NO _x
Nylon MXD-6	910	230	3.0	8.1	4.5	0.6	23.4	1.6
Nylon 6	915	220	9.9	60.3	12.0		48.4	1.0
Nylon 66	940	270	14.2	61.8	18.0		50.9	0.5

Condition of combustion : furnace temperature 700°C
air flow rate : 500 ml/min.

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(2) Environmental Impact of the Manufacturing Process

On the polymerization process, the raw materials of Nylon MXD-6 introduced into a closed vessel (autoclave) and polymerized in the presence of water under heat and high pressure followed by polymerization under atmospheric pressure.

During that process, water and a very little amount of metaxylylenediamine are distilled off. The amount of metaxylylenediamine involved in the distillate is approx. 0.5 wt% of total metaxylylenediamine introduced into a vessel. This distillate is treated by the activated sludge process in the same way as the distillate in the polymerization of Nylon 6 is treated, so that the distillate does not cause any environmental problems. Further, no volatile products are discharged to the atmosphere in the polymerization process. Nylon MXD-6 is now manufactured only in Japan in the amount of approx. 50 tons/year.

The air and water emission from the polymerization process and the film making process complies with the current Japanese regulations. (Exhibit H1)

There is no adverse environmental effects in the United States that can not be avoided, because the petitioner intends only to export Nylon MXD-6 film. In the future case of manufacturing the film in the United States, there would be also no adverse environmental effects that can not be avoided.

(3) Toxicological information

Acute oral LD-50 on the monomeric constituents is described in the Section E (Exhibit E-1, 2, 3).

3. Description of the Probable Adverse Environmental Effects that cannot be avoided.

There is no substantial adverse environmental effects that can not be avoided, as described in item 2.

4. Evaluation of Alternatives to the Proposed Action

As the substitutial adverse environmental effects are not identified for this proposed action, the evaluation of alternatives is considered to be unnecessary.

5. Description of the Relationship Between Local Short-term Uses of the Environment with Respect to the Proposed Action and the Maintenance and Enhancement of Long-term Productivity.

In Japan, there is neither local short-term impact nor long-term impact on the environment.

6. Description of Irreversible and Irretrievable Commitment of Resources that would be involved.

The consumption of raw materials in the manufacture of Nylon MXD-6 would be an irreversible commitment of resources. These could be partially recovered as fuel if Nylon MXD-6 would be disposed by incineration.

However, in Japan raw material consumed in the manufacture of Nylon MXD-6 is insignificant compared to that in the manufacture of all other polymers. Even though raw material consumption for Nylon MXD-6 is an irreversible commitment, this proposed action would have a net positive effect on the environment because the manufacture of replacing materials such as aluminum or glass, requires a much greater commitment of resources than Nylon MXD-6.

On the other hand, there is no irretrievable commitment of resources.

7. Discussion of the Objections raised by Other Agencies, Organizations, or Individuals that are known to the Applicant.

The Petitioner does not know any objection raised against the proposed action.

8. Risk-benefit Analysis.

As described above, the use of resources for the manufacture of Nylon MXD-6 would be infinitesimal compared to these overall total consumption in Japan. The amount of waste from Nylon MXD-6 is also infinitesimal compared to that of total plastic waste in Japan.

The amount of resources consumption and the waste load would be much less than the products replaced. We believe

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that the economic, technical and health benefits to the public of the proposed action would outweigh the action's potential risks to the environment.

E. Certification

The undersigned petitioner certifies the information furnished in this report is true, accurate and complete to the best of his knowledge.

Feb. 1, 1983



Masao Murano

Chief scientist

Katata Research Institute

Toyobo Co., Ltd.

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