SECTION H

ENVIRONMENTAL ASSESSMENT

Food Additive Petition 8B4569

1. Date: September 20, 1999

2. Name of petitioner: UBE Industries, Ltd.

3. Address: UBE Industries, Ltd.
1978-10 Kogushi, UBE
Yamaguchi 755, JAPAN

c/o Center for Regulatory Services
Attention: Dr. William A. Olson
2347 Paddock Lane
Reston, VA 20191

NEWEA
9/20/99

4. Description of the proposed action:

This petition is to permit manufacture of a Nylon 6/12 resin by the copolymerization of epsilon-caprolactam and omega-aminododecanoic acid.

a. **Requested approval:** The Nylon 6/12 resin which is the subject of this food additive petition is a Nylon 6/12 resin manufactured by the copolymerization of at least 80 weight percent of epsilon-caprolactam and no more than 20 weight percent of omega-~~aminododecanoic~~ acid. This petition is to add to the definition of Nylon 6/12 resins, 21 CFR 177.1500(a)(13), a new subparagraph (iii) to read Nylon 6/12 resins (CAS Registry Number 25191-04-2) are manufactured by copolymerization of a ration of at least 80 weight percent of epsilon-caprolactam and no more than 20 weight percent of omega-aminododecanoic acid. In addition, this petition is to revise 21 CFR 177.1500(b) with a new table item (13.3), Nylon resins with residual epsilon-caprolactam not to exceed 0.5 weight percent by weight and combined residual omega-laurolactam and omega-aminododecanoic acid not to exceed 0.1% by weight. For use only as specified in section 21 CFR 177.1395 of this chapter.

The specification for the new item 13.3 are as follows.

Specific Gravity 1.10 ± 0.15
Melting Point 380 - 400°F
Solubility in 4.2N HCl - Dissolves in 1 Hour
Viscosity Number - Greater than 140

Maximum extractable fraction in selected solvents (by weight percent).

Water	0.8
95 percent ethyl alcohol	---
Ethyl acetate	0.5
Benzene	0.5

This petition is also to modify 21 CFR 177.1395(b)(4) to include with the list of substances an additional listing for Nylon 6/12 to be as follows.

21 CFR 177.1395(b)(4)

Substances	Limitations
... Nylon 6/12 resins complying with 177.1500(b), item 13.3, of this chapter (CAS 25191-04-2). ...	For use with non-alcoholic foods at temperature not to exceed 100°C (212°F). Laminate structure with authorized food-contact materials yield no more than 0.15 milligram of epsilon-caprolactam and 0.04 milligram for both omega-laurolactam and omega-aminododecanoic acid per square inch when extracted with water at 100°C (212°F) for 5 hours.

The approval of this petition is for the use of Nylon 6/12 manufactured using epsilon-caprolactam and omega-aminododecanoic and for the same uses as previously approved Nylon 6/12 copolymer manufactured using epsilon-caprolactam and omega-laurolactam.

The laminate structures may be manufactured from polymers and adjuvants complying with 21 CFR 177.1390 and other polymeric resins listed consistent with the limitations for those resins and other substances which may be permitted as described in 21 CFR 174.5(d).

b. **Need for action:** The substance that is the subject of this food additive petition is intended to be as an alternative to the currently approved Nylon 6/12 resins.

c. **Locations of use:** Nylon 6/12 copolymer resins will be incorporated into food-packaging materials at production locations throughout the United States. Food-packaging materials are expected to be used by consumers in patterns corresponding to national population density and to be widely distributed across the country.

d. **Locations of disposal**: Disposal of food-packaging materials containing the proposed additive is expected to occur nationwide with the materials ultimately being deposited in municipal solid waste landfills, combusted, or (where possible) recycled.

5. Identification of substances that are the subject of the proposed action:

The petition material is chemically identical to that produced with the existing regulation for Nylon 6/12 as is manufactured using epsilon-caprolactam and epsilon-laurolactam.

1. Generic Name: Nylon 6/12 resins
2. Trade Names: UBE NYLON 6/12
3. Other Names: Polyamide 6/12 copolymer
4. Chemical Name:
   Azacyclotridecan-2-one, polymer with hexahydro-2H-azepin-2-one. This name conforms to the nomenclature adopted by Chemical Abstracts.
5. Chemical Abstracts Registry Number: 25191-04-2
6. Physical Description: The substance is white granular, and is similar in all respects to the existing regulated Nylon 6/12 copolymer, with the exception of viscosity number. Viscosity Number (mLG) is greater than 140, whereas, the Nylon 6/12 currently regulated in 21 CFR 177.1500(b) item 13.2 has a maximum viscosity (mLG) greater than 160.

6. Introduction of substances into the environment:

The polymer that is the subject of this food additive petition is Nylon 6/12 which is currently authorized by FDA regulations, with the only difference being the change in one of the starting materials.

a. **Introductions that occur as a result of manufacture**: There are no extraordinary circumstances pertaining to the manufacture of the substance.

b. **Introductions that occur as a result of use**: Little or no introduction of Nylon 6/12 copolymer resins into the environment will result from its use because it is almost completely incorporated into food-packaging materials and essentially all of it is expected to remain with the packaging throughout use of the product.

c. **Introductions that occur as a result of disposal:** The substance that is the subject of this regulation is identical the currently approved Nylon 6/12, and the use pattern will be used for the same purposes.

1) **Disposal by landfilling:** We have found that only extremely low levels of substances (e.g., monomers, oligomers, adjuvants, degradation products), if any, may leach from landfilled food-packaging materials and be introduced into the environment. This finding is based on-

a) migration studies and calculations that petitioners have performed to demonstrate the safety of food additives and

b) EPA's regulations in 40 CFR part 258 governing landfills.

Ref 1

This is the case with the existing Nylon 6/12, only low levels of substances are expected to leach in landfills from food-packaging materials containing Nylon 6/12 copolymer resins based on the migration studies [or on calculations] for these materials that were performed to demonstrate the additive's safety.

2) **Disposal by combustion:** Nylon 6/12 copolymer resins are composed of carbon, hydrogen, oxygen, and nitrogen elements commonly found in municipal solid waste. The complete combustion of this additive will produce carbon dioxide, nitrogen oxides, and water. Adding Nylon 6/12 copolymer resins to waste that is combusted will not alter significantly the emissions from municipal waste incinerators because the market volume of Nylon 6/12 copolymer resins [to be provided either under Format Item 9 or in a confidential section of the submission] is a small fraction of the municipal solid waste generated and disposed in the United States. We do not expect the combustion of Nylon 6/12 copolymer resins in municipal waste incinerators will threaten a violation of applicable emissions laws and regulations, ie., [insert citations of applicable laws, e.g., 40 CFR part 60 and/or the relevant State and local laws] because of their low levels compared to the amounts currently generated by municipal waste incinerators.

7. Fate of substances released into the environment:

No information need be provided on the fate of substances released into the environment as the result of use and/or disposal of Nylon 6/12 copolymer resins, because, as discussed under Format Item 6, only small quantities of substances, if any, will be introduced into the environment as a result of their use and/or disposal. Therefore, we do not expect the use and disposal of Nylon 6/12 copolymer resins will threaten a violation of applicable laws and regulations, e.g., the Environmental Protection Agency's regulations in 40 CFR parts 60 and 258.

8. Environmental effects of released substances:

No information need be provided on the environmental effects of substances released into the environment as a result of use and/or disposal of Nylon 6/12 copolymer resins, because, as discussed under Format Item 6, only small quantities of substances, if any, will be introduced into the environment as a result of their use and/or disposal. Therefore, we do not expect the use and disposal of the Nylon 6/12 copolymer resins will threaten a violation of applicable laws and regulations, e.g., the Environmental Protection Agency's regulations in 40 CFR parts 60 and 258.

9. **Use of resources:**

a. Basic information:

Market volume

The Nylon 6/12 as is the subject of this petition is expected to partially replace the amount of Nylon 6/12 as is currently used in laminate structures.

Types of food contact articles and food applications

The use of Nylon 6/12 as is the subject of this petition would be only for multi-laminate films. Its use would be consistent with the currently approved use of Nylon 6/12 and the other layers of the film, total thickness and total volume and size of containers are not expected to be different from those as currently used under existing regulations.

Disposal patterns

The Nylon 6/12 will be used only in multi-laminate films. It is not expected that there will be any significant recycling of the food-contact film. The disposal pattern for the proposed packaging would be 76% landfilled and 24% combusted. See Figure ES-3 in the Environmental Protection Agency's report on municipal solid waste.[2]

Ref. 2

b. Potential Impacts on Solid Waste Management Strategies

Source reduction

It is not expected that the approval of this food additive petition will affect source reduction in the food-packaging area or otherwise affect the amount or toxicity of solid waste.

Impacts on recycling

Nylon 6/12 copolymer resins will be used in a food-packaging film that is expected to compete with and replace other currently regulated food-packaging films. There is currently very limited, if any, recycling of food-contact films. Further, future recycling of food-contact films is not likely to occur because it is difficult to clean 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. Thus, FDA's action to permit use of Nylon 6/12 copolymer resins in contact with food has no potential to significantly affect existing recycling programs.[3]

Ref. 3 →

Impacts on landfill volume

It is not anticipated that there will be any impact upon landfill volume requirements.

c. Potential Impacts on Energy:

The Nylon 6/12 is manufactured using omega-aminododecanoic acid as a starting material can be polymerized under lower temperature which can save production energy and reduce production time. Therefore, there will be a small favorable impact upon energy utilization.

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10. Mitigation measures:

There are no adverse effects expected relating to the approval of this petition.

11. Alternatives to the proposed action:

There are no significant potential adverse environmental impacts expected.

12. List of preparers:

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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 UBE Industries, Ltd., Japan.

9/20/99

(Dat

(Signature of responsible official)

Masaru TABATA, Manager of Plastics, UBE America Inc.

(Name and title of responsible official, printed)

September 20, 1999
UBE/EA

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REFERENCES

1 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 groundwater monitoring systems. 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 collection systems, they are required to monitor groundwater and to take corrective action as appropriate.

2 The current EPA municipal solid waste report is Characterization of Municipal Solid Waste in the United States: 1997 Update, EPA 530-R-98-007, U.S. Environmental Protection Agency (5305W), Washington, DC 20460, May 1998. A paper copy of this report may be obtained by calling the RCRA Hotline at 1-800-424-9346. The report is also available in electronic format on the Internet System through the EPA Public Access Server at www.epa.gov.

3 The National Environmental Policy Act provides that "it is the continuing responsibility of the Federal Government to use all practicable means... to improve and coordinate Federal plans, functions, programs, and resources to the end that the Nation may enhance the quality of renewable sources and approach the maximum attainable recycling of depletable resources." 42 U.S.C. 4331(b)(6).