



Attachment # 9

Environmental Assessment
Food Contact Substance (21 CFR Part 25)

- 1) Date: March 27, 2008
- 2) Name of Notifier: Toyota Tsusho Corporation
Toyota Tsusho Marunouchi Bldg., 3-8-1, Marunouchi
Chiyoda-ku, Tokyo, 100-8320 JAPAN
- 3) Authorized Agent: William A. Olson, Ph.D.
Center for Regulatory Services, Inc.
5200 Wolf Run Shoals Road
Woodbridge, VA 22728-5755

- 4) Description of the Proposed Action:

Requested action:

It is proposed that the use of Dodecanoic acid, 12-amino-, polymer with ethane, 2,5-furandione, α -hydro-*w*- hydroxypoly(oxy-1,2-ethanediyl) as a polymeric antistatic agent for use in polymers for food contact applications.

Need for action:

The Dodecanoic acid, 12-amino-, polymer with ethane, 2,5-furandione, α -hydro-*w*- hydroxypoly(oxy-1,2-ethanediyl) and 1-propene would be used in film. This product, commercially marketed as Pelestat 300 is a polyether-polyolefin block copolymer used as a non-migratory antistatic agent for use in film.

Location of use:

This product would be manufactured in Japan. The material will be incorporated into articles to be used as food contact materials at food-packaging production sites throughout United States and Europe.

Location of disposal:

Disposal of the food contact substance (FCS) is expected to occur nationwide with the FCS ultimately being deposited in municipal solid waste landfills or combusted as a result of the disposal of the film.

- 5) Identification of the chemical substances that are the subject of the proposed action:

CAS Name:

000117

Dodecanoic acid, 12-amino-, polymer with ethane, 2,5-furandione, α -hydro-*w*- hydroxypoly(oxy-1,2-ethanediyl)

CAS Registry Number:
287916-86-3

Physical description:
A granulated, dust-free polymer with a white to slightly yellow color.

Impurities:
This information is contained in Part II, Section B3. Impurities of the FCN. Only very low amounts of these chemicals will be expected to enter the environment as a result of this action.

- 6) Introduction of substances into the environment:
- a) Introduction of substances into the environment as a result of manufacture:
This product will be manufactured in Japan. No extraordinary circumstances apply to the manufacture of the FCS.
 - b) Introduction of substances into the environment as a result of disposal:
 - 1) Landfills:
Based on the migration studies of the Dodecanoic acid, 12-amino-, polymer with ethane, 2,5-furandione, α -hydro-*w*- hydroxypoly(oxy-1,2-ethanediyl) in film, performed to demonstrate its safety, only very low levels of the FCS are expected to leach from these materials in landfills, we expect extremely low quantities to actually enter the environment; this finding is based on the EPA's regulations governing municipal solid waste landfills. In addition, introducing these substances into the environment will not threaten a violation of the EPA's regulations in 40 CFR part 258 that pertain to landfills.
 - 2) Combustion:
The FCS is composed of carbon, hydrogen, nitrogen, and oxygen elements commonly found in municipal solid waste. The complete combustion of this FCS in a properly functioning incinerator will produce only carbon dioxide and water. Because the market volume of the FCS is a small fraction of the municipal solid waste generated and disposed in the United States and Europe, adding the FCS to waste that is combusted will not alter significantly the emissions from municipal waste combustors. Because of the nature of the combustion products and their low levels compared to the amounts currently generated by municipal waste combustors, we do not expect that the combustion products from incineration of the film will cause a violation of applicable emissions laws and regulations.

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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 disposal of, because only small quantities of the substances, if any, will be introduced into the environment from its use and disposal. Therefore, the use and disposal of the FCS are not expected to threaten a violation of applicable laws and regulations, e.g., EPA's regulations in 40 CFR Parts 60 and 258.

8) Environmental effects of released substances:

No information need be provided on the fate of substances released into the environment as the result of use and/or disposal of Dodecanoic acid, 12-amino-, polymer with ethane, 2,5-furandione, α -hydro-~~w~~- hydroxypoly(oxy-1,2-ethanediyl) because only small quantities, if any, of the substances will be introduced into the environment as a result of the use and disposal of this product. Therefore, the use and disposal of the FCS is not expected to threaten a violation of applicable laws and regulations, e.g., EPA's regulations in 40 CFR Parts 60 and 258.

9) Use of resources and energy:

This item does not ordinarily require documentation because the proposed Dodecanoic acid, 12-amino-, polymer with ethane, 2,5-furandione, α -hydro-~~w~~- hydroxypoly(oxy-1,2-ethanediyl) antistatic agent is intended for the same use as other commercially available antistatic agents.

As the Anti-Static Durability Graph shows, Pelestat demonstrates certain surface resistivity after number of water washings while conventional antistatis totally loses its effect after 5 times of water washing.

So by incorporating Pelestat into End products, they can be re-used so many times, as a result, can save use of resources and energy dramatically compared to incorporating conventional antistatic. Reference information Anti-static Durability graph..

10) Mitigation measures

We identify no adverse environmental effects, based upon our review upon adequate and complete data and information.

11) Alternatives to the proposed action:

We identify no adverse environmental effects, based upon our review upon adequate and complete data and information

12) List of Preparers:

- a. Daigo Hagio
Toyota Tsusho Corporation
- b. William A. Olson, Ph.D.
Center for Regulatory Services, Inc.

13) Certification:

The undersigned certifies that the information presented is true, accurate, and complete to the best of the knowledge of Toyota Tsusho Corporation.

———  Takeshi Kubota
Group Leader

FCN Toyota Tsusho EA 6-25-08

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