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UNITIKA

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Environmental Assessment
For Fatty acids, coco, sesquiesters with polyethylene glycol

1. Date: March 8, 2011

2. Name of notifier: UNITIKA LTD.

3. Address: 31-3, Ujihinojiri, Uji-shi, Kyoto 611-0021, Japan

4. Description of the proposed action

a. Proposed action:

The food-contact substance (FCS) is Fatty acids, coco, sesquiesters with polyethylene glycol.
FCS is used as an antistatic agent for N6 film.
Maximum use level in food contact material is 0.04%.
Nylon 6 film is manufactured by melt-blending with FCS.

b. Need for action:

The film contained FCS has an excellent antistatic performance.
By utilizing antistatic property of FCS, printing and post processing will be improved and the risk during post processing by emission of static electricity will be completely reduced.
Product quality will be refined and upgraded.

c. Location of use

FCS is used as an antistatic agent in the manufacturing N6 film plant which is located outside of the United States.
The film contained FCS is used as the food packaging, and expected to be utilized in patterns corresponding to the national population density and to be widely distributed across the country.

d. Location of disposal

The locations where the FCS disposed from use are 1) landfills, where finished food-contact articles containing the FCS and degradation products, if any, are ultimately disposed and 2) wastewater treatment plants, where the FCS, if any, may potentially enter the environment after ingesting food by consumers, following migration of the FCS from finished food-contact articles into food.

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 FCS.

According to United States Environmental Protection Agency's "Municipal Solid Waste Generation, Recycling, and Disposal in the United States: Facts and Figures for 2008", 12.7% of municipal solid waste was combusted, 54.1% was discarded landfill, and 33.2% was recovered for recycling and composting. Total municipal solid waste in United States is 249.61 million of tons and plastic container and packaging was 13.01 million of tons, and 13.2% of plastic container and packaging was recycled.

5. Identification of the substance that is the subject of the proposed action:

Chemical name: Fatty acids, coco, sesquiesters with polyethylene glycol

Chemical Abstracts Service registry number: 61791-04-6

Number average molecular weight (GPC): 657

Weight average molecular weight (GPC): 744

Molecular formula: ((C2H4O) nH2O.Unspecified) x

Physical description

Melting point: 16 degrees centigrade

Specific gravity: 0.9967(20 degrees centigrade)

Viscosity (25℃): 57.1mPa・s

6. Introduction of substances into the environment

a. As a result of manufacture:

FCS is manufactured in Japan. Thus the substances as a result of manufacture will not be introduced into the United states environment. The production facilities for FCS operate in compliance with the environmental regulations of Japan.

The manufacture process of FCS is esterification of fatty acids, coco, and polyethylene glycol. It forms FCS and water. Water is removed outside.

No extraordinary circumstances are reasonably known to exist for the manufacture of the FCS that would cause or threaten to cause non-compliance with such regulations.

b. As a result of use:

The FCS is used as an antistatic agent for manufacturing Nylon 6 film by melt-blending process in Japan. The production facilities for Nylon 6 film operate in compliance with the environmental regulations of Japan. No extraordinary circumstances are reasonably known to exist for the proposed use of the FCS that would cause or threaten to cause non-compliance with such regulations.

c. As a result of disposal from use:

We will export to the United States the Nylon 6 film containing the FCS. We anticipate that as much as 30% of the FCS may migrate into food. Therefore, assuming no digestive degradation occurs, that portion of the FCS is anticipated to be eliminated into sewage for collection and treatment into wastewater. The other portion of the FCS remaining in the nylon film is expected to be collected as discarded food-packaging and managed as municipal solid waste disposed into landfills.

(1) Discussion for disposal into wastewater treatment facilities.

According to Attachment 1 "ANALYSIS REPORT", the estimated dietary intake(EDI) of FCS is 12 μ g/person/day.

According to United States Environmental Protection Agency's "SUMMARY OF CWNS 2008 TECHNICAL INFORMATION", Existing flow is 32345millions of gallons ($122.438 \times 10^6 m^3$) /day, Number of people served is 226 million people.

$12 \mu g / (122.438 \times 10^6 \times 10^6 ml / 226 \text{ million people}) = 0.022ppb$

The environmental introduction concentration (EIC) is about 0.02ppb. We assume that the FCS is eliminated as an undigested waste from the body. We expect that the FCS discharged into receiving waters is environmentally insignificant.

(2) Discussion for disposal into municipal solid waste facilities (landfill).

Any non-migrating FCS as a component of the nylon film will be subjected to conventional municipal solid waste (MSW) management.

Compared to 249.61 million tons of MSW, the amount of the FCS anticipated to enter the waste stream in the US is not significant because nylon food-packaging material is a small contributor to MSW. Additionally, the FCS disposed from use in landfills is unlikely to enter the environment because landfill management is expected to comply with local, state, and federal landfill regulations. Moreover, if combusted, the FCS will be ultimately degraded to CO_2 and water.

The amount of CO_2 released is insignificant to those released from other sources in the MSW.

7. Fate of substances released into the environment:

FCS is Fatty acids, coco, sesquiesters with polyethylene glycol, and easily biodegradable and hydrolyze.

Biochemical oxygen demand (BOD_5) of 0.1% FCS aqueous solution is 1510ppm.

This data is measured by supplier of FCS. This information is described in material safety data sheet.

8. Environmental effects of released substances:

As shown in the topics about environmental introduction-item 6c- and fate-item 7-posed after disposal from use of the FCS, we expect only very small emissions into the environment, if any at al, of the FCS to occur, and we expect that if any of those small emissions of the FCS do enter the environment that the quantities will be easily degraded into harmless products.

9. Use of resources and energy:

The use of FCS is intended to compete with and replace certain antistatic agents already used in Nylon 6 films of food contact articles, packaging and materials. Accordingly, no additional resources are expected to be consumed as a result of the approval of the proposed action.

FCS is used as an antistatic agent for N6 film. FCS is added to Nylon 6 film at a concentration of 0.04%, thus, it has a very minor use compared to the usage of Nylon 6. The use of FCS is not expected to have any effect on the use of resources and energy.

10. Mitigation measures:

There will be no adverse environmental impacts from the use or disposal of FCS or its degradation products and, thus, no mitigation procedure are needed.

11. Alternatives to the proposed action

No potential adverse environmental impacts have been identified for the proposed action, so no alternatives to the proposed action are contemplated.

12. List of preparers:

Mikio Kusunoki, General Manager, Film Quality Assurance Department, Film Division, UNITIKA LTD.

13. Certification

The undersigned official certifies that the information presented is true, accurate, and complete to the best of the knowledge of UNITIKA LTD.

14. Reference

* EPA, Municipal Solid Waste Generation, Recycling, and Disposal in the United States: Facts and Figures for 2008
* EPA, Clean Watersheds Needs Survey 2008 Report to Congress, Appendix Ⅰ, SUMMARY OF CWNS 2008 TECHNICAL INFORMATION
* Material Safety Data Sheet (MSDS) for fatty acids, coco, sesquiesters with polyethylene glycol. (Amended as of March 8, 2011)

15. Confidential Attachments

* Analysis Report No.09W08905 – Migration, PEG-fatty acid esters from Nylon 6
* Material Safety Data Sheet (MSDS) for fatty acids, coco, sesquiesters with polyethylene glycol. (CBI Version)

March 8, 2011
(Date)

[redacted]
(Signature of responsible official)

For Mikio Kusunoki, General Manager of film quality assurance department
(Name and title of responsible official, UNITIKA LTD. printed)