AKZO NOBEL

Environmental Assessment in support of FCN 717

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1) Date: March 23, 2007

2) Submitter: Akzo Nobel Polymer Chemicals LLC

3) Address: 525 W. Van Buren Street
Chicago, IL 60607

4) Description of Proposed Action

a. Requested action: To allow the use of formaldehyde, polymer with 1-naphthol as a production aid in the manufacture of ethylene vinyl acetate (EVA) copolymers.

The FCS will only be used as an antiscaling or release agent, applied on the internal parts of reactors employed in the production of EVA copolymers. The FCS is not intentionally added to EVA copolymers nor does the FCS perform any function in EVA copolymers.

The use of the FCS as an antiscaling/release agent in the production of PVC and acrylic copolymers has been previously approved by FDA as listed in 21 CFR 178.3860. The Environmental Assessment for the FCS in that use, and data and reports contained therein, is incorporated by reference in FAP 3B4380.

Based on data provided in the Food Contact Notification (FCN), it is estimated that less than 1 ppm of FCS will be present in the final EVA copolymers. The remaining FCS adheres to the internal parts of the reactor walls as intended or is flushed out of the reactors and into the wastewater disposal system at the EVA copolymer manufacturing site.

Therefore the data and conclusions presented in the Environmental Assessment for FAP 3B4380 also largely apply to this FCN EA. However, the overall use of the FCS for EVA copolymer production requested in this FCN is expected to be significantly less that the already approved use of the FCS for PVC and acrylic copolymer production. This is due to the fact that that the use of PVC and acrylic copolymers in food contact packaging is significantly more prevalent and extensive than is the use of EVA copolymers in food contact packaging.

b. Need for Action: The use of the FCS will significantly enhance the efficiency of the production of EVA copolymers. The use of the FCS prevents formation of polymer on reactor surfaces by inhibiting polymerization at the surfaces. Without the use of the FCS, EVA build-up on reactor walls will require much more frequent maintenance requiring that the reaction process be stopped so that the EVA build-up can be removed from reactor walls.

The aqueous solution of the FCS is easier to apply than other antiscaling agents, and excess FCS readily precipitates (solidifies) in the reactor wash water so that it can be easily separated and collected for proper disposal preventing unintended human contact or release to the environment.

c. **Locations of use /disposal:** The FCS is manufactured only in Italy. The FCS will be imported into the United States by Akzo Nobel. The European site is located within a chemical complex five kilometers from the nearest town. Wastes generated in the production of the FCS are collected and are treated in accordance with local, national and EU requirements. Because there will be no manufacturing of the FCS in the United States, there will be no U.S. occupational exposure or environmental release as a result of production of the FCS.

The overall use of the FCS for EVA copolymer production requested in this FCN is expected to be significantly less that the already approved use of the FCS for PVC and acrylic copolymer production. This is due to the fact that the use of PVC and acrylic copolymers in food contact packaging is significantly more prevalent and extensive than is the use of EVA copolymers in food contact packaging. The Consumption Factor (CF) for EVA copolymers (0.02) is only 8% of the combined CF for PVC (0.1) and acrylic (0.15) copolymers [0.02 / (0.1 + 0.15) X 100% = 8%]. Therefore the amount of food potentially contacting EVA copolymers is substantially less that the amount of food in the daily human diet that would contact PVC plus acrylic copolymers. In addition, the measured concentration of residual FCS in EVA copolymer of less than 1 ppm is four times less than the regulatory limit of 4 ppm FCS in PVC and acrylic copolymers.

With respect to customer use of the FCS at EVA production sites, it is expected that occupational exposure to the FCS will be minimal. During normal operations there is little potential for direct human exposure to the FCS. The formulated FCS will be steam sprayed into closed reactor vessels in a tightly controlled process so that workers are not exposed to live steam. Potential Inhalation or dermal exposure to the FCS should be minimal when the recommendations for use of personal protective equipment are followed in accordance with OSHA requirements in the United States. The oral route of occupational exposure is generally not considered a major route of potential occupation exposure.

With respect to environmental release from customer sites, the primary route of disposal is expected to be through water discharge to wastewater treatment plants as a result of flushing the FCS from reactors during the FCS application process.

The FCS is not expected to be present in EVA copolymers in measurable quantities. As described in the FCN, analysis of EVA copolymers made in reactors treated with the FCS showed no detectable amount of FCS with an analytical detection limit of one ppm. Therefore waste FSC would primarily be present in the reactor wastewater stream that is directly routed from the reactor process areas to the EVA manufacturing site wastewater treatment system.

5) Identification of the substance that is the subject of the proposed action: formaldehyde, polymer with 1-naphthol is a linear polymer of formaldehyde (CAS# 50-0-0) and 1-naphthol (CAS# 90-15-3), where the 1-naphthol is added in excess in order to completely consume the added formaldehyde. The FCS is identified by CAS# 25359-91-5. Additional chemical names for the FCS include: alpha-naphthol-formaldehyde polymer and poly(1-hydroxynaphthylmethane).

The chemical/physical properties, chemical structure, molecular weight distribution and IR spectral analysis of the FCS are incorporated by reference in FAP 3B4380. The FCS is a polymer of greater than 98% purity with an average molecular weight of ~ 1300 that would limit penetration through cell membranes.

The FCS is marketed in a formulated product with water, sodium hydroxide, polyvinyl alcohol and ethanol. The formulated product is a yellow transparent liquid having a solids content of 10%, a pH of 12.5, a density of 1.050 g/cm2 @20° C. and a viscosity of 30 mPa.s @20° C... The highly alkaline pH maintains the FCS in aqueous solution with the other components of the formulated product.

The FCS is currently cleared by FDA for use as an antiscaling/release agent in the production of PVC and acrylic copolymers as listed in 21 CFR 178.3860. The Environmental Assessment for the FCS in that use is incorporated by reference in FAP 3B4380.

In the European Union the FCS has been approved for use in food contact plastics. The active ingredient formaldehyde-1-naphthol, copolymer (= poly(1-hydroxynaphthylmenthane)), CAS RN 25359-91-5, is listed below PM/Ref. N. 54930 in Annex III Section A (incomplete list of additives fully harmonized at Community level) of Directive 2002/72/EC as amend by 2004/1/EC, 2004/19/EC and 2005/79/EC, and replacing the Directive 90/128/EEC (as amended by 92/39/EEC, 93/9/EEC, 95/3/EC, 96/11/EC, 2001/62/EC and 2002/17/EC) relating to plastic materials and articles intended to come into contact with foodstuffs with the restriction SML = 0.05 mg/kg. The Directive 2002/72/EC has been fully implemented into the relevant German Commodities Regulation, the Bedarfsgegenständeverordnung, specifically the Directive 2004/19/EC was adopted by Elfte Verordnung zur Änderung der Bedarfsgegenständeverordnung from 13.07.2005, published in the Bundesgestetzblatt I Nr. 44 from 20.07.2005, p 2150.

The FCS has been reviewed and approved for general food contact use or for use in food contact plastics in the following countries: Austria, Belgium, France, Germany, Italy, Luxembourg, Netherlands, Portugal, Slovakia and Spain. Specific references for each of these country approvals can be supplied to FDA upon request.

6) Introduction of substances into the Environment

a. Introduction of substance into the environment as a result of manufacture:
No extraordinary circumstances apply to the manufacture of this processing aid. The manufacturing site in Italy is compliant with all applicable emission and occupational safety requirements and the FCS is produced within a closed system.

b. Introduction of substances into the environment as a result of use/disposal.
The FCS will be used as a production aid in the manufacture of ethylene vinyl acetate (EVA) copolymers. The FCS will only be used as an antiscaling or release agent, applied on the internal parts of reactors employed in the production of EVA copolymers. Therefore the FCS is not intentionally added to EVA copolymers nor does the FCS perform any function in EVA copolymers.

The formulated FCS is injected into the reactor with steam and the FCS forms a thin film on the internal parts of reactors prior to the initiation of EVA polymerization reactions. FCS that does not adhere to the reactor vessel walls experiences a rapid change in pH from 12.5 to 8.2 causing its precipitation into a compact and gelatinous flake that deposits in the water collected in the bottom of the reactor vessel. The water layer containing the insoluble FCS is rinsed out of the reactor vessel prior to the introduction of the starting materials used in the copolymerization reaction.

During the EVA polymerization reaction, the FCS prevents formation of polymer on reactor surfaces by inhibiting polymerization at the surfaces. Based on laboratory data there was no FCS detected in EVA copolymers at a limit of detection of one ppm for the analytical method.

With respect to the applied amount of FCS, ~ 25% of the FCS remains on the walls on the reactor vessels while ~ 75% of the applied FCS is discharged as sludge in the water and washing liquids. Based on the poor water solubility of the FCS (< 0.01 g/L @ 20° C.) when diluted at neutral pH in the wastewater, the FCS forms an insoluble sludge-like material that can then be separated from wastewater. This solid material can then be disposed of as a waste.

The FCS is not expected to be present in the final EVA copolymers in measurable quantities. As described in the FCN, analysis of EVA copolymers made in reactors treated with the FCS showed no detectable amount of FCS with an analytical detection limit of one ppm. Therefore, it is not expected that appreciable amounts of the FCS will enter the environment through the use and disposal of EVA copolymers in food contact packaging.

c. Mode of introduction into the Environment:
As previously discussed, it is expected that most of the added FCS will be retained in the wastewater that leaves the reactor vessel and is directed to the EVA copolymer manufacturing facility wastewater treatment system. A smaller amount will be retained on the walls of the reactor vessels.

It is expected that the customer site has primary and secondary wastewater treatment systems installed to remove particulate and BOD/COD produced in the manufacturing process, directs water to a Publicly Owned Treatment Works (POTW) and/or discharges water to a natural waterway in conformance with a permit issued by the U.S. EPA under the National Pollution Discharge Elimination System (NPDES) under the Clean Water Act.

Primary treatment removes suspended matter that leaves the system as sludge. Secondary treatment utilizes biological degradation to remove BOD, but also reducing the loading of COD and AOX. Effluent discharged from a well-run secondary treatment system and released to natural waterways should not be an acute or chronic hazard to aquatic organisms because the composition of the effluent is closely regulated by the U.S. EPA under the Clean Water Act. Secondary treatment also generates sludge.

It is expected that FCS-containing sludge from the EVA copolymer manufacturing site will be land-filled, incinerated or land applied. Land filled or land applied FCS can be considered as an inert polymeric solid that would not be expected to leach into the soil in landfills.

It is not known what percentage of sludge containing the FCS would be incinerated versus being sent to a landfill. However, the incineration of sludge containing the FCS would be expected to represent only an extremely small fraction of the total solid waste that would be incinerated in the U.S. and therefore would not result in a notable increase in air emissions from all other sources.

d. Material Safety Data Sheet
The Material Safety Data Sheet (MSDS) is incorporated by reference in Food Contact Notification 717.

7) Fate of Substances released in the Environment:
The primary means by which the FCS substance is expected to be released into the environment is via land filling, land applying or incineration as an insoluble sludge-like component from the EVA copolymer manufacturing site. When landfilled or land applied it is expected that the FCS will biodegrade in a reasonable period of time.

8) Environmental effects of released substances:
There are biodegradation test data available on the potential environmental effects of the FCS. Use of the U.S. EPA modeling software (ECOSAR) did not retrieve any estimates of toxicity or environmental fate. Because the FCS is a polymer with average molecular weight ~ 1300 the FCS would not be expected to easily pass through biological membranes. The FCS has been shown to be 60% biodegradable in 28 days using the Closed Bottle Test (full report incorporated by reference in FAP 3B4380). Therefore, it can be concluded that low levels of the solidified FCS would not be expected to result in significant adverse environmental impacts (toxicity or accumulation).

9) Use of resources and energy:
The use of the FCS is expected to result in a decreased amount of waste EVA copolymer, decreased amounts of human labor needed to clean reactor vessel walls of EVA copolymers and an overall more efficient production of EVA copolymers. Reactor vessels would not have to be opened as often thus decreasing the potential for worker exposures to residual components and accidents. Energy usage would be expected to decrease because the number of stoppages and start-ups of the reaction equipment would be decreased.

10) Mitigation Measures:
No adverse environmental effects have been identified therefore there is no need to discuss mitigation measures.

11) Alternatives to the proposed action:
No adverse environmental effects have been identified therefore there is no need to discuss alternatives to the proposed action.

12) Preparer:
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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 Akzo Nobel Inc."

March 23, 2007
(Date)

(Signature of responsible official)

Edwin C. Bisinger Jr., PhD, DABT
Manager, Regulatory Toxicology
Akzo Nobel Inc.

14) References:

Food Additive Petition 3B4380 (incorporated by reference)
Food Contact Notification 717 (incorporated by reference)

15) Attachments:

None