

Attachment 40

Environmental Assessment

1. Date November 29, 2018

2. Name of Applicant / Submitter ADEKA CORPORATION

3. Address
ADEKA CORPORATION
7-2-35 Higashiogu Arakawaku
Tokyo 116-8554
Japan

All communications on this matter are to be sent in care of authorized official for the Notifier:

Dr. Andreas Tschech, Senior Consultant
WTConsulting GmbH
Weierweg 7
4410 Liestal
Switzerland
Phone: +41 61 923 3001, Fax +41 61 923 3002

4. Description of Proposed Action

The action requested in this notification is to provide for the use of Alcohols, C₁₀₋₁₄-branched, C₁₁-rich, reaction products with ethylene oxide, [(2-propenyl) methyl] oxirane and sulfamic acid (CAS nos. 403983-53-9 and 905843-50-7), as reactive emulsifier in emulsion polymerisation processes of water-based polymers which are intended to be used in the manufacture (1) of adhesives according to 21 CFR 175.105 and (2) of pressure-sensitive adhesives according to 21 CFR 175.125, except for use in contact with infant formula and breast milk.

The Food Contact Substance (FCS) is intended for use at levels up to 1% by weight of total monomers in adhesive polymers complying with 21 CFR 175.105 and 21 CFR 175.125. Adhesives containing the FCS will be used in the manufacture of packaging materials for food as well as in pressure sensitive adhesives applied to labels and films contacting food.

The FCS will be used as reactive emulsifier in emulsion polymerisation processes of water-based polymers. The FCS reacts like a monomer in the polymerisation process and covalently is bound into the polymer. After the polymerisation process no free surfactant is left that could migrate into food. Absence of free surfactant in adhesive polymers offers technical advantages, e.g. no or less foam formation during the polymerisation process, no foam formation on the polymer / adhesive film, better water resistance of the adhesive film.

Adhesives containing the FCS will be used in food contact materials that will be distributed in patterns corresponding to the population density of the United States. It is therefore expected that the FCS will be widely distributed across the country upon use. Therefore, it is anticipated that disposal will occur nationwide, with about 52.5% of the materials being deposited in land disposal sites, about 19% being combusted with energy recovery, and 34.7% being recycled and composted [1].

5. Identification of Substance that is the Subject of the Proposed Action

The Food Contact Substance that is subject of this notification is Alcohols, C₁₀₋₁₄-branched, C₁₁-rich, reaction products with ethylene oxide, [(2-propenyloxy) methyl] oxirane and sulfamic acid (CAS nos. 403983-53-9 and 905843-50-7).

6. Introduction of Substances into the Environment

Under 21 CFR 25.40(a), an environmental assessment ordinarily should focus on relevant environmental issues relating to the use and disposal from use, rather than the production, of FDA-regulated articles. Moreover, information available to the notifier does not suggest that there are any extraordinary circumstances in this case indicative of any adverse environmental impact as a result of the manufacture of the FCS. Consequently, information on the manufacturing site and compliance with relevant emissions requirements is not provided here.

No environmental release is expected upon the use of the subject FCS to fabricate packaging materials. In these applications, the FCS will be entirely incorporated into the finished food package or adhesive layer. Any waste materials generated in this process, e.g. plant scraps, are expected to be disposed of as part of the packaging manufacturer's overall nonhazardous solid waste in accordance with established procedures.

Disposal by the ultimate consumer of food contact materials produced using the subject FCS will be by conventional rubbish disposal and, hence, primarily by sanitary landfill or incineration. The FCS is composed of carbon, hydrogen, oxygen, nitrogen, and sulfur; elements that are commonly found in municipal solid waste.

We compared the projected third year market volume of the FCS, contained in a confidential attachment to this Environmental Assessment, to the annual municipal solid waste (MSW) production (262 million tons in 2015), and to the portion of that total that is landfilled, and conclude that the FCS will constitute an insignificant portion of the total MSW, as well as the amount of that total that is landfilled. Therefore, we expect no extraordinary circumstances that would suggest a significant environmental impact resulting from post-consumer disposal of food contact materials containing the FCS. Further, the proposed use of the FCS and corresponding market volume (available in confidential Attachment) show that the FCS will make up a very small portion of the total municipal solid waste currently combusted, estimated to be 12.8% of the 262 million tons total waste generated, or 33 million tons, as of 2015. [1]. Therefore, the FCS will not significantly alter the emissions from 40 CFR Part 60 compliant operating municipal solid waste combustors to threaten a violation of applicable emission laws and regulations (40 CFR Part 60 and/or relevant state and local laws).

In accordance with 40 CFR § 1508.27, the analysis of the significance of environmental impacts must include the degree to which the action threatens a violation of federal, state, or local laws imposed for the protection of the environment. In this context, 40 CFR § 98.2(a)(3), requires stationary fuel combustion sources which emit 25,000 metric tons (MT) CO₂ equivalents (CO₂-e) or more per year to report their GHG emissions to the US Environmental Protection Agency (EPA). Municipal solid waste (MSW) combustion facilities are stationary fuel combustion sources pursuant to 40 CFR § 98.30(a). The GHG emissions resulting from the use and disposal of the FCS relate to the incineration of articles containing the FCS in MSW combustion facilities. Such facilities are regulated by US EPA under 40 CFR § 98, which "establishes mandatory GHG reporting requirements for owners and operators of certain facilities that directly emit GHG". Part 2 of this regulation (40 CFR § 98.2) describes the facilities that must report GHG emissions and sets an annual 25,000 metric ton carbon dioxide equivalent emission threshold for required reporting.

To evaluate the significance of the environmental impact of these GHG emissions, we refer to CEQ regulation under 40 CFR § 1508.27, which defines 'significantly' as it relates to assessing the intensity of an environmental impact in NEPA documents. 40 CFR § 1508.27(b)(10) states that, when evaluating intensity of an impact, one should consider "whether the action threatens a violation of federal, state, or local law or requirements imposed for the protection of the environment." GHG emissions from MSW combustion facilities are regulated by 40 CFR § 98.2.

Based on the confidential market volume, the expected carbon dioxide equivalent emission, as shown in the confidential attachment to the Environmental Assessment, are below 25,000 metric tons on an annual basis. As the estimated GHG emissions are below the threshold for mandatory reporting, no significant environmental impacts are anticipated resulting from combustion of the FCS in MSW combustion facilities.

Only extremely small amounts, if any, of the FCS are expected to enter the environment as a result of the landfill disposal of food contact articles, in light of EPA's regulations governing municipal solid waste (MSW) landfills. EPA's regulations require new MSW 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 ground water monitoring systems, 40 CFR 258. Although owners and operators of existing active MSW landfills that were constructed before October 9, 1993 are not required to retrofit liners and leachate collection systems, they are required to monitor ground water and to take corrective action as appropriate.

The only potential source of environmental introductions of the FCS therefore will be due to the consumption and subsequent elimination of the minute amounts of the FCS that may migrate to food and subsequently be consumed by the consumer. The concentration of the FCS in the diet resulting from this FCN becoming effective is estimated in Attachment 31 of the FCN to be 0.1336 ppb. Assuming in the worst case that that FCS is eliminated unchanged, this concentration will be diluted significantly when 1) combined with other waters used in the household and then 2) again when these household waters are disposed of by sanitary sewer and subsequently combined with other municipal waters received at the POTW, and 3) again when the POTW discharges to surface waters.

7. Fate of Emitted Substances in the Environment

No significant effect on the concentrations of and exposures to any substances in the atmosphere are anticipated due to the proposed use of the FCS. The FCS has relatively high molecular weight and does not volatilize, and it is covalently bound into the adhesive polymer. Thus, no significant quantities of any substances will be released upon the use and disposal of food contact articles manufactured with the FCS.

As indicated above in item 6, the FCS will make up a very small portion of the total municipal solid waste currently combusted. Therefore, the FCS will not significantly alter the emissions from 40 CFR 60 compliant operating municipal MSW combustors, and incineration of the FCS will not cause municipal waste combustors to threaten a violation of applicable emission laws and regulations.

No significant effects on fresh water, estuarine, or marine ecosystems are anticipated due to the proposed use of the subject FCS because the FCS is covalently bound into the adhesive polymer. No significant quantities of any substance will be added to these water systems upon proper incineration of food contact articles, nor upon their disposal in landfills because the FCS, once bound into the adhesive polymer, does no longer exist as such.

Considering the factors discussed above, no significant effects on the concentrations of and exposures to any substances in terrestrial ecosystems are anticipated as a result of the proposed use of the subject FCS. In particular, virtually no leaching of the FCS may be expected to occur under normal environmental conditions when finished food contact articles are landfill disposed. Furthermore, the very low production of the FCS for use in food contact applications precludes any substantial release to the environment. Thus, there is no expectation of any meaningful exposure of terrestrial organisms to the FCS as a result of the proposed use of the FCS.

Considering the foregoing, we respectfully submit that there is no reasonable expectation of a significant impact on the environment due to the proposed use of the FCS in the manufacture of articles intended for use in contact with food.

8. Environmental Effects of Released Substances

As discussed previously, the only substances that may be expected to be released to the environment upon the use and disposal of food packaging materials fabricated with the subject FCS consist of extremely small quantities of combustion products and extractables, if any. Thus, no adverse effects on organisms in the environment are expected as a result of the disposal of food contact articles made with the subject FCS. In conclusion, no information needs to be provided on the environmental effects of substances released into the environment as a result of use and/or disposal of food contact articles made with the subject FCS. Therefore, the use and disposal of food contact articles made with the subject FCS are not expected to threaten a violation of applicable laws and regulations, e.g. EPA's regulations in 40 CFR part 60 pertain to municipal solid waste combustors and part 258 that pertain to landfills.

9. Use of Resources and Energy

As is the case with other food packaging materials, the production, use, and disposal of the FCS involve the use of natural resources such as petroleum products, coal, and the like. However, the use of the subject FCS in the fabrication of food contact materials is not expected to result in a net increase in the use of energy and resources, since the FCS is intended to be used in place of emulsifiers now on the market for use in producing adhesive polymers.

The partial replacement of other emulsifiers by the FCS is not expected to have any adverse impact on the use of energy and resources. Furthermore, adhesive polymers are not recovered for recycling. Food contact materials (adhesive polymers) produced with the FCS are expected to be disposed of according to the same patterns when they are used in place of current materials. Thus, there will be no impact on current or future recycling programs.

10. Mitigation Measure

As shown above, no significant adverse environmental impacts are expected to result from the use and disposal of food contact materials made from the subject FCS. This is primarily due to the minute levels of leaching of potential migrants from the finished article and the insignificant impact on environmental concentrations of combustion products of the adhesive polymers. Thus, the use of the subject FCS as proposed is not reasonably expected to result in any new environmental problem requiring mitigation measures of any kind.

11. Alternatives to the Proposed Action

No potential adverse environmental effects are identified herein, which would necessitate alternative actions to that proposed in this notification. The alternative of not approving the action proposed herein would simply result in the continued use of the materials which the subject FCS would otherwise replace. Such action would have no environmental impact.

12. List of Preparers

Dr. Andreas Tschech, WTConsulting GmbH, Weierweg 7, 4410 Liestal, Switzerland.

The undersigned official certifies that the information provided herein is true, accurate, and complete to the best of his knowledge



29 November 2018

[1] Advancing Sustainable Material Management: 2015 Fact Sheet. Assessing trends in material generation, recycling, composting, combustion with energy recovery and landfilling in the United States, July 2018. https://www.epa.gov/sites/production/files/2018-07/documents/2015_smm_msw_factsheet_07242018_fnl_508_002.pdf

Confidential attachment