

ATTACHMENT 11
ENVIRONMENTAL ASSESSMENT

1. **Date:** August 9, 2018
2. **Notifier:** Akzo Nobel Functional Chemicals LLC
3. **Address:** Akzo Nobel Functional Chemicals LLC

All communications on this matter are to be sent to:
Edwin C. Bisinger Jr., PhD, DABT
AkzoNobel Specialty Chemicals
525 W. Van Buren Street
Chicago, IL 60607 USA
Telephone: (312) 544-7191 (office)
Telephone: (312) 833-4464 (mobile)
email: edwin.bisinger@akzonobel.com

4. **Description of proposed action:**

The action requested in this notification is to permit the use of 1,2,4,5,7,8-Hexoxonane 3,6,9-trimethyl-, 3,6,9-tris(Et and Pr) derivs (CAS# 1613243-54-1) at levels of up to 0.08% by weight of polypropylene (PP) as a chain scission agent in the production of controlled rheology modified PP (CRPP), complying with 21 CFR 177.1520. This rheology modification of PP reduces the molecular weight of PP to produce the lower melt viscosity required to make the commercially desired end product. Rheology-modified PP is used in the production of PP food contact packaging. CRPP is used to produce single-use polypropylene (PP) food packaging in contact with all food types, and under conditions A through H and J.

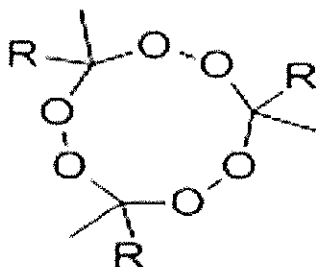
The FCS will replace the structurally similar organic peroxide, CAS Registry No. 24748-23-0 (FCN No. 67), currently used in the production of rheology-modified PP. The FCS results in a much lower crystallization point than CAS# 24748-23-0, and therefore, the FCS will have superior safety characteristics compared to the currently used organic peroxide. For example, at -25°C, the FCS does not form peroxide crystals. However, CAS# 24748-23-0 forms peroxide crystals below 0°C. Under extreme temperature conditions these peroxide crystals can violently decompose, as has been previously seen in safety laboratory tests.

Disposal of the rheology-modified PP in food packaging materials described in this FCN is expected to occur in the same manner as PP food packaging materials made with the currently used organic peroxide nationwide,

with the food packaging materials ultimately entering municipal solid waste landfill, being combusted, or being recycled. However, as the FCS is expected to replace the currently used organic peroxide, the overall amount of rheology-modified PP food packaging material wastes should not be expected to increase over currently generated amounts.

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

The FCS that is subject to this notification is "1,2,4,5,7,8-Hexoxonane, 3,6,9-trimethyl-, 3,6,9-tris(Et and Pr) derivs", CAS Registry No. 1613243-54-1. The FCS is a mixture of cyclic trimer ketone peroxides, with the chemical formula: C₁₂H₂₄O₆ - C₁₃H₂₆O₆ - C₁₄H₂₈O₆ - C₁₅H₃₀O₆. The FCS has a molecular weight of 264 up to 306 with an average of 273 g/mol, and is sold under the Trade Name Trigonox 501-CS40 as a colorless liquid. For the structural formula, see below:



R= ethyl or propyl

The FCS will be commercially sold as a 40% active peroxide (FCS) in 60% processing aid. The processing aid is described by the supplier, TOTAL, as: Hydrocarbons, C₁₀-C₁₃, n-alkanes, isoalkanes, cyclics, < 2% aromatics (tradename Spirdane D 60). The processing aid is used as a phlegmatizer that is added in the production process of the peroxide (FCS) to allow safe production, handling, transport and storage (under UN Regulations). The environmental assessment of the processing aid, Spirdane D60, is described in the attachment to this Environmental Assessment (see Attachment to Environmental Assessment Processing aid – Spirdane D60).

The FCS is very similar in chemical structure to the food contact substance that is the subject of effective FCN Number 67 (3,6,9-triethyl-3,6,9-trimethyl- 1,2,4,5,7,8-triperoxyxonane; CAS Registry No.24748-23-0). The FCS will replace the use of the peroxide described in FCN 67. The major chemical difference between the FCS and the FCN 67 peroxide is that the ethyl groups in the FCN No. 67 peroxide are replaced with ethyl and propyl groups in the FCS. The chemical mixture of the FCS results in a much lower crystallization point and therefore, the FCS will be far less susceptible to violent decomposition and will have superior safety characteristics.

6. Introduction of substances into the environment:

Under 21 C.F.R. § 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, the Notifier is not aware of information to 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.

The controlled rheology-modification process for PP (CRPP) is carried out under an inert atmosphere (nitrogen) and during the CRPP process the FCS completely decomposes. However, the following decomposition products may be formed and released as volatiles: methyl acetate (MA), methyl isobutyl ketone (MIBK), methyl ethyl ketone (MEK), methyl propyl ketone (MPK), ethyl acetate (EtOAc), propyl acetate (PA). These carbon-containing substances, have boiling points ranging from 50-100 degrees C. to 240-260 degrees C. and as such, are classified as volatile organic compounds or VOCs (See 40 CFR 51.100(s) and <https://www.epa.gov/indoor-air-quality-iaq/volatile-organic-compounds-impactindoor-air-quality>).

MIBK is a U.S. Environmental Protection Agency (EPA) designated 'hazardous air pollutant' (HAP)(<https://www.epa.gov/haps>; <https://www.epa.gov/haps/initial-list-hazardous-air-pollutants-modifications>). Under Title V of the Clean Air Act, there are major-source permitting thresholds for air pollutants (i.e., VOCs and HAPs). These specify 10 tons/year for a single HAP or 25 tons/year for any combination of HAPs or 100 tons/year for any air pollutant). Therefore, an evaluation of the emissions and environmental impact of these compounds is necessary.

Using FCS typical site consumption market volume and compositional data provided in the confidential attachment, the annual generation for each of the above identified decomposition products is calculated as follows. The results of these calculations are tabulated in the confidential EA attachment.

Annual substance production:

= (% Decomposition product / % FCS used) x (annual FCS typical site consumption, in kg FCS/year)

The EPA has developed a compilation of emission factors for air pollutants that are released as a result of specific industrial processes. An Air Pollutant Emission Factor (AP-42 emission factor) is a representative value that relates the quantity of a pollutant released to the atmosphere with an activity associated with the release of that pollutant.

The AP-42 emission factor for gaseous emissions resulting from manufacture of polypropylene is 0.35 kg/Mg (equals 0.35 kg/metric ton) of pollutant (<https://www.epa.gov/air-emissions-factors-and-quantification/ap-42-compilation-air-emission-factors>, Introduction to AP42 and Chapter 6.6.4 (Organic Chemical Process Industry – Polypropylene). Therefore, the annual amount of each compound emitted resulting from the manufacture of CRPP may be estimated by multiplying the amount of annual decomposition products by the 0.35 kg/metric ton AP-42 emission factor.

The above analysis is provided in the confidential attachment to the EA. The analysis shows that even assuming as a worst-case analysis that all such emissions are generated by one CRPP manufacturing facility, these emissions are below the U.S. EPA Title V required major-source permitting thresholds for air pollutants, i.e., 10 tons/year single HAP or 25 tons/year for any combination of HAPs or 100 tons/year for any air pollutant (See 40 CFR 51.100(s) and <https://www.epa.gov/indoor-air-quality-iaq/volatile-organic-compounds-impactindoor-air-quality>).

Further, Title V of the Clean Air Act requires major sources of air pollutants, and certain other sources, to obtain and operate in compliance with an operating permit. Sources with these "Title V permits" are required by the Act to certify compliance with the applicable requirements of their permits at least annually (7). Therefore, no significant environmental introductions resulting from the use of the FCS in the manufacture of CRPP are anticipated.

No environmental release is expected upon the use of the subject FCS in the fabrication of food-contact materials as the FCS is completely degraded during the rheology-modification process. Any waste materials generated in this process (e.g., plant scraps) are expected to be disposed as part of the manufacturer's overall nonhazardous solid waste in accordance with established procedures.

Disposal by the ultimate consumer of food contact articles made from CRPP will be by conventional disposal of municipal household waste, and hence, primarily by sanitary landfill, incineration, and recycling. Current conventional disposal practices for polypropylene products are primarily by sanitary landfill, incineration, or recycling; and disposal would be split between combustion with energy recovery and discards to landfill at the same proportion as typical municipal solid waste.

According to the U.S. Environmental Protection Agency's 2014 update describing municipal solid waste in the United States the disposition of total polypropylene in the containers and packaging by resin sub-category 9 was as follows (8):

Generation = 1,720,000 tons
Recycled = 60,000 tons
Recycled % of generation = 3.5%

(https://www.epa.gov/sites/production/files/2016-11/documents/2014_smm_tablesfigures_508.pdf, Table 8.)

Therefore, of 1,720,000 tons of polypropylene waste, 60,000 tons (3.5%) was recycled. The remaining 1,660,000 tons was either combusted or landfilled. Assuming this waste was discarded proportionately to the total plastics in this sub-category, 16.9% was combusted with energy recovery and 68.5% was landfilled.

The FCS consists of carbon, hydrogen, and oxygen. Therefore, if combusted, generation of the greenhouse gas (GHG) carbon dioxide is anticipated. However, because the FCS is not present in the CRPP, emission of GHGs sourced from the FCS as a result of combustion of articles manufactured with CRPP is not expected.

GHG emissions resulting from disposal relate to the incineration of CRPP articles in municipal solid waste (MSW) combustion facilities. Such facilities are regulated by the U.S. Environmental Protection Agency (U.S. EPA) under 40 C.F.R. § 98, which "establishes mandatory GHG reporting requirements for owners and operators of certain facilities that directly emit GHG." Part 2 of this regulation (40 C.F.R. § 98.2) describes the facilities that must report GHG emissions and sets an annual 25,000 metric ton carbon dioxide equivalent (CO₂-e) emission threshold for required reporting.

To evaluate the significance of the environmental impact of these GHG emissions, we refer to CEQ regulations under 40 C.F.R. § 1508.27, which defines 'significantly' as it relates to assessing the intensity of an environmental impact in NEPA documents. 40 C.F.R. § 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 under 40 C.F.R. § 98.2.

Based on the confidential market volume, the expected carbon dioxide equivalent emissions, as shown in the confidential attachment to the EA, are below 25,000 metric tons on an annual basis. As the estimated GHG emissions

are well below the threshold for mandatory reporting, no significant environmental impacts are anticipated resulting from combustion of the CRPP articles in MSW combustion facilities (see confidential EA attachment). The use of the FCS will not significantly alter the emissions from properly operating municipal solid waste combustors, and, therefore incineration of the FCS will not cause municipal solid waste combustors to threaten a violation of applicable emission laws and regulations (40 C.F.R. Part 60 under/or relevant state and local laws).

Additionally, because the FCS is not present in the CRPP and because the FCS is intended to replace other rheology modifiers authorized for use in the manufacture of RMPP, no impacts to current polypropylene recycling streams are anticipated.

7. Fate of Emitted Substances in the Environment

As discussed in Item 6, 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. Use of the FCS in the manufacture of controlled rheology-modified polypropylene will not cause polymer manufacturers to exceed U.S. EPA Title V mandatory major-source permitting thresholds for HAP/VOC air pollutants. Further, because the FCS contains only carbon, oxygen and hydrogen, the products of complete combustion are carbon dioxide and water. As described above, incineration of CRPP will not cause municipal waste combustors to threaten a violation of applicable emissions laws and regulations and GHG emissions are below the EPA level for mandatory reporting.

Therefore, no significant quantities of any substances will be released upon the use and disposal of finished materials manufactured with the FCS. As such a discussion of environmental fate is not required.

(a) Air

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 (see confidential attachment for VOC/HAP and GHS analyses).

As indicated above in item 6, the FCS will not be present in the total municipal solid waste currently combusted. Therefore, the FCS will not significantly alter the emissions from 40 CFR 60-compliant operating municipal solid waste combustors, or cause a violation of applicable emissions laws and regulations.

(b) Water

No significant effects on the concentrations of and exposures to any substances in fresh water, estuarine or marine ecosystems are anticipated due to

the proposed use of the FCS. The fate of the FCS in the aqueous environment does not need to be addressed because no significant introductions of substances into the environment were identified in item 6.

(c) Land

Considering the factors discussed above, no significant effects on the concentrations of and exposures to ant substances in terrestrial ecosystems are anticipated as a result of the proposed use of the FCS. In particular, because the FCS will not be present in waste materials, there will be no leaching of the FCS or any harmful substance under normal environmental conditions, and no meaningful exposure to terrestrial organisms.

Considering the foregoing discussion, we respectfully submit that there is no reasonable expectation of a significant impact on the concentration of any in the environment due to the proposed use of the FCS. Therefore, the environmental fate of substances does not need to be addressed due to the fact that no significant introduction of substances into the environment as a result of the proposed use of the FCS was identified under item 6.

8. Environmental Effects of Released Substances

As discussed previously, no significant quantities of any substances are expected to be released to the environment upon the use and disposal of food packaging materials manufactured with the FCS. Thus, no adverse effect on organisms in the environment is expected as a result of the use and disposal of the FCS.

In conclusion, no information needs to be provided on the environmental effects of substances released into the environment as a results of use and/or disposal of the FCS because, as discussed under item 6, only extremely small quantities, if any, of substances will be introduced into the environment as a result of use and/or disposal of CRPP articles. Therefore the use of the FCS and disposal of CRPP materials are not expected to threaten a violation of applicable laws and regulations, such as the EPA's Title V HAP/VOC major-source permitting thresholds and regulations in 40 CFR Parts 60 and 98.2 that 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 and use of the FCS will involve the use of natural resources such as water, petroleum products and coal, and the like. The replacement of the currently used peroxide

with the FCS is not expected to have an adverse impact on the use of energy and resources. It is expected that the manufacture of the FCS and its use in the production of controlled rheology modified PP food packaging articles will consume energy and resources in amounts comparable to the manufacture and use of the material currently used (CAS Registry No.24748-23-0). Therefore, the use of the FCS is not expected to result in a net increase in the use of energy and resources because the FCS will replace the peroxide currently used in the production of rheology modified PP.

Single-use food contact materials produced using the FCS are expected to be disposed of according to the same patterns when they are used in place of the current CRPP materials. There will be no impact on current or future recycling programs. Thus the approval of this notification is not expected to have any adverse impact on use of natural resources and energy.

10. Mitigation Measures

As described above, no significant adverse environmental impacts are expected to result from the use of the FCS and disposal of CRPP materials. This is primarily due to the minute levels, if any, of leaching of decomposition products from CRPP materials, and the insignificant impact on environmental concentrations of decomposition products of the FCS and combustion products of CRPP materials. Thus, no significant adverse environmental impacts were identified that require mitigation measures.

11. Alternatives to the proposed action

No potential adverse environmental effects discussed herein would necessitate alternative actions to those proposed in this Notification. The alternative of not approving the proposed action would result in the continued use of the less safe peroxide that the FCS is intended to replace.

12. Preparer

Edwin C. Bisinger Jr, PhD, DABT
AkzoNobel Specialty Chemicals
525 W. Van Buren Street
Chicago, IL 60607

Dr. Bisinger is currently a member of the Toxicology and Environmental Expertise Team for AkzoNobel, a Netherlands based manufacturer of coatings and specialty chemicals. He has held technical and managerial positions not only

in private industry, but also in the not-for profit sector (Corporate Toxicologist with Underwriters Laboratory), and is a former member of the U.S. Environmental Protection Agency (Environmental Scientist).

He received his PhD in occupational and environmental toxicology from the University of Illinois, School of Public Health with a focus in chemical risk assessment. He is a member of the Society of Toxicology and is a Diplomate of the American Board of Toxicology (DABT).

Dr. Bisinger has more than 25 years of experience in chemical risk assessment, toxicology study design and interpretation, and in new substance notifications. He has successfully filed several Food Contact Notifications (that included organic peroxide FCSs) with the U.S. FDA over the past 15 years.

13. Certification

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

DATE: August 9, 2018



Edwin C. Bisinger Jr., PhD, DABT
AkzoNobel Specialty Chemicals

Attachment to Environmental Assessment

Processing aid – Spirdane D60

The FCS will be commercially sold as a 40% active peroxide (FCS) in 60% solvent. The solvent is used as a phlegmatizer that is added in the production process of the peroxide (FCS) to allow safe production, handling, transport and storage (under UN Regulations). The solvent is described by the French supplier, TOTAL, as: Hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, < 2% aromatics (tradename Spirdane D 60). The processing aid has no function in the production of rheology modified PP food contact articles.

The FCS will be sold to companies that are engaged in the production of rheology modified PP, which is then used to produce food contact PP packaging. As is currently the case with rheology-modified PP food packaging materials, the single-use PP food contact articles are expected to be used by consumers in patterns corresponding to national population density and to be distributed within the United States.

Disposal of the rheology-modified PP in food packaging materials described in this FCN is expected to occur in the same manner as PP food packaging materials made with the currently used organic peroxide nationwide, with the food packaging materials ultimately entering municipal solid waste landfill, being combusted, or being recycled. However, as the FCS is expected to replace the currently used organic peroxide, the overall amount of rheology-modified PP food packaging material wastes should not be expected to increase over currently generated amounts.

9. Introduction of substances into the environment:

Environmental Introductions Resulting from the Manufacture of the FCS

Under 21 C.F.R. § 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, the Notifier is not aware of information to suggest that there are any extraordinary circumstances in this case indicative of any adverse environmental impact as a result of the use of the processing aid. Specifically, as set forth in FDA's guidance, extraordinary circumstances include situations where: 1) unique emission circumstances are not adequately addressed by general or specific emission requirements (including occupational) promulgated by Federal, State or local environmental agencies and the emissions may harm the environment; 2) a proposed action threatens a violation of Federal, State or local environmental laws or requirements (40 C.F.R. § 1508.27(b)(10)); and 3) production associated with a proposed action may adversely affect a species or the critical habitat of a species

determined under the Endangered Species Act or the Convention on International Trade in Endangered Species of Wild Fauna and Flora to be endangered or threatened, or wild fauna or flora that are entitled to special protection under some other Federal law (1). To the best of the Notifier's knowledge, no situations such as these apply to the use of the processing aid for the intended use. Consequently, information on the manufacturing site and compliance with relevant emissions requirements is not provided here.

Environmental Introductions Resulting from use of the FCS in the Manufacture of RMPP

During the rheology-modification process of PP, the majority of the processing aid (67%) remains within the formed single-use PP article. The processing aid is not a U.S. Environmental Protection Agency (EPA) designated 'hazardous air pollutant' (HAP).

A summary of the emissions to air of the processing aid during PP article production has been included in the confidential emissions spreadsheet that is part of the Environmental Assessment for the FCN. Assuming as a worst-case analysis that all such emissions are generated by one RMPP manufacturing facility, the emissions for the processing aid as well as the decomposition products from the PP process are below the U.S. EPA Title V required major-source permitting thresholds for air pollutants (i.e., 10 tons/year for a 4 See 40 CFR 51.100(s) and <https://www.epa.gov/indoor-air-quality-iaq/volatile-organic-compounds-impactindoor-air-quality> single HAP or 25 tons/year for any combination of HAPs or 100 tons/year for any air pollutant). Therefore, no significant environmental introductions to air resulting from the use of the processing aid are anticipated.

Environmental Introductions Resulting from Use of the RMPP (manufactured with the FCS) in Food-Contact Materials.

No environmental release of the processing aid is expected in the production of single-use PP food-contact materials. Disposal by the ultimate consumer of food contact articles made from the rheology-modified PP will be by conventional disposal of municipal household waste, and hence, primarily by sanitary landfill, incineration, and recycling. Current conventional disposal practices for polypropylene products are primarily by sanitary landfill, incineration, or recycling; and disposal would be split between combustion with energy recovery and discards to landfill at the same proportion as typical municipal solid waste.

According to the U.S. Environmental Protection Agency's 2014 update describing municipal solid waste in the United States the disposition of total polypropylene in the containers and packaging by resin sub-category 9 was as follows:

Generation = 1,720,000 tons
Recycled = 60,000 tons
Recycled % of generation = 3.5%

Therefore, of 1,720,000 tons of polypropylene waste, 60,000 tons (3.5%) was recycled. The remaining 1,660,000 tons was either combusted or landfilled. Assuming this waste was discarded proportionately to the total plastics in this sub-category, 16.9% was combusted with energy recovery and 68.5% was landfilled.

Regarding landfills, the processing aid is not expected to enter the environment as a result of landfill disposal of articles manufactured with rheology-modified PP: based on its lipophilic chemical properties the processing aid is considered to be basically “sequestered” within the PP article and would not be expected to be released under normal conditions even during rain storms.

Further, because EPA’s regulations governing municipal solid waste landfills (40 CFR Part 258) little, if any, of the processing aid would be expected to enter the environment as a result of the landfill disposal of the food-contact articles containing the FCS. These 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. Additionally, landfills are required to have groundwater monitoring systems. Although owners and operators of existing 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.

The processing aid consists of carbon and hydrogen. Therefore, if combusted, generation of the greenhouse gas (GHG) carbon dioxide may be anticipated. The GHG emissions resulting from disposal relate to the incineration of articles containing the processing aid in municipal solid waste (MSW) combustion facilities. Such facilities are regulated by the U.S. Environmental Protection Agency (U.S. EPA) under 40 C.F.R. § 98, which “establishes mandatory GHG reporting requirements for owners and operators of certain facilities that directly emit GHG.” Part 2 of this regulation (40 C.F.R. § 98.2) describes the facilities that must report GHG emissions and sets an annual 25,000 metric ton carbon dioxide equivalent (CO₂-e) emission threshold for required reporting.

To evaluate the significance of the environmental impact of these GHG emissions, we refer to CEQ regulations under 40 C.F.R. § 1508.27, which defines ‘significantly’ as it relates to assessing the intensity of an environmental impact in NEPA documents. 40 C.F.R. § 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 under 40 C.F.R. § 98.2.

Based on the confidential market volume, the expected carbon dioxide equivalent emissions, as shown in the confidential attachment to the EA, are well below 25,000 metric tons on an annual basis. As the estimated GHG emissions are well below the threshold for mandatory reporting, no significant environmental impacts are anticipated resulting from combustion of the processing aid in MSW combustion facilities. The processing aid will not significantly alter the emissions from properly operating municipal solid waste combustors, and, therefore incineration of the processing aid will not cause municipal solid waste combustors to threaten a violation of applicable emission laws and regulations (40 C.F.R. Part 60 under/or relevant state and local laws).

Additionally, because the FCS is intended to replace other rheology modifiers authorized for use in the manufacture of RMPP, the presence of the processing aid should add no significant impact on current polypropylene recycling streams.

10. Fate of Emitted Substances in the Environment

As discussed in Item 5, no significant effect on the concentrations of and exposures to any substances in the atmosphere are anticipated due to the proposed presence of the processing aid in the FCS. The presence of the processing aid during the manufacture of rheology-modified polypropylene will not cause polymer manufacturer's to exceed U.S. EPA Title V mandatory major-source permitting thresholds for HAP/VOC air pollutants. Further, because the processing aid contains only carbon and hydrogen, the products of complete combustion are expected to be carbon dioxide and water. As described above, incineration of the processing aid will not cause municipal waste combustors to threaten a violation of applicable emissions laws and regulations and GHG emissions are below the EPA level for mandatory reporting.

Therefore, no significant quantities of any substances will be released upon the use and disposal of PP single-use articles manufactured in the presence of the processing aid. As such a discussion of environmental fate is not required.

11. Environmental Effects of Released Substances

As discussed previously, no significant quantities of the processing aid are expected to be released to the environment upon the use and disposal of food packaging materials manufactured with the FCS. Thus, no adverse effect on organisms in the environment is expected as a result of presence and disposal of the processing aid. The presence of the processing aid during the manufacture of RMPP or during the disposal of PP single-use articles is not expected to threaten a violation of applicable laws and regulations, such as the EPA's Title V HAP/VOC major-source permitting thresholds and regulations in 40 CFR Parts 60 and 98.2 that pertain to municipal solid waste combustors and Part 258 that pertain to landfills.

8. Use of Resources and Energy

The processing aid is not produced in the United States and therefore the production will not involve the use of natural resources such as water, petroleum products and coal in the United States. The presence of the processing aid is not expected to result in a net increase in the use of energy and resources currently used in the production of rheology modified PP. Therefore the approval of this notification is not expected to have any adverse impact on use of natural resources and energy.

9. Mitigation Measures

No significant environmental impacts resulting from the proposed use of the processing aid have been identified. Therefore, no mitigation measures are required.

The FCN submitter requests approval so that a safer peroxide (the FCS) can replace an already regulated and currently used, chemically similar, but less safe peroxide. No new environmental impacts are expected.

10. Alternatives to the proposed action

No potential adverse environmental effects discussed herein would necessitate alternative actions to those proposed in this Notification. The alternative of not approving the proposed action would result in the continued use of the less safe peroxide that the FCS is intended to replace.