ATTACHMENT 15

ENVIRONMENTAL ASSESSMENT

1. Date: March 8, 2019

2. Name of Submitter: COATEX

3. Address: All communications on this matter are to be sent to the U.S. Agent for the Submitter:

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4. Description of proposed action:

a. Requested action:

The food contact substance (FCS) is a copolymer of acrylic acid and sodium phosphinate (also known as sodium hypophosphite), in neutralized form as the sodium, calcium and/or magnesium salts, developed by COATEX, to be used as an aid in the grinding and dispersion of mineral fillers in water; the resulting ground fillers will be used in the wet-end process to manufacture a paper or paperboard food-contact material. The maximum use level of the FCS in mineral filler will be 0.5% by weight, and the maximum use level of the filler in paper or paperboard will be 10% by weight, giving a maximum use level of the FCS in paper or paperboard of 0.05%.

b. Need for action:

The FCS described in this notification is intended to be used as a partial replacement for sodium polyacrylate homopolymers as an aid in grinding and dispersing mineral fillers for food-contact paper or paperboard materials.

c. Location of use/disposal:

The FCS dispersant will be used to manufacture mineral filler slurries either directly in paper mills or by the mineral filler producer for subsequent delivery to paper mills.

Disposal of paper or paperboard material containing bound mineral filler, and with it the major part of the FCS dispersant, is expected to occur nationwide when the corresponding packaging material is disposed of in municipal solid waste landfills, or is burned or recycled.

Disposal of the minor part of the FCS that is not incorporated into paper and paperboard, but is precipitated from paper mill wastewater effluent and/or adsorbed on wastewater treatment sewage sludge, is normally achieved by one of the following processes:

-Thermal disposal in incinerator plants
-Land disposal in suitable landfills
-Use as agricultural fertilizer by landfill application

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

General information concerning the chemical identity of the neutralized acrylic acid-sodium phosphinate copolymer food-contact substance (FCS) is provided below. (The average molecular weights, the chemical formulae, and the structure descriptions of the four sodium, calcium and/or magnesium salts listed below are provided in the confidential attachment to this Environmental Assessment (EA).)

- **Complete nomenclature**

  The FCS consists of the sodium, calcium and/or magnesium salts of a copolymer of acrylic acid and sodium phosphinate (sodium hypophosphite). Covered salts include calcium sodium; sodium; magnesium sodium; and sodium calcium magnesium. The ratio of acrylic acid to sodium phosphinate ranges from 16:1 to 33:1.The Chemical Abstracts name of the acidic copolymer itself is 2-propenoic acid, polymer with sodium phosphinate (1:1).[1]

- **Chemical name:**

  2-propenoic acid, polymer with sodium phosphinate (1:1), neutralized as follows:

  (a) 2-propenoic acid, polymer with sodium phosphinate (1:1), calcium sodium salt
  (b) 2-propenoic acid, polymer with sodium phosphinate (1:1), sodium salt
  (c) 2-propenoic acid, polymer with sodium phosphinate (1:1), magnesium sodium salt
  (d) 2-propenoic acid, polymer with sodium phosphinate (1:1), calcium magnesium sodium salt

- **CAS Registry No.:**

  (a) None available
  (b) 129898-01-7
  (c) 935545-65-6
  (d) None available

- **Monomer ratios**

  The FCS covers formulations of the sodium, calcium and/or magnesium salts of the copolymer of acrylic acid and sodium phosphinate in which the acrylic acid:sodium phosphinate ratios are within the range 16:1 to 33:1 (by weight).

- **Physical description**

  The pure salts of acrylic acid-sodium phosphinate copolymer are white powders. However, in their intended use, they are supplied in the form of pale yellow, aqueous solutions at around 35% solids by weight, with a specific gravity of about 1.2-1.3.

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[1] "(1:1)" refers to the ratio of sodium to phosphinate in the sodium phosphinate moiety, not to the ratio of 2-propenoic acid (acrylic acid) to sodium phosphinate in the copolymer.

6. Introduction of substances into the environment

a. Introduction of substances into the environment as a result of manufacture

No extraordinary circumstances apply to the manufacture of the FCS.

b. Introduction of substances into the environment as a result of use/disposal

As indicated previously in Item 4c, wastewater treatment sludges will be either land-applied, landfill-disposed, or incinerated. Paper and paperboard manufactured with the FCS will be land-disposed or incinerated as municipal solid waste, or recycled.

Processing waste from the manufacture of paper and paperboard

From Item 4a above, the maximum use level of the FCS in paper or paperboard is 0.05%.

During the wet-end phase of the papermaking process, the aqueous concentration of solids (fibers and fillers) varies between 0.5% and 2% by weight. Therefore, using the worst-case value of 2%, the overall maximum concentration of the FCS in wet-end process water ("white water") will be:

$$2\% \times 0.05\% = 0.001\ \%$$

(In the following calculations and elsewhere in this Assessment, it is assumed that the concentration values for the processes using the FCS are similar to those for the equivalent processes using sodium polyacrylate. This assumption is considered valid because:

(1) a very high proportion of the FCS is polyacrylate; and
(2) sodium polyacrylate represents an extreme version of the FCS in which the acrylic acid to phosphinate ratio approaches infinity.)

As described by Gliese (2006), at least 80% of sodium polyacrylate filler dispersant exits the papermaking process inside the paper material, firmly bonded to the constituent mineral particles, and thereby releasing no more than 20% to the white water.

Therefore, a maximum concentration of:

$$0.001\% \times 0.2 = 0.0002\% = 2 \text{ ppm FCS}$$

would be present as "free" dispersant in solution in white water. Since the paper-making process is a continuous one, the wastewater effluent treatment process is also continuous, and therefore release to the environment is continuous.

The 2 ppm free dispersant most likely consists of the lowest molecular weight fractions of the FCS, those which are the least adsorbed at the surface of mineral fillers. The 2 ppm concentration is a conservative and worst-case estimate which does not take in account coagulation and precipitation of the FCS by cationic retention aids and coagulants, which are always present to facilitate both paper sheet formation and filler retention.

Assuming this maximum level of 2 ppm of the FCS reaches the wastewater treatment plant of the paper mill, it will undergo at least primary and secondary treatments such as settling, coagulation, flocculation, and biological treatment in continuous activated sludge, in accordance with the best available techniques (as described by Pokhrel and Viraraghavan, 2004). Typically, precipitants such as cationic polyelectrolytes, alum, ferric chloride or lime will be used in the primary or tertiary treatments of the on-site sewage treatment plants of the paper mill. For example, Freeman and Bender (1993) demonstrated that sodium polyacrylate is efficiently removed in sewage treatment plants by adsorption on sludge and precipitation by ferric chloride. The water removal efficiency reaches 98%, i.e., only 2% of the maximum concentration of 2 ppm escapes the process.

Assuming that a similar 98% capture efficiency applies to the FCS, the concentration of the FCS at the outfall of the sewage treatment plant, where it reaches surface waters, would be:

$$<2 \text{ ppm} \times 0.02 = 0.04 \text{ ppm} = <40 \text{ ppb}$$

Further, this analysis indicates that the concentration of the FCS in sewage treatment plant sludge would be:

$$<2 \text{ ppm} \times 0.98 = <1.96 \text{ ppm}$$

Again, assuming that the FCS behaves similarly to sodium polyacrylate, once it is precipitated and adsorbed to the sewage sludge of the paper mill water treatment plant, it should stay strongly bound to the sludge and be disposed of with the sludge either by land application as agricultural fertilizer, by placement in a suitable landfill, or by thermal treatment in incinerator plants.

<u>Disposal of paper mill wastewater treatment sludge</u>

Land Application of Sludge

Because the FCS is expected to remain strongly bound to the sludge in the same manner as sodium polyacylate, as described above, no significant amounts, if any, of its constituents are expected to enter the environment as a result of land application of the sludge.

Landfill Disposal of Sludge

Once again, because the FCS remains strongly bound to the sludge and because of EPA regulations governing the operation of municipal solid waste (MSW) landfill operations (40 CFR 268), no significant amounts, if any, of its constituents are expected to enter the environment as a result of landfill disposal of wastewater treatment sludge.

Incineration of Sludge

The organic fraction of the FCS consists solely of carbon, oxygen and hydrogen, and no toxic combustion products are expected as a result of its proper incineration, only carbon dioxide and water; the inorganic fraction will generate non-volatile phosphates. The FCS will not significantly alter the emissions from properly operating wastewater sludge combustion facilities, and incineration of the FCS will not cause these facilities to threaten a violation of applicable emissions laws and regulations at 40 CFR Part 60 and/or relevant state and local laws. With respect to greenhouse gas (GHG) emissions resulting from incineration of paper mill wastewater treatment sludge, total annual emissions of GHGs are calculated to be less than 990 mT carbon dioxide equivalent (CO_2-e), well below the EPA 25,000 mT CO_2-e GHG emissions threshold for mandatory reporting described in 40 CFR 98.2 (see GHG emissions calculation below, after "Disposal of Paper and Paperboard Manufactured with the FCS – Incineration").

Disposal of Paper and Paperboard Manufactured with the FCS

Following use by consumers, food-contact paper or paperboard containing the subject FCS will primarily be disposed of by recycling, landfill or incineration.

Recycling

Recycling will not be impacted by the use of the FCS, as its presence in recycled paper materials will not impact the materials' fitness for use as a source of non-virgin fiber for the paper-making process. The presence of the FCS will not negatively affect the standard unit operations typically employed by paper mills that utilize recycled fiber.

Landfill

Because of EPA regulations governing the operation of municipal solid waste landfill operations (40 CFR 258), no significant amounts, if any, of the FCS constituents are expected to enter the environment as a result of landfill disposal of paper or paperboard materials.

Incineration

As noted above, the organic fraction of the FCS consists solely of carbon, oxygen and hydrogen, and no toxic combustion products are expected as a result of its proper incineration, only carbon dioxide and water; the inorganic fraction will generate non-volatile phosphates. The FCS will not significantly alter the emissions from properly operating MSW combustion facilities, and incineration of the FCS will not cause these facilities to threaten a violation of applicable emissions laws and regulations at 40 CFR Part 60 and/or relevant state and local laws. With respect to GHG emissions resulting from incineration of paper and paperboard containing the FCS, total annual emissions of GHGs are calculated to be less than 1140 mT CO_2-e, well below the EPA 25,000 mT CO_2-e GHG emissions threshold for mandatory reporting described in 40 CFR 98.2; see the following calculation:

GHG emission calculations

(a) GHG emissions from incineration of FCS in paper and paperboard

U.S. EPA statistics for municipal solid waste (MSW) indicate that 39,920,000 tons of paper and paperboard containers and packaging were generated in 2015; see U.S. EPA 2015 Municipal Solid Waste Report, "Advancing Sustainable Materials Management: 2015 Tables and Figures." July 2018, Table 5:

> https://www.epa.gov/sites/production/files/2018-07/documents/smm_2015_tables_and_figures_07252018_fnl_508_0.pdf

Of this waste, 1,710,000 tons (1,550,000 metric tons, mT) were combusted.

From Item 4a above, the maximum use level of the FCS is 0.05%. Making the very conservative (and unrealistic) assumption that 100% of all paper and paperboard containers and packaging in the US will be produced using the FCS, then 0.05% of 1,550,000 mT/year of combusted paper and paperboard waste, i.e., 775 mT/year, would consist of the FCS.

The carbon content of the 33:1 (w/w) acrylate-sodium phosphinate copolymer – the form of the FCS with the highest proportion of carbon – is approximately 37-40%, depending on the neutralization used. Thus, 40% of 775 mT/year, or 310 mT carbon/year, represents a worst-case scenario, and this equates to a carbon dioxide equivalent (CO2-e) emission of 1,140 mT/year:

> 0.05% FCS x 1,550,000 mT paper combusted = 775 mT FCS combusted annually.
> 775 mT FCS x 40% C in FCS x (44 g CO_2/12g C) = **1140 mT CO_2-e**

These total annual emissions of GHGs are far below the EPA 25,000 mT CO_2-e GHG emissions threshold for mandatory reporting described in 40 CFR 98.2. Therefore, no significant impacts are expected from incineration at MSW combustion facilities of paper and paperboard manufactured with the FCS.

(b) GHG emissions from combustion of FCS in paper mill sludge

As noted in (a) above, U.S. EPA statistics for municipal solid waste (MSW) indicate that 39,920,000 tons (36,200,000 mT) of paper and paperboard containers and packaging were generated in 2015. If it is once again conservatively assumed that 100% of all paper and paperboard containers and packaging in the US will be produced using the FCS, then the total amount of FCS used in the process will be 0.05% of 36,200,000 mT = 18,100 mT.

As noted above, it has been reported by Gliese (2006) that at least 80% of sodium polyacrylate filler dispersant exits the papermaking process inside the paper material, thereby releasing no more than 20% to the white water. Assuming that the same ratio applies to the FCS, then at least 80% of the 18,100 mT of FCS would be incorporated into the paper, and so no more than 20%, i.e., 3620 mT, would enter the waste stream, and 98% of this (3550 mT) would be incorporated into the paper mill sludge.

It has been recently reported that, in practice, approximately 19% of paper mill sludge is incinerated for energy recovery (Likon and Trebse, 2012).

> 19% x 3550 mT= 675 mT FCS combusted annually in sludge.
> 675 mT FCS x 40% C in FCS x (44 g CO_2/12g C) = **990 mT CO_2-e**

Once again, these total annual emissions of GHGs are far below the EPA 25,000 mT CO_2-e GHG emissions threshold for mandatory reporting described in 40 CFR 98.2. Therefore, no significant impacts are expected from incineration at paper mill sludge combustion facilities as a result of manufacturing paper and paperboard with the FCS.

7. Fate of substances released into the environment

a. Physical/chemical properties

Solubility: Measurements of partition coefficients (n-octanol/water) [See Attachment 4] show that the sodium salt of acrylic acid-sodium phosphinate copolymer is fully soluble in water, as are the sodium calcium, sodium magnesium and sodium calcium magnesium mixed salts. This was assessed for the ratio range of acrylic acid to sodium phosphinate relevant in this FCN (from 16:1 to 33:1).

pH: the pH of a 35% solution of the FCS is about 8.

Specific gravity: an aqueous solution with approximately 35% solids by weight has a specific gravity of about 1.2.

b. Environmental depletion mechanisms

No significant effect on the concentration of any substances in the atmosphere is anticipated due to the proposed use of the FCS, which is solid and does not volatilize. Thus, no significant quantities of the FCS or any substances originating from it will be released upon the use of food-contact paper or paperboard manufactured with the FCS. Moreover, as noted above in Item 6, the emissions regulations of 40 CFR 60 will not be violated by incineration of paper, paperboard and paper mill wastewater treatment sludge containing the FCS.

Once again, no studies on the environmental fate of the FCS are available. However, the environmental fate of sodium polyacrylate homopolymers has been extensively studied because huge quantities of the polymer are used in household detergents:

> Studies by Chiaudani and Poltronieri (1990), Langbein (1997), and Hamilton et al. (1997) show that the environmental fate of sodium polyacrylate is to be precipitated in the form of insoluble salts and thus removed from water systems, and to stay adsorbed on sewage sludge, sediment, or soil. Chiaudani and Poltronieri (1990) studied the environmental fate of sodium polyacrylate in soil using C^{14}-labeled sodium polyacrylate polymers with lysimeter testing. They showed, for example, that the highest M_w fractions (around 90%) accumulate in the first 15 mm of the soil and are not further removed or biodegraded, and thus cannot percolate to aquifers, whereas the lowest M_w fractions of sodium polyacrylate (around 10%) stay mobile, and are more difficult to precipitate or to adsorb onto soil particles.
>
> On the other hand, the lowest molecular weight fractions of sodium polyacrylate (M_w <1000 g/mol) show significant, though not complete, biodegradation (measured by rate of release of C^{14}-labeled carbon dioxide). Similar results are reported in HERA (2014) from earlier studies by Procter and Gamble. Further studies by Kawai (1994) and Larson et al. (1997) show that

sodium polyacrylate oligomers start to be metabolized by microorganisms below 7 monomer units (M_w in the range 500-700).

Because the FCS presents the same carboxylate functions as sodium polyacrylate homopolymer and in a very high proportion, it may be anticipated that the FCS will undergo an environmental fate very similar to that of sodium polyacrylate itself. It is expected that the highest Mw fractions are not degraded and are precipitated in the form of insoluble salts, are removed from water systems and stay adsorbed on sewage sludge, sediment or soil. This non-biodegradation aspect is confirmed by a test conducted on a similar product. This product was subjected to a biodegradation test in accordance with OECD 301E. Biodegradation of a solution by polyvalent bacteria from 3 different sources was calculated as 2% after 28 days, and the test substance was therefore categorized as non-biodegradable. (Study data are presented in the confidential attachment to this EA.)

8. Environmental Effects of Released Substances

Toxicity data for the acrylic acid-sodium phosphinate copolymer (acidic and neutralized versions of the FCS) show that it does not present any significant acute toxicity to aquatic test species, as follows:

A growth inhibition test on freshwater green algae (*Pseudokirchneriella subcapita*) was performed in May 2016 in accordance with OECD 201 using a 35% aqueous solution of the sodium/calcium salt of the copolymer with acrylic acid and sodium phosphinate in a 21:1 ratio. (The study is identified in the confidential attachment to this EA.) The test culture contained the 35% copolymer solution at a concentration of 100 mg/L. The biomass in the control culture increased exponentially by a factor of 60.3 within the 72-hour test period (a 16-fold minimum is required for the assay), while that in the test culture increased by a factor of 53.6, representing a yield inhibition of 11.5% and a growth rate inhibition of 3.2%. Thus, the concentration resulting in a 50% reduction relative to control in either yield (EyC50) or growth rate (ErC50) was >100 mg/L, and the test item was therefore considered to have no effect at the tested nominal concentration of 100 mg/L.

An acute 96-hour toxicity test on rainbow trout was performed in accordance with OECD 203 using a copolymer similar to that referred to above. The test article was added to aquarium water at concentration ranges of 100 to 1000 mg solids/L, for an assay using 10 fish per concentration. After 96 hours, there was no mortality at any concentration, nor any observed loss of equilibrium, exophthalmos, or effect on swimming behavior or respiratory function; the only observation was a slight effect on pigmentation at the highest concentration. Thus, the LC50 was >1000 mg/L. The same acute 96-hour toxicity test was performed on zebra fish; in this case, there was no mortality, nor any adverse observation (including any change in pigmentation) at any concentration after 96 hours. The LC50 was, once again, >1000 mg/L. (The study is identified in the confidential attachment to this EA.)

An additional 96-hour toxicity test of the similar copolymer referred to above was performed on brown shrimp (*Crangon crangon*) in seawater, using 20 shrimp per concentration (5 concentrations, range 1,000 to 10,000 mg solids/L, plus controls). Mortality was monitored at 6 time points; mortality at 96 hours was 15% in the 10,000 mg/L group, 10% in controls, and 5-25% in the intermediate concentration groups. Acute toxicity LC50 was therefore >10,000 mg/L at all time points. (The study is identified in the confidential attachment to this EA.)

A bioaccumulation study was performed in Japanese carp (*Cyprinus carpio*) using acrylic acid-sodium phosphinate copolymer, sodium salt, with an acrylic acid: sodium phosphinate ratio of 16:1 and a ^{14}C-label at the carboxyl carbon position of acrylic acid. Two concentration levels of labelled copolymer, 160 and 16 ppb, were prepared in 100-liter tanks. The fish were maintained in the tanks for up to 8 weeks, with intermediate sampling points at 3 days and at 1, 2, 3, 4 and 6 weeks. The sampled fish (2 per time point per concentration level) were killed and lipid extracted with organic solvent (benzene). Total radioactivity was calculated as the sum of radioactivity from the organic extract and from the residue. Results showed no accumulation over time at either concentration level. (The study is identified in the confidential attachment to this EA.)

Of the monomers, the environmental safety profile of sodium phosphinate itself should be even less of a concern than that of acrylic acid, so the replacement of a small proportion of acrylic acid with sodium phosphinate should represent no negative effect on safety. This is confirmed by the fact that acrylic acid is classified, among others, as Aquatic Acute Category 1 (H400 Very toxic to aquatic life) and Aquatic Chronic Category 2 (H411 Toxic to aquatic life with long lasting effects) – whereas sodium phosphinate is not classified as hazardous to the environment. Such information is available on the European Classification & Labelling Inventory[2] and on the safety data sheets provided by the suppliers of these substances.

<u>Effects related to the presence of the FCS in the outfall of paper mills' sewage treatment plants.</u>

As reported above, lethal concentrations of the FCS for 50% of the test population (LC_{50} or EC_{50}) were found to exceed 100 mg/L in an acute toxicity test in algae, 1,000 mg/L in fish, and 10,000 mg/L in shellfish. In comparison, the estimated worst-case concentration at the outfall of paper mills' on-site sewage treatment plants is estimated to be below 40 ppb or 0.04 mg/L (see Item 6.b), indicating a considerable margin of safety (from >2,500 to >250,000). Therefore, no significant effects related to the presence of the FCS in the outfall of paper mills' sewage treatment plants are expected.

<u>Effects related to the presence of the FCS in sludge</u>

As noted above, sludge containing adsorbed or precipitated FCS may be landfilled or used as agricultural fertilizer. The concentration of FCS in the sludge has been estimated at <1.96 ppm (<1.96 mg/kg). A chronic No-Observed Effect Concentration (NOEC) of 225 mg sodium polyacrylate per kg of soil has been reported for various crops, including corn, wheat and soybean (Freeman and Bender, 1993). Taking an Assessment Factor (AF) of 10x to address the uncertainty of the toxicity testing gives a Predicted No Effect Concentration (PNEC) = NOEC/AF = 225/10 = 22.5 mg/kg, which exceeds the estimated concentration of the FCS in the undiluted sludge itself (<1.96 mg/kg) by a factor of greater than 10. More recently, HERA (2014) reported a more refined but very similar PNEC value of 22.1 mg/kg of soil for homopolymers of acrylic acid and their sodium salts. Thus, the estimated maximum concentration of the FCS in treated soil is considered to pose no risk to the soil environment. Since the ecotoxicity of the FCS (with an acrylate content lower than that of the sodium polyacrylate homopolymer) is expected to be no higher than that of the homopolymer itself, and since the FCS is expected to be used far less extensively than the homopolymer, use of

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[2] For sodium phosphinate :
https://echa.europa.eu/fr/information-on-chemicals/cl-inventory-database/-/discli/details/86442
For acrylic acid :
https://echa.europa.eu/fr/information-on-chemicals/cl-inventory-database/-/discli/details/110237

the FCS should be at least as acceptable as the homopolymer from an environmental perspective.

9. Use of Resources and Energy

As is the case with other food packaging materials, the production, use and disposal of the FCS involves the use of natural resources such as fossil fuels. However, the use of the FCS as a mineral filler dispersant will directly substitute for a fraction of another additive currently used in the same food-contact applications. This partial replacement by the subject FCS will not have any adverse impact on the use of energy and resources. Manufacture of the FCS, and its conversion to finished food packaging materials, will consume energy and resources in amounts comparable to the manufacture and use of the additive that the FCS is intended to partially replace. Packaging materials produced using the subject FCS are expected to be disposed of according to the same patterns when they are used in place of the current materials. Thus, there will be no impact on current or future disposal or recycling programs.

10. Mitigation Measures

As discussed above, no significant adverse environmental impacts are expected to result from the manufacture, use and disposal of food-contact paper or paperboard containing the FCS. This is primarily due to the low environmental exposure to the FCS in surface waters or in soils, the insignificant impact on environmental concentrations of combustion products of the FCS, and the similar use of resources and energy in making the FCS and the additive it is replacing in food-contact paper or paperboard. Thus, the proposed use of the FCS is not reasonably expected to result in any increased environmental risk requiring mitigation measures of any kind.

11. Alternatives to the Proposed Action

No potential adverse environmental effects are identified herein which would require alternative actions to that proposed in this Notification. The alternative of not approving the action proposed herein (i.e., no action) would result in the continued use of the material which the subject FCS would otherwise replace.

12. List of Preparers

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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 COATEX SAS.

March 03, 2019
(Date)

[redacted]

Benoît Magny, Head of Innovation & Development, COATEX SAS
(Printed name and title of responsible official)

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