Environmental Assessment

1. Date: October 21, 2010

2. Name of Submitter: COATEX SAS

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

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4. Description of proposed action:

a. Requested action:

COATEX SAS, France, and its subsidiary COATEX Inc., USA, have developed a sodium polyacrylate polymer dispersant (CAS no. 9003-04-7) as an aid in the grinding of mineral fillers in water and in the use of the resulting ground fillers in the wet-end process to manufacture a paper or paperboard food-contact material. The maximum use level of sodium polyacrylate in mineral filler will be 0.5% by weight, and the maximum use level of the filler in paper will be 10% by weight, giving a maximum use level of sodium acrylate in paper of 0.05%.

b. Need for action:

The FCS described in this notification will be used in place of polyphosphates or acrylamide-acrylic acid copolymers as an aid in grinding and dispersing mineral fillers for food-contact paper or paperboard materials. Polyphosphate dispersants do not allow mineral fillers to be ground to the right fineness and do not provide stable mineral suspensions (slurries) for use in the automated processes of paper mills. Acrylamide-acrylic acid copolymers have a better efficacy than polyphosphates for grinding mineral fillers and are cleared for use under 21 CFR §176.110, but are thought to be more problematic in terms of environmental impact because residual acrylamide monomer is neurotoxic and is suspected to be carcinogenic and mutagenic to man. [1]

c. Location of use/disposal:

Sodium polyacrylate 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.

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[1] Toxicological Review of Acrylamide (CAS No. 79-06-1) in Support of Summary Information on the Integrated Risk Information System (IRIS). March 2010, U.S. Environmental Protection Agency, Washington, DC. EPA/635/R-07/009F.

Disposal of paper or paperboard material containing bound mineral filler, and with it the major part of sodium polyacrylate dispersant, is expected to occur nationwide when the corresponding packaging material is disposed of in municipal solid waste landfills, or is burned or recycled, as is the case for any food-contact material.

Disposal of the minor part of sodium polyacrylate, which is precipitated from paper mill wastewater effluent and/or adsorbed on wastewater treatment sewage sludge, is normally as follows:

-Thermal disposal in incinerator plants
-Land disposal in a suitable landfill
-Use as agricultural fertilizer

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

General information concerning the chemical identity of Sodium Polyacrylate FCS is provided below.

- **Complete nomenclature**

  The food-contact substance consists of the sodium salt of a straight-chain polyacrylic acid. The Chemical Abstracts name is 2-propenoic acid, homopolymer, sodium salt.

- **CAS registration number**

  9003-04-7

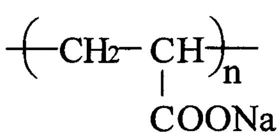
- **Molecular weight**

  The average molecular weight by weight, M_w, is 4500 g/mol.

- **Molecular formula**

  $(C_3H_3NaO_2)_n$

- **Structural formula**



- **Physical description**

  Pure sodium polyacrylate is a white powder. However, in its intended use, it is delivered as a viscous, light-colored, aqueous solution at around 40% solids by weight in water, with a specific gravity of about 1.3.

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 processing aid, sodium polyacrylate.

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

Use

The proposed use of sodium polyacrylate as a mineral filler dispersant in the manufacture of food-contact paper or paperboard in the USA corresponds to a maximum yearly marketing volume of 1000 metric tons per year. This worst-case value is based on estimated dispersant consumption for mineral filler to be used in food-contact material in the US market.

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. In the following calculation, we use the 2% concentration for worst-case assessment purposes.

Of these 2% of solids, the maximum proportion of mineral filler is 10% by weight and, of that 10%, a maximum proportion of 0.5% of sodium polyacrylate dispersant is needed. Therefore, the overall maximum concentration of sodium polyacrylate in wet-end process water (also called "white water") is:

$$2\% \times 0.10 \times 0.005 = 0.001\ \%$$

As described by Gliese [1], 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:

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

would be retrievable 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 sodium polyacrylate, those which are the least adsorbed at the surface of mineral fillers. The 2 ppm concentration is a conservative and worst-case calculation which does not take in account the coagulation and precipitation of sodium polyacrylate by cationic retention aids and coagulants, which are always present to facilitate both paper sheet formation and filler retention.

Then, assuming that this maximum level of 2 ppm of sodium polyacrylate 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 (continuous activated sludge), in accordance with the best available techniques as described by Pokhrel et al. [2]. 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.

Freeman and Bender [3] have demonstrated that 4500 M_w sodium polyacrylate is efficiently removed in sewage treatment plants by adsorption on sludge and precipitation by ferric chloride. The water removal efficiency reaches 98%, which means that only 2% escapes the process, and therefore the concentration of sodium polyacrylate at the outfall of the sewage treatment plant, when it reaches surface waters, is:

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

A Material Safety Data Sheet (MSDS) for sodium polyacrylate is appended to the end of this document.

Disposal in landfills

Disposal by the ultimate consumer of food-contact paper or paperboard containing the subject FCS will be primarily by recycling or incineration. Only extremely small amounts, if any, of sodium polyacrylate polymer constituents are expected to enter the environment as a result of the landfill disposal of paper or paperboard materials, in light of the Environmental Protection Agency's (EPA) regulations governing municipal solid waste landfills.

As described by Chiaudani et al. [4] and by Freeman and Bender [3], M_w 4500 sodium polyacrylate polymer does not adversely impact the operation of a sewage treatment plant (sludge sedimentation, treatment capacity, sludge dewatering) and is efficiently removed from water with a high yield (Freeman and Bender [3], Hamilton et al. [5]), e.g., 98% when ferric chloride is used as a precipitant in a continuous activated sludge waste water treatment plant. Therefore, once precipitated and adsorbed to the sewage sludge of the paper mill water treatment plant, sodium polyacrylate stays strongly bound to this sludge and is disposed of along with the sludge either by thermal disposal in incinerator plants, by placement in a suitable landfill, or by use as agricultural fertilizer.

Using the data from the "Use" discussion above:

Paper-making solids contain 10% filler.
Filler contains 0.5% sodium polyacrylate.
Therefore, paper-making solids contain:

$$0.1 \times 0.5\% = 0.05\% \text{ sodium polyacrylate}$$

Of this 0.05% of solids, >80% (or 0.04% of solids) remains with the paper and <20% (<0.01% of solids) is released to the treatment plant.

Thus, the manufacture of 1 metric ton of paper results in the release of <0.01% of 1 ton (<100 g) of sodium polyacrylate to the treatment plant, at least 98% of which (approximately 98 g) will be captured and disposed of in the treatment sludge.

Actual measurement of the mineral filler part in the sewage sludge of a paper mill allowed T. Gliese [1] to estimate that 70 grams of sodium polyacrylate per ton of paper produced are disposed of with this sewage sludge, which is in good agreement with the above worst-case calculation.

Mobility studies have demonstrated that once sodium polyacrylate is adsorbed onto the sludge and soil, it is unlikely to desorb and leach into the aquifer (Chiaudani [4]). Gliese [1] reported the concentration of sodium polyacrylate in the sewage sludge of a big paper mill to be 950 ppm.

The sludge containing adsorbed Sodium Polyacrylate may eventually be landfilled or used as agricultural fertilizer. In the case of the use as agricultural fertilizer, the concentration of polymer in sludge-amended soil can be estimated to be no more than 0.6 mg. kg^{-1} soil at the time of application (using the above value of 950 mg of sodium polyacrylate per kilogram of sludge and assuming a 0.2 kg/m^2 sludge application rate, soil depth of 0.2 m and soil density of 1600 kg/m^3):

$$(950 \text{ mg/kg} \times 0.2 \text{ kg/m}^2)/(0.2 \text{ m} \times 1600 \text{ kg/m}^3) = 950/1600 = 0.6 \text{ mg/kg}$$

Disposal by combustion

The organic part of polyacrylic acid sodium salt consists of carbon, oxygen, and hydrogen. No toxic combustion products are expected as a result of the proper incineration of this polymer. Due to the nature of the combustion products and their low levels compared to the amounts currently generated by municipal waste combustors, the additional combustion products from incineration of the polyacrylic acid sodium salt will not cause any violation of applicable emissions regulations.

7. Fate of substances released into the environment

a. Physical/chemical properties

Sodium polyacrylate is fully soluble in water but it will become insoluble by exchanging its sodium counter-ions with multivalent ones such as alkaline-earth metal ions (calcium or magnesium) or trivalent cations (iron or aluminum). The pH of a concentrated solution of the food-contact substance is about 8.5. An aqueous solution with approximately 40% solids by weight has a specific gravity of about 1.3.

Sodium polyacrylate stays firmly adsorbed at the surface of mineral particles except for low molecular weight fractions (below 1500 g/mol), which can desorb because they have fewer anchor groups. However, even these low molecular weight fractions can be precipitated if the majority of the pending carboxylate groups are bound to multivalent cations.

b. Environmental depletion mechanisms

No significant effect on the concentration of any substances in the atmosphere is anticipated due to the proposed use of sodium polyacrylate. The polymer is solid and does not volatilize. Thus, no significant quantities of polyacrylate or any substances originating from it will be released upon the use and disposal of food-contact paper or paperboard manufactured with sodium polyacrylate. The products of complete combustion of the polymer would be carbon dioxide and water; the concentrations of these substances in the environment will not be significantly altered by the proper incineration of the polymers in the amounts utilized for food packaging applications.

The environmental fate of 4500 M_w sodium polyacrylate homopolymers has been extensively studied because huge quantities of the polymer are used as co-builders in household detergents. Studies by Chiaudani [4], Langbein [6] and Hamilton [5] show that the environmental fate of 4500 M_w sodium polyacrylate is to be precipitated in the form of divalent or trivalent salts and thus removed from water systems and to stay adsorbed on sewage sludge, sediment or soil. Particularly, Chiaudani [4] studied the environmental fate of sodium polyacrylate in soil using C^{14}-labeled 4500 M_w sodium polyacrylate polymers and lysimeter testing. These studies showed that the highest M_w fractions of 4500 M_w sodium polyacrylate (around 90%) accumulate in the first 15 mm of the ground 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.

The same study states that the lowest molecular weight fractions of sodium polyacrylate (fractions with M_w below 1000 g/mol) are the only ones to show significant, though not complete, biodegradation (measured by rate of release of C^{14}-labeled carbon dioxide). Further studies by Kawai [7] and Larson [8] show that sodium polyacrylate oligomers start to be metabolized by micro-organisms below 7 monomer units (M_w in the range 500-700) but that the cutoff for complete biodegradation is even lower.

Low molecular weight fractions of sodium polyacrylate will not stay in surface waters but will react with water hardness (calcium and magnesium ions) and will precipitate in the sediments of aquatic environments (Chiaudani [4]).

8. Environmental Effects of Released Substances

Toxicity data for M_w 4500 sodium polyacrylate (Freeman and Bender [3]) show that this polymer does not present any significant acute toxicity to aquatic test species under USEPA toxicity classification guidelines. Indeed, M_w 4500 sodium polyacrylate has lethal concentrations for 50% of the test population (LC_{50} or EC_{50}) of >100 $mg.L^{-1}$ in all acute toxicity tests: Bacteria, Algae, Daphnia, and Fish. Additionally, M_w 4500 sodium polyacrylate shows a chronic No-Observed Effect Concentration (NOEC) of approximately 6 $mg.L^{-1}$ in Daphnia and much higher in fish (56 $mg.L^{-1}$). In comparison, the estimated worst-case sodium polyacrylate concentration at the outfall of paper mills' on-site sewage treatment plants is below 40 ppb (see § 6.b), i.e., <0.04 $mg.L^{-1}$. There is therefore a considerable margin of safety (greater than 150 x) between the NOEC of the most sensitive species tested and the estimated concentration of sodium polyacrylate in natural waters (6 $mg.L^{-1}$ vs 0.04 $mg.L^{-1}$). An additional Assessment Factor (AF) can be applied to address the uncertainty of the toxicity testing (Bascietto [9]). In this case an AF of 10 is appropriate based on the extent of toxicity testing performed.

Freeman and Bender's safety evaluation [3] compares the estimated concentration to the most sensitive NOEC divided by the AF. This AF reduces the safety margin to 15 x. Nevertheless the estimated environmental concentration is still much less than the NOEC/AF and this is considered acceptable to the aquatic environment.

Sludge containing adsorbed or precipitated sodium polyacrylate may be landfilled or used as agricultural fertilizer. In this case, the concentration of sludge-amended soils can be estimated

to be 0.6 mg.kg^{-1} soil at the time of application (see § 6.c). Additionally M_w 4500 sodium polyacrylate shows chronic No-Observed Effect Concentration (NOEC) in plants of 225 mg.kg^{-1} soil. Plants tested were corn, wheat, soybean (Freeman and Bender [3]).
Taking an Assessment Factor (AF) of 10 to address the uncertainty of the toxicity testing, the estimated concentration of sodium polyacrylate in soil, 0.6 mg.kg^{-1}, is less than the NOEC/AF of 22.5 mg.kg^{-1}. The safety margin is 37.5 (22.5/0.6) and thus the estimated environmental concentration of sodium polyacrylate is considered acceptable to the soil environment.

9. Use of Resources and Energy

As is the case with other food packaging materials, the production, use and disposal of polyacrylic acid sodium salts involves the use of natural resources such as petroleum products, coal, and the like. However, the use of sodium polyacrylate as a mineral filler dispersant will mainly substitute for the use of acrylamide-acrylic acid copolymers and will be used in the same food-contact applications. The formulation change will therefore have no net impact on the use of resources and energy.

10. Mitigation Measures

As shown above, no significant adverse environmental impacts are expected to result from the manufacture, use and disposal of food-contact paper or paperboard containing sodium polyacrylate. This is primarily due to the low and acceptable environmental exposure of sodium polyacrylate in surface waters or in soils, the insignificant impact on environmental concentrations of combustion products of the polymers, and the similar use of resources and energy in making the subject polymers and the materials they are intended to replace in food-contact paper or paperboard. Thus, the use of sodium polyacrylate 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 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 materials which the subject polymers would otherwise replace, mainly acrylamide-acrylic acid copolymers. This would have the following environmental impact: Workers in polymer plants would still suffer the risk of exposure to acrylamide monomer, which is neurotoxic and suspected to be carcinogenic and mutagenic to man.

In addition, acrylamide-acrylic acid copolymers are known to have higher acute toxicity to aquatic test species (algae, daphnia) than sodium polyacrylate.

12. List of Preparers

Henri Grondin, Research and Development Coordinator, M.Sc. in Chemistry, COATEX SAS
35 rue Ampère, F-69730 Genay, France.

13. Certification

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

October 21st, 2010
(Date)

[redacted]

(Signatur[redacted]

Henri Grondin, Research and Development Coordinator
(Printed name and title of responsible official)

14. References

[1] Gliese, T. 2006. Dispersants for fillers and coating pigments, Wochenblatt für Papierfabrikation, 134(22): 1314-1319
[2] Pokhrel, D, Viraraghavan, T. 2004. Treatment of pulp and paper mill wastewater - a review, Science of the Total Environment, 333: 37-58
[3] Freeman, M.B., Bender, T.M. 1993. An Environmental fate and safety assessment for a low molecular weight polyacrylate detergent additive. Environmental Technology, 14: 101-112
[4] Chiaudani, G., Poltronieri, P. 1990. Study on the environmental compatibility of polycarboxylates used in detergent formulations. Ing. Ambientale, 11: 1-43
[5] Hamilton, J.D., Morici, I.J., Freeman, M.B. 1997. Polycarboxylates and Polyacrylate Superabsorbents. / Polycarboxylates. Ecological Assessment Polymers: Strategies for Product Stewardship and Regulatory Programs / ed. by John D. Hamilton and Roger Sutcliffe: 87-102
[6] Langbein, I., 1997. Biological and physicochemical aspects of polycarboxylate behavior in the environment, Surfactant science series, 65: 247-261
[7] Kawai, F., 1994. Biodegradation of polyethers and polyacrylate, Studies in polymer science, 12: 24-38
[8] Larson, R. J., Bookland, E. A. & al., 1997. Biodegradation of acrylic acid polymers and oligomers by mixed microbial communities in activated sludge, Journal of Environmental Polymer Degradation, 5: 41-48
[9] Bascietto, J. D., Hinckley, J.and Slimak, M., 1990. Ecotoxicity and ecological risk assessment, Environ. Sci. Technol., 24(1): 10-15

15. Attachments

Material Safety Data Sheet (MSDS) for sodium polyacrylate

MATERIAL SAFETY DATA SHEET

coAtex
Additives Designers

~odium Polyacrylate

DATE: **21/10/2010**

1- Identification of the product and the company:

Trade Name:	**Sodium Polyacrylate**
Supplier:	
- Name:	COATEX Inc
- Address:	547 ECOLOGY LANE, CHESTER S.C., 29706
- Telephone:	(803) 377 - 1111
- Fax	(803) 581 - 5995
Emergency call:	
- Name	CHEMTREC
- Telephone	US (800) 424-9300 International (703) 527-3887

2- Composition / Information on ingredients:

Chemical Name:	**Sodium Polyacrylate (CAS 9003-04-7) in aqueous solution**
Hazardous components:	**NONE**

3- Hazards identification:

Adverse health effects:	**Does not show any specific hazard as long as good manufacturing practices are followed**
Physical and Chemical hazards:	
- Fire or explosion	NONE
Hazard classification:	**This material is NOT HAZARDOUS by OSHA Hazard Communication definition.**

4- First-aid measures:

Inhalation:	**If affected; remove to fresh air**
Skin contact:	**Wash affected area thoroughly with plenty of water**
Eye contact:	**Flush immediately with plenty of water. If irritation persists, see eye doctor**
Ingestion:	**No Known Ingestion effects. Consult a physician**

5- *Fire-fighting measures:*

Extinguishing media:	
- Appropriate:	Waterspray
	Foam
	Powder
	Carbon dioxide
- Unsuitable	NONE
Specific hazards:	**Dried product is combustible but does not show any particular risk in case of fire.**
Specific intervention methods:	**Appropriate protective equipment must be worn in case of fire**

6- *Accidental release measures:*

Personal Protective Equipment	
	Rubber gloves
	Safety eyewear
Precautions to protect environment	
	Prevent product from spreading in the environment
	Do not discharge into sewer
Cleaning methods:	
- Recovery:	Vacuum bulk liquid or absorb it with inert sorbent
- Cleaning / Decontamination:	Wash the affected area with plenty of water
- Disposal:	Dispose in accordance with federal, state and local regulations. Various options may be available

7- *Handling and storage:*

Handling:	
- Technical measures:	Does not require specific technical measures
- Safety procedures:	See section 8
Storage:	
- Conditions:	Stable under normal conditions
- Incompatibilities:	None known
- Containers:	
- recommended	Coated Steel, stainless steel. Plastic materials (e.g. polyethylene).
- not recommended:	Carbon steel. Aluminum and its alloys.

8- Exposure controls / personal protection:

Engineering controls:	**Does not necessitate specific or particular measures, provided general health and safety practices are observed**
Personal protective equipment:	
- Hand protection:	Rubber gloves
- Eye protection:	Safety eyewear

9- Physical and chemical properties:

Aspect:	
- Physical state:	Liquid
- Color:	Yellow to amber
Odor:	**Slight**
pH:	**8.5**
Flash point:	**> 100 °C, closed cup**
Boiling point:	**100 °C**
Vapor pressure:	**18 mm Hg @ 20 °C (water)**
Crystallization point:	**-5 °C**
Specific gravity:	**1.29**
Solubility:	
- in water:	Soluble
- in solvents:	Very Slight
Volatile part by weight:	**60% (water)**
n-octanol / water partition coefficient:	**Log Pow (estimated) <<3**

10- Stability and reactivity:

Stability:	**Stable if appropriately used**
Dangerous reactions:	
- Materials to avoid:	No dangerous reactions known
- Hazardous decomposition products:	None to our knowledge

11- Toxicological information:

Acute toxicity: **LD50 (oral, rat) > 2000 mg/kg**

Local effects:

Not classified as irritant for eyes according to 16 CFR 1500.41 criteria

Not classified as irritant for skin according to 16 CFR 1500.42 criteria

12- Ecological information:

Environmental fate: **Does not persist in water. Is removed through precipitation and absorption processes. Does not present a significant risk to aquatic organsims at low concentrations (see ecotoxicity).**

Degradability: **Poorly biodegradable**

Ecotoxicity:

- Impact on aquatic environment: LC50 (Fish: brachydanio rerio): 96h > 100 mg/l

EC50 (Daphnia: daphnia magna): 48h > 100 mg/l

IC50 (Algae): 72 hours > 100 mg/l

13- Disposal considerations:

Product residues:

- Prohibition: Do not discharge to sewer
- Destruction / elimination: Dispose in accordance with federal, state and local regulations. Various options may be available

Used packaging:

- Decontamination / washing: Empty packaging thoroughly and rinse with water before disposal
- Destruction / elimination: Dispose in accordance with federal, state and local regulations. Various options may be available

14- Transport information:

Ground transportation:

- DOT: Not regulated

Sea transportation:

- IMDG: Not regulated

Air transportation:

- IATA: Not regulated

Sodium Polyacrylate

DATE: **21/10/2010**

15- Regulatory information:

Federal:

- TSCA:	All components are either listed or otherwise comply with requirements
- SARA title III section 313:	This product does not contain any substance subject to reporting requirements at or above deminimis quantities

International:

- WHMIS (Canada)	Not a "controlled product" under the Canadian Workplace Hazardous Materials Information System (WHMIS)

16- Other information:

See technical data sheet

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