Environmental Assessment

1. Date October 17, 2014

2. Name of Submitter Nalco, an Ecolab Company

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4. Description of the Proposed Action

a. Requested Action

The purpose of this food-contact notification is to seek clearance for the use of Nalco's food-contact substance (FCS), glyoxalated anionic polyacrylamide resin (CAS Reg. No. 65505- 03-5), as a dry strength, wet strength, dewatering, and drainage additive for food-contact paper. The food-contact substance is similar to those identified in effective food-contact notifications 871, 979, and 1277. Although the glyoxalated anionic polyacrylamide resin, itself, remains substantively with the treated paper through use and disposal, the resin contains residual water-soluble monomers that are not incorporated into the paper, but instead are lost during the sheet-forming operation. These monomers (glyoxal) comprise more than 5% of the polymer on a solids basis.

b. Need for Action

The FCS is applied prior to the sheet-forming operation at a maximum concentration of 1 wt%, on a polymer basis, of the finished paper or paperboard. It is intended to increase both the dry and wet strength and drainage and dewatering efficiency of paper and paperboard. Paper products treated with the FCS are intended for use in contact with all foods under FDA's Conditions of Use A ("High temperature heat-sterilized (*e.g.*, over 212°F)") through H ("Frozen storage: Ready-prepared foods intended to be reheated in container at time of use"). We believe that a substantial amount of the monomers may be lost during paper processing. Thus, an EA is required.

c. Locations of use/disposal

The FCS is applied at the wet-end of the paper machine. The polymeric component of the FCS is expected to be retained by the paper fibers during paper production and through use and disposal of the finished paper and paperboard. The polymer component comprises much less than 5% of the finished food-contact article.

Food-contact articles made with paper containing the FCS will be utilized in patterns corresponding to the national population density and will be widely distributed across the country. Therefore, it is anticipated that disposal will occur nationwide, with about 80% of the materials ultimately being deposited in land disposal sites, and about 20% incinerated.[1] The types of environments present at and adjacent to the disposal locations are the same as for the disposal of any other food-contact material in current use. Consequently, there are no special circumstances regarding the environment surrounding either the use or disposal of food-contact paper prepared using the FCS.

Residual monomeric components of the FCS are expected to travel mainly with the paper mill whitewater. Environmental exposure to the monomeric components may occur following treatment of the white water in an onsite water treatment facility and subsequent release to, and treatment by, a publically owned treatment works (POTW).

5. Identification of Substances that are the Subject of the Proposed Action

a. Chemical Abstracts Service Name

2-Propenoic acid, polymer with ethanedial and 2-propenamide

b. Registry Number

65505-03-5

c. Trade or Common Name

Glyoxalated Anionic Polyacrylamide

d. Other Chemical Names

Acrylamide, acrylic acid, glyoxal polymer

e. Empirical Formula

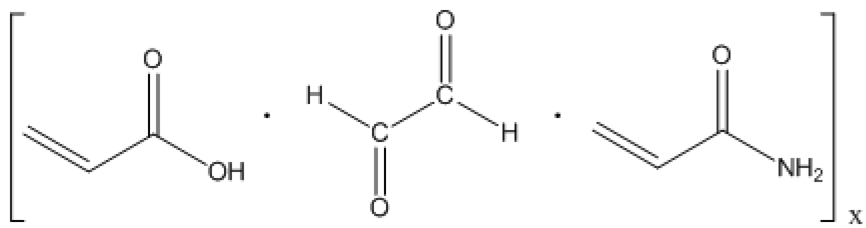
$(C_3H_5NO \cdot C_3H_4O_2 \cdot C_2H_2O_2)_x$

f. Molecular Weight

760-1700 kDa

g. Structure

[1] United States Environmental Protection Agency - *Municipal Solid Waste Generation, Recycling, and Disposal in the United States: Facts and Figures for 2012, http://www.epa.gov/osw/nonhaz/municipal/pubs/2012_msw_fs.pdf*

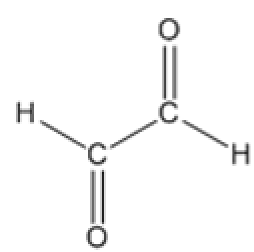
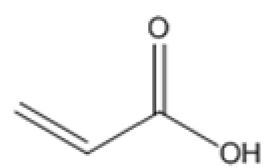
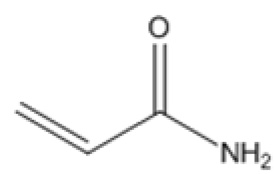


CAS# 79-10-7 CAS# 107-22-2 CAS#79-06-1

h. Physical Description

Clear to hazy, light yellow to yellow liquid (as 8% solids solution).

Residual monomers:

Glyoxal ($C_2H_2O_2$) 58 Da 107-22-2	Acrylic acid ($C_3H_4O_2$) 72 Da 79-10-7	Acrylamide (C_3H_5NO) 71 Da 79-06-1
		

6. Introduction of substances into the environment

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

There exist no extraordinary circumstances with respect to the manufacture of the food contact substance that would result in the introduction of the substance into the environment. This statement was made because it is expected that materials, e.g. paper scraps, will be disposed in accordance with established procedures. Therefore there are no environmental impacts expected as a result of the manufacture of the FCS.

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

Formulated products (~8% solids in water) containing the FCS and residual monomers is dosed into the wet-end of the paper machine at a rate of 13.7 wt% of dry weight fiber. Due to the reactivity of the FCS, it is expected to bind to, and be substantively retained by, the paper fibers. Consequently, no significant introductions of the FCS into the environment at the site of its use are expected.

The residual monomers are water soluble and therefore are not expected to be retained by the paper. The residual monomers are expected to travel mainly with the paper mill whitewater. The concentration of glyoxal in the white water may be estimated using standard assumptions

to be less than 6.2 ppm.[2] Because water is required for many purposes in a paper mill other than carrying pulp and additives, the estimated worst-case Environmental Introduction Concentration (EIC) for this proposed use of glyoxal would be much less than the amount estimated in Appendix D. Although cooling water may be discharged separately, cleaning and pulping water would be treated along with the white water in an onsite waste water treatment facility prior to release to the POTW (Publicly Owned Treatment Works) or to surface water. A mill-dependent dilution factor may be applied here depending on the types of operations employed at the mill, *e.g.*, the extent of water recycling that is performed, and whether the mill employs a pulping operation.

Disposal of paper articles is expected to be via landfilling and incineration. Incineration of food contact articles containing the FCS completely destroys the FCS, releasing carbon, nitrogen oxides. The FCS will compete with or replace, what is already currently used in industry. In light of the Environmental Protection Agency's (EPA) regulations governing municipal solid waste landfills (40 CFR Part 258) and MSW combustion units (40 CFR Part 60), we do not expect an increase of or significant introductions of FCS into the environment from the use and disposal of paper articles. Furthermore, we do not expect that the FCS will impact on the recyclability of treated paper.

7. Fate of substances released into the environment

Physical/chemical properties

Monomer	Glyoxal[3]	Acrylic Acid[4]	Acrylamide[5]
Log $K_{o/w}$	-0.85	0.36	-0.67 (estimated)
Water solubility	Miscible	>10 g/L at 20 ° C	2155 g/L at 30 ° C
Vapor Pressure (40% aqueous solution)	< 10^{-4} kPa	0.427 kPa	9.33×10^{-4} kPa at 20 ° C
Henry's law constant	≤3.38×10^{-4} Pa·m^3/mol @ 25° C	0.032 Pa m^3/mol @ 25 ° C	3.06×10^{-3} Pa m^3/mol
K_{oc}	2.1 liters/kg	Not applicable due to ionization	No significant adsorption
Fugacity (Air, Water, Soil/Sediment)	0.0751%, 38%, 61.8711%	2.8%, 40%, 57.1714%	0.0368%, 33.4%, 66.5692%

a. Air

2 The specifics of this estimate are provided in a confidential Addendum to this Environmental Assessment.

3 World Health Organization 2004, Glyoxal, *Concise International Chemical Assessment Document*, 57, International Programme on Chemical Safety II.

4 http://www.epa.gov/chemfact/s_acrlac.txt

5 http://www.epa.gov/chemfact/s_acryla.txt

No significant effect on the concentrations of and exposure to glyoxal in the atmosphere are anticipated due to the proposed production, use, and disposal of the FCS.

The subject FCS is transported and fed via closed systems. This eliminates any possible environmental introductions during these periods. In addition, the Henry's Law constant for glyoxal indicates that glyoxal does not volatilize easily from aqueous solutions such as Nalco's formulated product or paper mill process water. Glyoxal also undergoes photolytic decomposition with a measured 5 hour lifetime in sunlight. Hence, glyoxal will rapidly decompose in this environmental compartment. Similar to glyoxal, EPA estimated that acrylamide has a half-life of 6.6 h mostly due to photochemical activities[6]. Due to the high solubility of acrylamide, its volatilization from air is unlikely. The half-life of acrylic acid due to photochemical reactions is also estimated to be 6.6 hrs.[7] Therefore, the expected environmental concentration (EEC) of glyoxal in air due to the proposed use of the subject FCS would be expected to be negligible.

b. Soil and Water

No significant effect on the concentrations of and exposure to glyoxal in soil and water are anticipated due to the proposed production, use, and disposal of the FCS.

Glyoxal is very soluble in water and partitions well between soil organic carbon and water. Therefore, soil and water are the predominant target compartments for glyoxal. However, glyoxal rapidly decomposes photolytically. Its decomposition is also catalyzed by hydroxyl radicals and hydroxide ions. In addition, biodegradation tests indicate that glyoxal is readily biodegradable in both soil and water, and would therefore not be expected to persist or to accumulate above background levels.[8] Because glyoxal is endogenously produced during normal cellular metabolism by a multitude of enzyme independent pathways, there also exist a large number of microbial enzymes that catalyze the transformation of glyoxal to common intermediates in microbial catabolism.[9] Application of FDA's default 10-fold dilution factor for POTWs results in an EEC of less than 0.75 ppm (much less compared to the toxic levels) even before considering depletion due to microbial and abiotic degradation during treatment at the mill and again at the POTW.

Thus, we conclude that the use of the FCS as proposed in the notification will not be expected to alter normal background levels of glyoxal in soil or water, which is in consensus with the opinions from the Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers (SCCNFP).[10]

6 US EPA. 1994. Chemicals in the environment: acrylamide. EPA-749-F-94-005. Washington D. C.

7 GEMS: Graphical Exposure Modeling System FAP Fate of Atmos Pollut (1986).

8 OECD SIDS, Glyoxal, UNEP Publications. http://www.inchem.org/documents/sids/sids/107222.pdf

9 European Commission Health & Consumer Protection Directorate Scientific Committee on Consumer Products (SCCP), Opinion on Glyoxal, adopted during the 4th plenary of June 21, 2005 (SCCP/0881/05).

10 http://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_023.pdf

Under arobic conditions with high acrylamide content (e.g. 25 mg/kg), its half-life was estimated to be 18-45 hrs. Anaerobic conditions resulted in longer half-life.[11] In contrast to high acrylamide condition; EU risk assessment report estimated the half-life for the degradation of acrylamide in soil to be 30 days (mostly anaerobic). This report has reviewed a list of studies in acrylamide biodegradation, which specified acrylamide as readily biodegradable.[12]

Acrylic acid is also readily biodegradable, with more than 75% degraded after 8 weeks incubation under anaerobic conditions[13] and more than 80% degraded (to CO_2) after 22 days under aerobic conditions.[14]

To calculate the Estimated Environmental Concentrations (EEC), we used a dilution factor of 10, based on a study supported by the National Council for Air and Stream Improvement (NCASI)[15]. Therefore, EEC can be calculated as:

EEC = Expected Introduction Concentrations (EIC)/10 (dilution factor)

Monomer	EIC/ppm	EEC/ppm
Glyoxal	< 7.5	< 0.75
Acrylic Acid	< 0.01	< 0.001
Acrylamide	< 0.002	< 0.0002

The dilution factor is set as 10 in the calculation of EEC[15]. The calculated EICs for acrylic acid and acrylamide are below 0.001 ppm with the exact values included in Appendix A.

If any residual acrylamide and acrylic acid present in the product were released to the environment, the calculated EEC is negligible (refer to Appendix A- confidential information) compared to the ecotoxicity endpoints; therefore, acrylamide and acrylic acid would not cause any significant adverse effects on the environment.

8. Environmental effects of released substances

The following ecotoxicity summary was taken from the World Health Organization's Concise International Chemical Assessment Document (CICAD) Publication 57 for Glyoxal (2004), which may be found at the following URL:
http://whqlibdoc.who.int/publications/2004/924153057x.pdf.

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[11] Lande SS, Bosch SJ, and Howard PH. 1979. Degradation and leaching of acrylamide in soil. Journal of Environmental Quality, 8(1), 133-137.

[12] EU, 2000. Risk assessment of acrylamide (draft for peer review prepared by the UK Health and Safety Executive).

[13] Shelton DR, Tiedje JM. 1984. Appl Environ Microbiol 47: 850-7.

[14] Chou WL et al., 1978. Biotech Bioeng Symp 8: 391-414.

[15] EA for FCN 1272, Kemira Chemicals, Inc, dated Apr 8th, 2013.

Aquatic and Terrestrial Toxicity of Glyoxal

Species Tested (Reported test method)	End-point (effect)	Concentration (mg/liter)	Reference
Bacteria			
Pseudomonas putida (inhibition of cell multiplication)	16-h EC_{10}	46	Hoechst AG (1989)
	16-h EC_{50}	134	--
	196-h EC_{100}	389	--
Pseudomonas putida (inhibition of respiration)	EC_0	500	Gerike & Gode (1990)
Photobacterium phosphoreum (inhibition of bioluminescence)	5-min EC_{50}	755 ± 55	Chou & Que Hee (1992)
	15-min EC_{50}	554 ± 34	--
	25-min EC_{50}	429 ± 26	--
Anaerobes (not characterized) (inhibition of gas formation)	24-h-EC_0	200	Hoechst AG (1984f)
	24-h EC_{50}	625	--
Algae			
Pseudokirchneriella subcapitata (formerly Selenastrum capricornutum) (inhibition of growth)	96-h EC_{50}	149	Bollman et al. (1990)
Invertebrates			
Daphnia magna (water flea) (no details given)	24-h EC_{50}	430	OECD (1992)
Vertebrates			
Brachydanio rerio (zebra danio) (no details given)	24-h LC_{50}	1200	Hoechst AG (1991b)
	48-h LC_{50}	760	--
Leuciscus idus melanotus (orfe) (no details given)	48-h LC_{50}	>680	BUA (1997)
	96-h LC_{50}	460-680	--

Species Tested (Reported test method)	End-point (effect)	Concentration (mg/liter)	Reference
Pimephales promelas (fathead minnow) (mortality)	24-h LC_{50}	550	Conway et al. (1983)
	48-h LC_{50}	230	--
	96-h LC_{50}	215	--
Rhombus maximus (turbot) (mortality, abnormal behavior)	48-h EC_{50}	>500	Hoechst AG (1990)
	96-h EC_{50}	>500	--
Plants			
Helianthus tuberosus (Jerusalem artichoke) (inhibition of rhizome fragment proliferation)	EC_{30}	136	BUA (1997)
	NOEC	68	--

As discussed in Item 7 above and Appendix A, the maximum concentration at which the glyoxal is expected to enter the environment (EEC) can be estimated to be well below 0.62 ppm. The minimum measure of toxicity presented in the table above, the 16-hour EC_{10} for the inhibition of cell multiplication of *Pseudomonas putida*, is 46 parts per million (ppm). Thus, there exists a 100-fold margin of exposure, even before accounting for biotic and abiotic depletion mechanisms.

Due to the very low expected environmental concentration, and the fact that cellular organisms have very efficient enzymatic processes for metabolizing glyoxal, it may be concluded that production and use of the FCS will not lead to adverse environmental effects.

Aquatic and Terrestrial Toxicity of Acrylic acid

Species Tested (Reported test method)	End-point (effect)	Concentration (mg/liter)	Reference
Algae			
Chlorococcales (inhibition of assimilation efficiency)	24 hr EC50	118	Krebs, F., 1991
Invertebrates			
Daphnia magna (water flea) (immobilization rate)	24 hr LC50	270	Bringmann, G., and R. Kuhn, 1977
Brachionus calyciflorus (rotifer) (inhibition of reproduction)	48 hr EC50	27.9 (2.5-53)	Radix, P., 1999
Vertebrates			

Species Tested (Reported test method)	End-point (effect)	Concentration (mg/liter)	Reference
Leuciscus idus ssp. Melanotus (carp) (mortality)	48 hr LC50	315	Juhnke, I., and D. Luedemann, 1978

Acrylic acid is readily biodegradable, and can also go through hydrolysis and photooxidation.[16] Studies showed that acrylic acid would not persist in soil.[17] Based on the ecotoxicity endpoints above compared to the calculated environmental concentration (EEC) (refer to Appendix A-confidential information), we conclude that acrylic acid would not pose significant adverse impacts on the environment.

Aquatic and Terrestrial Toxicity of Acrylamide

Species Tested (Reported test method)	End-point (effect)	Concentration (mg/liter)	Reference
Invertebrates			
Daphnia magna (water flea) (behavioral changes)	48 hr EC50	98	Krautter, G.R., 1986
Aericamysis bahia Opossum Shrimp (mortality)	96 hr LC50	29.91 (24.49-36.53)	Carr, R.S., 1987
Gammarus pseudolimnaeus (mortality)	96 hr LC50	55.4 (40.3-76)	Brooke, L., 1987
Vertebrates			
Heteropneustes fossilis (Indian catfish) (mortality)	48 hr LC50	86.81 (80.06-94.15)	Shanker, R., and P.K.Seth, 1986
Lepomis macrochirus (Blue gill sunfish) (behavioral changes)	96 hr EC50	85	Krautter, G.R., 1986
Pimephales promelas (Fathead minnow) (behavioral changes)	96 hr EC50	86	Krautter, G.R., 1986

16 http://echa.europa.eu/documents/10162/05ecf0b5-6529-44e1-870f-5644a8f9cb19

17 2-Propen-1-aminium, N,N-dimethyl-N-2-propenyl-, chloride, (CAS No. 7398-69-8), High Production Volume Information System, U. S. Environmental Protection Agency. http://ofmpub.epa.gov/oppthpv/quicksearch.display?pChem=101980

9. Use of resources and energy

The production and use of the FCS will be similar to cationic Glyoxalated polyacrylamide (Cationic GPAM), which are authorized for the same use. Therefore, we do not anticipate any increase in the amount of energy and resources required in the process. In addition, there should be no effect on the recyclability of paper materials, which is based on the fact that FCS treatment of a paper sheet will not develop permanent wet strength that prevents it from being re-pulped and reused to make paper. It has been suggested that GPAM forms labile bonds and this polymer is not used to make paper with permanent wet strength.[18] Therefore, the use of GPAM will have no impact on the recyclability of paper materials.

10. Mitigation measures

No adverse environmental effects have been identified. Therefore, there is no need to discuss mitigation measures.

11. Alternatives to the proposed action:

No adverse environmental effects have been identified. The alternative of not approving the action proposed would result in the continued use of nearly identical products by paper industry; such action would have no environmental impact.

12. List of Preparers:

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Sr. Manager- WPS Business Partner & Regulatory Group Leader, Global Regulatory Affairs, Nalco, an Ecolab Company (7 years' toxicology and risk assessment experience)

Certification:

The undersigned official certifies that the information presented is true, accurate, and complete to the best knowledge of Nalco, An Ecolab Company.

17 Oct 2014
(Date)

(Signature of responsible official)

Mark Muellner, Ph.D., Senior Manager and WPS Group Leader
(Name and title of responsible official, printed)

References:

1. United States Environmental Protection Agency - *Municipal Solid Waste Generation, Recycling, and Disposal in the United States: Facts and Figures for 2012, http://www.epa.gov/osw/nonhaz/municipal/pubs/2012_msw_fs.pdf*

2. The specifics of this estimate are provided in a confidential Addendum to this Environmental Assessment.

3. World Health Organization 2004, Glyoxal, *Concise International Chemical Assessment Document*, 57, International Programme on Chemical Safety II.

4. http://www.epa.gov/chemfact/s_acrlac.txt

5. http://www.epa.gov/chemfact/s_acryla.txt

6. US EPA. 1994. Chemicals in the environment: acrylamide. EPA-749-F-94-005. Washington D. C.

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14. http://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_023.pdf

15. EA for FCN 1272, Kemira Chemicals, Inc, dated Apr 8th, 2013.

16. http://echa.europa.eu/documents/10162/05ecf0b5-6529-44e1-870f-5644a8f9cb19

17. 2-Propen-1-aminium, N,N-dimethyl-N-2-propenyl-, chloride, (CAS No. 7398-69-8), High Production Volume Information System, U. S. Environmental Protection Agency. http://ofmpub.epa.gov/oppthpv/quicksearch.display?pChem=101980

18. Handbook of Pulping and Papermaking (Second Edition), edited by Christopher J. Biermann, Academic Press, San Diego, 1996, Page x, ISBN 9780120973620

Attachment to FCN

Appendix A – Confidential Addendum to the Environmental Assessment for Glyoxalated Anionic Polyacrylamide

Appendix B- Confidential information on BFV and residual glyoxal method

Appendix C- Confidential information on measurement details of Acrylic Acid and Acrylamide