ATTACHMENT 13: ENVIRONMENTAL ASSESSMENT (EA)

1. Date: September 26, 2018

2. Name of Applicant/Notifier: SNF SAS

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4. Description of the Proposed Action

a. Requested Action

The purpose of this food contact notification (FCN) is the establishment of a clearance to permit the use of the food contact substance (FCS) specifically described as 2-Propen-1-aminium, N,N-dimethyl-N-2-propen-1-yl-, chloride (1:1), polymer with ethanedial and 2-propenamide, identified by CAS No. 32555-39-8, as a dry or wet strength agent employed prior to the sheet-forming operation in the manufacture of paper and paperboard. The paper and paperboard manufactured using the FCS is intended for use in producing, manufacturing, packaging, processing, preparing, treating, packing, transporting, or holding aqueous and fatty foods. The FCS, commonly referred to as glyoxylated cationic polyacrylamide resin, is the same FCS submitted in FCNs previously reviewed and approved by FDA in FCNs 871, 979, 1272, 1277, 1285 and 1553. This notification would be substitutional for existing regulated products by CFR and FCNs.

Although the glyoxalated cationic polyacrylamide resin, as a result of the paper and paperboard manufacturing processes, will remain substantively incorporated into and as a

component of finished paper and paperboard through use and disposal activities, the FCS contains residual water-soluble monomers which are not substantive and are, therefore, not incorporated into the finished paper or paperboard, but instead, will be lost during the sheet-forming operations at paper mills.

b. Need for Action

The FCS is applied prior to the sheet-forming operation at a maximum concentration of 0.5 % by weight of dry fibers in the finished paper or paperboard. It is intended to increase both the dry and wet strength 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-H) as prescribed at 21 CFR 176.170 (c), Table 2.

c. Locations of use/disposal

It should be noted that the FCN submitter is not a manufacturer of paper and/or paperboard. Rather, the FCN submitter intends to manufacture and sell the FCS to paper and paperboard manufacturers that will employ the FCS as an additive at the wet end of the paper and paperboard manufacturing processes. The FCS is retained by (adsorbed onto) the paper fibers during paper production and remains so up through the use and disposal of the finished paper and paperboard. The polymer component comprises less than 0.5% of the finished food contact article.

Food-contact paper and paperboard products 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 of such products will occur nationwide, with approximately 25.6% of the materials being recycled and the rest ultimately being deposited in land disposal sites or being incinerated (U.S. Environmental Protection Agency[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.

[1] *Advancing Sustainable Materials Management:* 2014 Tables and Figures (Assessing Trends in Material Generation, Recycling, Composting, Combustion with Energy Recovery and Landfilling in the United States, December 2016.) Table 5 - Paper and Paperboard Products in MSA, 2014 (Subtotal Containers and Packaging excluding Corrugated Boxes).

Residual amounts of the monomers used to manufacture the FCS are expected to be present in and travel mainly with the paper mill whitewater. Environmental exposure to the residual monomers may occur following treatment of the white water in an onsite water treatment facility and subsequent release to, and treatment by, a publicly owned treatment works (POTW).

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

a. Chemical Abstracts Service (CAS) Name

2-Propen-1-aminium, N,N-dimethyl-N-2-propen-1-yl-, chloride (1:1), polymer with ethanedial and 2-propenamide

b. CAS Registry Number

32555-39-8

c. Trade or Common Name

Glyoxalated Cationic Polyacrylamide

d. Other Chemical Names

Diallyldimethylammonium chloride polymer with acrylamide, reaction products with glyoxal

DADMAC, polymer with acrylamide and glyoxal

e. Empirical Formula

Variable (depending on monomer ratios)

f. Molecular Weight

Mn = $1.2*10^6$ g/mol; Mw = $4.1*10^6$ g/mol (Based on AUC)

g. Molecular formula

$[(C_8H_{16}NCl)_x \cdot (C_2H_2O_2)_y \cdot (C_3H_5NO)_z\ ]_n$

h. Physical Description

Clear to slightly hazy liquid (as 7.5% solution).

i. Residual monomer levels (maximum)

Monomer	CASRN	ppm	% (w/w)
2-Propenamide *Other name(s): Acrylamide*	79-06-1	<500	<0.05
2-Propen-1-aminium, N,N-dimethyl-N-2-propen-1-yl-, chloride (1:1) *Other name(s): Diallyldimethylammonium chloride, (DADMAC)*	7398-69-8	<100,000	< 10%
Ethanedial *Other name(s): Glyoxal*	107-22-2	<10,000	<1.0

6. Introduction of Substances into the Environment

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

At 21 CFR 25.40(a), it is stated, in part, that an "EA shall focus on relevant environmental issues relating to the use and disposal from use of FDA-regulated articles" rather than the production of FDA-regulated articles. Sites that will manufacture the FCS for sale to, and use by, the manufacturers of food contact paper and paperboard are required to manufacture the FCS in compliance with specific local, state, and Federal regulations. In light of this, the Notifier is not aware of any information to suggest that there are any extraordinary circumstances indicative of any adverse environmental impact that will result from the manufacture of the subject FCS. Consequently, information on the manufacturing site and compliance with relevant emissions requirements is not provided here.

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

Wastewater

Paper processors are among those industries required by EPA to meet industry specific effluent

pretreatment standards.[2] Therefore, the waste process water containing the FCS and the residual monomers present with the FCS are expected to be disposed of through the processing plant's onsite wastewater treatment facility before discharge either to surface waters under National Pollution Discharge Elimination System (NPDES) permitting or to a publicly-owned treatment works (POTW).

The FCS will be introduced into paper and paperboard manufacturing processes prior to the sheet-forming stage. The FCS will be supplied to paper mills as an aqueous solution (7.5% w/w) and will be dosed into the wet-end of the paper and paperboard manufacturing process at a rate of 0.5% by weight of dry fibers in the finished paper and paperboard. The FCS is designed to become totally incorporated and remain bound within the finished paper and paperboard. The potential of the paper slurry to retain the FCS is, in fact, much higher than the currently solicited use rate. Consequently, the Notifier does not expect that significant concentrations of the FCS will be released to the environment from the paper mills at which the FCS will be used in food contact paper and paperboard manufacturing operations. The basis for the Notifier's conclusion in this regard is provided and discussed in greater detail in the confidential Appendix to the EA.

The residual monomers, namely Acrylamide, Glyoxal, and DADMAC, are not expected to be retained by the paper and are expected to become components in the paper mill whitewater that will be sent to the on-site wastewater treatment facilities at paper mills.

The Environmental Introduction Concentrations (EICs) and Expected Environmental Concentrations (EECs) of the residual monomers can be calculated based on the following 'worst-case' assumptions:

• Maximum use level of 5 kg of FCS per metric ton (MT) of dry paper/board which translates to 66.7 kg of FCS based on an active concentration of 7.5% FCS as supplied (5 kg dosed ÷ 7.5% FCS = 66.7 kg),

• 100 cubic meters wastewater is generated per metric ton finished paper/paperboard[3], and

[2] See https://www3.epa.gov/npdes/pubs/pretreatment_program_intro_2011.pdf and see table of regulated industries at http://www.epa.gov/eg/industrial-effluent-guidelines

[3] The value of 100 cubic meters wastewater is a calculation of wastewater to be treated. Since the concentration of the pulp in the headbox is 1% v/v, there is 100 times more water than pulp.

• A 10-fold dilution of the wastewater containing the residual monomers occurs following on-site treatment at the paper mill at the time the treated wastewater is discharged to surface waters.[4]

Based on the above conservative assumptions, the EIC and EEC of each of the 3 residual monomers can be calculated as follows and are as shown below:

EIC (ppb) = $Conc.\ in\ \ product(\frac{mg}{kg})$ X $dosage(\frac{kg}{MT\ dry\ paper})$ X $\frac{1\ MT\ dry\ paper}{100\ m3\ wastewater}$ X $\frac{1\ m3\ water}{1000\ kg\ water}$ X $\frac{1000\ ppb}{1\ ppm}$

EEC (ppb) = EIC * 0.1

Residual monomer	Concentration in Product (mg/kg)	Dosage (kg/MT dry paper)	EIC (ppb)	EEC (ppb)	EEC (ppm)
Acrylamide (79-06-1)	500	67	335	33.5	0.03
DADMAC (7398-69-8)	100,000	67	67,000	6,700	6.7
Glyoxal (107-22-2)	10,000	67	6,700	670	0.7

Because water is required for many purposes in a paper mill other than carrying pulp and additives, the estimated worst-case EICs for this proposed use of the FCS would be less than the amount estimated above. Although cooling water generated at paper mills may be discharged separately, cleaning and pulping water would be treated along with the white water at an onsite wastewater treatment facility prior to release to the POTW or to surface water. A mill dependent dilution factor may also 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.

Additionally, as the subject FCS is intended to compete with, and replace, other Acrylamide/DADMAC copolymers already authorized for use as dry and wet strength additives in the manufacture of food contact paper and paperboard (21 C.F.R. § 176.170: "Components of paper and paperboard in contact with aqueous and fatty foods", and

[4] Rapaport, R.A., 1988. Prediction of consumer product chemical concentrations as a function of publicly owned treatment works treatment type and riverine dilution. Environmental Toxicology and Chemistry 7:107-115.

effective FCNs 871, 979, 1272, 1277, 1285 and 1553), no new environmental introductions of Acrylamide or DADMAC are expected as a result of this notification becoming effective.

Solid Wastes

Solid wastes, including disposal by users of paper products generated with the FCS, are expected to be disposed of by either landfill or incineration. The residual monomers are not expected to be present in finished paper and paperboard.

Landfill

In light of EPA's regulations governing municipal solid waste landfills, only extremely small amounts, if any, of the FCS is expected to enter the environment as a result of the landfill disposal of finished articles containing the FCS. EPA's regulations require new municipal solidwaste landfill units and lateral expansions of existing units to have composite liners and leachate collection systems to prevent leachate from entering ground and surface water, and to have groundwater monitoring systems. (40 C.F.R. Part 258). Although owners and operators of existing active 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.

Combustion

The food contact substance consists of carbon, hydrogen, nitrogen, chlorine and oxygen, elements commonly found in municipal solid waste.

To calculate the potential environmental introduction of the FCS due to combustion of finished articles, we have assumed that available carbon in the FCS would be converted to carbon dioxide, that available nitrogen will be converted to nitrous oxide, and assumed that 100% of the market volume will be combusted.

There is the potential for greenhouse gas (GHG) emissions to result from the use and disposal of the FCS during the incineration of articles containing the FCS in MSW

combustion facilities. Such facilities are regulated by the EPA under 40 C.F.R. Part 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 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."

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

7. Fate of substances released into the environment

a. Physical/Chemical properties

Physical and chemical properties[5]			
	Acrylamide	**DADMAC**	**Glyoxal**
Log Pow	-0.67	-2.49 (estimated)	-1.66
Water solubility	6.4×10^5 mg/L	Miscible (estimated)	1×10^6 mg/L
Vapor pressure	0.007 mm Hg	None	255 mg Hg

[5] https://chem.nlm.nih.gov/chemidplus/

		Environmental fate and pathways		
		Acrylamide	**DADMAC**	**Glyoxal**
Henry's Law constant	atm-m^3/mol	1E-009[6]	7.20E-012[6]	3.33E-009[6]
Koc	L/kg	0.195[7]	0.5391[8]	2.1[9]
BCF	—	<1[7]	3.16[10]	3.2[10]
Biodegradation in 28 days	%	>70[11]	40-50 [12]	>70 [9]

b. Air

No significant effect on the concentrations of and exposure to any of the components of the FCS in the atmosphere are anticipated due to the proposed production, use, and disposal. The subject FCS is transported and fed via closed systems. This eliminates any possible environmental introductions during these periods. Further, no significant environmental inductions were identified above as a result of combustion of paper and paperboard manufactured with the FCS. In regard to the residual monomers, the Henry's Law constant for the residual monomers indicates that they do not volatilize easily from aqueous solutions such as SNF's formulated product or paper mill process water. In addition, due to their low vapor pressures and high water solubility, the movement of these monomers into the atmosphere is not anticipated. Therefore, no significant quantities of any substances will be release to the atmosphere upon the manufacture, use and disposal of finished articles manufactured with the FCS.

c. Land

Considering the factors discussed above, no significant effects on the concentrations of and exposure to any substances in terrestrial ecosystems are anticipated as a result of the proposed use of the subject FCS. As discussed above, EPA's regulations for new and expanding landfills require

[6] HENRYWIN v3.20 EPA
[7] *European Chemicals Bureau*, EU/OECD Risk Assessment Report https://echa.europa.eu/documents/10162/50218bf9-ba0f-4254-a0d9-d577a5504ca7
[8] *EPI Suite KOCWIN* gives 108.8 L/kg from MCI (Molecular Connectivity Index) and 0.5391 from Log Kow.
[9] OECD 2003. OECD SIDS Document for Glyoxal (CAS No. 107-22-2). UNEP Publications. *Available at* http://www.inchem.org/documents/sids/sids/107222.pdf.
[10] BCFBAF v3.01 EPA
[11] *United States Testing Co., Inc.* Modified OECD Test (Wang, Feb. 20, 1991)
[12] OECD 301 A (Schwarz, 1999)

implementing preventative measures to significantly reduce or eliminate leachate.

On these bases, there is no reasonable expectation of a significant impact on the concentration of any substance in the environment due to the proposed use of the FCS in the production of food contact paper and paperboard.

d. Water

The FCS is incorporated into and is retained in the finished paper and paperboard. Therefore, no significant effect on the concentrations of and exposure to the FCS in water or wastewater treatment sludges are anticipated due to the proposed production, use, and disposal. The residual monomers are very soluble in water and their presence in wastewater is anticipated.

Acrylamide

Acrylamide is expected to be quickly degraded in water by biological processes (Abdelmagid 1982; EPA 2006c; Haberman 2002; WHO 2003 *in Toxicological Profile for Acrylamide, US Dept. of Health and Human Services, Agency for Toxic Substances and Disease Registry, Dec.2012)*[13] Additionally, acrylamide is not expected to significantly bioconcentrate in aquatic organisms due to its high water solubility and its ability to be degraded by microorganisms (EPA 2006c; Haberman 2002; WHO 2003)[14]

DADMAC

According to assertions presented in the EPA High Production Volume Test Plan for Diallyldimethylammonium chloride, DADMAC is readily biodegradable.[15]

Glyoxal

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

[13] In Toxicological Profile for Acrylamide, US Dept. of Health and Human Services, Agency for Toxic Substances and Disease Registry, Dec. 2012. https://www.atsdr.cdc.gov/toxprofiles/tp203.pdf
[14] Ibid.
[15] Test Plan for Diallyldimethylammonium Chloride (DADMAC) [CAS No. 7398-69-81 DADMAC HPV COMMITTEE, 2004. https://www.heritagesystemsinc.com/Downloads/WhitePapers/DADMAC-Environmental-Fate.pdf

radicals and hydroxide ions. Biodegradation tests indicate that glyoxal also is readily biodegradable in both soil and water and would therefore not be expected to persist or to accumulate above background levels. 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.[16]

8. Environmental effects of released substances

Acrylamide

According to the SIDS data package for Acrylamide[17] the lowest 96-hour LC50 reported for fish is 100 mg/l (*Lepomis macrochirus*); the lowest 48-hour EC50 for invertebrates is 98 mg/l (*Daphnia magna*); and the lowest 72-hour EC50 for algal growth inhibition is 33.85 mg/l (*Selenastrum capricornutum*) (based upon a 72-hour EC50 of 67.7 mg/l for a 50% acrylamide solution). The calculated acrylamide EEC (0.03pm) is several orders of magnitude lower than these ecotoxicity endpoints. Therefore, no significant environmental impact is anticipated.

DADMAC

The LC50 at 72 hours for Bluegill Sunfish (*Lepomis macrochirus*) is 56 mg/liter (Johnson, 1971, as cited in Test Plan for Diallyldimethylammonium Chloride (DADMAC) [CAS No. 7398-69-81 DADMAC HPV COMMITTEE, 2004).[18] ECOSAR structure activity on DADMAC predicts fish, daphnid, and blue-green algae toxicity of 464,28 and 33 mg/L respectively.[19] The calculated EEC (6.7 ppm) for DADMAC is at minimum 4 to 5-fold lower than these endpoints. Thus, significant environmental impact resulting from DADMAC is not anticipated.

Glyoxal

[16] *European Commission. Health & Consumer Protection Directorate* – General. Directorate C – Public Health and Risk Assessment. C7 – Risk Assessment. Scientific Committee on Consumer Products (SCCP) Opinion on Glyoxal (Adopted during the 4th plenary of June 21, 2005) (SCCP/0881/05)

[17] *SIDS Initial Assessment Profile – Acrylamide:* http://webnet.oecd.org/Hpv/ui/handler.axd?id=c81f3f95-e5f8-4857-91af-4c76b9094edb

[18] https://www.heritagesystemsinc.com/Downloads/WhitePapers/DADMAC-Environmental-Fate.pdf

[19] Ibid.

According to the SIDS data package for glyoxal[20] the lowest LC50 (96-hour) reported for fish is 215 mg/l (*Pimephales promelas*); the lowest EC50 (48-hour) for invertebrates is 404 mg/l (*Daphnia magna*); the lowest EC50 (96-hour) for algal growth inhibition is greater than 500 mg/l (*Scenedesmus subspicatus*).

As discussed in Section 7 above and in the confidential Appendix to the EA, the maximum concentration at which the glyoxal is expected to enter the environment (EEC) can be estimated to be below 1 ppm. The minimum measure of toxicity presented in the table above, the 16-hour EC10 for the inhibition of cell multiplication of *Pseudomonas putida*, is 46 ppm. Thus, there exists a 46-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.

Most Sensitive LC/EC 50		
Monomer/EEC	**Result**	**Endpoint**
Acrylamide/0.03 ppm	33.85 mg/L	$EC50_{growth\ inhibition}$/ *Selenastrum capricornutum*/72 hours
Glyoxal/0.7 ppm	215 mg/L	EC50/*Daphnia magna*/48 hours
DADMAC/ 6.7 ppm	56 mg/L	LC50/*Lepomis macrochirus*/72 hr

9. Use of resources and energy

The production and use of the FCS will compete with, and to a greater or lesser degree, replace existing products that are authorized for the same use. Therefore, use of the FCS would not be expected to result in a net increase in the use of natural resources and energy.

10. Mitigation measures

No adverse environmental effects have been identified resulting from the manufacture, use and

[20] *OECD SIDS Glyoxal Initial Assessment Profile* (http://www.inchem.org/documents/sids/sids/107222.pdf)

disposal of the FCS itself or the food contact paper and board. Therefore, use of the FCS would not be expected to result in any environmental impacts requiring mitigation measures of any kind.

11. Alternatives to the proposed action:

No adverse environmental effects have been identified. Therefore, there is no need to discuss alternatives to the proposed action. The alternative of not approving the action proposed would result in the continued use of identical products by the paper industry. Such action would have no significant environmental impact.

12. List of preparers:

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Certification:

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

[redacted]

Signature of Responsible Official

Dennis Marroni,
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SNF Group
Name & Title of Responsible Official, Printed

Date: September 26, 2018

References

1. *Advancing Sustainable Materials Management:* 2014 Tables and Figures (Assessing Trends in Material Generation, Recycling, Composting, Combustion with Energy Recovery and Landfilling in the United States, December 2016.) Table 5 - Paper and Paperboard Products in MSA, 2014 (Subtotal Containers and Packaging excluding Corrugated Boxes).

2. https://www3.epa.gov/npdes/pubs/pretreatment_program_intro_2011.pdf and see table of regulated industries at http://www.epa.gov/eg/industrial-effluent-guidelines

3. *Rapaport, R.A., 1988*. Prediction of consumer product chemical concentrations as a function of publicly owned treatment works treatment type and riverine dilution. Environmental Toxicology and Chemistry 7:107-115.

4. https://chem.nlm.nih.gov/chemidplus/

5. *European Chemicals Bureau*, EU/OECD Risk Assessment Report for acrylamide, https://echa.europa.eu/documents/10162/50218bf9-ba0f-4254-a0d9-d577a5504ca7

6. *OECD SIDS Glyoxal Initial Assessment Profile* (http://www.inchem.org/documents/sids/sids/107222.pdf)

7. *United States Testing Co., Inc.* Modified OECD Test (Wang, Feb. 20, 1991)

8. OECD 301 A (Schwarz, 1999)

9. In Toxicological Profile for Acrylamide, US Dept. of Health and Human Services, Agency for Toxic Substances and Disease Registry, Dec. 2012. https://www.atsdr.cdc.gov/toxprofiles/tp203.pdf

10. Test Plan for Diallyldimethylammonium Chloride (DADMAC) [CAS No. 7398-69-81 DADMAC HPV COMMITTEE, 2004. https://www.heritagesystemsinc.com/Downloads/WhitePapers/DADMAC-Environmental-Fate.pdf

11. *European Commission. Health & Consumer Protection Directorate* – General.

Directorate C – Public Health and Risk Assessment. C7 – Risk Assessment. Scientific Committee on Consumer Products (SCCP) Opinion on Glyoxal (Adopted during the 4th plenary of June 21, 2005) (SCCP/0881/05)

12. *SIDS Initial Assessment Profile* – Acrylamide: http://webnet.oecd.org/Hpv/ui/handler.axd?id=c81f3f95-e5f8-4857-91af-4c76b9094edb

13. https://www.heritagesystemsinc.com/Downloads/WhitePapers/DADMAC-Environmental-Fate.pdf

Attachment

Confidential Attachment to the Environmental Assessment