Environmental Assessment

1.	**Date**	April 7, 2017
2.	**Name of Applicant**	Omya International AG and its Affiliates
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4. Description of Proposed Action

The action requested in this food contact notification (FCN) is to permit the use of the substance ethanol, 2-amino- (CAS Reg. No. 141-43-5) (hereinafter MEA, the food contact substance, or FCS) as a component of fillers or coatings for food-contact paper and paperboard, at a maximum rate in the finished paper of 0.041 wt-% for filler applications and 0.01 wt-% for coating applications. The FCS is not for use in contact with infant formula and human milk. Finished materials and articles containing the FCS may be used in single use applications, for contact with all types of food, under the Conditions of Use E through G as described in FDA's Tables 1 and 2.[1]

The FCS is intended for use as dispersion and flotation agent for calcium carbonate that is in turn used as a filler and coating during the paper manufacturing process. The processing benefits provided by the FCS results in increased brightness, opacity, and cost-efficiency.

Omya does not manufacture the paper pulp or paper and paperboard that could contain the FCS. Instead, Omya plans to market the FCS-containing calcium carbonate to paper and paperboard mills in the U.S. Finished articles containing the FCS are expected to be utilized in patterns corresponding to the national population density and widely distributed across the country. Therefore, it is anticipated that disposal will occur nationwide. According to the US Environmental Protection Agency's (EPA) 2014 update regarding municipal solid waste in the United States, which is the most recent data available, 64.7% of paper and paperboard materials in MSW were recycled, leaving 28.4% of paper MSW for disposal in landfills or elsewhere and 6.9% for combustion.[2] More detailed data is provided by EPA on the recycling, combustion, and landfilling specifically of containers and packaging.[3] These data indicate

[1] U.S. Food and Drug Administration, *Food Types & Conditions of Use for Food Contact Substances*, http://www.fda.gov/Food/IngredientsPackagingLabeling/PackagingFCS/FoodTypesConditionsofUse/ucm109358.htm.
[2] U.S. Environmental Protection Agency, Office of Resource Conservation and Recovery (5306P), *Advancing Sustainable Materials Management: 2014 Fact Sheet*, November 2016, pg. 8, Table 1. Available at: https://www.epa.gov/sites/production/files/2016-11/documents/2014_smmfactsheet_508.pdf.
[3] U.S. Environmental Protection Agency, Office of Resource Conservation and Recovery (5306P), *Advancing Sustainable Materials Management: 2014 Tables and Figures*, December 2016, pg. 9, Table 5. Available at: https://www.epa.gov/sites/production/files/2016-11/documents/2014_smm_tablesfigures_508.pdf.

that 25.6% are recycled and of the remaining generated waste, 14.6% (1,260 of 8,640 thousand tons generated) was combusted and 59.8% (5,170 of 8,640 thousand tons generated) was landfilled.[4]

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

The FCS is ethanol, 2-amino- (CAS Reg. No. 141-43-5), with a chemical formula of (C_2H_7NO) and the following structure:

The FCS is intended for use as dispersion and flotation agent for calcium carbonate that is in turn used as a filler and coating during the paper manufacturing process. The typical physical and environmental properties for MEA are as follows:

Property	**Value**[5]
Appearance	Colorless, viscous liquid[a]
pH	12.1[b]
Melting point	10.4°C (50.7°F)[b]
Boiling Point	170.3°C (338.5°F)[b]
Vapor Pressure	0.5 hPa at 20°C[a]
Water Solubility	1 x 10^6 mg/L at 25°C[b]
Octanol-Water Partition Coefficient	Log P_{ow} −1.31 - −2.3[ab]
Acid Dissociation Constant	pKa 9.5 at 25°C[b]
Henry's Law Constant	0.00000963 Pa.m³/mol at 25 °C and pH 7[a]
Soil Mobility Partition Coefficient	K_{oc} 0.59[c]
Atmospheric Half-Life	3.6 hours[c]

5. Introduction of Substances into the Environment

a. Introduction of Substances into the Environment as a Result of Manufacture

Under 21 C .F.R. § 25.40(a), an environmental assessment ordinarily should focus on relevant environmental issues relating to the use and disposal from use, rather than the production, of FDA-regulated articles. The FCS is not manufactured by Omya, but rather is purchased from a supplier. The FCS may be manufactured in plants both inside and outside of the United States. When manufactured in the U.S., the plants meet all applicable federal, state and local environmental regulations. The

[4] Id.

[5] Values marked with "a" are sourced from OECD SIDS Initial Assessment Profile, *2-Aminoethanol* (15-17 October 2013), p. 3 http://webnet.oecd.org/Hpv/UI/handler.axd?id=27d71248-4be0-45ad-81bc-069b0fe7839c; "b" values are from HSDB, entry for 2-aminoethanol, select "Chemical/Physical Properties" in the Table of Contents, https://toxnet.nlm.nih.gov/cgi-bin/sis/search2/r?dbs+hsdb:@term+@rn+@rel+141-43-5; "c" values are from HSDB entry for 2-aminoethanol, select "Environmental Fate & Exposure" in the Table of Contents.

Notifier asserts that there are no extraordinary circumstances that would indicate the potential for adverse environmental impacts resulting from the manufacture of the FCS such as: 1) unique emission circumstances not adequately addressed by general or specific emission requirements (including occupational) promulgated by Federal, State or local environmental agencies where the emissions may harm the environment; 2) the proposed action threatening a violation of Federal, state or local environmental laws or requirements (40 C.F.R. § 1508.27(b)(10)); or 3) production associated with a proposed action may adversely affect a species or the critical habitat of a species determined under the Endangered Species Act or the Convention on International Trade in Endangered Species of Wild Fauna and Flora to be endangered or threatened, or wild fauna or flora that are entitled to special protection under some other Federal law. 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

The FCS is intended for use as dispersion and flotation agent for calcium carbonate that is in turn used as a filler and coating during the paper manufacturing process. Omya does not manufacture the paper pulp or paper and paperboard that could contain the FCS. Instead, Omya plans to market the FCS-containing calcium carbonate to paper and paperboard mills in the U.S. Potential environmental exposure would occur during paper processing and when the paper and paperboard products themselves (as packaging) are disposed by the user.

Waste Water:

We will assume that all of the FCS used in the filler application will enter the facility waste water processing system. Effluent from the pulp and paper processing will be treated via waste water treatment facilities before release into the environment.[6] The FCS is highly soluble in water, and based on the low K_{oc} is not expected to significantly adsorb to sewage sludge. A low Henry's Law constant (9.63×10^{-6} Pa.m^{3}per mol) indicates the FCS would not be expected to volatilize from water surfaces.[7] Additionally, as the FCS lacks functional groups that hydrolyze under environmental conditions (pH 5 to 9), hydrolysis is not expected.[8] MEA has been shown in several studies to be readily biodegradable, with degradation determined to be over 95% after 4 days.[9]

The intended technical effect of the MEA is to increase dispersion of the calcium carbonate filler added to food contact paper in order to increase brightness and opacity. A major application is in the production of bleached paper products.[10] Bryant, *et al*. have analyzed water use in paper and

[6] Water-discharging facilities producing pulp, paper, and paperboard are subject to the US Environmental Protection Agency's effluent guidelines and standards under the Clean Water Act, at 40 C.F.R. Part 430.
[7] OECD SIDS, p. 3.
[8] Id.
[9] Id.
[10] Grönfirs, J., *Use of Fillers in Paper and Paperboard Grades*, Final Thesis, Tampere University of Applied Sciences (May 2010), pp. 23-25, https://theseus.fi/bitstream/handle/10024/16226/Gronfors_Jarkko.pdf?sequence=1, which discusses the types of cartonboard typically used in food contact applications and identifies them primarily as using bleached chemical pulp.

paperboard production based on process and product type.[11] Although this reference does not specifically address the production of food contact paper, it does report information on the water use in various types of mills, including integrated pulp and paper mills, bleached kraft market pulp mills, and paper mills producing more and less than 100 tons paper/day.[12] The reported median water use levels for these types of facility (in thousand of gallons per short ton) are 22.9, 23.0, 3.6 and 12.0, respectively.[13] The report notes that specialty grade mills may have very high water use relative to other mills in their category,[14] which would include some mills producing food contact papers. In describing the water consumption rate data for paper mills producing greater than 100 air-dried short tons (ADST) per day, Bryant, et.al state, "[of] the 11 categories analyzed, mills producing paper and board with production rates greater than 100 tons/day had the lowest median water use at 3,600 gallons/ton." The histogram for this mill category (Fig. 3) shows that 14% of mills in this category (218 x 14% = 31 mills) use less than or equal to 1,000 gal/ton and 54% of these mills (218 x 45% = 118 mills) use less than or equal to 4,000 gal/ton per day. As summarized above, a reasonable conservative water consumption rate would be 1,000 gal/ton/day.

Assuming 1,000 gal/ton, the calculated daily water use would be:

$$\frac{1{,}000\ gal}{short\ ton\ paper} \times \frac{3.785\ L}{gal} \times \frac{1\ kg\ water}{L\ water} = 3{,}785\ kg\ water$$

Presence of MEA in the wastewater is anticipated only as a result of the filling application. The coating is applied during the dry-end of production (i.e., to the dried sheet) using a blade coating system. In Omya's experience, the only loss of water-containing MEA from the coating application would be minor losses to evaporation, while excess coating is returned to the system for reuse. The use level requested for the MEA in the filler application is 0.041% by weight relative to the weight of the finished paper.[15] This equates to 410 g of MEA being used per metric ton of paper produced, equivalent to 373 g/short ton.[16] The level of MEA in the water is therefore calculated as:

$$\frac{373\ g\ MEA}{short\ ton\ paper} \div \frac{3{,}785\ kg\ water}{short\ ton\ paper\ per\ day} = \frac{0.099\ g\ MEA}{kg\ water\ per\ day}$$

[11] Bryant, P.S., Malcolm, E.W., and Woitkovich, C.P., IPST Technical Paper Series Number 601 Pulp and Paper Mill Water Use in North America (December 1995), PDF p. 9, https://smartech.gatech.edu/bitstream/handle/1853/1920/tps-601.pdf

[12] Id., Table 2.

[13] Id.

[14] Id., p. 2.

[15] The underlying calculation for this use level is provided in the Confidential Attachment to this EA.

[16] 410 g ÷ 1.1 short ton/metric ton = 372 g.

At a 95% biodegradation rate, the level of MEA remaining after degradation would be 0.099 g/kg × (100%-95%) = 0.00495 g/kg. If we then use a 10-fold dilution factor for discharge to surface waters,[17] the estimated environmental concentration is 0.000495 g/kg, or 0.5 mg/kg (equivalent to 0.5 mg/L).

Air (Combustion):

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 food contact substance consists of carbon, hydrogen, nitrogen, 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 14.6% of the market volume will be combusted.

On August 1, 2016, the Council on Environmental Quality (CEQ) issued final guidance[18] to agencies regarding addressing GHG emissions and climate change impacts in NEPA documents. This guidance is "intended to help Federal agencies ensure their analysis of potential GHG emissions and effects of climate change in an EA or EIS is commensurate with the extent of the effects of the proposed action."[19] The GHG emissions resulting from the use and disposal of the FCS relate to 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." GHG emissions from MSW combustion facilities are regulated under 40 C.F.R. § 98.2. Based on the confidential market volume, the expected carbon dioxide equivalent emissions, as shown in the confidential attachment to the EA, are below 25,000 metric tons on an annual basis. As the estimated GHG emissions are well below the threshold for mandatory reporting, no significant environmental impacts are anticipated resulting from combustion of the FCS in MSW combustion facilities.

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[17] Rapaport, Robert A., 1988. *Prediction of consumer product chemical concentrations as a function of publically owned treatment works treatment type and riverine dilution*. Environmental Toxicology and Chemistry, 7(2), 107-115. Found online at: http://onlinelibrary.wiley.com/doi/10.1002/etc.5620070204/abstract.

[18] Council on Environmental Quality (CEQ), *Final Guidance for Federal Departments and Agencies on Consideration of Climate Change in National Environmental Policy Act Reviews*, August 1, 2016, available at: https://www.whitehouse.gov/sites/whitehouse.gov/files/documents/nepa_final_ghg_guidance.pdf.

[19] Id., p. 3.

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 solid-waste landfill units and lateral expansions of existing units to have composite liners and leachate collection systems to prevent leachate from entering ground and surface water, 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.

6. Fate of Emitted Substances in the Environment

a. Air

As described above, no significant quantities of any substances will be released to the atmosphere upon the use and disposal of finished articles manufactured with the FCS. Therefore, an assessment of the environmental fate of these substances is not required.

b. Water

As discussed above, the calculated EEC to surface waters is 0.5 mg/kg (equivalent to 0.5 mg/L). Based on the measured log Kow of -2.3 and an estimated bioconcentration factor (BCF) of 3.16, the FCS is not expected to bioaccumulate.[20] Based on a significant dataset, the lowest reliable aquatic toxicity values are reported as follows:[21]

Group	**Species**	**Acute LC_{50} or EC_{50}** (unless indicated)	**Chronic Toxicity**
Freshwater Fish	Goldfish	170 mg/L	--
	Brook trout	--	NOEC >14.1 mg/L (60 days) NOEC 1.77 mg/L (reproductive toxicity)
Freshwater Invertebrates	*Daphnia Magna*	32.6 mg/L	EC_{50} 2.52 mg/L (reproductive toxicity)
Saltwater Fish	Japanese killifish	--	NOEC 1.24 mg/L (reproductive toxicity)
Freshwater plants	Algae (*Pseudokirchneriella subcapitata*)	2.8 mg/L	--
Microorganisms	*Pseudomonas putida*	110 mg/L	--

[20] OECD, p. 3.
[21] Id., p. 3-4.

The most sensitive species and endpoint is the Japanese killifish, with an NOEC for reproductive toxicity of 1.24 mg/L. The calculated EEC of 0.5 mg/L is approximately three-fold lower below this endpoint. Moreover, we note that the most sensitive species is a saltwater species. We would expect that most if not all paper mills would be located along and discharge into freshwater bodies (saltwater would cause corrosion). It is our understanding that the dilution factor for discharge to surface waters which we have applied in developing the EEC contemplates only discharge to freshwater bodies. Thus, we would expect that an EEC for saltwater species would be significantly lower. With regard to freshwater species, the calculated EEC of 0.5 mg/L is nearly four-fold below the lowest NOEC for brook trout seen for reproductive toxicity.

c. Land

Considering the factors discussed above, no significant effects on the concentrations of and exposures 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 implementing preventive 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.

7. Environmental Effects of Released Substances

No significant introductions of the substances into the environment as a result of the proposed use of the FCS were identified above. Therefore, an evaluation of the environmental effects of the proposed use of the FCS is not required. In addition, the use and disposal of finished articles containing the FCS are not expected to threaten a violation of applicable laws and regulations, such as the EPA's regulations in 40 C.F.R. Part 60 that pertain to municipal solid waste combustors or and Part 258 that pertain to landfills.

8. Use of Resources and Energy

As is the case with other food contact substances, the production, use and disposal of the FCS involves the use of natural resources such as petroleum products and coal. The use of the FCS in the fabrication of food-contact materials is not expected to result in a net increase in the use of energy and resources, because the FCS is intended to be used in packaging which will be used in place of similar paper and paperboard materials now on the market for use in food packaging applications. The partial replacement of these types of materials by products containing the FCS is not expected to have any adverse impact on the use of energy and resources.

The FCS also is not expected to have a significant effect on paper recycling programs. Due to its affinity for water, MEA used in the filler application is expected to almost entirely remain with the whitewater in the processing plant. MEA used in the coating application may be present in paper that is recycled. When the paper for recycling is re-pulped, the MEA would be expected dissolve into the pulp slurry and

will be treated with other chemicals from the recycling process. For this reason, the intended use of MEA will have no effect on the recyclability of paper.

9. Mitigation Measures

As discussed above, no significant adverse environmental impacts are expected to result from the use and disposal of the FCS when present in waste water or in finished paper and paperboard. Therefore, the FCS is not reasonably expected to result in any new environmental issues that require mitigation measures.

10. Alternatives to the Proposed Action

No potential adverse environmental effects are identified herein that would necessitate alternative actions to that proposed in this FCN. If the proposed action is not approved, the result would be the continued use of the currently marketed materials that the subject FCS would replace. Such action would have no environmental impact.

11. List of Preparers

Dr. Mitchell Cheeseman, Steptoe & Johnson LLP, 1330 Connecticut Ave., NW, Washington, DC 20036.

Dr. Cheeseman holds a Ph.D. in Chemistry from the University of Florida. Dr. Cheeseman served for 18 months as a NEPA reviewer in FDA's food additive program. He has participated in FDA's NEPA review of nearly 800 food additive and food contact substance authorizations and he supervised NEPA review for FDA's Center for Food Safety and Applied Nutrition for five and a half years from 2006 to 2011.

Ms. Deborah C. Attwood, Steptoe & Johnson LLP, 1330 Connecticut Ave., NW, Washington, DC 20036.

Ms. Attwood has seven years of experience preparing environmental submissions to FDA for the use of food contact substances.

12. Certification

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

Date: April 7, 2017

Mitchell Cheeseman, Ph.D.

13. References

Bryant, P.S., Malcolm, E.W., and Woitkovich, C.P., IPST Technical Paper Series Number 601 *Pulp and Paper Mill Water Use in North America* (December 1995).

Council on Environmental Quality, *Final Guidance for Federal Departments and Agencies on Consideration of Climate Change in National Environmental Policy Act Reviews*, August 1, 2016.

Grönfirs, J., *Use of Fillers in Paper and Paperboard Grades*, Final Thesis, Tampere University of Applied Sciences (May 2010).

HSDB, entry for 2-aminoethanol.

OECD SIDS Initial Assessment Profile, *2-Aminoethanol* (15-17 October 2013).

Rapaport, Robert A., 1988. *Prediction of consumer product chemical concentrations as a function of publically owned treatment works treatment type and riverine dilution*. Environmental Toxicology and Chemistry, 7(2), 107-115.

U.S. Environmental Protection Agency, Office of Resource Conservation and Recovery (5306P), *Advancing Sustainable Materials Management: 2014 Fact Sheet*, November 2016.

U.S. Environmental Protection Agency, Office of Resource Conservation and Recovery (5306P), *Advancing Sustainable Materials Management: 2014 Tables and Figures*, December 2016.

U.S. Food and Drug Administration, *Food Types & Conditions of Use for Food Contact Substances*.

14. Attachments

Confidential Attachment to the Environmental Assessment.