Environmental Assessment

1. **Date** December 19, 2024 *

2. **Name of Applicant** LANXESS Corporation

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4. **Description of Proposed Action**

a. Requested Action

The action identified in this Food Contact Notification (FCN) is to provide for the use of the food contact substance (FCS) identified as dimethyl dicarbonate (DMDC; CAS RN 4525-33-1), as an antimicrobial agent in distilled spirit-based mixed alcoholic beverages, hard seltzer, and shandy at a maximum level of 250 ppm (0.025%). The FCS is not for use in contact with infant formula and human milk. Such uses were not included as part of the intended use of the substance in the FCN.

b. Need for Action

The FCS is used as an antimicrobial agent added to beverages prior to their packaging for consumption. The FCS reduces or eliminates pathogenic and non-pathogenic microorganisms that may be present in the beverage and increases the shelf-life of the packaged beverages.

c. Locations of Use/Disposal

The Notifier does not intend to produce finished food packaging materials from the FCS. Rather, the FCS will be directly added as an antimicrobial agent intended for use in beverages for human consumption in the United States. It is expected that the FCS and its hydrolysis products (mainly methanol and carbon dioxide; see additional details below) will remain in the beverage until ingestion by consumers and be subsequently excreted to publicly owned treatment works (POTW) or private septic tanks. Discharge of the FCS and hydrolysis directly to surface waters via direct excretion or after on-site pre-treatment at a facility in accordance with a permit issued under the National Pollutant Discharge Elimination System (NPDES) is not expected. After ingestion, these substances are either digested and/or metabolized to other substances or excreted largely intact. As previously noted in the Environmental Decision Memo for DMDC FCN 00035,[1] food substances with these use and disposal patterns are not expected to be toxic to organisms in the environment at the expected levels of exposure. Thus, use and disposal of such substances are not expected to result in significant environmental effects.

* Subsequent to this date, this EA was edited using the Adobe text editor tool to make several minor corrections of an editorial nature and to format for 508 compliant assistive technologies.

[1] https://wayback.archive-it.org/7993/20170606190527/https://www.fda.gov/Food/IngredientsPackagingLabeling/EnvironmentalDecisions/ucm154069.htm

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

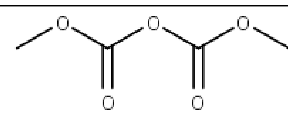
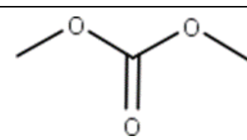
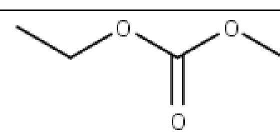
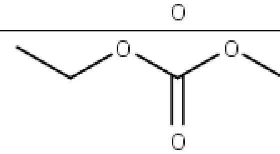
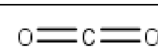
The Chemical Abstracts Service (CAS) name of the Notifier's FCS is dimethyl dicarbonate. The FCS performs its technical function by inactivating enzymes in any spoilage microorganisms present and completely dissociates within hours after being added to a beverage product. DMDC is highly reactive with nucleophilic agents with a hydrogen atom, such as water (i.e., hydrolysis), ethanol, and ammonia. The predominant reaction of DMDC in an aqueous solution is hydrolysis with the formation of methanol and carbon dioxide as shown below (Equation 1) which are the primary degradation products. The other main degradation products include methyl ethyl carbonate (MEC) and methyl carbamate (MC) which are formed by the presence of ethanol and ammonia in the beverage matrix as described in Equation 2 and Equation 3, respectively.

$DMDC + H_2O \rightarrow MeOH + CO_2$ (Equation 1)
$DMDC + EtOH \rightarrow MEC$ (Equation 2)
$DMDC + NH_4 \rightarrow MC$ (Equation 3)

Another main identified degradation product is dimethyl carbonate (DMC) which is a thermal degradation product which typically is formed during production of the FCS and is controlled/limited by the FCS specification (i.e., ≤0.2% DMC).

Due to its rapid hydrolysis/disassociation in a matter of hours (half-life around 20 min. at 20°C), the FCS is not present in the final product consumed.[2] Therefore, the environmental exposure of FCS is considered negligible. Instead, the environmental exposure of the FCS hydrolysis/degradation products formed in the beverage matrix for consumption is more appropriate and discussed herein. As such, the identities of the DMDC and degradation products identified above are provided below (Table 1).

Table 1. DMDC and associated hydrolysis/degradation products.

Name (alternative name / abbreviation)	**CAS Reg. No.**	**Molecular Formula**	**Structural Formula**	**Molecular Weight**
Dimethyl decarbonate (DMDC)	4525-33-1	$C_4H_6O_5$		134.09
Methanol (MeOH)	67-56-1	CH_4O		32.04
Dimethyl carbonate (DMC)	616-38-6	$C_3H_6O_3$		90.08
Ethyl methyl carbonate (MEC)	623-53-0	$C_4H_8O_3$		104.10
Carbamic acid, methyl ester (MC)	598-55-0	$C_2H_5NO_2$		75.07
Carbon dioxide	124-38-9	CO_2		44.01

2 Golden, D.A., Worobo, R.W. and Ough, C.S. 2005. Antimicrobials in food. Third Edition. Dimethyl dicarbonate and diethyl dicarbocarbonate. In: Eds Davidson PM, Sofos JN and Branen AL. Taylor & Frances Group. Boca Raton., USA, pp 305–326.

6. 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 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 manufactured in plants which meet all applicable federal, state, and local environmental regulations. The notifier asserts that there are no extraordinary circumstances pertaining to the manufacture of the FCS such as: 1) unique emission circumstances that are not adequately addressed by general or specific emission requirements (including occupational) promulgated by Federal, State or local environmental agencies and that may harm the environment; 2) actions 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 the proposed action that 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.

b. Introduction of Substances into the Environment as a Result of Use/Disposal

The direct introduction of FCS in the environment is not expected as the FCS is not incorporated into finished food contact articles and instead, added directly to beverages for human consumption as described above. The introduction of the FCS degradation products (mainly methanol and carbon dioxide) into the environment is expected from the consumption and subsequent excretion of beverages to which the FCS was added. Since the natural state of carbon dioxide (CO_2) is gas, it is expected that the degradation product will be released into the atmosphere in relatively small quantities compared to annual CO_2 emissions in the US. For the other FCS degradation products, these substances are either digested and/or metabolized to other substances or excreted largely intact into the POTW or private sewage systems where they will be susceptible to biodegradation.

As noted above, the FCS completely dissociates within hours after being added to beverage products, and due to its rapid hydrolysis/decomposition in a matter of hours, the FCS is not present in the final product consumed. Therefore, the relative amounts of degradation products of the FCS are relevant to assessing the impact of the FCS on the environment. The estimated conservative yields of FCS hydrolysis/degradation products in beverage solutions are provided in Table 2.

The methanol yield was conservatively derived based on the stoichiometry of the complete hydrolysis of DMDC in an aqueous environment, i.e., 100 parts DMDC to 47.8 parts methanol, i.e., 47.8% yield (EFSA, 2015 [3], JECFA, 1991 [4]; Worobo et al., 2021 [5]). The methyl ethyl carbonate (MEC) yield of 4.12% was derived based on the observation that 250 mg/L DMDC in alcoholic beverages is converted to ≤10.3 mg/L MEC (EFSA, 2015).[6] The DMC

[3] EFSA (European Food Safety Authority Panel on Food Additives and Nutrient Sources Added to Food). 2015. Scientific Opinion. Scientific opinion on the re-evaluation of dimethyl dicarbonate (DMDC, E 242) as a food additive. EFSA Journal. 13(12):4319.

[4] JECFA (Joint FAO/WHO Expert Committee on Food Additives). 1991. Toxicological evaluation of certain food additives and contaminants. Thirty-seventh meeting of JECFA, WHO Food Additives Series, No 28.

[5] Worobo, R.W., Cheng, R.M., Ough, C.S. 2021. Antimicrobials in Food. Fourth edition. Chapter 13 Dimethyl dicarbonate and diethyl dicarbonate. CRC Press.

[6] See footnote 3, EFSA 2015.

yield was derived based on the specification for DMC content in DMDC, i.e., ≤0.2%. The MC yield was derived based on the assumption that 250 parts DMDC yields 0.025 parts MC, i.e., 0.01% yield (EFSA, 2015).[7]

Table 2. Yields of hydrolysis/degradation products in beverage solutions.

DMDC Hydrolysis / Degradation Product	Yield (%) [(a)]
Methanol (MeOH)	47.8
Methyl ethyl carbonate (MEC)	4.12
Dimethyl carbonate (DMC)	0.2
Methyl carbamate (MC)	0.01

[(a)] Carbon dioxide makes up the remaining content of degradation products via the hydrolysis of DMDC in aqueous solutions.

Based on the high-water solubilities and low partition coefficients tabulated below (Table 3), the hydrolysis/degradation products will mainly partition to wastewater effluent during wastewater treatment and not to wastewater sludge under normal conditions. No degradation products are expected to partition significantly the sludge.

Table 3. Physicochemical properties of DMDC hydrolysis/degradation products.

DMDC Hydrolysis / Degradation Product	Physical State	Water Solubility	Partition Coefficient (KOC)
Methanol (MeOH)	Liquid	Miscible with water (1000 mg/mL at 25°C) [(a)]	0.13-0.61 L/kg (measured); 1 L/kg (calculated) [(a)]
Methyl ethyl carbonate (MEC)	Liquid	47,100 mg/L at 20 °C [(b)]	1.58 L/kg (measured) [(b)]
Dimethyl carbonate (DMC)	Liquid	114,700 mg/L at 20 °C [(c)]	2.9-6.65 L/kg (calculated) [(c)]
Methyl carbamate (MC)	Solid	>700,000 mg/L at 20 °C [(d)]	7.24 L/kg (calculated) [(e)]

a. ECHA (European Chemicals Agency). 2023. REACH Registration Dossier for Methanol. EC Number 200-659-6. Available at: https://echa.europa.eu/registration-dossier/-/registered-dossier/15569.

b. ECHA (European Chemicals Agency). 2021. REACH Registration Dossier for Carbonic acid, ethyl methyl ester. EC Number 433-480-9. Available at: https://echa.europa.eu/registration-dossier/-/registered-dossier/5747.

c. ECHA (European Chemicals Agency). 2023. REACH Registration Dossier for Dimethyl Carbonate. EC Number 210-478-4. Available at: https://echa.europa.eu/registration-dossier/-/registered-dossier/14944.

d. https://www.fishersci.dk/shop/products/methyl-carbamate-99-thermo-scientific/10451481.

e. EPA CompTox Chemicals Dashboard. 2023. Chemical Record for Methyl Carbamate. CAS RN 598-55-0. Available at: https://comptox.epa.gov/dashboard/chemical/env-fate-transport/DTXSID8020834.

MeOH, DMC, and MEC, are readily biodegradable based on available data (additional details shared below) and are expected to undergo significant degradation during aerobic conditions within POTW and sewage systems.[8] Therefore, based on the high expected removal rates of these substances in POTWs and sewage systems, negligible amounts of these degradation products are expected to be released into the environment. MC is not considered to be readily biodegradable (<60% depletion in 28 days) but is susceptible to

[7] *Ibid.*

[8] ECHA (European Chemicals Agency). 2023. REACH Registration Dossier for Methanol. EC Number 200-659-6. Available at: https://echa.europa.eu/registration-dossier/-/registered-dossier/15569; ECHA (European Chemicals Agency). 2023. REACH Registration Dossier for Dimethyl Carbonate. EC Number 210-478-4. Available at: https://echa.europa.eu/registration-dossier/-/registered-dossier/14944; ECHA (European Chemicals Agency). 2021. REACH Registration Dossier for Carbonic Acid, Ethyl Methyl Ester. EC Number 433-480-9. Available at: https://echa.europa.eu/registration-dossier/-/registered-dossier/5747

biodegradation (~47% depletion in 28 days).[9] Given that MC is still susceptible to biodegradation, albeit with slower degradation relative to the other substances, and the relative yield of MC from DMDC is estimated to be 0.01%, the expected concentration of MC in the environment is considered negligible.

Methanol

Methanol is readily biodegradable in freshwater based on the results of standard ready biodegradation tests that show 71.5 – 95% removal after 5 and 20 days, respectively. In marine water, degradation rates were found between 69 – 97 %.[10]

Dimethyl carbonate (DMC)

In a GLP- and OECD 301C-compliant study, 86% degradation of the DMC was observed after 28-days demonstrating that DMC was readily biodegradable.[11]

Ethyl methyl carbonate (MEC)

The ready biodegradation test indicates that MEC is readily biodegradable with 98% biodegradation after 28 days (passing 60% degradation within 10 days of passing 10%).[12]

Carbamic acid, methyl ester (MC)

A study was performed to assess the ready biodegradability of the test substance according to OECD Guideline 301D, in compliance with GLPs. In the test, MC was biodegraded to 47% after 28 days. Under the study conditions, the test substance was considered to be not readily biodegradable.[13]

Carbon dioxide, a greenhouse gas (GHG), is a degradation product from the FCS. However, no significant GHG emissions are expected. There is no landfill disposal resulting from the use or disposal of the FCS.

To assess the potential exposure of DMDC and or its degradation products, EPA's Exposure and Fate Assessment Screening Tool (E-FAST; Version 2014) was used to estimate conservative surface water concentrations based on the down-the-drain exposure model and without consideration of removal processes. [14] The parameters for this model are provided below:

Production Volume: 126,000 kg/yr
Wastewater Treatment Removal: 0%
Release Days: 365 days

[9] ECHA (European Chemicals Agency). 2021. REACH Registration Dossier for Methyl Carbamate. EC Number 209-939-2. Available at: https://echa.europa.eu/registration-dossier/-/registered-dossier/18202

[10] ECHA (European Chemicals Agency). 2023. REACH Registration Dossier for Methanol. EC Number 200-659-6. Available at: https://echa.europa.eu/registration-dossier/-/registered-dossier/15569

[11] ECHA (European Chemicals Agency). 2023. REACH Registration Dossier for Dimethyl Carbonate. EC Number 210-478-4. Available at: https://echa.europa.eu/registration-dossier/-/registered-dossier/1494

[12] ECHA (European Chemicals Agency). 2021. REACH Registration Dossier for Carbonic Acid, Ethyl Methyl Ester. EC Number 433-480-9. Available at: https://echa.europa.eu/registration-dossier/-/registered-dossier/5747

[13] ECHA (European Chemicals Agency). 2021. REACH Registration Dossier for Methyl carbamate. EC Number. 209-939-2. Available at: https://echa.europa.eu/registration-dossier/-/registered-dossier/18202

[14] US EPA (United States Environmental Protection Agency). 2014. Exposure and Fate Assessment Screening Tool (E-FAST) 2014. https://www.epa.gov/tsca-screening-tools/e-fast-exposure-and-fate-assessment-screening-tool-version-2014

The worst-case surface water concentration estimates for DMDC from E-FAST Model are tabulated below (Table 4).

Table 4. Conservative estimates for surface water concentration for DMDC using the E-FAST Model.

Table 4a. 50th Percentile Aquatic Exposure Estimates – Surface Water

Descriptor	Harmonic Mean (a)	30Q5 (b)	7Q10 (c)	1Q10 (d)
Stream Dilution Factor	134.85	39.66	24.22	20.08
Concentration (μg/L)	0.0227	0.0771	0.13	0.15

Table 4b. 10th Percentile Aquatic Exposure Estimates – Surface Water

Descriptor	Harmonic Mean (a)	30Q5 (b)	7Q10 (c)	1Q10 (d)
Stream Dilution Factor	7.95	1.80	1.00	1.00
Concentration (μg/L)	0.38	1.70	3.06	3.06

a. Harmonic Mean Flow (SFharmonic) — inverse mean of reciprocal daily arithmetic mean flow values. In other words, harmonic mean (H) is defined as H = n/[(1/x1) + (1/x2) +...+ (1/xn)] where x is a particular number in a group of measured values and n is the number of measurements in the series. These flows are used to generate estimates of chronic human exposures via drinking water and fish ingestion.

b. 30Q5 Flow (SF30Q5) — 30 consecutive days of lowest flow over a 5-year period. These flows are used to determine acute human exposures via drinking water.

c. 7Q10 Flow (SF7Q10) — 7 consecutive days of lowest flow over a 10-year period. These flows are used to calculate estimates of chronic surface water concentrations to compare with the COCs for aquatic life.

d. 1Q10 Flow (SF1Q10) — single day of lowest flow over a 10-year period. These flows are used to calculate estimates of acute surface water concentrations to compare with the COCs for aquatic life.

These estimates are considered to be a first-tier conservative assessment as no assumption for removal of DMDC by hydrolysis or wastewater treatment removal (e.g., biodegradation) as examples were included in the E-FAST model. Although these removal factors are known to occur, they were not factored into the model to be highly conservative.

Using the 10th Percentile Aquatic DMDC Concentration and the hydrolysis/degradation product yields, the estimated surface water concentrations (assuming no biodegradation) of DMDC hydrolysis/degradation products were conservatively determined and reported in the table below (Table 5).

Table 5. Estimated surface water concentrations of DMDC hydrolysis/degradation products.

DMDC Hydrolysis / Degradation Product	10th Percentile Aquatic DMDC Concentration (a)	Yield (b)	Estimated Aquatic DMDC Hydrolysis / Degradation Product Concentration (c) (ug/L)
Methanol (MeOH)	0.38	47.8%	0.18
Methyl ethyl carbonate (MEC)	0.38	4.12%	0.016
Dimethyl carbonate (DMC)	0.38	0.2%	0.00076
Methyl carbamate (MC)	0.38	0.01%	0.000038

a. The harmonic mean from the 10th Percentile Aquatic Exposure Estimate in Surface Water as determined by the E-FAST model.

b. Carbon dioxide makes up the remaining content of degradation products via the hydrolysis of DMDC in aqueous solutions.

c. [Estimated Aquatic DMDC Hydrolysis/Degradation Product Concentration (µg/L)] = [10th Percentile Aquatic DMDC Concentration] x [Yield]

7. Fate of Emitted Substances in the Environment

As described above, minute amounts of the FCS will be added directly to beverages for human consumption and its hydrolysis products (mainly methanol and carbon dioxide) will remain in the beverage until ingestion by consumers. Therefore, no significant quantities of any substances are expected to be released into the atmospheric, terrestrial, freshwater, estuarine, or marine ecosystems upon the use of the FCS. Furthermore, the hydrolysis/degradation products of the FCS (MeOH, MEC, DMC) except for MC are all readily biodegradable and thus not expected to persist in POTWs and sewage septic tanks.

Although MC was not readily biodegradable (less than 60% degraded within 28 days) in an OECD 301D assay, MC was still biodegraded to a significant degree (48%) after 28 days. Given its susceptibility to biodegradation, albeit slower compared to the DMDC hydrolysis products, and its low yield (0.01%) from DMDC, significant and prolonged exposures to this product are not expected.

As such there is no expectation of any meaningful substance exposure to terrestrial or aquatic organisms as a result of the use of the FCS as notified.

8. Environmental Effects of Released Substances

As discussed above, the FCS and its hydrolysis products are not reasonably expected to be released into the environment or if released, the amounts will be insignificant. The FCS degrades in the beverage in a matter of hours and its hydrolysis products (mainly methanol and carbon dioxide) will be directly ingested by consumers, digested and/or metabolized to other substances, or excreted largely intact. Based on these considerations, no significant adverse effect on organisms in the environment is expected as a result of the use of the FCS.

Methanol [15]

Data on the short-term toxicity of Methanol to fish, invertebrates and algae is tabulated below (Table 6).

Table 6. Summary data on short term toxicity of methanol to fish, invertebrates, and algae.

Exposure Duration	Test System	Species	Endpoint	Concentration (mg/L)
Short-term	Fish	*Pimephales promelas*	96-hr LC_{50}	28,100
	Fish	*Oncorhynchus mykiss*	96-hr LC_{50}	20,100
	Fish	*Lepomis macrochirus*	96-hr LC_{50}	15,400
	Invertebrate	*Daphnia magna*	96-hr EC_{50}	18,260
	Invertebrate	*Daphnia magna*	48-hr EC_{50}	>10,000
	Algae	*Selenastrum capricornutum*	96-hr EC_{50}	22,000

[15] ECHA (European Chemicals Agency). 2023. REACH Registration Dossier for Methanol. EC Number 200-659-6. Available at: https://echa.europa.eu/registration-dossier/-/registered-dossier/15569

No reliable studies concerning long-term toxicity of methanol due to BOD of methanol and rapid biodegradation were identified. Using available QSAR models, the long- term no observed effect concentrations (NOECs) in fish and invertebrates are 444 and 208 mg/L, respectively.[16]

Methanol has a low potential for adsorption or bioaccumulation, exhibits a very high solubility in water, and is readily biodegradable in both aerobic and anaerobic environments. In addition, results from the aquatic studies indicate no harmful effects. Therefore, the exposure of methanol to sediment organisms is highly unlikely. Additionally, the expected toxicity towards sediment organisms is low as understood from the available studies where an EC_{50} of 71700 mg/L for *Tubifex tubifex* and an LC_{50} of 54,890 mg/L were observed. Therefore, no adverse effects of methanol on sediment organisms derived from the intended uses of the FCS are expected.

Data on the long-term toxicity of methanol in soil organisms include terrestrial plants (monocots and dicots), earthworms, and terrestrial arthropods. Methanol has shown no toxicity to terrestrial organisms at up to 1000 mg/kg soil dry weight. Given that methanol has a low potential for adsorption or bioaccumulation, exhibits a very high solubility in water, and is readily biodegradable in both aerobic and anaerobic environments, the exposure of methanol to soil organisms is highly unlikely. Therefore, no adverse effects of methanol on soil organisms derived from the intended uses of the FCS are expected.

Dimethyl carbonate (DMC)[17]

Data on the short-term toxicity of DMC to fish, invertebrates, and algae is tabulated below (Table 7).

Table 7. Summary data on short term toxicity of DMC to fish, invertebrates, and algae.

Exposure Duration	Test System	Species	Endpoint	Concentration (mg/L)
Short-term	Fish	*Danio rerio*	96-hr EC50	>100 mg/L
	Invertebrate	*Daphnia magna*	48-hr EC50	>100 mg/L
	Algae	*Raphidocelis subcapitata*	96-hr EC50	>100 mg/L (nominal) / >57.29 (mg/L) measured

No long-term toxicity studies in fish were identified. In a long-term invertebrate toxicity assay with *Daphnia magna*, significant reproduction inhibition was not observed at up to 25.0 mg/L. Therefore, the NOEC can be estimated to be 25.0 mg/L DMC. The reproduction rate was decreased by 26.5 % at the highest test concentration of 100 mg/L. Due to the distribution of the data, the EC_{50} values for immobilization reproduction could not be calculated, however, they were estimated to be >100 mg/L.

The Mackay level 1 fugacity model indicates that DMC is distributed into two compartments, air (54.46%) and water (45.45%). Negligible amounts partition into soil, sediment, and biota. Therefore, the environmental risk to organisms in the sediment and soil compartments is negligible.

[16] US EPA (United States Environmental Protection Agency). 2012. ECOSAR™ Version 1.11. EPI (Estimation Programs Interface) Suite. Version 4.11. Available at: https://www.epa.gov/tsca-screening-tools/epi-suitetm-estimation-program-interface

[17] ECHA (European Chemicals Agency). 2023. REACH Registration Dossier for Dimethyl Carbonate. EC Number 210-478-4. Available at: https://echa.europa.eu/registration-dossier/-/registered-dossier/14944

Ethyl methyl carbonate (MEC) [18]

Data on the short-term toxicity of MEC to fish, invertebrates and algae is tabulated below (Table 8).

Table 8. Summary data on short term toxicity of MEC to fish, invertebrates, and algae.

Exposure Duration	**Test System**	**Species**	**Endpoint**	**Concentration (mg/L)**
Short-term	Fish	*Oncorhynchus mykiss*	96-hr EC50	>100 mg/L
	Invertebrate	*Daphnia magna*	48-hr EC50	>100 mg/L
	Algae	*Desmodesmus subspicatus*	72-hr EC50	>100 mg/L (nominal) / >62 mg/L(measured)

MEC has a high-water solubility, low partition coefficient, is readily biodegradable, and is not expected to partition or persist in the sediments or soils. Therefore, the environmental risk to organisms in the sediment and soil compartments is negligible.

Carbamic acid, methyl ester (MC) [19]

Data on the short-term toxicity of MC to invertebrates and algae is tabulated below (Table 9).

Table 9. Summary data on short term toxicity of MC to fish, invertebrates, and algae.

Exposure Duration	**Test System**	**Species**	**Endpoint**	**Concentration (mg/L)**
Short-term	Invertebrate	*Daphnia magna*	48-hr EC50	>1,000 mg/L
	Algae	*Raphidocelis subcapitata*	96-hr EC50	598 mg/L

While MC is not considered readily biodegradable, it has been shown to degrade (~47%) over 28 days. Because of exposure of MC from the FCS intended uses and in combination with minimal aquatic toxicity and potential for biodegradation, MC is believed to pose negligible risk to the organisms in the aquatic, sediment, and soil compartment.

A comparison of the aquatic toxicity values for DMDC hydrolysis/degradation products against the highly conservative environmental exposure concentration of

0.38 µg/L (does not account for wastewater treatment removal) derived from EPA's E-FAST down-the-drain model clearly indicates that there is negligible environmental risk form the proposed intended use of DMDC or it's degradation products.

For MeOH, the lowest identified acute aquatic toxicity endpoint of >10,000 mg/L. Comparing this value to the estimated exposure of 0.18 µg/L, the risk quotient (reference concentration / exposure) would be 5.6×10^7 (>10,000 mg/L / 0.00018 mg/L). Therefore, methanol as a degradation product of DMDC does not pose a risk to the environment. Methanol is readily biodegradable so prolonged exposure in the environment is not expected. Based on the physical-chemical properties (i.e. physical state, water solubility, partition coefficient), methanol is not expected to partition to the terrestrial compartment.

[18] ECHA (European Chemicals Agency). 2021. REACH Registration Dossier for Carbonic Acid, Ethyl Methyl Ester. EC Number 433-480-9. Available at: https://echa.europa.eu/registration-dossier/-/registered-dossier/5747

[19] ECHA (European Chemicals Agency). 2021. REACH Registration Dossier for Methyl Carbamate. EC Number 17209-939-2. Available at: https://echa.europa.eu/registration-dossier/-/registered-dossier/18202

For MEC, the lowest identified acute aquatic toxicity endpoint of >62 mg/L. Comparing this value to the estimated exposure of 0.016 µg/L, the risk quotient (reference concentration / exposure) would be 3.9 x 10^6 (>62 mg/L / 0.000016 mg/L). Therefore, MEC as a degradation product of DMDC does not pose a risk to the environment. MEC is readily biodegradable so prolonged exposure in the environment is not expected. Based on the physical-chemical properties (i.e. physical state, water solubility, partition coefficient), MEC is not expected to partition to the terrestrial compartment.

For DMC, the lowest identified acute aquatic toxicity endpoint of >57.29 mg/L. Comparing this value to the estimated exposure of 0.00076 µg/L, the risk quotient (reference concentration / exposure) would be 7.5 x 10^6 (>57.29 mg/L / 0.00000076 mg/L). Therefore, DMC as a degradation product of DMDC does not pose a risk to the environment. DMC is readily biodegradable so prolonged exposure in the environment is not expected. Based on the physical-chemical properties (i.e. physical state, water solubility, partition coefficient), DMC is not expected to partition to the terrestrial compartment.

For MC, the lowest identified acute aquatic toxicity endpoint of 598 mg/L. Comparing this value to the estimated exposure of 0.000038 µg/L, the risk quotient (reference concentration / exposure) would be 1.6 x 10^{10} (598 mg/L / 0.000000038 mg/L). Therefore, MC as a degradation product of DMDC does not pose a risk to the environment. MC is biodegradable (48% in 28 days) so prolonged exposure at significant concentrations in the environment is not expected. Based on the physical-chemical properties (i.e. physical state, water solubility, partition coefficient), MC is not expected to partition to the terrestrial compartment.

In summary, the hydrolysis/degradation products of DMDC do not pose a risk to the environment.

9. Use of Resources and Energy

The notified use of the FCS will not require additional energy resources for the treatment and disposal of wastes. The manufacture of the FCS will consume comparable amounts of energy and resources as similar products, and the raw materials used in the production of the FCS are commercially manufactured materials that are produced for use in a variety of chemical reactions and processes. Thus, the energy used for the production of the FCS is not significant.

10. Mitigation Measures

As discussed above, no significant adverse environmental impacts are expected to result from the use and disposal of food-contact materials containing the FCS. Thus, the use of the FCS as proposed is not expected to result in a significant impact on the environment. Therefore, the FCS is not expected to result in environmental issues requiring mitigation measures.

11. Alternatives to the Proposed Action

No significant adverse environmental effects are identified herein that would necessitate alternative actions to those proposed in this Food Contact Notification. The alternative of not allowing the FCN to become effective would be the continued use of the materials that the subject FCS would otherwise replace; such action would have no significant environmental impact.

12. List of Preparers

Benjamin L. Burruss, MS, RQAP-GLP, IBERA-Certified Environmental Risk Assessor, Managing Consultant, SafeBridge Consultants, 330 Seventh Ave, Suite 2001, New York, NY 10001. Mr. Burruss has 10 years of experience with FCN submissions and environmental assessments.

13. Certification

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

Date: December 19, 2024

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Benjamin L. Burruss, MS, RQAP-GLP
IBERA-Certified Environmental Risk Assessor
SafeBridge Consultants