Environmental Assessment

FCN 1649

1. **Date:** April 29, 2016

2. **Name of submitter:** Lanxess Corporation

3. **Address:** 111 RIDC Park West Dr., Pittsburgh, PA 15275-1112

All communications on this matter are to be agent/consultant for Lanxess:
Richard Kraska, Ph.D., DABT
GRAS Associates, LLC
27499 Riverview Center Blvd.
Suite 212
Bonita Springs, FL 34134
Telephone: (216)-470-7280
kraska@gras-associates.com

4. **Description of the proposed action:**

   a. **Requested action:**

The action requested in this Food Contact Notification (FCN) is the establishment of a clearance to permit the use of 2-methyl-2H-isothiazol-3-one (MIT) antimicrobial preservative as a component in the manufacturing of food contact articles.

The subject compound is intended for use as a preservative in formulations used in the manufacturing of polymer coatings that comply with 21 CFR 175.300 (Resinous and polymeric coatings) and 175.320 (Resinous and polymeric coatings for polyolefin films) and can-end and side-seam cements that comply with 21 CFR 175.300. The FCS will not be used in products for infants.

The FCS may be used in contact with all food types, except infant formula, under Conditions of Use A through H[1]. The maximum level of the FCS in the aqueous emulsions for the metal can coatings or polymeric coatings on polyolefin film would be 100 ppm. The maximum level of the FCS in the aqueous emulsion of the can-end or side-seam cement is 150 ppm.

   b. **Need for action:**

This FCS is a preservative used in the production of food-packaging materials. The food contact substance will be sold to manufacturers engaged in the production of polymer solution preparations

[1] Available at:
http://www.fda.gov/food/ingredientspackaginglabeling/packagingfcs/foodtypesconditionsofuse/default.htm
(Accessed January 20, 2016)

that will be sold to other companies to make coatings to be applied to food contact articles. The FCS will preserve these polymer solution formulations. The FCS has no function in final food contact articles.

The FCS is an anti-microbial preservative that is normally regulated by the U.S. Environmental Protection Agency (US EPA) under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). Lanxess has not registered any products with the FCS with US EPA. Lanxess intends to sell the FCS to customers outside the United States where a FIFRA registration is not necessary.

c. **Locations of use/disposal:**

The polymer and metal container production plants that purchase the FCS to add as a preservative to their food-contact articles are located outside of the United States. Local surface waters may receive liquid production wastes.

It is expected that food-contact articles that contain the FCS will ultimately be imported into the U.S. market and utilized in patterns corresponding to the national population density and widely distributed across the country. It is expected that end consumers will either recycle or dispose of metal cans into the trash, which will ultimately end up in landfills, at current observed recovery rates[2]. The EPA's current data for municipal solid waste generation, recycling and disposal, indicated that there was no significant recycling of flexible packaging[3]. It is expected that end consumers will dispose the flexible packaging in the trash, which will end up in the landfills. Specifically, EPA's 2013 information on MSW recovery indicate negligible recovery for every category of nondurable goods into which the FCS might be incorporated[4].

5. **Identification of substances that are the subject of the proposed action:**

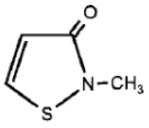
The identity of the FCS is summarized below:

a) Complete nomenclature: 2-methyl-2H-isothiazol-3-one

b) Chemical Abstracts Service (CAS) registration number: 2682-20-4

c) Molecular weight: 115.2 g/mol

d) Molecular formula: C_4H_5NOS

e) Structural (graphic) formula: 

[2] http://www.epa.gov/smm/advancing-sustainable-materials-management-facts-and-figures-report
[3] Ibid.
[4] Ibid.

f) Physical description: off-white and to be 9/1 10Y (value, chroma and hue respectively, 100%), pale amber and to be 8/4 7.5Y (value, chroma and hue respectively, 57.3% purity)

6. **Introduction of substances into the environment:**

a. **Introduction of substances into the environment as a result of manufacture:**

Under 21C.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. Moreover, information available to the manufacturer does not suggest that there are any extraordinary circumstances in this case indicative of any adverse environmental impact as a result of the manufacture of the food-contact substance.

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:**

Disposal by the end consumer of the FCS will be by landfill and recycling facilities. Based on confidential market volume estimates provided in a confidential attachment (Attachment 36), the proposed use of the FCS is expected to make up a very small portion of the total municipal solid waste (MSW) currently combusted. Therefore, incineration of the FCS will not cause municipal solid waste combustors to threaten a violation of applicable emissions laws and regulations (under 40 C.F.R. Part 60 or relevant state and local laws). Based on market volume estimates provided in a confidential attachment, the FCS will only account for a marginal amount of total MSW discards. 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 ground-water 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 collections systems, they are required to monitor ground water and to take corrective action as appropriate. The lack of any leaching is especially true in this case, considering that the subject substances will be cured with polymers of relatively high molecular weight that contain only minute levels of extractable material even under conditions that greatly exaggerate environmental exposure conditions.

In December 2014, the Council on Environmental Quality (CEQ) released a greenhouse gas (GHG) guidance document to aid agencies in the consideration of effects on climate change when assessing impacts from federal actions.[3] Because GHG emissions are expected from the proposed use of the FCS, we have analyzed GHG emissions. CEQ has set a threshold for quantitative disclosure of GHG emissions at 25,000 metric tons carbon dioxide equivalents ($CO_{2\text{-}e}$) per year. Based on information provided in the confidential attachment, combustion of the FCS would result in GHG emissions well below the CEQ threshold (when the CEQ threshold is exceeded, quantitative disclosure is warranted).

7. **Fate of substances released into the environment:**

a. **Physical/chemical properties**

Table 1. Physical and chemical properties

Water solubility[a]	1×10^6 mg/L
Dissociation constant in water[c]	-0.32 (predicted by SPARC version 4.6)
n-octanol/water partition coefficient	(K_{ow} = 0.326[a] or 0.5[b]
Vapor pressure	1.2 Pa at 25 °C[a] or 6.2×10^{-4} torr[b]
Henry's Law constant[a]	1.36×10^{-9} Pa-m^3/mol
Photostability at pH 7[c]	DT_{50} (aqueous, sunlight, 50 °N): 5.2 DT_{50} (aqueous, sunlight, 30-40 °N): 5.0
Soil adsorption, desorption[c]	Mean log10 K_{oc}: 0.778 Adsorption coefficient: 6.00

[a] Harlan Laboratory Certificate of Analysis (Attachment 25)
[b] MIT RED (EPA, 1996)
[c] List of endpoints document, Lanxess MIT, CAS 2682-20-4 (Attachment 39)

The FCS has high water solubility, low partition coefficient indicating no potential bio-accumulation, high volatility and a low Henry's Law constant (Table 1) but will be encased in polymer can and film coatings. According to the MIT RED (EPA, 1996), MIT is not susceptible to hydrolysis at acidic, neutral, or alkaline pH and no formaldehyde release was detected. The combustion products are expected to be oxides of carbon, hydrogen, sulfur, and nitrogen.

b. **Environmental depletion mechanisms**

Based on the physical and chemical properties of MIT (Table 1), the FCS present in aqueous media are not likely to partition into air based on the low Henry's Law constants but based on its vapor pressure, it could volatilize from soil in its pure state. Any material that leached out of its polymeric matrix and into the aquatic environment are expected to be soluble in water and to rapidly degrade to straight-chain nitrogenous carboxylic acids that eventually mineralize to carbon dioxide and formic acid. The low log K_{ow} indicates that sorption to soil, sludge, and sediments and bio-accumulation in aquatic organisms are expected to be limited (EPA, 2014).

(a) Air

No significant effect on the concentrations of and exposures to any substances in the atmosphere are anticipated due to the proposed use of the food-contact substance. The food-contact substance does not readily volatilize and will be cured in a polymeric coating. Furthermore, because the food-contact substance will make up a very small portion of the total municipal solid waste currently combusted, the food-contact substance will not significantly alter the emissions from properly operating municipal solid waste combustors, and therefore not threaten a violation of applicable emissions laws and regulations (i.e., 40 CFR Part 60).

(b) Water

The preservatives which are the subject of this notification are highly water soluble. However, the materials present in the consumer products are bound in the polymer matrix of can and film coatings and would not be released under normal environmental conditions. Any leachates of the FCS from the polymeric matrix that occur are expected to break down quickly to form straight chain nitrogenous carboxylic acids that eventually mineralize to carbon dioxide and formic acid under normal environmental conditions (EPA, 2014). In addition, residual FCS will be removed by common biological wastewater treatment facilities (DOW MIT MSDS, Attachment 37) and would not be expected to persist to enter surface water downstream of wastewater treatment (EPA, 2014). Due to its lack of persistence, the EPA has stated it is not planning to conduct an ecological risk assessment of the FCS. No significant effects on the concentrations of and exposures to any substances in freshwater, estuarine, or marine ecosystems are anticipated due to the proposed use of the subject preservative. The FCS is not expected to accumulate in the food chain due to its low K_{ow} bio-concentration potential. Despite its very toxic effect on aquatic organisms on an acute basis, the fate of the food-contact substance in the aqueous environment does not need to be addressed because no significant introductions of substances into the environment were identified in Item 6 above.

(c) Land

The FCS is not known to bind to soil or sediment (Dow MSDS, Attachment 37) and its potential for photo degradation and high water solubility suggests that any residual leaching out of the polymer matrix would quickly pass out of terrestrial habitats. Considering the factors discussed above, no significant effects on the concentrations of or exposures to any substances in terrestrial ecosystems are anticipated as a result of the proposed use of the food contact substance. In particular, the fact that the food-contact substance will be encased in a relatively high molecular weight polymer is expected to result in virtually no leaching of components of the food-contact substance under normal environmental conditions when the finished food-contact materials are disposed of. Thus, there is no expectation of any meaningful exposure of terrestrial organisms to the components of the food-contact substance as a result of the proposed use. Because there is no expectation that use and disposal of materials manufactured from the food contact substance will affect the concentration of any substance in the terrestrial environment, we respectfully suggest that no further consideration of environmental fate in the terrestrial environment is necessary.

8. **Environmental effects of released substances:**

As discussed previously, the only substances that may be expected to be released to the environment upon the use and disposal of food packaging materials fabricated with the subject polymer preservative consist of extremely small quantities of combustion products and leachates, if any. Thus, no adverse effect on organisms in the environment is expected as a result of the disposal of articles containing the food contact substance. Any residual amounts of the FCS entering the environment would degrade rapidly to non-toxic and non-persistent substances with no potential bio-accumulation. Acute exposure

is a danger to the most sensitive aquatic organism, *Psuedokirchneriella subcapitatta* (a freshwater green algae), at concentrations of 0.0104 mg/L (Lanxess Endpoint doc, Attachment 39). *Daphnia magna* has their mobility affected at 0.87 mg/L. Therefore, as no significant introductions of the substances into the environment as a result of the proposed use of the FCS were identified under Format Item 6, a quantitative evaluation of the environmental effects of the proposed use of the FCS is not required.

9. **Use of resources and energy:**

The food contact substance is intended to replace other similar polymer preservatives such as 5-Chloro-2-methyl-4-isothizolin-3-one (CMIT), 1,2-Dibromo-2,4-dicyanobutane, and other anti-microbial preservatives currently allowed in 175.300, 175.320, and Inventory of Effective Food Contact Notifications, and so no significant change in energy use is expected based on the approval of the requested use.

10. **Mitigation measures:**

No potential adverse environmental impact has been identified as a result of the proposed action. Therefore, no mitigation measures are necessary.

11. **Alternatives to the proposed action:**

No potential adverse environmental effects are identified herein which would necessitate alternative actions to that proposed in this Notification. The alternative of not approving the action proposed herein would simply result in the continued use of the materials which the FCS would otherwise replace; such action would have no environmental impact.

12. **List of preparers:**

Richard Kraska, Ph.D., DABT GRAS Associates, LLC 27499 Riverview Center Blvd. Suite 212 Bonita Springs, FL 34134	Qualifications: BS Chemistry Ph.D. Pharmacology 30 years experience in toxicology and regulatory affairs
Heather Adams, Ph.D. GRAS Associates	B.A. Biology Ph.D. Ecology and Evolutionary Biology Former EPA S.T.A.R. fellow
Amy Anstead, M.S. GRAS Associates	B.S. Marine Science M.S. Biology 15 years experience in environmental sciences

13. **Certification:**

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

April 29, 2016

Richard Kraska, Ph.D., DABT
Chief Scientific Officer and Executive Vice President
Co-Founder
GRAS Associates, LLC
Consultant to the Lanxess Corporation

14. **References:**

EPA, 1996. Reregistration Eligibility Decision (RED) for Methylisothiazolinone (MIT). Environmental Protection Agency, April 3, 1996.

EPA, 2014. Methylisothiazolinone/ Choloromethyliosthiazoline Preliminary Work Plan. Registration Review: Initial Docket Case Number 3092. Federal Document ID EPA-HQ-OPP-2013-0605-0045.

CEQ Guidance on Greenhouse Gases Accessed at:
https://www.whitehouse.gov/administration/eop/ceq/initiatives/nepa/ghg-guidance

EPA, 2013. Advancing Sustainable Materials Management: Facts and Figures Report.
http://www.epa.gov/smm/advancing-sustainable-materials-management-facts-and-figures-report

15. **Attachments:**

The following attachments in the FCN are relevant to this environmental assessment. Attachments which are considered confidential are indicated below.

Confidential EA attachment Lanxess_FINAL Revised 19Apr16.pdf (Attachment 36)

DOW MIT MSDS.pdf (Attachment 37)

Sigma-Aldrich_MSDS_MIT.pdf (Attachment 38)

List of End Points_MIT_Final_2015-01.pdf **Confidential** (Attachment 39)

80057_PC_CoA_Harlan-D56852_Batch-CHN-0707_2012-08_3.pdf **Confidential** (Attachment 25)