Environmental Assessment

1. Date	January, 24, 2025 *
2. Name of applicant/notifier	Dalian Bio-Chem Company Limited
3. Address	Floor 11, Yifang Financial Plaza, No.12 Gangdong Street, Zhongshan District, Dalian, Liaoning, China, 116001 Phone No. +86-13514244211 lsm@biofc.com

4. Description of proposed action

a) Requested Action

The action requested in this Notification is to establish a clearance for the food contact substance (FCS) of 2-Methyl-4-isothiazolin-3-one (CAS Reg. No. 2682-20-4) antimicrobial preservative as a component in the manufacturing of food contact articles.

Intended Use

As:

1. an antimicrobial in uncured liquid rubber latex used to manufacture repeat-use rubber gloves.
2. a preservative in coatings that comply with 21 CFR 175.300 and 175.320
3. a preservative in can-end and side-seam cements that comply with 21 CFR 175.300.
4. a preservative in aqueous formulations of adhesives that will be used under use conditions defined in 21 CFR 175.105.
5. a preservative in aqueous coating formulations used on paper under use conditions defined in 21 CFR 176.170.
6. a preservative in aqueous additive formulations (latex emulsions, fillers, binders, pigment slurries, and sizing solutions) used in paper and paperboard manufacturing to produce paper in compliance with 21 CFR 176.170 and 176.180.
7. a slimicide in the wet-end of paper manufacturing to produce paper in compliance with 21 CFR 176.170 and 176.180.

The FCS is not for use in contact with infant formula and human milk (see Limitations/ Specifications).

Limitations/Specifications

The FCS may be used in contact with all food types. The intended uses of No. 2~6 are subject to Conditions of Use A through H as described in Table 1. The maximum level of the FCS:

1. in latex emulsions for the manufacture of repeat-use gloves is 250 ppm;
2. in aqueous emulsions for can coatings or polymeric coatings on polyolefin film is 100 ppm;
3. in aqueous emulsions of can-end or side-seam cement is 150 ppm;
4. in adhesives is 150 ppm;
5. in paper coating formulations is 150 ppm, with the exception of la latex emulsions in paper coatings, where the maximum level is 250 ppm;

* Subsequent to this date, this EA was edited using the Adobe text editor tool to make several corrections to harmonize the EA to the final FCN regulatory language.

6. in aqueous additive formulations for use in paper is 150 ppm;
7. in the wet-end of paper manufacture is 150 ppm of dry weight fiber.
The FCS is not for use in contact with infant formula or human milk. Such uses are not included as part of the intended use of the substance in the FCN.

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 rubber gloves, coating, adhesives and paper and paperboard. The FCS has no function in final food contact articles.

The FCS is an anti-microbial preservative that is regulated by the U.S. Environmental Protection Agency (EPA) under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). This FCS (Extracide M50) of Dalian Bio-Chem has been registered with the U.S. EPA.

c) Locations of Use/Disposal

The Notifier does not intend to produce finished food-contact articles from the FCS. Rather, the FCS will be sold to manufacturers engaged in the production of food-contact materials and articles. Food contact articles produced with the FCS in the U.S. will be utilized in patterns corresponding to the national population density and will be widely distributed across the country. Therefore, it is anticipated that disposal will occur nationwide.

According to U.S. EPA data for 2018, approximately 50.0% of municipal solid waste (MSW) is currently deposited in land disposal sites, 11.8% is combusted, 23.6% is recycled, 8.5% is composted, and 6.1% is directed to other food management pathways[1]. As the FCS is expected to be primarily disposed of through combustion and land-filling (or recycling facilities for paper and metal cans use), to evaluate the most conservative environmental introduction of the FCS, we recalculate the disposal pattern based on only the quantities of MSW that are land-disposed or combusted. On this basis, we estimate that 19.1% of food-contact materials containing the FCS will be combusted annually[2].

5. Identification of substance that is the subject of the proposed action

The FCS that is the subject of this Notification is 2-Methyl-4-isothiazolin-3-one. Chemical information on this substance is presented below:

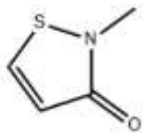
CAS Reg. No.: 2682-20-4

Chemical formula: C_4H_5NOS

Molecular weight: 115.15 g/mol

Structural Formula:

[1] Table 35 of Advancing Sustainable Materials Management: 2018 Tables and Figures. Assessing Trends in Material Generation and Management in the United States, U.S. Environmental Protection Agency, Office of Resource Conservation and Recovery, December 2020, available at:
https://www.epa.gov/sites/production/files/2020-11/documents/2018_tables_and_figures_fnl_508.pdf
2 This amount is calculated as follows: 11.8% combusted ÷ (11.8% combusted + 50.0% land disposed)= 19.1% combusted. The remaining 80.9% will be land-disposed.



6. Introduction of substances into environment

a) As a Result of Manufacture

Under 21 CFR 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 Notifier does not suggest that there are any extraordinary circumstances[3] in this case indicative of any adverse environmental impact as a result of the manufacture of the FCS. Consequently, information on the manufacturing site and compliance with relevant emissions requirements is not provided here.

b) As a Result of Use and Disposal

No significant environmental release is expected upon the use of the FCS in the manufacture of food-contact articles. In these applications, the FCS will be entirely incorporated into the finished food-contact articles. Any waste materials generated in the process are expected to be disposed as part of the manufacturer's overall non-hazardous solid waste in accordance with established procedures.

The FCS is expected to remain in the food-contact articles and, therefore, its disposal by the ultimate consumer will be by conventional rubbish disposal, and thus, primarily by sanitary landfill or incineration.

Air (Combustion):

Based on the physical and chemical properties of FCS, it presence in aqueous media are not likely to partition into air based on the low Henry's Law constants[4] 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 is 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 Kow[5] indicates that sorption to soil, sludge, and sediments and bio-accumulation in aquatic organisms are expected to be limited[6].

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 within a food contact materials or articles. Furthermore, because the food-contact substance will make up a very small portion of the total municipal solid

3 Such extraordinary circumstances would include: 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; or 3) production associated with a proposed action that may adversely affect a species or the critical habitat of a species

4 1.36 x 10-9 Pa-m3/mol; Environmental Assessment for Food Contact Notification FCN 1649; https://wayback.archive-it.org/7993/20190213190115/https://www.fda.gov/downloads/Food/IngredientsPackagingLabeling/EnvironmentalDecisions/UCM526786.pdf

5 EPA, Methylisothiazolinone. Reregistration Eligibility Decision (RED). EPA 738-R-98-012, 1998.

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

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).

The FCS is composed of carbon, hydrogen, oxygen, nitrogen and sulfur. Thus, carbon dioxide is expected to form upon combustion of the FCS. Based on the elemental composition of the FCS, a greenhouse gas GHG analysis was performed. This analysis is based upon the elemental composition of the FCS and assumes that 19.1% (described under 4(c)) of the annual market volume will be combusted.

MSW combustion facilities are regulated by the U.S. EPA under 40 CFR 98, which "establishes mandatory GHG reporting requirements for owners and operators of certain facilities that directly emit GHG" and sets an annual 25,000 metric tons carbon dioxide equivalent (CO_2-e) emission threshold for required reporting at 40 CFR 98.2 of this regulation. From this analysis, the expected CO_2-e emissions are below 25,000 metric tons on an annual basis and mandatory reporting would not be required.

To evaluate the significance of the environmental impact of these GHG emissions, we consider whether the action threatens a violation of federal, state, or local law or requirements imposed for the protection of the environment. As noted above, GHG emissions from MSW combustion facilities are regulated under 40 CFR §98.2. The expected carbon dioxide equivalent emissions, are below 25,000metric 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 the combustion of the FCS in MSW combustion facilities. As the FCS will not alter the emissions from properly operating MSW combustors and incineration of the FCS will not cause municipal waste combustors to threaten a violation of applicable Federal, State or local emissions laws and regulations (i.e., 40 CFR 60), no significant effect on the concentrations of and exposures to any substances in the atmosphere are anticipated due to the proposed use of the FCS.

Landfill:

Only extremely low levels, if any, of the FCS are expected to enter the environment as a result of the landfill disposal of food-contact articles, in light of the EPA's regulations governing municipal solid waste landfills. 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). These requirements are enforced by state solid-waste management programs. Therefore, based on MSW landfill regulations preventing leaching and state enforcement of these requirements, the food contact substance is not expected to reach the aquatic or terrestrial environment when disposed of via landfill.

Considering the factors discussed above, no significant effects on the concentrations of and exposures to any substance in terrestrial ecosystems are anticipated as a result of the proposed use of the subject FCS.

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. If this FCS is added at the wet end of the paper manufacture process, the FCS is not expected to be introduced into the land downstream of wastewater treatment[7].

Due to FCS 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 Kow bio-concentration potential. Despite its 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 there are no significant introductions of substances into the environment.

Therefore, we do not expect there are any extraordinary circumstances which would otherwise suggest a significant environmental impact on the aqueous environment resulting from post-consumer disposal of food-contact articles that contain the FCS due to the proposed use.

7. Fate of emitted substances in the environment

As discussed in Section 6, no significant quantities of the FCS will be released upon manufacture, use and disposal of food-contact articles containing the FCS. Considering the foregoing, we respectfully submit that there is no reasonable expectation of significant effects on the concentrations of and exposures to any substances in the atmospheric, aquatic or terrestrial environmental compartments. Accordingly, because there is no expectation of the FCS being introduced into the environment as a result of the proposed use of the FCS, the environmental fate of the FCS does not need to be addressed.

8. Environmental effects of released substances

As discussed previously, only extremely small and insignificant quantities of the FCS may be expected to be released into the environment during use and disposal of food-contact articles containing the FCS.

Based on these considerations, no adverse effect on organisms in the environment or the environment itself, is expected as a result of the disposal of articles containing the FCS. In addition, the use and disposal of the food-contact articles containing the FCS are not expected to threaten a violation of applicable laws and regulations, e.g., EPA's regulations in 40 CFR Parts 60 and 258.

9. Use of resources and energy

The proposed use of the FCS in this Notification will not require additional energy resources for the treatment and disposal of wastes as the FCS is expected to compete with, and to some extent replace

[7] EPA, 2014. Methylisothiazolinone/ Choloromethyliosthiazoline Preliminary Work Plan. Registration Review: Initial Docket Case Number 3092. Federal Document ID EPA-HQ-OPP-2013-0605-0045. Based on the reported anaerobic and aerobic aquatic metabolism half-lives ranging from about 5 to 9 hours, rapid degradation of MIT is indicated. The straight-chain degradates, including N-methylmalonamic acid (NMMA), are transient degradates that are rapidly biodegraded and were not reported to be formed at significant quantities in metabolism studies. In addition, these are not expected to enter surface water from wastewater treatment.

similar substances already on the market. Food-contact materials and articles containing the FCS are expected to be disposed according to the same patterns when it is used in place of current materials. Therefore, there will be no anticipated impact on current or future recycling programs.

The partial replacement of this type of material by the subject FCS is not expected to have any adverse impact on the use of energy and resources. Manufacture of the FCS, and its use in food-contact materials and articles, will consume energy and resources in amounts comparable to the manufacture and use of the currently cleared alternative FCS.

10. Mitigation measures

As shown above, no significant adverse environmental impacts are expected to result from the use and disposal of food-contact articles containing the FCS. This is primarily due to the minute levels of leaching of potential migrants from the finished item; the insignificant impact on environmental concentrations of combustion products of the FCS; and the close similarity of the FCS to the products it is intended to replace. Thus, the use of the FCS as proposed is not reasonably expected to result in any new environmental problem requiring mitigation measures of any kind.

11. Alternatives to proposed action

No potential adverse environmental effects are identified herein that would necessitate alternative actions to those 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 anticipated environmental impact.

12. List of preparers

Jenny Zhang, 4 years of experience related to the preparation of Food Contact Notifications and food packaging compliance matters under FDA food contact regulations. Regulatory analyst, REACH24H CONSULTING GROUP, 14th Floor, Building No. 3, Haichuang Technology Center, 1288 West Wen Yi Road, Hangzhou, China 311121

13. Certification

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

14. Attachment

Confidential Attachment to the Environmental Assessment (Attachment 15 in this Notification)

Date: January 24, 20254

Jenny Zhang,

Regulatory analyst Consultant for

Dalian Bio-Chem Company Limited