

Environmental Assessment

1. **Date** January 16, 2014
2. **Name of Applicant/Notifier** The Dow Chemical Company
3. **Address** All communications on this matter are to be sent to Mr. Garry M. Wiltshire, The Dow Chemical Company, 2020 Dow Center, D-214, Midland, Michigan 48674. Telephone: (986) 638-1557
4. **Description of the Proposed Action**

The action requested in this notification is to permit the use of OSP Lubricants as a lubricant with incidental food contact or a component of such lubricants under 21 CFR 178.3570.

The subject substance offers several technical properties that make it useful in lubricants. In particular, the FCS is compatible with mineral oils and synthetic hydrocarbon base oils. In addition, the FCS has high viscosity index values, low pour points and excellent film forming benefits.

The Notifier does not intend to produce finished lubricants from the subject polymers. Rather, the FCS will be sold to manufacturers engaged in the production of lubricants with incidental food contact. Such lubricants are used in the production of food and also in the production of food-contact materials.

Food-contact materials produced in equipment that use these polymers will be utilized in patterns corresponding to the national population density and will be widely distributed across the country. According to the U.S. Environmental Protection Agency's 2011 update regarding municipal solid waste in the United States, 53.6% of municipal solid waste generally was land disposed, 11.7% was combusted, and 34.7% was recovered for recycling and composting.¹ The types of environments present at and adjacent to these 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 materials prepared from the FCS.

¹ *Municipal Solid Waste in the United States: 2011 Facts and Figures*, EPA530-R-13-001, U.S. Environmental Protection Agency, Washington DC, 20460, www.epa.gov, May 2011.

5. Identification of Substance that Is the Subject of the Proposed Action

The FCS that is the subject of this Notification is: Oxirane, 2-ethyl, polymer with 2-methyloxirane, monododecyl ether, CAS Reg. Number 139873-90-8.

6. Introduction of Substances into the Environment

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. Moreover, information available to the Notifier 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 these copolymers. Consequently, information on the manufacturing site and compliance with relevant emissions requirements is not provided here.

No environmental release is expected upon the use of the FCS in equipment used to manufacture or process food. Small amounts, less than 10 ppm of lubricant, could be contained in food as a result of use and be consumed. Typical equipment using the FCS include gear boxes, compressors and hydraulic equipment. In these types of applications, when lubricant is disposed of it is considered used oil and falls under EPA's used oil management standards in 49 C. F. R. § Part 279. In addition, many states also regulate used oil and do not permit its disposal in municipal solid waste facilities. Used oil that is not recycled or reconditioned is typically burned for heat or energy. The U. S Department of Energy reported in 2006² that 945 million gallons of used oil were either burned, 83%, or recycled, 17%. Assuming about 7 pounds per gallon of oil, that is over 6.6 billion pounds of used oil annually. Given the low volume of the FCS compared to the large volume of used oils that are handled each year, the FCS represents a small fraction of the total of used oils. In addition, the FCS will be substitutional for lubricants or lubricant components that are already disposed of as used oils.

No environmental release is expected upon the use of the FCS in equipment used to fabricate food-contact materials. In these applications, only very trace incidental amounts of lubricant made from the FCS will be incorporated into the finished food package. Any waste materials generated in this process, *e.g.*, plant scraps, are expected to be disposed of as part of the packaging manufacturer's overall nonhazardous solid waste in accordance with established procedures.

Disposal by the ultimate consumer of food or food-contact materials that contain incidental amounts of the FCS will be by conventional rubbish disposal and, hence, primarily by sanitary landfill or incineration. The subject FCS consists of carbon, oxygen and hydrogen, elements that are commonly found in municipal solid waste. The trace amounts of lubricant in food or food packaging materials represent a very small portion of the total municipal solid waste currently combusted (estimated to be 29 million tons or

² Used Oil Re-refining Study to Address Energy Policy Act of 2005 Section 1838, U. S. Department of Energy, July 2006, http://fossil.energy.gov/epact/used_oil_report.pdf

11.7% of 250 million tons in 2011)¹ 2) the FCS will not significantly alter the emissions from properly operating municipal solid waste combustors³, and 3) incineration of polymers made from the FCS will not cause municipal solid waste combustors to threaten a violation of applicable emissions laws and regulations (40 CFR part 60 and/or relevant state and local laws.

Only extremely small amounts, 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 Environmental Protection Agency's (EPA) 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. 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 groundwater and to take corrective action as appropriate. The lack of any leaching is especially true considering that polymers made from the FCS are polymers that contain only minute levels of extractable material even under conditions that greatly exaggerate environmental exposure conditions. Even if a very small amount of substances leach from the landfilled food-packaging material into the landfill, we expect only extremely small amounts of substances, if any, to migrate from landfill leachate into the environment; this conclusion is based on EPA's regulations in 40 C.F.R. Part 258.

7. Fate of Emitted Substances in the Environment

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 polymers made from the FCS are of high molecular weight and do not volatilize. Combustion products of the FCS would be similar to those of used oils that are already burned as a means of disposal due to the FCS consisting of carbon, hydrogen and oxygen. Thus, no significant quantities of any new substances will be released upon the use and disposal of the FCS.

No significant introductions of substances into the environment as a result of the proposed use of the FCS were identified as discussed under Format Item 6. Consequently, evaluation of the environmental fate of the FCS or its combustion products is not required.

No significant effects on the concentrations of and exposures to any substances in fresh water, estuarine, or marine ecosystems are anticipated due to the proposed use of the subject copolymers. No significant introduction of substances into the aqueous environment is anticipated as a result of the proposed use of the FCS as discussed in Format Item 6.

³ Paul M. Sullivan; William H. Hallenbeck; Gary R. Brenniman, *Municipal Solid Waste Combustion*; University of Illinois at Chicago: Chicago, IL, 1993.

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 FCS. Thus, there is no expectation of any meaningful exposure of terrestrial organisms to the substance as a result of the proposed use of the FCS.

Considering the foregoing, we respectfully submit that 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 food-contact substance in the manufacture of articles intended for use in contact with food.

8. Environmental Effects of Released Substances

No significant introductions of substances into the environment as a result of the proposed use of the FCS were identified under Format Item 6. Consequently, evaluation of the environmental effects of the proposed use of the FCS is not required.

9. Use of Resources and Energy

The use of the FCS in equipment used to produce food or food-contact materials is not expected to result in a net increase in the use of energy and resources, since the FCS is intended to be used as a lubricant or component of lubricants and replace lubricants now on the market.

The partial replacement of these types of materials by the food-contact substance is not expected to have any adverse impact on the use of energy and resources. Manufacture of the FCS s will consume energy and resources in amounts comparable to the manufacture of other similar materials. Moreover, the FCS will replace similar lubricants that are collected as used oil and are typically disposed of by incineration for their btu value.

The FCS will be used as a component of repeat use lubricants or as a repeat use lubricant in equipment used to produce food or food-contact articles. Lubricants made from the FCS will find limited if any application to beverage bottling. Thus, we would not expect any impact on current or future recycling programs as a result of the use of the FCS.

10. Mitigation Measures

As shown above, no significant adverse environmental impacts are expected to result from the use and disposal of the FCS or of food-contact materials fabricated from the FCS. This is primarily due to the collection of the FCS as a used oil in very minor amounts compared to the used oils collected annually. Used oils are regulated by the U. S. EPA and many of the states and do not come into typical solid waste streams. Typical disposal of the FCS should result in no leaching of potential migrants since the FCS is not land filled, the insignificant impact on environmental concentrations of combustion products of the polymers; and the similarity of the subject FCS to the material 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 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 clearing 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. In view of the excellent qualities of the subject food-contact substance for use in food-contact applications, the fact that the polymer constituents are not expected to enter the environment in more than minute quantities upon the use and disposal and the absence of any significant environmental impact which would result from their use, the clearance of the use of the subject FCS as described herein by allowing this Notification to become effective is environmentally safe in every respect.

12. List of Preparers

Garry M. Wiltshire, Product Regulatory Technical Leader, The Dow Chemical Company, 2020 Dow Center, D-214, Midland, MI 48674,

13. Certification

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

Date: January 16, 2014



Garry M. Wiltshire