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Screening Assessment

Oils, lard, sulfurized
(Sulfurized lard oil)

Chemical Abstracts Service Registry Number
61790-49-6

Environment and Climate Change Canada
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Synopsis

Pursuant to section 68 of the Canadian Environmental Protection Act, 1999 (CEPA), the Minister of the Environment and the Minister of Health have conducted a screening assessment of oils, lard, sulfurized, hereinafter referred to as sulfurized lard oil. The Chemical Abstracts Service Registry Number (CAS RN[1]) for sulfurized lard oil is 61790-49-6. The substance is among those substances identified as priorities for assessment on the basis of other human health concerns.

Sulfurized lard oil does not occur naturally in the environment. It is primarily used in lubricants and greases. In 2011, there were no reports of manufacture above the reporting threshold of 100 kg for sulfurized lard oil; between 1000 and 10 000 kg of sulfurized lard oil was imported into Canada.

The ecological risk of sulfurized lard oil was characterized using the Ecological Risk Classification of organic substances (ERC). The ERC is a risk-based approach that employs multiple metrics for both hazard and exposure on the basis of weighted consideration of multiple lines of evidence for determining risk classification. Hazard profiles are established based principally on metrics regarding mode of toxic action, chemical reactivity, food web-derived internal toxicity thresholds, bioavailability, and chemical and biological activity. Metrics considered in the exposure profiles include potential emission rate, overall persistence, and long-range transport potential. A risk matrix is used to assign a low, moderate or high level of potential concern for substances on the basis of their hazard and exposure profiles. The ERC identified sulfurized lard oil as having a low potential to cause ecological harm.

Considering all available lines of evidence presented in this screening assessment, there is low risk of harm to organisms and the broader integrity of the environment from sulfurized lard oil. It is concluded that sulfurized lard oil does not meet the criteria under paragraphs 64(a) or (b) of CEPA as it is not entering the environment in a quantity or concentration or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity or that constitute or may constitute a danger to the environment on which life depends.

Sulfurized lard oil was not identified as posing a high hazard to human health on the basis of classifications by other national or international agencies for carcinogenicity, genotoxicity, developmental toxicity or reproductive toxicity.

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In Canada, although there are recognized commercial uses for lubricant products containing sulfurized lard oil, no consumer uses were identified. Sulfurized lard oil is not expected to be present in environmental media at significant concentrations due to low expected releases. On the basis of these considerations, exposure for the general population is not expected and the potential risk to human health is considered to be low.

On the basis of the information presented in this screening assessment, it is concluded that sulfurized lard oil does not meet the criteria under paragraph 64(c) of CEPA as it is not entering the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health.

It is concluded that sulfurized lard oil does not meet any of the criteria set out in section 64 of CEPA.

1. Introduction

Pursuant to section 68 of the Canadian Environmental Protection Act, 1999 (CEPA) (Canada 1999), the Minister of the Environment and the Minister of Health have conducted a screening assessment of sulfurized lard oil to determine whether this substance presents or may present a risk to the environment or to human health. This substance was identified as a priority for assessment on the basis of other human health concerns (ECCC, HC [modified 2007]).

The ecological risk of sulfurized lard oil was characterized using the Ecological Risk Classification of organic substances (ERC) (ECCC 2016a). The ERC describes the hazard of a substance using key metrics including mode of toxic action, chemical reactivity, food web-derived internal toxicity thresholds, bioavailability, and chemical and biological activity and considers the possible exposure of organisms in the aquatic and terrestrial environments on the basis of factors including potential emission rates, overall persistence and long-range transport potential in air. The various lines of evidence are combined to identify substances as warranting further evaluation of their potential to cause harm to the environment or as having a low likelihood of causing harm to the environment.

This screening assessment includes consideration of information on chemical properties, environmental fate, hazards, uses and exposures. Relevant data were identified up to July 2016. Empirical data from key studies as well as some results from models were used to reach conclusions. When available and relevant, information available from other jurisdictions was considered.

This screening assessment was prepared by staff in the CEPA Risk Assessment Program at Health Canada and Environment and Climate Change Canada and incorporates input from other programs within these departments. The ecological portion of this assessment is based on the ERC document which was subject to an external peer-review. Additionally, the ERC document (published July 30, 2016) and the draft of this screening assessment (published February 4, 2016) were each subject to 60-day public comment periods. While external comments were taken into consideration, the final content and outcome of the screening assessment remain the responsibility of Environment and Climate Change Canada and Health Canada.

This screening assessment focuses on information critical to determining whether a substance meets the criteria as set out in section 64 of CEPA by examining scientific information and

incorporating a weight of evidence approach and precaution.[2] The screening assessment presents the critical information and considerations that form the basis of the conclusion.

2. Substance identity

The substance oils, lard, sulfurized, herein referred to as sulfurized lard oil, is a biological UVCB (**U**nknown or **V**ariable Composition, **C**omplex Reaction Products or **B**iological Materials) substance. Sulfurized lard oil has the structure of a sulfurized triglyceride (Farng 2009); a triglyceride is an ester formed from glycerol and three unsaturated fatty acids, typically with one or more carbon-carbon double bonds (Hasenhuettl 2005). Upon reaction with sulfur, the carbon-carbon double bonds in a triglyceride form sulfur linkages that are responsible for the lubricating properties of a sulfurized triglyceride (Farng 2009). An example of such sulfurization is shown in Figure 2-1.

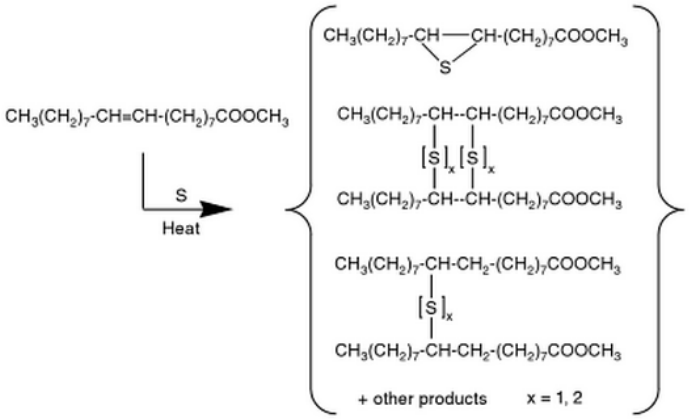

Figure 2-1. Sulfurization of an unsaturated ester with elemental sulfur (Farng 2009).

[2] A determination of whether one or more of the criteria of section 64 of CEPA are met is based upon an assessment of potential risks to the environment and/or human health associated with exposures in the general environment. For humans, this includes, but is not limited to, exposures from ambient and indoor air, drinking water, foodstuffs, and products available to consumers. A conclusion under CEPA is not relevant to, nor does it preclude, an assessment against the hazard criteria specified in the *Hazardous Products Regulations*, which are part of the regulatory framework for the Workplace Hazardous Materials Information System for products intended for workplace use. Similarly, a conclusion on the basis of the criteria contained in section 64 of CEPA does not preclude actions being taken under other sections of CEPA or other Acts.

3. Physical and chemical properties

Empirical data on the physical and chemical properties of sulfurized lard oil were not available. As the degree of sulfurization is unknown for sulfurized lard oil used in Canada, appropriate structural analogues for modelling physical and chemical properties could not be identified.

In general, triglycerides have low vapour pressures and are liquids or solids at room temperature. They are lipophilic and their solubility in water is low (Thomas 2000).

4. Sources and uses

Sulfurized lard oil does not occur naturally in the environment. It is used primarily in lubricants and greases. On the basis of information submitted pursuant to section 71 of CEPA (Canada 2012), there were no reports of manufacture above the reporting threshold of 100 kg for sulfurized lard oil in 2011; between 1000 and 10 000 kg of sulfurized lard oil was imported into Canada.[3]

In the United States, the national production volume for sulfurized lard oil was approximately 7.7×10^5 kg (1.7×10^6 lb) for the year 2011 (CDAT [modified 2014]).

In Canada, sulfurized lard oil is found in lubricants and greases, with applications in automotive, aircraft, and transportation, but no consumer uses for these products were identified (Canada 2012). Sulfurized fats are used extensively in lubricants such as metalworking fluids, tractor-transmission fluids, and greases. Sulfurized lard oil is the oldest, most widely used sulfur-based additive in commercial lubricants (Farng 2009). Globally, it is used in cutting fluids, lubricants and lubricant additives, and cooling agents for metal processing (CPCat 2014).

Additional uses for sulfurized lard oil are listed in Table 4-1.

Table 4-1. Status of additional uses in Canada for sulfurized lard oil

Use	Sulfurized lard oil
Food additive[a]	N
Food packaging materials[b]	Y (incidental additive (lubricant) with no food contact)
Internal Drug Product Database as medicinal or non-medicinal ingredients in disinfectant, human or veterinary drug products in Canada[c]	N

[3] Values reflect quantities reported in response to the survey conducted under section 71 of CEPA. See survey for specific inclusions and exclusions (Schedules 2 and 3).

Natural Health Products Ingredients Database[d]	N
Licensed Natural Health Products Database as medicinal or non-medicinal ingredients in natural health products in Canada[e]	N
List of Prohibited and Restricted Cosmetic Ingredients[f]	N
Notified to be present in cosmetics, on the basis of notifications submitted under the Cosmetic Regulations[g] to Health Canada	N
Formulant in pest control products registered in Canada[h]	N

Abbreviations: Y, YES; N, NO

[a] Health Canada (modified 2013)

[b] Personal communication, email from Food Directorate, Health Canada, to Risk Management Bureau, Health Canada, dated November 17, 2015; unreferenced

[c] DPD (modified 2015)

[d] NHPID (modified 2016)

[e] LNHPD (modified 2016)

[f] Health Canada (modified 2015)

[g] Personal communication, email from the Consumer Product Safety Directorate, Health Canada, to the Existing Substances Risk Assessment Bureau, Health Canada, dated August 28, 2015; unreferenced

[h] PMRA 2010; PMRA [modified 2013])

5. Potential to cause ecological harm

5.1 Characterization of ecological risk

The ecological risk of sulfurized lard oil was characterized using the ecological risk classification of organic substances (ERC) (ECCC 2016a). The ERC is a risk-based approach that considers multiple metrics for both hazard and exposure, on the basis of weighted consideration of multiple lines of evidence for determining risk classification. The various lines of evidence are combined to discriminate between substances of lower or higher potency and lower or higher potential for exposure in various media. This approach reduces the overall uncertainty with risk characterization compared to an approach that relies on a single metric in a single medium (e.g., LC_{50}) for characterization. Since sulfurized lard oil is a UVCB substance and could not be suitably represented by a single chemical structure, a manual judgement-based approach to classification was used. The following summarizes the approach, which is described in detail in ECCC 2016a.

For discrete substances as well as for UVCBs that could be suitably characterized on the basis of a single representative structure, hazard profiles based primarily on metrics regarding mode of toxic action, chemical reactivity, food web-derived internal toxicity thresholds, bioavailability, and chemical and biological activity were established. Exposure profiles were also composed of multiple metrics including potential emission rate, overall persistence, and long-range transport potential. Hazard and exposure profiles were compared to decision criteria in order to classify the hazard and exposure potentials for each organic substance as low, moderate, or high. Additional rules were applied (e.g., classification consistency, margin of exposure) to refine the

preliminary classifications of hazard or exposure. However, in the case of sulfurized lard oil, hazard and exposure could not be fully profiled due to the lack of a representative structure to estimate needed properties, and the lack of empirical data for these properties. Therefore, manual classification of hazard and exposure was performed by examining the UVCB constituents and DSL Inventory Update information and making decisions on the basis of consideration of similar substances and application of expert judgement.

A risk matrix was used to assign a low, moderate or high classification of potential risk for each substance on the basis of its hazard and exposure classifications. ERC classifications of potential risk were verified using a two-step approach. The first step adjusted the risk classification outcomes from moderate or high to low for substances that had a low estimated rate of emission to water after wastewater treatment, representing a low potential for exposure. The second step reviewed low risk potential classification outcomes using relatively conservative, local-scale (i.e., in the area immediately surrounding a point-source of discharge) risk scenarios, designed to be protective of the environment, to determine whether the classification of potential risk should be increased.

ERC uses a weighted approach to minimize the potential for both over and under classification of hazard and exposure and subsequent risk. The balanced approaches for dealing with uncertainties are described in greater detail in ECCC 2016a. The following describes two of the more substantial areas of uncertainty. Error in empirical or modeled acute toxicity values could result in changes in classification of hazard, particularly metrics relying on tissue residue values (i.e., mode of toxic action), many of which are predicted values from QSAR models. However, the impact of this error is mitigated by the fact that overestimation of median lethality will result in a conservative (protective) tissue residue used for critical body residue (CBR) analysis. Error of underestimation of acute toxicity will be mitigated through the use of other hazard metrics such as structural profiling of mode of action, reactivity and/or estrogen binding affinity. Changes or errors in chemical quantity could result in differences in classification of exposure as the exposure and risk classifications are highly sensitive to emission rate and use quantity. The ERC classifications thus reflect exposure and risk in Canada on the basis of what is believed to be the current use quantity, and may not reflect future trends.

Critical data and considerations used to develop the substance-specific profiles for sulfurized lard oil, and the hazard, exposure and risk classification results, are presented in ECCC (2016b).

Sulfurized lard oil was classified as having a moderate hazard potential based on a higher terrestrial Hazard Assessment Factor (HAF), but with low exposure potential. According to ERC for sulfurized lard oil, this substance was classified as having low potential for ecological risk. It is therefore unlikely that this substance results in concerns for organisms or the broader integrity of the environment in Canada.

6. Potential to cause harm to human health

6.1 Exposure assessment

No reports of sulfurized lard oil in any Canadian environmental media were identified. Sulfurized lard oil is expected to be a solid with low water solubility. There were no reports of manufacture above the reporting threshold of 100 kg for sulfurized lard oil in Canada (Canada 2012). Given that it is primarily used industrially and that volumes imported are relatively low, significant releases to the environment are not expected. As a result, exposure of the general population to sulfurized lard oil via environmental media is not expected.

Exposure of the general population through food or products available to consumers is not expected as sulfurized lard oil is not found in these sources. The presence of sulfurized lard oil in an incidental additive without food contact (lubricant) is not expected to result in exposure of the general population.

6.2 Health effects assessment

Sulfurized lard oil was not identified as posing a high hazard to human health on the basis of classifications by other national or international agencies for carcinogenicity, genotoxicity, developmental toxicity, or reproductive toxicity. It is also not on the European Chemicals Agency's Candidate List of Substances of Very High Concern for Authorisation (ECHA [modified 2015]). Further investigation of health effects is not warranted at this time given the low expected exposure of the general Canadian population.

6.3 Characterization of risk to human health

Exposure of the general population to sulfurized lard oil through environmental media, food, or the use of products available to consumers is not expected. On the basis of these considerations, the potential risk to human health is considered to be low.

6.4 Uncertainties in evaluation of risk to human health

Although there are some limitations in the exposure database (e.g., no environmental monitoring applications of sulfurized lard oil in transportation), given that the sources, uses, and properties of sulfurized lard oil are well characterized, a qualitative approach to risk characterization is considered appropriate for this assessment.

7. Conclusion

Considering all available lines of evidence presented in this screening assessment, there is low risk of harm to organisms and the broader integrity of the environment from sulfurized lard oil. It is concluded that sulfurized lard oil does not meet the criteria under paragraphs 64(a) or (b) of CEPA as it is not entering the environment in a quantity or concentration or under conditions that

have or may have an immediate or long-term harmful effect on the environment or its biological diversity or that constitute or may constitute a danger to the environment on which life depends.

On the basis of the information presented in this screening assessment, it is concluded that sulfurized lard oil does not meet the criteria under paragraph 64(c) of CEPA as it is not entering the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health.

Therefore, it is concluded that sulfurized lard oil does not meet any of the criteria set out in section 64 of CEPA.

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