

MICHIGAN DEPARTMENT OF ENVIRONMENTAL QUALITY

INTEROFFICE COMMUNICATION

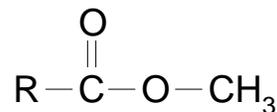
September 15, 2014

TO: File for Soybean Oil, Methyl Esters (CAS No. 67784-80-9)
FROM: Michael Depa, Air Unit, Air Quality Division
SUBJECT: Development of the Screening Level

The Initial Threshold Screening Level (ITSL) for soybean oil, methyl esters, also known as methyl soyate, is 16 µg/m³ (annual averaging time).

The following references or databases were searched to identify data to determine the screening level: United States Environmental Protection Agency's (EPA's) Integrated Risk Information System (IRIS), the Registry of Toxic Effects of Chemical Substances, the American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Values (TLV), National Institute of Occupational Safety and Health (NIOSH) Pocket Guide to Hazardous Chemicals, Environmental Protection Bureau Library, International Agency for Research on Cancer Monographs, Chemical Abstract Service (CAS) Online (1967- April 2008), National Library of Medicine, Health Effects Assessment Summary Tables, and National Toxicology Program Status Report. The EPA has not established a reference concentration (RfC) or a reference dose (RfD) for soybean oil, methyl esters.

Methyl Soyate (CAS No. 67784-80-9) is a mixture of long-chain fatty acid methyl esters (NTP, 2000). The molecular structure is:



Where R is typically 16 or 18 carbons and may contain one to three carbon-carbon double bonds (NTP, 2000).

A Lethal Dose Zero, LD0, of > 5000 mg/kg was obtained from Omni Tech International (2008). The report provides the following details:

Acute Oral Limit Test – Ten rats were each administered a single oral (gavage) dose of 5,000 milligrams of undiluted Methyl Soyate per kilogram of body weight (mg/kg) in accordance with standard testing guidelines published by the EPA's Office of Prevention, Pesticide and Toxic Substances (OPPTS 870.1100 [1998]). None of the rats died within a 14-day-0post observation period and no significant evidence of adverse health were found in any of the animals during the testing period or at necropsy. These data indicate the acute oral LD50 of Methyl Soyate is greater than 5,000 mg/kg.

An additional LD0 was referenced in a National Toxicology Program (NTP, 2000). The NTP report states:

According to the National Biodiesel Board, the acute oral LD50 of methyl soyate is >17.4 g/kg b.w. (species not identified) ... (NBB, 2000).

The reference to the LD0 cited by NTP from National Biodiesel Board (NBB, 2000) was sought in order to determine if the LD0 of 17.4 g/kg could be used to derive a screening level.

Unfortunately, the link provided in the NTP (2000) for LD0 study was broken. No additional details of the study design were available; therefore, the LD0 of 17.4 g/kg was not considered appropriate for derivation of the ITSL.

The LD0 from Omni Tech International (2008) provided enough details of how it was derived so that it was used to develop as screening level. In lieu of an LD50, as required in Rule 232(1)(h), using an LD0 instead of an LD50 results in a lower ITSL. This implies that the ITSL would be higher if an appropriate LD50 was available.

The LD0 from Omni Tech International (2008) was used to calculate the ITSL pursuant to Rule 232(1)(h). The average body weight (W_a) and the inhalation rate (I_a) of the rat (sex not given) was obtained from EPA, 1988.

$$\text{ITSL} = 1/500 \times 1/40 \times 1/100 \times \text{LD50}/(0.167) \times W_a/I_a$$

$$\text{ITSL} = 1/2000000 \times (5000 \text{ mg/kg})/(0.167) \times (0.395 \text{ kg})/(0.373 \text{ m}^3)$$

$$\text{ITSL} = 1.58 \times 10^{-2} \text{ mg/m}^3$$

$$\text{ITSL} = 16 \text{ } \mu\text{g/m}^3 \text{ (annual averaging time)}$$

The ITSL for soybean oil, methyl esters is 15 $\mu\text{g/m}^3$ based on annual averaging time.

EPA. 1988. Recommendation for and documentation of biological values for use in risk assessment. PB-88-179874.

NBB (2000) National Biodiesel Board, Fuel Fact Sheet. [<http://www.biodiesel.org/fuelfactsheet.htm>] <broken link>

NTP. 2000. Methyl Soyate. 67784-80-9. SUMMARY OF DATA FOR CHEMICAL SELECTION. Prepared for NCI by Technical Resources International, Inc., under contract no. N02-CB-07007 (10/00) http://ntp.niehs.nih.gov/ntp/htdocs/chem_background/exsumpdf/methylsoyate_508.pdf

Omni Tech International. 2008. Personal Communication from Jim Pollack with attachment: "Overview of Toxicity Testing of Methyl Soyate" from Michael J Norvell, PhD DABT, MJN Associated LLC. M.J.Norvel@Juno.com