SUMMARY OF DATA FOR CHEMICAL SELECTION

Methyl Soyate

67784-80-9

BASIS OF NOMINATION TO THE CSWG

Methyl soyate is brought to the attention of the CSWG because of its potential for rapidly increasing use. A technical product prepared from soy oil and methanol, methyl soyate is the most commonly used biodiesel fuel in the United States. If modest projections for the use of biodiesel, i.e., 8 percent of highway diesel consumption, are met in the next few years, biodiesel production could reach 2 billion gallons per year. Methyl soyate also shows promise as an industrial solvent to substitute for chlorinated hydrocarbon and fluorocarbon solvents, which would further extend its exposure potential.

Methyl soyate is a mixture of long-chain fatty acid methyl esters. This class of chemicals has not been well characterized as to carcinogenic activity; very limited evidence raises an unresolved question about possible weak activity as a skin tumor promoter. Fatty acid esters are generally nonmutagenic. Some researchers suggest that fatty acid ethyl esters may play a role in ethanol-induced organ damage.

Preliminary information on tailpipe emissions from vehicles run on biodiesel fuels suggests reduced emissions of carcinogens. Structure-activity analysis also supports the idea that methyl soyate is a green alternative to chlorinated solvents. Thus, independent testing to develop a safety profile for this potentially beneficial product appears warranted.

SELECTION STATUS

ACTION BY THE CSWG: 12/12/00

Studies requested:

Subchronic (90-day) skin painting study to characterize potential toxicity

Micronucleus assay

Priority: Moderately high

Rationale/Remarks:

Rapidly increasing production volume because of its use in the alternative fuel, biodiesel, which is gaining acceptance especially for use in fleet vehicles

Toxicity, especially from skin contact, is not well characterized

Emissions testing of vehicles run on soy or rapeseed biodiesel suggests significant health-related advantages to these alternative fuels

Coordinate testing with the United Soybean Board, which is actively promoting the development of methyl soyate products

CHEMICAL IDENTIFICATION

CAS Registry No: 67784-80-9

Chemical Abstracts Service Name: Soybean oil, methyl esters

Structure, Molecular Formula, and Molecular Weight: mixture of C16-C18 methyl esters

Structural Class: Fatty acid alkyl ester

Chemical and Physical Properties: The following information was derived from reports by the Department of Transportation (DOT) and the National Biodiesel Board (NBB) (DOT, 2000; NBB, 2000).

Description:	Pale yellow liquid, mild odor
Boiling Point:	>200 °C @ 760 mm Hg
Solubility:	Insoluble in water
Density/Specific Gravity:	0.88
Flash Point:	218 °C
Vapor Pressure:	<2 mm Hg
Reactivity:	Incompatible with strong oxidizing agents; possibility of spontaneous combustion ("oily rag" problem); no specific fire hazard problems during shipment

Technical Products and Impurities: Methyl soyate is produced by reacting soybean oil and methanol. It is the most commonly used biodiesel in the United States. Although methyl soyate is sometimes used interchangeably with biodiesel, "biodiesel" refers to the alkyl monoester of *any* vegetable oil or animal fat. In fact, rapeseed oil is commonly used in Europe to prepare biodiesel. The American Society of Testing and Materials provisional specification (PS 121) for biodiesel fuels applies to methyl soyate (NBB, 2000; Yahya & Marley, 1994).

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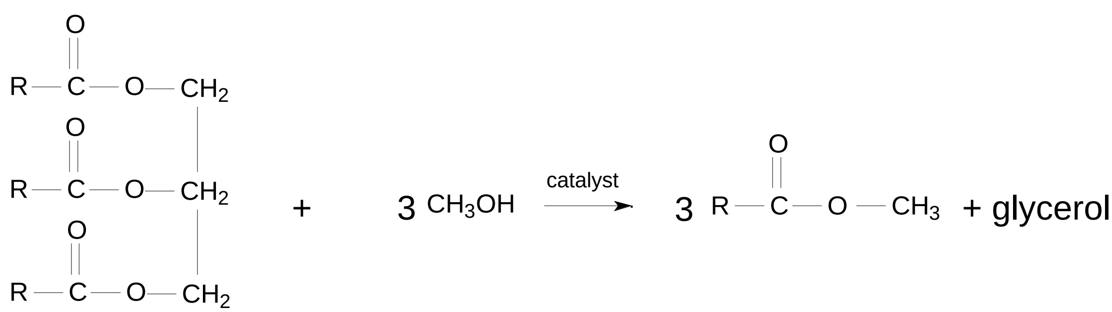
EXPOSURE INFORMATION

Production: Three synthetic pathways can be used to produce alkyl esters from oils and fats: base-catalyzed transesterification of the oil with alcohol; direct acid-catalyzed esterification of the oil with methanol; and conversion of the oil to fatty acids and then to alkyl esters with acid catalysis. The majority of alkyl esters are produced by the base-catalyzed method. A fat or oil is reacted with an alcohol, e.g., methanol, in the presence of a catalyst to produce glycerine and methyl esters (biodiesel). The catalyst is usually sodium or potassium hydroxide which has already been mixed with the methanol (NBB, 2000). This process is outlined in Figure 1.

Figure 1. Transesterification of Vegetable Oil to Biodiesel (Chevron, 2000)



R is typically 16 or 18 carbons and may contain one to three carbon-carbon double bonds.

Producers and Importers:

Soybeans are farmed in 29 states, making it the second largest cash crop in the United States. The production of methyl soyate has grown out of an effort on the part of the United Soybean Board (USB) to fund research for the commercialization of new uses of soybeans (AURI, 1999).

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Methyl soyate is listed in the EPA's Toxic Substances Control Act Inventory, but it was not found to be a high production volume chemical (>1 million lb) in 1990 or 1994 (EPA, 2000a; NLM, 2000a).

Use Pattern:

Several uses of methyl soyate are growing through the efforts of United Soybean Board which is researching soybean commercialization in the following areas: methyl ester solvents; lubricants; building composites, paints and coatings; plastics; emulsifiers and wetting agents; and pesticide carriers and adjuvants (USB, 2000a,b).

Methyl soyate shows promise as an industrial solvent to substitute for chlorinated hydrocarbon and fluorocarbon solvents for parts cleaning, carrier solvents, and resin removal and cleanup. Methyl soyate-based consumer products already on the market include car care products, hand cleaners, and paint strippers (AURI, 1999). For example, Vertec Gold™ is an industrial cleaning solvent intended to replace mineral spirits, lacquer thinner, xylene, methyl ethyl ketone, and other hydrocarbon degreasing solvents. A blend of methyl soyate and corn-derived ethyl lactate, Vertec Gold™ is sold in 5 gallon containers and 55 gallon drums (Vertec BioSolvents, 2000).

Methyl soyate is also the basis for the CytoSol process which allows the removal and recovery of spilled crude oil from coastal and inland spill sites. The CytoSol Biosolvent™ dissolves and extracts crude oil which is then washed from contaminated soil with cold water and recovered for use as a bunker fuel. This product has been listed by the EPA on the National Contingency Plan for oil spill cleanups (University of Illinois, 2000).

The primary use of methyl soyate appears to be the alternative fuel, biodiesel. Biodiesel is available neat, as blends with petroleum-derived diesel fuel, and as fuel

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additives. As an alternative fuel, biodiesel offers the advantage that it can substitute for petroleum diesel without engine modifications (Dzurik *et al.*, 2000; NBB, 2000).

Significant opportunities to replace imported oil with biofuels, including biodiesel, exist in the United States. Biodiesel in a conventional diesel engine gives a substantial reduction of unburned hydrocarbons, carbon monoxide, and particulate matter, and eliminates the sulfate fraction. Thus, a target market for biodiesel is in cities that must meet new federal clean air standards and in government fleets required to use alternative fuels (Anon., 1995; DOE, 2000a,b; Dzurik *et al.*, 2000).

The biggest obstacle to the acceptance of biofuels is their production costs which make them more expensive than petroleum-based transportation fuels (DOE, 2000b). Additional obstacles for biodiesel include low temperature startup and operability problems and a tendency to degrade some types of elastomers and rubber compounds which can impact fuel hoses and fuel pump seals (Dunn *et al.*, 1998; Henderson, 2000; NBB, 2000).

According to a report by Environment Canada, the use of soybean-based biodiesels is already fairly widespread in areas of the US where plant production is sufficient to meet commercial needs. In the US, more than 20 million miles have been driven on neat biodiesel and biodiesel blends, primarily in demonstration projects. Methyl ester made from rapeseed oil is in widespread use in Europe where blends with diesel are sold in petrol stations like any other fuel (Clark & Howard, 2000; DOT, 2000; Dzurik *et al.*, 2000; Environment Canada, 1999; Gómez Herrera, 1995; Henderson, 2000; NBB, 3000).

The primary US market for biodiesel appears to be a 20 percent blend with fossil-derived diesel fuel called B20. Presently, 13 companies actively market biodiesel and over 200 million gallons of biodiesel capacity exists. Dedicated biodiesel processing facilities are capable of doubling their production capacity within 18 months (NBB, 2000).

The National Renewable Energy Laboratory (NREL) quotes the National Biofuels Association as indicating that, with government incentives comparable to those provided for ethanol, biodiesel production could reach 2 billion gallons per year, about 8 percent of highway diesel consumption, in the next few years. At this level of market penetration, biodiesel would probably be used as a fuel mostly in bus fleets and heavy-duty trucks primarily as a 20 percent blend with fossil diesel (Clark & Howard, 2000).

As an additional marketing channel, after-market products containing methyl soyate biodiesel are sold as lubricity enhancers (University of Illinois, 2000). Several companies sell such diesel fuel additive packages, including Schaeffer Petroleum (SoyShield), Archer Petroleum (Soy-Guard), AEP/AGP (SoyGold), Farmland Industries/Cenex (SoyMaster), and Koch Performance Fuels (U.S. Soy Field Diesel) (DOE, 2000a; Henderson, 2000; Schumacher & VanGerpen, 2000). SoyShield, a methyl soyate blend combined with various additives, appears typical of these additive packages. One gallon of SoyShield is added for every 500 gallons of diesel fuel. SoyShield is available in cases (4 x 1 gallon), 5 gallon pails, and 30 and 55 gallon drums (Schaeffer Manufacturing Co., 1999).

Human Exposure: No data were found on consumer, environmental, or occupational exposure to methyl soyate in the available literature. Methyl soyate has been developed since the National Occupational Exposure Survey (NOES) was conducted by the National Institute for Occupational Safety and Health in 1981-1983.

Environmental Occurrence: Although the ingredients used to prepare methyl soyate, soybean oil and methanol, are derived from soybeans and corn, this commercially formulated product does not occur naturally in the environment.

According to the EPA, petroleum oils and vegetable oils [including soy oil] share common physical properties and can produce similar environmental effects, including coating animals and plants with oil and suffocating them by oxygen depletion, destroying food supplies and habitat, producing rancid odors, fouling shorelines and clogging water treatment plants, and forming products that linger in the environment for years. However, biodiesel degrades about four times faster than petroleum diesel. Within 28 days, pure biodiesel degrades 85 to 88 percent in water. A 20 percent blend degrades twice as fast as diesel fuel alone (EPA, 1998; NBB, 2000).

The use of neat biodiesel reduces carbon dioxide emissions from vehicle exhausts by more than 75 percent over petroleum diesel. Using B20 reduces carbon dioxide emissions by 15 percent. Biodiesel also reduces particulate matter by 22 percent, carbon monoxide by 20 percent, and sulfates by 20 percent. B20 reduces tailpipe emissions of unburned hydrcarbons by 7 percent and reduces the levels of polycyclic aromatic hydrocarbons (PAH) and nitrated PAHs by 13 and 50 percent, respectively (NREL, 2000; USDA, 2000).

Studies of the biodiesel fuels, rapeseed methyl ester and soybean oil methylesters (methyl soyate) have shown a decrease in the mutagenicity of diesel engine exhaust. Exhaust emissions from small diesel engines contained more black carbon and total polynuclear aromatic compounds and were significantly more mutagenic in *S. typhimurium* strains TA98 and TA100 than exhaust emissions from the engines burning biodiesel (Bünger *et al.*, 1998, 2000). A more limited study from a second investigative group reported similar findings for rapeseed biodiesel in *S. typhimurium* strain TA98 with and without S-9 (Carraro *et al.*, 1997).

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Regulatory Status:

No standards or guidelines have been set by NIOSH or OSHA for occupational exposure to or workplace allowable levels of methyl soyate. Methyl soyate was not on the American Conference of Governmental Industrial Hygienists (ACGIH) list of compounds for which recommendations or a Threshold Limit Value (TLV) or Biological Exposure Index (BEI) are made.

The OSHA permissible exposure limit of 5 mg/m^3 for oil mists may apply to some products containing methyl soyate (Schaeffer Mfg. Company, 2000).

Under the Clean Water Act (CWA), as amended by the Oil Pollution Act (OPA) of 1990, vegetable oils, including soybean oil, are considered oils. Facilities whose discharge could cause significant environmental harm are required to prepare a Facility Response Plan for oil spills (EPA, 1998).

Methyl soyate in its pure form is a designated alternative fuel under the Energy Policy Act of 1992 (EPAct), and biodiesel has been registered with the EPA as a fuel and as a fuel additive. Effective November 1998, B20 was also approved by Congress as an EPAct compliance strategy. In May 1999, the Department of Energy (DOE) issued new regulations which allowed federal, state or utility fleet vehicle managers to use biodiesel blends of 20 percent or higher to meet EPAct mandates (DOE, 1999; Kronenwetter, 1998; NBB, 2000).

On August 12, 1999, President Clinton signed Executive Order 13134, *Developing and Promoting Biobased Products and Bioenergy*, calling for the expanded use of bio-based fuels. It is anticipated that this Executive Order will help boost sales of biodiesel (NBB, 2000).

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Methyl esters of fatty acids produced from edible fats and oils have been approved as direct food additives for use in aqueous emulsions in dehydrating grapes to produce raisins (21 CFR 172.225). Methyl esters of higher fatty acids, including methyl myristate, methyl palmitate, methyl palmitoleate, methyl stearate, methyl oleate, methyl linoleate, methyl docosahexanoate, and methyl ecosapentanoate, are cleared by FDA as a supplementary source of fat for animal feed under 21 CFR 573.640. Methyl esters of the higher fatty acids are exempted from the tolerance requirements under 21 CFR 182.99 for use as adjuvants for pesticide chemicals applied to growing crops or raw agricultural commodities after harvest (FAME Taskforce, 1997).

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EVIDENCE FOR POSSIBLE CARCINOGENIC ACTIVITY

Human Data: No epidemiological studies or case reports investigating the association of exposure to methyl soyate and cancer risk in humans were identified in the available literature.

Because essentially no vapors are generated at normal temperatures, pure or neat biodiesel should not pose an inhalation hazard (DOT, 2000).

Animal Data:

Acute Studies. According to the National Biodiesel Board, the acute oral LD_{50} of methyl soyate is >17.4 g/kg b.w. (species not identified) and the 96-hr lethal concentration for bluegill is >1000 mg/L (NBB, 2000).

Prechronic/Subchronic Studies.
No information on the prechronic or subchronic toxicity of methyl soyate was found in the available literature.

Chronic/Carcinogenicity Studies. No 2-year carcinogenicity studies of methyl soyate in animals were identified in the available literature. Information on testing of individual fatty acid esters for carcinogenicity and tumor promotion is given below.

Methyl oleate applied to the skin of ST/a mice promoted the induction of malignant skin tumors and had weak activity as a complete carcinogen to the skin. Methyl oleate also showed some activity in promoting the induction of malignant lymphomas (Arffmann & Glavind, 1974). When given in the diet, this compound did not demonstrate carcinogenic activity during the 2-year observation period (Kiaer *et al.*, 1975).

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Methyl linoleate was tested for carcinogenicity toward the GI tract in male Wistar rats . Methyl linolate, fed by stomach tube, had no effect as a complete carcinogen and did not enhance the carcinogenesis of *N*-methyl-*N*-nitro-*N*-nitrosaguanidine (MNNG) after a maximum of 612 days (Arffmann *et al.*, 1981).

Short-Term Tests: No *in vitro* or *in vivo* studies evaluating methyl soyate for mutagenic effects were found in the available literature.

Methyl laurate, methyl palmitate, and methyl stearate were not mutagenic in the *S. typhimurium* reversion assay (strains not specified). *Cis*-methyl oleate was negative in the *Salmonella*/mammalian microsome assays conducted as part of NTP's chemical screening program (FAME Task Force, 1997).

In a study of the anticlastogenic potential of fatty acid methyl esters, lauric acid (C_{12}) up to nonadecanoic acid (C_{19}) methyl esters reduced the rate of aberrant metaphases in Chinese hamster bone marrow cells treated with busulfan. Bond saturation and number of double bonds had no influence on the anticlastogenic effects (Renner, 1986).

Metabolism: Although specific information on the metabolism of methal soyate was not found in the available literature, higher molecular weight fatty acid aliphatic methyl esters are readily hydrolyzed to the corresponding alcohol and acid and then generally oxidized to carbon dioxide and water via breakdown into two-carbon fragments which are used by the body for energy and building blocks for synthesis. During digestion, they are hydrolyzed to the free fatty acids for absorption from the intestine into the blood aided by lipase enzymes and bile salts. Once formed, the free fatty acid is metabolized by known oxidative processes or reconstituted into glyceride esters and stored in the fat depots of the body (FAME Task Force, 1997).

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Pure biodiesel looks and smells like a food product and could conceivably be ingested. If biodiesel is ingested, concerns have been expressed that enzymes in the body would break the ester back into its original components, raising the issue of methanol toxicity as a potential health hazard associated with biodiesel (DOT, 2000).

Other Biological Effects: No information specific to methyl soyate was identified in the available literature.

Administration of methanol by gavage to male Long-Evans rats increased the synthesis of endobiotic fatty acid methyl esters as evidenced by their concentrations in pancreas, liver, and brown fat (Kaphalia *et al.*, 1995).

According to Laposata, increasing evidence indicates that fatty acid ethyl esters play a role in ethanol-induced organ damage and may serve as long-term markers of ethanol intake (Laposata, 1999). Fatty acid ethyl esters have been found to accumulate in the fetus following ethanol administration to the mother (Bearer & Emerson, 1993). Fatty acid ethyl esters that were identified as myocardial metabolites of ethanol have been shown to induce mitochondrial dysfunction (Lange & Sobel, 1983).

Structure/Activity Relationships:

A traditional structure-activity analysis of methyl soyate, which is a mixture, could not be performed. Relevant information available on individual fatty acid methyl esters was incorporated under other sections of this Summary Sheet.

DOT (2000) raised concerns that the alkyl esters in methyl soyate could be metabolized to methanol. Although considerable information on the toxicity of methanol (CAS No. 67-56-1) exists in the available literature, no information

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was available on the carcinogenic effects of methanol in humans or animals. The American Methanol Institute Testing Group and BASF AG have sponsored methanol for such testing under EPA's HPV Challenge Program (EPA 2000b).

Methanol has been tested for mutagenic activity in several assays with the following results:

Inconclusive in micronucleus test for chromosome aberrations in mammalian polychromatic erythrocytes (NLM, 2000b)

Negative for cell transformation, clonal assay, in Syrian hamster embryo (SHE) cells (NLM, 2000b)

Negative for cell transformation, viral enhanced, in Syrian hamster embryo (SA7/SHE) cells (NLM, 2000b)

Negative for aneuploidy in *Neurospora crassa* (NLM, 2000b)

Negative for sister-chromatid exchange (SCE) *in vitro* in nonhuman cells (NLM, 2000b)

Negative for mutagenicity in *Salmonella typhimurium* strains TA98, TA100, TA1535, TA1537, & TA1538 w/wo S-9 (NLM, 2000c)

Negative for mutagenicity in *Escherichia coli* wp2 uvr A with and without S-9 (NLM, 2000c)

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