SOYBEAN OIL

This dossier on soybean oil presents the most critical studies pertinent to the risk assessment of soybean oil in its use in drilling muds. It does not represent an exhaustive or critical review of all available data. The majority of information presented in this dossier was obtained from the ECHA database that provides information on chemicals that have been registered under the EU REACH (ECHA). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch *et al.*, 1997).

Screening Assessment Conclusion – Soybean oil is classified as a **tier 1** chemical and requires a hazard assessment only.

1 BACKGROUND

Soybean oil is a vegetable oil extracted from the seeds of the soybean (*Glycine max*). Soybean oil is essentially triacylglycerols: fatty acids esterified to glycerol. The major unsaturated and saturated fatty acids in soybean oil are approximately: 56% linoleic acid ($C_{18:2}$), 21% oleic acid ($C_{18:1}$), 10% palmitic acid ($C_{16:0}$), 7% linolenic acid ($C_{18:3}$) and 4% stearic acid ($C_{18:0}$) (Zambiazi et al., 2007).

Manufacturers of both industrial and consumer products use soybean oil to replace petroleum and other volatile or hazardous ingredients, and increase product performance. Soybean oil is used in a variety of applications including rubber, fiber, coatings, solvents, plastics, lubricants and adhesives.

Soybean oil is a substance primarily composed of glycerides. They are expected to be rapidly and ultimately degradable and to have low aquatic toxicity. This substance and its degradation products are unlikely to cause harm in the environment.

2 CHEMICAL NAME AND IDENTIFICATION

Chemical Name (IUPAC): Soybean Oil

CAS RN: 8001-22-7

Molecular formula: Not applicable

Molecular weight: Not applicable

Synonyms: A6OIL;CAP 18;D04962;HY 3050;CT 7000;Soy oil; soybean; SOYA OIL; Bionatrol; CLINOLEIC.

3 PHYSICO-CHEMICAL PROPERTIES

Key physical and chemical properties for the substance are shown in Table 1.

Table 1 Overview of the Physico-chemical Properties of Soybean Oil

Property	Value	Klimisch score	Reference
Physical State	Oily; Colourless to Yellow liquid	2	Chemical Book
Density	917 kg/m^3 @ 25°C (lit.)	2	Chemical Book
Water Solubility	Immiscible with water	2	Chemical Book

4 DOMESTIC AND INTERNATIONAL REGULATORY INFORMATION

A review of international and national environmental regulatory information was undertaken (Table 2). This chemical is listed on the Australian Inventory of Chemical Substances – AICS (Inventory). No conditions for its use were identified. No specific environmental regulatory controls or concerns were identified within Australia and internationally for soybean oil.

NICNAS has assessed soybean oil in an IMAP Tier 1 assessment and concluded that it poses no unreasonable risk to human health or the environment. Soybean oil is a substance primarily composed of glycerides. They are expected to be rapidly and ultimately degradable and to have low aquatic toxicity. This substance and its degradation products are unlikely to cause harm in the environment[1]

Table 2 Existing International Controls

Convention, Protocol or other international control	Listed Yes or No?
Montreal Protocol	No
Synthetic Greenhouse Gases (SGG)	No
Rotterdam Convention	No
Stockholm Convention	No
REACH (Substances of Very High Concern)	No
United States Endocrine Disrupter Screening Program	No
European Commission Endocrine Disruptors Strategy	No

5 ENVIRONMENTAL FATE SUMMARY

A. Summary

Environmental fate data was not available for soybean oil. Environmental fate properties were evaluated using read-across for a similar substance in the group: fatty acids, soybean oil, conjugated. Substances in this group similar in chain length to fatty acids found in soybean oil are insoluble,

[1] https://www.industrialchemicals.gov.au/chemical-information/search-assessments-keywords?keywords=soybean+oil

immobile and have high adsorption to soil and sediment. Fatty acids occur naturally in all aquatic organisms and are ubiquitous in the aquatic environment, where fatty acids are predominantly readily biodegraded in an aerobic environment by microorganisms. As fatty acids are naturally stored in the form of triacylglycerols primarily within fat tissue until they are used for energy production (fat storage tactic), it is therefore considered that there will be no risk to aquatic organisms from potential bioconcentration/biomagnification of fatty acids (ECHA).

B. Partitioning

In water fatty acids are abiotically stable. Based on high insolubility and molecular structure (aliphatic, mostly saturated carbon chains) hydrolysis is not a relevant degradation pathway. Direct photolysis is not expected to contribute appreciably to the overall breakdown rate in water and soil, since the environmental degradation of these substances is predominantly of biotic nature (ECHA).

C. Biodegradation

The biodegradation data for the members of the fatty acids category includes standard biodegradation studies as well as modelling data (QSAR). The vast majority of the experimental results revealed ready biodegradability which was supported by reliable QSAR predictions. As summarized in the category justification, the members of the fatty acids will predominantly ready biodegrade (ECHA).

If a chemical is found to be readily biodegradable, it is categorised as Not Persistent since its half-life is substantially less than 60 days (DoEE, 2017).

D. Environmental Distribution

Based on the chemical structure and physical properties (insoluble), soybean oil is expected to have high adsorption to soil or sediment and be immobile. Estimated Koc values for linoleic acid (CAS No. 60-33-3) was 11,360 (ECHA) [Kl. Score = 2].

E. Bioaccumulation

A fish bioaccumulation study is available for the analogue substance C12 fatty acid-sodium laurate which showed negligible evidence of bioaccumulation potential in fish tissues with an estimated BCF of 255 L/kg after 28 days exposure (ECHA) [Kl. Score = 2].

As fatty acids are naturally stored in the form of triacylglycerols primarily within fat tissue until they are used for energy production (fat storage tactic), it is therefore considered that there will be no risk to aquatic organisms from potential bioconcentration/biomagnification of fatty acids (ECHA).

6 ENVIRONMENTAL EFFECTS SUMMARY

A. Summary

Soybean oil is expected to readily biodegrade be of low toxicity to environmental receptors.

B. Aquatic Toxicity

No study is available on the aquatic toxicity of fatty acids, soybean oil, conjugated (CAS 1176286 -43 -3) with fish, invertebrates or algae.

Soybean oil is of low acute toxicity concern to fish and invertebrates based on studies conducted on the surrogate compound glycerol trioleate (CAS No. 122-32-7) . The LC_{50} value of glycerol trioleate to fish has been reported to be 10,000 mg/L; and the EL_{50} of glycerol trioleate (WAF) to Daphnia indicates that is considerably greater than its water solubility (Willing et al., 2001).

C. Terrestrial Toxicity

Fatty acids occur in soils naturally, are part of physiological pathways and can be used as energy source. Thus, low toxicity is expected for terrestrial organisms exposed to the test substance (ECHA).

7 CATEGORISATION AND OTHER CHARACTERISTICS OF CONCERN

A. PBT Categorisation

The methodology for the Persistent, Bioaccumulative and Toxic (PBT) substances assessment is based on the Australian and EU REACH Criteria methodology (DEWHA, 2009; ECHA, 2008).

Soybean oil is expected to degrade in the environment and thus does not meet the criterion for persistence.

There are no specific data on the bioaccumulation potential for soybean oil but its expected degradation and read-across from a similar substance suggests that bioaccumulation is unlikely. Therefore, soybean oil does not meet the criterion for bioaccumulation.

Soybean oil is of low concern for toxicity and does not meet the criterion for this parameter.

The overall conclusion is that soybean oil is not a PBT substance.

B. Other Characteristics of Concern

No other characteristics of concern were identified for soybean oil.

8 SCREENING ASSESSMENT

Chemical Name	CAS No.	Overall PBT Assessment [1]	Chemical Databases of Concern Assessment Step		Persistence Assessment Step		Bioaccumulative Assessment Step	Toxicity Assessment Step			Risk Assessment Actions Required[3]
			Listed as a COC on relevant databases?	Identified as Polymer of Low Concern	P criteria fulfilled?	Other P Concerns	B criteria fulfilled?	T criteria fulfilled?	Acute Toxicity [2]	Chronic Toxicity[2]	
Soybean Oil	8001-22-7	Not a PBT	No	No	No	No	No	No	1	1	1

Footnotes:

1 - PBT Assessment based on PBT Framework.

2 - Acute and chronic aquatic toxicity evaluated consistent with assessment criteria (see Framework).

3 – Tier 1 – Hazard Assessment only.

Notes:

NA = not applicable

PBT = Persistent, Bioaccumulative and Toxic

B = bioaccumulative

P = persistent

T = toxic

9 REFERENCES, ABBREVIATIONS AND ACRONYMS

A. References

Chemical Book. Chemical Book database: https://www.chemicalbook.com/ChemicalProductProperty_EN_CB2703220.htm

Department of the Environment, Water, Heritage and the Arts [DEWHA]. (2009). Environmental risk assessment guidance manual for industrial chemicals, Department of the Environment, Water, Heritage and the Arts, Commonwealth of Australia.

Department of the Environment and Energy [DoEE]. (2017). Chemical Risk Assessment Guidance Manual: for chemicals associated with coal seam gas extraction, Guidance manual prepared by Hydrobiology and ToxConsult Pty Ltd for the Department of the Environment and Energy, Commonwealth of Australia, Canberra.

ECHA. ECHA REACH database: https://echa.europa.eu/information-on-chemicals/registered-substances

European Chemicals Agency [ECHA]. (2008). Guidance on Information Requirements and Chemical Safety Assessment, Chapter R11: PBT Assessment, European Chemicals Agency, Helsinki, Finland.

Klimisch, H.J., Andreae, M., and Tillmann, U. (1997). A systematic approach for evaluating the quality of experimental and toxicological and ecotoxicological data. Regul. Toxicol. Pharmacol. 25:1-5.

Willing, A. (2001). Lubricants based on renewable resources – an environmentally compatible alternative to mineral oil products. Chemosphere 43: 89-98.

Zambiazi, R.C., Przybylski, R., Zambiazi, M.W., and Mendonça, C.B. (2007). Fatty acid composition of vegetable oils and fats. B.CEPPA, Curitiba 25(1): 111-120.

B. Abbreviations and Acronyms

°C	degrees Celsius
°F	degrees Fahrenheit
AICS	Australian Inventory of Chemical Substances
COC	constituent of concern
DEWHA	Department of the Environment, Water, Heritage and the Arts
ECHA	European Chemicals Agency
EU	European Union
g/L	grams per litre
IUPAC	International Union of Pure and Applied Chemistry
kg/m^3	kilograms per cubic metre

PBT	Persistent, Bioaccumulative and Toxic
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
SGG	Synthetic Greenhouse Gases