LECITHIN

This dossier on lecithin presents the most critical studies pertinent to the risk assessment of lecithin 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 U.S. Cosmetic Ingredient Review on lecithin (CIR, 2001). Where possible, study quality was evaluated using the Klimisch scoring system (Klimisch et al., 1997).

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

1 BACKGROUND

Lecithin is a naturally occurring mixture of the diglycerides of stearic, palmitic and oleic acids, linked to the choline ester of phosphoric acid; it is found in living plants and animals. Lecithin is a UVCB substance. No studies are available. Lecithin is found in all living organisms; it is expected to be readily biodegradable and with no potential for bioaccumulation. No studies are available to evaluate the environmental hazard of lecithin however based on its biological essentiality it is not expected to be substantially toxic to environmental receptors.

2 CHEMICAL NAME AND IDENTIFICATION

Chemical Name (IUPAC): Lecithin

CAS RN: 8002-43-5

Molecular formula: $C_{43}H_{88}NO_9P$ (approximate) [CIR, 2001]

Molecular weight: 144.56 g/mol [CIR, 2001]

Synonyms: Lecithin, egg yolk lecithin; lecithins, egg yolk; lecithin, soybean; soybean phospholipid; lecithol: phosphatidylcholine; choline phospshoglyceride; and phospholutein

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 Lecithin

Property	Value	Reference
Physical state at 20°C and 101.3 kPa	Natural and refined grades vary from plastic to fluid, depending on free fatty acid and oil content and on the presence/absence of other diluents. Light yellow to brown. Amber, viscous liquid.	CIR, 2001
Melting Point	236 – 237°C[1]	CIR, 2001

[1] No information on the atmospheric pressure reported.

Property	Value	Reference
Specific Gravity	1.0305 @ 24°C; 1.02-1.06 @ 25°C	CIR, 2001
Solubility	Insoluble in water; partially soluble in water – readily hydrates to form emulsions.	CIR, 2001

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 lecithin.

NICNAS has assessed lecithin in an IMAP Tier 1 assessment and concluded that it poses no unreasonable risk to human health[2] .

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

No studies are available. Lecithin is found in all living organisms; it is expected to be readily biodegradable and with no potential for bioaccumulation. In mixed micelles, degradation almost exclusively affects the lecithin component through hydrolysis into free fatty acids and lysolecithin. Lecithins oxidise rapidly on exposure to air (CIR, 2001).

6 ENVIRONMENTAL EFFECTS SUMMARY

No relevant aquatic acute or chronic toxicity studies are available.

Physiological effects of lecithin in feed have been studied in aquatic animals. Purified deoiled dry forms of lecithin are used as supplements in aquaculture to enhance growth in early stages of development (Meyers, 1995).

[2] https://www.industrialchemicals.gov.au/chemical-information/search-assessments?assessmentcasnumber=8002-43-5

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).

Lecithin is a phospholipid that is found in living organisms. For example, it is a predominant phospholipid in membranes, in egg yolk, lung surfactant and amniotic fluid. Although there are no biodegradation studies on lecithin, it is expected to be readily biodegradable; thus it does not meet the screening criteria for persistence.

Lecithin is a naturally occurring phospholipid found in living organisms. It is not expected to bioaccumulate.

There are no aquatic toxicity studies on lecithin. As a naturally occurring phospholipid, it is not expected to meet the criteria for toxicity.

The overall conclusion is that lecithin is not a PBT substance.

B. Other Characteristics of Concern

No other characteristics of concern were identified for lecithin.

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]	
Lecithin	8002-43-5	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

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B. Abbreviations and Acronyms

°C	degrees Celsius
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
IUPAC	International Union of Pure and Applied Chemistry
KI	Klimisch scoring system
kPa	kilopascal
PBT	Persistent, Bioaccumulative and Toxic
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
SGG	Synthetic Greenhouse Gases
UVCB	Unknown or Variable Composition, Complex Reaction Products and Biological Materials