Amylodextrin

This dossier presents the most critical studies pertinent to the risk assessment of amylodextrin as it relates to its use in coal seam gas extraction activities. This dossier does not represent an exhaustive or critical review of all the available data. As there are no available studies for amylodextrin, this dossier is based on information obtained from similar read-across substance starch (CAS No. 9005-25-8). Where possible, the study quality was evaluated using the Klimisch scoring system (Klimisch et al., 1997).

Screening Assessment Conclusion- Amylodextrin is a polymer of low concern. Therefore, it is classified as a **tier 1** chemical and requires a hazard assessment only.

1 BACKGROUND

Amylodextrin is a short chain amylose that is produced by enzymatic hydrolysis of alpha-1,6 glycosidic bonds or debranching of amylopectin. Amylodextrin is a form of dextrin which is a low molecular weight carbohydrate polymer that is structurally characterized by glucose (D) units linked by glycosidic bonds. Dextrins are created when starch is heated in the presence of small amounts of moisture and an acid. Dextrins occur naturally in the human digestive system via the enzyme amylases which are catalysed by hydrolysis of starch in the human mouth.

Amylodextrin is expected to be biodegradable and does not bioaccumulate. Amylodextrin is not toxic to aquatic organisms.

2 CHEMICAL AND IDENTIFICATION

Chemical Name (IUPAC): (2*R*,3*S*,4*S*,5*R*,6*R*)-2-(hydroxymethyl)-6-[(2*R*,3*S*,4*R*,5*R*,6*S*)-4,5,6-trihydroxy-2-(hydroxymethyl)oxan-3-yl]oxyoxane-3,4,5-triol

CAS RN: 9005-84-9

Molecular formula: $C_{12}H_{22}O_{11}$

Molecular weight: 342.30 g/mol

Synonyms: Amylodextrin; starch, soluble; alpha-maltose; maltose

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 Amylodextrin

Property	Value	Klimisch score	Reference
Physical state at 20°C and 101.3 kPa	Solid	-	PubChem
Melting Point	240 °C (pressure not provided)	-	PubChem
Boiling Point	591.67 °C (pressure not provided)	-	EPISUITE

Property	Value	Klimisch score	Reference
Density	Not Available	-	-
Vapour Pressure	$7.1x10^{-15}$ Pa @ 25 °C	-	EPISUITE
Partition Coefficient (log K_{ow})	-5.12	-	EPISUITE
Water Solubility	52.2 g/L @ 20 °C	-	EPISUITE

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-ACIS (Inventory). No conditions for its use were identified. No specific environmental regulatory controls or concerns were identified within Australia and internationally for amylodextrin.

NICNAS has assessed amylodextrin in an IMAP Tier 1 assessment and it was concluded that this chemical poses no unreasonable risk to human health or the environment. It was also identified as a polymer of low concern[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 PROPERTIES

Amylodextrin is a form of dextrin, which is a low molecular weight carbohydrate polymer that is structurally characterized by glucose (D) units linked by glycosidic bonds. Dextrins are created when starch is heated in the presence of small amounts of moisture and an acid.

Amylodextrin is soluble in water. As a carbohydrate polymer, the substance is expected to be biodegradable.

[1] https://www.industrialchemicals.gov.au/chemical-information/search-assessments?assessmentcasnumber=9005-84-9%2C+

No bioaccumulation studies have been conducted on amylodextrin. A bioconcentration factor of 3.162 L/kg was estimated for the chemical using the log K_{ow} (-5.12) and the regression-based method in EPISUITE (USEPA, 2019). Based on this BCF, amylodextrin is not expected to bioaccumulate.

6 ENVIRONMENTAL EFFECTS SUMMARY

A. Summary

Amylodextrin is of low toxicity concern to aquatic organisms.

B. Aquatic Toxicity

Aquatic toxicity data is not available for amylodextrin or dextrin (CAS No. 9004-53-9). Therefore, available aquatic toxicity data is provided for similar substance starch (CAS No. 9005-25-8).

Acute Studies

Table 3 lists the results of acute aquatic toxicity studies conducted on starch.

Table 3 Acute Aquatic Toxicity Studies on Starch (CAS No. 9005-25-8)

Test Species	Endpoint	Results (mg/L)	Klimisch score	Reference
Orthopristis chrysoptera (pigfish)	96-h LC_{50}	>5,000	4	US EPA
Bairdiella chrysoura (silver perch)	96-h LC_{50}	>5,000	4	US EPA
Lagodon rhomboids (pinfish)	96-h LC_{50}	>5,000	4	US EPA

Chronic Studies

No chronic studies are available.

C. Terrestrial Toxicity

No studies are available.

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).

Amylodextrin as a carbohydrate polymer is expected to be readily biodegradable. Therefore, it does not meet the screening criteria for persistence.

Based on an estimated log K_{ow} of -5.12, amylodextrin does not meet the screening criteria for bioaccumulation.

There are no chronic toxicity studies on amylodextrin. The acute LC_{50} values for read-across similar substance starch are >1 mg/L. Therefore, amylodextrin does not meet the screening criteria for toxicity.

Therefore, amylodextrin is not a PBT substance.

B. Other Characteristics of Concern

No other characteristics of concern were identified for amylodextrin.

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]	
Amylodextrin	9005-84-9	Not a PBT	No	Yes	No	No	No	No	1	No Data	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

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.

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USEPA. ECOTOX Database. Available at: http://cfpub.epa.gov/ecotox/.

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
dw	dry weight
EC	effective concentration
ECHA	European Chemicals Agency
EU	European Union
g/cm^3	grams per cubic centimetre
g/L	grams per litre

IMAP	Inventory Multitiered Assessment and Prioritisation
IUPAC	International Union of Pure and Applied Chemistry
kPa	kilopascal
LC	lethal concentration
mg/kg	milligrams per kilogram
mg/L	milligrams per litre
NICNAS	National Industrial Chemicals Notification and Assessment Scheme
NOEC	no observed effective concentration
PBT	Persistent, Bioaccumulative and Toxic
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
SGG	Synthetic Greenhouse Gases