

**AUSTRALIAN INDUSTRIAL CHEMICALS INTRODUCTION SCHEME
(AICIS)**

POLYMER OF LOW CONCERN PUBLIC REPORT

Oxyclear® Additive 3500

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals Act 2019* (the IC Act) and *Industrial Chemicals (General) Rules 2019* (the IC Rules) by following the *Industrial Chemicals (Consequential Amendments and Transitional Provisions) Act 2019* (the Transitional Act) and *Industrial Chemicals (Consequential Amendments and Transitional Provisions) Rules 2019* (the Transitional Rules). The legislations are Acts of the Commonwealth of Australia. The Australian Industrial Chemicals Introduction Scheme (AICIS) is administered by the Department of Health, and conducts the risk assessment for human health. The assessment of environmental risk is conducted by the Department of Agriculture, Water and the Environment.

This Public Report is available for viewing and downloading from the AICIS website. For enquiries please contact AICIS at:

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**Executive Director
AICIS**

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SUMMARY

The following details will be published on our website:

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS SUBSTANCE	INTRODUCTION VOLUME	USE
PLC/1574	Indorama Ventures Oxides Australia Pty Limited	Oxyclear® Additive 3500	No	≤ 40 tonnes per annum	Component of food packaging

CONCLUSIONS AND REGULATORY OBLIGATIONS

Human Health Risk Assessment

Based on the assumed low hazard and the assessed use pattern, the assessed polymer is not considered to pose an unreasonable risk to the health of workers and the public.

As the assessed polymer will be used in materials with direct food contact, the public report of this assessment will be forwarded to Food Standards Australia New Zealand (FSANZ) for their information.

Environmental Risk Assessment

Based on the assumed low hazard and the assessed use pattern, the assessed polymer is not considered to pose an unreasonable risk to the environment.

Health and Safety Recommendations

- No specific engineering controls, work practices or personal protective equipment are required for the safe use of the assessed polymer itself. However, these should be selected on the basis of all ingredients in the formulation.

Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

- A copy of the SDS should be easily accessible to employees.
- If products and mixtures containing the assessed polymer are classified as hazardous to health in accordance with the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)*, as adopted for industrial chemicals in Australia, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation should be in operation.

Disposal

- Where reuse or recycling are not appropriate, dispose of the assessed polymer in an environmentally sound manner in accordance with relevant Commonwealth, state, territory and local government legislation.

Emergency Procedures

- Prevent from entering into soil, ditches, sewers, waterways and/or groundwater.
- Spills and/or accidental release of the assessed polymer should be handled by physical containment, collection and subsequent safe disposal.

Specific Requirements to Provide Information

This risk assessment is based on the information available at the time of the application. The Executive Director may initiate an evaluation of the chemical based on changes in certain circumstances. Under section 101 of the IC Act the introducer of the assessed chemical has post-assessment regulatory obligations to provide information to AICIS when any of these circumstances change. These obligations apply even when the assessed polymer is listed on the Australian Inventory of Industrial Chemicals (the Inventory).

Therefore, the Executive Director of AICIS must be notified in writing within 20 working days by the applicant or other introducers if:

- the assessed polymer is introduced in a chemical form that does not meet the PLC criteria;
- the final concentration of the polymer exceeds 6% in food packaging;
- the function or use of the assessed polymer has changed from a component of food packaging, or is likely to change significantly;
- the amount of assessed polymer being introduced has increased, or is likely to increase, significantly;
- the assessed polymer has begun to be manufactured in Australia;
- additional information has become available to the person as to an adverse effect of the assessed polymer on occupational health and safety, public health, or the environment.

The Executive Director will then decide whether an evaluation of the introduction is required.

Safety Data Sheet

The SDS of the assessed polymer was provided by the applicant. The accuracy of the information on the SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND APPLICATION DETAILS

Applicant

Indorama Ventures Oxides Australia Pty Limited (ABN: 67 083 984 187)
61 Market Rd
BROOKLYN VIC 3012

Protected Information (Section 38 of the Transitional Act)

Data items and details taken to be protected information include: chemical name, other names, CAS number, molecular and structural formulae, molecular weight, analytical data, polymer constituents, residual monomers/impurities and identity of analogue polymer.

2. IDENTITY OF POLYMER

Marketing Name

Oxyclear® Additive 3500

Molecular Weight

Number Average Molecular Weight (Mn) is > 1,000 g/mol.

3. PLC CRITERIA JUSTIFICATION

<i>Criterion</i>	<i>Criterion met</i>
Molecular Weight Requirements	Yes
Functional Group Equivalent Weight (FGEW) Requirements	Not applicable
Low Charge Density	Yes
Approved Elements Only	Yes
Stable Under Normal Conditions of Use	Yes
Not Water Absorbing	Yes
Not a Hazard Substance or Dangerous Good	Yes

The assessed polymer meets the PLC criteria.

4. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20 °C and 101.3 kPa	Off white to yellow solid pellets
Melting Point	225 – 240 °C
Density	1,100 – 1,200 kg/m ³
Water Solubility	Not expected to be soluble in water
Dissociation Constant	Contains no dissociable functional groups
Reactivity	Stable under normal environmental conditions
Degradation Products	None under normal conditions of use

5. INTRODUCTION AND USE INFORMATION

Maximum Introduction Volume of Assessed Chemical (100%) Over Next 5 Years

<i>Year</i>	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>
Tonnes	5	10	20	30	40

Use

The assessed polymer will be used as a resin additive in polyethylene terephthalate (PET) food packaging for direct food contact at $\leq 6\%$ concentration. It will not be manufactured in Australia. It will be imported in neat form as solid pellets for reformulation into plastic packaging.

The finished products will be used to package and protect oxygen-sensitive beverages and foods such as wine, beer, juice, food replacement drinks, milk and condiments.

6. HUMAN HEALTH RISK ASSESSMENT

No toxicological data were submitted. The assessed polymer meets the PLC criteria and is therefore assumed to be of low hazard. The risk of the assessed polymer to occupational and public health is not considered to be unreasonable given the assumed low hazard and the assessed use pattern.

The assessed polymer will be used in PET food packaging at $\leq 6\%$ concentration for direct food contact. The assessed polymer is designed to react with oxygen during use to extend the shelf-life of oxygen-sensitive beverages and foods. Given the potential for migration of oxidation by-products from the packaging, the applicant provided a detailed summary of a migration study that identified and quantified the oxidation by-products of an analogue polymer that was exposed to oxidative conditions, similar to those expected during use of the assessed polymer. A number of oxidation by-products were detected in food simulants; however, all were present in all tested food simulants at concentrations less than 10 ppb. The analogue polymer is essentially structurally identical to the assessed polymer and as such the migration study is expected to represent the assessed polymer.

Furthermore, the analogue polymer has been determined to fully comply with the US FDA food contact regulations for use at up to 6% concentration in PET food packaging applications for most food types, under a variety of conditions of use.

As the assessed polymer will be used in materials with direct food contact, the public report of this assessment will be forwarded to Food Standards Australia New Zealand (FSANZ) for their information.

7. ENVIRONMENTAL RISK ASSESSMENT

No ecotoxicological data were submitted. Polymers without significant ionic functionality are generally of low concern to the environment. Most of the assessed polymer will be irreversibly incorporated within PET food packaging. The PET food packaging may be recycled into other polymer products, but the final environmental fate will be to landfill as a part of the product. Release of the assessed polymer to the aquatic environment is not expected, as waste or residues generated during reformulation or use are expected to be collected and recycled or disposed of to landfill. When disposed of to landfill, the assessed polymer is expected to eventually degrade to form water and oxides of carbon.

The assessed polymer is expected to be insoluble in water based on structural considerations and is not expected to hydrolyse in the environmental pH range (4–9).

The assessed polymer is not expected to cross biological membranes due to its high molecular weight and low water solubility, and is therefore not expected to bioaccumulate.

Therefore, based on its assumed low hazard and reported use pattern, the assessed polymer is not considered to pose an unreasonable risk to the environment.