

**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME
(NICNAS)**

POLYMER OF LOW CONCERN PUBLIC REPORT

Polymer in TEGO VARIPLUS 1201 TF

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act) and Regulations. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the Australian Government Department of Health, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Australian Government Department of the Environment and Energy.

This Public Report is available for viewing and downloading from the NICNAS website or available on request, free of charge, by contacting NICNAS. For requests and enquiries please contact the NICNAS Administration Coordinator at:

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**Director
NICNAS**

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SUMMARY

The following details will be published in the NICNAS *Chemical Gazette*:

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS SUBSTANCE	INTRODUCTION VOLUME	USE
PLC/1396	Brenntag Australia Pty Ltd Evonik Australia Pty Ltd	Polymer in TEGO VARIPLUS 1201 TF	No	≤ 30 tonnes per annum	Additive in industrial ink

CONCLUSIONS AND REGULATORY OBLIGATIONS

Human Health Risk Assessment

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

Environmental Risk Assessment

Based on the assumed low hazard and the assessed use pattern, the notified 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 notified 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 notified 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 notified polymer in an environmentally sound manner in accordance with relevant Commonwealth, state, territory and local government legislation.

Emergency Procedures

- Spills and/or accidental release of the notified polymer should be handled by physical containment, collection and subsequent safe disposal.

Secondary Notification

This risk assessment is based on the information available at the time of notification. The Director may call for the reassessment of the polymer under secondary notification provisions based on changes in certain circumstances. Under Section 64 of the *Industrial Chemicals (Notification and Assessment) Act (1989)* the notifier, as well as any other importer or manufacturer of the notified

polymer, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified polymer is listed on the Australian Inventory of Chemical Substances (AICS).

Therefore, the Director of NICNAS must be notified in writing within 28 days by the notifier, other importer or manufacturer:

- (1) Under Section 64(1) of the Act; if
 - the notified polymer is introduced in a chemical form that does not meet the PLC criteria.
 - the final concentration of the notified polymer exceeds 5% in printing inks.
 - food migration data becomes available on the notified polymer.

or

- (2) Under Section 64(2) of the Act; if
 - the function or use of the notified polymer has changed from additive in industrial ink, or is likely to change significantly;
 - the amount of notified polymer being introduced has increased, or is likely to increase, significantly;
 - the notified polymer has begun to be manufactured in Australia;
 - additional information has become available to the person as to an adverse effect of the notified polymer on occupational health and safety, public health, or the environment.

The Director will then decide whether a reassessment (i.e. a secondary notification and assessment) is required.

Safety Data Sheet

The SDS of the product containing the notified 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 NOTIFICATION DETAILS

Applicants

Brenntag Australia Pty Ltd (ABN: 84 117 996 594)
260-262 Highett Road
HIGHETT VIC 3190

Evonik Australia Pty Ltd (ABN: 31 145 739 608)
Suite 33, 1 Ricketts Road
MOUNT WAVERLEY VIC 3149

Exempt Information (Section 75 of the Act)

Data items and details claimed exempt from publication: chemical name, other names, CAS number, molecular and structural formulae, molecular weight, polymer constituents, residual monomers/impurities, use details and manufacture/import volume.

2. IDENTITY OF POLYMER

Marketing Name(s)

TEGO VARIPLUS 1201 TF (product containing the polyurethane polyol polymer)

Molecular Weight

Number Average Molecular Weight (Mn) is > 1,000 Da

3. PLC CRITERIA JUSTIFICATION

<i>Criterion</i>	<i>Criterion met</i>
Molecular Weight Requirements	Yes
Functional Group Equivalent Weight (FGEW) Requirements	Yes
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 notified polymer meets the PLC criteria.

4. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20 °C and 101.3 kPa	Pale yellow solution (polymer in solvent)
Melting Point/Glass Transition Temp	Approximately 130 °C (isolated polymer)
Density	1,040 kg/m ³ at 20 °C (polymer in solution)
Water Solubility	Expected to be low based on the predominantly hydrophobic structure of the notified polymer.
Reactivity	Stable under normal environmental conditions
Degradation Products	None under normal conditions of use

5. INTRODUCTION AND USE INFORMATION

Maximum Introduction Volume of Notified 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	5-20	5-20	5-30	5-30	5-30

Use

The notified polymer will be imported at < 50% concentration in organic solvent in 50-190 kg steel drums. It will be reformulated into ink products which will contain the notified polymer at up to 5% concentration.

The inks containing the notified polymer (<5%) will be used in flexographic printing on plastic film under industrial settings only. The printed plastic films may be used in packaging food and other items.

6. HUMAN HEALTH RISK ASSESSMENT

No toxicological data were submitted. The notified polymer meets the PLC criteria and is therefore assumed to be of low hazard. Although not considered in this risk assessment, NICNAS notes that the notified polymer contains residual monomers that are classified as hazardous according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)*, as adopted for industrial chemicals in Australia.

The risk to workers when the notified polymer is used as proposed is not considered to be unreasonable.

The notified polymer will be used in inks for printing on food packaging and therefore may come in indirect contact with food. No migration studies on the notified polymer or any of its components were provided. However, the notifier advised that based on worst case estimations, the levels of residual components of the polymer that may migrate into food are in compliance with the Swiss “Ordinance of the FDHA on Materials and Articles (RS 817.023.21)”. All the components of the notified polymer are listed in the Annex 6 of this document and the estimated concentrations of the residual monomers and/or impurities are less than the maximum permitted concentrations stated in the list.

When used at proposed concentration and considering the estimated concentrations of the residual monomers and/or impurities, , the risk to public health is not considered to be unreasonable.

The public report of this assessment will be forwarded to Food Standards Australia New Zealand (FSANZ) for their information, as food contact with the notified polymer may occur.

7. ENVIRONMENTAL RISK ASSESSMENT

No ecotoxicological data were submitted. Polymers without significant ionic functionality are generally of low concern to the environment.

The notified polymer will be imported into Australia as a raw material and reformulated into ink products for printing on plastic film. It is estimated that up to 2% of the import volume is released as spills, container residues, container and equipment washings, and waste material. The total release from the blending process is expected to be < 20 kg per year. Liquid wastes are expected to be collected by licensed waste contractors for disposal in accordance with local regulations. Solid wastes containing the notified polymer are expected to be disposed of to landfill. The majority of the notified polymer will be bound within the cured printing matrix adhering to plastic film and will share the fate of printed articles.

It is anticipated that 50% of these printed articles will be disposed of to landfill and the remainder will be recycled at the end of their useful lifetime. During the recycling process, the ink and hence the notified polymer will be removed and is likely to partition to the solid/sludge waste that is expected to be disposed of to landfill. In landfill the notified polymer will be slowly degraded to form water and oxides of carbon and nitrogen. In the event that small quantities of the notified polymer are released to surface waters as a result of de-inking during the recycling process, the notified polymer is not expected to be released at ecotoxicologically significant concentrations. Due to the high molecular

weight of the notified polymer and its expected low water solubility, it is not expected to cross biological membranes, and is unlikely to bioaccumulate.

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

8. BIBLIOGRAPHY

Annexe 6 à l'Ordonnance du DFI sur les objets et matériaux du 23 novembre 2005 (RS 817.023.21):
Liste des substances admises pour la fabrication des encres d'emballage et exigences y relatives.
https://www.blv.admin.ch/dam/blv/fr/dokumente/gebrauchsgegenstaende/rechts-und-vollzugsgrundlagen/anhang-6-sr-edarfsgegenstaende.pdf.download.pdf/130401%20Annex%206_f.pdf
(accessed 8th March 2017)