File No: LTD/1941

December 2016

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Polymer in DPD-589 Dry Strength Resin

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the 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 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:

Street Address:	Level 7, 260 Elizabeth Street, SURRY HILLS NSW 2010, AUSTRALIA.
Postal Address:	GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.
TEL:	+ 61 2 8577 8800
FAX:	+ 61 2 8577 8888
Website:	www.nicnas.gov.au

Director
NICNAS

TABLE OF CONTENTS

SUMMARY

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

ASSESSMENT REFERENCE	APPLICANT	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
LTD/1941	Solenis Australia Pty Ltd	Polymer in DPD-589 Dry Strength Resin	ND*	≤ 485 tonnes per annum	Processing aid for paper manufacture

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available information, the notified polymer is not recommended for classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

The environmental hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS) is presented below. Environmental classification under the GHS is not mandated in Australia and carries no legal status but is presented for information purposes.

Hazard classification	*Hazard statement*
Acute (Category 2)	H401 – Toxic to aquatic life
Chronic (Category 2)	H411 – Toxic to aquatic life with long lasting effects

Human health risk assessment
Under the conditions of the occupational settings described, the notified polymer is not considered to pose an unreasonable risk to the health of workers.

When used in the proposed manner, the notified polymer is not considered to pose an unreasonable risk to public health.

Environmental risk assessment
On the basis of the PEC/PNEC ratio and the reported use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

Recommendations

CONTROL MEASURES

Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following engineering controls to minimise occupational exposure to the notified polymer during paper manufacturing:
  - Closed and automated processes where possible

- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer as introduced and during paper manufacturing:
  - Avoid skin and eye contact

- A person conducting a business or undertaking at a workplace should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer as introduced and during paper manufacturing:
  - Impervious gloves
  - Coveralls
  - Eye protection such as safety glasses or goggles

- A copy of the (M)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 or accidental release of the notified polymer should be handled by containment, collection and subsequent safe disposal.

Regulatory Obligations

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 chemical 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 chemical, 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 polymer has a number-average molecular weight of less than 1000;
  - the polymer is intended for use in contact with infant formula and breast milk;
  - the concentration of the polymer exceeds or is intended to exceed 0.4% in finished paper products;

or

(2) Under Section 64(2) of the Act; if
  - the function or use of the polymer has changed from a processing aid for paper manufacture or is likely to change significantly;
  - the amount of polymer being introduced has increased, or is likely to increase, significantly;
  - the polymer has begun to be manufactured in Australia;
  - additional information has become available to the person as to an adverse effect of the 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.

(Material) Safety Data Sheet
The (M)SDS of the notified polymer provided by the notifier was reviewed by NICNAS. The accuracy of the information on the (M)SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT
Solenis Australia Pty Ltd (ABN: 39 169 325 151)
7 Sir Thomas Mitchell Road
CHESTER HILL NSW 2162

NOTIFICATION CATEGORY
Limited: Synthetic polymer with Mn ≥ 1,000 Da.

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: molecular and structural formulae, molecular weight, analytical data, degree of purity, polymer constituents, residual monomers, impurities, additives/adjuvants, use details, and import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed for all physico-chemical endpoints.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
China (2015)
Korea (2015)

2. IDENTITY OF CHEMICAL

MARKETING NAME:
DPD-589 Dry Strength Resin (product containing the notified polymer at < 20% concentration)

CAS NUMBER
1659307-53-5

CHEMICAL NAME
1-Propanaminium, *N,N,N*-trimethyl-3-[(1-oxo-2-propen-1-yl)amino]-, chloride (1:1), polymer with ethenamine and 2-propenamide, hydrochloride

OTHER NAME
DPD-611 Dry Strength Resin

MOLECULAR WEIGHT
> 10,000 Da

ANALYTICAL DATA
Reference NMR, FTIR and GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
> 95%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Yellow liquids*

Property	Value	Data Source/Justification
Melting Point/Freezing Point	Not determined	Introduced in aqueous solution
Boiling Point	Not determined	Introduced in aqueous solution
Density	1,072 kg/m^3 at 23°C	(M)SDS*
Vapour Pressure	Not determined	Expected to be low based on high molecular weight
Water Solubility	> 150 g/L at 20 °C	Based on concentration in aqueous solution
Hydrolysis as a Function of pH	Not determined	Contains hydrolysable functionalities; however, not expected to significantly hydrolyse under environmental conditions (pH 4-9)
Partition Coefficient (n-octanol/water)	Not determined	Expected to be low based on high water solubility
Adsorption/Desorption	Not determined	Expected to adsorb to soil and sediment based on molecular weight and cationic charge
Dissociation Constant	Not determined	Expected to be ionised under environmental conditions (pH 4-9)
Flash Point	Not determined	Introduced in aqueous solution
Flammability	Not determined	Introduced in aqueous solution
Autoignition Temperature	Not determined	Introduced in aqueous solution
Explosive Properties	Not determined	Not expected to be explosive based on structure
Oxidising Properties	Not determined	Not expected to be oxidising based on structure

*For the marketed products containing the notified polymer at < 20% concentration

DISCUSSION OF PROPERTIES

Reactivity
The notified polymer is expected to be stable under normal conditions of use.

Physical hazard classification
Based on the submitted physico-chemical data depicted in the above table, the notified polymer is not recommended for hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified polymer will not be manufactured in Australia. The notified polymer will be imported into Australia as a component of an aqueous solution at < 20% concentration.

MAXIMUM INTRODUCTION VOLUME OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	10-100	10-100	100-485	100-485	100-485

PORT OF ENTRY
Sydney and Melbourne

TRANSPORTATION AND PACKAGING
The notified polymer will be imported into Australia as a component of an aqueous solution at < 20% concentration in 1000 L immediate bulk containers. These containers will be transported to the notifiers' warehouse followed by distribution to customer sites without any repackaging or reformulation.

USE
The notified polymer will be used as a processing aid in the manufacture of paper, paperboard, tissue and paper towel. The finished paper products may have food contact use.

OPERATION DESCRIPTION
The notified polymer will be imported at < 20% concentration in aqueous solution and will be transported to the end-user sites (paper mill) in its original packaging. The product will be moved to the production area of the paper mill and pumped from its container via pipeline to a dilution device (usually a static in-line mixer) where it will be diluted in fresh water. The diluted product containing the notified polymer at < 1.3% concentration will then be added to the paper stock (pulp, fillers and additives) prior to entry into the paper making-machine, where the final paper mixture will be de-watered and dried, and spooled onto rollers to produce finished paper. The finished paper will contain the notified polymer at < 0.4% concentration.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

Category of Worker	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Transport and warehouse workers	2-6	12-30
Process workers	8	50-100

EXPOSURE DETAILS
Transport and warehouse workers
Transport and warehouse workers may come into contact with the notified polymer at < 20% concentration only in the event of accidental rupture of containers.

Paper and pulp process workers
The paper manufacturing process will be largely enclosed and automated; however process workers may be exposed to the notified polymer at < 20% concentration during connection/disconnection of transfer lines and cleaning and maintenance. The principal route of exposure will be dermal while ocular exposure is also possible. Inhalation exposure is not expected given the expected low vapour pressure of the notified polymer and enclosed processes. Dermal and ocular exposure to workers should be mitigated through the expected use of personal protective equipment (PPE) including protective coveralls, impervious gloves and goggles.

6.1.2. Public Exposure
The product containing the notified polymer will only be used industrially and not sold to the public. The public may come into contact with finished paper products containing the notified polymer at < 0.4% concentration. However, public exposure to the notified polymer is expected to be very low as the polymer will be strongly adsorbed onto paper fibres, where it is expected to be relatively immobile. This immobility has been demonstrated in a migration study with paper treated with the notified polymer at 0.4% (active polymer/dry weight fibre) (see Public Health 6.3.2 for further details).

6.2. Human Health Effects Assessment
The results from toxicological investigations conducted on the notified polymer are summarised in the following table. For full details of the studies, refer to Appendix A.

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	LD50 > 2000 mg/kg bw; low toxicity

The notified polymer is of high molecular weight (> 10,000 Da) with low levels (< 2%) of low molecular weight species (< 1000 Da), therefore absorption across biological membranes is expected to be limited.

Based on a study conducted in rats, the notified polymer is of low acute oral toxicity. No other toxicity studies were provided for the notified polymer.

The notified polymer contains quaternary ammonium groups, which is of concern for corrosion and sensitization (Barratt *et al.,* (1994), Tsakovska *et al.,* (2007)). It also contains tertiary amine groups, which are of concern for corrosion/skin irritation (Hulzebos *et al.,* (2005)). However, the potential for irritation is likely to be reduced by the high molecular weight of the notified polymer and low levels of low molecular weight species.

Health hazard classification
Based on the available information, the notified polymer is not recommended for classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety
Based on the structure of the notified polymer, it may have irritation and sensitisation potential.

During the paper manufacturing process, there is potential for exposure of workers to the notified polymer at up to 20% concentration. This may occur during transfer processes, and cleaning and maintenance tasks. The notifier has stated that worker exposure is expected to be minimised through the use of personal protective equipment (PPE; e.g. gloves, goggles and protective clothing) and through the use of enclosed, automated processes.

Workers may have contact with finished paper products containing the notified polymer at < 0.4 % concentration. However exposure is not expected to be significant given the low concentration and limited bioavailability of the notified polymer.

Overall, based on the described use scenario and proposed controls, the risk to workers from use of the notified polymer is not considered to be unreasonable.

6.3.2. Public Health
The public may have contact with finished paper products (paperboard, tissue and paper towel) containing the notified polymer at < 0.4% concentration. However exposure is not expected to be significant given the low concentration and limited bioavailability of the notified polymer.

Finished paper products containing the notified polymer at < 0.4% concentration may have food contact use. The notifier submitted a migration study to determine the potential migration of low molecular weight oligomer from paper sheets treated with the notified polymer at 0.4% (active polymer/dry weight fibre). Migration levels were determined via GC/MS total ion chromatography in 10% and 50% ethanol extracts (at 40 ºC for 24-hours) which were used to mimic aqueous food and fat, respectively. Migration levels were 0.029 and 0.022 µg/in^2 in the 10% and 50% ethanol extracts, respectively, which correlated to 2.9 and 2.2 µg/kg food (assuming 0.01 kg food was in contact per square inch of packaging).

The notified polymer has been approved in the USA for food contact use at a level not to exceed 0.4% w/w of the finished paper on a dry basis (US FDA, 2016). However the notified polymer has not been approved for use in contact with infant formula and breast milk.

Overall, provided finished paper products containing the notified polymer are not intended for use in contact with infant formula and milk, the notified polymer when used as proposed is not considered to pose an unreasonable risk to public health.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified polymer will be imported as a processing aid for use as a dry-strength additive in paper manufacturing. No significant release of the notified polymer to the environment is expected from transport and storage processes. In the case of accidental spillage, spills containing the notified polymer are expected to be physically contained, absorbed on inert material and be disposed of to landfill or be discharged in accordance with local regulations.

RELEASE OF CHEMICAL FROM USE

At the industrial customers' site, the IBCs containing the notified polymer will be transported to the production area and the product containing the notified polymer will be pumped from the import container to a dilution device prior to entry into the paper making-machine. This process will be automated with no manual handling required and therefore, no significant release of the notified polymer is expected during this process.

Some residue of the notified polymer may remain in the empty import containers. These will be rinsed and the reinstate will be added to the process stream. Small spills and leaks may occur and these are expected to be collected using a suitable adsorbent for disposal to landfill.

RELEASE OF CHEMICAL FROM DISPOSAL

Used paper products are expected to be either released to landfill or enter the paper recycling stream. It is assumed that 50% of the paper to which the notified polymer is applied will end up in landfill and the remainder will undergo paper recycling processes.

7.1.2. Environmental Fate

No environmental fate data were submitted. Based on its chemical structure, the notified polymer is not expected to be readily biodegradable. However, since the notified polymer has a molecular weight much greater than 10,000 Da. and no significant percentage of low molecular weight constituents, the notified polymer is not expected to cross biological membranes and therefore is not expected to bioaccumulate.

Most of the notified polymer is expected to share the fate of the paper on which it is applied to, to be either disposed of to landfill or subject for paper recycling. The notified polymer disposed of to landfill along with used paper is not expected to be mobile, based on its cationic properties, or bioavailable, based on its large molecular size. It is assumed that 50% of the waste paper treated with the notified polymer will be recycled domestically. During recycling processes, waste paper is repulped using a variety of chemical agents, which, amongst other things, enhance detachment of inks and coatings from the fibres. Notified polymer discharged to waste water from paper recycling processes is expected to be efficiently removed through adsorption of the cationic polymer to sludge or by flocculation at waste water treatment plants (Boethling and Nabholz, 1997).

Sludge containing the notified polymer will be sent to landfill for disposal or agricultural land for remediation. The notified polymer will be bound to soil or sludge due to its cationic functions and is not expected to be mobile in the environment (Boethling and Nabholz, 1997). The notified polymer is expected to undergo slow degradation by biotic and abiotic processes, eventually forming water and oxides of carbon and nitrogen.

7.1.3. Predicted Environmental Concentration (PEC)

It is assumed that 50% of the used paper containing the notified polymer would be recycled and be released to sewers. Based on its cationic properties and high molecular weight, the predicted environmental concentration (PEC) has been calculated assuming 90% removal of the notified polymer from influent during sewage treatment plant (STPs) processes through partitioning to sediment or sludge (Boethling and Nabholz, 1997). As paper recycling is to be processed at facilities located throughout Australia, it is anticipated that such releases will occur over 260 working days per annum into the Australian effluent volume. The resultant PEC in sewage effluent on a nationwide basis is estimated as follows:

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	485,000	kg/year
Proportion expected to be released to sewer	50%	
Annual quantity of chemical released to sewer	242,500	kg/year
Days per year where release occurs	260	days/year
Daily chemical release:	932.69	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	22.613	million
Removal within STP	90%	Mitigation
Daily effluent production:	4,523	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	20.62	µg/L
PEC - Ocean:	2.06	µg/L

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1000 L/m^2/year (10 ML/ha/year). The notified chemical in this volume is assumed to infiltrate and accumulate in the top 10 cm of soil (density 1,500 kg/m^3). Using these assumptions, irrigation with a concentration of 20.62 µg/L may potentially result in a soil concentration of approximately 137.5 µg/kg. Assuming accumulation of the notified chemical in soil for 5 and 10 years under repeated irrigation, the concentration of notified chemical in the applied soil in 5 and 10 years may be approximately 0.68 mg/kg and 1.37 mg/kg, respectively.

7.2. Environmental Effects Assessment

The results from ecotoxicological investigations conducted on the notified polymer are summarised in the table below. Details of these studies can be found in Appendix B.

Endpoint	*Result*	*Assessment Conclusion*
Algal Toxicity	72 h E_rC50 = 1.9 mg/L	Toxic to algae
	72 h NOE_rC = 0.32 mg/L	Toxic to algae with long lasting effects

Based on the above acute ecotoxicological endpoint, the notified polymer is formally classified as "Acute Category 2; Toxic to aquatic life" under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) (United Nations, 2009). Based on its chronic toxicity endpoint and lack of ready biodegradability, the notified polymer is formally classified as "Chronic Category 2; Toxic to aquatic life with long lasting effects" under the GHS.

7.2.1. Predicted No-Effect Concentration

The predicted no-effects concentration (PNEC) has been calculated based on the acute endpoint for algae and a mitigation factor of 11. A safety factor of 1000 was used given acute endpoint is available for aquatic species representing one trophic level.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
EC50 (Algae, 72 h)	1.9	mg/L
Assessment Factor	1000	
Mitigation Factor	11	
PNEC:	20.9	µg/L

The notified polymer is a cationic polymer and is determined to be toxic to aquatic life based on the algal tests conducted in the laboratory media. However, under environmental conditions, the toxicity of the notified polymer is expected to be mitigated by the presence of dissolved organic carbon (DOC) and suspended solids. Cationic polymers react with DOC in environmental waters to form insoluble complexes, which settle out of water and therefore are not bioavailable to cause toxic effects. The mitigation factor is related to the charge density of the notified polymer.

Based on the established method for cationic polymer, the charge density for the notified polymer is calculated to be 0.7% (less than 3.5). Therefore, a mitigation factor of 11 is applied in this assessment to calculate the

PNEC and predict the more realistic environmental effects caused by the notified polymer (Boethling and Nabholz, 1997).

7.3. Environmental Risk Assessment

The Risk Quotient (Q = PEC/PNEC) has been calculated based on the predicted PEC and PNEC.

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River	20.62	20.9	**0.99**
Q - Ocean	2.06	20.9	**0.099**

The risk quotient for discharge of effluents containing the notified polymer to the aquatic environment indicates that the notified polymer is unlikely to reach ecotoxicologically significant concentrations based on its maximum annual importation quantity, cationic polymer properties and the mitigation effect of DOC on toxicity in natural environmental waters. Due to the cationicity and high molecular weight of the notified polymer, it is not expected to be bioaccumulative. Therefore, on the basis of the PEC/PNEC ratio and the assessed use pattern, the notified polymer is not expected to pose an unreasonable risk to the environment.

APPENDIX A: TOXICOLOGICAL INVESTIGATIONS

A.1. Acute toxicity – oral

TEST SUBSTANCE	DPD-589 (product containing the notified polymer at < 20% concentration in aqueous solution)
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method. EC Council Regulation No 440/2008 B.1 tris Acute Oral Toxicity – Acute Toxic Class Method.
Species/Strain	Rat/Wistar Crl:WI (Han)
Vehicle	None
Remarks - Method	No significant protocol deviations. The dose was adjusted for the concentration of the notified polymer in the test substance.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	3	2000	0/3
2	3	2000	0/3

LD50	> 2000 mg/kg bw
Signs of Toxicity	No mortality occurred throughout the study. Hunched posture and piloerection was observed for all animals on Day 1 and/or Day 2. Body weight gain was deemed similar to that expected for normal, untreated animals of the same age and strain.
Effects in Organs	No macroscopic abnormalities were seen during post-mortem examination.
CONCLUSION	The notified polymer is of low toxicity via the oral route.
TEST FACILITY	WIL (2015a)

APPENDIX B: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

B.2.1. Algal growth inhibition test

TEST SUBSTANCE	DPD-589 (product containing the notified polymer at < 20% concentration in aqueous solution)
METHOD	OECD TG 201 Fresh Water Algal, Growth Inhibition Test - Static
Species	*Pseudokirchneriella subcapitata* (green alga)
Exposure Period	72 hours
Concentration Range	Nominal: 0.625 – 62.5 mg/L Actual: Not reported
Auxiliary Solvent	None
Water Hardness	24 mg $CaCO_3$/L
Analytical Monitoring	None
Remarks - Method	Conducted in accordance with the test guidelines above, and in compliance with GLP standards and principles. A correction was made for the concentration of the notified polymer in the test substance. Preparation of test solutions started with the highest test concentration of 62.5 mg/L (final test) and subsequently diluted for lower test concentrations. Magnetic stirring period of 0.5 hours was applied to ensure complete dissolution in test medium.

RESULTS

Biomass		*Growth*	
EC50 *mg/L at 72 h*	*NOEC* *mg/L*	*EC50* *mg/L at 72 h*	*NOEC* *mg/L*
0.94	0.32	1.9	0.32

Remarks - Results	All validity criteria of the test guideline were satisfied. The EC_{50} for growth rate inhibition (72h-EC_{50}) was 12 mg/L with a 95% confidence interval ranging from 11 to 12 mg/L. Based on the active ingredient this corresponded to 1.9 mg/L (95% confidence interval 1.8-1.9 mg/L). The 72h-NOEC for both growth rate inhibition and yield inhibition was 2.0 mg/L, corresponding to an active ingredient concentration of 0.32 mg/L.
CONCLUSION	The notified polymer is considered to be toxic to algae.
TEST FACILITY	WIL (2015b)

BIBLIOGRAPHY

Barratt *et al.,* (1994) Development of an expert system rulebase for identifying contact allergens. Toxicology In Vitro. 8:837-839.

Boethling, RS & Nabholz VJ (1997) Environmental Assessment of polymers under the U.S. Toxic Substances Control Act. In: Hamilton, JD Sutcliffe R ed. Ecological Assessment of Polymers Strategies for Product Stewardship and Regulatory Programs, 1st ed. New York, Van Nostrand Reinhold, pp 187-234.

Hulzebos *et al.,* (2005) Use of structural alerts to develop rules for identifying chemical substances with skin irritation or skin corrosion potential. QSAR Combinatorial Science. 24:332-342.

NOHSC (2004) Approved Criteria for Classifying Hazardous Substances, 3rd edition [NOHSC:1008(2004)]. National Occupational Health and Safety Commission, Canberra, AusInfo.

Tsakovska *et al.,* (2007) Evaluation of SARs for the prediction of eye irritation/corrosion potential - structural inclusion rules in the BfR decision support system. SAR and QSAR in Environmental Research. 18: 221-235.

United Nations (2009) Globally Harmonised System of Classification and Labelling of Chemicals (GHS), 3rd revised edition. United Nations Economic Commission for Europe (UN/ECE), <http://www.unece.org/trans/danger/publi/ghs/ghs_rev03/03files_e.html>.

US FDA (2016) Inventory of Effective Food Contact Substances (FCS) Notifications, Food Contact Notification No. 1599. U.S. Food and Drug Administration, Maryland. <http://www.accessdata.fda.gov/scripts/fdcc/?set=FCN&id=1599>. Last accessed 29 November 2016.

WIL (2015a) Assessment of Acute Oral Toxicity with DOLENIS DPD-589 in the Rat (Acute Toxic Class Method) (Project No. 510604, December, 2015). s-Hertogenbosch, The Netherlands, WIL Research Europe B.V. (Unpublished report submitted by the notifier).

WIL (2015b) Fresh Water Algal Growth Inhibition Test with Solenis DPD-589 (Project No. 510605, December, 2015). s-Hertogenbosch, The Netherlands, WIL Research Europe B.V. (Unpublished report submitted by the notifier).