File No.: LTD/2077

May 2019

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

RESYDROL VAL 5547w

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	3
CONCLUSIONS AND REGULATORY OBLIGATIONS	3
ASSESSMENT DETAILS	6
1. APPLICANT AND NOTIFICATION DETAILS	6
2. IDENTITY OF CHEMICAL	6
3. COMPOSITION	
4. PHYSICAL AND CHEMICAL PROPERTIES	6
5. INTRODUCTION AND USE INFORMATION	7
6. HUMAN HEALTH IMPLICATIONS	
6.1. Exposure Assessment	8
6.1.1. Occupational Exposure	8
6.1.2. Public Exposure	9
6.2. Human Health Effects Assessment	9
6.3. Human Health Risk Characterisation	
6.3.1. Occupational Health and Safety	9
6.3.2. Public Health	10
7. ENVIRONMENTAL IMPLICATIONS	10
7.1. Environmental Exposure & Fate Assessment	
7.1.1. Environmental Exposure	
7.1.2. Environmental Fate	
7.1.3. Predicted Environmental Concentration (PEC)	
7.2. Environmental Effects Assessment	
7.2.1. Predicted No-Effect Concentration.	
7.3. Environmental Risk Assessment	
APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES	
APPENDIX B: TOXICOLOGICAL INVESTIGATIONS	
B.1. Acute Oral Toxicity – Rat	
APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS	15
C.1. Ecotoxicological Investigations	15
C.2.1. Algal Growth Inhibition Test	15
BIBLIOGRAPHY	16

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/2077	Allnex Resins Australia Pty Ltd	RESYDROL VAL 5547w	ND*	≤ 220 tonnes per annum	Component of coatings

^{*}ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard Classification

As only limited toxicity data were provided, the notified polymer cannot be classified according to the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia.

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 3	H402 – Harmful to aquatic life
Chronic Category 3	H412 - Harmful 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, 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 reformulation:
 - Enclosed/automated processes if possible
 - Local exhaust ventilation
- 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 during reformulation:
 - Avoid contact with skin and eyes
- 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
 during reformulation:

- Impervious gloves
- Safety glasses or goggles
- Protective clothing

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 chemical/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.

Storage

• The handling and storage of the notified polymer should be in accordance with the Safe Work Australia Code of Practice for *Managing Risks of Hazardous Chemicals in the Workplace* (SWA, 2012) or relevant State or Territory Code of Practice.

Emergency procedures

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

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.

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 chemical/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 g/mol;
 - the end use concentration of the notified polymer exceeds 15% for public /DIY use;

01

- (2) Under Section 64(2) of the Act; if
 - the function or use of the polymer has changed from a component of coatings, 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 chemical/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 notified polymer provided by the notifier was reviewed by NICNAS. The accuracy of the information on the SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

This notification has been conducted under the cooperative arrangement with Canada. The health and environmental hazard assessment components of the Canadian report were provided to NICNAS and, where appropriate, used in this assessment report. The other elements of the risk assessment and recommendations on safe use of the notified chemical were carried out by NICNAS.

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT

Allnex Resins Australia Pty Ltd (ABN: 25 000 045 572) 49 – 61 Stephen Road BOTANY NSW 2019

NOTIFICATION CATEGORY

Limited: Synthetic polymer with Mn \geq 1,000 g/mol

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details exempt from publication include: chemical name, CAS number, molecular and structural formulae, molecular weight, analytical data, polymer constituents, residual monomers, impurities, additives/adjuvants, use details, import volume and identity of manufacturer/recipients.

Variation of Data Requirements (Section 24 of the Act)

Schedule data requirements are varied for all physico-chemical endpoints.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT None

NOTIFICATION IN OTHER COUNTRIES Canada (2016)

2. IDENTITY OF CHEMICAL

MARKETING NAME RESYDROL VAL 5547w

MOLECULAR WEIGHT

Number average molecular weight (Mn) is > 1,000 g/mol

ANALYTICAL DATA

Reference GPC spectrum were provided.

3. COMPOSITION

Degree of Purity 93 - 98%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Yellow-brown liquid

Property	Data Source/Justification		
Melting Point	Ielting Point Not determined Liquid at room temperatu		
Boiling Point	Not determined	Not expected to boil based on high molecular weight. At elevated temperatures, the notified polymer decomposes	
Density Vapour Pressure	1,020 kg/m ³ at 20 °C Not determined	SDS Expected to be low based on high molecular weight	

Property	Value	Data Source/Justification
Water Solubility	Not determined	Expected to be dispersible in water based
		on its use in water-based coatings
Hydrolysis as a Function of	Not determined	Stable. Contains hydrolysable
pН		functionality however, the substance is a
		complex polymeric material which forms
		an inseparable emulsion when mixed with
D 11 G 07 1		water
Partition Coefficient	Not determined	The notified polymer is surface active and
(n-octanol/water)		estimations may not adequately
		characterise the partitioning behaviour.
		The notified polymer is expected to partition to phase boundaries
Surface Tension	36.8 mN/m at 23 °C	Measured. As surface tension < 60 mN/m,
Surface Telision	30.8 mrvm at 23 °C	the notified polymer is considered surface
		active
Adsorption/Desorption	Not determined	Dispersible in water and is expected to be
1		mobile, however, high molecular weight
		polymers adsorb to soil and sediment and
		thus have limited mobility
Dissociation Constant	Not determined	Contains dissociable functionality which
		is expected to dissociate at environmental
		pH 4-9
Flash Point	> 100 ° C	SDS
Flammability	Not determined	Not expected to be flammable based on
	AT . 1	flash point.
Autoignition Temperature	Not determined	Not expected to autoignite
Explosive Properties	Not determined	Contains no functional groups that would
Ovidisina Dramantias	Not determined	imply explosive properties
Oxidising Properties	Not determined	Contains no functional groups that would
		imply oxidising properties

DISCUSSION OF PROPERTIES

For details of the test on surface tension refer to Appendix A.

Reactivity

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

Physical Hazard Classification

Based on the limited physico-chemical data depicted in the above table, the notified polymer cannot be 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. It will be imported neat for reformulation into water-based wood coatings containing the notified polymer at $\leq 15\%$ concentration.

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

Year	1	2	3	4	5
Tonnes	≤ 20	≤ 50	≤ 100	≤ 180	≤ 220

PORT OF ENTRY

Sydney, Melbourne and Brisbane

TRANSPORTATION AND PACKAGING

The notified polymer will be imported by ship in 20 L pails, 200 L drums and 1 tonne intermediate bulk containers. The water-based wood coatings containing the notified polymer at $\leq 15\%$ concentration will be packaged in containers suitable for retail sale.

USF

The notified polymer will be used as a component of water-based wood coatings at $\leq 15\%$ concentration.

OPERATION DESCRIPTION

Reformulation

At the reformulation sites, the notified polymer will be combined using typical blending processes with other components into finished water-based wood coatings containing the notified polymer at $\leq 15\%$ concentration. The reformulation process is expected to be fully automated and performed under enclosed and controlled conditions.

End Use

The water-based wood coatings containing the notified polymer at $\leq 15\%$ concentration will be applied by professional painters and do-it-yourself (DIY) users by brush or roller to exterior wood surfaces. Application by spray is not anticipated.

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 storage	1-2	20
Warehouse/store	8	30
Dispatch	< 1	365
Reformulation	2	50
Quality Control	1	50
Retailers	1	30
Professional painters	8	50

EXPOSURE DETAILS

Transport and storage workers are not expected to be exposed to the notified polymer except in the unlikely event of an accident or container rupture.

Reformulation

Dermal and ocular exposure to the notified polymer at \leq 100% concentration may occur during the blending process, and cleaning and maintenance of equipment. Exposure should be minimised through the use of personal protective equipment (PPE: goggles, impervious gloves, protective clothing), as stated by the notifier. The use of automated and enclosed systems during the reformulation process should further minimise exposure to the notified polymer. Inhalation exposure to the notified polymer is not expected due to its assumed low vapour pressure and the use of enclosed systems.

End Use – Professionals

Dermal and ocular exposure to the notified polymer at \leq 15% concentration may occur during application of the wood coatings by brush or roller. Exposure should be minimised through the use of PPE (goggles, impervious gloves, protective clothing), as stated by the notifier. Inhalation exposure to the notified polymer is not expected as the coatings will not be applied by spray, in addition to the expected low vapour pressure of the notified polymer. Once the coatings are dried, the notified polymer will be bound within an inert solid matrix and will not be available for exposure.

6.1.2. Public Exposure

Finished wood coatings containing the notified polymer at \leq 15% concentration will be sold to the general public for DIY use. Dermal and ocular exposure to the notified polymer at \leq 15% concentration may occur during application of the wood coatings by brush or roller. It is expected that exposure to the notified polymer (at \leq 15% concentration) by DIY users will be lower than professional end users due to the relatively infrequent use of wood coatings and smaller scale of application. Inhalation exposure to the notified polymer is not expected as the coatings will not be applied by spray, in addition to the expected low vapour pressure of the notified polymer.

The public may come into contact with surfaces applied with the wood coatings containing the notified polymer at $\leq 15\%$ concentration. However, once the coatings are dried, the notified polymer will be bound within an inert solid matrix and will not be available for exposure.

6.2. Human Health Effects Assessment

The results from a toxicological investigation conducted on the notified polymer is summarised in the following table. For full details of this study, refer to Appendix B.

Endpoint	Result and Assessment Conclusion
Acute oral toxicity – rat	LD50 > 2,000 mg/kg bw; low toxicity

The notified polymer is of high molecular weight (> 1,000 g/mol) and contains low levels (< 1%) of low molecular weight species < 500 g/mol, therefore absorption across biological membranes is expected to be limited.

The notified polymer is of low acute oral toxicity based on a study conducted in rats.

The notified polymer is an anionic surfactant. Anionic surfactants have the potential to cause skin and eye irritation. The notified polymer also contains pendant methacrylate groups which have toxicity concerns associated with skin irritation, and skin and respiratory sensitisation. Given absorption of the notified polymer is expected to be limited, the potential for skin and respiratory sensitisation is expected to be low.

Health Hazard Classification

As only limited toxicity data were provided, the notified polymer cannot be classified according to the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia.

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety

Based on the structure of the notified polymer, it may have the potential to cause skin and eye irritation, and skin and respiratory sensitisation. However, the potential for skin and respiratory sensitisation is expected to be low. Systemic effects are not expected due to limited absorption of the notified polymer.

Reformulation

During reformulation workers may be at risk of skin and eye irritation, and skin and respiratory sensitisation effects when handling the notified polymer at $\leq 100\%$ concentration. However the risk is expected to be minimised by the use of enclosed and automated processes and PPE by workers.

End-use

During end-use, workers may be dermally exposed to the notified polymer at $\leq 15\%$ concentration during application of coatings containing the notified polymer by brush or roller. Inhalation exposure is not expected given the assumed low vapour pressure of the notified polymer and spray application is not expected. Given the relatively low use concentration of the notified polymer in finished coatings and limited absorption of the notified polymer, the potential for skin and respiratory sensitisation is not expected. The risk of irritation is also expected to be reduced by the proposed low use concentration and application methods (brush and roller). Workers using PPE (goggles, impervious gloves, protective clothing) will further reduce the potential for irritation and sensitisation.

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

6.3.2. Public Health

DIY users may be dermally exposed to the notified polymer at $\leq 15\%$ concentration during application of coatings containing the notified polymer by brush or roller. Inhalation exposure is not expected given the expected low vapour pressure of the notified polymer and spray application is not expected.

Given the relatively low use concentration of the notified polymer in finished coatings and limited absorption of the notified polymer, the potential for skin and respiratory sensitisation is not expected. The risk of irritation is also expected to be reduced by the proposed low use concentration and application methods (brush and roller).

Therefore, when used in the proposed manner, the notified polymer 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 neat for reformulation into water-based wood coatings. There is unlikely to be any significant release to the environment from transport and storage, except in the case of accidental spills and leaks. In the event of spills, the notified polymer is expected to be collected with adsorbents, and disposed of to landfill in accordance with local government regulations.

The reformulation process will involve blending operations that will be highly automated, and is expected to occur within a fully enclosed environment. Therefore, significant release of the notified polymer to the environment from this process is not expected. The reformulation process will be followed by automated filling of the formulated coatings into containers suitable for end use. Blending equipment will be cleaned with solvents, with waste liquids containing the notified polymer to be collected for disposal through licensed trade waste management services. Empty import containers are expected to be recycled or disposed of through licensed waste management services.

RELEASE OF CHEMICAL FROM USE

Coatings containing the notified polymer will be used by both professional and DIY users. During use, coatings containing the notified polymer are expected to be applied by brush and/or roller techniques.

During use, the notified polymer may also be released to the environment as accidental spills and container residues. These releases are expected to be collected and disposed of to landfill in accordance with local government regulations.

RELEASE OF CHEMICAL FROM DISPOSAL

The notified polymer in coatings is expected to share the fate of the substrate to which it has been applied, and is therefore predominantly expected to be disposed of to landfill.

Residues containing the notified polymer on application equipment are expected to be rinsed into containers, and then allowed to cure before disposal as solid wastes to landfill. As a worst case scenario, it is assumed that up to 5% of the coatings containing the notified polymer used by DIY users may be incorrectly disposed of to the sewer, drains, or ground from waste and washing of application equipment.

7.1.2. Environmental Fate

The majority of the notified polymer is expected to be cured within an inert coating matrix and is expected to share the fate of the articles to which it has been applied and will involve eventual disposal to landfill. Once cured the notified polymer is not expected to be bioavailable or bioaccumulative. The notified polymer is also expected to enter landfill as collected wastes and residues.

Bioaccumulation of the uncured notified polymer is unlikely, based on its high molecular weight. The notified polymer is dispersible in water and is expected to be mobile in soil, however, the polymer has potential to adsorb to soil and sediment based on its high molecular weight and anionic properties. Therefore, a significant portion of the notified polymer (> 50%) is expected to partition to sludge and sediment (Boethling and Nabholz, 1997) during wastewater treatment processes in sewage treatment plants (STPs). In surface waters and in landfill, the

notified polymer is expected to eventually degrade via biotic and abiotic processes to form water and oxides of carbon and nitrogen.

7.1.3. Predicted Environmental Concentration (PEC)

The calculation for the predicted environmental concentration (PEC) is summarised in the table below. Based on the reported use coatings for professional and DIY-users, a conservative release of 5% to sewers on a nationwide basis over 365 days per year is used for the notified polymer. It is also assumes a worst case scenario where none of the notified polymer is removed during STP processes.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	200,000	kg/year
Proportion expected to be released to sewer	5.000	%
Annual quantity of chemical released to sewer	10,000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	27.40	kg/day
Water use	200	L/person/day
Population of Australia (Millions)	24.386	million
Removal within STP	0	%
Daily effluent production:	4,877	ML
Dilution Factor – River	1.0	
Dilution Factor – Ocean	10.0	
PEC – River:	5.62	μg/L
PEC – Ocean:	0.56	$\mu g/L$

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be $1,000 \, \text{L/m}^2/\text{year}$ ($10 \, \text{ML/ha/year}$). The notified polymer in this volume is assumed to infiltrate and accumulate in the top 10 cm of soil (density $1,500 \, \text{kg/m}^3$). Using these assumptions, irrigation with a concentration of $5.62 \, \mu \text{g/L}$ may potentially result in a soil concentration of approximately $37.45 \, \mu \text{g/kg}$. Assuming accumulation of the notified polymer in soil for 5 and 10 years under repeated irrigation, the concentration of the notified polymer in the applied soil in 5 and 10 years may be approximately $187.3 \, \mu \text{g/kg}$ and $374.5 \, \mu \text{g/kg}$, respectively.

7.2. Environmental Effects Assessment

The results from an ecotoxicological investigation conducted on the notified polymer is summarised in the table below. Details of this study can be found in Appendix C.

Endpoint	Result	Assessment Conclusion
Algal Toxicity	72 h ErC 50 = 37.20 mg/L	Harmful to algae

Based on the above ecotoxicological endpoint for the notified polymer, it is expected to be harmful to algae. Therefore, under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) (United Nations, 2009), the notified polymer is formally classified as 'Acute Category 3; Harmful to aquatic life'. Based on the above acute ecotoxicity and unknown degradability, the notified polymer is formally classified as 'Chronic Category 3; Harmful 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 from the most sensitive endpoint for algae. A safety factor of 500 was used since an acute endpoint for only one trophic level was available.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
ErC50 (Algae, 72 h)	37.20	mg/L
Assessment Factor	500.00	
Mitigation Factor	1.00	
PNEC	74.40	$\mu g/L$

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	5.62	74.4	0.076	
Q – Ocean	0.56	74.4	0.008	

The risk quotient for discharge of treated effluents containing the notified polymer to the aquatic environment indicates that the notified polymer is unlikely to reach ecotoxicologically significant concentrations in surface waters, based on its maximum annual importation quantity. The notified polymer is not expected to be bioaccumulative based on its high molecular weight. On the basis of the maximum annual importation volume and assessed use pattern as a component of water-based wood coatings, the notified polymer is not expected to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Surface Tension 36.8 mN/m at 23 °C

Method OECD TG 115 Surface Tension of Aqueous Solutions Remarks Concentration: 10% w/w aqueous saturated solution

Test Facility Allnex (2015)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute Oral Toxicity – Rat

TEST SUBSTANCE Notified polymer

METHOD OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method

Species/Strain Rat/Wistar Vehicle Olive oil

Remarks – Method No significant protocol deviations

RESULTS

TEST FACILITY

Group	Number and Sex of Animals	Dose (mg/kg bw)	Mortality
1	3F	2,000	0/3
2	3F	2,000	0/3
LD50 Signs of Toxicity Effects in Organs	body weight.	f toxicity were noted. All ani	
Conclusion	The notified polym	er is of low acute toxicity via	the oral route.

Hameln rds (2016)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Ecotoxicological Investigations

C.2.1. Algal Growth Inhibition Test

TEST SUBSTANCE Notified polymer

METHOD OECD TG 201 Alga, Growth Inhibition Test

EC Council Regulation No 440/2008 C.3 Algal Inhibition Test

Species Desmodesmus subspicatus

Exposure Period 72 hours

Concentration Range Nominal: 1.0 – 100 mg/L

Actual: 2.0 - 77.4 mg/L

Auxiliary Solvent None

Water Hardness Not reported

Analytical Monitoring The content of the test item in the test solutions was estimated by

calculation based on the total organic carbon (TOC) of the test item and dissolved organic carbon (DOC) measurement (where DOC = TC (total

carbon) - IC (inorganic carbon)).

Remarks – Method A stock solution with a nominal loading rate of 100.5 mg/L was prepared

by stirring the test substance in algal medium. The definitive test was conducted at the nominal loading rates of 1.0, 3.2, 10, 32, and 100 mg/L of the test substance. The test was conducted in accordance with the test guideline above, with some deviations from the protocol reported. The temperature in the experiment was not within the required range of $21.0-24.0~\rm C$ (actual range was $22.1-24.6~\rm C$) and more than $\pm 2~\rm C$. However, as normal growth was observed, this deviation was deemed by the study authors as uncritical. The stock solutions were autoclaved for 20 minutes instead of the required 15 minutes. This was considered by the study authors as uncritical, as the goal of sterility was achieved. Mistakenly, no algae were added in the lowest concentrated treatment, hence this data was

not used for evaluation.

RESULTS

Biomass		Growth	
EyC50	NOEC	ErC50	NOEC
mg/L at 72 h	mg/L	mg/L at 72 h	mg/L
4.87	< 2.00	37.20	2.00

Remarks - Results

All validity criteria for the test were satisfied. The 72h ErC50 and EyC50 values of the positive control potassium dichromate were 0.79 mg/L and 0.39 mg/L respectively and showed sufficient statistical correspondence of the data with the dose-response-equation. The values were within the range of the laboratory. For the notified chemical, the test solutions were not renewed during the 72 h test period. The measured concentrations of the test substance lay between 74% and 162% (162% in lowest concentrated treatment) of the nominal concentrations at the beginning of the test and between 0% and 67% of the nominal concentrations at the end of the test. Therefore the biological results were based on the geometric mean of the measured concentrations.

CONCLUSION The test substance is considered to be harmful to algae.

TEST FACILITY LAUS GmbH (2018)

BIBLIOGRAPHY

- Allnex (2015) RESYDROL VAL 5547: Determination of Surface Tension in Liquid Solution (Study No. 283383, December, 2015). Drogenbos, Belgium, Allnex Analytical Laboratories (Unpublished report submitted by the notifier).
- Boethling, R.S., and Nabholz, J.V. 1997. "Environmental Assessment of Polymers under the U.S. Toxic Substances Control Act", in Ecological Assessment of Polymers, J.D. Hamilton and R. Sutcliffe (eds.). Van Nostrand, New York Howes, D. 1975. The percutaneous absorption of some anionic surfactants. *J. Soc. Cosmet. Chem.* 26: 47-63.
- Hameln rds (2016) RESYDROL VAL 5547w Acute Oral Toxicity (OECD 423) (Study code: 600326910, February, 2016). Modra, Slovak Republic, Hameln rds (Unpublished report submitted by the notifier).
- LAUS GmbH (2018) Determination of the toxicity of EXP-5547w against *Desmodesmus subspicatus* according to OECD 201 resp. EU C.3 (Study No. 18051801G301, July, 2018). Germany, LAUS GmbH (Unpublished report submitted by the notifier)
- SWA (2012) Code of Practice: Managing Risks of Hazardous Chemicals in the Workplace, Safe Work Australia, https://www.safeworkaustralia.gov.au/doc/model-code-practice-managing-risks-hazardous-chemicals-workplace
- 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