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

PUBLIC REPORT

Polymer in Sokalan® SR 400

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:

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**Director
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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 CHEMICAL	INTRODUCTION VOLUME	USE
LTD/2079	BASF Australia Ltd	Polymer in Sokalan® SR 400	ND*	< 50 tonnes per annum	Component in liquid laundry detergents

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard Classification

As no 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.

<i>Hazard Classification</i>	<i>Hazard Statement</i>
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 safe work practices to minimise occupational exposure during handling of the notified polymer:
 - 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:
 - Safety glasses
 - Impervious gloves
 - 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 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.

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 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 concentration of the polymer is $\geq 10\%$ in laundry detergents available to the public;or
- (2) Under Section 64(2) of the Act; if
 - the function or use of the polymer has changed from a component of liquid laundry detergents, 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.

Safety Data Sheet

The SDS of a product containing the notified chemical provided by the notifier was reviewed by NICNAS. The accuracy of the information on the SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)

BASF Australia Ltd (ABN: 62 008 437 867)
Level 12, 28 Freshwater Place
SOUTHBANK VIC 3006

NOTIFICATION CATEGORY

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

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

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

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(S)

None

NOTIFICATION IN OTHER COUNTRIES

Canada, China and Taiwan

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Sokalan® SR 400 (product containing < 40% notified polymer)

MOLECULAR WEIGHT

Number average molecular weight (M_n) is > 10,000 g/mol.

ANALYTICAL DATA

Reference GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY

> 95%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Yellowish liquid*

<i>Property</i>	<i>Value</i>	<i>Data Source/Justification</i>
Melting Point/Freezing Point	Not determined	Not isolated from aqueous solution
Boiling Point*	~100 °C at 101.3 kPa	SDS
Density*	1,060 kg/m ³ at 20 °C	SDS
Vapour Pressure	Not determined	Expected to be low based on the high molecular weight of the notified polymer
Water Solubility	Not determined	Expected to be soluble
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 partition to phase boundaries based on surface activity
Adsorption/Desorption	Not determined	Expected to adsorb to soil and sediment

Property	Value	Data Source/Justification
Dissociation Constant	Not determined	based on surface activity Contains cationic properties and is expected to be dissociated in the aquatic environment.
Flash Point	Not determined	Not isolated from aqueous solution
Flammability*	Not flammable	SDS
Autoignition Temperature*	Not self-igniting	SDS
Explosive Properties	Not determined	Contains no functional groups that imply explosive properties
Oxidising Properties	Not determined	Contains no functional groups that imply oxidising properties

* Property of the imported product Sokalan® SR 400 containing < 40% notified polymer

DISCUSSION OF PROPERTIES

Reactivity

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

Physical Hazard Classification

As no physico-chemical data were submitted for the notified polymer, 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 within Australia. The notified polymer will be imported into Australia at < 40% concentration for reformulation into liquid laundry detergents.

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>
<i>Tonnes</i>	< 50	< 50	< 50	< 50	< 50

PORT OF ENTRY

Melbourne and Sydney

IDENTITY OF RECIPIENT

BASF Australia Ltd

TRANSPORTATION AND PACKAGING

Products containing the notified polymer at < 40% concentration will be imported in 120 kg plastic containers and 1,000 kg intermediate bulk containers (IBCs) and transported by road. Following reformulation, finished laundry detergents containing the notified polymer at < 10% concentration will be packed in 1 – 2 L plastic bottles and transported by road.

USE

The notified polymer will be used as a component of liquid laundry detergents.

OPERATION DESCRIPTION

Reformulation for liquid laundry detergents

The imported product containing the notified polymer will typically be transferred by dip pipe or hose and pumped into a closed blending tank under local exhaust ventilation. After blending with other components, the finished liquid laundry detergents containing < 10% notified polymer will be transferred via automatic filling machines into appropriate containers for retail sales.

End-use

Consumers will open the product container and manually measure out the required volume of the detergent (typically 50 mL) using the cap of the container or a plastic measuring/dispensing cup before adding the detergent to the washing machine or hand-washing container.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

<i>Category of Worker</i>	<i>Exposure Duration (hours/day)</i>	<i>Exposure Frequency (days/year)</i>
Transport and warehouse	1 – 2	240
Process operators – reformulation	1 – 2	200
Quality control / reformulation	1 – 2	200
Packaging line – reformulation	4 – 8	200
Retail	1 – 2	365

EXPOSURE DETAILS

Transport, storage and retail workers may come into contact with the notified polymer only in the event of accidental rupture of packages.

Reformulation

Dermal and ocular exposure of workers to the notified polymer at < 40% concentration may occur during connection and disconnection of transfer lines, quality control and cleaning and maintenance of equipment. Exposure is expected to be limited through the use of enclosed systems and personal protective equipment (PPE) such as coveralls, safety glasses and impervious gloves, as stated by the notifier. Inhalation exposure is not expected given the estimated low vapour pressure of the notified polymer and formulation into an aqueous mixture.

End-use

Exposure of professional laundry workers to the notified polymer is expected to be of a similar extent to that experienced by consumers using laundry detergents containing the notified polymer in washing machines (see section 6.1.2).

6.1.2. Public Exposure

Dermal and ocular exposure of the public to laundry detergents containing the notified polymer at < 10% concentration may occur through spills and splashes during handling. Exposure from hand-washing processes is expected to be low as the notified polymer will be further diluted in the wash water.

Dermal exposure to the notified polymer from washed clothing/linen is expected to be low as the amount of residual polymer left on clothing is expected to be very low after the washing processes are complete.

6.2. Human Health Effects Assessment

No toxicity data were submitted for the notified polymer.

Based on the high molecular weight (> 10,000 g/mol), low percentages of low molecular weight species (< 500 g/mol and < 1000 g/mol), the notified polymer is not expected to be absorbed across biological membranes to a significant extent to cause systemic toxicity.

The notified polymer contains a structural alert indicative of possible irritation effects. Therefore, the potential for skin and eye irritation of the notified polymer cannot be ruled out.

Health Hazard Classification

As no 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

The notified polymer contains a structural alert for irritation and thus such effects cannot be ruled out.

Dermal and ocular exposure of workers to the notified polymer at the imported concentration of < 40% may occur during reformulation of liquid laundry detergents. The use of engineering controls (particularly the automation of processes) and personal protective equipment (skin and eye protection) during the reformulation is expected to minimise exposure and reduce the risk of potential irritation effects.

Dermal and ocular exposure of workers to the notified polymer at < 10% may occur during transfer of washing liquid and washing processes. At concentrations of < 10%, irritation effects are not expected.

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

Dermal and ocular exposure of the public to the notified polymer at < 10% concentration may occur during transfer of washing liquid and washing processes (e.g. hand washing). At concentrations of < 10%, irritation effects are not expected.

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 into Australia in 120 kg plastic jerricans and 1000 kg intermediate bulk containers (IBCs) as a component for reformulation into liquid laundry detergents. 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 products containing the notified polymer are expected to be collected with adsorbents, and disposed of to landfill in accordance with local government regulations. The notified chemical will typically be transferred in a highly controlled and/or enclosed system. Therefore, significant release of the notified polymer from this process to the environment is not expected. After blending into liquid laundry detergents, the end-use product containing the notified chemical will be transferred via automatic filling machines into appropriate containers (1L and 2L plastic bottles) for distribution to retail outlets.

Wastes containing the notified polymer generated during reformulation include equipment wash water, residues in import containers, and spilt materials. Release of the notified polymer could also result from residues remaining in empty import containers. These will be collected and either released to sewers, or disposed of to landfill in accordance with local government regulations. Empty import containers are expected to be recycled or disposed of to landfill.

RELEASE OF CHEMICAL FROM USE

The majority of the notified polymer is expected to be released to sewer across Australia as a result of its use in laundry detergents. A small proportion of the notified polymer is expected to be disposed of to landfill as residue in empty end-use containers.

RELEASE OF CHEMICAL FROM DISPOSAL

Wastes and residue of the notified polymer in empty containers are likely to either share the fate of the container and be disposed of to landfill, or be released to the sewer system when containers are rinsed before recycling through an approved waste management facility.

7.1.2. Environmental Fate

Following its use in liquid laundry detergents in Australia, the majority of the notified polymer is expected to enter the sewer system, before potential release to surface waters nationwide. Based on the results of a ready

biodegradability study, the notified polymer is not considered readily biodegradable (<10% in 28 days). For details of the environmental fate studies, please refer to Appendix A. Based on its surfactant properties, release to surface waters is unlikely to occur as partitioning to sludge and sediment is expected under environmental pH. The notified polymer is not expected to be bioaccumulative, due to its surfactant properties and high molecular weight. Therefore, in surface waters the notified polymer is expected to disperse and degrade through biotic and abiotic processes to form water and oxides of carbon and nitrogen.

A small proportion of the notified polymer may be applied to land when effluent is used for irrigation, or when sewage sludge is used for soil remediation. The notified polymer may also be applied to land when disposed of to landfill as collected spills and empty container residue. Residues of the notified polymer in landfill, soil and sludge are expected to eventually degrade through biotic and abiotic processes to form water and oxides of carbon and nitrogen.

7.1.3. Predicted Environmental Concentration (PEC)

Based on the reported use in liquid laundry detergents, it is assumed that 100% of the total import volume of the notified polymer will be released to the sewer. The release is assumed to be nationwide over 365 days per year. Assuming a worst-case of 0 % of the notified polymer being removed via absorption to sludge in the sewage treatment plant, the resultant predicted environmental concentration (PEC) in sewage effluent on a nationwide basis can be estimated:

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	50,000	kg/year
Proportion expected to be released to sewer	100.0	%
Annual quantity of chemical released to sewer	50,000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	136.99	kg/day
Water use	200.0	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:	28.09	µg/L
PEC – Ocean:	2.81	µg/L

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1000 L/m²/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 1500 kg/m³). Using these assumptions, irrigation with a concentration of 28.0 µg/L may potentially result in a soil concentration of approximately 0.187 mg/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 0.936 mg/kg and 1.87 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 A.

Endpoint	Result	Assessment Conclusion
Daphnia Toxicity	EC50 = 31.4 mg/L*	Harmful to aquatic invertebrates
Algal Toxicity	ErC50 = 20.6 mg/L*	Harmful to Algae
Inhibition of Bacterial Respiration	EC50 = >1000 mg/L	Not inhibitory to bacterial respiration

*Values based on experiments conducted with 3 mg/L humic acid. This concentration of humic acid is representative of natural waters in Australia (<https://www.elgalabwater.com/blog/total-organic-carbon-toc> accessed 22/03/2019 and Bolto et al., 2007).

Based on the above acute ecotoxicological endpoints for the notified polymer, it is expected to be harmful to aquatic invertebrates and 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’ and ‘Chronic Category 3; Harmful to aquatic life with long lasting effects’.

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 given two acute endpoint were available.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment			
EC50 (Alga)	20.60	mg/L	
Assessment Factor	500.00		
Mitigation Factor	1.00		
PNEC	41.20	µg/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	28.09	41.2	0.68
Q – Ocean	2.81	41.2	0.068

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 considered readily biodegradable, and is expected to have a low potential for bioaccumulation. On the basis of the PEC/PNEC ratio, maximum annual importation volume and assessed use pattern in liquid laundry detergents, the notified polymer is not expected to pose an unreasonable risk to the environment.

APPENDIX A: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

A.1. Environmental Fate

A.1.1. Ready Biodegradability

TEST SUBSTANCE	Notified Polymer (30.8% unspecified solution)			
METHOD	Determination of the Biodegradability and the Elimination in the CO ₂ /DOC Combination Test (ISO 9439, Annex D)			
Inoculum	Activated sludge from the wastewater treatment plant			
Exposure Period	28 days			
Auxiliary Solvent	None			
Analytical Monitoring	DOC, TOC and TIC			
Remarks – Method	The combined CO ₂ /DOC Test was conducted in 2 L incubation vessels with a test volume of 1.5 L. The test vessels were connected with two serial scrubbing bottles with total volume 250 mL filled with 100 mL 0.05 M sodium hydroxide solution for the absorption of carbon dioxide formed by the biodegradation processes. The incubation vessels were stirred continuously on magnetic stirrers, the aeration was performed with carbon dioxide free air at a flow of approximately 800 mL per hour. An inhibition control (containing the test substance and the reference substance) was also run.			
RESULTS				
	<i>Test Substance</i>		<i>Diethylene Glycol</i>	
	<i>Day</i>	<i>% Degradation</i>	<i>Day</i>	<i>% Degradation</i>
	28	<10%	14	74%
Remarks – Results	The biologically produced CO ₂ was determined by the TOC trapped less the TIC trapped and adjusted for abiotic removal of DOC (e.g. by adsorption to sludge). The reference item (diethylene glycol) attained 74% biodegradation after 14 days thereby confirming the suitability of the inoculums and test conditions.			
CONCLUSION	The notified polymer is not considered to be readily biodegradable.			
TEST FACILITY	BASF (2015a)			

A.2.1. Acute Toxicity to Aquatic Invertebrates

TEST SUBSTANCE	Notified Polymer (30.8% aqueous solution)			
METHOD	OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test (Modified) – Static			
Species	<i>Daphnia magna</i>			
Exposure Period	48 hours			
Auxiliary Solvent	None			
Water Hardness	240 mg CaCO ₃ /L			
Analytical Monitoring	None.			
Remarks – Method	The study was conducted as two experiments. One in standard test medium and one in standard test medium modified with 3 mg/L humic acid. The main modifications of the test were the reduced number of test concentrations (3) with a spacing factor of 10 and no concentration control analysis. Test concentrations of 0, 3.25, 32.5, 325 mg/L were prepared, based on the test substance mass with correction for purity.			

RESULTS

Standard Test Medium

Concentration of notified chemical (mg/L)		Number of <i>D. magna</i>	Number Immobilised	
Nominal	Actual		24 h	48 h
Control	ND	20	0	0
1	ND	20	0	0
10	ND	20	1	1
100	ND	20	3	20
Standard Test Medium modified with 3 mg/L humic acid				
Control	ND	20	0	0
1	ND	20	0	0
10	ND	20	0	0
100	ND	20	12	18

NOEC < 1 mg/L mg/L at 48 hours
 NOEC < 1 mg/L at 48 hours with 3 mg/L Humic acid
 EC50 17.2 mg/L at 48 hours
 EC50 31.4 mg/L at 48 hours with 3 mg/L Humic acid
 Remarks – Results The experiment was fully compliant with the validity criteria, the O₂ concentration > 3 mg/L in control and test vessels. The EC50 values were calculated using ToxCalc, but the methodology has not been specified.

CONCLUSION

The notified polymer is harmful to aquatic invertebrates.

TEST FACILITY

BASF (2015b)

A.2.2. Algal Growth Inhibition Test

TEST SUBSTANCE

Notified Polymer (30.8% aqueous solution)

METHOD

OECD TG 201 Alga, Growth Inhibition Modified Test- Static
 Species *Pseudokirchneriella subcapitata*
 Exposure Period 72 hours
 Concentration Range Nominal: 0 - 100 mg/L
 Actual: ND
 Auxiliary Solvent None
 Water Hardness Not measured
 Analytical Monitoring None.
 Remarks – Method The study was conducted as two experiments. One in standard test medium (Exp 1) and one in test Medium modified with 3 mg/L humic acid (Exp 2). In both studies the test concentrations were prepared by direct addition of between 3.25 - 325 mg/L of aqueous solution of the notified polymer. The total organic carbon (TOC) was not specifically measured in the supplemented medium.

RESULTS

	Biomass		Growth	
	ErC50 (mg/L)	NOEC (mg/L)	ErC50 (mg/L)	NOEC (mg/L)
Exp 1	ND	ND	< 3.25	< 3.25
Exp 2	ND	ND	20.6	3.25

Remarks – Results Experiment one, was fully compliant with the validity criteria. The cell multiplication factor in the untreated control (all replicates mixed together) was 256-fold after 72 hours (microscopically counted cell density: 128 × 10⁴ cells/mL). Experiment two, was fully compliant with the validity criteria. The cell multiplication factor in the control was 122-fold after 72

hours (microscopically counted cell density: 61×10^4 cells/mL).

CONCLUSION The notified polymer is harmful to algae.

TEST FACILITY BASF (2015c)

A.2.3. Inhibition of Microbial Activity

TEST SUBSTANCE Notified Polymer (30.8% aqueous solution)

METHOD OECD TG 209 Activated Sludge, Respiration Inhibition Test
EC Directive 88/302/EEC C.11 Biodegradation: Activated Sludge
Respiration Inhibition Test
Inoculum Activated sludge from a municipal wastewater treatment plant
Exposure Period 3 hours
Concentration Range Nominal: 62.5-1000 mg/L Actual:
Remarks – Method Test concentrations of between 203 - 3247 mg/L of 30.8% aqueous solution of the notified polymer were prepared. Two deviations from the study plan and the test guidelines were realized by 1) Exceeding the test temperature range of 20 ± 2 °C with 1.2 °C and
2) The measurement of oxygen consumption was lower than 7 mg/L in one test assay.

RESULTS
EC50 > 1000 mg/L
Remarks – Results All validity criteria for the test were met. The deviations from the test guidelines did not influence the results of the study. The EC50 of the reference substance 3,5-dichlorophenol was in the range of 2 - 25 mg/L in 3 hours. The results indicate that the microorganisms are responding normally to toxicant stress.

CONCLUSION The notified polymer does not inhibit bacterial respiration.

TEST FACILITY BASF (2015d)

BIBLIOGRAPHY

- BASF (2015a) Determination of the Biodegradability and the Elimination in the CO₂/DOC Combination Test (29G0029/15G035, April, 2015). Ludwigshafen, Germany, BASF SE, Department of Experimental Toxicology and Ecology (Unpublished report submitted by the notifier).
- BASF (2015b) Humic acid mitigation potential of the acute toxicity to the water flea *Daphnia magna* STRAUS (Screening) (85E0029/15001, November, 2015). Ludwigshafen, Germany, BASF SE, Department of Experimental Toxicology and Ecology (Unpublished report submitted by the notifier).
- BASF (2015c) Humic acid mitigation potential of the acute toxicity to unicellular green algae *Pseudokirchneriella subcapitata* (Screening) (85E0029/15002, November, 2015). Ludwigshafen, Germany, BASF SE, Department of Experimental Toxicology and Ecology (Unpublished report submitted by the notifier).
- BASF (2015d) Determination of the Inhibition of Oxygen Consumption in the Activated Sludge Respiration Inhibition Test (08G0029/15G036, April, 2015). Ludwigshafen, Germany, BASF SE, Department of Experimental Toxicology and Ecology (Unpublished report submitted by the notifier).
- Bolto B., Dixon D., Eldridge R. and King S. (2007) Removal of Natural Organic Matter from Drinking Water CSIRO Molecular Science Research Report No 7 CRC for Water Quality and Treatment accessed <https://www.waterra.com.au/publications> 24 April 2019.
- 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 >