File No: LTD/1665

August 2014

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Polymer in Accelerator A1

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.

For the purposes of subsection 78(1) of the Act, this Public Report may be inspected at our NICNAS office by appointment only at Level 7, 260 Elizabeth Street, Surry Hills NSW 2010.

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

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Director NICNAS

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SUMMARY

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

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
LTD/1665	Nuplex Industries (Aust) Pty Ltd Axalta Coating Systems (Australia) Pty Ltd	Polymer in Accelerator A1	ND*	≤ 1 tonne per annum	Component of putty products for automobile industry

^{*}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 for the Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

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 assessed 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 safe work practices to minimise occupational exposure during handling of the notified polymer as introduced in the products:
 - Avoid direct skin and eye contact
- In the interest of occupational health and safety, the following precautions should be observed when sanding putties containing the notified polymer:
 - The level of atmospheric nuisance dust should be maintained as low as possible. The Safe Work Australia exposure standard for atmospheric dust is 10 mg/m3.
- Based on the information provided, no specific engineering controls or personal protective equipment are required for the safe use of the notified polymer itself, however, these should be selected on the basis of all ingredients in the formulation.

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

- A copy of the (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 for the 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

The notified polymer should be disposed of to landfill.

Emergency procedures

• Spills or accidental release of the notified polymer should be handled by physical 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;

or

- (2) Under Section 64(2) of the Act; if
 - the function or use of the polymer has changed from a component of putty products for automobile industry, 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 and products containing the notified chemical provided by the notifier were 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(S)

Nuplex Industries (Aust) Pty Ltd (ABN: 25 000 045 572)

49-61 Stephen Road BOTANY NSW 2019

Axalta Coating Systems (Australia) Pty Ltd (ABN: 53 158 497 655)

15-23 Melbourne Road RIVERSTONE NSW 2765

NOTIFICATION CATEGORY

Limited: Synthetic polymer with Mn \geq 1,000 Da

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication: chemical name, molecular and structural formulae, molecular weight, analytical data, 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 as follows: all physico-chemical endpoints.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

P.E Soft Stopper (Putty product containing < 0.75% notified polymer)

P.E Fine Stopper (Putty product containing < 0.75% notified polymer)

Accelerator A1 (Product containing ≤ 70% notified polymer in styrene, not imported)

Beschleuniger A1 (Other name for Accelerator A1)

MOLECULAR WEIGHT

> 1,000 Da

ANALYTICAL DATA

Reference FTIR and GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY 100%

4. PHYSICAL AND CHEMICAL PROPERTIES

The notified polymer will not be isolated from the synthesis reaction mixture and the following physical-chemical properties represent a product containing $\leq 70\%$ notified polymer (Accelerator A1).

APPEARANCE AT 20 °C AND 101.3 kPa: Yellowish Liquid

Property	Value	Data Source/Justification
Melting Point	Not determined	Liquid at 20 °C
Boiling Point	Approximately 146 °C at 101.3 kPa	(M)SDS

Density	Approximately 1,070 kg/m³ at 20 °C	(M)SDS
Vapour Pressure	$< 1.3 \times 10^{-9} \text{ kPa}$	Estimated based on the NAMW > 1,000 Da (US EPA, 2013)
Water Solubility	insoluble	Measured
Hydrolysis as a Function of pH	Not determined	Contains hydrolysable functionalities. However, the notified polymer is not expected to be significantly hydrolysed under normal environmental conditions (pH $4-9$).
Partition Coefficient (n-octanol/water)	Not determined	The notified polymer is expected to partition to n- octanol since it is expected to be insoluble in water
Adsorption/Desorption	Not determined	Based on the structural characteristics (potentially cationic) and its expected lack of solubility in water, the notified polymer is expected to adsorb to soil and sediment and have low mobility in soil.
Dissociation Constant	Not determined	Contains dissociable functionalities. Therefore, the notified polymer has potential to be ionised under environmental pH range of $4-9$.
Flash Point	Approximately 37 °C	(M)SDS
Flammability	Flammable liquid	(M)SDS
Autoignition Temperature	Approximately 435 °C	(M)SDS
Explosive Properties	Not determined	Contains no functional groups that would imply explosive properties
Oxidising Properties	Not determined	Contains no functional groups that would imply oxidative properties

DISCUSSION OF PROPERTIES

Reactivity

The notified chemical will not be isolated from the solution when synthesised. If the notified polymer is heated, there is potential risk of exothermic polymerisation. Strong exothermic reactions with peroxides may occur in the presence of heavy metal ions.

Physical hazard classification

Based on the submitted physico-chemical data depicted in the above table, the solution of the notified polymer at $\leq 70\%$ concentration is recommended for hazard classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS)*, as adopted for industrial chemicals in Australia. The recommended hazard classification is presented in the following table.

Hazard classification	Hazard statement
Flammable Liquids	H226 – Flammable liquid and vapour

Based on the MSDS provided for Accelerator A1, the product containing \leq 70% of notified polymer is classified as following:

R10: Flammable

5. INTRODUCTION AND USE INFORMATION

Mode of Introduction of Notified Chemical (100%) Over Next 5 Years

The notified polymer will not be manufactured or reformulated in Australia. It will be imported as a component of finished putty products at concentrations of < 0.75%. Repackaging of the finished products is not expected.

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

Year	1	2	3	4	5
Tonnes	< 1	< 1	< 1	< 1	< 1

PORT OF ENTRY Sydney

IDENTITY OF RECIPIENTS

Nuplex Industries (Aust) Pty Ltd

Axalta Coating Systems (Australia) Pty Ltd

TRANSPORTATION AND PACKAGING

The notified polymer will be imported in 1 to 3 kg containers at concentrations of < 0.75% as a component of finished products. Imported products will be transported by road from the wharf to storage facilities. The notifiers stated that all packing and transporting will be in accordance with ADG7.

USE

The notified polymer will be used as a component of polyester resins in putties for the automotive refinishing industry.

OPERATION DESCRIPTION

The putty products will be mixed with a hardener and then applied using stopping blades to automobiles. Before curing, the putties are malleable and will be manipulated into the desired shape. After air drying (< 1 hour), the putties will form a rigid matrix, which will then be sanded and coated with primer, paint or topcoat.

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	1	10
Warehouse/Store	8	30
Dispatch	< 1	Daily
End users	8	50

EXPOSURE DETAILS

The notified polymer will be present in the finished putty products at concentrations of < 0.75%. Based on the operation description provided, the end-user of the putty products may have potential for dermal and ocular exposure to the notified polymer at concentrations up to 0.75%. The notifiers stated in the submission that personal protective equipment (PPE) will be used to minimise the potential for exposure to the notified polymer during the application.

Since the putty products containing the notified polymer also contain hazardous ingredients that pose a potential inhalation risk, it is stated by the notifiers that, when handling the products, workers must comply with occupational standards and best practise and wear appropriate PPE. Given the conditions of the end use with controls and PPE in place, inhalation exposure to the uncured notified polymer is not expected to be significant. In addition the expected low vapour pressure will limit any inhalation exposure to the notified polymer in the uncured putty. However, when sanding cured putties, there will be potential for inhalation exposure to dust containing the notified polymer at concentrations up to 0.75%.

Once the putty has cured the notified polymer will be bound within the polymer matrix of the putty and hence will not be bioavailable. Additional layers of surface coatings are also expected to be applied on top of the cured putties further reducing the possibility of exposure.

6.1.2. Public Exposure

Finished putty products containing the notified polymer will not be sold to the general public, and therefore public exposure to the uncured notified polymer is not expected unless an accidental release of the products occurs during transport.

The public may come into contact with the automobiles containing cured putty with the notified polymer present at < 0.75%. However, once the putty has cured the notified polymer will be bound within the polymer matrix of the putty and hence will not be bioavailable for exposure.

6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on a product containing $\leq 70\%$ of the notified polymer are summarised in the following table. For full details of the studies, refer to Appendix B.

Endpoint	Result and Assessment Conclusion
Mouse, skin sensitisation – Local lymph node assay	No evidence of sensitisation
Mutagenicity – bacterial reverse mutation	Non mutagenic

Toxicokinetics, metabolism and distribution

No study reports on toxicokinetics, metabolism and distribution were provided for the notified chemical.

The notified polymer has a high molecular weight (> 1,000 Da) and a low percentage (< 5%) of low molecular weight species < 500 Da; hence absorption across biological membranes is expected to be limited.

Skin sensitisation

A mouse local lymph node assay on a product containing $\leq 70\%$ of the notified chemical at up to 30% in concentration was conducted using a non-radioactive cell counting method and did not show evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation.

Mutagenicity/Genotoxicity

A preliminary bacterial reverse mutation test on a product containing $\leq 70\%$ of the notified chemical did not reveal evidence of mutagenicity.

Structural alerts

The notified polymer contains tertiary aromatic amine group which possesses skin irritation and carcinogenicity structure alerts. However, the extensive steric crowding of the side chains of the notified polymer may affect the ability of the polymer to be metabolically activated to be carcinogenic (Benigni et al., 2008).

Health hazard classification

As only limited toxicity data were provided, the notified polymer cannot be classified according to the *Globally Harmonised System for the 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 structural alert, the notified polymer may have potential for irritation. However, the risk of irritation effects from exposure to the notified polymer is expected to be limited by the low use concentrations (<0.75%).

During end use, workers have potential to be exposed to the putty products containing the notified polymer at concentrations up to 0.75%. Given that the notifier has stated that safe work practices and PPE are expected to be in place, and the low concentration of the notified polymer in the putty products exposure of workers to the notified polymer is predicted to be low.

Once the putty has cured, the notified polymer will be bound within the polymer matrix of the putty, and sealed by additional layers of surface coatings, hence will not be available for further exposure to workers.

Therefore, under the conditions of the proposed end use, given the protective measures in place, the risk of workers from use of the products containing the notified polymer is not considered to be unreasonable.

6.3.2. Public Health

The putty products containing the notified polymer are intended for use in industrial applications only. The public may come into contact with automobile parts treated with the putty products. However, the notified

polymer will be reacted into the matrix and will not be available for exposure after the putties are cured and coated.

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

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified polymer will not be manufactured, reformulated, or repackaged in Australia. Therefore, release of the notified polymer from these activities is not expected.

RELEASE OF CHEMICAL FROM USE

A maximum of < 1% of the total import volume of the notified polymer is expected to be present as waste from the application of putties. Waste may be generated from cleaning of equipment, spillage and from the disposal of packaging. The waste putty is expected to be disposed of to landfill. There is very little potential for aquatic exposure during use as the notified polymer will be irreversibly bound within the cured putty matrix and given its use pattern.

RELEASE OF CHEMICAL FROM DISPOSAL

The notified polymer in putties is expected to share the fate of the automobiles to which it has been applied. The cross-linked cured putty in the form of excess solid material and discarded articles is expected to, therefore, either be thermally decomposed during metal reclamation processes or disposed of to landfill. The notified polymer, in landfill, is expected to undergo slow degradation processes via biotic and abiotic pathways, eventually forming water and oxides of carbon and nitrogen.

7.1.2. Environmental Fate

No environmental fate data for the notified polymer were submitted. The majority of the notified polymer is expected to be cured into an inert matrix as part of its normal use pattern as putties for application to automotive vehicles by professionals. The majority of the notified polymer is likely to be disposed of by thermal decomposition or disposed of to landfill. Thermal decomposition will destroy the notified polymer, while disposal to landfill would result in its immobilisation because of the expected strong sorption to soil organic carbon. Given the notified polymer's use pattern, it is not expected to be released to surface water. Either in landfill or through thermal decomposition, the notified polymer is expected to, finally, be decomposed into water and oxides of carbon and nitrogen. The notified polymer has a low solubility in water and a high molecular weight, and is irreversibly combined in a putty matrix. Therefore, the notified polymer is not expected to be either bioavailable or bioaccumulative to aquatic organisms.

7.1.3. Predicted Environmental Concentration (PEC)

The predicted environmental concentration (PEC) has not been calculated for the notified polymer as ecotoxicologically significant quantities are not expected to be released to the aquatic environment based on its assessed use pattern.

7.2. Environmental Effects Assessment

The results from ecotoxicological investigations conducted on the notified polymer and the product containing the notified polymer are summarised in the table below. Details of the studies can be found in Appendix C.

Endpoint	Result	Assessment Conclusion
Fish Toxicity (96 h)	LL50 > 100 mg/L (WAF)	Not harmful to fish
Daphnia Toxicity (48 h)	EL50 > 46 mg/L(WAF)	Harmful to aquatic invertebrates
Algal Toxicity (72 h)	$E_r L50 > 100 \text{ mg/L (WAF)}$	Not harmful to algae
Inhibition of Bacterial Respiration (3 h)	EC50 = 4210 mg/L	Not inhibitory to microbial activity

WAF: water accommodated fraction

The notified polymer is not harmful to fish. Whilst the product containing the notified polymer is harmful to aquatic invertebrates, it is not harmful to algae and not inhibitory to microbial activity. The toxicity test for

daphnia was conducted for a product containing 70% of the notified polymer in 30% of styrene. The resulting toxicity may, therefore, not accurately reflect the actual toxicity of the notified polymer. Furthermore, the exerted toxicity from the daphnia toxicity test is likely to associate with styrene rather than the combined effect of the notified polymer and styrene. This assumption is supported by the literature that the toxicity value of styrene to daphnia stated in the provided study is consistent to those reported in the literature. Therefore, the notified polymer should not be classified under GHS for either the acute or chronic toxicity.

7.2.1. Predicted No-Effect Concentration

The predicted no-effect concentration (PNEC) has not been calculated for the notified polymer as, based on its assessed use pattern, ecotoxicologically significant quantities are not expected to be released to the aquatic environment.

7.3. Environmental Risk Assessment

The risk quotient (Q = PEC/PNEC) for the notified polymer has not been calculated as ecotoxicologically significant concentrations are not expected to be reached based on its assessed use pattern as a component of putties. The notified polymer is not likely to be released into the aquatic environment in a bioavailable form as the notified polymer is irreversibly combined in a putty matrix and is expected to adsorb to soil and sediment. Therefore, the risk of the notified polymer to the environment is not expected to be unreasonable based on its assessed use pattern.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Water Solubility Not soluble

Method OECD TG 105 Water Solubility.

EC Council Regulation No 440/2008 A.6 Water Solubility.

Remarks The determination of the water solubility of the notified polymer in the product (containing

up to 30% styrene) was performed with a Dissolved Organic Carbon (DOC) method. The measured DOC value was for styrene. The notified polymer does not contribute to the measured DOC value and that the water solubility of the notified polymer can be

disregarded.

Test Facility Bayer (2009)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Skin sensitisation – mouse local lymph node assay (LLNA)

TEST SUBSTANCE Beschleuniger A1 (Product containing ≤ 70% notified polymer in styrene)

METHOD OECD TG 429 Skin Sensitisation: Local Lymph Node Assay

Species/Strain Mouse/Hsd Win:NMRI

Vehicle DAE 433, a mixture of 40% dimethylacetamide, 30% acetone and 30%

ethanol

Remarks - Method Test substance was dissolved in the vehicle and a volume of 25 µL/ear was

administered epicutaneously on to the dorsal part of both ears of the test

animal for 3 consecutive days.

Measuring of cell count and weight per lymph node was used instead of radioactive labelling. The cell counts were conducted using a Coulter counter. Measuring of ear swelling after treatment was also included in the

assay.

 α -Hexyl cinnamic aldehyde was used as a positive control.

RESULTS

Concentration	Stimu	lation Index (Test/Control R	atio)
(% w/w)	Weight/node	Cells/node	Ear swelling/test
0 (vehicle control)	1.00	1.00	1.00
3	0.98	0.79	1.04
10	0.86	0.70	1.01
30	1.12	1.18	1.02

cell counts or for weights of the draining lymph nodes after application of

the test substance.

The "positive level" which is 1.3 for the cell count index for this breed of

mice was never reached or exceeded in any dose group.

Positive control showed expected positive results.

CONCLUSION There was no evidence of induction of a lymphocyte proliferative response

indicative of skin sensitisation to the test substance.

TEST FACILITY Bayer (2003)

B.2. Genotoxicity – bacteria

TEST SUBSTANCE Beschleuniger A1 (Product containing ≤ 70% notified polymer in styrene)

METHOD OECD TG 471 Bacterial Reverse Mutation Test.

EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test

using Bacteria.

Plate incorporation procedure (initial screening)

Pre incubation procedure (repeat test)

Species/Strain S. typhimurium: TA1535, TA1537, TA98, TA100, TA102

Metabolic Activation System Enzymatic fraction of Aroclor 1254 induced rat liver homogenate (S9)

Concentration Range in

a) With metabolic activation:
16 to 5,000 μg/plate
b) Without metabolic activation:
16 to 5,000 μg/plate

Vehicle DMS

The test substance was tested one plate per dose with plate incorporation procedure in initial screening. The repeat test was conducted one plate per dose with preincubation procedure.

RESULTS

Metabolic	Test Substance Concentration (µg/plate) Resulting in:				
Activation	Cytotoxicity in Preliminary Test	Cytotoxicity in Main Test	Precipitation	Genotoxic Effect	
Absent	·				
Test 1	> 5,000	-	$\geq 1,600$	Negative	
Test 2	-	$\geq 1,600$	$\geq 1,600$	Negative	
Present				-	
Test 1	> 5,000	-	$\geq 1,600$	Negative	
Test 2	-	$\geq 5,000$	$\geq 1,600$	Negative	

Remarks - Results

Dose levels above 500 $\mu g/plate$ produced weak and strain specific cytotoxicity. Due to the weakness of the effects, the cytotoxicity was not considered as significant by the study authors.

As the study was only conducted one plate per dose, a statistical comparison was not performed.

Positive controls produced the expected positive results.

CONCLUSION

The test substance was not mutagenic to bacteria under the conditions of

the test.

TEST FACILITY

Bayer (2002)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE Beschleuniger A1 (Product containing ≤ 70% notified polymer in styrene)

METHOD OECD TG 203 Fish, Acute Toxicity Test – Static Test

Species Zebra fish (Danio rerio)

Exposure Period 96 hours
Auxiliary Solvent Not reported
Water Hardness 79 mg CaCO₃/L

Analytical Monitoring Dissolved Organic Carbon (DOC) – Analysator: Multi N/C 3000 Analytik

Jena AG

Remarks – Method The test was conducted according to the guidelines above and good

laboratory practice (GLP) principles. No significant deviations from the

test guidelines were reported.

The fish ecotoxicity test was conducted in a Water Accommodated Fraction (WAF) of the test substance as it is a complex mixture and has low water solubility. The test was conducted as a limit test. A WAF of the nominal loading rate of 100 mg/L was prepared by shaking the test substance in water by using a rotating shaker for 24 h. Undissolved particles of the test substance were removed by centrifugation (20 min,

3,000 rpm). The clear WAF was used in the toxicity test.

RESULTS

Nominal Concentration	Number of Fish	Mortality (%)			
(WAF;mg/L)		24 h	48 h	72 h	96 h
Control	7	0	0	0	0
100	7	100	100	100	100

 $\begin{array}{cc} LL50 & > 100 \text{ mg/L at } 96 \text{ hours} \\ NOEL & 100 \text{ mg/L at } 96 \text{ hours}. \end{array}$

Remarks – Results All validity criteria for the test were satisfied. The exposure treatment was observed to be clear. The 96-hour LL50 was determined by visual

observed to be creat. The 36 hour E250 was determined by visual observation. The DOC of the treatment solution at the beginning of the test

was 12.8 mg/L.

CONCLUSION The notified polymer is not harmful to fish.

TEST FACILITY Dr. U. Noack (2003)

C.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE Beschleuniger A1 (Product containing ≤ 70% notified polymer in styrene)

METHOD OECD TG 202: Acute Immobilisation Test – Static Test

Species Daphnia magna STRAUS

Exposure Period 48 hours
Auxiliary Solvent Not reported
Water Hardness 254 mg CaCO₃/L

Analytical Monitoring Dissolved Organic Carbon (DOC) – Analysator: Multi N/C 3000 Analytik

Jena AG

Remarks - Method The test was conducted according to the guidelines above and good

laboratory practice (GLP) principles. No significant deviations from the test guidelines were reported. However, a solvent control was not included

in the toxicity test.

> The daphnia ecotoxicity test was conducted in Water Accommodated Fractions (WAFs) of the test substance as it is a complex mixture and has low water solubility. WAFs of the nominal loading rates of 6.4, 16, 40 and 100 mg/L were prepared by shaking the test substance in dilution water by using a rotating shaker for 24 h. Undissolved particles of the test substance were removed by centrifugation (20 min, 3000 rpm). The clear WAFs were used in the toxicity test. The lowest WAF treatment (2.6 mg/L) was prepared by diluting the WAF treatment of the loading rate of 6.4 mg/L with a factor of 2.

RESULTS

Nominal Concentration	Number of D. magna	% Immobilised	
(WAF; mg/L)	, c	24 h	48 h
Control	20	0	0
2.6	20	0	0
6.4	20	0	0
16	20	0	0
40	20	30	50
100	20	75	85

EL50 NOEL 46 (36 - 59) mg/L at 48 hours

16 mg/L at 48 hours

Remarks - Results

All validity criteria for the test were satisfied. The exposure treatment was observed to be clear. The 96-hour LL50 was determined by visual observation. The mean DOC of the treatments ranged between 0 to 25.96 mg/L.

Since a solvent control was not included in the toxicity test, it is not possible to determine if the resulting toxicity was either the combined toxicity (notified polymer plus styrene) or solely from styrene.

All exposure treatments (loading rates) were observed to be clear. The 48 h EL₅₀ was calculated by probit analysis using SigmaPlot software. The confidence intervals were calculated using the standard procedures according to Breitig and Tumpling (1982).

CONCLUSION

The product containing the notified polymer is harmful to aquatic invertebrates.

TEST FACILITY

Dr. U. Noack (2002a)

C.2.3. Algal growth inhibition test

TEST SUBSTANCE

Beschleuniger A1 (Product containing ≤ 70% notified polymer in styrene)

METHOD

OECD TG 201 Alga, Growth Inhibition Test.

Species Scenedesmus Subspicatus **Exposure Period** 72 hours

Nominal: Concentration Range

100 mg/L**Auxiliary Solvent** Not reported Water Hardness Not reported

Analytical Monitoring

Dissolved Organic Carbon (DOC) – Analysator: Multi N/C 3000 Analytik

Jena AG

Remarks - Method

The test was conducted according to the guidelines above and good

laboratory practice (GLP) principles. No significant deviations from the test guidelines were reported.

The algae ecotoxicity test was conducted in a Water Accommodated

Fraction (WAF) of the test substance as it is a complex mixture and has low water solubility. The test was conducted as a limit test. A WAF of the nominal loading rate of 100 mg/L was prepared by shaking the test substance in water by using a rotating shaker for 24 h. Undissolved particles of the test substance were removed by centrifugation (20 min, 3,000 rpm). The clear WAF was used in the toxicity test.

RESULTS

Bioma	uss (72 h)	Growth	ı (72 h)
$E_{y}L50$	$NOE_{y}L$	$E_r L 50$	NOE_rL
(mg/L)	(mg/L)	(mg/L)	(mg/L)
> 100	100	> 100	100

Remarks - Results All validity criteria for the test were satisfied. The exposure treatment was

observed to be clear. The DOC of the treatment at the beginning of the test was 16.1 mg/L. The NOEL was determined by verifying the statistical significance of biomass integrals and growth rates. One way analysis of variance (ANOVA) for homogeneity of variance by Bartlett's test, and Dennett's multiple comparison tests were used for growth rates and the

Bonferroni t-test was used for biomass integral test.

CONCLUSION The product containing the notified polymer is not harmful to algae.

TEST FACILITY Dr. U. Noack (2002b)

C.2.4. Inhibition of microbial activity

TEST SUBSTANCE Beschleuniger A1 (Product containing ≤ 70% notified polymer in styrene)

METHOD OECD TG 209 Activated Sludge, Respiration Inhibition Test.

Inoculum Activated sludge

Exposure Period 3 hours

Concentration Range Nominal: 100, 1800, 3200, 5600, 10000 mg/L

Actual: N/A

Remarks - Method The test was conducted according to the guidelines above and good

laboratory practice (GLP) principles. No significant deviations from the

test guidelines were reported.

RESULTS

IC50 4,210 (3,100 - 6,200) mg/L at 3 hours

NOEC Not reported

Remarks – Results The validation criteria for the control respiration rates and reference

material (3,5-dichlorophenol) EC₅₀ were satisfied.

CONCLUSION The product containing the notified polymer is not inhibitory to bacterial

respiration.

TEST FACILITY Bayer (2006)

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