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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

ADEKA REASOAP SR-10

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (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 Ageing, 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 Water Resources.

For the purposes of subsection 78(1) of the Act, this Full Public Report may be inspected at our NICNAS office by appointment only at 334-336 Illawarra Road, Marrickville NSW 2204.

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Director
NICNAS

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Nuplex Industries (Aust) Pty Ltd (ABN 25 000 045 572)
49-61 Stephen Road, Botany NSW 2019

Amtrade International Pty Ltd (ABN 49 006 409 936)
Level 6, 574 St Kilda Road, Melbourne VIC 3004

NOTIFICATION CATEGORY
Standard: Chemical other than polymer (more than 1 tonne per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:
Chemical identity, Composition, Import volumes, Specific use

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:
Melting Point/Freezing Point, Vapour pressure, Adsorption/Desorption, Flammability limits, Autoignition temperature, Explosive properties, Acute dermal toxicity, Eye irritation

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
USA (2004), Korea (2006)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Adeka Reasoap SR-10

METHODS OF DETECTION AND DETERMINATION

Remarks UV/vis, IR, NMR and GPC data were provided.

3. COMPOSITION

DEGREE OF PURITY
> 90%

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will be imported as neat liquid (100%) or as aqueous solution (25%) in 200 kg drums.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	10-30	10-30	10-30	10-30	10-30

USE
The notified chemical will be used in the manufacture of emulsion polymer for surface coating formulations.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
Sydney

IDENTITY OF MANUFACTURER/RECIPIENTS
Nuplex Industries (Aust) Pty Ltd

TRANSPORTATION AND PACKAGING
The notified chemical will be imported in 200 kg drums and transported by road from wharf to storage facility.

5.2. Operation description

At the manufacturing unit, the notified chemical will be charged to the reactor (5000 L registered pressure vessel fitted with condenser), stirred and prescribed thermal cycle followed under controlled conditions to manufacture the surface coating polymers.

Charging of the notified chemical into the reactor will be carried out via a drum spear, inserted directly into the received drum of the notified chemical. At the end of charging, the drum spear will be inserted into a 20 L bucket containing rinse water which will then be pumped into the reactor, cleaning the spear, pump and lines of residual notified chemical.

During polymerisation, water and monomer vapours will be condensed in the condenser and returned through sealed piping to the reactor. When all the monomers are converted to polymer and polymerisation is complete, the resulting dispersion will be pneumatically pumped through a sealed fitter into intermediate bulk storage (20-30 tonne tanks) or directly into the 1000 L IBC's or 200 L drums. The standard cycle for one batch is approximately 16 hours.

The dispersion will be sold to coatings manufacturers who will blend it with other used raw materials to produce surface coatings.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Charging product to reactor	1	0.25 hours/day	40 days per year

Exposure Details
Dermal and possible ocular exposure to the notified chemical may occur from drips, spills or splashes and/or from contact with the drum spear. One operator will be exposed per batch for a maximum of 15 mins (most likely 5 mins). Personal protective equipment, such as protective overalls, gloves, safety boots and safety glasses will be worn to prevent contact with the notified chemical.

There will be no quality control sampling or testing of the process. The notified chemical will be consumed in the polymerisation reaction, so negligible amounts are expected to be present in the manufactured polymer. Therefore, no exposure to the notified chemical will occur after its use.

5.4. Release

RELEASE OF CHEMICAL AT SITE

During charging of the raw materials to various vessels, air and small volumes of reactant vapours in the headspace of the vessels will be displaced through a closed vent system to a high temperature incinerator. At the time of manufacture of a polymer, there will be only small volumes of vapour emitted. The condenser attached to the reaction vessel will contain the vapours and the condensate will be returned to the reactor. After polymerisation is completed and the reactants are reduced to very low levels, the polymer will be pumped through enclosed filters to storage tanks or directly to the packing station.

The polymerisation, filtration and packing operation are efficient with losses of chemical dispersion mainly due to washing of the equipment. This will be done by hosing with a few hundred litres of water after each 5 tonne batch. Whenever possible, batches will be run in succession to minimise the need for washing. It is expected that less than 2% of the total annual importation of notified chemical will be released from manufacture to trade-waste sewer.

RELEASE OF CHEMICAL FROM USE

As all notified chemical will be consumed during polymer manufacture, its release is not expected from use.

5.5. Disposal

The notified chemical that will be disposed of to trade-waste sewer will undergo biological oxidation and chemical flocculation. The waste water will pass through a settling pond discharge point. Flocculated chemical will be disposed of to landfill. The notified chemical that is disposed of to landfill is expected to be inert in the environment. Over time, the notified chemical may eventually degrade via biotic and abiotic means to form predominantly simple organic compounds.

5.6. Public exposure

The only likely exposure of the public would occur in the event of accident during transportation. Exposure is not expected as the notified chemical will be consumed during polymerisation and will not be available to the public.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa Light yellowish liquid

Boiling Point ~ 100°C (pressure unspecified) (MSDS)

Density 1100 kg/m^3 (temperature unspecified) (MSDS)

Vapour Pressure 1.20×10^{-24} kPa at 25°C

Remarks Estimated using the MPBPWIN (v1.42) [US EPA EPI Suite (v3.20)]. The notified chemical is not expected to be volatile.

Water Solubility > 549 g/L at room temperature

METHOD OECD TG 105 Water Solubility.
EC Directive 92/69/EEC A.6 Water Solubility.
Remarks Simplified Flask Method
TEST FACILITY RCC (2006a)

Hydrolysis as a Function of pH

METHOD OECD TG 111 Hydrolysis as a Function of pH.
EC Directive 92/69/EEC C.7 Degradation: Abiotic Degradation: Hydrolysis as a Function of pH.

pH	*T (°C)*	*$t_{½}$ (days)*

4	25	> 365
7	25	> 365
9	25	> 365

Remarks The notified chemical is considered to be hydrolytically stable under representative environmental conditions.
TEST FACILITY RCC (2006e)

Partition Coefficient (n-octanol/water) log P_{ow} < -0.13 at 20°C

METHOD OECD TG 107 Partition Coefficient (n-octanol/water).
EC Directive 92/69/EEC A.8 Partition Coefficient.
Remarks Flask Method. As the test item was found to be surface active, the log P_{ow} was calculated from the individual solubilities of the notified chemical in water and in n-octanol.
TEST FACILITY RCC (2006d)

Adsorption/Desorption log K_{oc} = 5.258 (estimated)

METHOD Estimated using PCKOCWIN (v1.66)
Remarks Based on the estimated log K_{oc}, the notified chemical would have high affinity for the organic component of soils and sediments and therefore, is not expected to be mobile in these media.

Dissociation Constant pKa = 5.2

METHOD Similar to OECD TG 112 Dissociation Constants in Water.
Remarks 10 g of a 25% aqueous solution of notified chemical was added to 15 g water. The solution was adjusted to pH 12.00 with 40.1 mL of 0.1 N NaOH and then titrated against 0.1 N HCl to provide a titration curve from which the pKa was determined.

Particle Size Not applicable.

Flash Point 216ºC at 101.3 kPa (MSDS)

Flammability Limits Not determined

Remarks Based on its high flash point and low vapour pressure (216ºC), the notified chemical is not expected to be highly flammable.

Autoignition Temperature No experimental or predicted value has been determined.

Remarks Given a flash point of 216ºC, it is expected that the hazard posed by spontaneous ignition is minimal.

Explosive Properties Not predicted to be explosive

Remarks The notified chemical contains no functional groups that are associated with explosive properties.

Reactivity Stable under normal conditions.

Surface Tension 36.0 mN/m at 20.9ºC

METHOD OECD TG 115 Surface Tension of Aqueous Solutions.
EC Directive 92/69/EEC A.5 Surface Tension.
Remarks Concentration: ~0.1%. The notified chemical is surface active, as determined by means of a tensiometer, using the ring method.
TEST FACILITY RCC (2006d)

7. TOXICOLOGICAL INVESTIGATIONS

Endpoint and Result	*Assessment Conclusion*
Rat, acute oral	LD50 > 2500 mg/kg bw, low toxicity
Rat, acute dermal*	LD50 > 2000 mg/kg bw, low toxicity
Rat, acute inhalation	Not available
Rabbit, skin irritation	Moderately irritating
Rabbit, eye irritation*	Severely irritating
Mouse, skin sensitisation – LLNA**	Evidence of sensitisation
Rat, repeat dose oral toxicity – 28 days.	NOEL = 200 mg/kg bw/day
Genotoxicity – bacterial reverse mutation	Non mutagenic
Genotoxicity – *in vitro* chromosomal aberration	Genotoxic
Genotoxicity – *in vivo* micronucleus assay	Non genotoxic

*Analogue chemical
**Local lymph node assay

The analogue chemical contains reactive functional groups, which are likely to contribute to toxicity, e.g., irritation and sensitisation.

7.1. Acute toxicity – oral

TEST SUBSTANCE Notified chemical

METHOD
- Species/Strain: Rat/Sprague-Dawley CD strain rat
- Vehicle: Arachis oil BP
- Remarks - Method: There were no significant deviations from the protocol.

RESULTS

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

- LD50: > 2500 mg/kg bw
- Signs of Toxicity: There were no signs of systemic toxicity. All animals showed expected gains in bodyweight over the study period.
- Effects in Organs: No abnormalities were noted at necropsy.

CONCLUSION The notified chemical is of low toxicity via the oral route.

TEST FACILITY SafePharm Laboratories (2004)

7.2. Acute toxicity – dermal

TEST SUBSTANCE Analogue chemical (90%)

METHOD
- Species/Strain: Rat/Strain unknown
- Vehicle: Unknown
- Type of dressing: Unknown
- Remarks - Method: Unknown

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5 per sex	2000	0

LD50	> 2000 mg/kg bw
Signs of Toxicity - Local	Following removal of the dressing, moderate to severe dermal irritations indicated by inflammation of the epidermis and eschar formation were observed at the treatment site. The effects cleared over time. Some minor residual skin lesions were observed in 1 animal at the end of the 14-day observation period.
Signs of Toxicity - Systemic	There were no signs of systemic reaction to the treatment.
Effects in Organs	No abnormalities were recorded at the macroscopic examination on day 14.
Remarks - Results	None.

CONCLUSION The analogue chemical is of low toxicity via the dermal route.

TEST FACILITY Published reference on analogue chemical (2003)

7.3. Acute toxicity – inhalation

There was no acute inhalation toxicity test submitted. However as the notified chemical has a very low vapour pressure and inhalation exposure is not expected to be significant, inhalation toxicity study is not required.

7.4. Irritation – skin

TEST SUBSTANCE Notified chemical

METHOD OECD TG 404 Acute Dermal Irritation/Corrosion.
EC Directive 92/69/EEC B.4 Acute Toxicity (Skin Irritation).

Species/Strain	Rabbit/New Zealand White
Number of Animals	3
Observation Period	14 days
Type of Dressing	Semi-occlusive.
Remarks - Method	There were no significant deviations from the protocol.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema/Eschar	2	2	2	2	10 days	0
Oedema	1	1	0.7	2	72 hours	0

*Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal.

Remarks - Results	Mild to moderate, early–onset and transient signs of irritation such as erythema, oedema and scaling, was observed. These effects were no longer evident on test day 14, except for scaling, which was present in all animals 14 days after treatment, the end of observation period. The test item caused no staining of the treated skin. No corrosive effects were noted, and no clinical signs were observed.

CONCLUSION The notified chemical is moderately irritating to the skin.

TEST FACILITY RCC (2006b)

7.5.1 Irritation – eye (90% analogue chemical)

METHOD OECD TG 405 Acute Eye Irritation/Corrosion.

Species/Strain	Rabbit/Strain unknown
Number of Animals	3
Observation Period	Unknown
Remarks - Method	The test was compliant with GLP.

RESULTS

Remarks - Results	Twenty-four hours after exposure, the animals were observed to have reactions of the conjunctivae in the form of diffuse crimson red discoloration (individual blood vessels not easily discernible), together with distinct swelling and partial eversion of the eyelids. The cornea was slightly opaque over the entire surface, and the iris of one animal showed severe hyperaemia. Up to 72 hours after administration, these signs of irritation were largely unchanged and after 6 days, all signs of irritation began to diminish. Two animals were free from signs of irritation to the eye and mucosa after day 17, and the third animal after 24 days.
CONCLUSION	The notified chemical is severely irritating to the eye.
TEST FACILITY	Published reference on analogue chemical (2003)

7.5.2 Irritation – eye (28% analogue chemical)

METHOD	OECD TG 405 Acute Eye Irritation/Corrosion.
Species/Strain	Rabbit/Strain unknown
Number of Animals	3
Observation Period	Unknown
Remarks - Method	Draize test GLP compliance was not mentioned.

RESULTS

Remarks - Results	Corneal opacity, iritis and conjunctivitis in all test animals were reported. While the conjunctivitis appeared to improve in all 3 test animals approximately 8-10 days after exposure to the test material, corneal opacity and the circumcorneal injection in the iris were still present in 2 animals after 21 days.
CONCLUSION	The notified chemical is severely irritating to the eye.
TEST FACILITY	Published reference on analogue chemical (2003)

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

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 429: Skin Sensitisation: LLNA EC 2004/73/EC, B. 42: Skin Sensitisation: LLNA
Species/Strain	Mice/CBA/CaHsdRcc(SPF)
Vehicle	Acetone/olive oil (4/1, v/v)
Remarks - Method	Dose range based on a non-GLP pre-test.

RESULTS

Concentration (% w/v)	*Proliferative response (DPM/lymph node)*	*Stimulation Index (Test/Control Ratio)*
Test Substance		
0 (vehicle control)	459	1.0
1	1893	4.1
2.5	1942	4.2
5	2507	5.5
Positive Control		
0	314	1.0
5	910	2.9
10	1223	3.9

25	2725	8.7

Remarks - Results	No clinical signs were observed in any animals of the control group or the 1% group. On the third application day, slight ear swelling and erythema were observed at both dosing sites in all mice of the 2.5% group, which persisted for the reminder of the study. On the second application day, a slight to moderate ear swelling was observed at both dosing sites in all mice of the 5% group. On the third application day, a moderate ear erythema was also noted, persisting for the remainder of the study. A dose-response relationship was observed, but an EC3 value could not be determined because this calculation requires a S.I. value of less than 3.
CONCLUSION	There was evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the notified chemical.
TEST FACILITY	RCC (2005)

7.7. Repeat dose toxicity

TEST SUBSTANCE	Notified Chemical
METHOD	OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents.
Species/Strain	Crj:CD (SD) IGS rats (SPF)
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 28 days Dose regimen: 7 days per week Post-exposure observation period: 14 days
Vehicle	Purified water
Remarks - Method	There were no significant deviations from the protocol.

RESULTS

Dose mg/kg bw/day	*Number and Sex of Animals*	*Mortality*
0	6 M, 6 F	0
40	6 M, 6 F	0
200	6 M, 6 F	0
1000	6 M, 6 F	0
0	6 M, 6 F	0
1000	6 M, 6 F	0

Clinical Observations

No abnormalities were noted on body weights and food intakes during the dosing period; elevation of the limiting ridge of the forestomach was observed in males of the 1000 mg/kg bw/day group after necropsy.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

Hyperplasia of the squamous epithelium in the limiting ridge of the forestomach was observed in males of the 1000 mg/kg bw/day group at the termination of the dosing period. Haematological, blood chemical examinations and urinalyses were not affected significantly.

Effects in Organs

In the recovery test group, hyperplasia of the squamous epithelium in the limiting ridge of the forestomach was observed in males of the 1000 mg/kg bw/day group at the termination of the recovery period.

Remarks – Results

The noted effects of notified chemical were considered to be a result of the irritation of mucous membranes. Other effects were observed, but these were considered to be of no toxicological significance due to low incidence, lack of dose-response, or lack of correlation with the dosing regimen.

CONCLUSION

The No Observed Effect Level (NOEL) was established as 200 mg/kg bw/day in this study, based on elevation of the limiting ridge and hyperplasia of the squamous epithelium in the limiting ridge of the forestomach in males of the 1000 mg/kg bw/day group.

TEST FACILITY Hita Laboratory (2002a)

7.8. Genotoxicity – bacteria

TEST SUBSTANCE Notified chemical

METHOD Pre incubation procedure

Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100 E. coli: WP2uvrA
Metabolic Activation System	Phenobarbital/5,6-benzoflavone-induced rat liver S9 mix.
Concentration Range in Main Test	0, 4.88, 19.5, 78.1, 313, 1250, 5000 µg/plate
Vehicle	Distilled water
Remarks - Method	There were no significant deviations from the protocol.

RESULTS

Remarks - Results	There were no significant increases in the number of revertant colonies in the treatment groups when compared to the corresponding negative controls, in all test strains. The positive controls showed the appropriate responses, demonstrating the validity of the test system.

CONCLUSION The notified chemical was not mutagenic to bacteria under the conditions of the test.

TEST FACILITY Hita Laboratory (2002b)

7.9. Genotoxicity – *in vitro*

TEST SUBSTANCE Notified Chemical

METHOD Japanese standard test method: "Notification on Partial Revision of Testing Methods Relating to the New Chemical Substances" (Notification No. 700 of the Planning and Coordination Bureau, Environment Agency (EA), No. 1039 of the Pharmaceutical Affairs Bureau, Ministry of Health and Welfare (MHW) & No. 1014 (1986) of the Basic Industries Bureau, Ministry of International Trade and Industry (MITI), December 5, 1986 and Notification No. 287 of the Planning and Coordination Bureau, EA, No. 127 of the Environmental Health Bureau, HMW & No. 2 (1997) of the Basic Industries Bureau, MITI, October 31, 1997).

Cell Type/Cell Line	Chinese hamster lung fibroblasts (CHL/IU cells, clone No.11)
Metabolic Activation System	Phenobarbital/5,6-benzoflavone-induced rat liver S9 mix.
Vehicle	Distilled water
Remarks - Method	There were no significant deviations from the protocol.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	0, 113, 225, 450	6 h	24 h
Test 2	0, 87.5, 175, 350	24 h	24 h
Present			
Test 1	0, 156, 313, 625	6 h	24 h
Test 2	0, 156, 313, 469, 625	6 h	24 h

RESULTS

Metabolic Activation	*Test Substance Concentration (μg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent	> 410			
Test 1		> 225	> 450	negative
Test 2		> 175	> 350	negative
Present	> 460			
Test 1		> 313	> 625	positive
Test 2		> 469	> 625	positive

Remarks - Results: The frequencies of cells with chromosomal aberrations did not fluctuate remarkably between two culture flasks. The frequency in the negative control was below 5% and the frequencies of cells with structural aberrations excluding gaps in the positive controls were over 20%.

CONCLUSION: The notified chemical induced chromosomal aberrations in the presence of S9 mix, under the test conditions.

TEST FACILITY: Hita Laboratory (2002c)

7.10. Genotoxicity – *in vivo*

TEST SUBSTANCE: Notified Chemical

METHOD: OECD TG 474 Mammalian Erythrocyte Micronucleus Test.
EC Directive 2000/32/EC B.12 Mutagenicity - Mammalian Erythrocyte Micronucleus Test.

Species/Strain: Mouse/NMRI
Route of Administration: Oral
Vehicle: DMSO+PEG (1:9)
Remarks - Method: There were no significant deviations from the protocol.
The highest dose (2000 mg/kg) was estimated to be suitable by a pre-experiment for systemic toxicity.

Dose (mg/kg bw)	*Number and Sex of Animals*	*Sacrifice Time(hours)*
0	5M, 5F	24
500	5M, 5F	24
1000	5M, 5F	24
2000	5M, 5F	24
2000	5M, 5F	48
40 (positive control, CP)	5M, 5F	24

CP=cyclophosphamide.

RESULTS

Doses Producing Toxicity: Signs of toxicity, including reduction in spontaneous activity and ruffled fur, were observed in all treatment groups and in all animals treated with 2000 mg/kg bw/day.

Genotoxic Effects: There was no biologically relevant or statistically significant increase in the frequency of micronuclei in any of the treated groups.
Cyclophosphamide (40 mg/kg bw/day, administered orally) was used as a positive control, and this chemical induced a substantial increase in micronucleus frequency.

Remarks - Results: None

CONCLUSION: The notified chemical was not mutagenic under the conditions of this *in vivo* micronucleus assay.

TEST FACILITY: RCC (2006c)

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE	Notified chemical.
METHOD	OECD TG 301 C Ready Biodegradability: Modified MITI Test (I).
Inoculum	Activated sewage sludge
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	BOD (biochemical oxygen demand), TOC (total organic carbon), HPLC
Remarks - Method	No significant protocol deviations were reported.

RESULTS

Test substance		*Aniline*	
Day	*% Degradation BOD*	*Day*	*% Degradation*
7	1	7	56
14	1.33	14	70
21	0	21	73
28	0.66	28	73

Remarks - Results	The percentage of biodegradation determined by TOC and HPLC was 9%. The test validation criteria were satisfied, and therefore, it was concluded that the test conditions were valid.
CONCLUSION	The notified chemical cannot be classified as readily biodegradable according to the test guideline.
TEST FACILITY	Kurume Laboratory (2002)

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified chemical.
METHOD	OECD TG 203 Fish, Acute Toxicity Test - Static. EC Directive 92/69/EEC C.1 Acute Toxicity for Fish - Static.
Species	Zebra Fish (*Brachydanio rerio*)
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	125 mg $CaCO_3$/L
Analytical Monitoring	HPLC
Remarks – Method	No significant protocol deviations reported. The single test concentration of nominal 100 mg/L was freshly prepared by completely dissolving 600 mg of the test item in 6 L of test water using ultrasonic treatment for 10 minutes and stirring for 10 minutes at room temperature.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*				
Nominal	*Actual*		*1 h*	*24 h*	*48 h*	*72 h*	*96 h*
0	0	7	0	0	0	0	0
100	90-94	7	0	0	0	0	0

LC50	> 100 mg/L at 96 hours.
NOEC	100 mg/L at 96 hours.
Remarks – Results	In the control and in the 100 mg/L test, all fish survived until the end of the test and no visible abnormalities were observed. No remarkable observations were made concerning the appearance of the test medium. The test medium was a clear solution throughout the whole test duration.
CONCLUSION	The notified chemical was not harmful to fish at a concentration of 100 mg/L.
TEST FACILITY	RCC (2006h)

8.2.2. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test – Static. EC Directive 92/69/EEC C.2 Acute Toxicity for Daphnia – Static.
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	250 mg $CaCO_3$/L
Analytical Monitoring	HPLC
Remarks - Method	The test medium was prepared by dissolving 30.2 mg of test item completely in 300 mL of test water by intense stirring for 15 minutes at room temperature. No significant deviations from the test guidelines were reported.

RESULTS

Concentration mg/L		*Number of D. magna*	*Number Immobilised*	
Nominal	*Actual*		*24 h*	*48 h*
0	0	20	0	0
100	98-112	20	0	0

LC50	> 100 mg/L at 48 hours
NOEC	100 mg/L at 48 hours
Remarks - Results	The test medium was a clear solution throughout the duration of the test.
CONCLUSION	The notified chemical was not harmful to daphnids at a concentration of 100 mg/L.
TEST FACILITY	RCC (2006f)

8.2.3. Algal growth inhibition test

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 201 Alga, Growth Inhibition Test. EC Directive 92/69/EEC C.3 Algal Inhibition Test.
Species	*Scenedesmus subspicatus*
Exposure Period	72 hours
Concentration Range	Nominal: 0, 100 mg/L Actual: 0, 97-98 mg/L
Auxiliary Solvent	None
Water Hardness	24 mg $CaCO_3$/L
Analytical Monitoring	HPLC
Remarks - Method	No significant protocol deviations. 41.49 mg of test item was completely dissolved in 400 mL of test water by intense stirring for 15 minutes at room temperature.

RESULTS

Biomass		Growth	
E_bC_{50} mg/L at 72 h	NOEC mg/L	E_rC_{50} mg/L at 72 h	NOEC mg/L
> 100	100	> 100	100

Remarks - Results	The test medium was a clear solution throughout the duration of the test. Microscopic examination of the algal cells after 72 hours exposure showed no difference between the algae growing in test medium containing the test item at a nominal concentration of 100 mg/L and the algal cells in the control. The test validity criteria were satisfied.
CONCLUSION	The notified chemical did not have an inhibitory effect on the growth of algal at a test concentration of 100 mg/L.
TEST FACILITY	RCC (2006g)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

Environmental release of the notified chemical is expected to be limited to < 2% of total annual importation, arising from cleaning of the equipment. This quantity will be released as trade waste to sewer, however, it is expected that it will be removed by flocculation in the STP and ultimately disposed of to landfill. Release to the aquatic environment from the STP is expected to be minimal, and therefore, a Predicted Environmental Concentration (PEC) can not be calculated.

In landfill, the notified chemical is expected to associate with soil and be relatively immobile within the landfill environment. More than 98% of the total annual volume of notified chemical imported is expected to be consumed in the formulation of emulsion polymer for surface coating formulations.

9.1.2. Environment – effects assessment

Based on the results of three ecotoxicity limit tests supplied, the Predicted No-Effect Concentration (PNEC) has been calculated as follows.

PNEC for the Aquatic Compartment		
LC50	> 100	mg/L
Assessment Factor	100	

PNEC:	> 1,000	µg/L

9.1.3. Environment – risk characterisation

As significant release to the aquatic environment is not expected at any stage in the lifecycle of the notified chemical, a PEC has not been calculated and subsequently, it has not been possible to calculate a Risk Quotient. However, as the results of ecotoxicity tests indicate that the notified chemical is not expected to be harmful to aquatic organisms, the risk to the aquatic environment is therefore, expected to be acceptable.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Dermal exposure to the notified chemical is estimated based on the EASE model using reasonable worst case defaults for a particular activity (European Commission, 2003) as follows:

Activity	Estimated exposure for activity (mg/day)	Estimated exposure for notified chemical (mg/kg bw/day)*
Manual addition of liquids	420	6
Coupling and decoupling of transfer line	42	0.6

*for a 70 kg worker and a 100% dermal absorption factor

9.2.2. Public health – exposure assessment

As the notified chemical is only intended for use in industrial settings, public exposure to the notified chemical is not expected. Once the notified chemical is completely consumed in the manufacture of polymer in surface coating, public exposure is not expected.

9.2.3. Human health – effects assessment

Acute toxicity

The notified chemical was of low acute oral toxicity (LD50 > 2500 mg/kg) and the analogue of notified chemical was of low acute dermal toxicity (LD50 > 2000 mg/kg) in rats.

Irritation

The notified chemical was moderately irritating to rabbit skin and the analogue of notified chemical was severely irritating to rabbit eyes.

Irritation effects were noted in the acute dermal toxicity study using an analogue chemical, as moderate to severe dermal irritations indicated by inflammation of the epidermis and eschar formation. Some minor residual skin lesions were observed in 1 animal at the end of the 14-day observation period.

Sensitisation

There was evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the notified chemical in a mouse LLNA tested at 1-5%.

Repeated Dose Toxicity

The No Observed Effect Level (NOEL) was established for the notified chemical as 200 mg/kg bw/day, based on elevation of the limiting ridge and hyperplasia of the squamous epithelium in the limiting ridge of the forestomach in males of the 1000 mg/kg group. These effects were likely a result of the irritant nature of the notified chemical.

Mutagenicity

The notified chemical was not mutagenic to bacteria. It induced chromosomal aberrations *in vitro*, but clastogenicity was not observed in the *in vivo* micronucleus assay. Based on the weight of the available evidence, the notified chemical is not considered likely to be mutagenic or clastogenic in humans.

Based on the available data, the notified chemical is classified as a hazardous substance in

accordance with the *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2004).

9.2.4. Occupational health and safety – risk characterisation

Workers will need to have skin and eye protection during handling of the notified chemical given that the notified chemical is severely irritating to eyes and sensitising and moderately irritating to skin, such as charging of the notified chemical to reactor, cleaning of the drum spear, pump and lines of residual notified chemical at the manufacturing unit.

Based on a NOEL of 200 mg/kg bw/day, derived from a 28-day rat oral repeat dose study the margin of exposure (MOE) for various activities were calculated as follows:

Activity	Estimated exposure for notified chemical (mg/kg bw/day)	Margin of Exposure
Manual addition of liquid form	6	33
Coupling and decoupling of transfer line	0.6	330

MOE greater than or equal to 100 are considered acceptable taking into account intra- and inter-species differences. Therefore, the risk of systemic effects using modelled worker data may not be acceptable for workers involved in the manual transfer of the notified chemical in the absence of PPE. The MOE should be higher if workers use PPE (gloves, goggles and protective clothing). Dermal and ocular exposure is therefore expected to be well controlled and the risk of systemic effects for workers manually adding the notified chemical to the reactor is acceptable provided that adequate measures are in place to protect workers. Once in the reactor, the notified chemical will be completely consumed to manufacture the polymer. Subsequently residual unreacted notified chemical is negligible.

The notified chemical in the surface coating is negligible as it is completed consumed in the polymerisation reaction. Therefore the exposure to the notified chemical during use of surface coating formulations is not expected.

9.2.5. Public health – risk characterisation

As there will be no exposure of the public to the notified chemical the risk to the public from exposure to the notified polymer is considered to be acceptable.

10. CONCLUSIONS – ASSESSMENT LEVEL OF CONCERN FOR THE ENVIRONMENT AND HUMANS

10.1. Hazard classification

Based on the available data the notified chemical is classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)]. The classification and labelling details are:

R38 Irritating to skin
R41 Risk of serious eye damage
R43 May cause sensitisation by skin contact
S24 Avoid contact with skin
S25 Avoid contact with eyes
S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice
S37 Wear suitable gloves
S39 Wear eye/face protection

and

As a comparison only, the classification of notified chemical using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations 2003) is

presented below. This system is not mandated in Australia and carries no legal status but is presented for information purposes.

	Hazard category	*Hazard statement*
Skin irritation/corrosion	2	Causes skin irritation
Serious eye damage/eye irritation	2A	Causes serious eye irritation
Skin sensitisation	1	May cause an allergic skin reaction

10.2. Environmental risk assessment

The chemical is not considered to pose a risk to the environment based on its reported use pattern.

10.3. Human health risk assessment

10.3.1. Occupational health and safety

There is risk to occupational health and safety is considered to be acceptable under the conditions of the occupational settings described (expected to have control measures to protect workers from skin and eye exposure).

10.3.2. Public health

There is acceptable risk to public health when used in the proposed manner.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the notified chemical was provided by the notifier. It is published here as a matter of public record. The accuracy of the information on the MSDS remains the responsibility of the applicant.

11.2. Label

The label for the notified chemical was provided by the notifier. The accuracy of the information on the label remains the responsibility of the applicant.

12. RECOMMENDATIONS

REGULATORY CONTROLS

Hazard Classification and Labelling

- The Office of the ASCC, Department of Employment and Workplace Relations (DEWR), should consider the following health hazard classification for the notified chemical:
  - R38 Irritating to skin
  - R41 Risk of serious eye damage
  - R43 May cause sensitisation by skin contact

- Use the following risk phrases for products/mixtures containing the notified chemical:
  - ≥20%: R38, R41, R43
  - ≥10%: R41, R43
  - ≥5% conc < 10%: R36, R43
  - ≥1%: R43

Health Surveillance

- As the notified chemical is a skin sensitiser, employers should carry out health surveillance for any worker who has been identified in the workplace risk assessment as having a significant risk of sensitisation.

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified chemical as introduced:
  - Automated chemical transfer apparatus.
  - Exhaust ventilation during polymer manufacture.

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical as introduced:
  - Procedures designed to minimise spillage during transfer operations together with adequate clean up and disposal.

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical as introduced:
  - Gloves, goggles or faceshield and workwear that are impervious to the notified chemical

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

- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)], workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Environment

Disposal

- The notified chemical should be disposed of to landfill.

Emergency procedures

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

12.1. 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 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(2) of the Act; if
  - the function or use of the chemical has changed from use in the manufacture of emulsion polymer for surface coating formulations, or is likely to change significantly;
  - the amount of chemical being introduced has increased to more than 30 tonnes per

annum, or is likely to increase, significantly;
- if the chemical has begun to be manufactured in Australia;
- additional information has become available to the person as to an adverse effect of the chemical on occupational health and safety, public health, or the environment;
- holders of the certificate are to report any adverse health effects.

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

No additional secondary notification conditions are stipulated.

13. BIBLIOGRAPHY

European Commission (2003) Technical Guidance Document on Risk Assessment in Support of Commission Directive 93/67/EEC on Risk Assessment for New Notified Substances and Commission Regulation (EC) No 1488/94 on Risk Assessment for Existing Substances and Directive 98/8/EC of the European Parliament and of the Council Concerning the Placing of Biocidal Products on the Market – Part I. Institute for Health and Consumer protection, European Chemicals Bureau, European Communities.

FORS (Federal Office of Road Safety) (1998) Australian Code for the Transport of Dangerous Goods by Road and Rail (ADG code), 6th Edition, Canberra, Australian Government Publishing Service

Hita Laboratory (2002a) Twenty-Eight-Day Repeated-dose Oral Toxicity Study of SR-10N in Rats, Final Report May 2002, Study B11-0674 for Asahi Denka Co., Ltd. Tokyo, Japan. Chemical Evaluation and Research Institute, Hita Laboratory, Oita, Japan (Unpublished report submitted by notifier).

Hita Laboratory (2002b) Mutagencity Test of SR-10N Using Microorganisms, Final Report January 2002, Study K01-2650 for Asahi Denka Co., Ltd. Tokyo, Japan. Chemical Evaluation and Research Institute, Hita Laboratory, Oita, Japan (Unpublished report submitted by notifier).

Hita Laboratory (2002c) Chromosomal Aberration Test of SR-10 Using Cultured Mammalian Cells, Final Report February 2002, Study K06-0902 for Asahi Denka Co., Ltd. Tokyo, Japan. Chemical Evaluation and Research Institute, Hita Laboratory, Oita, Japan (Unpublished report submitted by notifier).

Kurume Laboratory (2002) Biodegradation study of notified chemical by microorganisms. 7 February 2002, Study 13809, Kurume Laboratory, Chemicals Evaluation and Research Institute, Japan.

NOHSC (1994) National Code of Practice for the Labelling of Workplace Substances [NOHSC:2012(1994)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.

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

NOHSC (2003) National Code of Practice for the Preparation of Material Safety Data Sheets, 2nd edn [NOHSC:2011(2003)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.

RCC (2005) Adeka Reasoap SR-10: Local Lymph Node Assay (LLNA) in Mice (Identification of Contact Allergens), Final Report October 2005, Study A31487 for Asahi Denka Co., Ltd. Tokyo, Japan. RCC Ltd Toxicology, Switzerland. (Unpublished report submitted by notifier).

RCC (2006a) Determination of the water solubility of Adeka Reasoap SR-10. Final Report March 2006, Study A31432 for Asahi Denka Co., Ltd. Tokyo, Japan. RCC Ltd Toxicology, Fullinsdorf, Switzerland (Unpublished report submitted by notifier).

RCC (2006b) Adeka Reasoap SR-10: Primary Skin Irritation Study in Rabbits (4-Hour Semi-Occlusive Application), Final Report January 2006, Study A31476 for Asahi Denka Co., Ltd. Tokyo, Japan. RCC Ltd Toxicology, Fullinsdorf, Switzerland (Unpublished report submitted by notifier).

RCC (2006c) Micronucleus Assay in Bone Marrow Cells of the Mouse with Adeka Reasoap SR-10, Final Report March 2006, Study A911602 for Asahi Denka Co., Ltd. Tokyo, Japan. RCC Cytotest Cell Research GmbH (RCC-CCR) Switzerland (Unpublished report submitted by notifier).

RCC (2006d) Determination of the Partition Coefficient (n-Octanol/Water) of Adeka Reasoap SR-10. Final Report 13 March 2006, Study A31443 for Asahi Denka Co., Ltd. Tokyo, Japan. RCC Ltd Toxicology, Fullinsdorf, Switzerland (Unpublished report submitted by notifier).

RCC (2006e) Hydrolysis Determination of Adeka Reasoap SR-10at Different pH Values. Final Report 9 March 2006, Study A31454 for Asahi Denka Co., Ltd. Tokyo, Japan. RCC Ltd Toxicology, Fullinsdorf, Switzerland (Unpublished report submitted by notifier).

RCC (2006f) Adeka Reasoap SR-10: Acute Toxicity to *Daphnia magna* in a 48-Hour Immobilization Test. Final Report 8 February 2006, Study A31500 for Asahi Denka Co., Ltd. Tokyo, Japan. RCC Ltd Toxicology, Fullinsdorf, Switzerland (Unpublished report submitted by notifier).

RCC (2006g) Adeka Reasoap SR-10: Toxicity to *Scenedesmus subspicatus* in a 72-Hour Algal Growth Inhibition Test. Final Report 10 February 2006, Study A31522 for Asahi Denka Co., Ltd. Tokyo, Japan. RCC Ltd Toxicology, Fullinsdorf, Switzerland (Unpublished report submitted by notifier).

RCC (2006h) Adeka Reasoap SR-10: Acute Toxicity to Zebra Fish (*Brachydanio rerio*) in a 96-hour Static Test. Final Report 29 September 2006, Study A79200 for Asahi Denka Co., Ltd. Tokyo, Japan. RCC Ltd Toxicology, Fullinsdorf, Switzerland (Unpublished report submitted by notifier).

SafePharm Laboratories (2004) Adeka Reasoap SR-10: Assessment of Acute Oral Toxicity in the Rat – Acute Toxic Class Method, Final Report November 2004, Study 744/202 for Asahi Denka Co., Ltd. Tokyo, Japan. SafePharm Laboratories Limited, Derbyshire, UK (Unpublished report submitted by notifier).

United Nations (2003) Globally Harmonised System of Classification and Labelling of Chemicals (GHS). United Nations Economic Commission for Europe (UN/ECE), New York and Geneva.