File No: LTD/958

June 2002

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME
(NICNAS)

FULL PUBLIC REPORT

Polymer in Dow Corning 31 Additive

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Street Address: 334 - 336 Illawarra Road MARRICKVILLE NSW 2204, AUSTRALIA.

Postal Address: GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.
TEL: + 61 2 8577 8800
FAX + 61 2 9577 8888.
Website: www.nicnas.gov.au

Director
Chemicals Notification and Assessment

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1. APPLICANT

Dow Corning Australia Pty Ltd (ABN/ACN: 3600 8444 166) of 3 Innovation Road, North Sydney NSW 2113 has submitted a limited notification statement in support of their application for an assessment certificate for **Polymer in Dow Corning 31 Additive**.

2. IDENTITY OF THE CHEMICAL

The chemical name, CAS number, molecular and structural formulae, molecular weight, spectral data, details of the polymer composition and details of exact import volume and customers have been exempted from publication in the Full Public Report and the Summary Report.

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C & 101.3 kPa:	Liquid, white to yellow
Boiling Point:	242 °C
Specific Gravity:	1.05 at 25 °C
Vapour Pressure:	Not determined (notifier estimates vapour pressure to be < 0.1 kPa at 20 ºC)
Water Solubility:	< 0.1 % mg/L at 25 °C
Partition Co-efficient (n-octanol/water):	Not determined (see comments below)
Hydrolysis as a Function of pH:	Not determined (see comments below)
Adsorption/Desorption:	Not determined (see comments below)
Dissociation Constant:	Not determined (see comments below)
Flash Point:	> 80 °C (closed cup)
Flammability Limits:	Upper Explosive Limit (vapour)= 4.7 %

	Lower Explosive Limit = 21.0 %
Autoignition Temperature:	430 °C
Explosive Properties:	Not provided.
Reactivity/Stability:	Heating the notified polymer above 150 ºC may result in trace quantities of formaldehyde being released.

3.1 Comments on Physico-Chemical Properties

Water Solubility:
The notifier assessed the water solubility of the notified polymer by visual assessment. A known amount of the notified polymer was added to water and the resulting solution was shaken at 23º C. This test indicates that the water solubility of the notified polymer is less than 0.1 %. Whilst this is a relatively insensitive limit, it is consistent with notified polymer's chemical structure. In previous notifications, the notifier has indicated that silicones are classed as having low water solubilities as indicated by their high partition coefficients, typically log P equals 4-5. However, the presence of substantial polyethylene glycol chains at both ends of the notified polymer would increase the water solubility.

Hydrolysis as a Function of pH:
Whilst it is noted that the notified polymer contains ester linkages that could undergo hydrolysis, this is unlikely to occur at environmental pH ranges 4–9, although, polydimethylsiloxanes are known to be unstable in landfill.

*Partition Coefficient:*As indicated above, polydimethylsiloxanes typically have log partition coefficients of 4-5 but this would be lower due to the presence of the polyethylene glycol chains.

Adsorption/Desorption:
The notified polymer is expected to be relatively immobile in soil due to its expected high molecular weight and expected low water solubility.
Dissociation Constant:
The notified polymer does not contain any ionisable groups.

4. PURITY OF THE CHEMICAL

Degree of Purity: 43 % (in Dow Corning ® 31 Additive)

Hazardous Impurities:

Chemical name: Methacrylic acid (2-propenoic acid,2-methyl-)

CAS No.:	79-41-4
Weight percentage:	3 %
Toxic properties:	At Concentrations equal to or more than 25%: Corrosive (C) • R34 - Causes burns. At Concentrations equal to or more than 2% and less than 25 %: Harmful (Xi) • R36/38 - Irritating to eyes and skin. Listed in the Exposure Standards for Atmospheric Contaminants in the Occupational Environment (NOHSC 1995a). Listed in the European Union Annex I of the EEC Council Directive 67/548/EEC (as updated by EC Council Directive 96/54/EC8 No Exposure Standard established
Chemical name:	Methylacrylic anhydride (2-propenoic acid, 2-methyl, anhydride)
CAS No.:	760-93-0
Weight percentage:	1 %
Toxic properties:	Poisonous by inhalation (Sax and Lewis 1996) Reported as an extremely hazardous substance in the EPA TSC Inventory. No Exposure Standard established

Non-hazardous Impurities (> 1% by weight):

Chemical name:	Methyacrylolyl ester polyoxyethylene Oxide Monoallyl Ether
Weight percentage:	(not provided by notifier)
CAS No.:	(not assigned)

Adjuvants: Propylene carbonate as a solvent or dispersing medium.

Chemical name:	Propylene carbonate
CAS No.:	108-32-7
Weight percentage:	≤ 50 %
Toxic properties:	At Concentrations equal to or more than 20%: Harmful (Xi) • R36 - Irritating to eyes. Listed in the European Union Annex I of the EEC

Council Directive 67/548/EEC (as updated by EC Council Directive 96/54/EC8)
No Exposure Standard established

5. USE, VOLUME AND FORMULATION

The notified polymer is used as an additive in UV radiation curable inks and varnishes where it promotes slip and levelling over oil based inks. The inks and varnishes containing the notified polymer are used to make packaging material and/or magazines.

The notified polymer will be imported as a 43% component of the product Dow Corning 31 Additive in sealed 20 and 200 litre steel drums. The steel drums will be transported to and stored at the customer's warehouse.

When required the Dow Corning 31 Additive product will be transported to the purchaser, where it is used in the formulation of radiation curable inks and varnishes. The concentration of notified polymer in the radiation curable inks and varnishes is 0.5-5.0 %.

The formulated radiation curable inks and varnishes will be sold to printing and coating companies in 5 or 20 litre pails. Inks/varnishes are applied using a flexographic anilox unit as a 2-micron thick coat to paper, -plastic, or -wood substrate and cured by UV-radiation.

The notifier plans to import 1.72 tonnes of the notified polymer per year for 5 years.

6. OCCUPATIONAL EXPOSURE

Transport and Storage
Following importation of the notified polymer in 20 and/or 200 litre steel drums, transport workers (20-50) will deliver the Dow Corning 31 Additive (or formulated inks and varnishes containing 0.5-5.0 % notified polymer in 5 or 20 litre pails), to the customer's warehouse for storage and transport to radiation curable ink and varnish formulators. Transport workers will also deliver the radiation curable inks and varnishes containing approximately 0.5-5.0 % notified polymer, to printing and coating companies for application on paper, plastic, and wood substrates. Waterside, warehouse and transport and storage workers (20-50) are unlikely to be exposed to the notified polymer unless the packaging is breached. These workers are not expected to be in contact with the pails for more than 2 hr per day for 2 days per year.

Formulation of radiation curable inks and varnishes
Contact with the notified polymer may occur during weighing and drumming off of the Additive containing the notified polymer. That is, during formulation mixing and packaging, approximately 20-50 workers will have the potential for exposure to the notified polymer on a regular basis (maximum duration of exposure of 8 hours/day, 5 days/week).

The notifier has indicated that a local exhaust system operates during the formulation of inks and varnishes and that formulation workers will wear protective equipment including PVC gloves, safety glasses and long sleeved overalls. Beyond this point, the formulation process is facilitated within a closed system.

Laboratory workers may also experience skin contact with the notified polymer during quality assurance testing. Laboratory workers will normally wear coats and safety glasses.

End Use
Approximately 100-200 application workers will have the potential for dermal exposure to inks/varnishes containing the notified polymer on a regular basis (maximum duration of exposure of 8 hours/day; 5 days/week). The potential for exposure to formulated inks containing the notified polymer is greatest during manual dispensing from 20 kg containers into the ink ducts attached to the printing machines. Workers (20-50) involved in manual dispensing of inks, washing rollers and ducts and loading of empty drums into washing machines have the potential for dermal exposure at 3 hours/day; 260 days/year.

Inks/varnishes are applied using a flexographic anilox unit as a 2-micron thick coat to paper, plastic, and wood substrates and cured by UV-radiation. The ink is manually dispensed by the operator from the container into the ink duct attached to the printing machine. The ink is then transferred via an anilox roll to the printing plate cylinder, which in turn transfers the ink image onto the substrate being printed. The printed substrate travels approximately 60 cm where it is exposed to a protected UV light source that cures the ink. Once on the substrate, the notified polymer is embedded in the matrix and therefore unavailable for further exposure.

Although, the printing and curing process occurs within a closed system, PPE (long sleeved overalls, safety glasses and PVC gloves) is worn during manual dispensing of inks, washing rollers and ducts and loading of empty drums into washing machines. Furthermore, quality control technicians (20), wear PPE, lab coats and safety glasses during QC sampling at 1 hour/day; 100 days/year.

7. PUBLIC EXPOSURE

Ink and varnish products, available only to commercial printing operations and containing up to 5% of the notified polymer will be formulated in Australia. The notified polymer will be imported in a product containing 43% of the notified polymer. The potential for public exposure during transport, storage, formulation and use of the notified polymer is expected to be negligible. The public will make contact with the notified polymer in the cured form via contact with printed material, however as the notified polymer is expected to be bound in the ink matrix it will not be bioavailable. Therefore, the potential for public exposure via all routes is expected to be negligible.

8. ENVIRONMENTAL EXPOSURE

8.1 Release
Release of Chemical

During formulation and use of the inks and varnishes it is estimated that up to 50 kg per annum of notified polymer waste will be generated. This will be derived from:

Residues in import containers <	5 kg/annum
Release from formulation of ink	20 kg/annum
Residues in formulation containers	< 5 kg/annum
Release from use of ink	< 20 kg/annum

It is anticipated that spills of the polymer solution and blended ink will be contained within the plant through the bunding systems in place. As the ink will be used in small batch quantities, it is expected that any spills will be relatively small in volume. Spills will be collected using absorbent material and removed by a licensed industrial waste contractor to a licensed waste landfill site.

Presumably, formulation equipment will be cleaned using solvent and licensed hazardous waste contractors will dispose waste from this process by incineration. Ink ducts and Anilox rollers will be periodically washed in washing machines using water and detergent. These liquid wastes will be collected by licensed hazardous waste contractors and treated by precipitation, centrifugation and flocculation. Solids wastes isolated from this process will be dried, encapsulated in concrete and disposed of in landfill while the remain aqueous solution will be released to sewer.

It is expected that import drums containing residual polymer solution will be used to collect liquid waste and unused ink, and when finished with, collected by a licensed hazardous waste contractor. The liquid contents will be disposed of as described above and the drums with any residual solid will be disposed of to a licensed waste landfill site.

The remainder of the notified polymer will be incorporated into ink and applied to paper, plastic and wood substrates.

8.2 Fate

8.2.1 Ready biodegradability

Test Substance	Dow Corning 31 Additive
Method	OECD TG 301 B Ready Biodegradability: CO2 Evolution Test.
Inoculum	Activated sludge
Exposure Period	28 days
Remarks - Method	The notified polymer was incubated for 28 days at a test substance concentration of 10 mg of carbon/L.

Results

Test substance		Sodium benzoate	
Day	% degradation	Day	% degradation
28	**53.1**	**28**	**94.4**

Remarks - Results	The biodegradation of the reference substance was 94.4%

	after 28 days, indicating the test conditions were valid. After 28 days, the test substance underwent 10% biodegradation, which indicates the notified polymer is not readily biodegradable in aerobic environments. The test substance was also found to be non-inhibitory to microorganisms.
Conclusion	The notified polymer in not readily biodegradable.
Test Facility	Wildlife International Pty, Easton, Maryland, USA, 2000a

8.2.2 Bioaccumulation

Data regarding the bioaccumulation potential of the notified polymer were not provided for this notification. The notified polymer's high molecular weight suggests that it is unlikely to cross biological membranes and therefore, bioaccumulate (Connell 1990).

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Summary of the acute toxicity of

Test	***Species***	***Outcome***	Reference
acute oral toxicity	rat	LD_{50} > 2000 mg/kg bw	Dow Corning TR 47959, (1999a)
acute dermal toxicity	rabbit	LD_{50} > 2000 mg/kg bw	Dow Corning TR 47960, (1999b)
skin irritation	rabbit	not irritating	Dow Corning TR 47961, (1999c)
eye irritation	rabbit	slightly to moderately irritating	Dow Corning TR 47962, (1999d)
skin sensitisation	guinea pig	not sensitising	Dow Corning TR 48404a/48404b, (2000)

9.1.1 Oral Toxicity (Dow Corning TR 47959, 1999a)

Species/strain:	rat/Sprague-Dawley [Crl: CD (SD)IGS BR]
Number/sex of animals:	5 per sex
Observation period:	14 days
Method of administration:	oral gavage
Test method:	OECD TG 401

Mortality:	none reported
Results:	
Clinical observations:	One male presented with slight red stains on the snout at 2h post exposure, dry rales at Day 2 and chromodacryorrhea and mal-occluded incisors at Day 14. These observations were not test-substance-related. Mean body weight gain initially decreased in males and females at Day 1 (-9 % and –8 %, respectively) following treatment. In the case of the latter, the body weights of 3 females at Day 1 deviated (approx -8 %) from the protocol specified range of 190-270 g. No other clinical signs were reported.
Morphological findings:	No abnormal morphological findings were reported
Comment:	The following protocol deviations were noted, and not considered to have compromised the study: • Relative humidity range (56-90 %) deviated from the OECD protocol specified range (30-70 %). • Immediate post-dose observations were not performed, only an (in-cage) viability check for mortality. • Body weight of three females at Day 1 deviated from the protocol specified range (190-270 g).
LD_{50}:	> 2000 mg/kg bw
Conclusion:	The notified polymer is of low toxicity via the oral route.

9.1.2 Dermal Toxicity (Dow Corning TR 47960, 1999b)

Species/strain:	rabbit/New Zealand White
Number/sex of animals:	5 per sex
Observation period:	14 days
Method of administration:	Semi-occlusive
Test method:	OECD TG 402
Mortality:	none reported
Clinical observations:	none reported
Macroscopic findings:	A slight red discoloration of the skin at the site of application was noted in two females at post-mortem. Additionally, a red discoloration of the dorsal treatment area

was noted in one of these animals. The latter finding was considered incidental and not test-substance related.

Comment: The following protocol deviations were noted, and not considered to have compromised the study:

- Relative humidity range (58-86 %) occasionally deviated from the OECD protocol specified range (30-70 %).

LD_{50}: > 2000 mg/kg bw

Result: the notified polymer was of low dermal toxicity in rabbits

9.1.4 Skin Irritation (Dow Corning TR 47961, 1999c)

Species/strain: rabbit/New Zealand White

Number/sex of animals: 3 female

Observation period: 1 h, 24 h, 48 h and 72 h post treatment

Method of administration: Semi-occlusive

Test method: OECD TG 404

Results:
Draize scores

Lesion	Mean Primary Dermal Irritation Score* Animal No.			Maximum Value at End of Observation Period
	1	**2**	**3**	
Erythema	**0**	**0**	**0**	**0**
Oedema	**0**	**0**	**0**	**0**

*Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal using the EEC Dermal Evaluation Criteria of each animal for erythema and oedema. Scores are summed and each total divided by 3.

Comment: The present study examined for the incidence of erythema, eschar formation and oedema using a Macroscopic Dermal Grading System based on the Draize Testing System (Draize, 1959).
Moreover, sites were evaluated for erythema and oedema including eschar formation, superficial and subepidermal tissue damage, exfoliation, desquamation and scarring using the OECD Test Guideline scoring system (Draize *et al*., 1944) and an Huntingdon Life Science procedure.

The following protocol deviations were noted, and not

considered to have compromised the study:

- Room temperature range (21-22 ºC) occasionally deviated from the OECD protocol specified range (17-23 ºC).
- Relative humidity range (58-74 %) deviated from the OECD protocol specified range (30-70 %).

Conclusion: The notified polymer is non-irritating to skin of rabbits.

9.1.5 Eye Irritation (Dow Corning TR 47962, 1999d)

Species/strain: rabbit/New Zealand White

Number/sex of animals: 3 females

Observation period: 1, 24, 48 and 72 hr ; Day 7, 10 and 14

Method of administration: ocular

Test method: OECD TG 405

Results:

Draize scores*:

Lesion	Mean Score** Animal No.			Maximum Value	Maximum Duration of Effect***	Maximum Value at End of Observation Period
	1	**2**	**3**			
Conjunctival:						
redness	**2.7**	**2.0**	**2.0**	**3.0**	**10 d**	**0.0**
chemosis	**1.3**	**1.3**	**1.0**	**2.0**	**72 h**	**0.0**
Iridial inflammation	**0.7**	**0.0**	**0.3**	**1.0**	**7 d**	**0.0**
Corneal opacity	**1.0**	**0.7**	**1.0**	**1.0**	**7d**	**0.0**

*All scores shown are for 'treated' eyes. Untreated control eyes (Lt eye of each animal) scored negative fo parameters.
**Calculated on the basis of the scores at, 24, 48, and 72 hours for EACH animal using EEC Criteria grading.
***Assessed over the total observation period.

Comment: The present study examined for the incidence of corneal opacity, iris lesions, conjunctiva erythema and conjunctiva chemosis using a macroscopic ocular grading system based on OECD Test Guidelines (Draize, 1959) and a Huntingdon Life Science procedure. The latter described grading for stain retention, stippling, area of corneal opacity, iridial rugae and conjunctival discharge and ulceration.

All animals exhibited moderate conjunctival irritation (including discharge), specifically chemosis (Draize score=2) and redness (Draize score=3) persisting thru to 72 h and Day-10 post exposure, respectively.

Whilst all three animals exhibited moderate (scattered/diffuse) corneal opacity during the first 48 h following treatment (Draize score=1), the opacities disappeared at the 10-day observation period. Details of the iris remained clearly visible at all times.

Iritis or slight iridial change were noted in 2 out of 3 animals (Draize score=1), persisting to Day-7 post exposure. All animals were free of ocular irritation within 14 days, denoting reversibility of irritative effects.

One animal also exhibited pannus (neurovascularization of the corneal surface) at Day-7 and 10, post exposure.

The following protocol deviations were noted, and not considered to have compromised the study:

- Relative humidity range (64-84%) deviated from the OECD protocol specified range (30-70 %).

Conclusion: Taken together, the data suggest that the notified polymer is slightly to moderately irritating to the eye.

9.1.6 Skin Sensitisation- Buehler Method (Dow Corning TC 48403 (2000a) and Dow Corning TR 48404 (2000b) [Study Retest]

(Note: Details presented herewith are common to both studies (unless stated otherwise) excepting that a rechallenge phase was omitted in the retest study).

Species/strain: Guinea pig/ Dunkin Hartley

Number of animals: Test (sensitisation) group: 20 (10 per sex)
Positive control group: 10 (5 per sex)
Irritation control group: 10 (5 per sex)
Re-Challenge Irritation control group (**TC 48403 only)** (5 per sex)

Results

Induction phase No dermal responses were detected during the observation study period in any test group animal following a 6 h exposure to 100 % of the notified polymer in either study

Positive Control One control animal of each sex treated with 100 % v/v hexylcinnamic aldehyde (HCA) in propylene glycol, presented with slight (well-defined) erythema. However, in the retest study, (TR 48404), two out of five male and 1/5 female controls, presented with moderate erythema progressing to severe by the end of the study.

Challenge phase No dermal or irritative responses were detected in either the

challenge or irritation control animals following 6 h exposure to 100 % notified polymer for either study. Accordingly, the Severity of Indices in the Test group and irritation control animals at 24 h and 48 h observation time points was 0 % (0.1 % in original study TC 48403) and 0 %, respectively. Accordingly, the Incidence Index of Sensitisation to the notified polymer was determined as 0 % for both studies.

Positive Control

In study TC 48403, irritation scores for irritation control animals treated with 100 % notified polymer and HCA (at 50 and 100 %) were either comparable or greater than responses for HCA positive control groups (HCA alone). Accordingly, a positive control re-challenge was performed using 25 % HCA treated naïve animals as irritation controls. However, only 1/10 HCA positive control animal exhibited moderate erythema (compared to 0/10 irritation control animals). Accordingly, study TC 48403 was considered invalid for the purposes of determining the skin sensitisation potential of the notified polymer.

In the retest study (TR 48404), 3 out of 10 positive control animals (HCA at 100 % and 25 %) exhibited moderate erythema at 24 h post exposure. The Incidence Index of Sensitisation score for these animals was 30 %, validating the positive control test procedure and providing confidence in the test article results. Additionally, HCA irritation control (25 % and 100 %) treated animals showed no positive dermal response.

	Test animals		***Positive control animals******	
Challenge Concentration (% v/v)	***24 hours****	***48 hours****	***24 hours***	***48 hours***
25	-	-	3/10**	0/10**
100	0/20**	0/20**	3/10**	0/10**

* time after patch removal
** number of animals exhibiting positive response
***25 % HCA in propylene glycol; 100 % HCA administered as received

Comment:

- Topical application of 100 % notified polymer (undiluted) at induction and for 6 h. was repeated once per week, for three weeks. Dermal evaluations were conducted at 24 and 48 h following each

treatment period and dermal response scored according to the method by Bueher and Ritz (1980).
- In retest study (TR 48404), the (100 %) HCA irritation control animals were reduced in numbers to 9/10, as one animal was excluded due to a clipping injury.

The following protocol deviations were noted, and not considered to have compromised the study
- Room temperature range (20-24 ºC) occasionally deviated from the OECD protocol specified range (18-23 ºC).
- Relative humidity range (26-28 %) deviated from the OECD protocol specified range (30-70 %).

Conclusion: There was no evidence of reactions indicative of skin sensitisation to the notified polymer under the conditions of the test.

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* Reverse Mutation Assay (Dow Corning TR 48855, 2000c)

Strains: *S. typhimurium*:
TA1535, TA1537, TA100, TA98.
E. coli: WP2 uvrA (pKM101) and WP2 (pKM101)

Metabolic activation: 10 % rat liver (SD) S9 fraction from animals pre-treated with 500 mg/kg bw Aroclor 1254

Concentration range: with and without metabolic activation: 100, 333, 1000, 3333 and 5000 µg/plate[1].

Vehicle: Dimethyl sulfoxide (DMSO)

Test method: OECD TG 471 and OECD TG 472 Bacterial Reverse Mutation Test.

Results: No significant dose dependent increases in the numbers of revertants (mutant frequency) were recorded for any strain, either in the presence or absence of metabolic activation, indicating nonmutagenicity potential of the notified polymer. A normal background lawn (evaluation code 1) and a lack of decreased revertant numbers indicated no observable cytotoxicity in either the absence or presence of metabolic activation (S9 mix)

Positive control values in the absence or presence of metabolic activation (S9 mix) were increased at least 5-fold

(TA 100) over the mean values of their vehicle controls, demonstrating positive mutagen identification and promutagen metabolism by the tester strains and S9 mix, respectively.
No protocol deviations were reportedExperiments were performed in triplicate.

[1]doses tested in the mutagenicity assay were selected on the basis of a dose range-finding assay using strains TA100 and WP2*uvr*A in the presence and absence of metabolic activation. Doses tested were: 6.67, 10.0, 33, 67, 100, 333, 667, 1000, 3333 and 5000 ug/plate No toxicity was observed in the dose range-finding assay and therefore the highest dose (5000 ug/plate) of the notified polymer tested was also used in the mutagenicity assay.
[2]various vehicle solutions (purified water, dimethyl sulfoxide, ethanol and acetone) were tested for homogeneity with the notified polymer to achieve a target stock concentration up to 500 mg/mL

Conclusion: The notified polymer was not mutagenic to bacteria under the conditions of the test.

9.4 Overall Assessment of Toxicological Data

The notified polymer was of low acute oral toxicity in rats and low acute dermal toxicity in rabbits. Furthermore, the notified polymer was slightly to moderately irritating to the eye but not irritating to the skin in rabbits. The notified polymer was not considered to be a skin sensitiser in guinea pigs using the Buehler method.

The notified polymer was not considered to be mutagenic in bacteria.

Based on the data provided, the notified polymer would not be classified as hazardous according to the National Occupational Health and Safety Commission *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999).

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

10.1 Inhibition of microbial activity

Test Substance	Dow Corning 31 Additive
Method	OECD TG 209 Activated Sludge, Respiration Inhibition Test.
Inoculum	Activated sludge
Exposure Period	3 hours
Concentration Range Nominal	1-1000 mg/L
Results	
EC50	> 1000 mg/L
Remarks – Results	The effect on activated sludge microorganisms was assessed at test substance concentrations of 1, 3, 10, 30, 100, 300 and 1000 mg/L. The EC50 of the reference substance, 3,5-

	dichlorophenol was 11.9 mg/L after 3 h, indicating the test conditions were valid. The mean respiration rate for the control was 39.95 mg/O_2/L/h. The test substance at 1, 3, 10, 30, 100, 300 and 1000 mg/L exhibited respiration rates of 50.1, 45.3, 56.6, 85.5, 84.0, 41.4 and 53.1 mg/O_2/L/h, respectively.
Conclusion	The notified polymer is non-inhibitory to sludge microorganisms.
Test Facility	Wildlife International Pty, Easton, Maryland, USA, 2000b

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The majority of the notified polymer will be incorporated in printed material. Prior to leaving the printers, the printed material is irradiated with UV light, which promotes a free radical polymerisation process to form a high molecular weight, cross-linked compound. Therefore, once incorporated into the printed material, the notified polymer is consumed and poses little risk to the environment.

Licensed hazardous waste contractors will dispose the wastes derived from the cleaning of formulation equipment by incineration, which is expected to produce water vapour and oxides of carbon and silicon. Ink ducts and Anilox rollers will be periodically washed in washing machines using water and detergent. These liquid wastes will be collected by licensed hazardous waste contractors and treated by precipitation, centrifugation and flocculation. Solids wastes isolated from this process will be dried, encapsulated in concrete and disposed of in landfill while the remain aqueous solution will be released to sewer.

In landfill, any notified polymer will associate with the soil matrix and not leach into the aquatic environment. Polydimethylsiloxanes are unstable in landfill and on dry sediments (Hamelink, 1992; Lehmann *et al*, 1994a and 1994b) because under dry conditions, clay minerals catalyse their hydrolytic decomposition to smaller molecules, some of which may be volatile and enter the atmosphere. However, when released to the atmosphere, low molecular weight organosilanes are apparently rapidly degraded through photolysis (Hamelink 1992). Therefore in landfill, the notified polymer would eventually degrade through abiotic and biotic process and therefore poses little risk to the environment.

On the basis of the available information, the overall environmental hazard of the notified polymer is expected to be low.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Hazard assessment

Limited toxicity studies on the notified polymer were provided. However, based on the available data, the notified polymer in Dow Corning 31 Additive is expected to be of low acute dermal toxicity, slightly to moderately irritating to the eye but not irritating to the skin, and not considered to be a skin sensitiser. It is not mutagenic to bacteria (with and without S9 metabolic activation).

Based on the available experimental results and relevant toxicological data, the notified polymer in Dow Corning 31 Additive is not considered to be as a hazardous substance according to the NOHSC *Approved Criteria for Classifying Hazardous Substances (*NOHSC, 1999).

Occupational Health and Safety
Limited toxicity studies on the notified polymer were provided. However, based on the available data, the notified polymer in Dow Corning 31 Additive is expected to be of low acute dermal toxicity, slightly to moderately irritating to the eye but not irritating to the skin, and not considered to be a skin sensitiser. It is not mutagenic to bacteria (with and without S9 metabolic activation).

Based on the available experimental results and relevant toxicological data, the notified polymer in Dow Corning 31 Additive is not considered to be as a hazardous substance according to the NOHSC *Approved Criteria for Classifying Hazardous Substances.*

Occupational Health and Safety
The notified polymer in Dow Corning 31 Additive will be imported as a commercial free-flowing liquid. It will be formulated with other ingredients to produce UV radiation curable inks and varnishes suitable for application on paper, plastic, and wood substrates. During processing into finished articles, the notified polymer is bound within a polymer matrix.

There is a limited potential for dermal and eye exposure when handling the notified polymer. Exposure by these routes is greatest during formulation of inks and varnishes and the application of inks/varnishes to substrates. Accordingly, operators opening drums, weighing and manually dispensing the notified polymer from 20 kg containers into ink ducts attached to the printing machines may experience dermal exposure.

Exposure is reduced by local exhaust system engineering controls during the formulation of inks and varnishes and use of protective equipment including PVC gloves, safety glasses and long sleeved overalls. Beyond this point, the application process is conducted within a closed system. Considering the low inherent toxicity of the notified polymer, engineering controls and use of PPE, the risk of adverse health effects for these workers is low.

There is minimal risk of exposure to end-users to substrates and articles containing the notified polymer. Once bound to the substrate however, the notified polymer is not bioavailable.

Under normal working conditions, storage and transport workers will handle sealed packages of products containing the notified polymer. Notwithstanding accidental spillage, there are negligible occupational health risks for these workers.

Public health
The notified polymer will be imported in a product containing 43% of the notified polymer. Ink and varnish products formulated in Australia containing up to 5% of the notified polymer will only be available to commercial printing operations. The potential for public exposure during transport, storage, formulation and use of the notified polymer is expected to be negligible. Whilst the public will make contact with the notified polymer in the cured form

via contact with printed material, the notified polymer is expected to be bound in the ink matrix and therefore will not be bioavailable. Therefore, the potential for public exposure via all routes is expected to be negligible.

There is not expected to be any significant risk to the public associated with the use of the substance in inks and varnishes by commercial printers.

13. RECOMMENDATIONS

Control Measures
Occupational Health and Safety

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer.
  - overalls, safety glasses and PVC or rubber gloves.

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

- A copy of the MSDS should be easily accessible to employees.

- Spills/release of the notified polymer should be contained as described in the MSDS (i.e. Contain with absorbent material and transfer to a sealable waste container) and the resulting waste disposed of in landfill.

- Good personal hygiene should be practised to minimise the potential for ingestion;

- A copy of the MSDS should be easily accessible to employees.

If products containing the notified polymer are hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (ref), workplace practices and control procedures consistent with State and Territory hazardous substances regulations must be in operation.

14. SECONDARY NOTIFICATION

The Director of Chemicals Notification and Assessment must be notified in writing within 28 days by the notifier, other importer or manufacturer:

(1) Under Section 64(2) of the Act:
  - if any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.

No additional secondary notification conditions are stipulated.

15. MATERIAL SAFETY DATA SHEET

The MSDS for the notified polymer was provided in a format consistent with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994).

This MSDS was provided by the applicant as part of the notification statement. It is reproduced here as a matter of public record. The accuracy of this information remains the responsibility of the applicant.

16. REFERENCES

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Wildlife International Pty (2000b) Project number 406E-115: Activated Sludge Respiration Test of Dow Corning 31 Additive; (unpublished report submitted by Dow Corning).

Attachment 1

The Draize Scale (Draize, 1959) for evaluation of skin reactions is as follows:

Erythema Formation	*Rating*	*Oedema Formation*	*Rating*
No erythema	0	No oedema	0
Very slight erythema (barely perceptible)	1	Very slight oedema (barely perceptible)	1
Well-defined erythema	2	Slight oedema (edges of area well-defined by definite raising	2
Moderate to severe erythema	3	Moderate oedema (raised approx. 1 mm)	3
Severe erythema (beet redness)	4	Severe oedema (raised more than 1 mm and extending beyond area of exposure)	4

The Draize scale (Draize *et al*., 1944) for evaluation of eye reactions is as follows:

CORNEA

Opacity	*Rating*	*Area of Cornea involved*	*Rating*
No opacity	0 none	25% or less (not zero)	1
Diffuse area, details of iris clearly visible	1 slight	25% to 50%	2
Easily visible translucent areas, details of iris slightly obscure	2 mild	50% to 75%	3
Opalescent areas, no details of iris visible, size of pupil barely discernible	3 moderate	Greater than 75%	4
Opaque, iris invisible	4 severe		

CONJUNCTIVAE

Redness	*Rating*	*Chemosis*	*Rating*	*Discharge*	*Rating*
Vessels normal	0 none	No swelling	0 none	No discharge	0 none
Vessels definitely injected above normal	1 slight	Any swelling above normal	1 slight	Any amount different from normal	1 slight
More diffuse, deeper crimson red with individual vessels not easily discernible	2 mod.	Obvious swelling with partial eversion of lids	2 mild	Discharge with moistening of lids and adjacent hairs	2 mod.
Diffuse beefy red	3 severe	Swelling with lids half-closed	3 mod.	Discharge with moistening of lids and hairs and considerable area around eye	3 severe
		Swelling with lids half-closed to completely closed	4 severe		

IRIS

Values	*Rating*
Normal	0 none
Folds above normal, congestion, swelling, circumcorneal injection, iris reacts to light	1 slight
No reaction to light, haemorrhage, gross destruction	2 severe

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