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**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION
AND ASSESSMENT SCHEME**

FULL PUBLIC REPORT

Phenolic Resin R22910

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Street Address: 92 -94 Parramatta Rd CAMPERDOWN NSW 2050, AUSTRALIA
Postal Address: GPO Box 58, SYDNEY NSW 2001, AUSTRALIA
Telephone: (61) (02) 9577 9514 FAX (61) (02) 9577 9465

Director
Chemicals Notification and Assessment

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FULL PUBLIC REPORT**Phenolic Resin R22910****1. APPLICANT**

3M Australia Pty Ltd of 2-74 Dunheved Circuit, St Marys NSW 1760 (ABN 90 000 100 096) has submitted a standard notification statement in support of their application for an assessment certificate for **Phenolic Resin R22910**.

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.

Marketing Name: R22910 (73% notified polymer)
Moleculok (73% notified polymer)
Diblend R22740 (19% notified polymer)
Scotchkote (0.66% notified polymer)

3. PHYSICAL AND CHEMICAL PROPERTIES

Where indicated, the following physicochemical properties are for the imported solid Diblend product. Other properties are for the 73% aqueous polymer solution.

Appearance at 20°C & 101.3 kPa: Dark brown viscous liquid

Melting Point: 65.6°C (Diblend)

Specific Gravity: 1.2

Vapour Pressure: 2.4 kPa at 25°C

Water Solubility: 2838 mg/L, QSAR estimate. See comments below.

Partition Co-efficient (n-octanol/water): log K_{ow} = 1.95 (measured). See comments below.
log K_{ow} = 2.87, QSAR estimate. See comments below.

Hydrolysis as a Function of pH: No hydrolysable functional groups are present. See comments below.

Adsorption/Desorption:	$K_{oc} = 863$, QSAR estimate. See comments below.
Dissociation Constant:	$pK_a = 8-10$ See comments below.
Flash Point:	Not applicable
Particle Size:	$>1.7\text{mm}$ 69.9% $1.7\text{mm} - 1.18\text{mm}$ 11.9% $1.18\text{mm} - 850\mu\text{m}$ 6.5% $850 - 630\mu\text{m}$ 3.6% $630 - 10\mu\text{m}$ 8.2% $<10\mu\text{m}$ 0.07% (Diblend)
Flammability Limits:	Not applicable
Autoignition Temperature:	Thermal decomposition occurs at $>200^\circ\text{C}$.
Explosive Properties:	Not explosive
Reactivity/Stability:	Stable

3.1 Comments on Physico-Chemical Properties

The water solubility was estimated using a software-based QSAR (Quantitative Structure Activity Relationships) method (ECOSAR) based on the measured value for $\text{Log } K_{ow}$ of 1.95 (see below), but the equation used was not indicated. Lyman et al (1996) give a number of QSARs for estimation of water solubility from $\text{Log } K_{ow}$ values, and using the measured value for $\text{Log } K_{ow}$ of 1.95 together with the molecular weight of 610 g/mol, equation 2.14 of Lyman estimates the water solubility as 18.5 g/L. Both these QSAR estimates appear to be seriously in contradiction with the fact that the polymer is capable of being supplied as a 73% aqueous solution, although the estimate based on the equation of Lyman is obviously the better of the two.

The polymer contains no functional groups that are likely to be susceptible to hydrolytic degradation in the environmental pH region between 4 and 9.

The notifier provided a summary report on the determination of the n-octanol/water partition coefficient using the shake flask method of OECD TG 107. In this method a solution of Moleculok in n-octanol was stirred with different volumes of water for five minutes and after phase separation the concentration of the polymer was determined in each phase using UV detection. The partition coefficient was found to be between 77.87 and 97.35 (mean 90.57). The mean value for $\text{Log } K_{ow}$ was determined as 1.95. Neither the temperature nor the pH of the aqueous phases were indicated in the summary report.

The estimated value for $\text{Log } K_{ow}$ was calculated using the ECOSAR program on the basis of molecular fragmentation of the tetramer assuming none of the phenolic hydroxy groups is ionised. This is probably the reason that the measured $\text{Log } K_{ow}$ is an order of magnitude lower than the QSAR estimate.

The QSAR estimated value for K_{oc} (again derived from an equation employing the estimated value for $\text{Log } K_{ow}$) indicates that the polymer would have some affinity for the organic component of soils and sediments and should have limited mobility in these media. This is in contradiction with the high water solubility which suggests that the polymer would have little affinity for organic material. However, if released to natural waters it is probable that phenolic-associated groups would form insoluble salts with metal ions such as Ca^{2+} and Fe^{3+} and in this form would become assimilated into sediments or become associated with the surfaces of clay minerals. In these situations, mobility will be limited.

4. PURITY OF THE CHEMICAL

Degree of Purity:	97%
Hazardous Impurities:	Residual monomer (3%)
Non-hazardous Impurities (> 1% by weight):	None
Additives/Adjuvants:	None

5. USE, VOLUME AND FORMULATION

The notified polymer will be used as a component of anti-corrosion coatings for underground metal pipes. The polymer will be imported in a product (Diblend) at 19% as solid flakes in 205L plastic-lined metal drums. Diblend will be formulated into a powdercoating (Scotchkote) containing 0.66% of the notified polymer.

Sixty-six tonnes of the notified polymer will be imported annually for the first 5 years.

6. OCCUPATIONAL EXPOSURE

Transport and Storage

The notified polymer will be imported as a Diblend product in the form of solid flakes in lined, 205L steel drums and transported to a single reformulation site. After reformulation into a Scotchkote powdercoating, the coating will be transported to customers in similar 205L steel drums. Because drums will remain unopened prior to and after reformulation, exposure to the notified polymer for the 4 workers involved in waterside handling and transport will only occur in the event of accidental puncture of containers of Diblend and Scotchkote.

Formulation of Powdercoating

Import containers of Diblend will be opened manually and the Diblend flakes poured into a enclosed dry blending vessel via a hopper. After heating and mixing with other powdercoating components, the molten coating mix is transferred via gravity feed to an enclosed conveyor belt and then to chilled rollers. Cooled, flattened mix is then ground, sieved and transferred via enclosed conveyor to a filling machine where the mix is repacked

for transport to powdercoating customers.

Six manufacturing operators and 3 laboratory staff have potential exposure to the notified polymer during powdercoating manufacture and quality control. Dermal and ocular exposure may occur during opening of import drums. Inhalation exposure is also possible, but given good general ventilation and the physical form of the Diblend (flakes) with a low proportion of inhalable particles ($0.07\% > 10\mu\text{m}$), is less likely. To control exposure, workers will wear coveralls and gloves. Overall, inhalation exposure to vapours and dusts will be limited via engineering controls consisting of exhaust ventilation fitted to the hopper, blending vessel, grinder and filling machine and the enclosure of conveyor belts. The manufacturing processes are automated and apart from opening of import drums, no manual handling is required normally by manufacturing staff.

Sampling of formulated powdercoat mix will be conducted by laboratory staff and there is potential for exposure at this point. This is unlikely to be conducted under exhaust ventilation but good general ventilation, the physical form of the mix (flakes), the low percentage of notified polymer present (0.66%) and the short period of sampling makes inhalation exposure unlikely. Inhalation exposure in the laboratory will be controlled further by fume hoods fitted with exhaust ventilation. To control dermal and ocular exposure to the notified polymer, laboratory staff will wear laboratory coats, safety glasses and gloves.

Powdercoat Application

Twenty coating application workers will be responsible for spraying the Scotchkote powdercoat electrostatically onto heated pipes. This operation will occur during two 8 hour daily shifts for up to 200 days per year. Workers will open drums of Scotchkote manually and transfer the contents to a hopper connected to an enclosed spray booth. The cleaning and furnace heating of pipes and application and curing of powdercoat within an enclosed exhaust ventilated spray booth will be conducted automatically.

Inhalation, dermal and ocular exposure to the notified polymer may occur during the opening and transfer of Scotchkote to the spray hopper. Good general ventilation and personal protective equipment consisting of disposable overalls, gloves, chemical goggles or face shield will limit exposure.

Although the coating process is automated, exposure, mainly dermal, may occur during cleaning of spray equipment and routine maintenance of plant. If workers are required to enter the spray booth for maintenance, inhalation exposure may occur also. If exhaust ventilation on the spray booth is not operating during maintenance, exposure must be controlled by a negative pressure organic vapour and particle respirator or a supplied air respirator.

When the powdercoat is cured, the notified polymer is expected to be immobilised and therefore exposure of workers to the polymer during the handling of coated pipes is unlikely.

7. PUBLIC EXPOSURE

The notified polymer will not be sold to the public and will be used as an industrial coating only. Consequently, public exposure is likely to be negligible, except in the event of an accidental spill during transport.

8. ENVIRONMENTAL EXPOSURE

8.1 Release

The notifier indicated that around 0.2% of the imported diblend may be left in the drums after emptying, which is equivalent to an annual residual of around 700 kg of the diblend and 132 kg of the notified polymer. This material will be placed into landfill with the empty drums. A further 0.5% of diblend (annually around 1.75 tonnes) may also be lost during manufacture of the final Scotchkote blend from spills and other minor accidents, and this could result in release of a further 330 kg of the notified polymer. This material would also be placed into landfill, so that overall formulation activities may release a maximum of 500 kg of the polymer into landfill each year. The notifier also indicated that significantly smaller quantities of the polymer may also be discharged into the air and into the domestic sewer system, and these were estimated as being around 1 kg per annum and 0.5 kg per annum respectively.

Further release of the polymer is anticipated during application of the coating to the pipes. It was estimated that another 132 kg of the notified polymer may remain as residuals in the emptied drums of Scotchkote, and this would be placed into land fill. However, spray application of coatings invariably entails losses through overspray, and while much of this is recovered and re-used, the notifier stated that up to 10% of the coating material could be lost. This amounts to approximately 1000 tonnes per annum of unused Scotchkote containing approximately 6.6 tonnes of the new polymer which would be collected from the floor of the oven and placed into landfill.

Most of the new polymer will become incorporated into a crosslinked protective (anti-corrosive) polymeric coating for large steel pipes which will be buried in the ground or possibly laid across the sea floor. Since the coating containing the polymer has been formulated as a protection for the steel in this environment, it is expected that it would resist either physical or biological degradation, and release of the free polymer is considered very unlikely.

Overall releases of the new polymer from formulation and application activities are estimated as around 7.3 tonnes per annum (around 11% of total imports), almost all of which will be placed into landfill. Little is expected to be released during the lifetime of the coated pipes in the ground.

It was indicated that the notified polymer contains some residual monomer, and it is likely that this would be to the atmosphere as vapour during the curing process. A maximum of one tonne per annum may be released in this manner.

8.2 Fate

The solid waste generated in the manufacturing, formulation and application of the coating will be disposed to landfill. Due to its high water solubility, leaching of the uncured polymer from landfill is considered likely and the polymer mobile. However, the phenolic hydroxy

groups are likely to have affinity for metal ions in landfill leachate and so the polymer may form insoluble metal salts which would probably become assimilated into organic sediments or loosely bound to the surface of clay particles in the landfill which would decrease potential mobility. Although no biodegradation data specific to the polymer was provided, one of the monomers and its analogue are recognised as being at least slowly degraded through microbiological action (Verschueren, 1996), and the notifier also presented data obtained from the Hedset Database indicating that the monomer is 98% degraded after 21 days in the presence of sewage sludge, and that in a second test 80% of the BOD had been degraded in 14 days. Similar degradation behaviour is likely to be true for oligomers based on these monomers, and consequently the notified polymer is expected to be at least slowly degraded through biological and abiotic processes operative in the landfill and very little is likely to leach into the wider water compartment.

Due to the high water solubility the polymer is not expected to cross biological membranes and therefore should not bioaccumulate (Connell, 1989).

At the end of their lives, pipes coated with the formulation containing the polymer would most likely be removed for recovery of their steel content. During smelting of the scrap steel the polymer would be incinerated with production of water vapour and oxides of carbon.

9. EVALUATION OF TOXICOLOGICAL DATA

No toxicity data were submitted for the notified polymer other than a *Salmonella typhimurium* reverse mutation assay and a mouse micronucleus test. As the notified polymer is a phenolic resin, a related phenolic 1,2-benzenediol (catechol) was used as an analogue for other toxicity endpoints. For the analogue, all toxicological data were obtained from Cosmetic Ingredient Review (1986).

9.1 Acute Toxicity

Summary of the acute toxicity of 1,2-benzenediol.

<i>Test</i>	<i>Species</i>	<i>Outcome</i>	<i>Reference</i>
acute oral toxicity	several species	LD ₅₀ 100-300mg/kg	See 9.1.1 below
acute dermal toxicity	rabbit	LD ₅₀ 800mg/kg	Flickinger (1976)
acute inhalation toxicity	rat	LC ₅₀ >1mg/L	Flickinger (1976)
skin irritation	rabbit	Moderate irritant	Flickinger (1976)
eye irritation	rabbit	Severe irritant	Flickinger (1976)
skin sensitisation	guinea pig	Sensitising	Baer et al (1967)

9.1.1 Oral Toxicity (Cosmetic Ingredient Review, 1986)

The oral toxicity of the analogue is summarised below.

Species	LD ₅₀ (mg/kg)	Reference
Rabbit	200	Clayton and Clayton (1981)
Dog	300	Raff and Ettling (1966); Clayton and Clayton (1981)
Cat	100	Clayton and Clayton (1981)
Pig	200	Clayton and Clayton (1981)
Rat	260 - 300	Lehman et al (1951); Flickinger (1976)
Mouse	300	Lehman et al (1951)
Guinea pig	200	Lehman et al (1951)

Result: The analogue was of moderate acute oral toxicity in rats and other species.

9.1.2 Dermal Toxicity (Flickinger, 1976 in Cosmetic Ingredient Review, 1986)

Catechol was applied at doses of 0.25, 0.5, 1.0 and 2.0g/kg to the intact and abraded skin of 16 rabbits (4 per dose) for 24 hours. The rabbits were observed for 14 days. Deaths occurred in the 3 highest dose groups (1/4, 2/4 and 4/4). An acute dermal LD₅₀ of 800mg/kg was established.

Dead animals displayed subdermal hyperaemia and oedema. In surviving animals, Catechol induced moderate erythema and slight oedema with necrosis at application sites and persistent epidermal flaking.

Result: The analogue was of moderate dermal toxicity in rabbits.

9.1.3 Inhalation Toxicity (Flickinger, 1976 in Cosmetic Ingredient Review, 1986)

Groups of 6 female Harlan-Wistar albino rats were exposed to 1.5, 2.0 and 2.8g/m³ catechol-water aerosols (13.0, 14.5 and 17.0% catechol respectively) for 8 hours and then observed for 14 days. No deaths occurred, weight gains were normal and no treatment-related lesions were observed at necroscopy.

At the end of the observation period, all rats in the highest dose group and 2/6 in the mid-dose group showed blackened and missing toes and tail tips. Also at these two highest doses, tremors were observed within 6-7 hours of exposure and continued for 24 hours after cessation of exposure.

The highest dose corresponds to a catechol load of 476mg/m³ over 8 hours or approximately 1000mg/m³ over 4 hours. Therefore, a 4-hour acute inhalation LC₅₀ of >1mg/L was established for catechol.

Result: The analogue was at most of moderate acute inhalational toxicity in rats.

9.1.4 Skin Irritation (Flickinger, 1976 in Cosmetic Ingredient Review, 1986)

Catechol at 500mg/kg was applied to the intact and abraded skin of male albino rabbits for 24 hours. Catechol induced slight to moderate erythema and slight oedema of intact areas and corrosion of abraded areas. A primary irritation index of 5.5 out of a maximum of 8 was scored. Irritation was decreased at 72 hours compared to 24 hours. After 14 days, intact areas were free of irritation except for slight epidermal flaking. Necrotic areas showed sloughing.

Result: The analogue was moderately irritating to the skin of rabbits.

9.1.5 Eye Irritation (Flickinger, 1976 in Cosmetic Ingredient Review, 1986)

Catechol (0.1g) was tested for eye irritation in 6 male albino rabbits. After application, moderate erythema and oedema, exudate and corneal opacity were observed. Animal discomfort was also reported. At 24 hours, severe erythema, oedema, discharge, iritis and dense corneal opacities were observed. At day 14, keratoconus and pannus formation was observed.

Draize scores were 103 at 24 hours and 78 at 72 hours out of a maximum of 110.

Result: The analogue was severely irritating to the eyes of rabbits.

9.1.6 Skin Sensitisation (Baer et al, 1967 in Cosmetic Ingredient Review, 1986)

Guinea pigs (8-12 animals) received single weekly induction injections of catechol in Freund's complete adjuvant (FCA) for 3 weeks into the nuchal area, inguinal-axillary region and footpads successively. The total dose per animal was 1 mg. Animals were then challenged topically 4 weeks later with 5µL of catechol/acetone solutions. The maximal amount of catechol applied was 1µmol (610µg).

No sensitisation was observed with challenges < 0.2µmol. At higher doses, most animals were sensitised. Sensitised animals were also reactive to 3-methyl and 3-propyl catechol.

Result: The analogue was sensitising to the skin of guinea pigs.

9.2 Repeated Dose Toxicity (Gisvold, 1977 and Nakamura, 1981 in Cosmetic Ingredient Review, 1986)

In a 2 year feeding study in rats, catechol was administered to groups of 12-18 animals at concentrations of 0.0625 - 1.0% (31.25 - 500mg/kg/day). Mortality rates were similar to controls. At a dose of 0.25% (125mg/kg/day), hepatic cell hyperplasia was observed. The NOAEL was not stated. However, the LOAEL can be taken as 125mg/kg/day.

In a 20 week drinking water study in mice, catechol was administered at concentrations of 0.1 – 4.0 g/L (20-800 mg/kg/day). No adverse effects were observed at 0.1g/L. Animals given 4.0g/L showed a 55% increase in body weight and increases in some organ weights. A NOAEL of 0.1g/L was assigned.

9.3 Carcinogenesis and Tumour Promotion (Cosmetic Ingredient Review, 1986)

Catechol was tested for carcinogenicity by bladder implantation. Cholesterol pellets (10mg) containing 20% catechol were implanted into the bladders of mice. Nineteen survived to 25 weeks. A tumour incidence of 20% was recorded with one mouse developing papilloma and three developing carcinomas. Cholesterol alone was also similarly implanted. Seventy-seven mice survived to 25 weeks. A tumour incidence of 12% was recorded with four mice developing adenomas or papillomas and five developing carcinomas of the bladder. On the basis of these results, catechol was not considered carcinogenic in mice (Boyland et al, 1964 in Cosmetic Ingredient Review, 1986).

Thirty Swiss mice were each given a topical 75µg dose of 7,12-dimethylbenz(a)anthracene in acetone as initiator. After 10 days and at five times per week for 67 weeks, a 1% catechol solution in acetone was applied topically as promotor. No tumour-promoting activity for catechol was observed (Hecht et al, 1975 in Cosmetic Ingredient Review, 1986).

Fifty female Swiss mice were treated topically on the back with 150µg benzo(a)pyrene (BaP) as initiator and 14 days later with a total of 2mg catechol in acetone (0.1mL). Mice received catechol 3 times per week for 448 days. Fifty mice were treated with acetone alone, 100 remained untreated and 2 groups of mice were treated with BaP and with phorbol myristate acetate (PMA) and anthralin as positive controls. In these experiments, catechol was considered inactive as a tumour promotor (Van Duuren and Goldschmidt, 1976 in Cosmetic Ingredient Review, 1986).

In contrast to an absence of tumour-promoting activity, catechol possesses cocarcinogenic activity. Fifty female Swiss mice received topical applications of 2mg catechol with 5µg BaP in 0.1mL acetone 3 times per week for 52 weeks. Twenty-six mice survived to 52 weeks. In these, eighty-six skin papillomas were found in 35 mice with 31 showing squamous cell carcinomas. Of 50 mice receiving BaP alone, 14 papillomas and 10 squamous cell carcinomas of the skin occurred in 13 mice. No skin tumours were observed in untreated or acetone-treated mice. Catechol displayed cocarcinogenic activity by enhancing the carcinogenicity of BaP (Van Duuren, Katz and Goldschmidt, 1973 in Cosmetic Ingredient Review, 1986).

In earlier experiments, catechol was also shown to hinder tumour growth. Mice received Sarcoma-180 cells subcutaneously. Twenty-four hours later and on every second day for 7 treatments the mice were injected similarly with 0.2ml of a 5mg/mL solution of catechol. Tumour growth was inhibited (Yamafuji and Murakami, 1968 in Cosmetic Ingredient Review, 1986).

9.4 Genotoxicity

Limited genotoxicity data were provided for the notified polymer.

9.4.1 *Salmonella typhimurium* Reverse Mutation Assay (Shen, 2000)

<i>Strains:</i>	Salmonella typhimurium TA 98, 100, 102, 1535 and 1537
<i>Metabolic activation:</i>	10% Aroclor-induced rat liver homogenate, S9 fraction
<i>Concentration range:</i>	1, 10, 100, 500 and 1000µg/plate
<i>Test method:</i>	OECD TG 471
<i>Comment:</i>	Precipitation and cytotoxicity was observed at a range-finding concentration of 5000µg/plate. Positive and negative controls behaved appropriately.
<i>Result:</i>	The notified polymer was non mutagenic under the conditions of the test.

9.4.2 Micronucleus Assay in the Bone Marrow Cells of the Mouse (Shen, 2000)

<i>Species/strain:</i>	Mouse, Arc(S)
<i>Number and sex of animals:</i>	2 groups of 5 females per dose
<i>Doses:</i>	Preliminary study: 100, 200 and 500mg/kg; main study 50, 100 and 200mg/kg
<i>Method of administration:</i>	Intraperitoneal injection of test substance in 0.9% NaCl
<i>Test method:</i>	OECD TG 474
<i>Comment:</i>	<p>All animals in preliminary studies showed piloerection. Mice given 500mg/kg also exhibited severe motor depression and one mouse died within 30 minutes. Animals receiving 200mg/kg exhibited subdued behaviour.</p> <p>No statistically significant increase in micronucleated polychromatic erythrocytes (PCE) was observed in animals treated with the notified chemical. A statistically significant decrease in the PCE/normochromatic erythrocyte ratio was seen at 200mg/kg in mice sacrificed at 24 hours after treatment. However, the ratios at 48 hours and at other doses were normal.</p> <p>Positive and negative controls behaved appropriately.</p>
<i>Result:</i>	The notified polymer was non clastogenic under the conditions of the test.

9.4 Toxicokinetics (Cosmetic Ingredient Review, 1986)

In mice, catechol is absorbed readily from the gastrointestinal tract and through skin. In rabbits after oral administration, approximately 18% is excreted as an ethereal sulfate, approximately 70% as a monoglucuronide and 2% as free uncombined catechol (Garton and Williams, 1949 in Cosmetic Ingredient Review, 1986). Part of the catechol is oxidised also to o-benzoquinone (Forsyth and Quesnel, 1957 in Cosmetic Ingredient Review, 1986).

In humans, a colour test was used to examine 24 hour urine samples of workers exposed to atmospheric catechol for 7-9 hours. Similar urine samples taken from the same workers exposed to unpolluted air served as controls. Although catechol values from workers exposed to catechol were higher than those not exposed, the differences were not statistically significant. Urine measurements over 24 hours enabled a calculated biological half-life of inhaled catechol in humans to be determined as 3-7 hours (Hirosawa et al, 1976 in Cosmetic Ingredient Review, 1986).

9.5 Overall Assessment of Toxicological Data

On the basis of toxicological data supplied for an analogue (catechol), the notified polymer can be classified according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999a).

The analogue catechol is rapidly absorbed by the body and metabolised to o-benzoquinone and acid conjugates. In a worker inhalation study, the biological half-life was 3-7 hours. The notified chemical has a higher MW, so absorption is likely to be reduced. Metabolism is likely to be similar to catechol due to structural similarity.

The analogue was of moderate acute oral and dermal toxicity. On the basis of oral and dermal toxicity, the notified polymer would be classified Harmful (Xn) with the risk phrase R21/22 – Harmful in Contact with Skin and if Swallowed.

In an acute inhalation study in rats with the analogue at doses up to 476mg/m³, no deaths occurred and so an LC₅₀ could not be established.

In irritation tests, the analogue induced moderate skin and severe eye irritation. On the basis of skin and eye irritation, the notified polymer should be classified Irritant (Xi) with the risk phrase R36/38 – Irritating to Eyes and Skin. In humans, eczematous dermatitis has been reported as a result of catechol contact with skin (ACGIH, 1999).

The results of a skin sensitisation study of catechol in guinea pigs were noted in the Cosmetic Ingredient Review (1986). Positive results were reported although few details were given. Catechol has not been classified as a skin sensitizer (National Occupational Health and Safety Commission, 1999b) and, on this basis, there is insufficient evidence available to classify the notified polymer as a skin sensitizer.

In a 2 year feeding study in rats, hepatic hyperplasia was reported with catechol doses of 125mg/kg/day. A NOAEL was not stated. In a 20 week drinking water study in mice, significant increases in body weight and some organ weights were observed at a maximum dose of 4g/L. No effects were observed at 0.1g/L. On this basis, a NOAEL of 0.1g/L for catechol was assigned.

In a number of separate studies in mice, catechol was shown to possess cocarcinogenic activity but not tumour-promoting activity alone. Catechol is classified by IARC as possibly carcinogenic to humans (Group 2B) (International Agency for Research on Cancer, 1999).

The notified polymer was non mutagenic and non clastogenic in a bacterial reverse mutation assay and a mouse micronucleus test respectively.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

No experimental ecotoxicological data were provided and instead some estimated LC₅₀ values for the notified polymer using QSARs were provided. These relations are correlations between known experimental toxicity data and the value of the n-octanol/water partition coefficient (via Log K_{ow}) of compounds that are close structural analogues of the notified polymer. The veracity of the calculated estimates for toxicity parameters (eg LC₅₀ values) are critically dependent on the value for Log K_{ow} substituted into the QSARs, and clearly the most reliable toxicity estimates would be derived from an experimentally determined value for Log K_{ow}. Use of Log K_{ow} values which are themselves estimated on the basis of chemical structure through correlations further compound the uncertainties in the estimated LC₅₀ values.

The estimated toxicity data based on the both the measured value for Log K_{ow} of 1.95 and the QSAR estimated value of 2.83 are presented below, but as indicated should be treated with caution.

QSAR estimated ecotoxicity data for the notified polymer

Test	Estimated Result	Estimated Result
	Log K _{ow} = 2.83 (ECOSAR estimate)	Log K _{ow} = 1.95 (measured)
Fish	96 h LC ₅₀ = 9.22 mg/L	96 h LC ₅₀ = 75.14 mg/L
Daphnia	48 h LC ₅₀ = 11 mg/L	48 h LC ₅₀ = 26.88 mg/L
Green algae	96 h EC ₅₀ = 40 mg/L	96 h EC ₅₀ = 262.00 mg/L

According to the toxicity scale provided by Mensink et al (1995), these toxicity end point estimates indicate that the new polymer may be moderately toxic to practically non toxic to aquatic organisms. However, despite the caution in using these estimates, the use pattern of the notified polymer indicates that very little is likely to leach into the water compartment so potential toxicity to aquatic organisms is not a crucial issue in assessing environmental hazard for the proposed use.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The use of the new polymer as a component of protective coatings for large steel pipes is not expected to constitute a hazard to the environment.

The use of the new polymer as a component of protective coatings for large steel pipes is not expected to constitute a hazard to the environment.

A maximum of 10% of the imported material may be released during formulation of the powder coating and application of the coating to steel pipes, and the majority of this will be placed into landfill. Small quantities of polymer (less than 10 kg per annum) may also be released to the atmosphere and sewer.

Although the polymer is soluble in water and likely to be leached by landfill waters, the phenolic hydroxy groups are likely to form insoluble salts with metal ions in the water and so the polymer will become associated with sediments or clay particles which would decrease potential mobility. Consequently, very little of the polymer released during pipe coating processes is likely to reach the wider water compartment. The notified polymer is expected to be at least slowly degraded through biological and abiotic processes operative in landfill situations and would be mineralised to water, carbon dioxide and methane.

Once the polymer is incorporated into the coating on the pipes, it is part of a highly crosslinked epoxy based polymer mass which is expected to be inert and from which no release is expected.

The coated pipes will be laid in trenches in the ground, or possibly over the sea floor in some cases, but the chemically inert nature of the protective polymer coating will preclude release of the new polymer during the lifetime of the pipes.

At the end of their useful life, the steel pipes coated with material containing the polymer are likely to be recovered and re-smelted for metal recovery, and here the polymer would be destroyed through incineration.

Only toxicity data derived from Quantitative Structure Activity Relationships (QSARs) were provided by the notifier, and these indicate that the notified polymer may be moderately toxic to practically non toxic to aquatic organisms. Due to the inherent uncertainties associated with this approach these data should be treated with caution, but as indicated above very little of the polymer is likely to reach the water compartment.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Hazard Assessment

On the basis of moderate oral and dermal toxicity and moderate skin and eye irritant properties for an analogue (catechol), the notified polymer is classified Harmful (Xn) and Irritant (Xi) with the risk phrase R21/22 – Harmful in Contact with Skin and if Swallowed and R36/38 – Irritating to Eyes and Skin. An early sensitisation study of catechol in guinea pigs reported positive results but few details were given and on this basis there is insufficient evidence to classify the notified polymer as a skin sensitiser.

The notified polymer was non mutagenic and non clastogenic in a bacterial reverse mutation assay and mouse micronucleus test respectively but in a number of separate studies in mice, the analogue catechol was shown to possess cocarcinogenic activity. Therefore, catechol is classified by IARC as possibly carcinogenic to humans (Group 2B). By analogy, the notified polymer should be similarly considered.

Occupational Health and Safety

Both during reformulation into powdercoat and application of the powdercoat to pipes, a high degree of automation limits the opportunity for exposure of workers to the notified polymer. For reformulation of Diblend into powdercoat, the reformulation process is conducted using automated enclosed plant and exhaust ventilation fitted to the hopper, blending vessel, grinder and filling machine. Apart from the handling of import containers, little manual intervention is required. Similarly, the spray application of powdercoat to pipes and curing is automated and conducted within enclosed exhaust ventilated spray booths. The main opportunity for worker exposure to the notified polymer occurs during manual opening and handling of import drums of Diblend (19% polymer), quality analysis sampling of resultant Scotchkote powdercoat (0.66% polymer) and the reopening and handling of drums of Scotchkote for application to pipes. Dermal and ocular exposure may occur during these activities and, given a small proportion of notified polymer as inhalable particles in imported Diblend ($0.07\% < 10\mu\text{m}$), inhalation exposure may occur also during opening of import containers.

Workers involved in formulating the powdercoat will wear coveralls/laboratory coats, gloves and, in the case of laboratory workers, safety glasses. Workers involved in spray application of powdercoat will wear disposable overalls, gloves and chemical goggles or face shield. It must be noted that if dermal or ocular exposure occurs, irritation is likely and systemic toxicity via skin absorption may occur. Toxicity may also occur if the notified polymer is ingested.

Despite the lack of sufficient evidence for classification of the notified polymer as a sensitiser, positive reactions in a majority of animals in a guinea pig study indicate also that dermal exposure to the notified polymer may result in skin sensitisation. Therefore, appropriate dermal, ocular and pulmonary protection is essential. In the case of workers servicing spray equipment, inhalation protection is also indicated and exposure should be controlled by a negative pressure organic vapour and particle respirator or supplied air respirator. Also, given the small proportion of notified polymer in Diblend in the form of inhalable particles and the possibility of polymer-induced sensitisation, in addition to dermal protection it would be prudent for workers to wear a negative pressure particle respirator during opening of import containers.

Given the high degree of engineering exposure control during formulation and powdercoating application and the low concentration of polymer in the powdercoating, the risk of irritation and systemic toxicity for workers handling the notified polymer would be assessed as low.

Public Health

The notified polymer will not be sold to the public. Consequently, public exposure throughout all phases of its life cycle is likely to be negligible and so the public health risk is assessed as negligible.

13. RECOMMENDATIONS

The following risk phrases are required on the label of products/mixtures containing the notified polymer:

If polymer present at $\geq 25\%$: R21/22
If polymer present at $\geq 20\%$: R36/38

To minimise occupational exposure to Phenolic Resin R22910, the following guidelines and precautions should be observed:

- Protective eyewear, chemical resistant industrial clothing and footwear and impermeable gloves should be used during occupational use of the products containing the notified polymer;
- A negative pressure particle respirator should be worn by workers when opening containers of imported Diblend;
- Spray application of powdercoating containing the notified polymer must be conducted in accordance with the NOHSC Spray Painting National Guidance Material (National Occupational Health and Safety Commission, 1999c);
- Spillage of the notified polymer should be avoided. Spillages should be cleaned up promptly with absorbents which should be put into containers for disposal;
- A copy of the MSDS should be easily accessible to employees.

Guidance in selection of protective eyewear may be obtained from Australian Standard (AS) 1336 (Standards Australia, 1994) and Australian/New Zealand Standard (AS/NZS) 1337 (Standards Australia/Standards New Zealand, 1992); for industrial clothing, guidance may be found in AS 3765.2 (Standards Australia, 1990); for impermeable gloves or mittens, in AS 2161.2 (Standards Australia/Standards New Zealand, 1998); for occupational footwear, in AS/NZS 2210 (Standards Australia/Standards New Zealand, 1994a); for respirators, in AS/NZS 1715 (Standards Australia/Standards New Zealand, 1994b) and AS/NZS 1716 (Standards Australia/Standards New Zealand, 1994c) and other internationally accepted standards.

If products containing the notified polymer are hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (National Occupational Health and Safety Commission, 1999a), workplace practices and control procedures consistent with State and Territory hazardous substances regulations must be in operation.

14. 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* (National Occupational Health and Safety Commission, 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.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the Act, secondary notification of the notified chemical may be required if any of the circumstances stipulated under subsection 64(2) of the Act arise. In addition, in accord with subsection 64(1), the Director must be notified if any additional health effects or toxicological information become available for the notified polymer or its analogue catechol.

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Attachment 1

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

<i>Erythema Formation</i>	<i>Rating</i>	<i>Oedema Formation</i>	<i>Rating</i>
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

<i>Opacity</i>	<i>Rating</i>	<i>Area of Cornea involved</i>	<i>Rating</i>
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

<i>Redness</i>	<i>Rating</i>	<i>Chemosis</i>	<i>Rating</i>	<i>Discharge</i>	<i>Rating</i>
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

<i>Values</i>	<i>Rating</i>
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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