File No: NA/998

May 2002

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Chemical in RX 3211

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Director
Chemicals Notification and Assessment

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1. APPLICANT

BASF Akzo Nobel Automotive OEM Coatings Pty Ltd (ACN 092 127 501) & Akzo Nobel Pty Ltd (ACN 000 119 424) of 51 McIntyre Road SUNSHINE VIC 3020 has submitted a standard notification statement in support of their application for an assessment certificate for 'Chemical in RX 3211'.

2. IDENTITY OF THE CHEMICAL

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

Marketing Name: RX 3211

Other Names: Blocked isocyanate.

3. PHYSICAL AND CHEMICAL PROPERTIES

Physical and chemical properties were determined on RX 3211 containing 80% notified chemical, unless specified.

Appearance at 20°C & 101.3 kPa: A non-volatile soft solid (chemical in RX 3211).
A pale yellow viscous liquid (RX 3211)

Boiling Point: 114-173°C

Specific Gravity: 1 060 kg/m^3.

Vapour Pressure: Not determined. The solvent free polyisocyanate adduct is not volatile at 105°C.

Water Solubility: 445 mg/L at 20ºC (see comments below).

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).
Particle Size:	Not applicable - the notified chemical is a liquid.
Flash Point:	14°C (MIBK) (for solvent solution).
Flammability Limits:	Not determined.
Autoignition Temperature:	448°C (MIBK) (for solvent solution).
Explosive Properties:	Not explosive.
Reactivity/Stability:	No decomposition up to 120°C. Incompatible with strong mineral acids, strong alkalis and strong oxidising agents.

3.1 Comments on Physico-Chemical Properties

Water solubility was determined at Nippon Paint Company using a method equivalent to OECD TG 105 Water Solubility: Flask Method. A saturated solution of the notified chemical was prepared by adding 1 g to 100 g distilled water at 20°C. The saturated aqueous solution was decanted through a 0.45 µm filter. The concentration of the notified chemical in the filtrate was determined by HPLC. The notified chemical would be classified as moderately soluble in water (Mensink *et al*., 1995).

Hydrolysis as a function of pH was not determined. The notified chemical contains ketoxime groups that can participate in hydrolysis reactions but will not tend to under environmental conditions, pH 4-9.

Partition coefficient (n-octanol/water) was not determined. The notified chemical is moderately soluble in water therefore it is expected to have a relatively low log Pow.

Adsorption/desorption was not determined. The notified chemical is moderately water soluble and is likely to be mobile in soils.

Dissociation constant was not determined. The notified chemical does not contain any functional groups that are likely to dissociate under environmental conditions, pH 4-9.

4. PURITY OF THE CHEMICAL

Degree of Purity: High.

5. USE, VOLUME AND FORMULATION

The notified chemical will form a component of an automotive primer.

The notified chemical will be manufactured in Australia. However, it will be imported from overseas partially in the first year. Up to 50 tonnes of the notified chemical will be introduced annually in the first 5 years.

The notified chemical will be synthesised in an organic solution (RX3211) at 80%. It will be further formulated into an aqueous emulsion at 6.53%, then a finished emulsion at 6%. At the car painting sites, the finished emulsion will be mixed with other paint components prior to application to automotive bodies and parts.

6. OCCUPATIONAL EXPOSURE

Synthesis of the notified chemical and formulating it into aqueous emulsion and finished emulsion will take place at one workplace in Australia. Workers are likely to be exposed to the notified chemical during the following activities:

- Storage and transport of the imported chemical in RX 3211 to the formulation plant.
- Synthesis of the notified chemical and formulation of the intermediate aqueous emulsion and the finished emulsion.
- Transport of the finished emulsion to the car manufacturing facility.
- Application of the paint primer.

Importation

Dockside and transport personnel are unlikely to be exposed to the imported chemical in RX 3211 unless there is accidental puncture of the bulk containers.

Synthesis and formulation

Synthesis and formulation operators
The notified chemical will be manufactured locally in an organic solvent. Raw materials will be added to a reactor using an automated, enclosed process. After synthesis, the solution containing the notified chemical at a concentration of 80% will be stored in bulk until it is required for reformulation. The notified chemical will be then blended to a concentration of 6.5% with various polymers in an aqueous emulsion. The aqueous emulsion will be cooled before blending with additional components to form a finished emulsion, containing the notified chemical at a concentration of 6.0%.

Although the notified chemical, intermediate aqueous emulsion and final paint additive emulsion are manufactured in closed vessels, several groups of workers may receive transient dermal and/or ocular exposure to the notified chemical during routine operations. Twenty-five reactor operators working 12 hours/day for 80-100 days/year may be exposed by skin contact to the chemical during processing and quality analysis sampling of RX 3211 (containing 80% notified chemical), the aqueous emulsions and finished emulsion (both containing <10% polymer). Exposure may also occur from inadvertent leaks and during transfer of finished emulsion to storage tanks. Quality sampling is conducted under exhaust ventilation and so inhalation exposure is unlikely.

Two maintenance personnel working up to 2 hours/day for 80-100 days/year may be exposed also via the skin and eyes during routine equipment cleaning and maintenance.

Industrial controls at the synthesis and formulation site include the use of automatic adding system, enclosed vessels, fixed transfer lines and local exhaust ventilation to control exposure during the synthesis and formulation processes. The notifier also indicates that atmospheric monitoring of isocyanates will be conducted at the workplace. Medical testing is conducted routinely for workers exposed to individual hazardous materials. Plant personnel will wear chemical resistant gloves, overalls and goggles. In addition, organic vapour respirators may also be used if required. This personal protective equipment (PPE) will be required to control exposure not only to the notified chemical but also to other components of the paint additive emulsion, for example, organic solvents.

Laboratory analysis
Five laboratory technicians/chemists working 12 hours/day for 80-100 days/year may be exposed to the notified chemical during sample analysis. Exposure to the notified chemical and other emulsion ingredients in the laboratory environment will be controlled through the use of ventilated fume cupboards and PPE consisting of overalls/laboratory coats, gloves and safety glasses conforming to recognised standards.

Storage and internal transport
Four on-site storage/transport personnel working 2-4 hours/day for 100-130 days/year may be exposed to the notified chemical during storage of the finished emulsion and loading in tankers prior to bulk transport.

Bulk filling will be conducted under exhaust ventilation. Again, exposure to the final emulsion containing <10% notified chemical is likely to be limited to splashes to skin and eyes as a result of manipulation of transfer lines.

Transport
The finished emulsion containing the notified chemical will be transported by road from the manufacturing site to car manufacturers in bulk tankers. Ten transport personnel working 1-2 hours/day for 40-50 days/year will be responsible for transport of the bulk emulsion in 20-25 kL lots to the end user.

Exposure to the notified chemical during storage and transport would be considered low and would only be envisaged following accidental puncture of the bulk containers.

Painting application

Paint Mixing and Application
At the customer site the finished emulsion will be stored in bulk tanks until it is required at which time it will be pumped into the application tank and blended with pigment pastes and water to make up the primer. Car bodies will be coated with the primer by a dipping process. Once coating has occurred the car bodies will be rinsed with water to remove excess primer. The primer will be cured on the car bodies by baking.

At the painting site, the finished aqueous emulsion will be unloaded by up to 10 tank operators working 1-2 hours/day for 20 days/year from bulk transport containers through enclosed transfer lines to an electro-coat tank where the emulsion is mixed with other paint

components prior to application to automotive bodies. At this point, the notified chemical is present at concentrations of less than 1% and the process is fully enclosed and automated. Skin contact with the notified polymer may occur during transfer and mixing operations.

Ten application/curing operators working 1-2 hours/day for 20 days/year may be exposed to the notified polymer during application of the final paint to automotive bodies and parts by dipping. Subsequent curing of the paint by oven baking will occur under exhaust ventilation. Although this is an automated process, dermal and ocular exposure of these workers may occur as a result of accidental splashes. Two maintenance personnel working 1-2 hours/day for 15 days/year who will conduct routine equipment cleaning and maintenance may be exposed similarly.

After curing, the notified chemical will be locked in a paint matrix and so occupational exposure at this stage is unlikely.

Workers including the maintenance personnel at the painting sites will wear chemical resistant gloves, overalls and goggles. Organic vapour respirators may also be worn if required.

Laboratory Analysis
Five laboratory technicians/chemists working 1-2 hours/day for 50 days/year may be exposed to the notified chemical during sampling of final paint. Exposure to the notified chemical and other paint ingredients will be controlled through the use of ventilated fume hoods and personal protective equipment consisting of coveralls/laboratory coats, gloves and safety glasses conforming to recognised standards.

7. PUBLIC EXPOSURE

Members of the public may be exposed to the notified chemical following transport accidents or environmental contamination. Such exposure is unlikely. The notified chemical is not available to the public. The notified chemical is a bound component of the primary coating of vehicle body work and is not accessible to human contact. The primary coating is ultimately covered by several other coats of paint and contact with the notified chemical is further prevented. The potential for exposure of the public to the notified chemical is assessed as negligible.

8. ENVIRONMENTAL EXPOSURE

8.1 Release

Release of Chemical at Site
It is expected that the release of the notified chemical during manufacturing and formulation will be minimised by the automated nature of these processes. The notifier estimates that up to 200 kg per annum of the chemical may be released as a result of accidental spills or leaks, up to a further 100 kg may be released as residue on filters collected during the manufacturing process. Spills will be contained by bunding and the notified chemical will be collected using absorbent material such as sand or vermiculite and disposed of to landfill. In

rare cases some product may be rejected resulting in the disposal of up to 6 000 kg to incineration.

Release of Chemical from Use
At the customer site the application process used should fully contain the notified chemical. Water used to wash excess primer off the cars will be recycled back into the tanks. The dipping tanks are to be washed out periodically and the resultant wash water released to the trade waste pit. The waste water is to be treated by a caustic agent which flocculates the cationic finished emulsion. The flocculated solids are then to be disposed of to landfill and the remaining waste water released to the sewer. The notifier estimates that up to 60 kg of the chemical may be released in this manner.

No release of the notified chemical into the environment is expected once the primer is cured onto motor vehicles. The notified chemical will become incorporated into the inert, primer matrix.

Disposal
Notified chemical collected from spills/leaks or filter residue will be disposed of to landfill.

Notified chemical released due to rejected product will be disposed of by incineration.

8.2 Fate

No environmental fate data were provided for the notified chemical. However, surrogate data were available for biodegradability.

8.2.1. Ready biodegradability

Test Substance	Vestanat B 1358/100
Method	OECD TG 301 F Ready Biodegradability: Manometric Respirometry Test.
Inoculum	Activated sludge micro-organisms
Exposure Period	28 days
Auxiliary Solvent	None
Remarks - Method	The test compound is insoluble in water therefore the test solutions were ultrasonicated to disperse the compound. The test substance is similar to the notified chemical, in that it has the same functional groups and is produced from the same type of compounds, except that Vestanat B 1358/100 is trimeric.

Results

Vestanat B (9.7mg/ mL)		Aniline (9.5 mg/ mL)	
Day	% degradation	Day	% degradation
28	-4	28	105

Remarks - Results	No biodegradation of the test substance occurred during the test period. The reference compound reached 87% biodegradation after 14 days and 105% after 28 days, confirming the validity of the test. In the toxicity control, containing both the test substance and the reference substance, 41% biodegradation was achieved after 14 days. According to the test guidelines, it can assumed that at this level of biodegradation the test substance is not inhibitory to activated sludge micro-organisms.
Conclusion	The test substance, Vestanat B 1358/100, is not readily biodegradable. Ready biodegradation of the notified chemical is also unlikely to occur under the same test conditions.
Test Facility	Insitute für Biologische Analytik und Consulting IBACON GmbH (2001)

8.2.2. Bioaccumulation

No bioaccumulation data were provided. The low molecular weight indicates that the notified chemical has the potential to bioaccumulate. However, bioaccumulation is not expected to occur due to the moderate water solubility and low aqueous exposure of the notified chemical.

9. EVALUATION OF TOXICOLOGICAL DATA

No toxicity studies on the notified chemical are available. The notifier provided four toxicity reports on Vestanat B 1358/100 which is accepted as an analogue chemical for the notified chemical.

9.1 Summary of Toxicological Investigations

Endpoint & Result	*Assessment Conclusion*
Rat, acute oral LD50 >2 000 mg/kg bw	low toxicity
Rabbit, skin irritation	non-irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation - adjuvant test	no evidence of sensitisation.

9.2 Acute Toxicity

9.2.1 Acute Oral Toxicity

TEST SUBSTANCE	Vestanat B 1358/100

METHOD: OECD 423 Acute Oral Toxicity – Acute toxic class method.
EC Directive 92/69/EEC B.1 Acute Toxicity (Oral).

Species/Strain	Rat/Wistar
Vehicle	Propylene glycol
Remarks - Method	GLP & QA.

RESULTS

Group	*Number & Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	3/sex	2 000	0/6

LD50	>2 000 mg/kg bw
Signs of Toxicity	Lethargy, hunched posture, laboured respiration, rales, piloerection, uncoordinated movements, and/or chromodacryorrhoea were observed between day 1 and 7. Scabs were noted in one female from day 8 till termination.
Effects in Organs	No findings noted.
Remarks - Results	

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

TEST FACILITY: NOTOX (2001a).

9.2.2 Skin Irritation

TEST SUBSTANCE: Vestanat B 1358/100

METHOD: OECD 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	72 hours.
Vehicle	Water.
Type of Dressing	Semi-occlusive.
Remarks - Method	GLP & QA.

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	0	0	0	0	-	0
Oedema	0	0	0	0	-	0

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

Remarks - Results None.

CONCLUSION The notified chemical is non-irritating to skin.

TEST FACILITY NOTOX (2001b).

9.2.3 Eye Irritation

TEST SUBSTANCE Vestanat B 1358/100

METHOD OECD 405 Acute Eye Irritation/Corrosion.
EC Directive 92/69/EEC B.5 Acute Toxicity (Eye Irritation).
Species/Strain Rabbit/New Zealand White
Number of Animals 3
Observation Period 72 hours.
Remarks - Method GLP & QA.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	*2*	*3*			
Conjunctiva: redness	0.3	0.3	0.3	2	24 hours	0
Conjunctiva: chemosis	0.3	0	0	2	24 hours	0
Conjunctiva: discharge	0	0	0	1	1 hour	0
Corneal opacity	0	0	0	0	-	0
Iridial inflammation	0	0	0	1	1 hour	0

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

Remarks - Results None.

CONCLUSION The notified chemical is slightly irritating to the eye.

TEST FACILITY NOTOX (2001c).

9.2.4 Skin Sensitisation

TEST SUBSTANCE Vestanat B 1358/100

METHOD OECD 406 Skin Sensitisation – Magnusson & Kligman.
EC Directive 96/54/EC B.6 Skin Sensitization - Magnusson & Kligman.
Species/Strain Guinea pig/Dunkin-Hartley
PRELIMINARY STUDY Maximum non-irritating concentration:

	intradermal: 0.1% topical: 50%
MAIN STUDY	
Number of Animals	Test Group: 20 Control Group: 10
INDUCTION PHASE	Induction Concentration intradermal: 0.5% topical: 50%
Signs of Irritation	Very slight to well defined erythema were observed in 18/20 test animals after intradermal induction. No irritation was observed after topical induction.
CHALLENGE PHASE	
1st challenge	topical application: 20%
Remarks - Method	GLP & QA. The vehicle for intradermal and topical inductions was corn oil. Petrolatum was used as the vehicle in challenge.
RESULTS	No positive reactions.
Remarks - Results	No positive controls were included in the study.
CONCLUSION	There was no evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.
TEST FACILITY	Research Toxicology Centre (2000)

9.3 Overall Assessment of Toxicological Data

Vestanat B 1358/100 was of low acute oral toxicity in rats. It was not a skin irritant but a slight eye irritant in rabbits. Vestanat B 1358/100 was not a skin sensitiser in guinea pigs.

The notifier provided toxicity information on related substances: the blocking agent and the isocyanate.

The blocking agent is classified as Xi with R36 (Irritating to eyes) and R43 (May cause sensitisation by skin contact) on the NOHSC *List of Designated Hazardous Substances* (NOHSC, 1999a). In addition, EU have added R40(3) (Carcinogen Category 3, Harmful) to the blocking agent. The data from IUCLID Dataset (2000) indicates that the blocking agent is of low acute oral, inhalation toxicity in rats, high acute dermal toxicity in rabbits. It was a slight skin irritant and severe eye irritant in rabbits, and a skin sensitiser in guinea pigs. When the blocking agent was given repeatedly by inhalation, the NOAEL was 3 ppm (11 mg/m^3) in mice based on minimal to moderate severe olfactory epithelium degeneration, and 1 020 mg/m^3/day in rats based on the changes in haematological parameters, spleen and liver weights, and accumulation of iron in spleen. In the repeat oral dose studies, the NOAEL was determined to be less than 25-40 mg/kg/day based on the changes in haematological parameters, organ weights, and toxicity in the blood system in rats. In repeated inhalation studies, the blocking agent was also found to be a liver oncogen in the male rats at 75 ppm,

and in the male mice at 374 ppm. The NOAEL for reproductive and postnatal toxicity was determined to be 200 mg/kg/day via gavage based on extramedullary haematopoiesis and haemosiderosis in adult livers and spleens in a two generation study in rats. Although no effects of developmental toxicity and teratogenicity were observed in the studies, the NOAEL for maternal toxicity was found to be 60 mg/kg/day in rats and 14 mg/kg/day in rabbits.

The blocking agent was not genotoxic in a series in vitro assays such as Ames test, mouse lymphoma assay, sister chromatid exchange assay, unscheduled DNA synthesis and other chromosome aberration assay. Negative results were also observed in several in vivo cytogenetic assays in rat, mouse and Drosophila melanogaster.

The isocyanate is classified as Toxic with R23 (Toxic by inhalation), and Xi with R36/37/38 (Irritating to eyes, respiratory system and skin) and R42/43 (May cause sensitisation by inhalation and skin contact) on the NOHSC *List of Designated Hazardous Substances* (NOHSC, 1999a). NOHSC has established a national exposure standard of 0.02 mg/m^3 (TWA) and 0.07 mg/m^3 (STEL) with "sensitiser" notation, for all isocyanates (as-NCO) (NOHSC, 1995), and lists isocyanates on Schedule 3, 'Hazardous substances for which health surveillance is required' (NOHSC, 1994a). Hazardous Substances Data Bank (HSDB) records that the isocyanate is of low acute oral toxicity and high acute inhalation toxicity in rodents. It is a moderate skin and eye irritant in rabbits and a skin sensitiser in guinea pigs.

The notifier provided a published scientific paper regarding an in vitro method for predicting sensitising properties of inhaled chemicals (Wass and Belin, 1990). Experimental results showed that isocyanates became non-reactive after they had been blocked with chemicals such as caprolactam, butanone oxime, malonic acid diethylester, or isononyl phenol. This suggests that blocked isocyanates may have a significantly reduced respiratory toxicity when comparing with unblocked isocyanates.

The notifier indicated that any residual of monomers were not expected in the notified chemical due to the conditions of manufacture and stochiometry of the reaction. The blocked isocyanate, regarded as low concern for PLCs based on extensive investigation by US EPA, is stable. Therefore, the notified chemical is expected to have significantly lower reactivity than an isocyanate or ketoxime. Based on the toxicity data of the analogue and the related substances, the notified chemical is expected to be of low acute oral, dermal and inhalation toxicity. It would not be a skin irritant or skin sensitiser but may be a slight eye irritant. Based on the information provided, the notified chemical cannot be classified as a hazardous substance according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999b).

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

No ecotoxicological data were provided for the notified chemical. The notifier has provided some information on the environmental effects of the parent compounds, an isocyanate and a blocking agent. These chemicals are more reactive than the notified chemical therefore the following data do not necessarily predict its environmental toxicity.

Acute toxicity to fish

Results

Remarks – Results	Not determined for the notified chemical. The 96 hour EC50 of the blocking agent for three species, *Pimelas promelas* (flathead minnow), *Leuciscus idus* (ide) and *Poecilia reticulata* (guppy), ranged from > 320 to 843 mg/L. The 48 hour EC50 of the isocyanate compound for *Leuciscus idus* was 1.7 mg/L.
Conclusion	One of the parent compounds of the notified chemical, the blocking agent, would be classified as practically non-toxic to fish and the other parent compound, an isocyanate, would be classified as moderately toxic to fish (Mensink *et al*. 1995).

Acute/chronic toxicity to aquatic invertebrates

Results

Remarks - Results	Not determined for the notified chemical. The 48 hour NOEC of the blocking agent for *Daphnia magna* was > 500 mg/L. No data is available for the toxicity of the isocyanate compound to fresh-water invertebrates.
Conclusion	The blocking agent would be classified as practically non-toxic to daphnids (Mensink *et al*. 1995).

Algal growth inhibition test

Results

Remarks - Results	Not determined for the notified chemical. The 72 hour EC50 (growth) of the blocking agent for *Scendesmus subspicatus* was 83 mg/L. No data is available for the isocyanate compound.
Conclusion	The blocking agent would be classified as slightly toxic to algae (Mensink *et al*. 1995).

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

Exposure assessment

Environmental exposure will not occur once the primer containing the notified chemical has been cured on to car bodies. The majority of the notified chemical will be incorporated into the inert, polymeric matrix of the primer and covered with other coating layers. At the end of their useful lives, cars coated with the primer containing the notified chemical would be

consigned to metal reclamation plants or landfill. When recycled the notified chemical would be converted to water vapour and oxides of carbon and nitrogen by the blast furnaces.

Up to 360 kg per annum of the notified chemical may be released during manufacturing, formulation and end use activities. The majority of this material will be disposed of directly to landfill. Up to 60 kg per annum of this material may be released into waste water. Waste water will be passed through interceptor pits and contained for treatment with a caustic agent prior to discharge to the sewer as trade waste. The flocculated solids will be disposed of to landfill. Some of the notified chemical may remain in the water compartment to be released to the sewer. In the aquatic environment the notified chemical may persist because it is hydrolytically stable and not readily biodegradable

In landfill the notified chemical is likely to leach out of soils/sediments and partition into the water compartment due to its low molecular weight and moderate solubility in water. A chemical with the same parent compounds, and thus the same functional groups, was not readily biodegradable according to OECD TG 301F. Similarly, the notified chemical is not likely to be readily biodegradable and may persist in landfill, degrading only slowly through abiotic and biotic processes.

Effects assessment
No ecotoxicological data were provided in the notification dossier. However, under normal usage of the chemical, environmental exposure is expected to be minimal.

The notifier has provided some information on the ecotoxicity of the parent compounds of the notified chemical. This data indicates that the blocking agent shows no significant toxicity to aquatic organisms but the isocyanate is moderately toxic to fish and possibly to Daphnia and algae although no data are available for these organisms. Due to the very different structure and functionality, the relevance of this information to the notified chemical is unclear. However, aquatic exposure will be very low.

Risk characterisation
The notified chemical does not pose a significant hazard to the environment based on its reported use pattern because there will be very low environmental exposure. The majority of the notified chemical will be reacted into the inert, polymeric matrix of the automobile primer when exposed to heat during application. The primer will be applied to the automobiles in a closed system by a dipping process. Exposure will also be reduced by additional, durable coating layers.

Any release that is likely to occur as a result of accidental spills and equipment cleaning during primer formulation and application will not present a hazard to the environment because the amount of notified chemical released will be very small.

Assessment level of concern for the environment
The chemical is not considered to pose a risk to the environment based on its reported use pattern.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Hazard Assessment
No toxicity studies on the notified chemical are available. The notifier provided toxicity reports on the analogue Vestanat B 1358/100. Vestanat B 1358/100 was of low acute oral toxicity in rats. It was neither a skin irritant nor a skin sensitiser but a slight eye irritant.

The notifier also provided some toxicity information on two related substances, an isocyanate and a blocking agent. Both of them are on the NOHSC *List of Designated Hazardous Substances* (NOHSC, 1999a). The blocking agent is classified as Xi with R36 (Irritating to eyes) and R43 (May cause sensitisation by skin contact). In addition, EU have added R40(3) (Carcinogen Category 3, Harmful) to the blocking agent. The isocyanate is classified as Toxic with R23 (Toxic by inhalation), and Xi with R36/37/38 (Irritating to eyes, respiratory system and skin) and R42/43 (May cause sensitisation by inhalation and skin contact). NOHSC has established a national exposure standard for all isocyanates (as-NCO) (NOHSC, 1995), and listed isocyanates on Schedule 3, 'Hazardous substances for which health surveillance is required' (NOHSC, 1994a).

Based on the toxicity data of the analogue and the expected lower toxicity compared to the related substances, the notified chemical is expected to be of low acute oral, dermal and inhalation toxicity. It would not be a skin irritant or skin sensitiser but may be a slight eye irritant. Based on the information provided, the notified chemical cannot be classified as a hazardous substance according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999b).

The notifier classified RX 3211 as a hazardous substance with Dangerous Goods Class 3. The Material Safety Data Sheet (MSDS) for RX 3211 states that it is harmful if swallowed and may cause irritation to nose, throat and gastrointestinal tract, eyes and skin. Chronic inhalation of excessive concentrations of vapours may produce effects on the central nervous system. These effects are based on the effects of organic solvents in RX 3211.

For some chemicals in the finished emulsion, NOHSC has allocated exposure standards for methyl isobutyl ketone (TWA 50 ppm or 205 mg/m^3, STEL 75 ppm or 307 mg/m^3), 2-butoxyethanol (TWA 25 ppm or 121 mg/m^3) and nitric acid (TWA 2 ppm or 5.2 mg/m^3, STEL 4 ppm or 10 mg/m^3).

Occupational Health and Safety
Chemical in RX 3211 will be manufactured in Australia or imported from overseas. RX 3211 will be formulated into aqueous emulsion and finished emulsion at the notifier's facility, and then applied as a component in the automotive primers at the car manufacturing sites.

The notified chemical is transported in containers during importation and distribution. The potential for exposure to the notified chemical during transport and storage would be considered low and would only be envisaged following accidental puncture of the containers. Therefore the health risk for transport workers is assessed as low.

Exposure to the notified chemical for synthesis, formulation, maintenance and laboratory workers at the formulation site may occur from contact with RX 3211 (80% notified chemical) or aqueous and finished emulsions (<10% notified chemical). Fixed transfer lines and enclosed vessels are used in the synthesis and formulation processes. In addition, ventilation systems are equipped in the workplaces. Given these engineering controls and likely low systemic toxicity of the notified chemical, the overall health risk for workers

involved in synthesis and formulation is assessed as low. PPE worn by the workers includes chemical resistant gloves, overalls, goggles, and organic vapour respirators.

At the car manufacturing sites, the finished emulsion containing the notified chemical will be mixed in a storage tank, which will be used to coat automotive bodies by dipping. At this point, exposure to diluted notified chemical (<1%) would only occur as a result of contact with the final paint. As this process is automated, the possibility of exposure is low and would be envisaged only following accidental spillage during routine operations, maintenance or laboratory analysis. Given the likely low toxicity of the notified chemical, the health risk to these workers involved in painting process would be assessed as low.

Following curing of the paint, the polymer will be cross linked with other paint components to form a high molecular weight stable film. In this form, the chemical is essentially unavailable for absorption and thus the health risk to workers from the notified polymer after paint curing would not be significant.

Public Health
In its application, the notified chemical is a bound component of the primary coating of vehicle body work and is not accessible to human contact. The primary coating is ultimately covered by several other coats of paint and contact with the notified chemical is further prevented. The low likelihood of exposure to the notified chemical and the low toxicity of the notified chemical suggest that it will not pose a significant hazard to public health when used as proposed.

13. RECOMMENDATIONS

Control Measures

Occupational Health and Safety

No special precautions are required for the notified chemical; however, due to the presence of hazardous components in the emulsions and final paint:

- Employers should implement the following engineering controls to minimise occupational exposure:

- Enclosed fixed transfer lines for transfer operations;
- Enclosed mixing vessels;
- Exhaust ventilation during synthesis, formulation, quality control analysis, storage and paint application;

- Employers should implement the following safe work practices to minimise occupational exposure during handling of emulsions and final paint:

- NOHSC exposure standards for all of the components of the final paint mix should not be exceeded in the workplace;
- Prevent splashes and spills;

- Employers should ensure that the following PPE is used by workers to minimise occupational exposure to the emulsions and final paint:

  - Safety goggles, chemical resistant industrial clothing and footwear, and impermeable gloves. Where engineering controls and work practices do not reduce vapour and particulate exposure to safe levels, an organic vapour respirator should also be used;

  - 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;

- If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances*, 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 by landfill.

Emergency procedures

- Spills/release of the notified chemical should be handled by containing and collecting with inert absorbent material such as sand or vermiculite, placed into sealed containers and disposed of by landfill.

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 Subsection 64(1) of the Act; if
  – If the use pattern of the notified chemical changes such that increased exposure to the aquatic environment is anticipated. In this case a full set of physico-chemical and ecotoxicity reports should be provided.

(2) 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.

14. MATERIAL SAFETY DATA SHEET

The MSDS for RX 3211containing the notified chemical was provided in a format consistent with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994b).

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. REFERENCES

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NOTOX (2001b) Primary skin irritation/corrosion study with Vestanat B 1358/100 in the rabbit (4-hour semi-occlusive application), Project 318364, NOTOX, The Netherlands (unpublished report provided by notifier).

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Wass U and Belin L (1990) An in vitro method for predicting sensitising properties of inhaled chemicals, Scand J Environ Health, 16:208-214.

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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