File No: PLC/243

September 2001

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Kaneka Silyl SAX 350

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act* 1989 (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the National Occupational Health and Safety Commission which also conducts the occupational health & safety assessment. The assessment of environmental hazard is conducted by the Department of the Environment and the assessment of public health is conducted by the Department of Health and Aged Care.

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Director
Chemicals Notification and Assessment

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1. APPLICANT

Mitsui & Co (Australia) Ltd of Level 46 – Gateway, 1 Macquarie Place, Sydney NSW 2000 (ABN 64 004 349 795) has submitted a notification statement in support of their application for an assessment certificate for the synthetic polymer of low concern (PLC) Kaneka Silyl SAX 350.

2. IDENTITY OF THE CHEMICAL

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

Marketing names: Kaneka Silyl SAX 350
Kaneka MS Polymer S203H

3. POLYMER COMPOSITION AND PURITY

Details of the polymer composition have been exempted from publication in the Full Public Report.

4. PLC JUSTIFICATION

The notified polymer meets the PLC criteria.

5. PHYSICAL AND CHEMICAL PROPERTIES

Property	Result	Comments
Appearance	light yellow viscous liquid	
Melting point	not determined	
Density	980 – 1020 kg/m^3	
Water solubility	< 10 mg/L	based on notified polymer with

		lower molecular weight
Particle size	not applicable	
Viscosity	6 – 10 Pa.s at 23ºC	
Flammability	combustible	
Flash point	237ºC	
Explosive properties	not expected to be explosive	
Stability/reactivity	reacts with water	
Hydrolysis as function of pH	not determined	rapid crosslinking after addition of catalyst
Partition coefficient	not determined	see comments below
Adsorption/desorption	not determined	see comments below
Dissociation constant	no groups which can dissociate are present	

5.1 Comments on physical and chemical properties

The partition coefficient of the notified polymer was not determined. However, the octanol and water solubilities of the lower MW notified polymer were determined in accordance with OECD Test Guideline 105, using the flask method. The octanol solubility of the polymer was determined to be > 600 g/L, and the partition coefficient was calculated to be > 4.8. The notified polymer can therefore be regarded as hydrophobic and is expected to preferentially partition into the organic phase.

The adsorption/desorption behaviour of the notified polymer was not determined. However, the partition coefficient indicates that the polymer will be immobile in soils.

6. USE, VOLUME AND FORMULATION

Use:
The notified polymer will be used as a component of sealants for wall joints, gap-filling sealants and industrial adhesives for trade and public sale. The notified polymer is mixed with a catalyst and crosslinks on contact with atmospheric moisture.

Manufacture/Import volume:
The notifier estimates that 10 tonnes per annum notified polymer will be imported in the first five years.

Formulation details:
The notified polymer will initially be imported in end use product form, packaged in typical containers for products of the type. Such containers may include cartridges and tubes, with capacities under 1 L. The products will contain of the order of 30 % notified polymer. At a later date, import of the pure notified polymer in 200 L drums will commence and the products will be formulated in Australia and packaged in end use product containers. The

notifier indicates that initially the products containing the notified polymer will be directed towards the building trade, but retail sales may be developed at a later date.

7. OCCUPATIONAL EXPOSURE

Exposure route	Exposure details	Controls indicated by notifier
Formulation		
Compounding and packing (300 workers, daily)		
dermal, pure notified polymer.	The notified polymer will be mixed with fillers, additives, pigment and catalyst in closed vessels and filled into cartridges; dermal exposure may occur when connecting and disconnecting transfer hoses and if intervention at the packing line is required.	Enclosed automated process with local exhaust ventilation Safety gloves, goggles and industrial clothing; a respirator if mists or sprays are generated.
End use		
Building workers (1000 workers, daily)		
dermal, 30 % notified polymer	The products containing the notified polymer are expected to be applied directly from cartridges, although the uncured sealant may be worked using trowels or similar implements.	Not stated.
Transport and storage		
Waterfront, transport, storage and retail workers (not stated)		
none	No exposure is expected unless an accident involving damage to the packaging occurs.	Not stated.

8. PUBLIC EXPOSURE

Public exposure through importation, transportation and reformulation is expected to be negligible.

The sealants containing the notified polymer will be available for trade and public sale. Although the target market is primarily the building trade, retail sales to the public may also occur. The product will be applied directly from the cartridges, and may be worked using trowels or similar implements. Public exposure to the uncured and cured product is most likely to be through dermal contact. Once cured it is expected that the polymer will not be bioavailable.

9. ENVIRONMENTAL EXPOSURE

9.1. Release

Transport
Accidental spillage of the notified polymer may occur during transport to either the formulator, distributor, or end user. However, the polymer cures on contact with atmospheric moisture at the time of release to form a crosslinked inert solid of very high molecular weight. Damaged container drums are likely to be opened and allowed to air-cure. Therefore, any environmental release is likely to be easily collected and disposed of, and any environmental impact from a spill is likely to be minor.

Reformulation
The notifier estimates that a few kg of sealant or adhesive, likely to be around 1 %, may be left in the drums after they are emptied prior to blending (ie 2 kg left in every 200 L drum). If it is assumed that 10 tonnes of the notified polymer are imported each year, the residues will total 100 kg per annum. Waste polymer may also generated when the formulated material is packaged into cartridges. This is likely to be up to 1 % (100 kg). Overall, up to 200 kg per annum of polymer waste could be released to the environment from the reformulation process.

End User – Tradesmen and DIY
The notifier has not provided an estimate of polymer waste generated from the application of the notified polymer to substrates. However, it is likely that up to 5 % (500 kg) per annum of notified polymer waste will be produced as residual inert material adhering to building material substrates, and this would be wiped up with rags or paper towels. Once exposed to the atmosphere the material would react with water vapour and become incorporated into a semi solid (rubbery) mass. The rags and paper would be disposed of to existing waste streams established for building products. This waste is likely to ultimately be disposed of to landfill.

The notifier estimates that up to 10 mL (2 % of a 500 g cartridge) of the notified polymer will be left as residue in used cartridges. A total of 200 kg waste polymer per annum may be released by this route. Residues will react with atmospheric moisture to form an inert material. Cartridges and cured polymer will be disposed of to landfill along with household and commercial waste streams.

Overall, up to 700 kg of waste polymer is likely to be generated from the application of the polymer to building materials.

Overall Release
Release of uncured notified polymer is unlikely since the formulated product contains catalyst which causes it to crosslink on exposure to the atmosphere. Overall, up to 900 kg per annum of the notified polymer in cured form may go to landfill from the above routes.

9.2. Fate

The majority of the notified polymer in cured and crosslinked form will be incorporated as part of sealant masses in building materials. When buildings are demolished, it is likely that

the building materials and associated sealant masses will be placed into landfill or incinerated with building wastes.

The notified polymer is not expected to be readily biodegradable but, on prolonged exposure to bacterial action, the polymer is expected to be substantially mineralised. In landfill the sealant mass containing the notified polymer and its breakdown products would slowly degraded as a consequence of microbiological processes with release of gases such as carbon oxides and methane, and silicates. Incineration would destroy the polymer with release of water vapour, oxides of carbon, and silicates.

Bioaccumulation of the notified polymer is unlikely because of its high molecular weight (Connell, 1990).

10. EVALUATION OF HEALTH EFFECTS DATA

10.1 Acute Toxicity

Toxicity data for several close analogue polymers, 5B25, M-3 and MSP-20A, was provided by the notifier. These polymers contain structurally similar chains to the notified polymer, and are terminated with the same reactive functional group. Accordingly, they are accepted as appropriate analogues for determination of the toxicity properties of the notified polymer.

Summary of the toxicity of analogue polymers

Test	*Species*	*Test Material*	*Outcome*	*Reference*
acute oral toxicity	rat	5B25	LD_{50} > 5000 mg/kg	(Kanegafuchi , 1987a)
skin irritation	rabbit	MSP-20A	non-irritant	(Kanegafuchi , 1977)
		5B25	non-irritant	(Kanegafuchi , 1987b)
eye irritation	rabbit	5B25	slight irritant	(Kanegafuchi , 1987c)
		M-3	non-irritant	(Kanegafuchi , 1987d)
genotoxicity	*E. coli, S. typhimurium*	5B25	non-mutagenic	(Kanegafuchi , 1987e)
		M-3	non-mutagenic	(Kanegafuchi , 1987f)

10.1.1 Oral Toxicity (5B25) (Kanegafuchi, 1987a)

Species/strain: rat/SD(SPF)

Number/sex of animals: 5/sex

Observation period:	14 days
Method of administration:	gavage; dose 5000 mg/kg; test material used as supplied
Test method:	OECD TG 401
Mortality:	there were no premature decedents during the study
Clinical observations:	no clinical signs of toxicity were observed
Morphological findings:	no gross abnormalities were seen at necropsy
LD_{50}*:*	> 5000 mg/kg
Result:	the test material was of very low acute oral toxicity in rats

10.1.2 Skin Irritation (MSP-20A) (Kanegafuchi, 1977)

Species/strain:	rabbit/Japanese albino
Number/sex of animals:	3 male
Observation period:	7 days
Method of administration:	semi-occlusive patch; 0.5 g test material used as received; 24 hr exposure
Test method:	not stated
Comment:	no skin reactions to the test material were observed
Result:	the test material was non-irritating to the skin of rabbits

10.1.3 Skin Irritation (5B25) (Kanegafuchi, 1987b)

Species/strain:	rabbit/Japanese White (SPF)
Number/sex of animals:	6 male
Observation period:	3 days
Method of administration:	semi-occlusive patch; 0.5 mL test material used as received; 4 hr exposure
Test method:	OECD TG 404
Comment:	no skin reactions to the test material were observed

Result: the test material was non-irritating to the skin of rabbits

10.1.4 Eye Irritation (5B25) (Kanegafuchi, 1987c)

Species/strain: rabbit/Japanese White

Number/sex of animals: 9 male

Observation period: 14 days

Method of administration: 0.1 mL test material (used as received) was instilled in the conjunctival sac of the left eye; the treated eyes of 3 animals were irrigated with water 30 seconds after instillation; the untreated right eye served as control

Test method: OECD TG 405

Draize scores of unirrigated eyes:

	Time after instillation														
Animal	***1 hour***			***1 day***			***2 days***			***3 days***			***7 days***		
Cornea	all Draize scores were zero														
Iris	all Draize scores were zero														
Conjunctiva	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***
1	0	0	1	0	0	1	0	0	1	0	0	0	0	0	0
2	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0
3	1	0	1	0	0	0	0	0	0	0	0	0	0	0	0
4	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0
5	0	0	1	0	0	1	0	0	1	0	0	1	0	0	1
6	1	0	1	0	0	0	0	0	0	0	0	0	0	0	0

[1] see Attachment 1 for Draize scales
r = redness c = chemosis d = discharge

Irrigated eyes: all conjunctival reactions (grade 1 redness – 2 animals and grade 1 discharge – 3 animals) cleared by 24 hr

Comment: conjunctival discharge in animal 5 cleared by day 10; hair loss below the inner canthus was observed in animal 5; this cleared by day 14

Result: the test material was slightly irritating to the eyes of rabbits

10.1.5 Eye Irritation (M-3) (Kanegafuchi, 1987d)

Species/strain:	rabbit/Japanese White
Number/sex of animals:	3 male
Observation period:	3 days
Method of administration:	0.1 g test material (used as received) was instilled in the conjunctival sac of one eye; the untreated eye served as control
Test method:	OECD TG 405
Comment:	all Draize scores at 1, 24, 48 and 72 hours were zero; scores for conjunctival discharge were not reported
Result:	the test material was non-irritating to the eyes of rabbits

10.2 Genotoxicity

10.2.1 *Salmonella typhimurium* and *Escherichia coli* Reverse Mutation Assay (5B25) (Kanegafuchi, 1987e)

Strains:	*S. typhimurium*: TA98, TA100, TA1535, TA1537 *E. coli*: WP2 *uvr*A
Metabolic activation:	rat liver S9 fraction from animals pretreated with Arochlor 1254; 10 % in standard cofactors
Concentration range:	15, 50, 150, 500, 1500 and 5000 μg/plate; test material dissolved in ethanol
Positive controls:	with S9: TA98, TA100: 2-aminoanthracene 0.5 μg/plate TA1535, TA1537: 2-aminoanthracene 2 μg/plate WP2 *uvr*A: 2-aminoanthracene 80 μg/plate without S9 TA98: 2-nitrofluorene 1 μg/plate TA100: *N*-ethyl-*N*′-nitro-*N*-nitrosoguanidine 3 μg/plate TA1535: *N*-ethyl-*N*′-nitro-*N*-nitrosoguanidine 5 μg/plate TA1537: 9-aminoacridine 80 μg/plate WP2 *uvr*A: *N*-ethyl-*N*′-nitro-*N*-nitrosoguanidine 2 μg/plate
Test method:	Japanese Ministry of Labour Kihatsu No. 107, modified
Comment:	two independent tests were performed in triplicate, using the plate incorporation method; no signs of toxicity were

	reported; precipitate was observed at 5000 µg/plate in preliminary testing
	no positive responses were observed with any tester strain in the presence or absence of metabolic activation
	large increases in the number of revertant colonies were seen for the positive controls in all cases, indicating that the test system responded appropriately
Result:	the test material was non mutagenic under the conditions of the test

10.2.2 *Salmonella typhimurium* and *Escherichia coli* Reverse Mutation Assay (M-3) (Kanegafuchi, 1987f)

Strains:	*S. typhimurium*: TA98, TA100, TA1535, TA1537 *E. coli*: WP2 *uvr*A
Metabolic activation:	rat liver S9 fraction from animals pretreated with phenobarbital and 5,6-benzoflavone; 10 % in standard cofactors
Concentration range:	156, 313, 625, 1250, 2500 and 5000 µg/plate; test material dissolved in 1:1 dimethyl sulphoxide and acetone
Positive controls:	with S9: TA98, TA100: 2-aminoanthracene 0.5 µg/plate TA1535, TA1537: 2-aminoanthracene 2 µg/plate WP2 *uvr*A: 2-aminoanthracene 20 µg/plate
	without S9 TA98: AF-2 0.05 µg/plate TA100, WP2 *uvr*A: AF-2 0.01 µg/plate TA1535: *N*-ethyl-*N*′-nitro-*N*-nitrosoguanidine 5 µg/plate TA1537: 9-aminoacridine 80 µg/plate
	AF-2: 2-(2-furyl)-3-(5-nitro-2-furyl)acrylamide
Test method:	Japanese Ministry of Labour Kihatsu No. 261
Comment:	two independent tests were performed in triplicate, using the plate incorporation method; no signs of toxicity were observed
	no positive responses were observed with any tester strain in the presence or absence of metabolic activation

	large increases in the number of revertant colonies were seen for the positive controls in all cases, indicating that the test system responded appropriately
Result:	the test material was non mutagenic under the conditions of the test

10.3 Overall Assessment of Toxicological Data

Test results for close analogue polymers were provided by the notifier for acute oral toxicity, skin and eye irritation, and induction of point mutations in bacteria. The analogues are accepted as being appropriate to indicate the toxicity of the notified polymer.

The analogue 5B25 was found to be of very low acute oral toxicity in rats (LD_{50} > 5000 mg/kg) and non-irritating to rabbit skin. It was a slight irritant in rabbit eyes; conjunctival redness and discharge cleared by 24 hours in four animals, although discharge persisted in one animal beyond day 2 and in another beyond day 7. It was non-mutagenic in the bacterial point mutation assay. The analogue M-3 was found to be non-irritating to rabbit eyes, and non-mutagenic in the bacterial point mutation assay. The analogue MSP-20A was found to be non-irritating to rabbit skin.

The notified polymer has high molecular weight (> 10000) and low levels of residual monomers and low molecular weight species, and does not contain other hazardous impurities.

Based on the above information, the notified polymer is not classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (Approved Criteria) (NOHSC, 1999).

11. EVALUATION OF ENVIRONMENTAL EFFECTS DATA

No ecotoxicological data were provided.

12. ENVIRONMENTAL RISK ASSSESSMENT

The notified polymer is imported as a raw material for building sealants and adhesive formulations and would only be exposed to the environment as part of a crosslinked polymer mass with little potential for leaching or escape of fugitive vapours.

It is expected that up to 700 kg of the polymer would be placed into landfill with residues from application activities, and a further maximum of 200 kg from the reformulation process. At the end of their serviceable lives, building materials containing the notified material will be placed into landfill with other industrial wastes, or incinerated. Although the notified polymer is unlikely to be readily biodegradable, in landfill the sealant mass containing the

notified polymer is likely to undergo slow decomposition to water and gases which may include oxides of carbon, and silicates. Incineration of building wastes will generate oxides of carbon and silicates.

No ecotoxicity data for the notified polymer was provided in the notification, but very little of the polymer is expected to be released to the water compartment. If the polymer is released to water it is likely to rapidly react and become an inert mass.

The low aquatic exposure of the polymer as a result of the proposed use indicates that the overall environmental risk should be low.

13. HEALTH AND SAFETY RISK ASSESSMENT

13.1. Hazard assessment

The notified polymer satisfies the criteria for assessment as a Synthetic Polymer of Low Concern. Although it contains a reactive functional group, this is at a low level, and the associated hazard is reduced because of the very high molecular weight of the notified polymer.

Test results for close analogue polymers were provided by the notifier for acute oral toxicity, skin and eye irritation, and induction of point mutations in bacteria. The analogues are accepted as being appropriate to indicate the toxicity of the notified chemical. One analogue was found to be a slight irritant to rabbit eyes, while the other tests gave negative results. The notified polymer is not classified as a hazardous substance for the endpoints studied in accordance with the Approved Criteria.

13.2. Occupational health and safety

Occupational exposure to the notified polymer may occur during reformulation, where neat notified polymer is handled, or during application of building products containing the notified polymer at approximately 30 %. Exposure will be predominantly dermal, as the polymer is viscous and non-volatile, reducing the risk of inhalation exposure to vapours or aerosols or ocular exposure to splashes.

During reformulation, the notified polymer will be handled in an enclosed system, and little exposure is expected apart from contact with drips and spills on connecting and disconnecting transfer hoses. During end-use, the exposure will be much more widespread, and under poorly controlled conditions. Dermal contact may occur in a variety of ways, including the use of the fingers to apply or smooth and shape the sealant. The products containing the notified polymer should be used in accordance with directions and applied only from the cartridge or by trowel.

Dermal contact with the notified polymer is not expected to result in significant occupational risk, due to the lack of skin irritant potential, and as dermal absorption of the notified polymer across the skin or other biological membranes is unlikely due to the high molecular weight.

The notified polymer is of low concern to human health and safety and the standard work procedures for handling the sealants should be sufficient to ensure that it is used safely.

13.3. Public health

Public exposure is likely to be limited to dermal exposure to the uncured and cured product. Analogue polymers have been determined not to be skin irritants, and therefore the notified polymer at a concentration of 30 % in the product should not present a significant risk to public health. Other toxicological studies indicate low toxicity and therefore the notified polymer is unlikely to pose a significant hazard to public health.

14. MSDS AND LABEL ASSESSMENT

14.1. MSDS

The MSDS of the notified polymer provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 1994a). It is published here as part of the assessment report. The accuracy of the information on the MSDS remains the responsibility of the applicant.

14.2. Label

The label for the notified polymer provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC, 1994b). The accuracy of the information on the label remains the responsibility of the applicant.

15. RECOMMENDATIONS

Control Measures

Occupational Health and Safety

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer in end-use products:
  - Use of sealants or other products containing the notified polymer should be in accordance with the manufacturer's safety directions.

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer as introduced:
  - Protective eyewear, chemical resistant industrial clothing and footwear and impermeable gloves should be used during occupational use of the products containing the notified polymer; where engineering controls and work practices do not reduce vapour and particulate exposure to safe levels, an air fed 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.

15.1 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(1) of the Act; if
  – the notified polymer is introduced in a chemical form that does not meet the PLC criteria.

or

(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.

16. REFERENCES

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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.
		Swelling with lids half-closed	3 mod.	Discharge with moistening of lids and hairs and considerable area around eye	3 severe
Diffuse beefy red	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

Draize, J. H., Woodward, G., Calvery, H. O. (1944) Methods for the Study of Irritation and Toxicity of Substances Applied Topically to the Skin and Mucous Membranes, J. Pharmacol. Exp. Ther. 82 : 377-390.

Draize J. H. (1959) Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics. Association of Food and Drug Officials of the US, 49 : 2-56.