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**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION
AND ASSESSMENT SCHEME**

FULL PUBLIC REPORT

Actilane SP061

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For enquiries please contact the Administration Coordinator at:

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**Actilane SP061****1. APPLICANT**

Asia Pacific Specialty Chemicals Pty Ltd of 15 Park Road, Seven Hills NSW 2147 (ABN 32 00 316 138) has submitted a limited notification statement in support of their application for an assessment certificate for **Actilane SP061**.

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 and the Summary Report.

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C & 101.3 kPa:	Colourless liquid
Boiling Point:	> 100°C
Melting Point:	< -20°C
Specific Gravity:	1.11 at 20°C
Vapour Pressure:	Not determined - likely to be low considering the high molecular weight.
Water Solubility:	Not determined – 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 relevant – polymer is a liquid.

Flash Point:	> 100°C (closed cup)
Flammability Limits:	Not flammable. The polymer is combustible.
Autoignition Temperature:	Not expected to autoignite.
Explosive Properties:	Not explosive.
Reactivity/Stability:	Reactive – see comments below.

3.1 Comments on Physico-Chemical Properties

The water solubility was not determined but based on the structure is expected to be low. At low concentrations, the notified polymer is dispersable in water due to its hydrophilic sites but not readily dissolvable in water due to its hydrophobic backbone and high molecular weight. However it is claimed that at higher concentrations (eg. 50%) a clear solution is formed.

The notified polymer contains urethane and ester linkages that could be expected to undergo hydrolysis under extreme pH conditions. However, in the environmental pH range of 4 to 9, significant hydrolysis of the urethane and ester linkages is unlikely to occur.

The partition coefficient of the notified polymer has not been determined due to its expected low water solubility, and its likely hydrophobic nature, indicative of partitioning into the octanol phase. However, it is estimated, based on the major constituent, that the notified polymer is likely to have a log Pow value of approximately 3.

No adsorption/desorption tests were conducted. The notified polymer is expected to be relatively immobile in soil due to its high molecular weight and expected low water solubility. The notified polymer is not expected to dissociate.

The notified polymer contains pendant acrylate groups that are classified as reactive functional groups of high concern. Polymerisation of such groups may occur by the action of heat, UV or ionising radiation or by free radical producing initiators, leading to thermal decomposition with the liberation of irritant vapours. Contact with alkalis and strong oxidants should also be avoided. However, the MSDS indicates that a phenolic inhibitor has been added to the notified polymer to limit polymerisation.

4. PURITY OF THE CHEMICAL

Degree of Purity: > 99%

Hazardous Impurities: The notified polymer contains a large quantity of unreacted acrylate esters (10-20%) which are regarded as skin, eye and respiratory irritants (R36/37/38).

Non-hazardous Impurities

(> 1% by weight): None

Additives/Adjuvants: None

5. USE, VOLUME AND FORMULATION

The notified polymer will be imported as a 100% polymer solution and used in the manufacture of UV screen printing inks. The concentration of the polymer in the finished ink will be < 20%. The inks will be used on paper, cardboard and other materials used for indoor advertising.

The notified polymer will be imported in 200 L steel drums at the rate of 2 tonnes per annum in the first year rising to 6 tonnes per annum by the fifth year.

6. OCCUPATIONAL EXPOSURE

Import and Transport

The notified polymer will be imported in 200L steel drums and transported by road to a single site for storage and reformulation. Six to eight personnel working 1-2 hours/day for 50 days/year will handle containers of polymer and formulated ink. Because the containers will remain unopened prior to reformulation and then prior to use at printers, exposure of waterside workers, drivers and warehouse workers to the notified polymer during storage and transport would only be envisaged following accidental puncture of import drums of polymer and drums or pails of formulated ink.

Ink Manufacture

Three quality control technicians working 2-3 hours/day for 24 days/year will open import drums manually and pour the notified polymer into exhaust ventilated 500L blending pots. Following the addition of other components such as pigments, initiators and monomers, the ink mix will be blended automatically at ambient temperature and then pumped via closed transfer lines into either 200L steel drums or 10 kg plastic pails. Following storage, the ink will then be transported by road to print customers.

Skin and eye contact may occur when handling the notified polymer and ink. Also, aerosols may be formed when pouring the notified polymer into the mixer. However, inhalation exposure is minimised as local exhaust ventilation is fitted to areas of potential aerosol formation, eg. mixing pots.

Technicians will also sample imported polymer and formulated ink for quality analysis and thus may experience dermal or ocular exposure to the neat or diluted (< 20%) polymer via slops and spills. Protective clothing, gloves and goggles/face shield are worn by workers during manufacture of the screen inks.

End-use (Printing)

Printers working normal 8 hour days for 100-150 days/year will open drums or pails of ink and manually pour the ink onto open print screens which are then recharged 4 times per hour during a print run. Printers will also wash screens with cleaning fluid. Skin and eye exposure

to the notified polymer may occur from slops and spills during the recharging and cleaning of print screens and the disposal of ink wash. In a similar fashion to formulation workers, printers are expected to wear protective clothing, gloves and safety glasses that will control dermal and ocular exposure.

The pouring of the inks containing the notified polymer onto screens of large surface area may predispose to aerosol or vapour formation. Also, volatile components of the notified polymer may be liberated during the UV curing process which immediately follows screen printing. At the end of the process, no uncured polymer is left. Licenced waste contractors may also be exposed to the notified polymer when collecting waste polymer and inks and used containers.

7. PUBLIC EXPOSURE

The notified polymer and products containing the notified polymer are not available for sale to the general public. The potential for public exposure to the notified chemical during transport, reformulation or disposal is likely to be negligible. Although the public may on occasion make dermal contact with the cured, dried form of ink containing the notified polymer when handling printed advertising material, public exposure is expected to be low.

8. ENVIRONMENTAL EXPOSURE

8.1 Release

The notifier estimates 0.5 % of the notifier polymer's yearly import volume will be lost to landfill as residues in used import drums and in cleaning fluids from the ink manufacturing process. Used import drums and pails will also be disposed of in landfill by licensed waste disposal contractors. Any ink spills will be taken up by absorbent material and disposed of to licensed waste landfill site. It is estimated that approximately 30 kg of the notified polymer will be lost in this manner. There will be no release to the sewer.

Uncured ink from the printing process will be gathered along with screen cleaning residues and passed on a licensed waste disposal contractor for incineration. It is estimated that between 80 and 120 kg/annum of the notified polymer will be disposed of from the printing process by the fifth year. The notifier acknowledges that some accidental spillage may also occur during this process and estimates that less than 1% or less than 60 kg of the notified polymer will be lost in this manner. These spills will be taken up by absorbent material and disposed of in a licensed waste landfill site.

The ultimate fate of the printed advertising material will be disposal in landfill. It is unlikely that any of the advertising material will be recycled as the inks of which the notified polymer is a component are not recommended for deinking processes.

8.2 Fate

The majority of the notified polymer will be incorporated in printed advertising material. However, prior to leaving the printers, the advertising material is irradiated with UV light which promotes the pendant acrylate groups on the notified polymer to undergo a free radical

polymerisation process to form a high molecular weight, crosslinked polymer. Therefore, once incorporated into the printed material, the notified polymer is expected to be immobile and pose little risk to the environment.

The wastes containing the notified polymer generated during the manufacture process and from spills will go to landfill. The notified expects the polymer to have relatively low water solubility and a log partition coefficient of approximately 3, which suggests that in landfill, the notified polymer will associate with the soil matrix and not leach into the aquatic environment.

Liquid wastes containing the notified polymer will be incinerated by licensed waste disposal contractors and are expected to produce water vapour and oxides of nitrogen and carbon.

The polymer is not expected to cross biological membranes, due to its high molecular weight and low water solubility, and as such should not bioaccumulate (Connell, 1990).

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

A single skin irritation test was provided for Actilane SP061.

<i>Test</i>	<i>Species</i>	<i>Outcome</i>	<i>Reference</i>
skin irritation	rabbit	Non-irritant	Liggett, 1992

9.1.1 Skin Irritation (Liggett, 1992)

<i>Species/strain:</i>	Rabbits, New Zealand White
<i>Number/sex of animals:</i>	2 males, 4 females
<i>Observation period:</i>	72 hours
<i>Method of administration:</i>	0.5 ml of test substance applied under gauze pads to shaved, intact and abraded skin in the dorso-lumbar region and held under waterproof strapping for 24 hours.
<i>Test method:</i>	OECD TG 404

Draize scores:

<i>Time after treatment</i>	<i>Animal #</i>					
	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>	<i>6</i>
<i>Erythema</i>						
24 hours	0 ^a	0	0	0	0	0

72 hours	0	0	0	0	0	0
<i>Oedema</i>						
24 hours	0	0	0	0	0	0
72 hours	0	0	0	0	0	0

^a see Attachment 1 for Draize scales

Comment: No dermal responses to treatment were observed in any animal throughout the observation period.

Result: The notified chemical was not irritating to the skin of rabbits.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

No ecotoxicological data were provided.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The majority of the notified polymer will be incorporated into a high molecular weight and stable print formulation. Prior to leaving the printers, the advertising material is irradiated with UV light which promotes a free radical polymerisation process to form a high molecular weight, crosslinked polymer. Therefore, once incorporated into the printed material, the notified polymer is expected to be immobile and pose little risk to the environment.

Waste containing the notified polymer will be disposed of to landfill, where it is expected that the polymer would associate with the soil matrix and not leach because of its expected low water solubility. The majority of wastes containing the notified polymer such as those from unused ink blend and cleaning will be incinerated producing water vapour and oxides of carbon and nitrogen.

The notified polymer is not expected to cross biological membranes due to its high molecular weight and predicted low water solubility and as such should not bioaccumulate.

The low environmental exposure of the notified polymer as a result of the proposed use indicates the overall environmental hazard should be low.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Hazard Assessment

No toxicological data other than a skin irritation study were submitted for the notified polymer. This submitted study shows that the polymer is not a skin irritant in rabbits. The polymer has a NAMW > 1000 and so absorption across biological membranes would be expected to be restricted. However, the notified polymer contains approximately 30% of species with MW < 1000 and the MSDS warns of possible irritation to skin, eyes and the

respiratory system and the tendency of acrylates to cause skin sensitisation. On this basis of known adverse effects of acrylates and in the absence of a full set of toxicity data, the notified polymer carries a hazardous classification in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999b) with the assigned risk phrases R36/37/38 – Irritating to Eyes, Respiratory System and Skin.

The notified polymer is susceptible to further polymerisation in the presence of heat, UV or ionising radiation or other initiators. The commercial form of the polymer carries a phenolic inhibitor to reduce this reactivity risk.

Occupational Health and Safety

For formulation workers, skin and eye irritant effects are possible from slops and spills during opening and decanting of imported containers of neat polymer and formulated inks containing < 20% polymer. Similar effects are also possible during quality analysis sampling of imported polymer solution and the formulated inks. Inhalation exposure may occur also. The polymer contains unreacted acrylate esters and if inhalation exposure occurs, respiratory irritation may occur. Engineering controls consisting of exhaust ventilation fitted to points of potential aerosol formation, eg mixing pots will reduce this risk of respiratory irritation.

Printers have recourse to handle the diluted notified polymer in formulated inks and dermal and ocular irritation are possible also for these workers when recharging and cleaning print screens. Inhalation exposure to irritant vapours may also occur if engineering controls such as local exhaust ventilation are not in place. Once the ink is UV-cured, the potential for exposure to the notified polymer is negligible.

Exposure to the notified polymer during import and transport would only be envisaged following accidental puncture of steel drums of imported neat polymer or steel drums or plastic pails of formulated inks. For workers involved in these activities, despite the possibility of irritation upon acute exposure to the polymer, the health risk would be assessed as low.

Because of the possibility of irritation following acute exposure and sensitisation following repeated exposure, it is important that exposure to the notified polymer be controlled during ink manufacture. Together with suitable engineering controls, personal protective equipment consisting of impervious clothing, gloves and eye protection should be worn during use of the polymer. Due to the risk of irritant effects during screen printing, printers who use inks containing the notified polymer should similarly protect against dermal and ocular exposure by using impervious clothing, gloves and eye protection.

Public Health

The risk to public health from the notified polymer is likely to be very low because exposure is likely to be very brief and infrequent and given potential exposure only to cured inks, the notified chemical is unlikely to be bioavailable.

13. RECOMMENDATIONS

Regulatory controls

Labelling

Suppliers should label the notified polymer with the signal word “Hazardous” and the following risk and safety phrases:

R36/37/38	Irritating to Eyes, Respiratory System and Skin
S15	Keep Away From Heat

Control measures (for manufacturer/formulator/end-user)

OHS

To minimise occupational exposure to the notified polymer:

- Local exhaust ventilation should be provided in areas where inhalation exposure may occur;
- Avoid generation of aerosols when handling eg. during decanting from drums.

Employees should wear the following personal protective equipment to minimise occupational exposure to the notified polymer:

- Polyethylene or polypropylene protective eyewear, industrial clothing and footwear and gloves. Protective equipment based on PVC and rubber are not recommended as absorption of the notified polymer may occur.
- A negative pressure organic vapour respirator should be used where engineering controls and work practices do not reduce aerosols and/or vapour to less than 2 ppm or 5.9 mg/m³ (exposure standard for acrylic acid (NOHSC 1995)).

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).

Environmental

The following precautions should be taken regarding storage of the notified chemical:

- Storage should occur between 5 and 25°C.
- Storage containers must not be completely filled. In order to ensure inhibition of polymerisation, air should not be excluded from the containers.

Spills/release of the notified chemical should be handled by absorption into sand, earth or a dry material.

Secondary notification

If the notifier or any other importer or manufacturer of the notified chemical becomes aware of any circumstances listed in subsection 64(2) of the Act, they must notify the Director in writing within 28 days. The Director will then decide whether secondary notification is required.

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

If products and mixtures containing [the notified chemical] are classified as hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 1999b) then workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

14. MATERIAL SAFETY DATA SHEET

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

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

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the Act, the director must be informed if any of the circumstances stipulated under subsection 64(2) of the Act arise, and secondary notification of the notified chemical may be required. No other specific conditions are prescribed.

16. REFERENCES

Connell D W (1990) General characteristics of organic compounds which exhibit bioaccumulation. In Connell D. W., (Ed) *Bioaccumulation of Xenobiotic Compounds*. CRC Press, Boca Raton, USA.

Liggett MP (1992) Photomer 7086. Skin irritation to the rabbit. Huntington Research Centre Ltd., Huntington, Cambridgeshire, UK.

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National Occupational Health and Safety Commission (1995) *Adopted National Exposure Standards for Atmospheric Contaminants in the Occupational Environment*, [NOHSC:1003(1995)]. In: *Exposure Standards for Atmospheric Contaminants in the Occupational Environment: Guidance Note and National Exposure Standards*. Australian Government Publishing Service, Canberra.

National Occupational Health and Safety Commission (1999a) List of Designated Hazardous Substances [NOHSC:10005(1999)]. Australian Government Publishing Service, Canberra.

National Occupational Health and Safety Commission (1999b) Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(1994)]. Australian Government Publishing Service, Canberra.

Standards Australia (1990) Australian Standard 3765.2-1990, Clothing for Protection against Hazardous Chemicals Part 2 Limited protection against specific chemicals. Standards Association of Australia.

Standards Australia (1994) Australian Standard 1336-1994, Eye protection in the Industrial Environment. Standards Association of Australia.

Standards Australia/Standards New Zealand (1992) Australian/New Zealand Standard 1337-1992, Eye Protectors for Industrial Applications. Standards Association of Australia/Standards Association of New Zealand.

Standards Australia/Standards New Zealand (1994a) Australian/New Zealand Standard 2210-1994, Occupational Protective Footwear. Standards Association of Australia/Standards Association of New Zealand.

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

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.