

File No. NA/616
August 1998

**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION
AND ASSESSMENT SCHEME**

FULL PUBLIC REPORT

Polymer in Liquitint Violet LS

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 (NIGNAS) 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 Family Services.

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3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	a viscous dark purple liquid (Liquitint Violet LS)
Boiling Point/Melting Point:	not measured
Specific Gravity:	approx. 1.2 (calculated result) for Liquitint Violet LS = 1.08 (measured)
Vapour Pressure:	not determined but expected to be low (see comments below)
Water Solubility:	soluble (see comments below)
Partition Co-efficient (n-octanol/water):	$\log P_{ow} = 0.611$ (Liquitint Violet LS)
Hydrolysis as a Function of pH:	of Liquitint Violet LS: $T_{1/2} = 114$ days (pH 9.0, 20°C) $T_{1/2} = 10$ days (pH 9.0, 40°C) $T_{1/2} > 5$ days (pH 4 and 7, 50°C) therefore $T_{1/2} > 1$ year (pH 4 and 7, 20°C)
Adsorption/Desorption:	not determined (see comments below)
Dissociation Constant:	not determined (see comments below)
Flash Point:	260°C
Flammability Limits:	not determined
Autoignition Temperature:	not determined
Explosive Properties:	stable
Reactivity/Stability:	the polymer and the product are not reactive, however, the polymer is organic in nature and may react in contact with oxidising agents

Comments on Physico-Chemical Properties

The polymer's vapour pressure, water solubility, adsorption/desorption and dissociation constant have not been determined. The vapour pressure is expected to be low due to its relatively high molecular weight.

The polymer is highly water soluble and the product Liquitint Violet LS is a 40% solution of the polymer in water. Solubilities as high as 442 mg.L⁻¹ were tested in the fish toxicity study (Geger & Bucksath, 1996). The notified polymer is a charged salt with quaternary ammonium functionality, and is expected to completely dissociate under environmental conditions.

As Liquitint Violet LS is coloured, hydrolysis was monitored by the absorption of a solution of the material, as measured by spectrophotometry. Preliminary testing, performed at 50°C, indicated a T_{1/2} greater than 1 year at 20°C for pH 4.0 and 7.0. Further testing was carried out to determine the half-life at pH 9.0. These results indicate the polymer is stable at the lower pH, but slowly hydrolysed under more alkaline conditions.

The octanol-water partition coefficient of Liquitint Violet LS was calculated according to liquid chromatography ASTM (American Society for Testing and Materials) method E1 147-92 under the guidance and conditions of OECD test guideline 117. Due to its expected high water solubility and delocalised charge, the polymer would not normally be expected to adsorb to soil. However, quaternary ammoniums are known to react with dissolved organic carbon in water to form part of the sediments, and become completely inactivated on contact with soils (Nabholz et al., 1993).

4. PURITY OF THE CHEMICAL

Degree of Purity: high

Hazardous Impurities: none

5. USE, VOLUME AND FORMULATION

The notified polymer will not be manufactured in Australia. It will be imported in 18 kg high density polyethylene drums as the aqueous product Liquitint Violet LS containing 40% of the notified polymer. The product will be warehoused at the notifier's site and supplied to laundry detergent manufacturers throughout Australia. The volumes of the

notified polymer imported will be less than 500 kg during year 1 to 3 and 1 000 kg in year 4 and 5.

The notified polymer is a colourant for use in household soaps and detergents, typically laundry detergents, fabric softeners and cleaning solutions. It is an inert additive that is expected to replace powdered dyestuffs, and is designed to provide bright colouration without chemically affecting the material being coloured. Concentration of the notified polymer in final products will be between 100 and 500 ppm, although the notifier indicated that the polymer could be used in these products at up to 5000 ppm. The polymer has been used in these applications in the USA, Canada and Europe.

At the formulation sites, either automatic or manual methods will be used to manufacture laundry detergents.

At the sites where those product formulators have automated systems, the drum is lanced and the colourant then transferred to storage tanks, with subsequent blending and filling accomplished by full automated systems. The blending process involves the simple addition of surfactants and other ingredients (including colourant) in an aqueous medium in a closed blending vessel. The final products will be supplied to the domestic market in 1 and 2 L polyethylene bottles.

Where tasks are undertaken manually at formulation sites, workers will open the containers, measure out the colorant, add it to the blending tank and fill the final product into containers.

The final concentrations of the notified polymer in the products and the product packaging size will be the same as that from the automatic formulation method.

6. OCCUPATIONAL EXPOSURE

The vapour pressure of the notified polymer is expected to be very low due to its high molecular weight and the form (aqueous solution) in which it is presented. Thus, inhalation exposure is considered to be negligible and dermal contamination would be the main route of occupational exposure. As splashing may occur while handling the notified polymer, eye exposure would be possible.

Workers are unlikely to be exposed to the notified chemical during the blending process if it is enclosed, as there should be little release during the transfer and mixing operations. During the automated filling process, there may be worker exposure if overfilling of the containers occurs. Dermal exposure may also occur during equipment cleaning and maintenance. The notifier stated that workers at the automatic formulation sites will wear cotton overalls, PVC/latex gloves, safety helmets, glasses and boots/shoes.

There will be up to 10 blending operators performing manual blending with an estimated potential exposure of 8 hours per day on 50 days per year. Skin contamination with the notified chemical may occur at manually—operated formulation sites during the transfer, mixing and filling operations. Eye contamination is also possible due to splashing. The notifier stated that workers will wear overalls, gloves, helmets, safety glasses and footwear.

As transport and warehouse workers will handle only the sealed product, the occupational exposure for these workers is considered to be negligible unless an accident occurs.

7. PUBLIC EXPOSURE

There may be widespread public exposure to the notified polymer in domestic laundry products sold directly to the public. The notified polymer will be released into the environment when the domestic laundry products are disposed of or recycled. It does not significantly hydrolyse across the pH range (4-7) but there is evidence of slow hydrolysis occurring at pH 9 ($T_{1/2}$ = 114 days). The polymer is used at very low levels (typically 100 - 500 ppm), has a high molecular weight (and therefore does not readily cross biological membranes) and is highly water soluble and easily washed from the skin and clothing.

8. ENVIRONMENTAL EXPOSURE

Release

The notifier anticipates little or no release of the notified substance during product manufacture. As industry practice is not to clean equipment between product batches, residues in blending vessels effectively become part of the next product batch. Colourant containers will be rinsed before disposal in landfill, with the rinsate added to the product being formulated. Should a spill occur, the product will be washed to a trade waste sewer with copious volumes of water.

The notified substance is used to colour domestic laundry products. As such, it will be almost entirely released to the sewer after use. Product containers will be either recycled or sent to landfill with other household garbage.

Fate

Polymer discharged to sewer is expected to rapidly react with the dissolved organic carbon (DOC) in the water column, forming an insoluble flocculent that should be removed with the sludge (Nabholz et al., 1993). The sludge will either be sent to landfill or incinerated. Incineration products will include water vapour, oxides of

carbon and nitrogen, together with chloride salts in the ash.

Polymer disposed of to landfill should be contained, quickly becoming immobile by absorbing to soil.

The inherent biodegradability of the product Liquitint Violet LS was determined according to OECD Test Guideline 302B (Modified Zahn-Wellens Test) (Lebertz, 1993). Under the conditions of the test, 25% of the material was degraded within 42 days calculated on the basis of DOC elimination, indicating an “inherent biodegradability”, of the material. The test was prolonged as at 28 days an increase in degradation was measured. However, no further degradation was observed after day 28, through to day 42. There is no indication in the report if the material inhibited the activity of the inoculum in the test medium.

9. EVALUATION OF TOXICOLOGICAL DATA

Toxicity data was provided for Violet PPO3, a polymer (sulfate instead of chloride salt) closely related to the notified polymer in the submission. This data was accepted as surrogate data for the notified polymer.

9.1 Acute Toxicity

Summary of the acute toxicity of Violet PPO3.

<i>Test</i>	<i>Species</i>	<i>Outcome</i>	<i>Reference</i>
acute oral toxicity	rat	LD ₅₀ > 5 000 mg.kg ⁻¹	(Lemen, 1987a)
skin irritation	rabbits	slightly irritating	(Lemen, 1987b)
eye irritation	rabbit	non-irritating	(Lemen, 1987c)

9.1.1 Oral Toxicity. (ref) (Lemen, 1987a)

<i>Number/sex of animals.</i>	5/sex
<i>Observation period.</i>	14 days
<i>Method of administration:</i>	oral (gavage), vehicle: distilled water
<i>Clinical observations.</i>	coloured urine and faeces
<i>Mortality.</i>	None
<i>Morphological findings:</i>	no gross lesions

<i>Test method.</i>	limit test, similar to OECD TG 401 (Organisation for Economic Co-operation and Development, 1995 1996)
<i>LD₅₀:</i>	> 5 000 mg/kg
<i>Result.</i>	Violet PP03 was of low acute oral toxicity in rats

9.1.2 Skin Irritation (Ref) (Lemen, 1987b)

<i>Species/strain.</i>	rabbit/New Zealand White
<i>Number/sex of animals.</i>	6 males
<i>Observation period.</i>	72 hours
<i>Method of administration.</i>	Violet PPO3 (0.5 mL) was applied to intact and abraded skin for 24 hours

Draize scores (Draize, 1959)

<i>Time after treatment (days,)</i>	<i>Animals</i>					
	<i>Intact Skin #</i>			<i>Abraded Skin #</i>		
	1	2	3	1	2	3
Erythema						
1	0 ^a	0	0	1	1	0
2	0	0	0	1	0	0
3	1	0	0	1	0	0
4	1	0	0	1	0	0
5	0	0	0	1	0	0
6	1	0	0	1	1	0

^a see attachment 1 for Draize scales

<i>Clinical Observation:</i>	Draize scales of oedema were zero for all rabbits during days 1 to 3
<i>Test method.</i>	similar to OECD TG 404 (Organisation for Economic Co-operation and Development, 1995-1996)
<i>Result:</i>	Violet PP03 was slightly irritating to the skin of rabbits

9.1.3 Eye Irritation (Lemen, 1987c)

<i>Species/strain.</i>	rabbit/New Zealand White
<i>Number/sex of animals.</i>	6 males
<i>Observation period:</i>	72 hours
<i>Method of administration.</i>	Violet PPO3 (0.1 mL) was applied in the everted lower lid of the left eye, with the right eye serving as the untreated control; the treated eyes were not washed
<i>Draize scores (Draize, 1959).</i>	Draize scales for cornea and iris were zero for all the animals during study; the scales for conjunctivae were zero for redness, chemosis and discharge except for one rabbit had a score of 1 for redness at 24 hours
<i>Test method:</i>	similar to OECD TG 405 (Organisation for Economic Co-operation and Development, 1995-1996)
<i>Result.</i>	Violet PPO3 was not irritating to the eyes of rabbits

9.2 Overall Assessment of Toxicological Data

Violet PPO3, a closely related polymer and accepted as a surrogate for the notified polymer, was of low acute oral toxicity in rats (LD₅₀ greater than 5 000 mg/kg). It was a slight skin irritant but not an eye irritant in rabbits.

Based on the available data, Polymer in Liquitint Violet LS cannot be classified as hazardous according to NOHSC *Approved Criteria for Classifying Hazardous Substances* (National Occupational Health and Safety Commission, 1994a).

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The notifier provided the following ecotoxicity studies.

Both studies were performed according to US EPA test methods and Good Laboratory Practice Standards. All results are based on mean measured concentrations, with measured values indicating that the test solutions were stable in the test systems under the test conditions.

Test	Species	Results (95% conf. limits)	Reference
Acute Toxicity ^a 96 hour Flow through US EPA 797.1400	Rainbow trout (<i>Oncorhynchus mykiss</i>)	LC ₅₀ = 390 mg/L (217-442 mg/L) NOEC = 109 mg/L	(Geger & Bucksath, 1996)
Growth Inhibition ^b 96 hour Static US EPA 797.1050	Algae (<i>Selenastrum capricornutum</i>)	EC ₅₀ = 1.7 mg/L (1.5-1.9 mg/L) NOEC = 0.45 mg/L	(Ziegler & Bucksath, 1996)

a) Mean measured concentrations were control, 33.0, 63.6, 109, 217 and 442 mg/L

b) Mean measured concentrations were control, 0.12, 0.24, 0.45, 0.87, 1.8 and 3.7 mg/L

Fish

The mean-measured concentrations represented 96±9.2% of the nominal test concentrations. The controls were clear throughout the test, while all the test concentrations were a dark blue colour and increased in darkness with concentration. All test chambers were free of precipitate and surface film during the study.

Due to the concentration of the dye in the test chambers it was not possible to observe the fish. Therefore, fish were randomly netted and held near the surface to determine behaviour. For this reason, accurate biological observations of sublethal effects could not be made until the end of the study when fish were placed in clear water.

At concentrations up to and including 109 mg/L, all fish were assumed normal throughout the test and found to be normal at 96 hours, except one fish at 33.0 mg/L and 96 hours which displayed a loss of equilibrium. Effects after 48 hours were noted in test concentrations higher than 109 mg/L. At 271 mg/L, 7 fish were observed surfacing and displaying laboured respiration. However, at 96 hours all fish bar one (which displayed dark discolouration) were found to be normal in this test concentration.

Fish deaths were only observed in the 442 mg/L test concentration (maximum concentration tested), with 6 at 72 hours and another 7 at 96 hours (cumulative total of 13). Only one fish

was observed as normal at 96 hours, with the remaining six displaying surfacing behaviour, loss of equilibrium and/or quiescence.

Daphnia

A daphnid study was not supplied. Nabholz, *et al.* (1993) claim that water soluble, cationic (quaternary ammonium) polymers with molecular weights > 1 000 are of concern. These polymers react with biological membranes. While algae are assumed to be the most sensitive species during acute exposures, fish and aquatic invertebrates are more sensitive during chronic exposure (Nabholz *et al.*, 1993).

However, it is also understood that dissolved organic carbon (DOG) binds with cationic polymers of NAMW > 1 000 with low molecular weight species <10% <500 and <25% <1 000. This neutralises the positive charges, making the cationic chemical less toxic and less bioavailable, i.e. the toxicity is highly mitigated by the presence of DOG (Nabholz *et al.*, 1993). Therefore, while initial considerations indicate that the polymer will be highly toxic to daphnids, actual toxicity without test data is difficult to determine.

Algae

The mean-measured concentrations represented $91 \pm 3.1\%$ of the nominal test concentrations. The 0.45, 0.87, 1.8 and 3.7 mg/L test solutions were observed to be purple in colour with no visible precipitate, with colour intensity increasing with the increase in test concentrations. The 0.12 and 0.24 mg/L test solutions, and control were observed not to have a purple colour.

Cell counts were conducted at 24, 48, 72 and 96 hours for each replicate of the control and each test concentration. The multiple means test showed a significant inhibition effect ($p < 0.05$) on growth in the 0.87, 1.8 and 3.7 mg/L test concentrations as compared to the control. The 96 hour BC_{10} and BC_{90} were calculated to be 0.30 mg/L (95% confidence limits = 0.19 and 0.41 mg/L) and greater than 3.7 mg/L, respectively.

As the test material is a dye and all solutions above 0.24 mg/L were purple in colour, a primary factor in the inhibition of the growth of the algae is the reduction of available light. The notifier has not performed a modified growth inhibition test to differentiate between a reduced growth of algae due to real toxic effects of the notified polymer on the algal cells, or due to an indirect effect, a reduced algal growth by light absorption in coloured test solutions. As deleterious effects can be caused by the interception of light (shading effect) necessary for algal growth, the authors claim that the toxicity observed may have been due to physical factors rather than chemical. However, it should be noted that for environmental purposes, growth inhibition, whether due to chemical or physical factors, is still of relevance. Algistatic effects may still lead to an undesirable environmental impact if exposure is continuous.

Summary

The ecotoxicity data for the notified polymer indicates that it is practically non-toxic to fish moderately to highly toxic to algae. It is unclear how toxic the polymer will be to aquatic invertebrates. However, it may exhibit significant toxicity towards these species.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

It is expected that the polymer will have wide distribution in the aquatic environment because of its use as a component of household soaps and detergents. As the product will be used throughout Australia and sent to sewage treatment plants in both city and country locations, a predicted environmental concentration (PEC) based on continental use has been calculated:

Import Volume	1 000 kg
Amount discharged to sewer	100%
Volume discharged per day	2.74 kg (1 000 kg/365 days)
Sewer output per day *	2 700 ML
Concentration in Sewage Treatment Plant	1.01 µg/L (ppb)

*Sewer output based on an Australian population of 18 million, each using 150 L water per day.

If this scenario was limited to Melbourne, with a population greater than 3 million and 500 ML of waste water treated per day, the PEC would be about 5.50 ppb (safety factor of 310 for EC₅₀ of most sensitive aquatic organism tested, *Selenastrum capricornutum*). Both PECs are prior to any removal through adsorption to sludge in the sewage treatment process (expected to be significant) or further dilution in receiving waters.

The minor amount remaining as residues in product containers after use should be confined to landfill. Any leaking polymer will be rapidly and completely adsorbed to soil, where it should undergo slow biodegradation.

The notified chemical is not likely to present a hazard to the environment when it is stored, transported and used in the typical manner.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Based on the available data, the notified polymer is of low acute toxicity, slightly irritating to the skin but not irritating to the eyes. No information is available on its long term effects. Based on the available data, the notified polymer would not be classified as a hazardous substance. Unreacted monomers are low in concentration, with a maximum of 2% total, so they are unlikely to contribute to the overall health risk resulting from exposure to the polymer.

Skin contamination is the most likely form of exposure to the notified polymer, but it is unlikely to be absorbed through the skin because of its high molecular weight. Inhalation exposure is expected to be low as the notified polymer has a low vapour pressure and will

only be handled as an aqueous solution.

The health risk to workers during formulation is expected to be low as the transfer and mixing processes at most sites are enclosed and the filling process is usually automated. Also, the workers are provided with personal protective equipment to enable them to minimise exposure. Therefore adverse health effects are likely to be confined to possible skin irritation resulting from skin contamination experienced during maintenance or the handling of spills during the transfer or filling operations. Where formulation and filling of containers is less automated, the risk of skin contamination and subsequent skin irritation will be greater.

The health risk for transport and warehouse workers handling products containing the notified polymer is expected to be negligible unless the packaging is breached, for example during accidents.

The notifier states that water soluble dyes, which are very similar chemically to the notified polymer, have been used in the industry for years without adverse effect on human health or the environment. Based on the very low levels of the notified polymer present in the products, the high molecular weight, and the toxicological characteristics of a closely related polymer, it is considered that the notified polymer will not pose a significant hazard to public health.

13. MATERIAL SAFETY DATA SHEET

The MSDS for Liquitint Violet LS containing the notified chemical was prepared in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (National Occupational Health and Safety Commission, 1 994b). The possible skin irritant effects of the notified chemical should be added.

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.

14. RECOMMENDATIONS

To minimise occupational exposure to the polymer in Liquitint Violet LS the following guidelines and precautions should be observed:

- Safety goggles should be selected and fitted in accordance with Australian Standard (AS) 1336 (Standards Australia, 1994) to comply with Australian/New Zealand

- Standard (ASfNZS) 1337 (Standards Australia/Standards New Zealand, 1992);
- Industrial clothing should conform to the specifications detailed in AS 2919 (Standards Australia, 1987) and AS 3765.1 (Standards Australia, 1990);
- Impermeable gloves or mittens should conform to AS 2161.2 (Standards Australia/Standards New Zealand, 1998);
- All occupational footwear should conform to AS/NZS 2210 (Standards Australia/Standards New Zealand, 1994);
- Spillage of the notified chemical should be avoided, spillages should be cleaned up promptly with absorbents which should then be put into containers for disposal;
- Good personal hygiene should be practised to minimise the potential for ingestion;
- A copy of the MSDS should be easily accessible to employees

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the Act, secondary notification of the notified chemical shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise.

The notifier is required to supply a daphnia acute toxicity test result and report if annual import quantities are to rise above one tonne or if uses are proposed where much more concentrated releases to the aquatic compartment are likely.

16. REFERENCES

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Standards Australia/Standards New Zealand (1998) AS/NZS 2161.2:1998 Occupational protective gloves, Part 2: General requirements, Standards Australia/Standards New Zealand.

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Attachment 1

The Draize Scale for evaluation of skin reactions is as follows:

<i>Erythema Formation</i>	<i>Rating</i>	<i>Cedema Formation</i>	<i>Rating</i>
No erythema	0	No oedema	0
Very slight erythema (barely perceptible)	1	Very slight oedema (barely perceptible)	
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 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)	
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>Chemiosis</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.
		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

<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