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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

PHOTOPIA BLUE AQ-T/LYB421

This Assessment has been compiled in accordance with the provisions of *the Industrial Chemicals (Notification and Assessment) Act 1989, as amended* and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by Worksafe Australia which also conducts the occupational health & safety assessment. The assessment of environmental hazard is conducted by the Department of the Environment, Sport, and Territories and the assessment of public health is conducted by the Department of Health, Housing, Local Government and Community Services.

For the purposes of subsection 78(1) of the Act, copies of this full public report may be inspected by the public at the Library, Worksafe Australia, 92-94 Parramatta Road, Camperdown NSW 2050, between the hours of 10.00 a.m. and 12.00 noon and 2.00 p.m. and 4.00 p.m. each week day except on public holidays.

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

Photopia Purple AQ-R/WPL404

1. APPLICANT

Bonds, 56 Jones Street, Wentworthville NSW 2145

2. IDENTITY OF THE CHEMICAL

Based on the nature of the chemical and the data provided, Photopia Blue AQ-T/LYB421 is not considered to be hazardous. Therefore the details of chemical name, molecular and structural formula, CAS number, spectral data, molecular weight, purity, impurities and volume of import have been exempted from publication in the Full Public Report and the Summary Report.

Trade name: Photopia Blue AQ-T/LYB421

Method of detection and determination:

Separation and structure elucidation was by ultra-violet, infrared, nuclear magnetic resonance and mass spectroscopy, and high performance liquid chromatography.
Data were consistent with the structure of the notified chemical.

3. PHYSICAL AND CHEMICAL PROPERTIES (1)

Appearance at 20°C and 101.3 kPa: Yellow powder

Odour: Odourless

Melting Point/Boiling Point: Decomposes prior to melting and boiling even at reduced pressure.

Density: 1300.4 kg/m^3 at 24°C

Vapour Pressure: 7.0×10^{-6} Pa at 25°C

Water Solubility: $< 2 \times 10^{-4}$ g/L at 20°C

Fat Solubility:	43.7mg/100g at 37°C
Partition Co-efficient (n-octanol/water) log $P_{O/W}$:	> 6.2 at 20°C
Hydrolysis as a function of pH:	Not provided
Adsorption/Desorption:	Not provided
Dissociation Constant	Not provided
Flash Point:	Not applicable
Flammability Limits:	Not flammable
Combustion Products:	Oxides of carbon
Pyrolysis Products:	Not provided
Decomposition Temperature:	Below 252°C
Decomposition Products:	Not provided
Autoignition Temperature:	Did not show autoignition below the temperature range in which it thermally decomposes.
Explosive Properties:	Did not explode as a result of impact, friction, or flame.
Reactivity/Stability:	Does not have any oxidizing properties.
Particle size distribution:	Virtually all of the material has a particle size greater than 45 µm although most of the fraction below this value is below 10µm.

The substance was not soluble in water under the conditions of the test applied. Therefore solubility tests could not be conducted. The value given is the limit of detection by spectrophotometry. This is acceptable.

Hydrolysis tests were not conducted due to the low solubility in water and the absence of hydrolysable groups in the structure. This is acceptable.

Adsorption/desorption tests were not performed, as the substance is virtually insoluble in 0.01 M Ca Cl_2 solution, and therefore there is no suitable study method. This is acceptable. Relatively strong adsorption to the soil may be expected.

4. PURITY OF THE CHEMICAL

Additives/Adjuvants: None

5. INDUSTRIAL USE

Photopia Blue AQ-T/LYB421 is a photochromic dye that will be imported for use in the textile industry. It will be imported into Australia as a 1% component of a formulated paste known as Photopia Aqualite Ink. During use Photopia Aqualite Ink will make up 20% weight/fabric weight of a mixture which will dye fabrics. No reformulation will take place.

6. OCCUPATIONAL EXPOSURE

Photopia Blue AQ-T/LYB421 will be imported into Australia as a 1 % w/w constituent of a formulated product known as Photopia Aqualite Ink. The ink will be imported and transported in paper cartons of 20 kg net which have been packed in 100 kg iron drums. These will be repackaged on arrival in Australia. Contact during storage and transportation of the chemical is expected to be negligible.

The dyeing process involves 2-3 workers per factory at factories in Sydney and Wentworthville. During the dyeing process Photopia Aqualite Ink paste containing Photopia Blue AQ-T/LYB421 is measured into a container and diluted with water and other dye solvents. After mixing for 10 minutes, the solution is pumped automatically into the colouring machine. The pre-treated fabric

is added to the solution and the temperature is raised to 70°C by indirect hot water vapour. The dyeing is completed after 20-25 minutes and the process is concluded by rinsing and the addition of a softening agent.

An industrial ventilation fan is intended to be used to remove steam but significant amounts of Photopia Blue AQ-T/LYB421 will not be vaporised.

7. PUBLIC EXPOSURE

There is a low potential for public exposure to Photopia Blue AQ-T/LYB421 during manufacturing processes. The notified chemical will be in paste form, minimising the formation of dusts. Photopia Blue AQ-T/LYB421 is of low solubility in water and has a very low vapour pressure, so will not be discharged to the atmosphere during the dyeing process. Factory wastewater is to be treated with pigment precipitants, and the sedimented waste dyes are dehydrated by filter press to form a wet cake which can be disposed of by landfill or incineration. The public is therefore unlikely to be exposed to the notified chemical in effluent, recreational or drinking water.

Unfixed Photopia Blue AQ-T/LYB421 will not be available to the public. Although widespread contact will occur with the dyed fabric, by this stage the notified chemical will be irreversibly bound to the fibre, from which absorption should be negligible.

8. ENVIRONMENTAL EXPOSURE

. Release

The notifier states that the neat substance will not normally be discharged directly to the sewage system or aqueous environment. The notified substance has a fixation degree of 98.9%, when applied in the prescribed manner (but this rate may drop to 60 - 70% at 50% on the weight of fibre if conditions are varied) and is adhered by means of a fixing agent-resin (a report has been attached to support the amount of exhaustion of dye). Release of unfixed dye to the sewers should be negligible.

The dyes and pigments are disposed of at the colouring factories with the waste water which is treated in the water treatment area. This area employs a coagulation process which coagulates dyes and pigments in the water by the application of alum, for example.

The sedimented waste dyes and pigments are dehydrated by the filter press to form a wet cake. This is then transferred to the waste disposal area for disposal by landfill or incineration. Release of unfixed dye to the sewers should be negligible.

Fate

The major environmental exposure to the dye would occur through the release of unfixed dye into the effluent by textile factories using the dye. The concentration of the notified substance in textile wastewater has been estimated as 0.24 ppm (report provided). This value is slightly greater than the limit of solubility. The dye is expected to be associated with the wet cake from the water treatment process at the dyeing factories.

Incineration of the notified substance is unlikely to produce toxic compounds.

The notified substance is unlikely to leach from landfill due to its insolubility in water and high log K_{ow}. The majority of the substance will be bound to cloth and will eventually be disposed of by landfill with other domestic refuse.

- **Biodegradation**

The notified chemical attained 8% degradation at a concentration of 10 $mg.L^{-1}$ and 5% at 20 $mg.L^{-1}$ (OECD TG 301B)(2) and therefore cannot be seen as readily biodegradable.

- **Hydrolysis**

The notified chemical is unlikely to hydrolyse under environmental conditions due to its insolubility in water and the absence of hydrolysable groups in the structure.

- **Bioaccumulation**

The notified chemical has physico-chemical properties that indicate it has the potential to bioaccumulate : it is insoluble

in water, and has a log K_{ow} of > 6.2 and molecular weight of 445. However, exposure to aquatic organisms is likely to be low due to the dye's low concentration in wastewater and its expected association with the sludge at wastewater treatment plants. Therefore, bioaccumulation from the proposed use is expected to be negligible.

9. EVALUATION OF TOXICOLOGICAL DATA

Under the *Industrial Chemicals (Notification and Assessment) Act, 1989* toxicity data are not required for chemicals manufactured or imported in volumes less than 1 tonne/year. However, the following studies were provided and have been assessed.

9.1 Acute Toxicity

Table 1 Summary of the acute toxicity of Photopia Blue AQ-T/LYB421

Test	Species	Outcome	Ref
Oral	Rat	LD_{50}: > 2000 mg/kg	3
Dermal	Rat	LD_{50}: > 2000 mg/kg	4
Skin Irritaton	Rabbit	Non-irritant	5
Eye Irritation	Rabbit	Non-irritant	6
Skin sensitisation	Guinea-Pig	Non-sensitising	7

9.1.1 Oral Toxicity (Ref No:3)

This study was carried out in accordance with *OECD Guide-lines for Testing of Chemicals No: 401*.

Ten Sprague-Dawley rats (5 male and 5 female) were administered 2000 mg/kg of test substance by gavage. The animals were observed for deaths and the incidence of behavioural and clinical abnormalities 1/2, 1, 2 and 4 hours after dosing and subsequently once daily for 14 days. At the end of 14 days the animals were killed and subjected to gross pathological examination.

There were no deaths or signs of systemic toxicity noted during the study. All animals showed expected gain in bodyweight. No abnormalities were noted at necropsy.

The results of this study indicate that Photopia Blue AQ-T/LYB421 has an acute oral LD_{50} > 2000 mg/kg.

9.1.2 Dermal Toxicity (Ref No:4)

This study was carried out in accordance with *OECD Guide-lines for Testing of Chemicals No: 402*.

Ten Sprague-Dawley rats (5 male and 5 female) were administered a single dose of Photopia Blue AQ-T/LYB421 at 2000 mg/kg by semi-occlusive application to the shaved dorsal area for a period of 24 hours. The animals were observed 1/2, 1, 2 and 4 hours after dosing and subsequently once daily for 14 days prior to being killed for gross pathological examination. There were no deaths or signs of systemic toxicity during the study. Desquamation was noted at the treatment sites of four females 4 and 5 days after treatment. Small superficial scattered scabs were noted on the remaining female 4 to 6 days after treatment. No other signs of skin irritation were noted. All animals showed expected gain in bodyweight during the study. No abnormalities were noted at necropsy.

The results of this study indicate that the dermal LD_{50} for Photopia Blue AQ-T/LYB421 is > 2000 mg/kg.

9.1.3 Skin Irritation (Ref No:5)

This study was carried out in accordance with *OECD Guide-lines for Testing of Chemicals No: 404*.

A single dose of 0.5 g of Photopia Blue AQ-T/LYB421 in 0.5 ml of distilled water was administered by semi-occlusive application to the clipped back of three New Zealand White strain rabbits. The patches were applied for 4 hours. The site of application was observed 1, 24, 48, and 72 hours after removal of the patch.

Very slight erythema was observed in one animal 1 hour after removal of the dressing. All treated skin sites appeared normal 24 hours later and no oedema or necrosis was observed in any of the animals.

The results of this study indicate that Photopia Blue AQ-T/LYB421 is a non-irritant to rabbit skin.

9.1.4 Eye Irritation (Ref No:6)

This study was carried out according to *OECD Guide-lines for Testing of Chemicals No: 405*.

Three New Zealand White strain rabbits were used for the study. One hundred microlitres of Photopia Blue AQ-T/LYB421 was instilled into the conjunctival sac of three rabbits with the other eye being used as control. The eyes were examined 1, 24, 48 and 72 hours following treatment. One hour after instillation of the chemical, redness of the conjunctiva was observed in all three animals and persisted in one animal to 24 hours. No adverse corneal or iridial effects were noted during the study.

The results of this study indicate that Photopia Blue AQ-T/LYB421 is a non-irritant to the rabbit eye.

9.1.5 Skin Sensitisation (Ref No:7)

The study was carried out in accordance with the *OECD Guide-lines for testing of Chemicals No: 406*

The test used was the guinea-pig maximisation test of Magnusson and Kligman. The skin reactions were assessed according to a four point scale.

Preliminary study

To determine the dose level for intra-dermal injection in the main study, 1%, 5%, 10% or 25% w/v solutions of Photopia Blue AQ-T/LYB421 were injected into four albino Dunkin-Hartley guinea-pigs. A dose of 25% w/v was selected for intra-dermal induction in the main study as this was the highest concentration that did not cause local necrosis or ulceration.

To determine the dose level for topical induction in the main study, 2 guinea-pigs (intradermally injected with Freund's Complete Adjuvant nine days earlier) were treated with 50%, 25%, 10% and 5% w/w Photopia Blue AQ-T/LYB421 in arachis oil. The highest concentration producing only mild to moderate dermal irritation after a 48 hour occlusive application, 50% w/w, was selected for topical induction in the main study.

The dose levels selected for topical challenge in the main study were 10% and 5% w/w as these were the two highest non-irritating concentrations of Photopia Blue AQ-T/LYB421 after occlusive application to the flank.

Induction and Challenge Study

Thirty albino guinea-pigs of the Dunkin-Hartley strain (20 test and 10 control animals) were used.

Three pairs of intra-dermal injections were made into the clipped inter-scapular region of each guinea-pig. The injected solutions were: Freund's Complete Adjuvant plus distilled water in the ratio 1:1, a 25% w/v dilution of Photopia Blue AQ-T/LYB421 in arachis oil and a 25% w/v dilution of Photopia Blue AQ-T/LYB421 in a 1:1 preparation of Freund's Complete Adjuvant plus arachis oil. One week later the same area was treated with an occlusive topical application of 50% w/v of Photopia Blue AQ-T/LYB421 for 48 hours. Control animals were similarly treated but without the use of the test substance. The sites were evaluated 1 and 24 hours after removal of the patches.

Following topical induction skin reactions were unable to be assessed due to yellow staining. No reactions were seen in the control animals.

Challenge Study

weeks after the topical induction application, the test and control animals were challenged topically using 10% or 5% Photopia Blue AQ-T/LYB421 in arachis oil by occlusive application, for 24 hours, at two different sites. The challenge sites were evaluated at 24 hours after removal of the patches. Animals were rechallenged on previously untreated areas of skin using the same concentrations of the notified chemical then assessed 48 hours later.

No skin reactions were observed in test or control animals 24 or 48 hours after challenge or rechallenge. Bodyweight gains in the test group were comparable to those observed in the control group.

The results of this study indicate that Photopia Blue AQ-T/LYB421 is not a skin sensitiser in guinea-pigs at the concentrations tested.

9.1.6 Evaluation For Weak Skin Irritancy By Microscopic Observation (8)

Data from a human skin irritation study was provided by the notifier and has been assessed. The test was based on "The Evaluation Method (Kawai's Method) of Skin Patch Tests Based on Microscopical Observation" (9). It is a non-OECD method.

The test was carried out on 20 healthy male and female volunteers. Seven patches of Aqualite Photopiacolor (mixture of Photopia Aqualite Ink Purple, Yellow and Blue) were applied to the volar surface of the forearm (four sites on the right arm and four on the left). One patch containing the negative control was also used. The control consisted of di(stearo amino ethylene)amide epichlorhydrin condensate. The patches were taken off after 24 hours. Macroscopic examination of the skin was done 30-60 minutes after removal of patches for any signs of erythema. Following this, Susuki's universal microscopic printing method was used to prepare skin replicas from the sites of patch application for microscopic observation.

According to the degree of abnormal reaction observed, four ranks of judgement of skin irritancy may be given. These are described by the B score which is defined as the number of subjects who show deepened skin furrows from the control substance subtracted from the number of subjects who show the same reaction from the test substance.

. Negative: No microscopic or macroscopic changes are observed, or the abnormal reaction is less severe than the reaction to the control substance.

. Almost Negative: If B score is 2 or less.

. Almost Positive: If B score is 3.

. Positive: When B score is more than 4 or if one or more subjects show loss of the triangular configuration of the skin furrow pattern or if there is any macroscopic inflammation.

In this study Aqualite Photopiacolor obtained a score of 2B (almost negative) and therefore the results indicate that it is a non irritant to the skin.

9.2 Genotoxicity

9.2.1 *Salmonella typhimurium* Reverse Mutation Assay (Ref No:10)

This study was carried out in accordance with the *OECD Guidelines for Testing Chemicals No 471.*

Photopia Blue AQ-T/LYB421 was tested in two independent experiments. The dose range used in the preliminary study was 0, 312.5, 625, 1250, 2500 and 5000 µg/plate. The doses selected for the main study were 0, 8, 40, 200, 1000 and 5000 µg/plate. *Salmonella* strains TA98, TA100, TA1535, TA1537 and TA1538 both in the presence and absence of S9 mix were used. Positive controls used without activation were 9-aminoacridine, N-ethyl-N'-nitro-N-nitrosoguanidine, 4-nitro-o-phenylenediamine and 4-nitroquinoline-1-oxide. 2-Aminoanthracene and benzo(a)pyrene were used as positive control in experiments using activated S9 mix. All positive controls produced marked increases in the number of revertant colonies within the normal range.

No significant increases in the number of revertant colonies of bacteria were recorded for any of the strains of *Salmonella typhimurium* used, at any dose level of the test substance either with or without metabolic activation. The test substance caused no toxicity to the bacterial lawn at the concentrations used but did cause a precipitate at over 5000 µg per plate which did not interfere with the scoring of colonies.

The results indicate that Photopia Blue AQ-T/LYB421 is not genotoxic toward *Salmonella typhimurium*.

9.3 Overall Assessment of Toxicological Data

Photopia Blue AQ-T/LYB421 has low acute oral and dermal toxicity in the rat with LD_{50s} > 2000. In a patch test on human skin Aqualite Photopiacolor containing Photopia Blue AQ-T/LYB421 elicited an "almost negative" reaction. The notified chemical is neither a skin nor eye irritant to the rabbit, nor a skin sensitiser in the guinea pig. It is not mutagenic towards *Salmonella typhimurium* either in the presence or absence of metabolic activation.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

As the notified chemical is a low volume chemical substance, it is not a requirement that environmental effect studies are submitted. However, the notifier has provided test results for Photopia Blue AQ-T/LYB421 in a 48 hour Acute Toxicity Static test using *Daphnia magna* as a test species (11). The 48 hour EC_{50} was established to be ≤ 1.0 $mg.L^{-1}$ and the 48 hour NOEC was also ≤ 1.0 $mg.L^{-1}$. This value represents the highest concentration that could be prepared due to the limited solubility in water and auxiliary solvent permitted in the OECD guidelines. This result indicates that the notified substance may be moderately toxic to the test organism used. No effects were noted up to the limit of solubility.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The proposed use of Photopia Blue AQ-T/LYB421, a photochromic dye for use in the textile industry, is unlikely to present a significant environmental hazard as exposure to the aquatic environment is expected to be negligible. The majority of the notified substance will be bound to cloth and will eventually be disposed of by landfill with other domestic refuse. The notified substance in waste water from the textile factories is expected to be associated with the sludge at water treatment plants, following coagulation. Disposal of sludge by incineration and/or landfill is not expected to present a major hazard to the environment.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Photopia Blue AQ-T/LYB421 has been in use in Japan and the EEC and no adverse effects related to exposure have been reported.

Skin or eye contact may occur during repackaging and during the initial dilution and mixing stage unless appropriate care is taken. Photopia Blue AQ-T/LYB421 is unlikely to pose an inhalation hazard as it is formulated in a paste, has a low vapour pressure (7.0×10^{-6} Pa at 25°C), and the majority of its particles are over 45µm diameter.

Based on the results of animal studies, and a single study on human skin, human exposure to Photopia Blue AQ-T/LYB421 is unlikely to cause eye or skin irritation, or sensitisation.

Under normal conditions of use, public exposure to unfixed Photopia Blue AQ-T/LYB421 is expected to be negligible, since it is intended for industrial application only. Public exposure to the notified chemical will be limited to contact with dyed material from which it is unlikely to be absorbed.

13. RECOMMENDATIONS

To minimise occupational exposure (and public/environmental if recommendations have been made by these agencies) to Photopia Blue AQ-T/LYB421 the following guidelines and precautions should be observed:

. during the textile dyeing process, local exhaust ventilation should be used;

. if engineering controls and work practices do not sufficiently reduce exposure to a safe level then the following personal protective equipment should be used:

  - rubber gloves which conform to the Australian Standard 2161 (12),

  - protective clothing including overalls, and a PVC which conform to apron Australian Standard AS 3765 (13),

  - eye protection which conforms to Australian Standard AS 1337 (14).

. The MSDS should be easily accessible to all employees.

14. MATERIAL SAFETY DATA SHEET

The Material Safety Data Sheet (MSDS) for Photopia Blue AQ-T/LYB421 was provided in Worksafe Australia format (Ref No:15). The MSDS was provided by Bonds as part of their notification statement. It is reproduced here as a matter of public record. The accuracy of this information remains the responsibility of Bonds.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act), secondary notification of Photopia Blue AQ-T/LYB421 shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise. Secondary notification should also be made if the substance is to be discharged directly to the sewage system or the aqautic environment without prior coagulation. No other specific conditions are prescribed.

16. REFERENCES

(1) Photopia Blue AQ-T/LYB421, Determination of Physico-Chemical Properties. Project No: 482/11. Data on File. Safepharm Laboratories, Derby, U.K.

(2) Assessment of the ready biodegradability (modified sturm test) of Photopia Blue AQ-T/LYB421. Project No: 482/5. Data on File. Safepharm Laboratories, Derby, U.K.

(3) Photopia Blue AQ-T/LYB421: Acute Oral Toxicity (Limit Test) In The Rat. Project No: 461/6, 1992. Data on File. Safepharm Laboratories, Derby, U.K.

(4) Photopia Blue AQ-T/LYB421: Acute Dermal Toxicity (Limit Test) In The Rat. Project No: 482/2, 1992. Data on File. Safepharm Laboratories, Derby, U.K.

(5) Photopia Blue AQ-T/LYB421: Acute Dermal Irritation Test In The Rabbit. Project No: 461/7, 1992. Data on File. Safepharm Laboratories, Derby, U.K.

(6) Photopia Blue AQ-T/LYB421: Acute Eye Irritation Test In The Rabbit. Project No: 461/8, 1992. Data on File. Safepharm Laboratories, Derby, U.K.

(7) Photopia Blue AQ-T/LYB421: Magnusson & Kligman Maximisation Study In The Guinea-Pig. Project No: 461/9. Data On File. Safepharm Laboratories, Derby, U.K.

(8) Replica Method - Evaluation For Weak Skin Irritancy By Microscopic Observation. 1991. Data On File. Kawai Medical Laboratory For Cutaneous Health, Kyoto, Japan.

(9) Evaluation Method (Kawai's Method) of Skin Patch Tests Based on Microscopical Observation K.Kawai, Fragrance Journal 2:7 (pages not given) (1974)

(10) Photopia Blue AQ-T/LYB421: Reverse Mutation Assay "Ames Test" Using *Salmonella Typhimurium*. Project No: 461/10. Data On File. Safepharm Laboratories, Derby, U.K.

(11) The acute toxicity of Photopia Blue AQ-T/LYB421 to *Daphnia Magna*. Project No: 482/8. Data on File. Safepharm Laboratories, Derby, U.K.

(12) Australian Standard 2161-1978: *Industrial Safety Gloves and Mittens (excluding Electrical and Medical Gloves)*. Standards Association of Australia Publ., Sydney (1978).

(13) Australian Standard 3765-1990: *Clothing for Protection Against General or Specific Chemicals*, Standards Association of Australia Publ., Sydney (1990).

(14) Australian Standard 1337-1984: *Eye Protectors for Industrial Applications*, Standards Association of Australia Publ., Sydney (1984).

(15) National Occupational Health and Safety Commission, Guidance Note for the Completion of a Material Safety Data Sheet, 2nd. Edition, AGPS, Canberra, 1990.