File No: STD/1343

December 2009

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Leucophor A

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (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 Department of Health and Ageing, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of the Environment, Water, Heritage and the Arts.

For the purposes of subsection 78(1) of the Act, this Full Public Report may be inspected at our NICNAS office by appointment only at 334-336 Illawarra Road, Marrickville NSW 2204.

This Full Public Report is also available for viewing and downloading from the NICNAS website or available on request, free of charge, by contacting NICNAS. For requests and enquiries please contact the NICNAS Administration Coordinator at:

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Director
NICNAS

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FULL PUBLIC REPORT

This notification has been carried out under the approved foreign scheme provisions (Canada) of Section 44 of the Act. The health and environment hazard assessment of the Canadian report was provided to NICNAS and where appropriate used in this assessment report. The other elements of the risk assessment and recommendations on safe use of the notified chemical were carried out by NICNAS.

Leucophor A

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Chemcolour Industries Australia Pty Ltd (ABN: 70 125 602 271)
Monash Business Park, 20-22 Gardiner Rd
Notting Hill VIC 3168

NOTIFICATION CATEGORY
Standard: Chemical other than polymer (more than 1 tonne per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:
Chemical name, CAS number, Molecular Formula, Structural Formula, Molecular weight, Purity, Identity of impurities.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
No variation to the schedule of data requirements is claimed.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
Canada (2007)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Leucophor A (~30% notified chemical in aqueous solution)

OTHER NAME(S)
Leucophor 0503E
Leucophor 0531E

MOLECULAR WEIGHT
500 - 1000 Da

ANALYTICAL DATA
Reference NMR, IR, HPLC, UV spectra were provided.

3. COMPOSITION

DEGREE OF PURITY > 70%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS None

ADDITIVES/ADJUVANTS None

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: Light yellow, compact powder

Property	Value	Data Source/Justification
Melting Point	48.2 - 121°C	Measured
Boiling Point	Decomposition from 263°C	Measured
Density	963 kg/m^3 at 20°C	Measured
Vapour Pressure	3.4 x 10^{-32} Pa at 25°C	Calculated based on the calculated bp (Meissner's method) using the Modified Watson Correlation (OECD 104)
Water Solubility	> 608 g/L at 20°C	Measured (EEC 92/69 A.6; OECD 105, HPLC). A saturated solution of the notified chemical in water could not be obtained.
Hydrolysis as a Function of pH	$t_{1/2}$ > 1 yr at 25°C	Measured (OECD 111). If released to the environment, abiotic degradation by hydrolytic mechanisms is expected to be slow.
Partition Coefficient (n-octanol/water)	log P_{OW} < -4	Calculated using the ratio of solubilities in n-octanol and water
Surface Tension	56.4 mN/m at 20°C	Measured (OECD 115)
Adsorption/Desorption	log K_{oc} < 1.25	Measured (OECD 121)
Dissociation Constant	pK_a = -2.70	Calculated (PALLAS v4.0). The notified chemical is expected to be fully ionised in the environmental pH range of 4–9.
Particle Size	Range: 0.5 - 150 µm Inhalable fraction (<100 µm): 98.59% Respirable fraction (<10 µm): 2.12% MMD* = 33.1 µm	Measured
Flash Point	Not determined	Low vapour pressure solid
Flammability	Not highly flammable	Measured
Autoignition Temperature	333.4°C	Measured
Explosive Properties	Not expected to be explosive	Estimated based on oxygen balance and calorimetric tests
Oxidising Properties	Not expected to be oxidising	Estimated

* MMD = Mass Median Diameter

DISCUSSION OF PROPERTIES

For full details of some of the tests on physical and chemical properties, refer to Appendix A.

Reactivity

The notified chemical is expected to be stable under normal conditions of use.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS

The notified chemical will be imported in aqueous solution at concentrations of approximately 30%.

MAXIMUM INTRODUCTION VOLUME OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	30-50	30-50	30-50	30-50	30-50

PORT OF ENTRY
Sydney

IDENTITY OF RECIPIENTS
Shoalhaven Paper Mill - Paperlinx

TRANSPORTATION AND PACKAGING
The product containing the notified chemical at ~ 30% concentration (Leucophor A) will be shipped to Australia in 1000L intermediate bulk containers (IBCs) and transported by road to warehouses for storage or to the end use site.

USE
The notified chemical will be used as an optical brightener agent to increase the whiteness of paper during paper production.

OPERATION DESCRIPTION
The product containing the notified chemical will be pumped from the IBC into a storage tank and subsequently transferred to the paper whitening machine, perhaps following mixing with other components. It will then be applied to the paper (to the pulp and/or as a surface coating). This is expected to be a closed system. After application the notified chemical is expected to be fixed into the paper matrix at a level of 7g/kg dry paper.

6. HUMAN HEALTH IMPLICATIONS

6.1 Exposure assessment

6.1.1 Occupational exposure

NUMBER AND CATEGORY OF WORKERS

Category of Worker	*Number*	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Transport	5	2	12
Operations	2	1	50

EXPOSURE DETAILS
Dermal and ocular exposure of workers to the notified chemical may occur during connection/disconnection of hoses, or cleaning/maintenance of equipment. Such exposure is only likely to occur accidentally and workers are expected to wear personal protective equipment (PPE) such as gloves and safety glasses/face shields to minimise exposure levels. Following application to the paper, the notified chemical is expected to be fixed into the paper cellulose matrix and not be available for exposure.

6.1.2. Public exposure
The notified chemical will not be used by the public. The public may come into contact with finished paper products, however, the notified chemical is expected to be fixed into the paper cellulose matrix, with minimal leaching from or migration within papers anticipated during use. Thus it is not expected to be available for exposure.

6.2. Human health effects assessment

Toxicological studies conducted with the notified chemical (> 70% purity) were submitted, and a summary of the results is presented below.

Test	Species	Dose	Result
Acute oral	rat (female)	2000 mg/kg bw	LD_{50} > 2000 mg/kg bw
Acute dermal	rat	2000 mg/kg bw	LD_{50} > 2000 mg/kg bw
Dermal irritation	rabbit	0.5 g	slight irritant
Eye irritation	rabbit	0.1 ml ≈ 35 mg	slightly irritating
Skin sensitization	mouse	5%, 10% and 25%	not a skin sensitizer
28-Day repeated dose	rat	50, 200 and 1000 mg/kg bw/day	NOAEL = 1000 mg/kg bw/day
Bacterial reverse mutation	S. typhimurium and E. coli	3-5000 µg/plate	not mutagenic
Chromosome aberration assay	Chinese hamster V79 lung cells	100-2850 µg/ml	clastogenic in the absence of metabolic activation
			non-clastogenic with metabolic activation
Micronucleus test	mouse	500, 1000 and 2000 mg/kg bw	not clastogenic

Uptake of the notified substance following dermal contact would be limited by its high molecular weight (MW 500 - 1000 g/mol), high water solubility (> 608 g/L) and expected low octanol-water partition coefficient (log Kow < - 4).

Acute studies

An acute oral study was performed in 6 female rats. The animals were dosed at 2000 mg/kg bw by oral gavage after an overnight fast. There were no mortalities or clinical signs of systemic toxicity during the observation period. All animals showed the expected weight gains and no abnormalities were noted at necropsy. The notified substance has a low acute oral toxicity with an oral LD_{50} > 2000 mg/kg bw.

An acute dermal study was performed in rats (5/sex). The notified substance (2000 mg/kg bw) was moistened in purified water and applied to the intact shaved skin of the animals and covered with a semi-occlusive dressing for 24 hours. There were no mortalities or clinical signs of systemic toxicity during the test or observation period. All animals gained the expected weight and no abnormalities were noted at necropsy therefore the notified substance has a low acute dermal toxicity in rats with an LD_{50} >2000 mg/kg bw.

An acute dermal irritation assay was performed in rabbits (1 male/2 females) using 0.5 g of the notified substance. It was applied to the shaved intact skin and covered with a semi-occlusive dressing for a 4 hour exposure. There were no mortalities or clinical signs of systemic toxicity during the test or observation period. A very slight to well-defined erythema was noted in all animals from the 1-48 hour reading and very slight erythema persisted in 2/3 animals up to 72 hours. Very slight swelling was observed in 2 animals at the 1 hour reading and scaling was present in one animal at 72 hours, therefore the notified substance is considered a slight irritant.

An acute eye irritation assay was performed in rabbits (1 male/2 females). The test substance (0.1g) was instilled in the conjunctival sac of the left eye and remained unwashed. There were no mortalities or signs of systemic toxicity during the observation period. There were no abnormalities noted with the cornea or iris at any time point. However, slight to moderate reddening of the conjunctiva was present in all animals at 1 hour and slight reddening persisted in 2 animals up to 24 hours. Slight swelling of the conjunctiva (chemosis) to obvious swelling with partial eversion of the lids was present in 2 animals 1 hour after treatment. Slight to moderate reddening of the sclera was present in all animals at 1 hour and slight reddening persisted in one animal up to 24 hours. Slight ocular discharge was observed in one animal 1 hour after treatment. The notified substance is slightly irritating to rabbit eyes.

Skin sensitisation

A local lymph node assay was performed in mice (4 females/dose) to determine the potential for skin sensitisation. The notified substance (25 µl) was applied to the ear of the animals at doses of 5%, 10% and 25% in ethanol:water (7:3 v/v) for 3 consecutive days. 25% was the highest non-irritant and technically applicable concentration in the chosen vehicle in a range-finding test. There were no mortalities or clinical signs of systemic toxicity during the test period and all animals gained the expected weight. High dose animals showed slight erythema on the ear which persisted for 2 days. Stimulation Index (SI) values of 0.9, 1.1, and 1.6 were obtained respectively. Since no dose generated an SI value above 3, it is not possible to calculate the EC3 value, however, the notified substance is not considered a skin sensitiser under the conditions of this local lymph node assay.

Subchronic studies

A 28-day repeated dose study was performed in rats (5/sex/dose) with an additional 5 animals/sex for the control and high dose groups to be used as recovery animals. The animals were dosed at approximately 50, 200 and 1000 mg/kg bw/d in a feed study for 28 consecutive days. Additional control and high dose animals were kept for an additional 14 days without dosing. One high dose female demonstrated hunched posture, ruffled fur and pale skin at day 4 and was sacrificed at day 4, however the effects were not thought to be test substance related. Minor increases in food consumption, a shift from low to medium and high fluorescence reticulocytes and minor changes in electrolytes were observed but not considered adverse as they were either still within historical control values, were not dose dependent or no corresponding microscopic findings were found. Minor increases in the mean absolute and relative kidney weights in high dose males and in the mean absolute and relative adrenal weights of high dose females were observed, but did not reach statistical significance with the exception of the kidney weights (relative to body weight) in high dose males. However in the absence of any microscopic changes, these effects were not considered toxicologically significant. In the absence of any significant adverse effect the notified substance has a NOAEL = 1000 mg/kg bw/day and is considered to have a low repeated dose toxicity.

Genotoxicity

A bacterial reverse mutation assay (Ames test) was performed with *Salmonella typhimurium* strains TA 98, TA 100, TA 1535 and TA 1537 as well as the *Escherichia coli* strain WP2uvrA- in both the presence and absence of metabolic activation using both the plate incorporation and the pre-incubation techniques. The notified substance was used at a concentration range of 3- 5000 µg/plate for an exposure period of 48 hours. The test substance did not cause any reduction in the background lawn at any of the concentrations tested therefore it is not cytotoxic. The test substance did not increase the frequency of revertant colonies for any of the bacterial strains, at any concentration in either the presence or absence of metabolic activation. Positive controls generated a significant increase in the number of revertant colonies in both the presence and absence of metabolic activation. Therefore the notified substance is not mutagenic *in vitro*.

A chromosomal aberration assay was performed in Chinese hamster V79 lung cells. The cells were exposed to the notified substance at a concentration range of 93.8 - 2850 µg/ml in the absence of metabolic activation and 100 - 1425 in the presence of metabolic activation with exposure times of 4, 18 or 28 hours. Harvest times were at 18 and 28 hours. Cytotoxicity was observed at concentrations of 400 µg/ml and above in the absence of S9 and at 712.5 µg/ml in the presence of S9. In all other experimental parts, except for Exp IB (+S9) concentrations showing cytotoxicity were not scorable. In Experiment IA, there were no biologically relevant increases in chromosomal aberrations in the absence of metabolic activation but in the presence of metabolic activation, an increase in chromosomal aberrations was observed at concentrations of 178.1 and 356.3 µg/ml (5.0 and 6.5% respectively). These results were not reproducible and not considered biologically relevant. However, in the absence of metabolic activation with a preparation interval of 28 hours, a biologically relevant increase in chromosomal aberrations were seen at 187.5 and 375 µg/ml (6.5% and 9.5% respectively). To confirm these results a repeat experiment was performed at concentrations of 300 and 400 µg/ml (8.5 and 8.8% respectively) in the absence of metabolic activation and a biologically relevant increase in chromosomal aberrations was observed. In all experiments, there was no increase in the occurrence of polyploid. The positive controls, Ethylmethane sulfonate and cyclophosphamide induced a statistically significant increase in the number of chromosomal aberrations in both the presence and absence of metabolic activation. In conclusion, the notified substance is considered clastogenic *in vitro* in the absence of metabolic activation.

A micronucleus test was performed in mice (5/sex/dose). The notified substance was administered by oral gavage at doses of 500, 1000, and 2000 mg/kg bw with an additional 5 animals/sex/dose at the high dose which were evaluated at 48 hours instead of 24 hours. There were no mortalities observed during the test period and clinical signs were limited to ruffled fur seen in all animals at the 2 and 6 hr observation time points. There were

no changes in the ratio of PCE to erythrocytes at any of the doses tested although a small decrease was observed at the high dose at 48 hours, however, the test substance is not considered toxic to the bone marrow. There were no statistically or biologically relevant increases in the frequency of micronuclei at any preparation interval or dose level, therefore the notified substance is not considered clastogenic *in vivo*.

Clastogenicity was observed in the chromosomal aberration test using Chinese hamster V79 cells in the absence of metabolic activation, however, there was not clastogenicity present in an *in vivo* mouse micronucleus assay, and other structurally similar compounds were not clastogenic, therefore the potential for the notified substance to be clastogenic *in vivo* is very low.

Health hazard classification
Based on the available data the notified chemical is not classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human health risk characterisation

6.3.1. Occupational health and safety
The available toxicological information indicates that the notified substance has low acute oral and dermal toxicities in rats with LD_{50}'s > 2000 mg/kg bw. It is a slight dermal and eye irritant, and not a skin sensitizer in a local lymph node assay. It has low subchronic toxicity with a NOAEL of 1000 mg/kg bw/day. It is not mutagenic in an Ames test. It is clastogenic *in vitro* using Chinese hamster V79 lung cells but it is not clastogenic *in vivo* using the mouse micronucleus test.

There is potential for occupational exposure to the notified chemical (~ 30%) during connecting/disconnecting hoses and cleaning/maintenance of equipment, mainly *via* the dermal and ocular routes. Such exposure is expected to be minimal due to the use of PPE and the closed nature of the equipment used.

Given the available test data on the notified chemical and the expected low exposure levels, the notified chemical is not considered to pose an unacceptable risk to workers.

6.3.2. Public health
The notified chemical is expected to be fixed into the cellulose matrix of the paper. Thus, based on the expected minimal exposure, the risk to the public presented by the notified chemical is not considered to be unacceptable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE
The notified chemical will be imported as a product for use as a brightening agent in the manufacture of paper. No significant release of the notified chemical to the environment is expected from transport and storage processes.

RELEASE OF CHEMICAL FROM USE
At the industrial customers' site, the product containing the notified chemical will be pumped into a storage tank from where it will be dosed to the paper whitening machine. The notified chemical will be used at the wet-end of the white paper manufacturing process and can be added to both paper pulp and to the surface of paper. It is assumed that at least 90% of the notified chemical will adsorb onto the paper fibre during the application processes. The remainder may be released into waste water produced by the manufacturing process. The notifier indicates that the customer has on-site wastewater treatment facilities. The notified chemical would only be released from the paper mill in the backwater/effluent discharge after treatment. The treatment process will be completely enclosed and water will not be released from the site until the treatment process has finished.

RELEASE OF CHEMICAL FROM DISPOSAL
Empty IBCs containing residual notified chemical will enter the second-hand IBC market for reuse through a

professional IBC recycling company. It is expected that residues in the import containers would be washed out on-site at the paper mill and the rinsates treated in the on-site water treatment facility. Alternatively, aqueous rinsates from used IBCs would be washed out at the recycling company facility and the residues discharged to sewer after appropriate on-site water treatment. The losses of notified chemical in container residues are estimated to be <1% per annum.

It is assumed that 50% of the paper to which the notified chemical is applied will end up in landfill and the rest will undergo paper recycling processes.

7.1.2 Environmental fate

The notified chemical reached a biodegradation rate of 32% after 28 days (OECD 301F) which indicates it is partially biodegradable aerobically but not readily biodegradable. The notified chemical is stable to hydrolysis in the environmental pH range of 4–9 and abiotic degradation mediated by hydrolytic mechanisms is therefore expected to be slow.

The removal efficiency for the notified chemical in waste water treatment plants based on the combined effects of biodegradation and adsorption is approximately 55%. The notified chemical is therefore not expected to be fully removed from the effluents of waste water treatment plants. Any quantities of notified chemical discharged in treated effluent are expected to be relatively mobile in aquatic systems based on the high water solubility of the chemical and its low tendency to partition from water to soil. The rate of abiotic degradation may be slow based on the apparent hydrolytic stability of the chemical and it may persist in the water column. Although potentially persistent in the water compartment, the notified chemical is unlikely to bioconcentrate in aquatic organisms based on the low estimated log P_{OW} < -4 and the relatively large molecular dimensions of the chemical.

During recycling processes, waste paper is repulped using a variety of chemical agents, which, amongst other things, enhance detachment of inks and coatings from the fibres. The reported adsorption/desorption coefficient (log K_{oc} < 1.25) indicates that the notified chemical will not strongly adsorb to soil and sediment in the sludge fraction. Therefore, a significant proportion of the notified chemical is expected to remain in the effluent water from both on-site waste water treatment plants and municipal water treatment plants to which treated effluent from paper recycling facilities may be discharged. Sludge (containing the notified chemical) generated during the recycling process will be sent to landfill for disposal. In landfill, leaching of the notified chemical could occur due to its high water solubility and low binding affinity for soil.

In either landfill or water, the notified chemical will ultimately decompose to water, oxides of carbon and nitrogen, and inorganic salts.

7.1.3 Predicted Environmental Concentration (PEC)

At the paper mill, waste water from the manufacturing process will undergo on-site secondary treatment prior to discharge into a river with an estimated daily flow rate of 130 ML. For a worst case release scenario it is assumed that 10% of the annual import quantity of the notified chemical (5000 kg) is not retained in the paper manufactured on-site but instead is released in the water discharged into the on-site secondary water treatment plant. It is further assumed that none of the chemical is removed by adsorption or biodegradation prior to release to the river and that releases occur on 260 days each year. Based on this scenario, the maximum daily discharge rate of notified chemical is 19.2 kg/day which could result in concentrations of up to 148 µg/L notified chemical (= 19.2×10^9 µg day^{-1} / 130×10^6 L) in the river receiving effluent from the paper mill.

Up to 50% of the imported quantity of notified chemical that is applied to paper at the paper mill (22500 kg (= 0.9 × 45000 kg)) could potentially enter paper recycling in Australia. The typical concentrations of the notified chemical in surface waters resulting from paper recycling can be calculated using a worst case continental model in which it is assumed that none of the notified chemical entering waste water treatment plants (either on-site or municipal) is removed from the effluents.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import Volume	50,000	kg/year
Proportion expected to be released to sewer	45%	
Annual quantity of chemical released to sewer	22,500	kg/year
Days per year where release occurs	260	days/year
Daily chemical release:	86.54	kg/day
Water use	200	L/person/day

Population of Australia (Millions)	21.161	million
Removal within STP	0%	
Daily effluent production:	4,232	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	20.45	µg/L
PEC - Ocean:	2.04	µg/L

Based on the above calculations, the maximum PEC for the notified chemical in surface water is 168.5 µg/L (= 148 + 20.45) for river water and 16.8 µg/L (= 148/10 + 2.04) for ocean waters receiving combined effluents from paper recycling and paper manufacture.

7.2. Environmental effects assessment

The results from ecotoxicological investigations conducted on the notified chemical are summarised in the table below.

Study	Duration	Endpoint	Value	Test Method	Assessment Conclusion
Fish Toxicity (Zebrafish)	96h	LC50 NOEC	> 100 mg/L = 100 mg/L	OECD 203; EEC 92/69 C.1	Not harmful
Daphnia Toxicity (*Daphnia magna*)	48h	EC50 NOEC	> 100 mg/L = 100 mg/L	OECD 202; EEC 92/69 C.2	Not harmful
Algal Toxicity (*Scenedesmus subspicatus*)	72h	EC50(b) EC50(r) NOEC(b)	= 93 mg/L > 100 mg/L = 22 mg/L	OECD 201; EEC 92/69 C.3	Not harmful*
Activated Sludge Respiration Inhibition	3h	EC50 NOEC	> 1000 mg/L = 1000 mg/L	OECD 209	Not harmful

* Based on EC50(r)

Based on the experimental ecotoxicity test results, the notified chemical is not expected to be acutely harmful to aquatic organisms.

7.2.1 Predicted No-Effect Concentration

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
LC50/EC50	> 100	mg/L
Assessment Factor	100	
PNEC	> 1,000	µg/L

The PNEC for the aquatic compartment has been calculated using a LC50/EC50 value of > 100 mg/L and an assessment factor of 100 since toxicity endpoints are available for species from all three aquatic trophic levels.

7.3. Environmental risk assessment

Risk Assessment	***PEC µg/L***	***PNEC µg/L***	***Q***
Q - River:	168.5	> 1000	< 0.17
Q - Ocean:	16.8	> 1000	< 0.017

The Risk Quotient (Q = PEC/PNEC) has been calculated to be <1 for both river and ocean discharges of industrial effluents containing the notified chemical. These calculations were based on conservative estimates for the release rates of the notified chemical from paper manufacture and paper recycling facilities that likely overestimate the concentration of the chemical in aquatic systems. The absence of any significant observed ecotoxicological effects combined with the relatively low concentration of the chemical occurring in surface waters, even at the theoretical worst case levels, indicates that there is a low risk to the aquatic environment from the intended use of the notified chemical as an optical brightener in paper manufacture.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available data the notified chemical is not classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)].

Human health risk assessment
Under the conditions of the occupational settings described, the notified chemical is not considered to pose an unacceptable risk to the health of workers.

When used in the proposed manner, the notified chemical is not considered to pose an unacceptable risk to public health.

Environmental risk assessment
On the basis of the PEC/PNEC ratio and the reported use pattern, the notified chemical is not considered to pose a risk to the environment.

Recommendations

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical as introduced:
  - Avoid skin and eye contact

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical as introduced:
  - Gloves

  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 chemical are classified as hazardous to health in accordance with the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)] workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Disposal

- The notified chemical should be disposed of to landfill.

Emergency procedures

- Spills or accidental release of the notified chemical should be handled by physical containment, collection and subsequent safe disposal.

Regulatory Obligations

Secondary Notification
This risk assessment is based on the information available at the time of notification. The Director may call for the reassessment of the chemical under secondary notification provisions based on changes in certain circumstances. Under Section 64 of the *Industrial Chemicals (Notification and Assessment) Act (1989)* the notifier, as well as any other importer or manufacturer of the notified chemical, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified chemical is listed on the Australian Inventory of Chemical Substances (AICS).

Therefore, the Director of NICNAS must be notified in writing within 28 days by the notifier, other importer or manufacturer:

(1) Under Section 64(2) of the Act; if
- the function or use of the chemical has changed from an agent used in paper production, or is likely to change significantly;
- the amount of chemical being introduced has increased from 50 tonnes per annum, or is likely to increase, significantly;
- the chemical has begun to be manufactured in Australia;
- additional information has become available to the person as to an adverse effect of the chemical on occupational health and safety, public health, or the environment.

The Director will then decide whether a reassessment (i.e. a secondary notification and assessment) is required.

No additional secondary notification conditions are stipulated.

Material Safety Data Sheet
The MSDS of a product containing the notified chemical provided by the notifier was reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Flammability Not highly flammable

Method	EC Directive 92/69/EEC A.10 Flammability (Solids).
Remarks	During a preliminary test, the test substance ignited with a flame (contact time of 2 minutes) but it did not propagate.
Test Facility	RCC (2005)

Autoignition Temperature 333.4ºC

Method	EC Directive 92/69/EEC A.16 Relative Self-Ignition Temperature for Solids.
Remarks	Leucophor A showed an exothermic reaction starting at about 250°C. A maximum temperature of 437.3°C was measured in the sample cube during the exothermic reaction. At the end of the measurement, the test item was carbonized and coloured black. Leucophor A shows a relative self-ignition temperature at about 333.4°C.
Test Facility	RCC (2006)

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