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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Tinolux BMC

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Ciba Speciality Chemicals Pty Ltd
235 Settlement Road,
Thomastown VIC 3074
ABN 97 005 061 469

NOTIFICATION CATEGORY
Limited-small volume: Chemical other than polymer, (1 tonne or less per year)

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:
Chemical name
Molecular formula
Molecular weigh
Structural formula
Spectral data
Purity
Identity and % weight of impurities and adjuvants
Specific use of the notified chemical
Concentration of notified chemical in end use products
Import volumes

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:
Boiling point
Density
Particle size
Flammability limits
Explosive properties

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
Korea, KECI

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Tinolux BMC

METHODS OF DETECTION AND DETERMINATION

METHOD	Infrared spectroscopy, UV/VIS spectroscopy, HPLC, Ion chromatography
Remarks	Reference spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
<80%

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will not be manufactured in Australia. It will be imported as a component of solid and liquid formulations that will be added to fabric care products.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	<1	<1	<1	<1	<1

USE
Ingredient used in laundry fabric detergents and treatments.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
Melbourne

IDENTITY OF MANUFACTURER/RECIPIENTS
Ciba Speciality Chemicals Australia

TRANSPORTATION AND PACKAGING
The formulations containing <15% notified chemical will be imported in 30kg non-removable head high-density polyethylene jerry cans for the liquid formulation and 25kg plastic lined cardboard boxes for the solid formulation. The notified chemical will be imported by sea and stored at the notifiers warehouse where it will be distributed by road throughout Australia to local formulators.

5.2. Operation description

The notified chemical will not be manufactured in Australia, but is a component in solid and liquid formulations that will be added to fabric care products. The solid formulation is incorporated as a post dosage ingredient to dry blends or spray dried base powders. The incorporation of the amount of solid product is dependant upon the local washing conditions and the specific detergent formulation. Concentrations of the solid formulation are related to detergent weights.

At laundry detergent manufacturing sites
The liquid formulation can be incorporated into the detergent slurry before spray drying or sprayed directly on the powder. It can also be added to pre-processed granules by dry mixing process. In some cases, a pre-dilution might be needed in order to obtain a homogeneous distribution throughout the laundry care product, due to the small amounts required for photobleaching effects.

For any of the above mentioned reformulation processes, the loading operation is carried out under a fume extractor and blending occurs in closed mixing tank under local exhaust ventilation. Personal protective equipment, such as overall, respirator, gloves and eye protection will be worn when carrying out these activities.

Recommended concentrations of the solid and liquid Tinolux BMC formulations in relation to fabric care product weight are:

Detergent powders 0.01-0.04%; resulting in <0.006% of notified chemical in the end-use product
Detergent bars – 0.01 – 0.02%; resulting in <0.003% of notified chemical in the end-use product
Liquid detergents – 0.01 – 0.04%; resulting in <0.006% of notified chemical in the end-use product
After Rinses – 0.01 – 0.03%; resulting in <0.005% of notified chemical in the end-use product

Typical operation procedure for formulation of dry detergents includes spray-drying process during which dry and liquid ingredients are mixed into slurry in a tank called crutcher. The slurry is than heated and pumped to the top of a tower where it is sprayed through nozzles under high pressure to

produce small droplets that fall through a current of hot air, forming hollow granules as they dry. The dryed granules are collected from the bottom of the spray tower where they are screened to achieve a relatively uniform size. After granules have been cooled, heat sensitive ingredients are added.

To achieve higher density of powder detergents a method of agglomeration is used where the row liquid and dray ingredients are blended in the presence of liquid binder. During which process particles of the raw materials collide and adhere to each other forming larger particles. This process is similar to the dry mixing process during which dray ingredients are mixed to produce dray detergent mixtures. Small quantities of liquids may also be added for binding.

Liquid and gel detergent products are manufactured by batch or continuos blending process during which raw ingredients are mixed with hight energy mixers in the presence of stabilizing agents.

Formulated laundry care products would be packaged for end-use and transported by road to retail stores where they will be handled by storage and retial store personnel.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration h/day*	*Exposure Frequency*
Waterside workers	10-20	2-3	Once a month
Transport drivers to customers	50-100	3-4	200 days per year
Transport drivers interstate		12	40-50 days per year
Warehouse workers	2-4	1	200 days per year
Process workers/reformulation site	4-8	8	200 days per year
Retail workers	5000	5-8	200 days per year

Exposure Details

Transport and storage workers would be exposed to the notified chemical only if the packaging was damaged. Dockside and warehouse workers routinely wear cotton overalls and steel-capped boots. In the case of accidental spill or leak, standard clean up procedures would ensue with the appropriate personnel wearing the appropriate personal protective equipment to clean the spill.

Process workers at the reformulation site are more likely to be exposed to the notified chemical during the reformulation process. Exposure may be dermal, ocular and by inhalation during connecting and dosing the notified chemical into the mixer. To minimise exposure, the loading operation is carried out under a fume extractor and, blending occurs in a closed tank under local exhaust ventilation. All workers are expected to wear protective clothing, respirator, gloves and safety glasses when carrying out these activities.

Workers involved in packaging the final detergent formulations may be exposed to a maximum of 0.006% of the notified chemical.

Transport and storage workers of the end use products and retail workers, may be exposed to the notified chemical only in the case that packaging is damaged and an accidental spill or breakage occurs. The main routes of exposure are expected to be dermal, ocular and by inhalation. If spill occurs workers involved in cleaning would have to wear personal protective equipment as described above for workers involved in transport and storage of the imported formulation containing the notified polymer.

Laundry workers will be exposed to maximum of 0.006% of notified chemical when opening the containers and adding the detergent to the washing machine. The main route of exposure will be dermal. Some inhalation and ocular exposure is also possible.

5.4. Release

RELEASE OF CHEMICAL AT SITE

The following table summarises the expected environmental release notified chemical, as a result of importation, transportation and reformulation.

Source of release	% Annual Volume	Released to
Residual in import containers	≤1%	Landfill
Accidental spills	≤2.5%	Landfill, if not recycled
Reformulation equipment cleaning	≤3%	Trade Waste Sewer

Any spills that can be reclaimed will be recycled and reincorporated into the reformulation processes. Solid spills, which have become contaminated will be collected using an industrial vacuum cleaner and will be disposed of to landfill. Liquid spills and liquid wastes, arising from equipment cleaning, will be released to the sewer via the on-site waste water treatment facility.

RELEASE OF CHEMICAL FROM USE
With the exception of a small proportion of notified chemical remaining as residual within consumer packaging, which is expected to be disposed of to domestic landfill, the majority will be disposed of to sewer after use, where the notified chemical should remain associated with the aquatic compartment.

5.5. Disposal
When disposed of to landfill the notified chemical should slowly degrade via biotic and abiotic processes. However, if disposed of to sewer, it is expected to rapidly degrade via photolysis to form simpler metabolites.

5.6. Public exposure
Public exposure to a variety of laundry products containing the notified chemical is expected when handling liquid or solid detergent products containing up to 0.006% of notified chemical. The primary source of exposure to the notified chemical will be dermal and inhalation. Accidental ocular or oral exposure is possible.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa — Fine, black powder
Bluish granular solid formulation
Blue green liquid formulation

Melting Point/Freezing Point — The notified chemical does not melt under the conditions of the test.

METHOD — OECD TG 102 Melting Point/Melting Range.
EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
Remarks — A not well defined endothermic heat effect was observed between 25°C and 200°C. The endothermic heat effect observed is not due to the melting of the test item, since the sample was still a powder after the measurement.
TEST FACILITY — RCC (2001)

Boiling Point — > 679°C

METHOD — Calculated using Meissner's method (Lyman et al., 1990)
Remarks — The molar refraction and parachor values necessary for the calculation of the boiling point, were computed by summing the contributions for each atom or substructure and multiple bond in the compound.
TEST FACILITY — RCC (2001a)

Density — 570 kg/m^3 at 20°C

Remarks — Information from MSDS for Tinolux BMC Solid

Vapour Pressure — 4.5×10^{-22} kPa at 25°C

METHOD — OECD TG 104 Vapour Pressure.
EC Directive 92/69/EEC A.4 Vapour Pressure.

Remarks Vapour pressure was calculated using modified Watson Correlation based on Lyman et al., 1990
The calculated vapour pressure should be regarded as an estimation as the ionic character of the notified chemical was not taken into account. The real vapour pressure value must be lower than the calculated one.

TEST FACILITY RCC (2001a)

Water Solubility 474 g/L at 20ºC

METHOD OECD TG 105 Water Solubility.
EC Directive 92/69/EEC A.6 Water Solubility.

Remarks Simplified Flask Method. After mixing a total of 10.20 g and 10.29 g of test substance with 10 mL of water, respectively, a dark turquoise, viscous solution was obtained. It was scarcely possible to determine by visual judgement if complete dissolution was achieved. Analysis was made by spectrophotometer.

TEST FACILITY RCC (2001b)

Hydrolysis as a Function of pH Not determined

Remarks The notified chemical does not contain any groups which can undergo hydrolysis

Partition Coefficient (n-octanol/water) log Pow ≤ - 4.1.at 20ºC

METHOD OECD TG 107 and 117 Partition Coefficient (n-octanol/water).
EC Directive 92/69/EEC A.8 Partition Coefficient.

Remarks A preliminary test indicated that neither the HPLC method nor the flask-shaking method were considered suitable for the determination of the partition coefficient. Thus, the low P_{OW} value was estimated from its relative solubility in n-octanol and in water. The n-solubility was determined to be 36.3 mg/L, and water solubility was determined to be ≥ 474 g/L (as reported above). The formula used to estimate log P_{OW} was:

$$\log_{10} P_{OW} = \log_{10}\left(\frac{equilibrium(c_{n-octanol})}{equilibrium(c_{water})}\right)$$

TEST FACILITY RCC (2001c)

Adsorption/Desorption Not determined

Remarks The notified chemical is not expected to bind strongly to organic matter in soil based on water solubility and the estimated log P_{OW} value.

Dissociation Constant Not determined

Remarks The notified chemical contains strangely acidic groups which are expected to have pKa values of -1 to 1.

Particle Size 50-200 µm

Remarks Information from Technical Data Sheet by Ciba Specialty Chemicals for the imported solid formulation containing the notified chemical.

Absorption maximum 665-680 nm

Remarks Information from Technical Data Sheet by Ciba Specialty Chemicals for the imported solid formulation containing the notified chemical measured in 1:1 ethanol : water solution.

Flash Point >100ºC

Remarks Information from MSDS for Tinolux BMC Liquid

Autoignition Temperature 450ºC

Remarks Information from MSDS for Tinolux BMC Solid

Explosive Properties Not determined

Remarks Not expected to be explosive
TEST FACILITY

Reactivity

Remarks Tinolux BMC solid and liquid products are stable under normal storage conditions

7. TOXICOLOGICAL INVESTIGATIONS

Limited toxicological data for the notified chemical was submitted. These include: acute oral toxicity, bacterial mutagenicity and photocarcinognicity,
In addition, the following information on analogues was used for assessment of toxicological effects:

- IUCLID data set on Phthalocyanine blue ECB (2000)
- IUCLID data set on Phthalocyanine green ECB (2000a)
- *Fabris C. (2001) Published report
- *Fabris C. (2006) Published report

The information from the sources outlined above can be summarized as follows:

Endpoint	*Results with notified chemical*	*Results with analogues*	*Assessment Conclusion*
Rat, acute oral	LD50 >2000 mg/kg bw		low toxicity
Skin irritation		negative in rabbit and guinea pig with both analogues	non-irritating
Eye irritation		negative in rabbit and guinea pig with both analogues	non-irritating
Skin sensitisation		Negative in test with humans and mixture of chemicals and in guinea pigs (no details on the type of tests)	no evidence of sensitisation
Rat, repeat dose toxicity – gavage 28 days.		Based on results for Phthalocyanine blue	NOEL 40 mg/kg bw
Genotoxicity – bacterial reverse mutation	negative		non mutagenic
Genotoxicity – in vitro: CHC-cells, mammalian and mouse lymphoma cells and rat hematocytes		Negative based on Phthalocyanine blue	non genotoxic
Photocytotoxicity– published research studies*	Photocytotoxic at μM concentration range		photocytotoxic
Carcinogenicity- 49 week exposure in the presence of equivalent of sun light in mice	Inconsistent and reversible changes in the yield of tumours and time to appearance of tumours		No conclusion can be made from the study
Reproductive toxicity		No effects on fertility of both sexes with Phthalocyanine blue	No evidence of reproductive toxicity

7.1. Acute toxicity – oral

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method. EC Directive 96/54/EEC B.1 Acute Oral Toxicity – Acute Toxic Class

	Method.
Species/Strain	Rat/ HanBril: WIST (SPF)
Vehicle	distilled water
Remarks - Method	The test material was suspended in distilled water at a concentration of 0.2g/ml and administered by gavage at a volume of 10mg/kg bw. The animals were examined for clinical signs daily during the acclimatisation period; four times during test day 1 and once during test days 2-15. Mortality/viability was recorded daily during the acclimatisation period and together with clinical signs at the same time intervals on test day 1. On test days 2-15 the mortality/viability was examined twice daily. Body weights were recorded on day 1 (prior to administration) and on days 8 and 15. All animals were necropsied at the end of the study and examined macroscopically. No protocol deviations noted.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	3/sex	2000	0

LD50	>2000 mg/kg bw
Signs of Toxicity	None
Effects in Organs	None
Remarks - Results	All animals survived until the end of the study period. No clinical signs were evident during the course of the study. The body weight of the animals was within the range commonly recorded for this strain and age. No macroscopic findings were observed at necropsy.

CONCLUSION The notified chemical is of low toxicity via the oral route.

TEST FACILITY RCC (2001d)

7.2. Genotoxicity – bacteria

TEST SUBSTANCE Notified chemical

METHOD	OECD TG 471 Bacterial Reverse Mutation Test. EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria. Pre incubation procedure- test 1 Plate incorporation procedure – test 2
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100 *E. coli*: WP2uvrA
Metabolic Activation System	Phenobarbital/β-naphthoflavone induced rat liver S9
Concentration Range in Main Test	a) With metabolic activation: 33; 100; 333; 1000; 2500; 5000 µg/plate b) Without metabolic activation: 33; 100; 333; 1000; 2500; 5000µg/plate
Vehicle	Deionised water
Remarks - Method	Appropriate reference mutagens were used as positive controls and showed a distinct increase of induced revertant colonies. No protocol deviations noted.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	>5000	>5000	>5000	None

Test 2	>5000	>5000	>5000	None
Present				
Test 1	>5000	>5000	>5000	None
Test 2	>5000	>5000	>5000	None

Remarks - Results: No cytotoxicity occurred in the test groups with and without metabolic activation.

CONCLUSION: The notified chemical was not mutagenic to bacteria under the conditions of the test.

TEST FACILITY: RCC (2001e)

ADDITIONAL INVESTIGATIONS

7.3. Photo-carcinogenicity

TEST SUBSTANCE: Notified chemical

METHOD: In house method
- Species/Strain: Albino hairless mice
- Route of Administration: Experiment A: oral – diet, ad libitum
  Experiment B: Dermal – bathing for 2 min in solution of notified Chemical, 30-60 min prior to exposure to UV light
- Exposure Information: Total exposure: 48 weeks
  Dose regimen:
  Experiment A: 7 days per week feeding/5 days UV exposure
  Experiment B: 5 days per week bathing followed by UV exposure
- Vehicle: Experiment A: pelleted mouse chow
  Experiment B: deionized water or laundry-type wetting detergent
- Physical Form: Experiment A: solid
  Experiment B: liquid
- Remarks - Method: Free moving mice were exposed in the cages for 5 days per week to 150 J/m^2 of xenon arc solar simulator (erythema effective energy or equivalent to 30 min of mid-day sunlight).
  'Tumour history' was recorded according to the following criteria:
  Presumptive tumour: 0.25-0.5 mm lesion
  Tumours: >1 mm
  If presumptive tumour was determined to be a lesion distinct than a tumour or spontaneously diapered this was recorded in the history.
  Results were reported as:
  Incidence (I) - survivors that have or have had one or more tumours plus animals which died after acquiring tumour, divided by all animals
  Yield (Y) – average number of tumours per surviving animal

  Spontaneous tumours were seen in less than 1% of unirradiated mice

RESULTS

Experiment A

Group	*Number and Sex of Animals*	*Detergent*	*Dose mg/kg diet*	T_{50}	*YT*
1	108	-	0	50.7	54.8
2	108	+	12	51.9	55.1
3	108	+	12	50.6	53.7

Experiment B

Group	*Number of Animals (random sex)*	*Detergent*	*Dose mg/L*	t_{50}	*YT*
1	108	-	0	56.8	68.5
2	108	-	1200	56.2	70.4
3	108	+	0	60.3	79.8
4	108	+	120	56.1	67.3
5	108	+	1200	60.0	85.4

T_{50} – Time (in weeks) to 50% incidence for tumours ≥1 mm
YT – Time (in weeks) yielding mean yield of one ≥1 mm tumour per animal

Mortality and Time to Death
Experiment A:
There were no significant differences in survival of control and any of the two treatment groups females.
Males treated with the notified chemical in the absence of detergent had significantly decreased survival compared to the controls and to the group treated with notified chemical in the presence of detergent.
Experiment B:
In this experiment survival of two groups of males was decreased in a statistically significant manner. Smaller percentage of males survived in the groups bathed with detergent or with 1200 mg/L of notified chemical as compared to males bathed in detergent with 120 mg/L of notified chemical. The result for females were different and showed that survival was reduced in the group bathed in detergent with 120 mg/L of notified chemical when compared to controls bathed in water.

Clinical Observations
None

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis
Not performed

Effects in Organs – General
Not performed

Effects in Organs – Tumours
Yield of tumours
When compared to untreated control after 50 weeks, there was statistically significant increase of all tumours (including > 1mm) in the group treated by the oral route with the notified chemical without detergent but not with detergent.
However, in Experiment B where animals were exposed to the notified chemical by bathing, yield of tumours was increased in all groups treated with the notified chemical independently of the presence or absence of detergent. This difference appears to be nonsignificant at 60 weeks of the study.
There was no statistically significant difference in the yield of tumours larger than 1 mm at 60 weeks, except in the group bathed with 1200 mg/L notified chemical with detergent as compared to that with notified chemical only.

Number of animals with tumours
The only statistically significant difference in percentage of animals with skin tumours by the end of the study was detected in Experiment A (animals treated by the oral route). Females treated with notified chemical without detergent showed decreased appearance of tumours of any size (including < 1mm) as compared to controls.

Remarks – Results
The authors of the study pointed out that "In the evaluation of these studies it is important to realize that they do not constitute an assay for carcinogenic activity….rather, to determine whether the substance can modify the course of the carcinogenesis induced by a moderately effective stimulus (exposure to simulated sunlight)"

CONCLUSION

Survival:
The notified chemical may affect survival of animals exposed to it by the oral or dermal route in the presence of UV irradiation. The underlying mechanisms for the possible effect are not clear.
Carcinogenesis:
The notified chemical may affect appearance of tumours in animals exposed to it by the oral or dermal route in the presence of UV irradiation. The underlying mechanisms for the possible effect are not clear.

TEST FACILITY Temple University (1981)

8. ENVIRONMENT

8.1. Environmental fate

No environmental fate test reports were submitted, however the notifier states that the notified chemical is not readily biodegradable, but with respect to photodegradability, has a half-life of 20-30 minutes.

8.2. Ecotoxicological investigations

No environmental fate test reports were submitted, however the notifier reports the following end points for the notified chemical.

- Acute toxicity to fish, LC_{50}, 96 h >100 mg/L
- Acute toxicity to *Dapnhia*, EC_{50}, 48 h >100 mg/L
- Toxicity to Algae, E_bC_{50}, 72 h <1 mg/L (Estimated)

The notifier commented that in standard algal growth tests inhibition is expected, however due to rapid photodegradation, this should be mitigated considerably during daylight.

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

A small proportion of the total annual volume of notified chemical is expected be released to landfill as a result of accidental spills and as residual within containers. In the landfill environment, the notified chemical may potentially be mobile, based on the low log P_{OW} value. Over time it should slowly degrade via biotic and abiotic processes.

The vast majority of the total annual volume of notified chemical is expected to be released to sewer. The following Predicted Environmental Concentration (PEC) has been calculated on a worst case basis, assuming the entire annual volume is disposed of to sewer, and not allowing for any photodegradation or removal within STPs.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	1,000	kg/year
Proportion expected to be released to sewer	100.000%	
Annual quantity of chemical released to sewer	1,000.000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	2.74	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	20.496	million
Removal within STP	0%	
Daily effluent production:	4,099	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	0.67	µg/L

PEC - Ocean:	0.07	µg/L

9.1.2. Environment – effects assessment

As test reports have not been provided, and as the algal end-point value has been estimated, an assessment factor of 1000 has been applied when calculating the Predicted No-Effect Concentration:

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
EC50 (Alga).	<1.00	mg/L
Assessment Factor	1,000.00	
PNEC:	<1.00	µg/L

9.1.3. Environment – risk characterisation

Based on the above PEC and PNEC calculations, the following Risk Quotients have been calculated.

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River:	0.67	<1	>0.668
Q - Ocean:	0.07	<1	>0.067

As the Q values are below, the notified chemical is not expected to pose an unacceptable risk to the aquatic environment at projected import volumes, taking into account expected photoinstability.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Transport, storage and Retail Workers

No worker exposure to the notified chemical is expected during transport and storage except in an unlikely event of an accident caused by damage to the packaging that would result in leak or spill. Under these circumstances, dermal, ocular and inhalation exposure may occur to a maximum of 15% notified chemical for transport and storage workers and maximum of 0.006% for retail workers.

Dockside and warehouse workers routinely wear cotton overalls and steel-capped boots. For retail workers the use of impervious gloves, cotton overalls or apron and eye protection is recommended for use in case of cleaning of accidental spill.

Formulation Site

Dermal, ocular and inhalation exposure to notified chemical (15%) is possible for process workers when connecting and dosing the notified chemical into the mixer. The loading operation is carried out under a fume extractor and blending occurs in a closed mixing tank under local exhaust ventilation. Personal protective equipment includes coveralls, respirator, gloves and eye protection when carrying out the above activities. Limited exposure is expected as the loading operation is carried out under a fume extractor and, blending occurs in a closed tank under local exhaust ventilation. All workers will wear protective clothing, respirator, gloves and safety glasses when carrying out these activities. This will minimise possible exposure to the notified chemical.

Intermittent dermal exposure to the detergent preparations containing maximum of 0.006% of notified chemical is also possible for laboratory workers when collecting samples for testing. The exposure would be minimized by wearing coats, gloves and eye protection.

Workers on the filling line may also be exposed to detergent preparations which contain up to 0.006% of the formulated solid and/or liquid product. Workers will wear coveralls, gloves and eye protection when carrying out these activities.

There is potential for exposure for maintenance workers to up to 15% of notified chemical during routine maintenance and cleaning of the production area. Workers involved in

maintenance and cleaning of equipment will wear gloves and coveralls, therefore exposure to notified chemical will be negligible.

Laundry workers will have frequent exposure to maximum of 0.006% of notified chemical. The main route of exposure will be dermal and via inhalation. However it is expected that laundry workers will not have direct dermal contact to the detergent during routine use as workers are likely to scoop the required quantity and pour into the washing machine. Furthermore, prolonged hand contact with the detergent or final wash is not expected because of the likelihood that the worker will wash his/her hands.

Inhalation exposure to the notified chemical is not expected to be significant considering the low concentration of the notified chemical, it's low vapour pressure, large particle size (solid detergent) and that aerosols are not expected to be generated during end use.

9.2.2. Public health – exposure assessment

Public exposure to the notified chemical is expected to be frequent and through direct contact mainly during use of laundry washing powder, liquid, bars and after-rinsing products. The maximum concentration of the notified chemical in these products will be up to 0.006%. Dermal exposure is possible when pouring the detergents into machine or buckets for duration of <1 min/use (Appendix F; HERA 2005). Longer exposure of ~10 min/use is likely for hand washing with solid detergent bars containing up to 0.003% of notified chemical (Appendix F; HERA 2005).

During use by the public the notified chemical will be further diluted to up to 10^{-5} % to 10^{-6} % by adding the detergent products to water in laundry machines, buckets or sink (when hand washing). This is based on 60-90g of laundry detergent in 50 – 200L water in laundry machines or buckets as recommended for use by the notifier. This is consistent with the estimated 01-1% of detergent in hand wash solution in European Commission, 2003 reference.

Some inhalation and only accidental ocular and oral exposure is also possible. However, due to the low vapour pressure of the notified chemical inhalation exposure is not expected to be significant.

The systemic exposure to notified chemical via the dermal route is estimated to be 0.6 ng/kg bw /day for hand wash. This is based on Dermal exposure parameters for hand-washing with powder detergents in European Commission (2003) and 10^{-5}% of notified chemical in the washing water.)

After washing, the worst case systemic exposure to the notified chemical via the dermal route by contact with washed fabrics is estimated to be 29,7 μg/kg bw/day. This is based on dermal exposure parameters for powder detergents, indirect exposure in European Commission (2003) and 0.006% in liquid detergent. However, 20-70% of the residual notified chemical is expected to be photo-inactivated after drying in the sun, resulting in at least 20% reduced exposure.

Topical dermal exposure to notified chemical via wearing the washed clothes is estimated to be an equivalent of 3^{-11}% . This is based on the following assumptions:

90g detergent containing 0.006% of notified chemical used per load –recommended by notifier

5% detergent residue deposited on cloth; 1% weight fraction transferred to skin; 1kg load of fabric density 10 mg/cm^2 (HERA, 2005)

1cm^2 fabric = 1cm^3 (for % concentration conversion)

9.2.3. Human health – effects assessment

Acute toxicity

The notified chemical has low toxicity via the oral route with LD50>2000 mg/kg bw.

Irritation and Sensitisation

Based on the summary provided for the analogues the notified chemical is expected not to be irritating to the skin and eyes. It is also not expected to be a skin sensitiser.

Repeated Dose Toxicity (sub acute, sub chronic, chronic.

Based on the summary provided for the analogue Phthalocyanine blue, a subchronic (28 days) exposure of rats to the notified chemical by gavage may cause changes in red blood cell count, haemoglobin and packed cell volume in males at doses > 200 mg/kg. In addition, increase of absolute weights of lung, spleen, adrenal and salivary gland and, a tendency for increased relative weight of the spleen may be caused at dose of 100mg/kg in males. Based on the summary report provided, a No Observed Effect Dose (NOEL) was reported for this analogue at 40mg/kg bw (lowest concentration tested).

Mutagenicity

The notified chemical is not mutagenic in bacteria in the standard Ames test. Information on the analogue Phthalocyanaine blue with several mammalian cultured cells also suggests absence of mutagenic potential in vitro.

Photocytotoxicity

The notified chemical and similar analogues (substituted phthalocyanines) are reported to have cytotoxic activity at concentrations as low as 1μM or 10^{-4}% in the presence of light in the visible spectra 665-680 nm under controlled in vitro conditions (Fabris et al, 2001; Fabris et al, 2006; Halkitos K, 1999; Huang et al, 2005). The mechanism by which the notified chemical exhibits the cytophototoxic effect is not entirely clear but it may be through DNA damage (Hunting et al, 1994) and/or other cellular processes that cause apoptosis i.e. cell death in transformed cell lines (Fabris et al, 2001; Fabris et al, 2006; Halkitos K, 1999; Huang et al, 2005). The significance of the photoytotoxic potential of the notified chemical in vivo is not clear, however some toxic effect on skin cells cannot be excluded if exposure occurs to higher concentrations of notified chemical in the presence of light. No criteria for classification for photocytotoxicity have been established based on the Approved Criteria for Classifying Hazardous Substances (NOHSC, 2004).

Carcinogenicity

No conclusion can be made about the carcinogenicity of the notified chemical in the absence or presence of light, based on the submitted photocarcenogenicity study in mice as the results failed to show consistent or dose dependent trend in the effect of the notified chemical on tumour yield of time of tumour appetence. However, some statistically significant increase of all tumours (including > 1mm) in the group treated with the notified chemical by the oral route was observed after 50 weeks. On the other hand, the effect was not seen when treatment included detergent in addition to the notified chemical. Also, when applied via the dermal route the notified chemical caused increased yield of tumours at 50m weeks independently of the presence of detergent. However, the increase appears to be non-significant at 60 weeks of the study except in the in the group bathed with 1200 mg/L but not with detergent.

The mutagenicity studies with the notified chemical in bacteria and with the analogues in mammalian cells in vitro, suggest that the notified chemical does not have a mutagenic potential that could contribute to carcinogenicity in the absence of light. Hoverer, in the presence of light interference with the cell cycle regulating processes cannot be excluded. In fact, the notified chemical and similar analogues are being investigated as potential agents for Photodynamic therapy (PDT) of cancer cells. The phototoxic potential of these chemicals demonstrates significant toxicity of transformed cells in vitro (Fabris et al, 2001; Fabris et al, 2006; Halkitos K, 1999; Huang et al, 2005) but may also have some unwanted toxic effects when applied at high doses, >100 mg/kg bw, in animals (Antonella BJ et al, 2005).

Based on the available data the notified chemical is not expected to be carcinogenic under the conditions of use and in the absence of light.

Toxicity for reproduction

Based on the information for Phthalocyanine blue the notified chemical is not expected to cause adverse effects on the reproductive ability of males or females.

Observations on Human Exposure

There are no toxicological data in humans. However, products containing the notified chemical have been used in laundry detergents since pre 1985 in USA, Europe, Switzerland and no

adverse effects have been reported by the notifier.

Based on the available data, the notified chemical is not classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2004).

9.2.4. Occupational health and safety – risk characterisation

Considering the toxicological data provided for the notified chemical and similar analogues and the low likelihood of exposure to up to 15% of notified chemical under the conditions of operational processes as described, the risk is acceptable to workers involved in formulation operation.

The notified chemical has low acute toxicity via the oral route (LD50>2000 mg/kg bw), and it is not mutagenic to bacteria. Based on the data from analogues it is not expected to be irritating to skin and eyes and also it is not expected to cause skin sensitisation reactions. Based on similar results it is not expected to be mutagenic to human cells.

However, some toxic cellular effects cannot be excluded if exposure to the notified chemical occurs in the presence of light. Therefore, PPE is recommended when handling the notified chemical during the formulation and quality testing process.

Based on the exposure pattern of the laundry workers described in section 9.2.1, the low toxicity of the notified chemical, and its low concentration in the detergent (maximum 0.006), the risk for the laundry workers is considered acceptable.

9.2.5. Public health – risk characterisation

The public can potentially have dermal exposure to maximum of 0.003% of notified chemical if using solid bar detergents and to maximum of 10^{-5} % when using powder or liquid detergents for hand washing.

Considering the low acute toxicity of the notified chemical and the toxicological data for similar analogues that indicate absence of irritating effects to the skin and eyes, the estimated risk of acute dermal exposure to the notified chemical is low.

The toxicological data for analogues to the notified chemical also suggest absence of skin sensitising effects for this group of chemicals and therefore low risk for skin sensitisation from the use of detergents containing the notified chemical at concentration of up to 0.006%.

Considering the maximum systemic exposure of 0.6 ng/kg/day for hand wash and the NOEL of 40mg/kg bw/day for the analogue Phthalocyanine blue, a margin of exposure of >>1000 is calculated, suggesting no significant risk for systemic adverse effects for use of the detergent products containing 0.003- 0.006% of the notified chemical.

Considering the maximum systemic exposure of 29.7 µg/kg/day for indirect contact with notified chemical through waring washed cloth and the NOEL of 40mg/kg bw/day, a margin of exposure of >1000 is calculated, suggesting no significant risk for systemic adverse effects from use of the notified chemical for washing of cloth that will be in contact with skin.

Considering the estimated dermal exposure to residue of 10^{-11} % the risk of adverse effects through waring the washed cloth is negligible.

10. CONCLUSIONS – ASSESSMENT LEVEL OF CONCERN FOR THE ENVIRONMENT AND HUMANS

10.1. Hazard classification

Based on the available data the notified chemical is not classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*.

10.2. Environmental risk assessment

The chemical is not considered to pose a risk to the environment based on its reported use volume and pattern.

10.3. Human health risk assessment

10.3.1. Occupational health and safety

The risk to occupational health and safety is considered acceptable under the conditions of the occupational settings described.

10.3.2. Public health

There is No Significant Concern to public health if used according to instructions of use.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the products containing the notified chemical provided by the notifier were in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC 2003). They are published here as a matter of public record. The accuracy of the information on the MSDS remains the responsibility of the applicant.

11.2. Label

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

12. RECOMMENDATIONS

CONTROL MEASURES

Occupational Health and Safety

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical as introduced and formulated:
  - Protective gloves
  - Goggles
  - Overalls

  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 NOHSC *Approved Criteria for Classifying Hazardous Substances*, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Disposal

- The notified chemical should be disposed of by incineration or to landfill.

Emergency procedures

- Spills or accidental release of the notified chemical should be handled by physical

containment, collection and subsequent safe disposal.

12.1. Secondary notification

The Director of Chemicals Notification and Assessment must be notified in writing within 28 days by the notifier, other importer or manufacturer:

(1) Under Section 64(1) of the Act; if
- the importation volume exceeds one tonne per annum notified chemical:
  - full aquatic toxicity results and reports as well as results and reports for photodegradation should be provided.

or

(2) Under Section 64(2) of the Act:
- if any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.

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