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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

TKP 50048

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act* 1989 (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the National Occupational Health and Safety Commission which also conducts the occupational health & safety assessment. The assessment of environmental hazard is conducted by the Department of the Environment and the assessment of public health is conducted by the Department of Health and Aged Care.

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Director
Chemicals Notification and Assessment

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FULL PUBLIC REPORT

TKP 50048

1. APPLICANT

Ciba Specialty Chemicals (ACN 005 061 469) of 235 Settlement Rd THOMASTOWN 3074 has submitted a limited notification statement in support of their application for an assessment certificate for TKP 50048 and has not applied for any information to be exempt from publication in the Full Public Report and Summary Report.

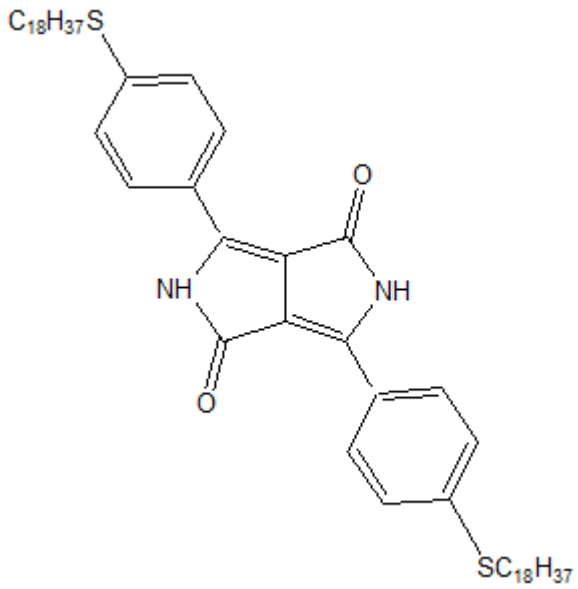
2. IDENTITY OF THE CHEMICAL

Chemical Name: 3,6-bis(4-octadecylsulfanyl-phenyl)-2,5-dihydro-1-pyrrolo[3,4-c]pyrrole-1,4-dione

Chemical Abstracts Service (CAS) Registry No.: 247089-62-9

Molecular Formula: C54H84N2O2S2

Structural Formula:



Marketing Name: TKP 50048

Molecular Weight:	857.4
Method of Detection and Determination:	Infrared (IR) and ultraviolet/visible (UV/Vis) spectroscopy; impurities by extraction, ion chromatography, titration, nuclear magnetic resonance and mass spectroscopy and gas chromatography.
Spectral Data:	IR and UV/Vis spectra were provided.

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C & 101.3 kPa:	Red powder.
Melting Point:	Cromophtal Red 2030 NW Pigment decomposes without apparently melting at temperature > 380°C – see notes below.
Boiling Point:	Decomposition of sample at temperature > 220°C – see notes below.
Density:	No data provided for notified chemical; density of Cromophtal Red 2030 NW Pigment is 1600 kg/m3 at 20°C.
Vapour Pressure:	No data provided.
Water Solubility:	< 0.1 mg/L at 20°C – see notes below.
Particle Size:	Not determined.
Partition Co-efficient (n-octanol/water):	See notes below.
Hydrolysis as a Function of pH:	Not determined – see notes below.
Adsorption/Desorption:	Not determined – see notes below.
Dissociation Constant:	Not determined – see notes below.
Flash Point:	Not determined.
Flammability Limits:	Not highly flammable (EC method A.10).
Autoignition Temperature:	Not determined.
Explosive Properties:	Not determined.
Reactivity/Stability:	Does not emit (flammable) gas in contact with water.

3.1 Comments on Physico-Chemical Properties

Water solubility of TKP 50048 was determined in a preliminary test (Ciba Specialty Chemicals, 2000b) as being < 0.1 mg/L using the protocols of OECD TG 105. A more definitive column elution test could not be performed due to the apparent insoluble nature of the material in all common organic solvents. Considering its chemical structure, the notified chemical would not be expected to be soluble due to the presence of two hydrophobic C18 chains in the molecule together with the absence of any other highly polar or ionic functional groups.

No study on the rate of hydrolysis was performed due to the expected very low water solubility of the notified chelmical. However, it contains no functional groups which are susceptible to hydrolysis in the environmental pH region 4<pH<9.

Experimental determination of the n-octanol/water partition function of the notified chemical was not attempted because a preliminary calculation indicated that log Kow would be > 6, and neither of the accepted OECD experimental methods (the shake flask and HPLC methods) are suitable for determinations of such high values of this parameter. Instead this parameter was calculated for the notified chemical TKP 50048 (Notox, 2000b) using the Rekker calculation method which is based on summing contributions to log Kow from functional groups within the molecule and making appropriate allowances for various intramolecular interactions and other structural features within the molecule. The estimated value for Kow was $10^{20.3}$ (ie. log Kow = 20.3) which is unrealistically high by many orders of magnitude. In the authoritative work by Lyman *et al* (1990), these workers have correctly pointed out that estimates of log Kow derived from molecular fragmentation methods greater than 6 should be treated with great caution. Nevertheless, since the molecule contains a large hydrocarbon component and no highly polar groups, it is expected to have a high affinity for the oil phase and little for water, so that it would have a large value for log Kow, possibly > 6 but very much lower than the calculated estimate of 20.3.

Although no data were provided, in keeping with the expected low water solubility and high affinity for the oil phase, the notified chemical would be expected to have a high affinity for the organic component of soils and sediments and would be immobile in these media.

Unlike saturated cyclic amines, the pyrrole nitrogen exhibits no basicity (Sykes, 1986) and so dissociation constant data are not relevant for this chemical.

4. PURITY OF THE CHEMICAL

Degree of Purity:	98.2%
Hazardous Impurities:	None identified.
Non-hazardous Impurities (> 1% by weight):	3 components related to the notified chemical present at a total of 1.8%. One chlorine-containing component at a concentration of 1%.
Additives/Adjuvants:	None.

5. USE, VOLUME AND FORMULATION

The notified chemical is used as a pigment coating for warp prevention of plastic articles. It will be imported in 10 kg antistatic polythene lined boxes at less than 50 kg in the first year and 50 – 100 kg per year for the following four years. The notified chemical will comprise up to 5% of the imported pigment and be present in the final product at up to 0.01%.

6. OCCUPATIONAL EXPOSURE

Transport and storage
Storage and transport workers are unlikely to be exposed to the notified chemical unless the packaging is breached.

Formulation of masterbatch pellets
Laboratory trials are used to establish formulations and involve up to 200 g of the notified chemical and occur intermittently. Testing of incoming raw materials may involve up to one hour of handling every three months. Dermal and/or inhalation exposure is possible but limited by the use of personal protective equipment.

The pigment particles coated with the notified chemical will be compounded with other ingredients by extrusion to produce a masterbatch containing up to 10% of the pigment containing up to 5% notified chemical. Six to eight factory sites will produce masterbatch containing the notified chemical. Overall in Australia, 20 workers will handle the notified chemical up to 1 hour per day, 30 days per year for the weighing/blending process and 50 workers will handle the notified chemical up to 2 hours per day, 30 days per year for extrusion/granulation. Workers will weigh and add the notified chemical into a blending vessel where the notified chemical is mixed with other ingredients. The mix is extruded and diced to produce the masterbatch in pellet form. During the hot-melt extrusion process, the notified chemical becomes encapsulated within the polymer matrix. The plastic pellets are bagged ready for distribution to customers.

Weighing is carried out in a purpose-built weigh station designed for the handling of fine powders and provided with local exhaust ventilation. The pigment powder is free-flowing and packed in small anti-static polythene bags to facilitate dispensing and complete removal of the powder from the bag. Particle size information was not provided by the notifier. The main exposure to the notified chemical should occur by skin contact during weighing and feeding of the powder into the blending vessel. All workers involved in the production of masterbatch will typically wear personal protective equipment including gloves, safety glasses and overalls. Respiratory equipment is available for use if the local exhaust ventilation is inadequate. Local exhaust ventilation is employed during weighing, dispensing, blending and packing of pellets containing the notified chemical. Similarly, the extruder loading and exit areas are fitted with local exhaust ventilation to capture fugitive emissions from the heated polymer.

Manufacture of plastic products
At the manufacturing sites, the masterbatch will be added and mixed with the polymer base and other ingredients into the hopper of an injection moulding machine. Once heated, the polymer melt is injected into a mould to form the shape of the plastic article required (in this

case a soft drink crate). Since the notified chemical is encapsulated in the compounded plastic pellets, worker exposure to the notified chemical *per se* during incorporation with plastic products is not possible. During these activities, workers are typically required to wear gloves and eye protection. Local exhaust ventilation is in place, and would capture any fugitive emissions from the notified chemical when heated.

End use
End users of plastic articles containing the notified chemical are potentially exposed to the notified chemical. However, since the notified chemical is encapsulated in these products, worker exposure is negligible.

7. PUBLIC EXPOSURE

The public may be exposed to the notified chemical following transport accidents involving the breakage of the containers in which it is imported. Such accidents are unlikely. When accidents do occur public exposure may be enhanced if any of the spilled pigment powder becomes windborne. Members of the public may also be exposed to the notified chemical as an environmental contaminant. This is also unlikely. The notified chemical will be used for industrial applications and will not be sold to the public. The most likely public contact with the notified chemical is expected to be by means of contact with it as an ingredient of the pigment used in the finished article. However it will be present in these articles at a low concentration and in an integrated state inaccessible to human contact. The potential for human exposure to the notified chemical is assessed as negligible.

8. ENVIRONMENTAL EXPOSURE

8.1 Release

Small quantities of the pigment could be lost during preliminary mixing of the pigment with polymer and other components prior to extrusion of the masterbatch, and all of this is likely to be placed into landfill. Small spills of pigment would be swept up and either returned to the mix or disposed of with other factory waste to landfill. It is expected that the mixing and extrusion operations would be performed using vacuum extraction/filtration so that any particulate matter (eg. pigment particles) released to the air would be captured and retained on the filters. All solid material retained on the filters would also be placed into landfill.

On occasions the extrusion equipment would be cleaned out and some solid scrap material would be removed from the equipment and also placed into landfill, as would any of the granulated masterbatch lost during packaging.

Apart from spills, no release of the chemical during dry mixing of the masterbatch compound with polymer, filler and other materials is expected during injection moulding of the final articles although it is possible that some scrap plastic may be produced during finishing of the final products. All such waste would be placed into landfill.

While no details of likely release of the pigment coated with the new chemical were provided in the notification dossier, large releases are not expected and if it is assumed that 2% is lost during masterbatch preparation and a further 3% lost as scrap and waste from extrusion

moulding, then total losses associated with manufacturing activities are 5%, which amounts to a maximum annual release of 5 kg, all of which will be placed into landfill.

8.2 Fate

From the above discussion on release patterns, it is apparent that the fate of most of the notified chemical will be dependent on degradation processes taking place in landfill.

The company provided a report (Notox, 2000c) on the ready biodegradation of a red powder which was designated as TKP 50048. However, since the company has indicated that the notified chemical (ie. TKP 50048) is a pale yellow powder, while it is usually sold and used as a 5% component of the red pigment Cromophtal Red it is possible that the biodegradation test was in fact performed with the red pigment rather than with the notified chemical itself.

The test conducted was a CO_2 evolution test (modified Sturm test) performed according to the protocols of OECD TG 301 B. Two duplicate tests were conducted with the test material (nominal concentration equivalent to approximately 24 mg/L organic carbon based on the molecular formula for TKP 50048 ($C_{54}H_{84}N_2O_2S_2$) incubated with sewage sludge over a 28-day test period. The quantity of CO_2 evolved was monitored over this period and, when compared with the theoretical quantity of CO_2 associated with complete degradation of the new chemical, the results indicated 2 and 7 % degradation respectively over the 28-day test period. In contrast, a reference compound (sodium acetate) was degraded to 84% over the test period, which demonstrated the viability of the bacteria used in the test. While the degradation figures above appear to be very small, the notified chemical comprises only around 5% of the red pigment, and since it is unlikely that the pigment particles themselves would be biodegradable, these results may in fact indicate that the compound is biodegradable. Certainly the large alkyl groups in the molecule (comprising 60% of the molecule) could be at least ultimately biodegradable but, without definite knowledge of the biodegradation characteristics of the pigment material in the core of the particles, this remains only a possibility.

In a toxicity control test where both sodium acetate and the red test substance were incubated together with the sludge, the presence of the test material – either the pigment material or the TKP 50048 coating - had an inhibitory effect on the respiration of the sewage bacteria.

Although it is likely that the plastic in some of the containers and other articles containing the pigment may be recycled into other products, eventually all of the notified chemical is expected to finish up in landfill.

Most of the compound deposited into landfill will be enclosed within a polymer matrix with only small quantities resulting from spills of the pigment left in the free state. Nevertheless, as the polymer matrices break down through the slow biological and abiotic processes operative in landfills, the compound will be “liberated” and then slowly attacked and degraded by the native bacteria. During biodegradation under aerobic conditions the compound would eventually mineralise to water, sulphate and oxides of carbon and nitrogen.

Although very little of the chemical is likely to be released to the water compartment, the relatively high molecular weight (857 g/mole) indicates a low potential for bioaccumulation despite the expected low water solubility and high value of log Kow (Connell, 1990).

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Summary of Toxicological Investigations

Endpoint & Result	*Assessment Conclusion*
Rat, acute oral LD50 > 2000 mg/kg bw	low toxicity
Rabbit, skin irritation	non-irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation - adjuvant test.	no evidence of sensitisation
Genotoxicity - bacterial reverse mutation	non mutagenic

9.2 Acute Toxicity

9.2.1 Acute Oral Toxicity

TEST SUBSTANCE: TKP 50048

METHOD: OECD 423 Acute Oral Toxicity – Acute Toxic Class Method. EC Commission Directive 96/54/EC, Part B.1 - Acute Toxicity – Oral, Acute Toxic Class Method.

Species/Strain	Rat/Wistar
Vehicle	propylene glycol
Remarks - Method	None

RESULTS

Group	*Number & Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	3/sex	2000	None

LD50	> 2000 mg/kg bw
Signs of Toxicity	alopecia in one female on days 3 and 4; red staining of the nose in one male immediately after dosing; red skin of various body parts and/or red faeces due to staining by the test substance in all animals during the observation period
Effects in Organs	None
Remarks - Results	None

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

TEST FACILITY: Notox (2000d)

9.2.2 Acute Dermal Toxicity

No data provided.

9.2.3 Acute Inhalation Toxicity

No data provided.

9.2.4 Skin Irritation

TEST SUBSTANCE	TKP 50048
METHOD	OECD 404 Acute Dermal Irritation/Corrosion. EC Commission Directive 92/69/EEC, B.4, Acute Toxicity – Skin Irritation.
Species/Strain	Rabbit/New Zealand White
Number of Animals	3 males
Observation Period	72 hours
Vehicle	ethanol
Type of Dressing	Semi-occlusive.
Remarks - Method	None.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema/Eschar	0	0	0	0	0	0
Oedema	0	0	0	0	0	0

*Calculated on the basis of the scores at 24, 48, & 72 hours for EACH animal.

Remarks - Results	Due to red staining of the skin by the test substance, erythema could not be scored in all animals after 1 and 24 hours.
CONCLUSION	The notified chemical is non-irritating to skin.
TEST FACILITY	Notox (2000e)

9.2.5 Eye Irritation

TEST SUBSTANCE	TKP 50048
METHOD	OECD 405 Acute Eye Irritation/Corrosion. EC Commission Directive 92/69/EEC, B.5, Acute Toxicity – Eye Irritation.
Species/Strain	Rabbit/New Zealand White
Number of Animals	3 males
Observation Period	72 hours
Remarks - Method	Samples of 28 mg were instilled into eyes.

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	*2*	*3*			
Conjunctiva: redness	0	0	0.33	1	24 hours	0
Conjunctiva: chemosis	0	0	0			
Conjunctiva: discharge	0	0	0			
Corneal opacity	0	0	0			
Iridial inflammation	0	0	0			

*Calculated on the basis of the scores at 24, 48, & 72 hours for EACH animal.

Remarks - Results: Red staining of the fur on the head and paws was noted throughout the observation period. Remnants of the test substance were present in the eyes of all animals on day 1 and on the outside of the eyelids of all animals on day 2.

CONCLUSION: The notified chemical is slightly irritating to the eye.

TEST FACILITY: Notox (2000f)

9.2.6 Skin Sensitisation

TEST SUBSTANCE: TKP 50048

METHOD: OECD 406 Skin Sensitisation – Maximisation test. EC Commission Directive 96/54/EC, Part B.6, Skin Sensitisation.

Species/Strain: Guinea pig/Dunkin-Hartley.

PRELIMINARY STUDY: Maximum non-irritating concentration:
intradermal: 10% (necrosis observed was assumed to be due to the vehicle, propylene glycol)
topical: 50%

MAIN STUDY

Number of Animals: Test Group: 10 Control Group: 5

INDUCTION PHASE: Induction Concentration
intradermal: 10%
topical: 50%

Signs of Irritation: Signs of necrosis were seen at the injection sites of control animals and were, therefore, due to treatment with the vehicle, propylene glycol.

CHALLENGE PHASE

1st challenge: topical application: 50%

Remarks - Method: One day prior to topical induction, irritation was induced by

application of 10% SDS.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after:*			
		1st challenge		*2nd challenge*	
		24 h	*48 h*	*24 h*	*48 h*
Test Group	50%	0	0	-	-
Control Group	50%	0	0	-	-

Remarks - Results: Red staining was observed at all test substance treated skin sites, 24 and 48 hours after challenge. This staining did not hamper the scoring of the skin reactions.

CONCLUSION: There was no evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.

TEST FACILITY: Notox (2000g)

9.3 Repeat Dose Toxicity

No data provided.

9.4 Genotoxicity

9.4.1 Genotoxicity-Bacteria

TEST SUBSTANCE: TKP 50048

METHOD: OECD 471 Bacterial Reverse Mutation Test. EEC Directive 92/69. Annex V of the EEC Directive 67/548/EEC, Part B: Methods for the Determination of Toxicity, B.13: Mutagenicity: *Escherichia coli* – Reverse Mutation Assay, with strain WP2*uvr*A only; B.14: Mutagenicity: *Salmonella typhimurium* – Reverse Mutation Assay.

Species/Strain: *S. typhimurium*:
TA1535, TA1537, TA98, TA100
E. coli: WP2 *uvr*A

Metabolic Activation System: Rat liver microsomal fraction (S9)

Concentration Range in Main Test: a) With metabolic activation: 3,10, 33, 100, 333, 1000, 3330 and 5000 microgram/plate (experiment 1); 1, 3, 10, 33, 100 microgram/plate (experiment 2).
b) Without metabolic activation: 3,10, 33, 100, 333, 1000,

	3330 and 5000 microgram/plate (experiment 1); 1, 3, 10, 33, 100 microgram/plate (experiment 2).
Vehicle	ethanol

RESULTS

Metabolic Activation	*Test Substance Concentration (microgram/plate) Resulting in:*			
	Cytotoxicity in PreliminaryTest	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Present				
Test 1	Not Done	None	33 microgram/plate and up	None
Test 2	Not Done	None	33 and 100 microgram/plate	None
Absent				
Test 1	Not Done	None	33 microgram/plate and up	None
Test 2	Not Done	None	33 and 100 microgram/plate	None

Remarks - Results None

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

TEST FACILITY Notox (2000h)

9.5 Overall Assessment of Toxicological Data

The notified chemical was of very low acute oral toxicity in rats, was not a skin irritant and was a slight eye irritant in rabbits, was not a skin sensitiser in guinea pigs and was not mutagenic in bacteria.

The notified chemical was not a hazardous substance according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999).

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

No ecotoxicity data were provided.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

It is not expected that the notified chemical will constitute a hazard to the environment when used as a coating for pigment particles in polymer products in the manner indicated by the notifier.

A maximum of 5 kg of the chemical may be placed into landfill each year together with waste resulting from formulation and manufacture of coloured polymer masterbatch as well as from end use injection moulding of polymer into final products such as plastic containers and other articles. At the end of their useful lives, old containers and articles containing the chemical would most likely be placed into landfill although some may be recycled for recovery of the polymers.

After incorporation into polymer articles, the pigment particles coated with the notified chemical are bound into the polymer matrix with little potential for release, and consequently little release of the notified chemical is expected from finished articles.

However, once placed into landfill it is expected that the polymer matrix would slowly degrade and break down through slow abiotic and biological processes operative there with release of the pigment particles coated with the notified chemical. It is probable that these particles would become associated with the soil, and the chemical (as well as the pigment "core" particle) would slowly degrade through biological and abiotic processes. The notified chemical will mineralise to water, sulphate and oxides of carbon and nitrogen.

No ecotoxicity data for the notified chemical were available but, since it is unlikely that any would reach the water compartment no hazard to the aquatic compartment is likely when used as indicated.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

Hazard Assessment

The notified chemical was of very low acute oral toxicity in rats, was not a skin irritant and was a slight eye irritant in rabbits, was not a skin sensitiser in guinea pigs and was not mutagenic in bacteria.

Based on the limited toxicological data provided, the notified chemical was not a hazardous substance according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999).

The notified chemical is imported as a coating on pigment particles. The MSDS for the pigment specifies that the NOHSC exposure standard of 10 mg/m3 (TWA) for nuisance dusts (NOHSC, 1995) should be observed. Although no particle size determination was reported for the pigment, a high proportion of the particles can be assumed to be of respirable size (less than 10 microns).

Occupational Health and Safety

Storage and transport workers are unlikely to be exposed to the notified chemical unless the packaging is breached. Therefore, the risk of adverse health effects to these workers should be low.

The greatest occupational exposure to the notified chemical is likely to be in the formulation of polymer masterbatches containing the pigment on which the notified chemical is coated. After the formulation of the masterbatches, the polymer will be encapsulated in the polymer matrix and will only slowly migrate to the surface of the polymer pellets or articles. Therefore the exposure to the notified chemical of workers manufacturing articles containing the notified chemical should be low. Minor exposure to workers who handle articles may occur due to slow diffusion of the notified chemical to the surface of the article.

Workers who blend the masterbatch will weigh out the notified chemical in a dispensary which is designed for handling fine pigments, and local exhaust ventilation will be used to minimise inhalation exposure. Transfer to the blender and then to the extruder will also occur under local exhaust ventilation. Although inhalation exposure of respirable particles may occur, and some dermal exposure is likely, the risk of adverse health effects in masterbatch preparation is likely to be low due to the probable low toxicity of the notified chemical. Nevertheless, due to the eye irritant effects and the general irritation of nuisance dusts, workers handling the chemical should wear safety gloves, goggles, overalls, and a dust mask. Laboratory workers may potentially be more likely to be exposed to the notified chemical while performing their tests but these tests should occur only intermittently throughout the year.

On balance, the probable low hazard of the notified chemical, its low concentration in the pigment powder, the probable use of engineering controls and the generally short duration of exposure for most workers suggest that the risk of adverse health effects is low.

Public Health

It is expected that public contact with the notified chemical will be limited to contact with it as a coating on pigment particles - the state in which it is imported. Any contact is likely to dermal but may possibly involve the membranes of the eyes, mouth and nose under windy conditions. The notified chemical has a low vapour pressure and will not be inhaled under ordinary conditions. It is not likely that a member of the public will contact the notified chemical as an environmental contaminant. As an integral part of the end-use product, it will not be accessible to human contact. The low likelihood of exposure to the notified chemical and the toxicological profile of the notified chemical suggest that it will not pose a significant hazard to public health when used in the proposed manner.

13. RECOMMENDATIONS

Regulatory controls

- The NOHSC exposure standard for nuisance dust of 10 mg/m3 (NOHSC, 1995) and the ACGIH TLV for respirable particles of 3 mg/m3 (ACGIH, 1998).

Control Measures

Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified chemical as introduced:

- local exhaust ventilation should be employed during weighing out and addition of pigment to blending machines, during laboratory tests and during extrusion of masterbatches.

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical as introduced:
  - spillage of the pigment coated with the notified chemical should be avoided; spillage should be cleaned up in a manner which serves to minimise dust clouds.

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical as introduced:
  - PVC gloves, overalls, safety glasses or goggles and, if ventilation is inadequate, a dust mask.

  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.

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 notified chemical is to be imported neat or the import volume is greater than 1 tonne per year a full toxicological package and complete physico-chemical properties should be submitted

or

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

No additional secondary notification conditions are stipulated.

14. MATERIAL SAFETY DATA SHEET

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

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

15. REFERENCES

American Conference of Government Industrial Hygienists (1998) TLVs and Other Occupational Exposure Values.

Ciba Specialty Chemicals (2000a) Test Substance TKP 50048. Report on Melting Temperature. Study No. FC-99/6T.MP. Ciba Specialty Chemicals Inc, Basel, Switzerland (unpublished report submitted by Ciba Specialty Chemicals Inc).

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Notox (2000b) Determination of the Partition Coefficient (N-Octanol/Water) of TKP 50048. Study No. 279372. Notox B V, 's-Hertogenbosch, The Netherlands (unpublished report submitted by Ciba Specialty Chemicals Inc).

Notox (2000c) Determination of "Ready" Biodegradability: Carbon Dioxide Evolution Test (Modified Sturm Test) with TKP 50048. Study No. 279462. Notox B V, 's-Hertogenbosch, The Netherlands (unpublished report submitted by Ciba Specialty Chemicals Inc).

Notox (2000d) Assessment of Acute Oral Toxicity with TKP 50048 in the Rat (Acute Toxic Class Method). Study No. 279416. Notox B V, 's-Hertogenbosch, The Netherlands (unpublished report submitted by Ciba Specialty Chemicals Inc).

Notox (2000e) Primary Skin Irritation/Corrosion Study with TKP 50048 in the Rabbit (4-hour Semi-Occlusive Application). Study No. 279427. Notox B V, 's-Hertogenbosch, The Netherlands (unpublished report submitted by Ciba Specialty Chemicals Inc).

Notox (2000f) Acute Eye Irritation/Corrosion Study with TKP 50048 in the Rabbit. Study No. 279438. Notox B V, 's-Hertogenbosch, The Netherlands (unpublished report submitted by Ciba Specialty Chemicals Inc).

Notox (2000g) Assessment of Contact Hypersensitivity to TKP 50048 in the Albino Guinea Pig (Maximisation Test). Study No. 279449. Notox B V, 's-Hertogenbosch, The Netherlands (unpublished report submitted by Ciba Specialty Chemicals Inc).

Notox (2000h) Evaluation of the Mutagenic Activity of TKP 50048 in the Salmonella typhimurium Mutation Assay and the Escherichia coli Reverse Mutation Assay (with Independent Repeat). Study No. 279451. Notox B V, 's-Hertogenbosch, The Netherlands (unpublished report submitted by Ciba Specialty Chemicals Inc).

Sykes P (1986) Mechanism in Organic Chemistry, 6th edition, Longman, pp 72-74.

Attachment 1

The Draize Scale (Draize, 1959) for evaluation of skin reactions is as follows:

Erythema Formation	*Rating*	*Oedema Formation*	*Rating*
No erythema	0	No oedema	0
Very slight erythema (barely perceptible)	1	Very slight oedema (barely perceptible)	1
Well-defined erythema	2	Slight oedema (edges of area well-defined by definite raising	2
Moderate to severe erythema	3	Moderate oedema (raised approx. 1 mm)	3
Severe erythema (beet redness)	4	Severe oedema (raised more than 1 mm and extending beyond area of exposure)	4

The Draize scale (Draize *et al*., 1944) for evaluation of eye reactions is as follows:

CORNEA

Opacity	*Rating*	*Area of Cornea involved*	*Rating*
No opacity	0 none	25% or less (not zero)	1
Diffuse area, details of iris clearly visible	1 slight	25% to 50%	2
Easily visible translucent areas, details of iris slightly obscure	2 mild	50% to 75%	3
Opalescent areas, no details of iris visible, size of pupil barely discernible	3 moderate	Greater than 75%	4
Opaque, iris invisible	4 severe		

CONJUNCTIVAE

Redness	*Rating*	*Chemosis*	*Rating*	*Discharge*	*Rating*
Vessels normal	0 none	No swelling	0 none	No discharge	0 none
Vessels definitely injected above normal	1 slight	Any swelling above normal	1 slight	Any amount different from normal	1 slight
More diffuse, deeper crimson red with individual vessels not easily discernible	2 mod.	Obvious swelling with partial eversion of lids	2 mild	Discharge with moistening of lids and adjacent hairs	2 mod.
Diffuse beefy red	3 severe	Swelling with lids half-closed	3 mod.	Discharge with moistening of lids and hairs and considerable area around eye	3 severe
		Swelling with lids half-closed to completely closed	4 severe		

IRIS

Values	*Rating*
Normal	0 none
Folds above normal, congestion, swelling, circumcorneal injection, iris reacts to light	1 slight
No reaction to light, haemorrhage, gross destruction	2 severe

Draize, J. H., Woodward, G., Calvery, H. O. (1944) Methods for the Study of Irritation and Toxicity of Substances Applied Topically to the Skin and Mucous Membranes, J. Pharmacol. Exp. Ther. 82 : 377-390.

Draize J. H. (1959) Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics. Association of Food and Drug Officials of the US, 49 : 2-56.