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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

DISPONIL PGE 110

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:

Street Address:	334 - 336 Illawarra Road MARRICKVILLE NSW 2204, AUSTRALIA.
Postal Address:	GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.
TEL:	+ 61 2 8577 8800
FAX	+ 61 2 8577 8888
Website:	www.nicnas.gov.au

Director
NICNAS

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Cognis Australia Pty Ltd
4 Salina Drive
Tullamarine VIC 3043

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, Spectral Data, Purity, Identity of Hazardous Impurities, Import Volumes, Details of Use, and Identitiy of Recipients.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:
Acute dermal toxicity, melting point/freezing point, hydrolysis as a function of pH, adsorption/desorption, dissociation constant, flammability limits, and autoignition temperature.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
USA (1997)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Disponil PGE 110

MOLECULAR WEIGHT
>500 Da

ANALYTICAL DATA
Reference GC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY >95%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS

Chemical Name	*Ethylene oxide*		
CAS No.	75-21-8	*Weight %*	*< 0.0001*

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (>1% by weight) None

ADDITIVES/ADJUVANTS None

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: Yellowish liquid

Property	Value	Data Source/Justification
Melting Point/Freezing Point	-	Not determined.
Boiling Point	694°C at 101.3 kPa	Estimated.
Density	1040 kg/m^3 at 20°C	Measured.
Vapour Pressure	2.81×10^{-15} kPa at 20°C	Estimated.
Water Solubility	Miscible at pH 1, 7 and 10 at 20°C	Measured. The notified chemical is miscible in water in all proportions up to 1:1 (w/w).
Hydrolysis as a Function of pH	Not determined	Does not contain functional groups susceptible to hydrolysis
Partition Coefficient (n-octanol/water)	log P_{ow} = 0.63 at 20°C	Estimated using WPWIN. Based on the structure and its use, the notified chemical is expected to be a non-ionic surfactant and hence an accurate measure of its partition coefficient cannot be obtained.
Adsorption/Desorption	log K_{oc} = 1	Estimated using PCKOCWIN v 1.66. The notified chemical is expected to be a non-ionic surfactant and hence an accurate measure of its adsorption coefficient cannot be obtained.
Dissociation Constant	Not determined	Contains no functional groups dissociable in the environmental pH range (4-9).
Particle Size	-	Not determined as the notified chemical is in liquid form.
Flash Point	190°C at 101 kPa	Measured
Flammability Limits	-	Not determined.
Autoignition Temperature	-	Not determined.
Explosive Properties	-	Not determined

DISCUSSION OF PROPERTIES
For full details of tests on physical and chemical properties, refer to Appendix A.

Reactivity
Given the structure, the notified chemical is not reactive under normal conditions. Terminal hydroxy groups can react given suitable conditions.

Dangerous Goods classification
Based on the available data the notified chemical is not classified, according to the Australian Dangerous Goods Code (NTC, 2007).

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will not be manufactured in Australia and will be imported as a minor ingredient (<4%) in polymer emulsion intended for use in preparing coating and adhesive products. It is expected that approximately 70% of the notified chemical will be imported into Sydney and about 30% into Melbourne.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	3-10	3-10	5-15	5-15	5-20

PORT OF ENTRY
Sydney and Melbourne

IDENTITY OF MANUFACTURER/RECIPIENTS
The notified chemical will be imported and will not be manufactured in Australia.

TRANSPORTATION AND PACKAGING
The product (emulsions) containing the notified chemical will be imported in 50 kg or 220 kg (200 L) drums or IBCs of 1000 to 1100 kg in Full Container Loads (FCLs) and will be taken to the importer's warehouse or that of their customer, by road, normally as part of an FCL. In the future, it is expected that the notified chemical will be mainly imported in bulk "flexibags" of 22 tonnes capacity in FCLs.

USE
The notified chemical is intended to be used as a stabiliser for polymer dispersions in coatings and adhesives at up to 2%. The most likely applications in Australia are in interior decorative paint and adhesives for wood and paper.

OPERATION DESCRIPTION
The blending of polymer dispersion containing the notified chemical with other coating or adhesive ingredients is expected to be carried out in purpose-built stainless steel blenders, usually equipped with high-shear rotors to properly disperse ingredients. The notified chemical will be pumped directly from the imported containers into the blender. After quality control, the blended mixture will be transferred via a closed system to filling machine.

Typically, two such batches would be completed per day of use. Both the blending and filling-off processes are normally automated. The final concentration of notified chemical in the finished coating and adhesives formulation will be up to 2%.

After emptying, the drums that contained the notified chemical will be rinsed with process liquid into the blending vessel and the washings kept for charging as part of the first batch charge in the next campaign. Rinsed and drained drums are expected to be sent to a drum recycler.

It is expected that the blending and filling off equipment will be cleaned after the end of the campaign for a given range of common-base products by flushing the system with process liquid. It is expected that rinsings will be filled out as a "heel" for charging into the first batch of the next campaign.

It is expected that coating application of end-use products will be either by brushing or by roller. Coatings and/or adhesive products may also be applied by DIY users.

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 & storage	2	0.5	5 to 10
Process operator	2	1 (2 X 0.5)	70 to 90
Laboratory technician	1	0.33	70 to 90
End-use applicators	>1000	3	100 to 200

EXPOSURE DETAILS
Transport workers and storemen are not expected to be exposed to the notified chemical except in the unlikely event of an accident. Dockside and warehouse workers routinely wear cotton overalls and steel-capped boots.

Occupational exposure is possible during blending, filling-up, and the application of the blended coatings or adhesives containing the notified chemical. Potential routes of occupational exposure are dermal, ocular and inhalation.

During blending, the notified chemical will be pumped directly from the containers into the blender and the blended mixture will be transferred via a closed system to a multi-head automatic filling machine. Therefore, workers can only be exposed to the notified chemical during connecting and disconnecting transfer hoses. The

use of local exhaust ventilation and personal protective equipment (gloves, coverall, face shield) are expected to reduce exposure to the notified chemical.

Occupational exposure may also occur during the end-use application of the products containing the notified chemical in emulsions coatings or in adhesives (wood/paper). Coating applications will be mainly by brushing or by roller and use in adhesives by manual application to wood/paper. The notifier states that all personnel handling the polymer dispersions/coatings containing the notified chemical are required to use appropriate PPE. All employees also undertake basic safety training and induction and are trained in the use of PPE, including instructions for emergency situations.

While it is expected that application will be by brush or roller, application by spray may also occur.

Exposure estimation

The primary route of systemic absorption is via dermal exposure. In the absence of scientific data on dermal and inhalation absorption, 100% dermal and inhalation absorption value is used in the exposure estimation. From the proposed operation description, the expected dermal exposures to the notified chemical can be categorised into two groups: (1) Incidental exposures during blending and (2) exposures during application and use.

1. Incidental exposures during blending:

The highest probable exposure of this kind is during the coupling and uncoupling of transfer lines for the product containing the notified chemical (maximum concentration 4%). For worst-case estimates, this is assumed to occur daily (although in practice it may be less frequent). The dermal exposure during such processes has been described as a probable half-hand exposure (420 cm^2) and an exposure level of 0.1 mg/cm^2/day to an adult male worker (70 kg body weight (bw) (EC, 2003). Considering the maximum concentration of the notified chemical at 4%, the combination of these gives a worst-case dermal exposure of:

(0.1 mg/cm^2/day x 0.04 (4%) × 420 cm^2 × 100% absorption)/70 kg bw = 0.024 mg/kg bw/day

The dermal exposures that are expected during sampling or other formulation steps (where the notified chemical is diluted) are likely to be lower than this estimate.

2. Exposures during application and use:

Dermal exposure to the notified chemical is expected during the application of coatings and adhesive products (maximum concentration 1%). For worst-case estimates, this is assumed to occur daily (although in practice it will likely be less than that). Measured data for dermal exposure during the brush and roller application of relatively viscous, low volatility liquid products on surfaces has been described by the RISKOFDERM project, which has described reasonable worst-case exposures of 6500 mg/scenario, and typical-case exposures of 1000 mg/scenario (Marquart *et al*, 2006). Workers (professional users) are not expected to wear PPE during application of decorative paints (apart from perhaps a long-sleeved shirt or similar). The combination of these factors (70 kg bw (EC, 2003), gives an expected dermal exposure range of:

(1000× 0.01)/70 kg bw) to (6500× 0.01)/70 kg bw) = 0.14-0.93 mg/kg bw/day

This exposure estimate is expected to be additionally conservative, as it does not account for interactions of the notified chemical within coating products that might limit the extent of its bioavailability. Once applied to the substrate, the notified chemical is expected to be trapped within the dried polymeric layer of the coating, and therefore should not be readily available to cause exposure.

6.1.2. Public exposure

Some coatings and/or adhesive products may be applied by DIY users. Therefore, public may be exposed to the notified chemical when applying the products containing the notified chemical.

Following application, the notified chemical will be locked in the cured coating or adhesives on any object that may be handled by public. Public exposure is not expected as the notified chemical is not bioavailable.

Exposure estimation
Dermal exposure of the public to the notified chemical is expected during the application of coatings and adhesive products (maximum concentration 1%). For worst-case estimates, this is assumed to occur daily (although in practice it will likely be less than a few days per year). Measured data for dermal exposure during the brush and roller application of relatively viscous, low volatility liquid products on surfaces has been described by the RISKOFDERM project, which has described reasonable worst-case exposures of 6500 mg/scenario, and typical-case exposures of 1000 mg/scenario (Marquart *et al*, 2006). Members of the public are not expected to wear PPE during application of decorative paints (apart from perhaps a long-sleeved shirt or similar). The combination of these factors, for adult males and females (60 kg bw (EC, 2003), gives an expected dermal exposure range of:

(1000× 0.01)/60 kg bw) to (6500× 0.01)/60 kg bw) = 0.17-1.08 mg/kg bw/day

This exposure estimate is expected to be additionally conservative, as it does not account for interactions of the notified chemical within coating products that might limit the extent of its bioavailability. Once applied to the substrate, the notified chemical is expected to be trapped within the dried polymeric layer of the coating, and therefore should not be readily available to cause exposure.

6.2. Human health effects assessment

The results from toxicological investigations conducted on the notified chemical are summarised in the table below. Details of these studies can be found in Appendix B.

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	oral LD50 >2000 mg/kg bw in male and ≤2000 mg/kg bw in female harmful
Rat, acute dermal toxicity	Not submitted
Rat, acute inhalation toxicity	Not submitted
Rabbit, skin irritation	non-irritating
Rabbit, eye irritation	irritating
Guinea pig, skin sensitisation – adjuvant test	no evidence of sensitisation
Rat, repeat dose oral toxicity – 90 days.	NOEL=30 mg/kg bw/day NOAEL=90 mg/kg bw/day
Mutagenicity – bacterial reverse mutation	non mutagenic
Genotoxicity–In vitro mammalian cell gene mutation test	non genotoxic
Genotoxicity-In vitro mammalian cell gene mutation test	non genotoxic
Genotoxicity–in vivo mouse bone marrow micronucleus test	non genotoxic

Toxicokinetics, metabolism and distribution:
No data were available to assess toxicokinetics, metabolism and distribution of the notified chemical. Based on the log Kow and molecular weight >1000, dermal absorption may occur.

Acute toxicity:
The oral LD50 was >2000 mg/kg bw in male rats and ≤2000 mg/kg bw in female rats. The notified chemical is harmful via the oral route. No information was submitted on inhalation toxicity.

Irritation and Sensitisation:
The notified chemical was not irritating to the skin of rabbit and was irritating to the eyes of rabbit. It was not a skin sensitiser in guinea pigs.

Repeated Dose Toxicity (sub chronic):
In an oral toxicity study in rats, the notified chemical was administered orally by gavage once daily (5 days/week) for 90 days at 0, 30, 90 or 270 mg/kg bw/day. A recovery group of the high dose groups was also observed for 29 days after the termination of the main study. The most relevant findings were the effects on liver and adrenal glands and the inflammatory and proliferative reactions of the mucosa of the forestomach.

The No Observed Effect Level (NOEL) was 30 mg/kg bw/day, based on the presence of test-substance related findings in the forestomach of the animals of the 90 mg/kg bw/day group and the effect on liver and adrenal glands of the animals of the 270 mg/kg bw/day group. Only minor local reactions of the mucosa of the

forestomach of the male animals of 30 mg/kg bw/day were observed.

Mutagenicity:
The notified chemical was found to be non-mutagenic in a bacterial reverse mutation test and also showed no evidence of clastogenicity, either with or without metabolic activation, in mouse bone marrow micronucleus test. The notified chemical was also not mutagenic in mammalian cell gene mutation test in Chinese Hamster V79 Cells (V79/HPRT). Based on these results, the notified chemical is not expected to be genotoxic.

Carcinogenicity:
No data were available to assess the potentials for carcinogenicity.

Toxicity for reproduction:
No data were available to assess the potentials for toxicity for reproduction.

Health hazard classification
Based on the acute oral toxicity test, the notified chemical is classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

Although the notified chemical is an eye irritant in rabbits, the test scores does not warrant classification for eye irritation.

6.3. Human health risk characterisation

6.3.1. Occupational health and safety
The notified chemical was harmful via the oral route, with acute oral LD50 being >2000 mg/kg bw in male rats and ≤2000 mg/kg bw in female rats. The notified chemical was not irritating to the skin of rabbit, but was moderately irritating to the eyes of rabbit. It was not a skin sensitiser in guinea pigs. The notified chemical is not expected to be genotoxic.

In an oral toxicity study in rats, the most relevant findings were the effects on liver and adrenal glands and the inflammatory and proliferative reactions of the mucosa of the forestomach. The NOEL was found to be 30 mg/kg bw/day test substance, based on the presence of test-substance related findings in the forestomach of the animals of the 90 mg/kg bw/day group and the effect on liver and adrenal glands of the animals of the 270 mg/kg bw/day group.

During transport and storage, the risk of worker exposure is minimal as workers will only be exposed to the notified chemical in the case of an accident involving damage to the packaging. As dockside and warehouse workers routinely wear cotton overalls and steel-capped boots, the risk of occupational exposure will be further minimised and considered acceptable.

There is risk for potential occupational exposure during blending, filling-up, and the application of the blended coatings or adhesives containing the notified chemical. The main routes of occupational exposure are *via* dermal, ocular and inhalation.

The blending operation is an automated process and the notified chemical will be pumped directly from the containers into the blender and the blended mixture will be transferred via a closed system to a multi-head automatic filling machine. Therefore, workers can only be exposed to the notified chemical during connecting and disconnecting transfer hoses and exposure is expected to be minimal during this process. Considering that the use of local exhaust ventilation and personal protective equipment (gloves, coverall, face shield) are expected to further reduce any potentials of exposure to the notified chemical, the risk to workers is expected to be low and acceptable.

Exposure may also occur during quality assurance testing and sampling at the time of blending. Considering that these workers will handle small quantity of sample for a short period of time and that the notified chemical is present at low concentration (up to 4%), exposure is considered to be low and acceptable. The packaging process is carried out by a multi-head automatic filling machine. Dermal contact would be the main route of occupational exposure during packaging. Considering the low concentration (up to 2%) of the notified chemical in the finished products, the risk of exposure to workers is expected to be low and acceptable.

Exposure to the end-use products (emulsion coatings or adhesives) containing the notified chemical is expected during the end-use applications. Coating applications will be mainly by brushing or by roller and use in adhesives by manual application to wood/paper. The notifier states that all personnel handling the polymer dispersions/coatings containing the notified chemical are required to use appropriate PPE. All employees also undertake basic safety training and induction and are trained in the use of PPE. Considering the above and that the notified chemical is present at a low concentration (up to 2%) in the finished products, the risk to workers during end use applications is expected to be low and is considered acceptable.

The notified chemical is an eye irritant. However, based on the concentration of the notified chemical in the formulations as introduced (<4%) and in finished products (<2%), the risk of eye irritancy for workers is low.

Inhalation exposure may occur if the end-use products were to be applied by spray application. As information on inhalation toxicity is not available, controls to reduce exposure would be needed to ensure safe use.

In addition, there may be some risk of systemic effects upon repeated exposure, given that dermal absorption is probable. A combination of the exposure estimates above with the NOAEL of the notified chemical (90 mg/kg bw/day) gives the following Margin of Exposure (MoE) values:

MoE (exposure during blending)	=	(90 mg/kg bw/day)/(0.024 mg/kg bw/day)
	=	3750
MoE (exposures during application)	=	(90 mg/kg bw/day)/(0.14-0.93 mg/kg bw/day)
	=	643-97

These MoE values, based on conservative exposure estimates, show a sufficient safety margin (>100 or closer to 100 at the worst-case) to conclude that the notified chemical is unlikely to pose an unacceptable risk of systemic effects in workers upon repeated exposure during blending and application.

6.3.2. Public health

Public exposure to the notified chemical is possible as some coatings and/or adhesive products may be applied by DIY users. Specific precautions are not recommended for public use. Following application, the risk of public exposure is expected to be low as the notified chemical will be locked in the cured coating or adhesives on any object and is not bioavailable. Therefore, considering the above and that the notified chemical is present at a low concentration (up to 2%) in the finished end-use products, the risk to public health is low and considered acceptable.

Spray application by the public of products containing the notified chemical is not expected, but could occur. As information on inhalation toxicity is not available, controls to reduce exposure would be needed to ensure safe use.

A combination of the exposure estimates above with the NOAEL of the notified chemical (90 mg/kg bw/day) gives the following MoE values:

MoE (public use) = (90 mg/kg bw/day)/(0.17-1.08 mg/kg bw/day) = 529-83

Considering the high variability of exposure estimated using available references (1000-6500 mg/scenario), the MoE range for public is 83-529. MOE greater than 100 is considered acceptable for safe use of the notified chemical by DIY users. Although the lowest MoE is <100, this situation is considered an overestimation of the risk considering that DIY users may not use the products repeatedly over a long period of time. Therefore, the risk to public is considered acceptable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified chemical is manufactured overseas and imported into Australia and there will be no release from these activities. The notified chemical is reformulated into polymer emulsions for coatings or adhesives. Empty drums or flexi-bags containing the notified chemical are rinsed, with the rinsings added to the next batch of emulsion coating. The notifier indicates that up to 1% (200 kg per annum) of the contents may remain in the empty drum or flexi-bag after rinsing. Similarly during blending equipment maintenance and cleaning, washings will be retained and added to the next batch.

Spills on-site are expected to be contained with no release to the environment. Spills are expected to be recovered to the extent practicable. The remainder is expected to be adsorbed to inert material and disposed of to an authority landfill.

RELEASE OF CHEMICAL FROM USE

The notifier has indicated that the notified chemical will be used in paints and adhesives for interior decorative applications. The paints containing the notified chemical will be applied almost entirely by roller and brush. Residual paint/coatings containing the notified chemical may be released to the environment from disposal of excess paint or from cleaning of equipment.

Professional painters are expected to brush out excess paint onto newspaper or rags etc before rinsing brushes and rollers and capturing the rinse in a container. The waste paint/adhesive in the container will be allowed to cure before disposal as solid waste. The waste water may be disposed of to ground away from waterways. Excess paint in containers is expected to be stored for later use or disposed of to authority landfill.

DIY painters may follow the same practice as professional painters, however, it has been estimated that between 10 and 15% of paint remains unused by householders at the end of a job. Much of this may be used for subsequent jobs but DEWHA estimates that residue in used paint cans will account for approximately 5% of the paint containing the notified chemical. Incorrectly disposed of paints (containing the notified chemical) from waste and washing of equipment may be released to sewer, drains or ground.

The fate of the coating or adhesive cured on the substrate will be shared with the fate of the coated article, which ultimately is expected to be landfill.

RELEASE OF CHEMICAL FROM DISPOSAL

Rinsed drums from re-formulators are expected to be handled by licensed drum recyclers. Rinsed flexi-bags used to import the notified chemical are expected to be disposed of to authority landfill. Waste paints or adhesive coatings containing the notified chemical will be disposed of predominantly to authority landfill as part of a cured mass.

7.1.2 Environmental fate

The overwhelming portion of the imported quantity of notified chemical will be immobilised within the cured coatings on architectural structures. The ultimate fate of this portion of the notified chemical will be determined by the fate of building structures and other domestic waste articles. In most cases this will involve disposal to landfill at the end of their useful lives. The notified chemical would be degraded slowly in landfill by abiotic and biotic processes to oxides of carbon and water vapour. A small proportion of the imported quantity of the notified chemical may be released into sewers through incorrect disposal of residual paints or coatings. As a non-ionic surfactant the notified chemical is expected to partition to phase boundaries and some removal in STPs can be expected. In aquatic ecosystems, the notified chemical is expected to biodegrade and is unlikely to bioaccumulate.

For the details of the environmental fate studies, refer to Appendix C.

7.1.3 Predicted Environmental Concentration (PEC)

A small amount of paint or adhesives containing the notified chemical may be released to sewer due to incorrect disposal of residual formulated product in cans or on rollers and brushes. As a worst case it is assumed that 5% of the formulated product containing the notified chemical may be released to sewer nationwide per year with no degradation or removal in the STP. For this scenario the PEC may be calculated as follows:

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	20 000	kg/year
Proportion expected to be released to sewer	5%	
Annual quantity of chemical released to sewer	1000	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)	21.167	million
Removal within STP	0%	
Daily effluent production:	4232	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	0.65	µg/L
PEC - Ocean:	0.06	µg/L

In practice the release is likely to be much lower as a more likely estimate of the amount disposed of to sewer is 0.2% of total paint sales (APMF 2006). The notified chemical is also likely to biodegrade.

7.2. Environmental effects assessment

The results from ecotoxicological investigations conducted on the notified chemical are summarised in the table below. Details of these studies can be found in Appendix C.

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity (48 hours)	LC50 21 mg/L	Harmful
Daphnia Toxicity (24 hours)	EC50 63 mg/L	Harmful
Algal Toxicity (72 hours)	E_rC50 4.7 mg/L	Toxic

7.2.1 Predicted No-Effect Concentration

Toxicity tests of the notified chemical for species from three trophic levels were submitted. Accordingly a safety factor (Assessment Factor) of 100 is applied to the end-point for the most sensitive species (*Scenedesmus subspicatus*).

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment			
Endpoint (Algae growth)	4.7		mg/L
Assessment Factor	100		
Mitigation Factor		1.00	
PNEC:	47		µg/L

7.3. Environmental risk assessment

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River	0.65	47	**0.01**
Q - Ocean	0.06	47	**< 0.01**

The majority of the notified chemical is expected to remain with paint or adhesive coatings in which it is incorporated. There will be limited release to the environment from the use of the notified chemical when used for its intended purpose. Incorrect disposal of paint products may lead to limited aquatic environmental exposure. However, on the basis of the Risk Quotient (Q = PEC/PNEC), the risk is acceptable.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available data the notified chemical is classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* [NOHSC: 1008(2004)], with the following risk phrase:

Xn: R22 Harmful if swallowed

As a comparison only, the classification of the notified chemical using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations 2003) is presented below. This system is not mandated in Australia and carries no legal status but is presented for information purposes.

	Hazard category	***Hazard statement***
Acute toxicity	Category 4	Harmful if swallowed
	Acute 2	Toxic to aquatic life

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

REGULATORY CONTROLS
Hazard Classification and Labelling

- The Office of the ASCC, Department of Employment and Workplace Relations (DEWR), should consider the following health hazard classification for the notified chemical:
  - Xn: R22 Harmful if swallowed

- Use the following risk phrases for products/mixtures containing the notified chemical:
  - ≥25%: R22 Harmful if swallowed

Material Safety Data Sheet

- The MSDS provided by the notifier should be amended as follows:
  - The MSDS of the products imported containing the notified chemical should contain the local address and emergency telephone number.

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following safe work practice to minimise occupational exposure during handling of the notified chemical as introduced and as diluted for use in the products::
  - Avoid contact with eyes

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical as introduced and as diluted for use in the products:
  - Safety glasses

  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.

- If products containing the notified chemical are applied by spray, use of spray paints containing the notified chemical should be in accordance with the NOHSC National Guidance Material for Spray Painting (NOHSC, 1999).

Public Health

- Products marketed to the public containing the notified chemical should not recommend application by spraying.

Disposal

- The notified chemical should be disposed of to authority landfill.

Storage

- No particular measures are required for storage.

Emergency procedures

- Spills or accidental release of the notified chemical should be handled by physical containment. Recover to the extent practicable, then soak up using inert absorbent material (sand, silica gel, sawdust, universal binder). Place in suitable containers for disposal. Do not flush to sewer or waterways.

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 use as a stabiliser for polymer dispersion in coatings and adhesives, or is likely to change significantly;
- the amount of chemical being introduced has increased from 20 tonnes, 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 the products containing the notified chemical provided by the notifier were reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Boiling Point 694ºC at 101.3 kPa

Method WPWIN estimate using Adapted Stein & Brown method
Remarks
Test Facility Cognis Gmbh & Co KG

Density 1040 kg/m^3 at 20ºC

Method DIN 51757 V 4-94 (mod)
Remarks
Test Facility Cognis Gmbh & Co KG

Vapour Pressure 2.81×10^{-15} kPa at 20ºC

Method WPWIN estimate using modified Grain method
Remarks
Test Facility Cognis Gmbh & Co KG

Water Solubility Miscible at pH 1, 7 and 10 at 20ºC

Method Based on OECD TG 105 Water Solubility.
Remarks Modified Flask Method. Tested at pH 1, 7 and 10. Sequential additions of 5 g aliquots of test substance up to 100 g were added to 100 mL of pH adjusted distilled water. After ~ 5 minutes of mixing, the solubility was determined by visual inspection. The notified chemical was miscible with water in all proportions up to the limit tested (1:1 w/w) in each case. The temperature of the test is unspecified but assumed to be 20°C in accordance with the Test Guideline.
Test Facility Cognis GmbH (undated)

Flash Point 190ºC at 101 kPa

Method ISO2719-88
Remarks
Test Facility Cognis Gmbh & Co KG

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

The test substance used in these studies was notified chemical.

B.1. Acute toxicity – oral

TEST SUBSTANCE Notified chemical

METHOD
EC L257, 1983 Acute Toxicity (Oral).
Internal Method-Limit test
(Study summary was only
available in English)

RESULTS

Species/Strain	Rat/Wistar
Vehicle	Distilled water
Remarks - Method	No significant protocol deviations. The test compound was administered by single gavage in distilled water and an application volume of 10 mL/kg bw.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5M/5F	1400	*1M/0F*
2	5M/5F	2000	1M/5F

LD50	>2000 mg/kg bw in male ≤2000 mg/kg bw in female
Signs of Toxicity	Difficult respiration, reduced body temperature, squatting attitude, diarhoea, blood in nose and mouth.
Remarks – Results	No symptoms 14 days after application.

CONCLUSION The notified chemical is harmful via the oral route

TEST FACILITY HENKEL (1986a)

B.2. Irritation – skin

TEST SUBSTANCE Notified chemical

METHOD OECD TG 404 Acute Dermal Irritation/Corrosion.
EC Directive 92/69/EEC B.4 Acute Toxicity (Skin Irritation).
(Study summary was only available in English)

Species/Strain	Rabbit/New Zealand White
Number of Animals	5
Vehicle	None
Observation Period	72 hrs
Type of Dressing	Occlusive
Remarks - Method	No significant protocol deviations.

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Erythema/Eschar	0	0		0
Oedema	0	0		0

*Calculated on the basis of the scores at 24, 48, and 72 hours for ALL animals.

Remarks - Results	No erythema or other symptoms were observed.

CONCLUSION The notified chemical is non-irritating to the skin.

TEST FACILITY HENKEL (1986b)

B.3. Irritation – eye

TEST SUBSTANCE Notified chemical

METHOD OECD TG 405 Acute Eye Irritation/Corrosion.
EC Directive 92/69/EEC B.5 Acute Toxicity (Eye Irritation).
(Study summary was only available in English)

Species/Strain Rabbit/New Zealand White
Number of Animals Four
Observation Period 10 days
Remarks - Method Applied undiluted

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Conjunctiva: redness	1.92	3	<10 days	*0*
Conjunctiva: chemosis	1.08	2	<7 days	*0*
Conjunctiva:discharge	1.83	3	<10 days	*0*
Corneal opacity	0.25	1	72 hr	*0*
Iridial inflammation	0	0	-	0

*Calculated on the basis of the scores at 24, 48, and 72 hours for ALL animals.

Remarks - Results

CONCLUSION The notified chemical is irritating to the eyes.

TEST FACILITY HENKEL (1986c)

7.6. Skin sensitisation

TEST SUBSTANCE Notified chemical

METHOD OECD TG 406 Skin Sensitisation – adjuvant test.
EC Directive 96/54/EC B.6 Skin Sensitisation – adjuvant test.
(Study summary was only available in English)

Species/Strain Guinea pig/Pirbright White
PRELIMINARY STUDY Maximum Non-irritating Concentration:
intradermal: not stated
topical: not stated
MAIN STUDY
Number of Animals Test Group: 40 (2 X 20) Control Group: 20
Induction Phase Induction Concentration:
intradermal injection: 5% aqueous
topical application: 1% vaseline
Signs of Irritation
CHALLENGE PHASE
1st challenge topical application: 1% in vaseline
2nd challenge topical application: 1% aqueous
3rd challenge intracutaneous application: 0.5% aqueous
Remarks – Method Induction was carried out at relatively low concentrations of the notified chemical.

RESULTS Intracutaneous injection of the test substance did not induce stronger reactions than the vehicle in the control animals.

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after:*			
		1st challenge		*2nd challenge*	
		24 h	*48 h*	*24 h*	*48 h*
Test Group		3	0	3	2
Control Group		8	4	1	3

Remarks – Results The re-treatment showed slight skin irritation on a number of animals, including control animals. Therefore, this reaction of the animals could not be considered as positive effect, but was related to the diluent (vaseline) used.
The application of the notified chemical did not induce stronger reactions in comparison to those of the control animals. However, it is noted that the use of diluent complicated the proper reading of 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 HENKEL (1981)

B.4. Repeat dose toxicity

TEST SUBSTANCE Notified chemical

METHOD OECD TG 408 Repeated Dose 90-Day Oral Toxicity Study in Rodents.
EC Directive 88/302/EEC B.26 Sub-Chronic Oral Toxicity Test: 90-Day Repeated Oral Dose Study using Rodent Species.

Species/Strain Rats/Winstar
Route of Administration Oral – gavage
Exposure Information Total exposure days: 90 days
Dose regimen: 5 days per week
Post-exposure observation period: 29 days
Vehicle Distilled Water
Remarks - Method

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	10M/10F	0	0
II (low dose)	10M/10F	30	0
III (mid dose)	10M/10F	90	0
IV (high dose)	10M/10F	270	0
V (control recovery)	5M/5F	0	0
VI (high dose recovery)	5M/5F	270	0

Mortality and Time to Death
There was no mortality.

Clinical Observations

The animals of the groups 2 (30 mg/kg bw/day) and 3 (90 mg/kg bw/day) showed no treatment-related symptoms.
After the 2nd week after application, animals of the group 4 showed slight up to distinct salivation, which was partially reddish/brownish coloured. After the 4th week, the female animals of the group showed protrusion of the head into the bedding combined with slight up to severe salivation. After the 5th week, some animals of the group 4 showed salivation and brownish discolouration of the skin of the neck and mandibula before as well as after the application.
The transient decrease of the body weight and body weight gain of the group 4 males, from week 9 up to week 13, was due to 4 animals because of application failure. There was a decrease in food and water consumption in group 4 animals due to application failure. The author has not clarified the meaning of application failure.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis
Haematology: In the groups 2-3 animals, no significant deviations were observed in any parameter and the values were similar to the control groups. There were slight increase in neutrophils and bands and slight decrease in lymphocytes in male animals of group 4 and slight increase in neutrophils in females of group 4. Results were within normal standard deviation of the historical values and it is possible that lesions in the forestomach were responsible for the results.
Clinical chemistry: In the animals of the groups 2-3 and the males of the group 4, no significant deviations could be observed in any parameter and the values were similar to the control groups. In the female animals of the group 5, there was increase in the ALT and glucose. Results were within normal standard deviation of historical range.

Effects in Organs
Macroscopy:
No test substance-related effects were noticed on eyes.
The absolute weight of the liver was increased in a dose-dependent manner in all animals, the increase being significant only at the highest dose tested (270 mg/kg bw/day). Similarly, the relative weight of the liver also increased in a dose-dependent manner in all animals, the increase being significant at 90 and 270 mg/kg bw/day of the test substance. The absolute and relative weights of the adrenal glands increased significantly, only at the highest dose tested (270 mg/kg bw/day).
Both organs were also weighed at the autopsy of the recovery animals, where no significant differences were found in the liver and adrenal gland weights of the males and females of the highest dose group (270 mg/kg bw/day), as compared to the control group.
Microscopy:
Test-substance related findings in the liver were observed in the animals of the high dose groups (270 mg/kg bw/day). The liver showed centrolobular hypertrophy of slight up to mild degree, which was more pronounced in the female than in the male animas. The animals of the 30 and 90 mg/kg bw/day test-substance group showed no test-substance-related findings in the liver and adrenal glands.
In the animals in the high dose group (270 mg/kg bw/day), the mucosa of the forestomach showed epithelial hyperplasia of mild up to high degree. There were also subepithelial cellular infiltrates and some cases of ulcerations. The forestomach of the males of the 30 and 90 mg/kg bw/day groups and females of the 90 mg/kg bw/day groups showed hyperkeratosis, epithelial hyperplasia, subepithelial infiltrates and some cases of ulcerations. The females of the 30 mg/kg bw/day group showed no test-substance related findings in the forestomach. The lesions in the forestomach are not test substance related and are most likely as a result of the local reaction of test substance in the forestomach due to gavage method of administration.
The animals of the recovery group in the 270 mg/kg bw/day test-substance group showed epithelial hyperplasia of mild degree in the forestomach of some animals. This was considered as a regular regeneration of the epithelium of the forestomach, however the regeneration was not completed after a treatment free period of 29 days.

Remarks – Results
The most relevant findings were the effects on liver and adrenal glands and the inflammatory and proliferative reactions of the mucosa of the forestomach. Most changes had reversed after the 29 days of recovery period, apart from mild degree of epithelial hyperplasia in the forestomach of some animals in the 270 mg/kg bw/day group, as evidence of regeneration.

CONCLUSION

The No Observed Effect Level (NOEL) was found to be 30 mg/kg bw/day test substance, based on the presence of test-substance related findings in the forestomach of the animals of the 90 mg/kg bw/day group and the effect on liver and adrenal glands of the animals of the 270 mg/kg bw/day group. Only minor local reactions of the mucosa of the forestomach of the male animals of 30 mg/kg bw/day were observed.
The No Observed Adverse Effect Level (NOAEL) was found to be 90 mg/kg bw/day test substance, based on the presence of test-substance related local non-specific findings in the forestomach of the animals of the 90 mg/kg bw/day group and the effect on liver and adrenal glands of the animals of the 270 mg/kg bw/day group.

TEST FACILITY Henkel KGaA (1996)

B.5. 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.

Species/Strain	*S. typhimurium*: TA1538, TA1535, TA1537, TA98, TA100, TA102
Metabolic Activation System	Liver fraction (S9 mix) from rats pretreated with Aroclor 1254
Concentration Range in Main Test	a) With metabolic activation: 8, 40, 200, 1000, 5000 µg/plate. b) Without metabolic activation: 8, 40, 200, 1000, 5000 µg/plate
Vehicle	Distilled water
Remarks - Method	No significant protocol deviations. Plate incorporation method. The test material was tested up to the maximum recommended dose level of 5000 µg/plate. Toxic effects were noted, starting at a concentration of 600 µg/plate or higher. Precipitations were not 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	Not stated	≥600	Not noted	Negative
Test 2	Not stated	≥600	Not noted	Negative
Present				
Test 1	Not stated	≥600	Not noted	Negative
Test 2	Not stated	≥600	Not noted	Negative

Remarks - Results No significant increases in the frequency of revertant colonies were recorded for any of the bacterial strains, with any dose of the test material, either with or without metabolic activation. The positive controls significantly increase the frequency of revertant colonies observed.

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

TEST FACILITY Henkel KGaA (1994)

B.6. Genotoxicity – in vitro

TEST SUBSTANCE Notified chemical

METHOD OECD TG 476 In vitro Mammalian Cell Gene Mutation Test.

Cell Type/Cell Line	Chinese Hamster V79 Cells (V79/HPRT)
Metabolic Activation System	Liver fraction (S9 mix) from rats pretreated with Aroclor 1254
Vehicle	Minimal Essential Medium (MEM)
Remarks - Method	A pre-test was performed in order to determine the concentration range

for the mutagenicity experiments. The highest concentration produced a low level of survival and the survival at the lowest concentration was approximately in the range of the negative control.
After the exposure, subculturing was continued and initial harvesting was done on Day 8-9. After further subculturing, final harvesting was done on Day 16-18.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*
Absent		
Test 1	3.0, 10.0, 15.0, 20.0	4 hours
Test 2	3.0, 10.0, 15.0, 20.0	4 hours
Present		
Test 1	10.0, 30.0, 60.0, 95/0,	4 hours
Test 2	10.0, 60.0, 100.0, 150.0	4 hours

RESULTS

Concentration levels at 15 µg/mL and higher caused severe toxic effects and could not be evaluated in experiments without metabolic activation. Due to detoxifying properties of the metabolic activation system, higher concentrations up to 150 µg/mL could be tested in experiments with metabolic activation.
In both experiments (with and without S9 mix), the range of the negative and solvent controls was from 0.6 up to 12.3 mutants/10^6 cells; the range of the groups treated with the notified chemical was from 0.0 up to 19.8 mutants/10^6 cells. Increase in mutant colonies in test 1 attributed to low values of solvent control. EMS and DMBA were used as positive controls and showed a distinct increase in induced mutant colonies.
No relevant increases of gene mutations were observed with and without metabolic activation in the presence of notified chemical.

CONCLUSION

The notified chemical did not induce gene mutations at the HRPT locus in V79 cells. Therefore, the notified chemical was considered to be non-mutagenic in this HRPT assay.

TEST FACILITY

CCR (Cytotest Cell Research) (1994)

B.7. Genotoxicity – in vitro

TEST SUBSTANCE

Notified chemical

METHOD

OECD TG 476 In vitro Mammalian Cell Gene Mutation Test.
EC Directive 2000/32/EC B.17 Mutagenicity - In vitro Mammalian Cell Gene Mutation Test.

Cell Line	L5178Y, mouse origin
Metabolic Activation System	Phenobarbital/b-naphthoflavone induced rat liver fraction (S9 mix)
Vehicle	Deionised water
Remarks - Method	No significant protocol deviations.

The potential of the notified chemical to induce mutations by means of the mouse lymphoma thymidine kinase locus assay using the cell line L5178Y was tested.
A pre-test was performed in order to determine the concentration range for the main test.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Expression Time*
Absent			
Test 1	5.0, 10.0, 20.0, 40.0, 80.0	4 hours	72 hours
Test 2	5.0, 10.0, 20.0, 40.0, 80.0	4 hours	72 hours
Present			

Test 1	20.0, 40.0, 80.0, 120.0	4 hours	72 hours
Test 2	20.0, 40.0, 80.0, 120.0	4 hours	72 hours

RESULTS

No substantial and reproducible increase of the mutation frequency was observed. The total number of mutant colonies/10^6 cells remained well within the range of our historical data. An isolated minor increase of the mutation frequency was observed in the presence of metabolic activation at 40 µg/mL in test 1 and at 20 40 µg/mL in test 2. However, no increases occurred in the corresponding parallel culture under identical conditions or at even higher concentration of both culture. Therefore, these isolated minor increases were judged as biologically irrelevant fluctuations.

The range of the negative and solvent controls was from 51 up to 167 mutant colonies/10^6 cells; the range of the evaluated groups treated with the notified chemical was from 61 up to 183 mutant colonies/10^6 cells. The positive controls showed a distinct increase in induced total mutant colonies and an increase of the relative quantity of small verus larges colonies.

Remarks - Results: Distinct toxic effects, indicated by less than 50% of relative cloning efficiency 1 or relative total growth in both parallel cultures, occurred at 80 µg/mL and above in the absence of metabolic activation. In the presence of metabolic activation, relevant toxic effects occurred at 120 µg/mL and above. The cytotoxic effects showed a very steep dose dependency in the upper concentration range. The recommended toxic range of 10-20% of survival was generally covered.

CONCLUSION: Under the conditions of the test, the notified chemical did not induce mutations in the mouse lymphoma thymidine kinase locus assay using the cell line L5178Y in the absence and presence of metabolic activation.

TEST FACILITY: RCC-CCR (Cytotest Cell Research) (2006)

B.8. Genotoxicity – in vivo

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 474 Mammalian Erythrocyte Micronucleus Test.
EC Directive 2000/32/EC B.12 Mutagenicity - Mammalian Erythrocyte Micronucleus Test.

Species/Strain: Mouse/NMRI
Route of Administration: Oral – gavage
Vehicle: Distilled water
Remarks - Method: The doses were used as per the demand of the sponsor. Bone marrow smears were prepared at 24 hours (vehicle control, positive control, low dose, intermediate dose) or at 12, 24 and 48 hours (high dose) after dosing.

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Sacrifice Time hours*
I (vehicle control)	5 males, 5 females	0	24
II (low dose)	5 males, 5 females	300	24
III (mid dose)	5 males, 5 females	600	24
IV (high dose)	15 males, 15 females	1200	12, 24, 48
V (positive control, CP)	5 males, 5 females	40	24

CP=cyclophosphamide.

RESULTS

Doses Producing Toxicity: 1200 mg/kg bw

Genotoxic Effects	Negative
Remarks - Results	The high dose turned out to be toxic and one male and one female each died within 24 hours after administration. Bone marrow smears from these animals were prepared and evaluated. Mean values of micronucleated polychromatic erythrocytes (MPCEs) of 2.4% (males) and 2.7% (females) were found for vehicle control group. In the notified chemical treated animals, mean MPCE values range from 2.2 to 3.3% in males and from 0.8 to 2.0% in females. The statistical analysis did not show any significant difference with biological relevance versus the vehicle control. Treatment with the positive control induced statistically significant increases in the incidence of MPCEs with a group mean value of 32.6% in males and 18% in females. The notified chemical was demonstrated to be cytotoxic to the bone marrow (i.e., statistically significant decreases in the ratio of polychromatic to normochromatic erythrocytes was found) in female animals of the high dose group at 48 hour sampling time.
CONCLUSION	The notified chemical was not clastogenic under the conditions of this in vivo mouse bone marrow micronucleus test.
TEST FACILITY	ToxLab (1997)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

Test Substance	Notified chemical
METHOD	ISO 14593 draft Ready Biodegradability: CO_2 Evolution Test (Headspace).
Inoculum	Activated sewage sludge from an STP (Hochdahl), treating mainly municipal wastewater.
Exposure Period	28 days
Auxiliary Solvent	Nil
Analytical Monitoring	CO_2 evolution, trapped with NaOH with subsequent back titration
Remarks - Method	The ISO 14593 protocol is understood to have the same methodology as OECD 301B (Modified Sturm Test). It is understood to be more prescriptive in its sewage sludge concentration (European Commission 2005). Significant protocol deviations were not reported. The test sample was evaluated using 15 mg TOC/L and 50 mL of effluent solution/L culture solution. Results from CO_2 evolution measurements were confirmed by TOC analysis of test solutions after 28 days.

RESULTS

Test substance		*Sodium benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
4	10	4	93
8	35	8	94
14	43	14	97
25	55	25	98
28	62	28	98

Remarks - Results	It is noted that the positive control rapidly (4 days) reached 93% degradation. It is not known what influence the ISO 14593 protocol had on this. However, the test is regarded as valid if > 60% of the theoretical CO_2 evolution occurs within 14 days. The test substance did not pass the 10 day window sub-criterion and cannot be classified as readily biodegradable.
CONCLUSION	The notified chemical cannot be classified as being readily biodegradable, but is biodegraded.
TEST FACILITY	Henkel KGaA (1997a)

C.1.2. Bioaccumulation

CONCLUSION	Based on the notified chemical's high water solubility, surface activity and its biodegradability it is unlikely to bioaccumulate.

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	Notified chemical
METHOD	German standard method corresponding to OECD TG 203 Fish, Acute Toxicity Test – 48 hour, Static Test.

Species	Golden orfe (*Leuciscus idus)*
Exposure Period	48 hours
Auxiliary Solvent	None
Water Hardness	Not specified
Analytical Monitoring	Visual
Remarks – Method	No significant deviations from standard protocol are recorded. However, the exposure time is only 48 hours and the concentrations of the test substance and actual mortalities are not recorded.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*			
Nominal	*Actual*		*3 h*	*6 h*	*24 h*	*48 h*
15*	-	10	NR	NR	NR	0
30*	-	10	NR	NR	NR	10

* Various concentrations and control but not recorded. LC0 and LC100 recorded.

LC50	22 mg/L at 48 hours. DEWHA has calculated the geometric mean, which has a more conservative value of 21 mg/L.
NOEC	15 mg/L at 48 hours.
Remarks – Results	The method of calculation of the LC50 was not recorded but appears to be similar to the geometric (21 mg/L) and arithmetic mean (22.5 mg/L) of the LC0 and LC100.

CONCLUSION The notified chemical is harmful to fish.

TEST FACILITY Henkel KGaA (1997b)

C.2.2. Acute toxicity to aquatic invertebrates

Test Substance Notified chemical

METHOD	German standard method corresponding to OECD TG 202 Daphnia, Acute Toxicity Test – 24 hour, Static Test.
Species	Daphnia (*Daphnia magna)*
Exposure Period	24 hours
Auxiliary Solvent	None
Water Hardness	Not specified
Analytical Monitoring	Visual
Remarks – Method	No significant deviations from standard protocol are recorded. However, the exposure time is only 24 hours and the concentrations of the test substance and actual mortalities are not recorded.

RESULTS

Concentration mg/L		*Number of Daphnids*	*Mortality*		
Nominal	*Actual*		*3 h*	*12 h*	*24 h*
40*	-	20	NR	NR	0
100*	-	20	NR	NR	20

* Various concentrations and control but not recorded. LC0 and LC100 recorded.

LC50	70 mg/L at 24 hours. DEWHA has calculated the geometric mean, which has a more conservative value of 63 mg/L.
NOEC	40 mg/L at 24 hours.
Remarks – Results	The method of calculation of the LC50 was not recorded but appears to be the arithmetic mean (70 mg/L) of the LC0 and LC100.

CONCLUSION The notified chemical is harmful to invertebrates.

TEST FACILITY Henkel KGaA (1997c)

C.2.3. Algal growth inhibition test

TEST SUBSTANCE Notified chemical

METHOD DIN 38412 (part 9) understood to be equivalent to OECD TG 201
Species Green alga (*Scenedesmus subspicatus)*
Exposure Period 72 hours
Concentration Range Nominal: 1, 3, 10, 30, 100, 300 and 1000 mg/L
Actual: Not Measured
Auxiliary Solvent None
Water Hardness Not reported
Analytical Monitoring Coulter Counter for algal cells.
Remarks - Method No significant deviations from standard protocol. Three replicates of ~10^4 cells/mL at various concentrations of test substance and a control were exposed to continuous light of ~ 2000 Lux. The growth relative to the control was determined.

RESULTS

Biomass		*Growth*	
E_bC50	*NOEC*	*E_rC50*	*NOEC*
mg/L at 72 h	*mg/L*	*mg/L 0 -72 h*	*mg/L*
2.5	1.0	4.7	Not Determined

Remarks - Results The pH rose in accordance with observed algal growth as is expected. All pH values remained between 7.8 and 8.7 during the test. The mean biomass in the controls increased by a factor of 45 over the 72 hour test period. The inhibition of algal growth showed a clear dose response.

The EC50 values were calculated by log probits, but a 95% confidence interval could not be calculated due to the uncertainty in the values.

CONCLUSION The notified chemical is toxic to algae.

TEST FACILITY Henkel KGaA (1995)

C.2.4. Inhibition of microbial activity

TEST SUBSTANCE Notified chemical

METHOD DIN 38412
Inoculum *Pseudomonas putida*
Exposure Period 16 hours
Concentration Range Nominal: 0.1-10000 mg/L

Remarks – Method The test study was submitted in German, with no translation, but it is not a scheduled requirement. The data is obtained from the notifier's summary.

RESULTS
IC50 > 10 000 mg/L
NOEC 10 000 mg/L

CONCLUSION The test substance is not inhibitory to *Pseudomonas putida*

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