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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Sanduvor 3058

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Director
NICNAS

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Clariant (Australia) Pty Ltd (ABN: 30 069 435 552)
675 Warrigal Road
Chadstone VIC 3148

AND

PPG Industries Australia Pty Ltd (ABN: 82 055 500 939)
McNaughton Road
Clayton VIC 3168

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

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: chemical name, other names, CAS number, molecular formula, structural formula, spectral data, composition, import quantity, concentration of notified chemical in the product Sanduvor 3058, information on potential users, and reference details for notifications in other countries.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows:

Adsorption/desorption, Acute dermal toxicity, Melting point/Freezing point

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None.

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Sanduvor 3058

SPECTRAL DATA

METHOD	Nuclear Magnetic Resonance (NMR), Infrared (IR) and Ultraviolet/Visible (UV/Vis) spectroscopy.
Remarks	Reference spectra were provided.

METHODS OF DETECTION AND DETERMINATION

METHOD	UV/Vis, IR and NMR spectroscopy.

3. COMPOSITION

DEGREE OF PURITY
High

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
Contains a single hazardous impurity at < 10% which causes severe burns (R35).

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

ADDITIVES/ADJUVANTS
None.

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will be imported either as the technical grade product Sanduvor 3058 (>90% notified chemical) or as a component of finished paint products with the notified chemical present at 0.5-3.0% based on the solid binder. The concentration of the notified chemical in final liquid coatings will be 0.25 - 1.5%. The notified chemical will not be manufactured in Australia.

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

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

USE
UV light absorber for automotive paints

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY
Melbourne or Sydney.

IDENTITY OF MANUFACTURER/RECIPIENTS
Clariant (Australia) Pty Ltd
675 Warrigal Road
Chadstone Vic 3148

TRANSPORTATION AND PACKAGING
The notified chemical will be imported as a component of paint products or as Sanduvor 3058. Paint products will contain the notified chemical at a concentration of 0.5-3.0% based on the solid binder. The product Sanduvor 3058 is classified as a dangerous good, Class 9, (Environmentally hazardous substance, liquid; UN 3082) according to the International Maritime Dangerous Goods code. Finished paint products will not be classified as dangerous goods.

The product Sanduvor 3058 will be imported in 60 L steel closed head drums. Imported paint products will be packaged in either 20 L jerricans or 200 L steel drums and locally reformulated paint products will be packaged in 200 L steel drums.

5.2. Operation description

No manufacture of the notified chemical will take place in Australia. Reformulation of the notified chemical will occur at PPG Industries Australia Pty Ltd.

Laboratory work.
Paint manufacture and testing:
The ingredients required for making the paint, including the notified chemical, are combined in a container in the laboratory with stirring. Such paint is then sprayed onto panels in a spraybooth fitted with appropriate extraction. The panels are baked in an oven and the finished paint film is subjected to

various tests.

Paint Formulation

The notified chemical is pumped from the original packaging into the closed mixing vessel via a hatch. The other ingredients are added to the mixer and the product is sampled (500 mL) for testing.

QC testing involves adjustment of the paint containing the notified chemical. Viscosity is adjusted by adding solvent, and panels are sprayed for baking and testing. Several tests such as solids, viscosity and wpl are performed on the wet paint.

When approved, the paint containing the notified chemical is filled into 200 L drums through dedicated pipework and filling equipment. The filling equipment automatically places a short fill pipe through the bung hole in the top of the drum and fills the drum.

Paint Application

The 200 L drums of paint are pumped into the circulating mix tank using a dedicated lance, pipework and pump. Once in the tank, solvent is added to adjust the paint to application viscosity.

Operators use the final paint products to spray specific areas of cars that are not painted by robots.

Cleaning of spray equipment:
During production breaks operators use cloths dampened with solvent to clean residual paint from the spray equipment.

5.3. Occupational Exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Clariant and PPG			
Warehouse and stores	6	0.5 hours/day	200 days/year
PPG SITE			
Laboratory			
Paint manufacture and testing	3	8 hours/day	80 days/year
Paint formulation			
Paint make-up	18	4 hours/day	200 days/year
QC testing	3	4 hours/day	200 days/year
Filling into drums	3	4 hours/day	200 days/year
CUSTOMER SITE			
Paint application			
Adding paint to circulation tank	18	2 hours/day	200 days/year
Hand spray pick-up	30	8 hours/day	200 days/year
Cleaning of spray equipment	18	2 hours/day	200 days/year

Exposure Details

Warehouse and stores

Exposure to the notified chemical (at a concentration >90%) is unlikely to occur, except in the event of an accidental spillage and breach of packaging.

Laboratory work.

Paint manufacture and testing:

Workers may be exposed to the notified chemical (maximum concentration >90%) by dermal or ocular routes or by inhalation during testing of the paints. Exposure should be minimised by the use of spraybooths fitted with appropriate extraction during spray painting tests, as well as various engineering controls and the use of personal protective equipment appropriate to the materials they are handling.

Paint Formulation

During formulation of the notified chemical into finished paint products, worker exposure to the notified chemical (maximum concentration >90%) may occur by dermal or ocular exposure to residues on containers. Exposure should be minimised by use of mechanical ventilation systems.

During QC testing, exposure to the notified chemical (concentration up to 3%) may occur by skin or ocular contact with paint drips and cleaning equipment. Potential for exposure by inhalation of paint droplets generated in the spraying process is minimised by engineering controls; the paint is only sprayed in a properly designed spraybooth.

When the final product is filled into drums, workers may be exposed to the notified chemical (concentration up to 3%) by skin or ocular contact with residues dripping off the fill pipe, and in manually cleaning the pipe.

Paint Application:

Dermal, ocular and inhalation exposure may occur during hand spray application of the paint. However, significant exposure will be mitigated by:

- air downdraft in the spraybooth removing atomised paint that does not land on the cars.
- operators wearing vapour masks that filter atomised paint
- operators wearing full protective clothing to prevent skin contact with the paint

Cleaning of spray equipment:
Dermal and ocular exposure to the notified chemical (concentration up to 3%) may occur during cleaning procedures.

5.4. Release

RELEASE OF CHEMICAL AT SITE
No manufacture of the new chemical will take place in Australia. Reformulation of the chemical will occur at PPG Industries Australia Pty Limited. Release of the new substance during normal use at the reformulation site (PPG Clayton) and the automotive manufacturer's end-use site will be minimal due to the highly controlled nature of the processes at both industrial sites.

At the reformulation site (PPG Clayton) and the automotive manufacturer's end-use site, wastes from the cleaning processes are collected and processed on site to recover solvent. The solid material containing the notified chemical left over from these processes will be removed by a licensed waste disposal contractor and disposed of in secure landfill. Drums containing residues of the notified substance will be sent to a drum recycler where the residues are incinerated.

RELEASE OF CHEMICAL FROM USE
It is intended that all of the finished paint products containing the notified chemical will be used for automotive purposes. The paint products are to be applied by spraying in spray booths by both manual spray and automatic electrostatic atomised spray techniques to the internal and external surfaces of car bodies. Transfer efficiencies will be approximately 35% for hand spray and 80% for the automatic method. The resultant overspray is collected in the spray booth water and then chemically treated in water scrubbing systems. The paint material which is removed by the scrubbers is separated out using flotation techniques. This separated sludge is then removed for incineration by licensed waste removal contractors.

Paint waste containing the notified chemical will be generated from three main areas:

(i) Overspray from the application process

(ii) Flushing and cleaning of application and mixing equipment

(iii) Empty paint containers.

Average transfer efficiency is estimated as 75% for the combined manual and automated electrostatic application equipment in use. It is estimated that 90% of the paint is applied by the automatic sprayers

and 10% applied by manual guns. Therefore, on average, 25% of the paint, and hence the notified chemical will be lost through overspray. This loss is estimated to be up to 2500 kg per annum based on the maximum volume of notified chemical introduced (10 tonnes). This overspray is collected by the spraybooth air and water filtration systems. Cleaning of waste from spraybooths is carried out by licensed waste disposal contractors. The waste is taken off-site for incineration.

Cleaning of application and mixing equipment will generate waste paint, which is collected and treated in the same way as spraybooth waste. It is estimated up to 5% of waste (500 kg) will be generated in this operation based on normal usage. Residues of paint remaining in drums/cans after emptying is assumed to be 1%.

5.5. Disposal

The need for disposal of the new chemical will be limited and would only be required if spillage occurred or when emptied product packaging is recycled. It is estimated that up to 400 g of the liquid substance (0.4%) may remain in packaging. A maximum of 40 kg of the notified chemical per year would be incinerated during recycling processes.

It is expected that disposal of solid paint residues will be through a licensed waste disposal contractor to an approved landfill site and that residues in emptied drums will be incinerated by drum recyclers. Residues of paint remaining in drums/cans will cure in the containers, which will be disposed of to landfill.

5.6. Public exposure

The potential for exposure of the public to the notified chemical during normal industrial storage, handling and transportation is minimal. Only in extreme cases of inappropriate handling, or accidents during transportation, would there be any likelihood of the notified chemical being released from the packaging for exposure to the public.

6. PHYSICAL AND CHEMICAL PROPERTIES

Test reports were provided in German with summaries in English.

Appearance at 20ºC and 101.3 kPa	Yellow, viscous liquid
Melting Point/Freezing Point	Not determined
Remarks	The notified chemical is a liquid at 20ºC
Boiling Point	Approximately 240ºC (according to MSDS)
Remarks	The determination of the boiling point is achieved by measuring the vapour pressure (dynamic method). The measured temperature should not exceed 350ºC. The boiling point was determined as an average value with an accuracy of ±0.5ºC. It is not clear from the report what temperature was determined but the MSDS reports a melting temperature of 240ºC.
TEST FACILITY	Hüls AG (1991a)
Relative Density	D^{20}_4 1004 kg/m^3 at 20ºC
METHOD	DIN 51757
Remarks	The relative density was measured by the Pycnometer method
TEST FACILITY	Hüls AG (1991b)
Vapour Pressure	6.2 x 10^{-7} kPa at 25ºC.
Remarks	The vapour pressure was determined at 25ºC by graphical extrapolation from the vapour pressure curve.
TEST FACILITY	Hüls AG (1991c)
Water Solubility	<0.05 mg/L at 20ºC

METHOD EU guidelines official gazette No. L251/44 (A6), Paragraph 6.3.2
Remarks The Column elution method was used to determine the solubility of the notified chemical. After concentrating the test substance, thin layer chromatography was used to determine the amount of test substance. After the measurement was made the test substance was dissolved in methanol and analysed by gas chromatography by comparing it with a freshly prepared sample. No major changes of the test substance occurred at 20°C within 3 weeks. Standard deviation cannot be determined because all values were below the limit of determination of 0.05 mg/L.
TEST FACILITY Hüls AG (1991d)

Surface Tension 35.1 mN/m at 20ºC

METHOD DIN 53914
Remarks The surface tension was measured by the Ring method using Du Nuoy – tensiometer with thermostat.
TEST FACILITY Hüls AG (1991e)

Fat (or n-octanol) Solubility >100,000 mg/100 g fat simulant (HB 307) at 37°C

METHOD No guideline was provided.
Remarks 19.9, 33.9, 49.9, 59.8% of the notified chemical in standard fat HB 307 was determined using UV/VIS Spectrometer (450-800 nm). Standard fat and the notified chemical were miscible in all proportions at 37°C.
TEST FACILITY Hüls AG (1990a)

Hydrolysis as a Function of pH

METHOD EU guideline C.10 (pH dependent hydrolysis)

pH	*T (°C)*	*t½*	*T (°C)*	*t½*
4	40	17 h		
7	60	135 h	70	17 h
9	40	45 h		

Remarks In this test the use of the solubiliser allowed the test substance to achieve solubility up to 1 mg/L. Usually 2 samples were taken for each pH and each reaction time. However, at least 7 measurements were required in one test. Thin layer chromatography was used to determine the amount of the notified chemical. The reaction rates at pH 4, 7 and 9 and at temperatures of 40, 60 and 40°C, respectively, were measured. At pH 7, the reaction rate was also measured at 70ºC. It was observed that all tests were prone to show relatively scattered measured values with multiple determinations.
TEST FACILITY Hüls AG (1991f)

Partition Coefficient (n-octanol/water) log Pow at 23ºC = 7.46

METHOD OECD test guideline 107 and 117
Remarks The partition coefficient was determined by a HPLC method by comparing with 7 reference substances. Log Kow of the test substance was determined from the linear regression of the log Kow of the reference substances.
TEST FACILITY Hüls AG (1991g)

Adsorption/Desorption Not determined

Remarks Based on the high partition coefficient and the low water solubility of the notified chemical, it is expected that the notified chemical is likely to be adsorbed to soils.

Dissociation Constant Not determined

Remarks The notified chemical contains no dissociative functional groups.

Particle Size	Not applicable, liquid substance
Flash Point	219°C at 101.7 kPa
METHOD	Pensky-Martens Closed Cup DIN 51758
Remarks	English translations of the original German test reports were not provided.
TEST FACILITY	Hüls AG (1990b)
Flammability Limits	The substance does not develop gases in contact with water and is not readily ignitable
TEST FACILITY	Hüls AG (1991h)
Autoignition Temperature	385°C
Remarks	English translations of the original German test reports were not provided.
TEST FACILITY	Hüls AG (1990c)
Explosive Properties	Not classified as an explosion hazard
Remarks	English translations of the original German test reports were not provided.
TEST FACILITY	Hüls AG (1991i)
Reactivity	The notified chemical is stable under normal conditions. Thermal decomposition may produce carbon oxides and nitrogen oxides.

7. TOXICOLOGICAL INVESTIGATIONS

Note that many of the toxicological investigations were performed using the notified chemical at lower purity than specified in the notifier's submission.

Endpoint and Result	*Assessment Conclusion*
Rat, acute oral LD50 > 3000 mg/kg bw	low toxicity
Rat, acute inhalation LC50 2.61 mg/L/4 hour	inconclusive
Rabbit, skin irritation	severely irritating
Rabbit, eye irritation	non-irritating
Guinea pig, skin sensitisation – adjuvant test	evidence of sensitisation
Rat, oral repeat dose toxicity – 28 days.	NOAEL 15 mg/kg/day
Genotoxicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vivo Mammalian Erythrocyte Micronucleus Test	non genotoxic

7.1. Acute toxicity – oral

TEST SUBSTANCE	Notified chemical (< 90% purity, 2 well defined impurities)
METHOD	OECD TG 401 Acute Oral Toxicity – Limit Test.
Species/Strain	Rat/ Bor: WISW (SPF TNO)
Vehicle	None
Remarks - Method	The test material was administered undiluted by gavage to each of five male and five female rats at a single dose level of 3000 mg/kg. All of the animals were sacrificed at the end of the 14-day investigation period, dissected and microscopically examined.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
Treated	5/sex	3000	0

LD50	> 3000 mg/kg bw
Signs of Toxicity	No signs of toxicity
Effects in Organs	No evidence of macroscopically detectable organ changes.
Remarks - Results	The increase in body weight was unaffected by the treatment.

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

TEST FACILITY Hüls AG (1988a)

7.2. Acute toxicity – dermal

Not conducted

Remarks - Results The study was not conducted due to the likelihood of severe irritation, as shown in the submitted skin irritation study, and the potential for irritated skin to affect skin absorption.

7.3. Acute toxicity – inhalation

TEST SUBSTANCE Notified chemical (< 90% pure)

METHOD

Species/Strain	Albino rats, (Sprague-Dawley).
Vehicle	Acetone
Method of Exposure	Whole body exposure.
Exposure Period	4 hours
Physical Form	Liquid aerosol
Particle Size	88% of the droplets were respirable. MMAD = 2.7 μm
Remarks - Method	A group of rats was exposed continuously for 4 hours to a test atmosphere containing an aerosol of the test substance. A second group acting as a control received acetone vapour for 4 hours. During preliminary trials it had been shown that the test substance was too viscous to be aerosolised. Aerosolisation was found to be optimal using an 80 % (w/w) solution of the test substance in acetone. The flow rate was 0.6 mL/minute. After 4 hours the supply of test substance was discontinued and the exposure chamber was allowed to clear before the rats were removed for examination. The control group was treated similarly but received only acetone vapour for 4 hours. The feed rate of acetone to the atomiser was 0.15 ml/minute so as to give an acetone concentration at least as high as that for the test group.

RESULTS

Group	*Number and Sex of Animals*	*Concentration < mg/L >*		*Mortality*
		Nominal	*Actual*	
Test	5/sex	2.71	2.61	0
Control	5/sex	0	0	0

LC50	> 2.61 mg/L/4 hours
Signs of Toxicity	Partial closing of the eyes, wetness around the eyes and snout and exaggerated respiratory movements were the main clinical signs evident during exposure. The signs were considered to be consistent with exposure to a mildly irritant aerosol. Observations were made post exposure when the rats were removed for examination. Clinical signs evident at this time and persisting for several days included exaggerated breathing and a matted appearance of the fur. The exaggerated respiratory movements persisted for 5 days following exposure. All rats were normal in appearance and behaviour at Day 10 of the observation period. There were no deaths during the study.
Effects in Organs	There were no findings in any of the rats that were considered to be of toxicological importance.
Remarks - Results	The mean exposure concentration to the notified chemical was 2.61 mg/L of air. The variation (range of concentrations x 100/mean) was 3%, which is within acceptable limits. The concentration was the highest attainable with the method described. On average 88% of the droplets were 6 µm or less in aerodynamic diameter and therefore of respirable size, and 8% of the particles were less than 1 µm aerodynamic diameter. By calculation the mass median aerodynamic diameter (MMAD) was 2.7 µm and the standard geometric deviation (og) was 2.03.
CONCLUSION	At 2.61 mg/L/4 hours the notified chemical presented low toxicity, however, under the conditions of this test it was not possible to classify the inhalation toxicity of the notified chemical, as the concentration tested was too low.
TEST FACILITY	Huntingdon Research (1991)

7.4. Irritation – skin

TEST SUBSTANCE	Notified chemical (< 90% purity, 2 well defined impurities)
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion.
Species/Strain	Rabbit, small white Russian, Chbb-SPF, Male
Number of Animals	3
Vehicle	None
Observation Period	14 days
Type of Dressing	Semi-occlusive.
Remarks - Method	The notified chemical was applied undiluted to the shaven dorsal skin of rabbits and exposed for 4 hours.

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	3.7	3.3	3.3	4	10 days	0
Oedema	4	4	4	4	10 days	0

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

Remarks - Results	Single dermal application of 0.5 cm^3 of the notified chemical had a strong irritant effect on male rabbits.

CONCLUSION The notified chemical is severely irritating to the skin.

TEST FACILITY Hüls AG (1988b)

7.5. Irritation – eye

TEST SUBSTANCE Notified chemical (< 90% purity, 2 well defined impurities)

METHOD OECD TG 405 Acute Eye Irritation/Corrosion.
Species/Strain Rabbit, small white Russian, Chbb-SPF
Number of Animals 3
Observation Period 6 days
Remarks - Method For testing the acute irritant effect on eyes and mucosa, 0.1 cm^3 of the product was applied in each case to the sac.

72 hours after application, the treated eyes were checked for cornea damage with Na fluorescein solution and then rinsed with warm physiological saline. Evaluation took place 1, 24, 48, and 72 hours, and 6 days after application.

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	0.33	0.67	0.33	2	72 h	0
Conjunctiva: chemosis	0.33	0.33	0.33	1	48 h	0
Conjunctiva: discharge	0	0	0	0	0	0
Corneal opacity	0	0.67	0	2	48 h	0
Iridial inflammation	0	0	0	0	0	0

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

Remarks - Results

CONCLUSION The notified chemical is slightly irritating to the eye.

TEST FACILITY Hüls AG (1988c)

7.6. Skin sensitisation

TEST SUBSTANCE Notified chemical (purity < 90%)

METHOD OECD TG 406 Skin Sensitisation – (Maximisation Test).
Species/Strain Guinea pig
Dunkin Hartley, Pirbright White, BOR: DHPW (SPF).
PRELIMINARY STUDY Maximum Non-Irritating Concentration:
Topical: 100% occlusive bandage
Intradermal: 0.25-10% in corn-germ oil (irritant effects were noted at all concentrations)
Injection of 2.5% solution caused medium to severe erythema in both animals, slight edema formation in the first animal and barely perceptible edema formation in the second animal. Injection with 1%, 0.5% and 0.25% solutions in the first animal lead to medium to severe erythema and a very slight edema formation, and in the second animal lead to definite erythema and edema. Treatment with corn-germ oil only also resulted in definite erythema and edema.
MAIN STUDY

Number of Animals	Test Group: 20 per induction exposure Control Group: 10 per induction exposure
INDUCTION PHASE	Induction Concentration: Intradermal: 2.5 % in corn-germ oil Topical: 100 %
Signs of Irritation	*Intradermal* One hour after the intradermal injection of Freund's adjuvant (50 % in fully demineralized water), 27 of 40 animals exhibited medium to heavy reddening and swelling at the injection sites. Thirteen animals exhibited severe reddening and swelling connected with necrosis formation. After 24 hours, these severe irritation phenomena were observed at the injection sites in all of the animals. The injections of the test substance in a vehicle led to definite reddening and to very slight to definite swelling. The intracutaneous injections with the vehicle alone showed somewhat lesser irritation than the injections of the test substance in the vehicle. The injection sites treated with test substance in Freund's adjuvant (FCA) and the vehicle resulted in medium to severe reddening and medium swelling one hour after the administration; in one animal, it led to the formation of necrosis at the injection sites. 24 hours later, severe reddening and swelling along with necrosis were observed at the injection sites of 18 test animals; 2 test animals exhibited medium reddening and swelling. The injections with FCA and the vehicle led to primary, definite reddening and swelling. 24 h after the administration, these irritation phenomena had intensified. 4 of 20 control animals exhibited necrotic changes at the injection site. The animals exhibited moderate to severe erythema and oedema 24 h after the SDS pre-treatment (day 7) in the entire injection range. *Topical* One hour after removal of the occlusive bandage (49 h after the administration), the application area of the animals of both the test group and of the two control groups exhibited very severe reddening, swelling, necrosis, and partly bloody wounds. 72 h after the administration, these severe irritant effects had scabbed and crusted over.
CHALLENGE PHASE	
1st challenge	Topical: 100%
2nd challenge	Topical: 100%
Remarks - Method	The intradermal induction treatment took place with 2.5% test substance in corn-germ oil; the topical induction treatment with 100% test substance (as delivered) took place after a prior 24-hour pre-treatment of the skin in the injection region with sodium dodecyl sulfate salt (10% in Vaseline). The two topical challenge treatments were carried out with 100% test substance (as delivered).

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after:*			
		1st challenge		*2nd challenge*	
		48 h	*72 h*	*48 h*	*72 h*
Test Group	100 %	10/20	11/20	10/20	7/20
Control Group		0	0		0

Remarks - Results	*First challenge treatment:* 24 h after removal of the occlusive bandage (48 h after the administration), 10 of 20 treated test animals exhibited skin reactions, one

animal had merely a very light skin reddening, 3 animals had clearly defined reddening and very light swelling, and one animal had a medium to severe skin reddening and definite swelling of the skin in the application area. 10 animals of the test group and all animals of control group 1 exhibited no irritant phenomena.

72 hours after administration, 11 animals of the test group exhibited very slight to definite reddening and mostly very slight swelling, which sometimes healed with scab formation. 9 test animals and the animals of control group 1 showed no irritant phenomena of any kind at this observation time.

Second challenge treatment
For 10 animals of the test group, 48 hours after challenge, irritant phenomena were observed on the skin. While 2 test animals exhibited only very slight reddening, in 4 animals very slight reddening and swelling was observed, and in one animal, there was definite reddening connected with a very slight swelling. For 3 animals, the challenge treatment led to definite reddening and swelling. The other animals of the test group and the animals of control group 2 showed no irritant phenomena at this time.

72 hours after administration, 7 test animals still exhibited very slight to definite reddening and swelling, as well as scab formation. For other animals of the test group, and all animals of control group 2, no irritant phenomena were observed.

CONCLUSION There was evidence of reactions indicative of skin sensitisation to the notified chemical under the conditions of the test.

TEST FACILITY Hüls AG (1990d)

7.7. Repeat dose toxicity

TEST SUBSTANCE Notified chemical (< 90% purity)

METHOD OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents.
EC Directive 96/54/EC B.7 Repeated Dose (28 Days) Toxicity (Oral).

Species/Strain	Sprague – Dawley CD strain rats.
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 28 days; Dose regimen: 7 days per week; Post-exposure observation period: 0 days
Vehicle	Arachis oil B.P.
Remarks - Method	The test material was administered by gavage to three groups, each of five male and five female Sprague-Dawley CD strain rats, for twenty-eight consecutive days, at dose levels of 15, 150 and 1000 mg/kg/day. A control group of five males and five females was dosed with vehicle alone (arachis oil B.P.). Clinical signs, bodyweight, food and water consumptions were monitored during the study. Haematology and blood chemistry were evaluated for all animals at the end of the study. All animals were subjected to a gross necropsy examination and a limited histopathological evaluation of tissues from high dose and control animals was performed.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
I (control)	5 M 5F	0	0
II (low dose)	5 M 5 F	15	0
III (mid dose)	5 M 5 F	150	0
IV (high dose)	5 M 5 F	1000	0

Mortality and Time to Death
No deaths occurred during the study.

Clinical Observations
High dose animals of either sex showed clinically observable signs of toxicity from day 5 onwards including increased salivation.

Intermediate and low dose animals showed no clinical signs which could be considered attributable to the toxicity of the test material.

Bodyweight
High dose females showed a possible slight reduction in bodyweight gain compared with that of controls over the treatment period.

Food Consumption
No treatment-related effects were detected.

Water Consumption
No overt intergroup differences were detected.

Haematology
No treatment-related effects were detected.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis
Clinical Chemistry
High dose animals of both sexes and intermediate dose males showed a statistically significant reduction ($p<0.001$ males, $p<0.01$ females) in plasma bilirubin compared with controls. High dosed males showed a slight but statistically significant reduction in plasma sodium ($p<0.001$) and inorganic phosphorus ($p<0.05$) concentration compared with controls. High dose females showed a statistically significant increase ($p<0.01$) in blood glucose. All female treatment groups showed a statistically significant reduction ($p<0.05$) in plasma chloride. There was a statistically significant decrease in alanine aminotransferase (ALAT) in the low and medium female dose groups ($p<0.05$) and also a reduction of creatinine in all female treatment groups.

Effects in Organs
No treatment-related macroscopic abnormalities were detected at necropsy.

Organ Weights
Intermediate and high dose males showed a slight but statistically significant increase in liver weight, both absolute and relative to bodyweight compared with controls, whilst relative liver weight was also elevated in high dose females. Several of the individual values were abnormally high for rats of this strain and age and although there was no further evidence to support a hepatic change, a treatment-related liver effect cannot be entirely ruled out for these animals.

Histopathology
No treatment-related microscopic abnormalities were observed.

Remarks – Results
Treatment-related liver effects could not be ruled out for all treated animals.

CONCLUSION
The No Observed Adverse Effect Level (NOAEL) was established as 15 mg/kg bw/day in this study, based on effects seen on clinical chemistry and organ weights at 150 and 1000 mg/kg/day. No NOEL was established.

TEST FACILITY Safepharm Laboratories Limited (1992)

7.8. Genotoxicity – bacteria

TEST SUBSTANCE Notified chemical (< 90% purity)

METHOD EC Directive 2000/32/EC B.14 Mutagenicity – Reverse Mutation Test using Bacteria.
Plate incorporation procedure/Pre incubation procedure

Species/Strain *S. typhimurium*: TA1538, TA1535, TA1537, TA98, TA100.
Metabolic Activation System Aroclor-active S9-fraction whose enzyme activity was determined with aminoanthracene on strain TA100.
Concentration Range in Main Test a) With metabolic activation: 8 - 5000 µg/plate
b) Without metabolic activation: 8 - 5000 µg/plate
Vehicle Dimethyl sulphoxide
Remarks - Method Two tests were performed:
Main test with and without the use of an Aroclor-induced metabolic system.

Preincubation test with and without the use of a metabolic system induced with Aroclor (96hr incubation time).

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Main Test	*Precipitation*	*Genotoxic Effect in Main Test*	*Genotoxic Effect in Preincubation Test*
Absent				
Test 1	>5000	>1000	None	None
Test 2	>5000	>1000	None	None
Present				
Test 1	>5000	>1000	None	None
Test 2	>5000	>1000	None	None

Remarks - Results In the main test with S9-mix, in strain TA 1537 at concentrations of 8 and 40 µg/dish, factors >2 occurred (indication of mutagenesis). The test substance is nonetheless to be viewed as non-mutagenic, since no dosage-effect correlation is present and the factors could not be confirmed in the preincubation test.

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

TEST FACILITY Hüls AG (1991j)

7.9. Genotoxicity – in vivo

TEST SUBSTANCE Notified chemical (< 90% purity)

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

Species/Strain Mouse / BOR: NMRI (SPF Han.)
Route of Administration Oral – gavage
Vehicle Corn germ oil
Remarks - Method In order to determine the dose to be used in the micronucleus test, a preliminary test was conducted with 2000 mg test substance per kg body

weight. At this dose, there were no fatalities within the observation period of 48 hours after administration of the substance, so a limit test with a dose of 2000 mg/kg body weight was conducted as the main test.

No deviations to the protocol were noted.

RESULTS

Doses Producing Toxicity	>2000 mg/kg/bw
Genotoxic Effects	None
Remarks - Results	The mice treated with cyclophosphamide (the control) showed a great increase in the incidence of micronuclei in polychromatic erythrocytes and a statistically significant reduction in the PCE/NCE ratio in comparison with the control animals treated with the vehicle. Male and female mice treated with the test substance did not show a statistically significant increase in the number of polychromatic erythrocytes having micronuclei at any bone marrow sampling time in comparison with the control animals. There was a significant reduction in the PCE/NCE ratio in comparison with the negative controls only among the female animals at the 24 hours collection time.

CONCLUSION The notified chemical was not clastogenic under the conditions of this test.

TEST FACILITY Hüls AG (1992)

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

TEST SUBSTANCE Notified chemical (< 90% purity)

METHOD Modified OECD-sturm based on EC Directive 84/499/EC C.5 and OECD Guideline No. 301B

Inoculum	Activated sludge from the municipal water-treatment plant in Marl-West, Germany
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	TAC
Remarks - Method	The test substance at test concentrations of 10 and 20 mg/L was placed into a defined, liquid nutrient medium that was inoculated with activated sludge. The evolved CO_2 was bound in a sodium hydroxide solution in the form of sodium carbonate. The decomposition was monitored after 3, 6, 12, 17, 20, 24, and 28 days by means of a TAC analysis of the bound CO_2. A reference control sodium benzoate at 20 mg/L was used to validate the test.

RESULTS

Test substance		*<Reference Substance>*	
Day	*% Degradation*	*Day*	*% Degradation*
28	21	24	100

Remarks - Results The notified chemical attained a level of decomposition of 20% (10 mg/L) and 21% (20 mg/L) within 28 days. The test substance did not achieve 60% biodegradation within 10 days of 10% biodegradation being

observed. The reference substance, sodium benzoate, achieved 100% decomposition within 24 days, confirming the validity of the test.

The cumulative CO_2 evolution in the blind batch was 52.29 mg/3 L. This value does not meet the quality criteria of EC-Guideline 84/499/EC C 5, which specifies a maximum value of 50 mg CO_2/3 L. However, this value does correspond to the Draft OECD Guideline "301 CO_2 Evolution Test" (Draft OECD Guidelines for Testing of Chemicals "Ready Biodegradability", June, 1990) as it allows a CO_2 quantity of 70 mg/L.

CONCLUSION The notified chemical cannot be classed as readily biodegradable.

TEST FACILITY Hüls AG (1991k)

8.1.2. Bioaccumulation

On the basis of the log Kow of 7.46 and the high fat solubility of the notified chemical, it is expected to have the potential for bioaccumulation.

8.2. Ecotoxicological investigations

8.2.1. Acute toxicity to fish

TEST SUBSTANCE Notified chemical (< 90% purity)

METHOD

Species	Gold orf *Leuciscus idus melanotus* HECKEL
Exposure Period	96 h
Auxiliary Solvent	Methanol
Water Hardness	15^0 dH [German degrees of water hardness]
Analytical Monitoring	None
Remarks – Method	Ten fish were used per test pond at a measured test concentration of 0.582 mg/L and for a solvent control under a flow-through condition. Mortality of the fish was observed at 24, 48, 72 and 96 h. Monitoring of the pHs, dissolved oxygen concentrations and temperatures during the test were not reported.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*			
Nominal	*Actual*		*24h*	*48h*	*72h*	*96h*
0.5	0.582	10	0	0	0	0
0 (Control)	0 (Control)	10	0	0	0	0
0 (Solvent Control)	0 (Solvent Control)	10	0	0	0	0

LC50	>0.5 mg/L at 96 hours.
NOEC (or LOEC)	0.5 mg/L at 96 hours.
Remarks – Results	The measured concentrations were 0.582, 0.559, 0.442, 0.806, and 0.100 mg/L at the respective time points of 0, 24, 48, 72 and 96 h. Since the test concentration dropped below 80% of the initial concentration despite the use of the flow-through method, the average of all measured values was taken as the exposure concentration. The results showed that the notified chemical did not have any acute toxic effect on fish up to a nominal concentration of 0.5 mg/L.

CONCLUSION The notified chemical is practically non-toxic up to its limit of test solubility (0.5 mg/L).

TEST FACILITY Hüls AG (1993)

8.2.2.1 Acute toxicity to aquatic invertebrates

TEST SUBSTANCE Notified chemical (< 90% purity)

METHOD EG Guideline 84/449/EWG Part C2
Species *Daphnia magna*
Exposure Period 48 hours
Auxiliary Solvent Acetone
Water Hardness None
Analytical Monitoring None
Remarks - Method The mother organisms were kept in an M4-medium produced by Elendt in 1-litre glass beakers for the breeding. The young organisms that hatched overnight were transferred into the test water and were used for the test. Test concentrations ranging from 0.5-9.0 mg/L were used together with a blank control, a solvent control and a reference control (potassium dichromate) in the test. A total of 20 organisms were used at each test concentration with 4 replicates of 5 organisms each.

RESULTS

Concentration mg/L Nominal	*Number of D. magna*	*Number Immobilised*	
		24 h [acute]	*48 h [acute]*
0	19*	0	0
0.15	20	0	1
0.30	20	1	3
0.60	20	1	5
1.20	20	0	4
2.50	20	4	7
5.0	19*	5	10
9.0	20	19	20
Acetone	19*	0	0

* 19 organisms were available for the test

LC50 2.7 mg/L (CL: 1.8 – 4.1 mg/L) at 48 hours
NOEC (or LOEC) 0.15 mg/L at 48 hours
Remarks - Results After 48-h exposure, the maximum concentration where no immobilization (<10%) occurs was 0.15 mg/L of product and the minimum concentration where 100% immobilization occurs was 9.0 mg/L. No results were provided for the effect of potassium dichromate on the organisms, the pH values and the dissolved oxygen values during the test.

CONCLUSION The notified chemical is considered to be moderately toxic to *Daphnia magna*.

TEST FACILITY Hüls AG (1991l)

8.2.2.2 Chronic toxicity to aquatic invertebrates

TEST SUBSTANCE Notified chemical (< 90% purity)

METHOD OECD TG211 Daphnia sp. Reproduction test.
Species *Daphnia magna*
Exposure Period 21 days
Auxiliary Solvent Dimethylformamide
Water Hardness 250 mg $CaC0_3$/L

Analytical Monitoring	HPLC
Remarks – Method	Based on the results of the preliminary range finding study, *Daphnia magna* were exposed (10 replicates of a single daphnid per group) to an aqueous dispersion of the test material over a range of test concentrations of 0.00032, 0.0010, 0.0032, 0.010 and 0.032 mg/L for a period of 21 days. The test dispersions were renewed 3 times per week. The numbers of live and dead adult daphnids and young daphnids (live and dead) were determined daily. The daphnids were fed daily with an algal suspension. The numbers of live and dead of the Parental (P1) generation, the numbers of live and dead Filial (F1) daphnia and the number of discarded unhatched eggs were counted. Dissolved oxygen concentrations, pH and temperatures were recorded before and after each test media renewal.

RESULTS

LC50	0.0090 mg/L at 21 days
NOEC	0.0032 mg/L at 21 days
Remarks – Results	The 14 and 21 day EC_{50} (immobilisation) values, for the parental daphnia generation (P_1) were calculated to be 0.018 (CL: 0.010 - 0.032 mg/L) and 0.0090 mg/l (CL: 0.0063 - 0.013 mg/L), respectively. The 21-day EC50 (reproduction) value was calculated to be 0.0090 mg/L (CL: 0.0063-0.0013 mg/L). The LOEC was considered to be 0.010 mg/L on the basis that at this test concentration significantly fewer live young per adult ($P<0.05$) were produced when compared to the solvent control and significant mortalities (immobilisation) were observed in the parental generation. The NOEC was considered to be 0.0032 mg/L on the basis that at this test concentration there were no mortalities (immobilisation) observed in the parental generation (P_1) and that there were no significant differences ($P>0.05$) between the 3 solvent controls and the 0.0032 mg/L test group in terms of numbers of live young produced per adult by Day 21. Preliminary chemical analysis showed that the test material after filtration and centrifugation was dispersed throughout the diluent rather than being in solution. It also showed that the test material adsorbed to algal cells, which were used as feed during the study. Therefore, it was considered inappropriate to analyse samples of either filtered or centrifuged test media during the definitive study. Consequently, samples were taken from the fresh media at the beginning of each media renewal and from the old or expired test media at the end of each media renewal period. The samples were analysed directly without pre-treatment. Analysis of the fresh test preparations showed measured test concentrations ranging from 84% to 118% of nominal values, indicating that the test system was correctly dosed throughout. However, a marked decline was shown from analysis of the old or expired test media with all measured values being less than the limit of quantitation (LOQ) with the exception of the 0.010 mg/L test group on Day 2 and the 0.032 mg/L test group on Day 5, which showed measured test concentrations of 22% and 17%, respectively. Analysis was not performed for the 0.00032 mg/L test group from Day 9 onwards as this test concentration was shown to be <LOQ, which was assessed down to 0.00080 mg/L. The marked decline in the measured test concentrations shown over each renewal period was considered to be due to adsorption of the test material to the algal cells used as food for the daphnids and possible ingestion of the test material directly by the filter feeding actions of the test organisms.

Given the marked decline in measured test concentrations the results were also based on the time-weighted mean measured concentrations. The 14 and 21-Day-EC_{50} (immobilisation) values, for the parental daphnia generation (P_1) were calculated to be 0.0056 (CL: 0.0033-0.0096 mg/L) and 0.0031 mg/L (CL: 0.0023-0.0042 mg/L), respectively. The 21-day EC50 (reproduction) value was calculated to be 0.0031 mg/L (CL: 0.0023-0.0042 mg/L).

The LOEC was considered to be 0.0033 mg/L on the basis that at this test concentration significantly fewer live young per adult ($P<0.05$) were produced when compared to the solvent control and significant mortalities (immobilisation) were observed in the parental generation.
The NOEC was considered to be 0.0013 mg/L on the basis that at this test concentration there were no mortalities (immobilisation) observed in the parental generation (P_1) and that there were no significant differences ($P>0.05$) between the solvent control and the 0.0013 mg/L test group in terms of numbers of live young produced per adult by Day 21.

Dissolved oxygen concentrations, pHs and temperatures were within acceptable limits during the test. Throughout the study the freshly prepared test media were observed to be clear, colourless solution. However, the old test media were observed to be green tinged solutions due to the presence of algae used as feed for daphnids.

CONCLUSION The notified chemical is considered to be highly toxic to *Daphnia magna*.

TEST FACILITY SafePharm Laboratories (2001a).

8.2.3. Algal growth inhibition test

TEST SUBSTANCE Notified chemical

METHOD EC Directive 92/69/EEC C.3 Algal Inhibition Test.

Species	Green Alga (*Scenedesmus subspicatus*)
Exposure Period	72 hours
Concentration Range	Nominal: 0.80 mg/L Actual: 0.011 mg/L
Auxiliary Solvent	Dimethylformamide
Water Hardness	None
Analytical Monitoring	HPLC
Remarks - Method	Following a preliminary range-finding study, *Scenedesmus subspicatus* were exposed to an aqueous solution of the test material at a nominal concentration of 0.80 mg/L (six replicate flasks) for 72 hours, under constant illumination and shaking at a temperature of 24 ± 1^0C. Three replicate flasks each for the control and solvent control were also used. Samples of the algal population were removed at 0, 24, 48 and 72 h and cell concentrations determined for each control and treatment group, using a Coulter® Multisizer II Particle Counter. The pH of each control, solvent control and test solution were determined at the beginning and after 72 h of exposure.

RESULTS

Biomass		*Growth*	
EbC_{50} (mg/L) at72 h	*NOEC mg/L at 72 h*	*ErC_{50} (mg/L) at 72 h*	*NOEC (mg/L) at 72 h*

> 0.011 (time-weighted mean measured value)	0.011(time-weighted mean measured value)	>0.011 (time-weighted mean measured value)	0.011 (time-weighted mean measured value)

Remarks - Results

No inhibition on the growth of the alga as compared to the controls was observed at the nominal test concentration of 0.8 mg/L. The test concentration of 0.80 mg/L was the highest attainable test concentration based on a preliminary solubility work, which indicated that a test concentration of 0.80 mg/L could be obtained using dimethylformamide.

Preliminary recovery analyses were performed on test samples prepared at a concentration of 0.80 mg/L. Samples were taken for analysis with no pre-treatment, in culture medium alone, and in the presence of algal cells, after single and double filtration (0.2 µm), and after centrifugation for 30 minutes.

Recovery analysis with no pre-treatment, in culture medium alone, showed nominal concentrations of test material were obtained. In the presence of algal cells the recovery rate was reduced to 84% of nominal, thereby indicating immediate absorption of the test material to algal cells. After single filtration (0.2 µm) a measured concentration of 44% of nominal was achieved and after double filtration (0.2 µm) a measured concentration of 27% of nominal was achieved. These results indicate that the test substance appeared to be adsorbed to the filter matrix. Centrifugation resulted in a reduction in the measured concentration to 2% of nominal, indicating that a large proportion of the test material was present as a dispersion at the test concentration of 0.80 mg/L.

Based on these results it was considered appropriate to analyse samples taken from the definitive study with no pre-treatment and after 30 minutes centrifugation. The results of the centrifuged samples gave a measure of the concentration of the test material in solution and hence bioavailability to the algae.

In order to confirm that the correct dosing procedures were followed a sample was prepared in culture medium alone (no algal cells) at a concentration of 0.80 mg/L. Chemical analysis of this sample showed a measured test concentration of 116% of nominal indicating that the correct dosing procedures were followed. Chemical analysis of the test solutions at 0 hours showed measured concentrations ranging from 50% to 56% of nominal for the uncentrifuged samples and a value of 3% of nominal for centrifuged samples. This agreed with the recovery analysis, which indicated that the test material was adsorbed to algal cells.

A marked decline was shown in the measured test concentrations at 72 h with values ranging from 23 to 24% of nominal for the uncentrifuged samples to <1% of nominal for the centrifuged samples. This decline was considered to be due to further adsorption of the test material to algal cells.

The results were based on the time-weighted mean measured test concentrations of the centrifuged samples. Exposure of *Scenedesmus subspicatus* to the test material, based on the time-weighted mean measured test concentrations gave EC_{50} >0.011 mg/L and a NOEC of 0.011 mg/L.

CONCLUSION

The notified chemical was considered to be practically non-toxic up to its limit of test solubility (0.8 mg/L).

TEST FACILITY

SafePharm Laboratories (2001b).

8.2.4. Inhibition of microbial activity

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 209 Activated Sludge, Respiration Inhibition Test. EEC Commission Directive 87/302/EEC US EPA Ecological Effects Test Guidelines OPPTS 850.6800
Inoculum	A mixed population of activated sewage sludge micro-organisms from the aeration stage of the Severn Trent Water Plc sewage treatment plant at Belper, Derbyshire, UK
Exposure Period	3 hours
Nominal Concentration	0.050 mg/L and 1000 mg/L – Limit Test
Water Hardness	100 mg/L as $CaCO_3$
Remarks – Method	The test material was aerated for a period of 3 hours at 21^{o}C in the presence of activated sewage sludge with the addition of a synthetic sewage as a respiratory substrate. The rate of respiration was determined after 30 minutes and 3 hours contact time and compared to data for the control and a reference material, 3, 5-dichlorophenol. The definitive study was conducted using two methods of dispersing the test material in the test system, one using a single test concentration of 0.050 mg/L prepared using an auxiliary solvent acetone, the other using a test concentration of 1000 mg/L prepared by direct dispersion in the test water with the aid of ultrasonication.
RESULTS	
IC50	>0.050 mg/L
NOEC	0.050 mg/L
Remarks – Results	In the single test vessel prepared using a preliminary solution in auxiliary solvent to give a test concentration of 0.050 mg/L, no inhibition of the respiration rate of activated sewage sludge was observed. The 3-hour EC_{50} and NOEC were determined to be >0.050 mg/L and 0.05 mg/L, respectively. The effect of the test material on the respiration rate of activated sewage sludge was also conducted at a single test concentration of 1000 mg/L prepared by direct dispersion of the test material in test water with the aid of ultrasonication. Inhibition of respiration of the activated sewage sludge did not occur and the 3-hour EC_{50} and NOEC were determined to be >1000 mg/L and 1000 mg/L, respectively. The EC50 estimate of 10 mg/L for the 3 h contact time for the reference is within the acceptable range, thus validating the test.
CONCLUSION	The notified chemical is considered not to be inhibitory to sewage micro-organisms.
TEST FACILITY	SafePharm Laboratories (1999)

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The products containing the notified chemical are likely to be used throughout Australia. The notified chemical is considered to be practically insoluble in water and has a high partition coefficient. Thus it is likely to be associated with soil when it is disposed of to landfill. The notified chemical is considered to be not readily biodegradable. It is expected that waste

generation and disposal will occur in a diffuse manner owing to the nationwide use of the paint products with the majority being released through overspray (accounting for up to 2500 kg annually), which will eventually be incinerated. The major environmental exposure is expected to be due to the disposal of waste from the coatings manufacture to landfill and from the cleaning processes. If spilt on land, the notified chemical is expected to become immobilized in the soil layer. Due to its expected low water solubility and high partition coefficient, the notified chemical will remain bound within the soils and sediments of the landfill and to be slowly degraded by the biotic and abiotic processes. Waste generated during paint manufacture (40 kg) and application (500 kg) are expected to be landfilled or be incinerated by a licensed waste disposal contractor.

Under normal usage, the notified chemical is not expected to enter the aquatic environment. Most of the notified chemical will be incorporated into automotive re-finish paint, which upon drying, will be inert. The polymer incorporated in this matrix will ultimately be disposed of along with the automobile, which will generally go to metal recyclers. The paint matrix will be destroyed via incineration producing oxides of nitrogen and carbon and water.

Due to the nature of the release pattern, a Predicted Environmental Concentration (PEC) cannot be estimated. In the event that the notified chemical enters the aquatic environment, it is expected to partition into sediment and sludge owing to its low water solubility and high partition coefficient.

9.1.2. Environment – effects assessment

The most sensitive species was daphnia with a chronic 21 days NOEC of 0.0032 mg/L. A predicted no effect concentration (PNEC) of 0.032 µg/L has been derived by dividing the end point of 0.0032 mg/L by a safety factor of 100.

9.1.3. Environment – risk characterisation

A risk quotient cannot be calculated, as an accurate PEC cannot be estimated. However, the notified chemical is not expected to pose any significant risk to the environment. The usage pattern and the anticipated nationwide use of the product indicate that the levels of release of the chemical to the environment will be low. Under normal usage there will be no release into the aquatic environment.

Given the above, the overall environmental risk is expected to be acceptable.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Warehouse and storage workers would only be exposed to the notified chemical in the case of accidental spillage due to rupture of containers.

During small scale manufacture and testing of the paints, the main route of worker exposure to the notified chemical is likely to be dermal contact or inhalation, particularly when spraying. However, the use of a spraybooth should preclude most inhalation exposure. In addition, the notified chemical is present in the paints at low concentrations (maximum concentration of 3%), which should also minimise exposure.

During blending of the paint, QC testing, drum-filling operations and cleaning operations, exposure to the notified chemical would mainly occur as a result of skin contact with residues on containers. However, the low concentration of 3% notified chemical in the final paint means that worker exposure should be low and, in the case of spraying, will be minimised by the use of spraybooths.

At the customer sites, workers may be exposed to the notified chemical (at up to 3%) via dermal contact during adjustment of the paint to application viscosity. At these sites inhalation exposure should be mainly controlled by the use of spraybooths. However, for minor tasks in difficult areas of the car, manual application is required. In this case, PPE is used to control exposure. For exposure to spray this should involve use of a respirator, and for dermal and eye contact, gloves and goggles, respectively.

9.2.2. Public health – exposure assessment

The notified chemical is not available for sale to the public. The potential for public exposure to the notified chemical during transport, reformulation and end use of paints containing the notified chemical is likely to be negligible. Members of the public may make dermal contact with the notified chemical as a minor component of cured paints on automobiles. However, in this instance it will not be bioavailable.

9.2.3. Human health – effects assessment

The notified chemical was of low acute oral toxicity (LD50 > 3000 mg/kg bw), was slightly irritating to eyes, severely irritating to skin, and showed evidence of skin sensitisation. In addition, it was found to be non-mutagenic in bacteria and non-genotoxic in a mouse micronucleus test.

The LC50 for the acute inhalation toxicity of the notified chemical was found to be >2.61mg/L/4 hour when the chemical was administered as an aerosol. As there were no significant adverse effects seen during the study, it seems likely that the notified chemical is of low acute inhalation toxicity.

The notified chemical was found to have a NOAEL of 15 mg/kg/day in a 28-day repeated dose study in rats.

Note that the impurities present in the test substance may have contributed to the observed toxicity. In particular, one such impurity is known to cause severe burns.

According to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2004), the notified chemical is classified as:

R38 – Irritating to skin

R43 – May cause sensitisation by skin contact

9.2.4. Occupational health and safety – risk characterisation

The technical grade product Sanduvor 3058 (>90% notified chemical) that will be imported into Australia is classified as hazardous, specifically it is severely irritating to skin and may cause skin sensitisation. However, the risk to workers involved in paint manufacture will be mitigated by the mainly automated processes, ventilation systems and spraybooths used (for laboratory scale and QC testing). Exposure is expected to mainly occur via contact with residues, splashes or spills, and should be minimised by the use of appropriate PPE.

The risk of skin irritation from exposure to paint products (< 3% notified chemical) should be minimal, as the paints will not be classified as skin irritants at such concentrations. However, there is potential for skin sensitisation and possibly respiratory irritation. As the paints will be used under controlled conditions where most of the paints are robotically applied in correctly designed spraybooths, the risk to workers is low provided there are adequate safety measures in place. When spraying has to be done by hand, workers will be wearing PPE including respirator, gloves, goggles and overalls.

In summary, the risk presented by the notified chemical is acceptable, provided that workers use local exhaust ventilation, and skin, eye and respiratory protection.

9.2.5. Public health – risk characterisation

Members of the public will only make contact with a dried form of the notified chemical in automobile paints. The risk to public health from the notified chemical is likely to be low because the notified chemical is unlikely to be bioavailable and is present at low concentrations.

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

10.1. Hazard classification

Based on the available data the notified chemical is classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*. The classification and labelling details are:
R38 – Irritating to skin
R43 – May cause sensitisation by skin contact
R51 – Toxic to aquatic organisms
R53 – May cause long term adverse effects in the aquatic environment

and

As a comparison only, the classification of 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	*Hazard category*	*Hazard statement*
Skin Sensitisation	1	May cause an allergic skin reaction
Irritant	2	Causes skin irritation
Hazardous to the aquatic environment	2	Toxic to aquatic life

10.2. Environmental risk assessment

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

10.3. Human health risk assessment

10.3.1. Occupational health and safety

There is Low Concern to occupational health and safety under the conditions of the occupational settings described.

10.3.2. Public health

There is No Significant Concern to public health when used as described.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

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

11.2. Label

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

12. RECOMMENDATIONS

REGULATORY CONTROLS
Hazard Classification and Labelling

- The Office of the ASCC, Department of Employment and Workplace Relations (DEWR), should consider the following [health, environmental and physico-chemical] hazard classification for the notified chemical:
  - R38 Irritating to skin

- R43 May cause sensitisation by skin contact

- Use the following risk phrases for products/mixtures containing the notified chemical:
  - ≥ 20% R38, R43
  - ≥ 1% R43

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified chemical as introduced and as diluted for use, in final paint products:
  - Minimise spills and drips
  - Where possible, automated processes should be used to reduce worker contact
  - Use closed systems for reformulation
  - Use of engineering controls in spray painting to minimise exposure of workers.

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical as introduced and in finished paint products:
  - Spray application of paint containing the notified chemical should be in accordance with the NOHSC *National Guidance Material for Spray Painting* (NOHSC, 1999b)
  - Workers using spray products containing the notified chemical should be instructed in their proper handling and use, including information about the additional risks posed by spray application.

- 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 final paint products:
  - Chemical resistant gloves
  - Protective clothing
  - Safety glasses or goggles
  - Industrial clothing
  - Respiratory protection during spray painting, or if aerosols are formed
  - Full body protection during spray painting

  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.

Environment

Disposal

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

Emergency procedures

- In case of spillage prevent the material from entering drains or water courses. Remove with liquid binding material such as sand, soil or diatomaceous earth.

12.1. Secondary notification

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

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

The Director will then decide whether secondary notification is required.

No additional secondary notification conditions are stipulated.

13. BIBLIOGRAPHY

Hüls AG (1988a) Acute Oral Toxicity of *notified chemical* for rats (Report No: 1255), Hüls AG, D-4370 Marl, Germany (Unpublished report submitted by notifier).

Hüls AG (1988b) Test of the Acute Skin Irritant Effect of *notified chemical* (Report No. 1256), Hüls AG, D-4370 Marl, Germany (Unpublished report submitted by notifier).

Hüls AG (1988c) Test of the Acute Irritant Effect on Eyes and Mucosa of *notified chemical* (Report No. 1257), Hüls AG, D-4370 Marl, Germany (Unpublished report submitted by notifier).

Hüls AG (1990a) Translation from German: Fat Solubility, Hüls AG, D-4370 Marl, Germany (Unpublished report submitted by notifier).

Hüls AG (1990b) German Test Report: Flash Point, Hüls AG, D-4370 Marl, Germany (Unpublished report submitted by notifier).

Hüls AG (1990c) German Test Report: Autoignition Temperature, Hüls AG, D-4370 Marl, Germany (Unpublished report submitted by notifier).

Hüls AG (1990d) Testing the Sensitivity of the Skin of Guinea Pigs to *notified chemical* (Report No. HS 90/0009), Hüls AG, D-4370 Marl, Germany (Unpublished report submitted by notifier).

Hüls AG (1991a) Translation from German: Boiling Point, Hüls AG, D-4370 Marl, Germany (Unpublished report submitted by notifier).

Hüls AG (1991b) Translation from German: Relative Density of Liquids According to DIN 51 757, Hüls AG, D-4370 Marl, Germany (Unpublished report submitted by notifier).

Hüls AG (1991c) Translation from German: Vapour Pressure, Hüls AG, D-4370 Marl, Germany (Unpublished report submitted by notifier).

Hüls AG (1991d) Translation from German: Water Solubility – Column Elution Method, Hüls AG, D-4370 Marl, Germany (Unpublished report submitted by notifier).

Hüls AG (1991e) Translation from German: Surface Tension According to DIN 53 914, Hüls AG, D-4370 Marl, Germany (Unpublished report submitted by notifier).

Hüls AG (1991f) Translation from German: Abiotic Degradation According to EU Guideline C.10 (pH Dependent Hydrolysis), Hüls AG, D-4370 Marl, Germany (Unpublished report submitted by notifier).

Hüls AG (1991g) Translation from German: Partition Coefficient n-Octanol/Water (P_{ow}-value) - HPLC-Method, Hüls AG, D-4370 Marl, Germany (Unpublished report submitted by notifier).

Hüls AG (1991h) Translation from German: Flammability (Solid/Liquid): Substances Which Develop Flammable Gases in Dangerous Quantities When in Contact with Water or Humid Air, Hüls AG, D-4370 Marl, Germany (Unpublished report submitted by notifier).

Hüls AG (1991i) German Test Report: Explosive Properties, Hüls AG, D-4370 Marl, Germany (Unpublished report submitted by notifier).

Hüls AG (1991j) Determination of the Mutagenesis of *notified chemical* in the Salmonella/Mammal Microsome Mutagenesis Test According to Ames Testing Using Guideline 84/449/EWG B.14 (Report No. AM - 91/1), Hüls AG, D-4370 Marl, Germany (Unpublished report submitted by notifier).

Hüls AG (1991k) Determination of the Biological Decomposition of *notified chemical* in the Modified OECD Sturm Test (Report No: ST – 44/91), Hüls AG, D-4370 Marl, Germany (Unpublished report submitted by notifier).

Hüls AG (1991l) Determination of the Effects of *notified chemical* on the Motive Ability of *Daphnia magna* (Report No: DK 462), Hüls AG, D-4370 Marl, Germany. (Unpublished report submitted by notifier).

Hüls AG (1992) In Vivo Micronucleus Test on the Mouse with *notified chemical* (Report No. MK-92/0009), Hüls AG, D-4370 Marl, Germany (Unpublished report submitted by notifier).

Hüls AG (1993) Translation from German: Supplement to the Concluding Report F-1205 Determination of the Acute Effect of *notified chemical* on Fish, Hüls AG, D-4370 Marl, Germany (Unpublished report submitted by notifier).

Huntingdon Research (1991) Acute Inhalation Toxicity Study in Rats 4-Hour Exposure (Report No. DNN 58/911021), Huntingdon Research Centre Limited, Cambridgeshire, England (Unpublished report submitted by notifier).

NOHSC (1994) National Code of Practice for the Labelling of Workplace Substances [NOHSC:2012(1994)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.

NOHSC (1999) National Guidance Material for Spray Painting. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.

NOHSC (2003) National Code of Practice for the Preparation of Material Safety Data Sheets, 2nd edn [NOHSC:2011(2003)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.

Safepharm Laboratories (1992) Twenty-Eight Day Sub-Acute Oral (Gavage) Toxicity Study in the Rat (Report No. 395/16), Safepharm Laboratories Limited, Derby, U.K. (Unpublished report submitted by notifier).

Safepharm Laboratories (1999) Assessment of the Inhibition Effect on the Respiration of Activated Sewage Sludge (Report No: SPL 1232/001), Safepharm Laboratories Limited, Derby, U.K. (Unpublished report submitted by notifier).

Safepharm Laboratories (2001a) Daphnia Magna Reproduction Test (Report No: SPL 1232/003), Safepharm Laboratories Limited, Derby, U.K. (Unpublished report submitted by notifier).

Safepharm Laboratories (2001b) Algal Inhibition Test (Report No: SPL 1232/002), Safepharm Laboratories Limited, Derby, U.K. (Unpublished report submitted by notifier).

NOHSC (2004) Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(2004)]. National Occupational Health and Safety Commission, Canberra, AusInfo.

United Nations (2003) Globally Harmonised System of Classification and Labelling of Chemicals (GHS). United Nations Economic Commission for Europe (UN/ECE), New York and Geneva.