File No: LTD/1702

January 2014

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

SHP-100

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 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.

For the purposes of subsection 78(1) of the Act, this Public Report may be inspected at our NICNAS office by appointment only at Level 7, 260 Elizabeth Street, Surry Hills NSW 2010.

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

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Director
NICNAS

TABLE OF CONTENTS

SUMMARY

The following details will be published in the NICNAS *Chemical Gazette:*

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
LTD/1702	Akzo Nobel Pty Ltd	SHP-100	ND*	< 1 tonne per annum	Component of automotive coatings

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available information, the notified chemical is not recommended for classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

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

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

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

Recommendations

CONTROL MEASURES

Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical as introduced:
  - Avoid contact with skin and eyes

  Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

- A copy of the (M)SDS should be easily accessible to employees.

- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS)* as adopted for industrial chemicals in Australia, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation should be in operation.

Disposal

- The notified chemical should be disposed of to landfill.

Emergency procedures

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

Regulatory Obligations

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

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

(1) Under Section 64(1) of the Act; if
- the importation volume exceeds one tonne per annum notified chemical;

or

(2) Under Section 64(2) of the Act; if
- the function or use of the chemical has changed from a component of automotive coatings, or is likely to change significantly;
- the amount of chemical being introduced has increased, 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.

(Material) Safety Data Sheet
The (M)SDS of the notified chemical provided by the notifier was reviewed by NICNAS. The accuracy of the information on the (M)SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Akzo Nobel Pty Ltd (ABN: 91 000 017 354)
51 McIntyre Road
SUNSHINE NORTH VIC 3020

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

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: chemical name, other names, CAS number, molecular and structural formulae, molecular weight, analytical data, degree of purity, impurities, additives/adjuvants, use details, import volume, site of reformulation and identity of manufacturer/recipients.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as for all physico-chemical endpoints.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
US EPA

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
SHP-100

MOLECULAR WEIGHT
< 500 Da

ANALYTICAL DATA
Reference IR spectrum was provided.

3. COMPOSITION

DEGREE OF PURITY
> 95%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Colourless liquid

Property	Value	Data Source/Justification
Freezing Point	< -15 °C	(M)SDS
Boiling Point	250 °C at 101.3 kPa 153 °C at 1.9 kPa	Calculated (M)SDS
Density	1,130 kg/m^3 at 20 °C	(M)SDS
Vapour Pressure	2.54×10^{-4} kPa at 20 °C	Calculated
Water Solubility	1.3×10^2 g/L at 25 °C	Calculated (WSKOW v1.42; US EPA, 2011)
Hydrolysis as a Function of pH	Not determined	The notified chemical does not contain hydrolysable functionalities
Partition Coefficient (n-octanol/water)	log Pow = - 0.2	Calculated (KOWWIN v1.68; US EPA, 2011)
Adsorption/Desorption	log K_{oc} = - 0.008	Calculated by log Kow method (KOCWIN v2.00; US EPA, 2011)

Dissociation Constant	Not determined	The notified chemical does not contain readily dissociable functionalities
Flash Point	156 °C at 101.3 kPa (Cleveland open cup)	(M)SDS
Flammability	Not determined	Not expected to be flammable based on the flash point
Autoignition Temperature	Not determined	Not expected to undergo autoignition
Explosive Properties	Not determined	Contains no functional groups that imply explosive properties
Oxidising Properties	Not determined	Contains no functional groups that imply oxidative properties

DISCUSSION OF PROPERTIES

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

Physical hazard classification
Based on the submitted physico-chemical data depicted in the above table, the notified chemical is not recommended for hazard classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will be imported into Australia as a component of an emulsion at 3-10% concentration for reformulation locally.

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

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

PORT OF ENTRY
Melbourne

TRANSPORTATION AND PACKAGING
The notified chemical will be imported into Australia as a component of an emulsion at 3-10% concentration in 200 kg drums for local reformulation into pigment paste. The products containing the notified chemical will be transported from the port of entry by road to the reformulation site. After reformulation, the pigment products containing < 1% notified chemical will be transported in 200 kg drums by road to car manufacture facilities.

USE
The notified chemical will be used as a component of primer in automotive coatings at < 1% concentration.

OPERATION DESCRIPTION
Reformulation
At the reformulation site, the emulsion containing the notified chemical (3-10% concentration) will be transferred from the import containers into an enclosed and automated blending tank. Therein, the notified chemical will be mixed with other ingredients. When blending is complete, a sample will be taken by QA staff for testing. The resulting pigment paste containing the notified chemical (< 1% concentration) will then be dispensed into 200 kg drums for supply to end-users.

End-use
At car manufacturing facilities, the pigment paste containing the notified chemical (< 1% concentration) will be pumped to an application tank and mixed with other components to form the finished primer. The primer will be applied to cars and car parts by a dipping process, and then cured by oven baking. The mixing process will be enclosed, and both mixing and dipping processes will be automated.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

Category of Worker	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Reformulation - reactor/blending operators	8	25-35
Reformulation - maintenance personnel	1	5
Reformulation - laboratory staff	2-4	10
Reformulation - storage and handling	2-4	25-35
Transport – delivery	1-2	25-35
Application - electrocoat tank operators	1-2	20
Application - application/curing operators	1-2	20
Application - maintenance personnel	1-2	15
Application - laboratory staff	1-2	50

EXPOSURE DETAILS

Transport and storage workers may come into contact with the notified chemical in the imported emulsion (3-10% concentration) or as a component of pigment paste (< 1% concentration) only in the event of accidental rupture of containers.

Reformulation

Reformulation will be largely enclosed and automated; however workers may be exposed (dermal and ocular) to the notified chemical at 3-10% concentration when transferring the emulsion from import containers to the mixing tank or transferring pigment paste from the mixing tank to the repackaging containers, during quality control testing and maintenance and cleaning tasks. Dermal and ocular exposure to workers should be further mitigated through the use of personal protective equipment (PPE) including protective coveralls, impervious gloves and goggles and local exhaust ventilation. Inhalation exposure is not expected as the notified chemical has an estimated low vapour pressure at ambient temperatures.

End-use

The primer formation and application processes will be largely enclosed and automated; however workers (application operators and service technicians) may be exposed (dermal and ocular) to the notified chemical at < 1% concentration during quality control operations and maintenance and service tasks. Inhalation exposure to the notified chemical is not anticipated due to the estimated low vapour pressure of the notified chemical and enclosed processes. Dermal and ocular exposure to workers should further be mitigated through the use of PPE including protective coveralls, impervious gloves and goggles.

Once the primer is cured and dried, the notified chemical will be bound within a hard durable coating matrix and will not be bioavailable.

6.1.2. Public Exposure

The notified chemical will be used in industrial settings only and will not be sold to the public. The public may come into contact with cars and car parts coated with primer containing the notified chemical. However, once the primer is cured and dried, the notified chemical will be bound within a hard durable coating matrix and will not be available for exposure.

6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on the notified chemical or an analogue (identity is exempt information) are summarised in the following table. For full details of the studies conducted on the notified chemical, refer to Appendix B.

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity*	LD50 = 6610 mg/kg bw; low toxicity
Guinea pig, acute oral toxicity	LD50 = 3960 mg/kg bw; low toxicity
Rabbit, acute dermal toxicity*	LD50 = 24,000 mg/kg bw; low toxicity
Rat, acute inhalation toxicity*	LC50 > 5.4 mg/L/4 h

Rabbit, skin irritation*	slightly irritating
Rabbit, eye irritation*	moderately irritating
Guinea pig, skin sensitisation – adjuvant test*	no evidence of sensitisation
Rat, repeat dose oral toxicity – 28 days	NOEL = 1000 mg/kg bw/day
Mutagenicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro chromosomal aberration	non genotoxic

* Test substance is an analogue.

Toxicokinetics
Limited data are available on the toxicokinetic properties of the notified chemical. Based on the molecular weight (< 500 Da), the notified chemical has a potential to cross the gastrointestinal (GI) tract by passive diffusion or to be dermally absorbed after exposure. However, given the high water solubility and hydrophilic nature, dermal absorption is expected to be limited. The notified chemical has a low estimated vapour pressure; thus inhalation exposure is expected to be negligible.

Toxicokinetic studies conducted on an analogue administered intraperitoneally to rats showed that 90% of the administered dose was excreted in urine within 24 hours, with the entire dose excreted by day 8.

The notified chemical is highly water soluble and therefore if inhaled at low levels is likely to be cleared from the upper respiratory tract readily through mucociliary action.

Acute toxicity.
No acute toxicity data for the notified chemical were submitted. An analogue of the notified chemical was found to be of low acute oral toxicity in rats and guinea pigs (Reddy, 2005).

The analogue chemical was also found to be of low acute dermal toxicity in rabbits and of low acute inhalation toxicity in rats (Reddy, 2005).

Based on studies conducted on the analogue chemical, the notified chemical is not expected to be acutely toxic.

Irritation and sensitisation.
No irritation and sensitisation data for the notified chemical were submitted. In studies conducted in rabbits, an analogue chemical was found to be mildly irritating to the skin and moderately irritating to the eye (Reddy, 2005). The analogue chemical is also classified as an eye irritant under HSIS.

The analogue chemical was not considered as a skin sensitiser when challenged at 75% in aqueous solution in a Guinea pig maximisation test (Reddy, 2005).

Based on studies conducted on an analogue chemical, the notified chemical may present as a moderate skin and eye irritant and is not expected to be a skin sensitiser.

Repeated dose toxicity.
In a 28 day repeat dose oral toxicity study in rats the NOEL for the notified chemical was established as 1000 mg/kg bw/day based on no test substance-related changes at the highest dose tested.

Mutagenicity/Genotoxicity.
The notified chemical was negative both in a bacterial reverse mutation study and in an *in vitro* chromosomal aberration study.

Health hazard classification
Based on the available information, the notified chemical is not recommended for classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety
The notified chemical is expected to be of low hazard presenting only as a potential skin and eye irritant. This is further supported by the fact that an analogue of the notified chemical is classified as an eye irritant. Given workers will only be exposed to the notified chemical at up to 10% concentration, the risk of irritation effects is

expected to be low. Therefore, the risk of the notified chemical to occupational health is not considered to be unreasonable given the assumed low hazard and the assessed use pattern.

6.3.2. Public Health

The notified chemical will be used in industrial settings only and will not be sold to the public. The public may come into contact with cars containing the notified chemical. However, once the primer containing the notified chemical is cured, the notified chemical will be bound within a coating matrix and will not be bioavailable. Therefore, when used in the proposed manner, the risk to public health is not considered to be unreasonable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified chemical will not be manufactured in Australia. Therefore, release of the notified chemical from this activity is not expected. Reformulation of the notified chemical will take place in Australia. However, accidental spillage from this process is expected to be limited due to the automated nature of the blending process which is typically in closed chambers. Accidental spills/leaks of the notified chemical during blending are expected to be contained in a bunded area and to be collected and disposed of to landfill.

During the reformulation process, it is estimated by the notifier that up to 2 kg of the total annual import volume of the notified chemical (due to sampling, maintenance and waste from the cleaning of equipment) is expected to be disposed of to landfill as solid waste. Under normal circumstances, there will be no rejected reformulated product. However, in a rare event, the notifier estimates that up to 20% (1,000 kg × 20% = 200 kg) of the total annual import volume of the notified chemical may be disposed of to landfill as rejected product. Wastewaters from the reformulation process are expected to be contained in the internal interceptor pit for treatment (flocculation) before it is released to the sewer as trade waste.

RELEASE OF CHEMICAL FROM USE

The materials containing the notified chemical are currently only used in the automotive industry. The potential release scenarios of the notified chemical at the industrial coating plants include:

a) Road tanker delivery to plants

No significant release of the product containing the notified chemical is expected during transport. In the unlikely event of a spill, the product containing the notified chemical will either be contained and disposed of to landfill or will be drained to the on-site interceptor pit.

b) Electrocoat (e-coat) immersion tank

Automotive bodies and parts are passed through the electrocoat tank by conveyor where the electrodeposition coating (e-coating) is deposited on the surface. The e-coat tank is replenished with additional coating. Overflow and excess coating is expected to be recycled or directed to internal interceptor pits. Residues collected from filtration of the e-coat tank contents are also expected to be directed to internal interceptor pits. It is expected the filters will eventually be dried and disposed of to landfill. No significant release of the notified chemical is expected at this stage.

c) E-Coat wash water tanks

Rinsing of the automotive metal surfaces after deposition is conducted by a closed loop process, with successive rinses, each feeding back to the previous rinse. The final rinse drainings and filtration residues are expected to be directed to the on-site interceptor pits. The notifier estimated that the amount of the notified chemical entering the waste treatment system would be a maximum of 2% of the total import volume. Up to 95% of solids are removed from wastewater during on site treatment. Sludge from the on-site interceptor pits, containing residues of the notified chemical, is expected to be disposed of to landfill, and effluent is expected to be directed to local sewage treatment plants (STPs).

RELEASE OF CHEMICAL FROM DISPOSAL

The notified chemical is expected to share the fate of the coated automobile parts, and at the end of the car's useful life, the coated metal articles will be sent to metal reclamation facilities or be disposed of to landfill.

Residual notified chemical in empty import containers, up to 2% (1,000 kg × 2% = 20 kg) of the total import volume is expected to be disposed of to landfill during drum recycling.

7.1.2. Environmental Fate

No environmental fate data were submitted for the notified chemical. The notified chemical will become irreversibly bound to form part of an inert coating matrix during the heat curing process. The notified chemical will share the fate of the coated automotive parts, which will involve eventual disposal to landfill or thermal decomposition during metal reclamation. In its cured form, the notified chemical is not expected to be bioavailable or mobile in the environment. Bioaccumulation of the uncured chemical is unlikely due to its high water solubility and low n-octanol/water partition coefficient.

Most of the solids (up to 95%) in waste streams generated from the electrodeposition coating process are expected to be captured by on-site interceptor pits. Sludge from treatment plants may be collected for disposal to landfill or used in soil remediation. However, due to its high water solubility, the notified chemical in the waste streams may not be captured by these systems and could be released to the sewer. If released to sewer, the notified chemical is not expected to significantly partition to sludge and sediment in STPs due to its hydrophilicity and low molecular weight. Therefore, some of the notified chemical is expected to be released to the receiving waters along with the effluents. In receiving waters, the notified chemical is expected to disperse and degrade. The notified chemical will eventually degrade in landfill and water, or by thermal decomposition during metal reclamation processes, to form water and oxides of carbon and sulfur.

7.1.3. Predicted Environmental Concentration (PEC)

The notified chemical in wastewaters from e-coat wash water tanks (1,000 kg × 2% = 20 kg) is expected to be contained in internal interceptor pits. The Predicted Environmental Concentration (PEC) was calculated for the worst case scenario assuming that 100% of the notified chemical contained in wastewater treated on site will be released to sewer annually. It was further assumed that 0% of the notified chemical released to the local STP will partition to sludge. The release of the notified chemical will occur over 260 days per annum into the local STP. This corresponds to release only on working days, based on a 5 day work week. The average daily flow of the applicable local STP is 329 ML/day. The results of the calculation are shown in the table below.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Annual quantity of chemical released to internal interceptor pits	20	kg/year
Removal within internal interceptor pits	0%	
Annual quantity of chemical released to sewer	20	kg/year
Days per year where release occurs	260	days/year
Daily chemical release:	0.077	kg/day
Individual Sewage Treatment Plant Average Daily Flow:	329	ML/day
Removal within STP	0%	**Mitigation**
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	0.23	µg/L
PEC - Ocean:	0.02	µg/L

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1000 L/m^2/year (10 ML/ha/year). The notified chemical in this volume is assumed to infiltrate and accumulate in the top 10 cm of soil (density 1500 kg/m^3). Using these assumptions, irrigation with a concentration of 0.23 µg/L may potentially reult in a soil concentration of approximately 1.6 µg/kg. Assuming accumulation of the notified chemical in soil for 5 and 10 years under repeated irrigation, the concentration of notified chemical in the applied soil in 5 and 10 years may be approximately 7.8 µg/kg and 15.6 µg/kg, respectively.

7.2. Environmental Effects Assessment

No ecotoxicity data were submitted. Environmental effects endpoints for the notified chemical estimated by ECOSAR (v1.11; US EPA, 2012) are summarised in the table below.

Endpoint	*Result (mg/L)*	*Assessment Conclusion*
Fish	LC50 (96 h) > 1,000	Not expected to be harmful to fish
Daphnia	LC50 (48 h) > 1,000	Not expected to be harmful to aquatic invertebrates

Algal	EC50 (96 h) > 1,000	Not expected to be harmful to algae

Since the notified chemical is not expected to be harmful to the aquatic life, it has not been classified under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS; United Nations, 2009).

7.2.1. Predicted No-Effect Concentration

The Predicted No-Effect Concentration (PNEC) was calculated using one of the estimated toxicity endpoints for the notified chemical and an assessment factor of 1000. The conservative assessment factor of 1000 was used since the estimated ecotoxicity endpoints were used in lieu of the measured data for the notified chemical.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
EC50 (fish/daphnia/algae)	> 1,000	mg/L
Assessment Factor	1,000	
PNEC:	> 1,000	µg/L

7.3. Environmental Risk Assessment

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River:	0.23	> 1,000	< 0.0001
Q - Ocean:	0.02	> 1,000	< 0.0001

The Risk Quotients (Q = PEC/PNEC) for a conservative discharge scenario have been calculated to be much less than 1 for both riverine and marine compartment. The notified chemical is not expected to be bioaccumulative or harmful aquatic organisms. On the basis of the assessed use pattern, the notified chemical is not considered to pose an unreasonable risk to the environment.

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Repeat dose toxicity

TEST SUBSTANCE	Notified chemical
METHOD	Similar to OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents.
Species/Strain	Rats/Sprague-Dawley (Crj:CD(SPF))
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 28 days Dose regimen: 7 days per week Post-exposure observation period: 14 days
Vehicle	Pure water
Remarks - Method	No significant protocol deviations

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
control	6 per sex	0	0
low dose	6 per sex	20	0
mid dose	6 per sex	140	0
high dose	6 per sex	1000	0
control recovery	6 per sex	0	0
high dose recovery	6 per sex	1000	0

Mortality and Time to Death

No test substance related deaths occurred during the study.

Clinical Observations

No changes were noted in all animals during the treatment and recovery periods.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

There were no changes ascribed to the test substance detected in both the treatment and recovery periods.

Effects in Organs

There were no changes ascribed to the test substance detected in the necropsy or histopathology in both the treatment and recovery periods.

CONCLUSION

The No Observed Effect Level (NOEL) was established by the study authors as 1000 mg/kg bw/day in rats, based on the absence of test substance related toxicological significant effects at any of the doses administered.

TEST FACILITY Kashima Laboratory (1996)

B.2. Genotoxicity – bacteria

TEST SUBSTANCE	Notified chemical
METHOD	Similar to OECD TG 471 Bacterial Reverse Mutation Test. Pre incubation procedure
SPECIES/STRAIN	S. typhimurium: TA100, TA1535, TA1537 and TA98 E. coli: WP2uvrA
METABOLIC ACTIVATION SYSTEM	S9 mix from phenobarbital/β-naphthoflavone induced rat livers
CONCENTRATION RANGE IN MAIN TEST	a) With metabolic activation: 313-5000 µg/plate b) Without metabolic activation: 313-5000 µg/plate
VEHICLE	Distilled water
REMARKS - METHOD	A preliminary toxicity test (156-5000 µg/plate) was performed on all strains used in main tests to determine the toxicity of the test substance.

In the main tests, aliquots of 0.5 mL of either test substance, positive, or negative control solution was used at five concentrations up to 5000 µg/plate. The negative control was ethanol and positive controls were 2-(2-furyl)-3-(5-notro-2-furyl)acrylamide, sodium azide, N-ethyl-N'-nitro-N-nitrosoguanidine, and 9-aminoacridine in the absence of S9 mix and 2-aminoanthracene and benzo[a]pyrene in the presence of S9 mix.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	> 5000	> 5000	unknown	Negative
Test 2		> 5000	unknown	Negative
Present				
Test 1	> 5000	> 5000	unknown	Negative
Test 2		> 5000	unknown	Negative

Remarks - Results

No toxicologically significant increases in the frequency of revertant colonies were recorded for any of the bacterial strains, with any dose of the test substance, either with or without metabolic activation.

All the positive control chemicals used in the test induced marked increases in the frequency of revertant colonies thus confirming the activity of the S9-mix and the sensitivity of the bacterial strains.

CONCLUSION

The test substance was not mutagenic to bacteria under the conditions of the test.

TEST FACILITY

JOIC (1994)

B.3. Genotoxicity – in vitro

TEST SUBSTANCE

Notified chemical

METHOD

Similar to OECD TG 473 In vitro Mammalian Chromosome Aberration Test.

Species/Strain: Hamster
Cell Type/Cell Line: Chinese hamster lung cell line (CHL/IU)
Metabolic Activation System: S9 mix from phenobarbital/5,6-benzoflavone induced rat liver
Vehicle: Distilled water
Remarks - Method: Doses up to 5000 µg/mL were chosen for the main test based on the results of a cell growth inhibition test that showed that the concentration of 50% cell growth inhibition was above 5000 µg/mL.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	1250*, 2500*, 5000*	24	24
Test 2	1250*, 2500*, 5000*	48	48
Test 3	1250*, 2500*, 5000*	6	24
Present			
Test 1	1250*, 2500*, 5000*	6	24

*Cultures selected for metaphase analysis.

RESULTS

Metabolic	*Test Substance Concentration (µg/mL) Resulting in:*

Activation	*Cytotoxicity in Preliminary Test*	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	> 5000	> 5000	> 5000	Negative
Test 2	> 5000	> 5000	> 5000	Negative
Test 3	> 5000	> 5000	> 5000	Negative
Present				
Test 1	> 5000	> 5000	> 5000	Negative

Remarks - Results

The maximum dose level selected for the main experiments was based on the results of the preliminary study, and was up to the recommended dose of 5000 µg/mL.

The test substance did not induce significant increase in the incidence of cells with structural and numerical chromosomal aberrations, irrespective of the presence or absence of a metabolic activation system and the length of treatment duration in any of the exposure groups.

CONCLUSION

The test substance was not clastogenic to CHL cells treated *in vitro* under the conditions of the test.

TEST FACILITY

RIASBT (1994)

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