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August 2018

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

RX094107

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the 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 and Energy.

This Public Report is 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

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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
STD/1655	BASF Australia Ltd	RX094107	ND*	≤ 10 tonne/s per annum	Component of automotive coatings

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available information, the notified chemical cannot be classified according to the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia.

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 assumed low hazard and the reported 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 painting operations:
  - Avoid breathing vapours/spray
  - Apply product in a well-ventilated area

- A person conducting a business or undertaking at a workplace should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical during painting operations:
  - Respiratory protection

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

- Spray applications should be carried out in accordance with the Safe Work Australia Code of Practice for *Spray Painting and Powder Coating* (SWA, 2015) or relevant State or Territory Code of Practice.

- A copy of the 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 of 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

- Where reuse or recycling are not appropriate, dispose of the notified chemical in an environmentally sound manner in accordance with relevant Commonwealth, state, territory and local government legislation.

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(2) of the Act; if
  - the function or use of the chemical has changed from 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.

No additional secondary notification conditions are stipulated.

Safety Data Sheet
The SDS of products containing the notified chemical provided by the notifier were reviewed by NICNAS. The accuracy of the information on the SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
BASF Australia Ltd (ABN: 62 008 437 867)
Level 12
28 Freshwater Place
SOUTHBANK VIC 3006

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 and structural formulae, molecular weight, analytical data, degree of purity, residual monomers, impurities, additives/adjuvants, use details, and import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: hydrolysis as a function of pH, flammability limits, autoignition temperature, explosive properties, oxidising properties, reactivity, acute dermal toxicity, acute inhalation toxicity, repeated dose toxicity, acute fish toxicity, algal growth inhibition test, and bioaccumulation.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
EU (REACH)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
923-625 G2 HS Clear Universal VOC
923-525 MS Clear G2

MOLECULAR WEIGHT
> 500 g/mol

ANALYTICAL DATA
Reference NMR, IR, GC, and UV spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
> 98%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: liquid

Property	Value	Data Source/Justification
Melting Point	-62 °C	Measured glass transition point
Boiling Point	430 °C at 101.3 kPa	Measured
Density	904.4 kg/m^3 at 20 °C	Measured
Vapour Pressure	< 0.001 kPa at 25 °C	Estimated based on QSAR analysis
Dynamic Viscosity	3832 mPa/s	Measured
Kinematic Viscosity	855 mm^2/s	Measured
Water Solubility	< 0.0001 g/L at 20 °C	Measured
Hydrolysis as a Function of pH	Not determined	Contains no hydrolysable functionality
Partition Coefficient (n-octanol/water)	log P_{ow} > 6.5	Measured
Adsorption/Desorption	Not determined	Expected to be immobile in soil based on its low water solubility
Dissociation Constant	Not determined	Contains no dissociable functionalities
Flash Point	300 °C	Measured
Flammability	Not determined	Chemical is not expected to be a flammable liquid as its flash point is > 93 °C
Autoignition Temperature	Not determined	Not expected to autoignite based on flash point.
Explosive Properties	Not determined	Contains no functional groups that would imply explosive properties.
Oxidising Properties	Not determined	Contains no functional groups that would imply oxidising properties.

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

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 of 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 not be manufactured in Australia. The notified chemical will be imported as a component of an automotive coating product at a concentration of < 10%.

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

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

PORT OF ENTRY
Melbourne and Sydney

TRANSPORTATION AND PACKAGING
The notified chemical will be imported into Australia as a component of an end-use formulation at < 10 % concentration.

The imported coating products containing the notified chemical (at < 10% concentration) will be available in metal cans of ≤ 10 L volume for distribution. Due to the presence of flammable solvent, the liquid solution containing the notified chemical has a dangerous goods classification of Class 3. Therefore, the products containing the notified chemical will be transported, packaged and stored in accordance with the Australian Code for the Transport of Dangerous Goods (NTC, 2018).

USE
The notified chemical will be used in surface coatings for automotive OEM (Original Equipment Manufacturer) and refinish applications.

OPERATION DESCRIPTION
No reformulation, repackaging or manufacture of the notified chemical will take place within Australia. The products containing the notified chemical will be transported to the notifier's warehouse prior to distribution to end-users.

Coating products containing the notified chemical (at < 10% concentration) will be applied to automotive bodies and parts by spraying. Spray applications may occur within or outside spray booths. Spray painting workers will open the cans containing the notified chemical and transfer it to spray equipment.

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)*
Transport and storage	1 – 2	20
Operators	8	300

EXPOSURE DETAILS
The notified chemical will be imported (at concentrations of < 10%) in sealed cans containing the end-use coating products. No significant exposure to transport and storage workers is anticipated to occur, unless in the event of an accident the containers are breached.

Workers may be exposed (ocular, dermal and inhalation) to the notified chemical at concentrations < 10% during the transfer, application, and cleaning of the coating and spray equipment. According to the notifier, dermal, ocular and inhalation exposure to workers is expected to be minimised through the use of personal protective equipment (PPE) such as coveralls, goggles, impervious gloves and the use of enclosed processes, local exhaust ventilation and breathing masks or respirators where ventilation is inadequate.

6.1.2. Public Exposure
Coating products containing the notified chemical (at concentrations < 10%) are intended for industrial use only and direct exposure to the public is not expected. Once the coating has dried, the notified chemical will be part of an inert matrix and will not be available for exposure.

6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on the notified chemical are summarised in the following table. For full details of the studies, refer to Appendix B.

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	LD50 > 2,500 mg/kg bw; low toxicity
Rabbit, skin irritation	slightly irritating
Rabbit, eye irritation	slightly irritating
Mouse, skin sensitisation – Local lymph node assay	no evidence of sensitisation
Mutagenicity – bacterial reverse mutation	non mutagenic
Genotoxicity – *in vitro* mammalian cell gene mutation test in mouse lymphocytes	non genotoxic
Genotoxicity – *in vitro* mammalian cell gene mutation test in human lymphocytes	non genotoxic

Toxicokinetics, metabolism and distribution
No toxicokinetic data on the notified chemical were submitted. For dermal and gastrointestinal absorption, molecular weights below 100 Da are favourable for absorption and molecular weights above 500 Da do not favour absorption (ECHA, 2017). Dermal uptake is likely to be low to moderate if the water solubility is between 1-100 mg/L and may be limited if the partition coefficient (log P) values are greater than 4 (ECHA, 2017). Gastrointestinal absorption is also likely to be high if the partition coefficient (log P) values are greater than 4. Absorption of the notified chemical through the skin and gastrointestinal tract is expected to be low based on the partition coefficient (log P > 6.5), water solubility (< 0.1 mg/L) and molecular weight (> 500 g/mol).

Studies on analogue chemicals showed low levels of absorption and bioaccumulation, and are expected to primarily be metabolised and excreted through the urine and faeces (unpublished report submitted by notifier).

Acute toxicity
The notified chemical is of low acute oral toxicity based on a study conducted in rats. No information on toxicity following dermal or inhalation toxicity was submitted.

Irritation and sensitisation
The notified chemical was slightly irritating to the skin and eyes of rabbits.

The notified chemical is not expected to be a skin sensitiser based on a study conducted in mice.

Repeated dose toxicity
Information on repeated dose toxicity and reproduction/developmental toxicity following oral exposure is available for analogue chemicals. The notified chemical is a C36 dimer diol and the analogue chemicals were carboxylic acids, rather than alcohols, with a similar structure. Based on information provided by the notifier, no toxicologically relevant effects were observed in rats following long term oral exposure to high doses in a subchronic study. In a subchronic oral toxicity study, adaptive changes in clinical chemistry parameters and histopathology were observed. In a reproduction/developmental toxicity screening study, no toxicologically relevant effects were observed at the high dose tested. Based on similarities between the notified chemical and the analogues, the notified chemical is expected to have low repeated dose toxicity. Toxicity following repeated dermal exposure would be expected to be very low due to the likely very low dermal absorption (unpublished report submitted by notifier). No information was submitted on toxicity following repeated inhalation exposure.

Mutagenicity/Genotoxicity
The notified chemical was non-genotoxic in a bacterial reverse mutation assay, an *in vitro* mammalian cell gene mutation test in mouse lymphocytes and in an *in vitro* mammalian chromosome aberration test in cultured peripheral human lymphocytes.

Health hazard classification
Based on the available information, the notified chemical cannot be classified according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia.

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety

Based on the information available for both the notified chemical and analogues, the notified chemical is expected to be of low hazard, with potential for slight skin and eye irritation.

Exposure of workers to the notified chemical (at ≤ 10% concentration) may occur during transport, transfer, application, and cleaning operations. The notified chemical is considered to be slightly irritating, although at the reduced concentration of ≤ 10% irritant effects from the notified chemical are unlikely.

There is no information available on the toxicity of the notified chemical via inhalation. Inhalation exposure to workers may occur during application of surface coatings containing it and subsequently control measures including the use of automated processes and PPE (impervious gloves, goggles, coveralls, and respiratory protection should be in place to minimise worker exposure.

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

6.3.2. Public Health

The public may also come into contact with the coatings containing the notified chemical. However, in such cases exposure is not expected as the notified chemical will be bound within an inert matrix and will not be available for exposure.

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

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified chemical will be imported as a component of end-use automotive coating products. Spills or accidental release of the products containing the notified chemical during import, storage, and transport are expected to be adsorbed on suitable materials and disposed of to landfill in accordance with local government regulations.

RELEASE OF CHEMICAL FROM USE

The coating products containing the notified chemical will be applied to automotive bodies and parts by spraying. The majority of these spray applications will occur in spray booths.

The main release of the notified chemical is likely to be from overspray during use, estimated by the notifier to account for up to 30% of the total annual import volume. The overspray will be trapped onto spray booth filters before disposal to landfill in accordance with local government regulations. As estimated by the notifier, the liquid waste from cleaning of application equipment contains up to 1% of import volume of the notified chemical, which will be collected, treated and disposed of to landfill in accordance with local government regulations.

RELEASE OF CHEMICAL FROM DISPOSAL

Most of the notified chemical is expected to share the fate of the articles to which it has been applied, either subjected to metal reclamation processes or being disposed of to landfill at the end of their useful lives. Empty import and end use containers containing residues of notified chemical are expected to be collected by an approved waste management facility for safe disposal.

7.1.2. Environmental Fate

A biodegradation test conducted on the notified chemical shows that it is not readily biodegradable (17% degradation in 28 days in OECD 301B test). For details of the biodegradation test, refer to Appendix C. As a result of its use pattern, most of the notified chemical is expected to share the fate of the articles to which it has been applied, as described previously. During metal reclamation, the notified chemical will thermally decompose

to form water vapour and oxides of carbon. In landfill, the notified chemical will be present as cured solids and will be neither bioavailable nor mobile. Therefore, release of the notified chemical to the aquatic environment is expected to be minimal. In landfill, the notified chemical is expected to eventually degrade via biotic and abiotic processes to form water and oxides of carbon.

7.1.3. Predicted Environmental Concentration (PEC)

The predicted environmental concentration (PEC) has not been calculated as release of the notified chemical to the aquatic environment will be limited based on its reported use pattern as a component of automotive coating products.

7.2. Environmental Effects Assessment

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

Endpoint	*Result*	*Assessment Conclusion*
Chronic Daphnia Toxicity	21 d EL50 > 100 mg/L 21 d NOEL ≥ 100 mg/L	Not harmful to aquatic invertebrates up to its water solubility limit

The chronic Daphnia toxicity endpoint above shows that the notified chemical is not harmful to aquatic invertebrates up to its water solubility limit.

The notifier also submitted acute and chronic toxicity data for acceptable analogues of the notified chemical. The results of these tests indicate that the notified chemical is unlikely to be harmful to aquatic organisms up to its water solubility limit. Therefore, the notified chemical was provisionally not 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-effects concentration (PNEC) has not been calculated as the notified chemical is unlikely to be harmful to aquatic organisms up to its water solubility limit.

7.3. Environmental Risk Assessment

The Risk Quotient (Q = PEC/PNEC) has not been calculated as the notified chemical is not expected to be harmful to aquatic organisms up to its water solubility limit, and release of the notified chemical to the aquatic environment will be limited based on its reported use pattern. Therefore, based on the assumed low hazard and the reported use pattern as a component of automotive coating products, the notified chemical is not expected to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Melting Point 62 °C

Method	Similar to OECD TG 102 Melting Point/Melting Range EC Council Regulation No 440/2008 A.1 Melting/Freezing Temperature
Remarks	Differential Scanning Calorimetry (DSC). No melting point was obtained. Instead, a glass transition temperature was measured.
Test Facility	Croda (2012)

Boiling Point 430 °C at 101.3 kPa

Method	Similar to OECD TG 103 Boiling Point EC Council Regulation No 440/2008 A.2 Boiling Temperature
Remarks	Differential Scanning Calorimetry (DSC)
Test Facility	Croda (2012)

Density 904.4 kg/m^3 at 20 °C

Method	ASTM D4052 ISO 12185
Remarks	U tube.
Test Facility	Croda Nederland (2012)

Dynamic Viscosity 3832 mPa/s at 20 °C

Method	Equivalent to ISO 12555
Remarks	Brookfield rotational viscometer
Test Facility	Croda Nederland (2012)

Kinematic Viscosity 855 mm^2/s at 20 °C

Method	Equivalent to ASTM D445 or ISO 3104
Remarks	Ubbelohde glass capillary viscometer
Test Facility	Croda Nederland (2012)

Water Solubility < 0.0001 g/L at 20 °C

Method	EC Council Regulation No 440/2008 A.6 Water Solubility
Remarks	Column Elution Method
Test Facility	Henkel (2012)

Partition Coefficient (n-octanol/water) log P_{ow} > 6.5

Method	OECD TG 117 Partition Coefficient (n-octanol/water). EC Council Regulation No 440/2008 A.8 Partition Coefficient.
Remarks	HPLC Method
Test Facility	Harlan (2012a)

Flash Point 300 °C

Method	Similar to EC Council Regulation No 440/2008 A.9 Flash Point Consistent with ISO 2719, ATM D 93 and IP34
Remarks	Closed cup method.
Test Facility	CCE (2012)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE: Notified chemical

METHOD
- Species/Strain: Rat/Sprague-Dawley CD (Crl:CD® (SD) IGS BR)
- Vehicle: Arachis oil BP
- Remarks - Method: GLP compliant. No deviations from the protocol.

RESULTS

Group	*Number and Sex of Animals*	*Dose (mg/kg bw)*	*Mortality*
1	3 F	2,000	0/3
2	3 F	2,000	0/3

- LD50: > 2,500 mg/kg bw
- Signs of Toxicity: No signs of systemic toxicity were observed.
- Effects in Organs: No abnormalities observed at necropsy.
- Remarks - Results: All animals made the expected bodyweight gains.

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

TEST FACILITY: SafePharm (2004a)

B.2. Irritation – skin

TEST SUBSTANCE: Notified chemical

METHOD
- Species/Strain: Rabbit/New Zealand White
- Number of Animals: 3 F
- Vehicle: None
- Observation Period: 14 days
- Type of Dressing: Semi-occlusive; 6 cm^2 patch.
- Remarks - Method: GLP compliant. No deviations from the protocol.

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	1	1.7	1.3	2	< 14 days	0
Oedema	1	1	1	2	< 7 days	0

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

- Remarks - Results: Very slight erythema and oedema were observed in one animal following exposure with full recovery by day 7. Well-defined erythema and oedema was observed in two animals 40 minutes after exposure with a lessening of these effects observed 24 hour after exposure. Well-defined erythema was observed in both animals at the 48 hour observation with the effect persisting in one animal, while recovery was indicated in the second animal. Both animals exhibited very slight erythema at the 7 day observation. Very slight oedema was observed in these two animals at the 48 and 72 hour observation, and no oedema was observed at day 7.

  All animals had recovered by the day 14 observation.

CONCLUSION The notified chemical is slightly irritating to the skin.

TEST FACILITY Notox (1987)

B.3. Irritation – eye

TEST SUBSTANCE Notified chemical

METHOD OECD TG 405 Acute Eye Irritation/Corrosion
EC Council Regulation No 440/2008 B.5 Acute Toxicity (Eye Irritation)
Species/Strain Rabbit/New Zealand White (Hsdlf:NZW)
Number of Animals 2 M
Observation Period 3 days
Remarks - Method GLP compliant.
No deviations from the protocol.

RESULTS

Lesion	*Mean Score* Animal No.*		*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2			
Conjunctiva: redness	0.7	0.3	1	< 72 hours	0
Conjunctiva: chemosis	0.3	0	1	< 48 hours	0
Conjunctiva: discharge	0	0	1	-	0
Corneal opacity	0	0	0	-	0
Iridial inflammation	0	0	0	-	0

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

Remarks - Results Slight conjunctival irritation was observed in both animals at 1 hour after exposure. Slight conjunctival redness persisted in both animals at the 24 hour observation, persisting in one animal at the 48 hour observation. Conjunctival chemosis persisted in one animal at the 24 hour observation. One animal exhibited full recovery at the 48 hour observation, with both animals fully recovered at the 72 hour observation.

No body weight gain was observed in one animal, while a non-significant loss (0.6%) in body weight was observed in second animal.

CONCLUSION The notified chemical is slightly irritating to the eye.

TEST FACILITY Harlan (2012b)

B.4. Skin sensitisation – mouse local lymph node assay (LLNA)

TEST SUBSTANCE Notified chemical

METHOD OECD TG 429 Skin Sensitisation: Local Lymph Node Assay
EC Regulation No. 440/2008 B.42 Skin Sensitisation (Local Lymph Node Assay)
Species/Strain Mouse/CBA/Ca (CBA/CaOlaHsd)
Vehicle Acetone/olive oil 4:1
Preliminary study Yes
Positive control Not conducted in parallel with the test substance, but had been conducted previously in the test laboratory using α-hexylcinnamaldehyde (85%).
Remarks - Method GLP compliant
No deviations from the protocol.

No signs of toxicity observed during a preliminary screening test with the chemical at 100% concentration. This was chosen as the highest dose.

RESULTS

Concentration (% w/w)	*Number and sex of animals*	*Proliferative response (DPM/lymph node)*	*Stimulation Index (Test/Control Ratio)*
Test Substance			
0 (vehicle control)	4 F	2754.34	-
25	4 F	8107.32	2.94
50	4 F	7917.86	2.87
100	4 F	6444.62	2.34

Remarks - Results: No signs of toxicity were observed in any of the animals.

Positive control has previously been shown to confirm the validity of the test (Stimulation Index of 5.76).

CONCLUSION: There was no evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the notified chemical.

TEST FACILITY: Harlan (2012c)

B.5. Genotoxicity – bacteria

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 471 Bacterial Reverse Mutation Test
EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria
Plate incorporation procedure

Species/Strain: *Salmonella typhimurium*: TA1535, TA1537, TA98, TA100
Escherichia coli: WP2uvrA$^-$

Metabolic Activation System: S9 fraction from phenobarbitone/β-naphthoflavone induced rat liver.

Concentration Range in Main Test: a) With metabolic activation: 50 - 5,000 µg/plate
b) Without metabolic activation: 50 - 5,000 µg/plate

Vehicle: Acetone

Remarks - Method: GLP compliant.
No deviations from the protocol.
Preliminary assay established the dose range chosen in the two experiments.
Positive controls: without metabolic activation – N-ethyl-N'-nitro-N-nitrosoguanidine (TA100, TA1535, WP2uvrA$^-$), 9-aminoacridine (TA1537), 4-nitroquinoline-1-oxide (TA98); with metabolic activation – 2-aminoanthracene (TA100, TA1535, TA1537, WP2uvrA$^-$), benzo(a)pyrene (TA98) .

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	> 5,000	> 5,000	≥ 1,500	negative
Test 2		> 5,000	≥ 1,500	negative
Present				
Test 1	> 5,000	> 5,000	≥ 1,500	negative
Test 2		> 5,000	≥ 1,500	negative

Remarks - Results: No visible reduction in the background bacterial lawn was observed at any concentration level, in the absence or presence of metabolic activation.

Clear, oily precipitate was observed at ≥ 1,500 µg/plate. However, this did not interfere with the scoring of revertant colonies.

No significant dose related increase in the number of revertants, in the presence or absence of metabolic activation was observed.

Positive and negative controls performed as expected.

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

TEST FACILITY SafePharm (2004b)

B.6. Genotoxicity – *in vitro* Mammalian Cell Gene Mutation Test

TEST SUBSTANCE Notified chemical

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

Species/Strain	Mouse
Cell Type/Cell Line	Lymphocyte
Metabolic Activation System	S9 fraction from phenobarbital/β-naphthoflavone induced rat liver.
Vehicle	Dimethyl sulfoxide.
Remarks - Method	GLP compliant. No deviations from the protocol.

Preliminary assay established the dose range chosen in the two experiments. Greasy oily precipitate observed at ≥ 78.13 µg/mL. Precipitate limited exposure of the test substance to the cells, which limited the maximum dose that could be tested.

Positive controls: without metabolic activation – ethylmethanesulphonate; with metabolic activation – cyclophosphamide.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	0, 9.77, 19.53, 39.06, 78.13, 156.25, 312.5, 625, 1250	4 h	24 h
Test 2	0, 9.77, 19.53, 39.06, 78.13, 156.25, 312.5, 625, 1250	24 h	24 h
Present			
Test 1	0, 9.77, 19.53, 39.06, 78.13, 156.25, 312.5, 625, 1250	4 h	24 h
Test 2	0, 9.77, 19.53, 39.06, 78.13, 156.25, 312.5, 625, 1250	4 h	24 h

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	≥ 1,250	> 1,250	≥ 78.13	none
Test 2		> 1,250	≥ 78.13	none
Present				
Test 1	≥ 1,250	> 1,250	≥ 156.25	none
Test 2		> 1,250	≥ 78.13	none

Remarks - Results No statistically significant or biologically relevant increase in mutation frequency was observed in the presence or absence of metabolic activation.

Positive and negative controls performed as expected

CONCLUSION The notified chemical was not clastogenic to mouse lymphocytes treated *in vitro* under the conditions of the test.

TEST FACILITY Harlan (2013a)

B.7. Genotoxicity – *in vitro* Mammalian Chromosome Aberration Test

TEST SUBSTANCE Notified chemical

METHOD OECD TG 473 *In vitro* Mammalian Chromosome Aberration Test
EC Directive 2000/32/EC B.10 Mutagenicity - *In vitro* Mammalian Chromosome Aberration Test

Species/Strain	Human
Cell Type/Cell Line	Lymphocyte
Metabolic Activation System	S9 fraction from phenobarbital/β-naphthoflavone induced rat liver.
Vehicle	Dimethyl sulfoxide.
Remarks - Method	GLP compliant. No deviations from the protocol. Preliminary assay established the dose range chosen in the two experiments. Maximum dose was based on observations of oily precipitate observed at 5,000 µg/mL, and slight toxicity at 2,500 µg/mL. Positive controls: without metabolic activation – mitomycin C; with metabolic activation – cyclophosphamide.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	0*, 78.13, 156.25, 312.5, 625*, 1,250*, 2,500*	4 h	24 h
Test 2	0*, 78.13, 156.25, 312.5*, 625*, 1,250*, 2,500*	24 h	24 h
Present			
Test 1	0*, 78.13, 156.25, 312.5, 625*, 1,250*, 2,500*	4 h	24 h
Test 2	0*, 78.13, 156.25, 312.5*, 625*, 1,250*, 2,500*	4 h	24 h

*Cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	≥ 5,000	> 2,500	> 2,500	none
Test 2		> 2,500	> 2,500	none
Present				
Test 1	≥ 5,000	> 2,500	> 2,500	none
Test 2		> 2,500	> 2,500	none

Remarks - Results Slightly toxic at precipitating dose level.

No statistically significant or biologically relevant increase in the number of cells with chromosome aberrations was observed in the presence or absence of metabolic activation.

Positive and negative controls performed as expected.

CONCLUSION The notified chemical was not clastogenic to human lymphocytes treated *in vitro* under the conditions of the test.

TEST FACILITY	SafePharm (2004c)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 301 B Ready Biodegradability: CO_2 Evolution Test
Inoculum	Activated sludge from a domestic sewage treatment plant
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	CO_2 was analysed by Tekmar-Dohrmann Apollo 900 TOC analyser and Ionics 155B TOC analyser
Remarks - Method	No significant deviations from the test guidelines were reported. The test substance was directly added to the test medium. A toxicity control was run.

RESULTS

Test substance		*Sodium benzoate*	
Day	*% Degradation*	*Day*	*% Degradation*
6	5	6	66
14	12	14	72
22	20	22	72
28	17	28	76

Remarks - Results	All validity criteria for the test were satisfied. The percentage degradation of the reference compound, sodium benzoate surpassed the threshold level of 60% within 14 days indicating the suitability of the inoculums. The toxicity control exceeded 25% biodegradation after 14 days showing that toxicity was not a factor inhibiting the biodegradability of the test substance. The degree of degradation of the test substance after 28 days was 17%.
CONCLUSION	The test substance is not readily biodegradable
TEST FACILITY	SafePharm Laboratories (2004d)

C.2. Ecotoxicological Investigations

C.2.1. Chronic toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 211 Daphnia sp. Reproduction test – Semi static
Species	*Daphnia magna*
Exposure Period	21 days
Auxiliary Solvent	None
Water Hardness	220-388 mg $CaCO_3$/L
Analytical Monitoring	High Performance Liquid Chromatography with Mass Spectrometry (HPLC-MS)
Remarks - Method	No significant deviations from the test guidelines were reported. Water Accommodated Fraction (WAF) of a 100 mg/L loading rate was prepared by adding the test substance to the test medium, stirring for 23 hours and standing for 1 hour. Then, the supernatant of the suspension was siphoned as the WAF. The test medium was renewed 3 times per week. The concentration of the test substance was measured at Days 0, 9, 19 (fresh media) and 2, 12, 21 (old media).

RESULTS

	Test Concentration (nominal; mg/L)					
	Control	1.0	3.2	10	32	100
Survival (% of control)	100	100	100	100	100	100
Total no. offspring released by survived *Daphnia*	109	115	114	114	106	104

21 day EL50	>100 mg/L
21 day NOEL	100 mg/L
Remarks - Results	All validity criteria for the test were satisfied. The mean number of offspring produced per surviving adult in the control group was 109. The measured test substance concentration in the control vessel was < Limit of Quantitation (LOQ), and in the 100 mg/L nominal concentration vessel was from <LOQ to 0.714 mg/L.
CONCLUSION	The test substance is not harmful to aquatic invertebrates up to its water solubility limit.
TEST FACILITY	Harlan (2013b)

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