File No: STD/1449

September 2013

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

CL 100-B in Safebrake 10M

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the Department of Health and Ageing, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of Sustainability, Environment, Water, Population and Communities.

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

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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/1449	Clariant (Australia) Pty Ltd	CL 100-B in Safebrake 10M	ND*	< 300 tonnes per annum	Ingredient in brake fluid

*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 to the notified chemical:
  - Avoid eye contact

  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 in accordance with local regulations for recycling, re-use or recovery of calorific content.

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, or is likely to change significantly;
- the amount of chemical being introduced has increased from 300 tonnes per annum, or is likely to increase, significantly;
- the chemical has begun to be manufactured in Australia;
- additional information has become available to the person as to an adverse effect of the chemical on occupational health and safety, public health, or the environment.

The Director will then decide whether a reassessment (i.e. a secondary notification and assessment) is required.

No additional secondary notification conditions are stipulated.

(Material) Safety Data Sheet
The (M)SDS of the product containing 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)
Clariant (Australia) Pty Ltd (ABN: 30 069 435 552)
Office Park, Building 5, L2, 530-540 Springvale Road,
GLEN WAVERLEY VIC 3150

NOTIFICATION CATEGORY
Standard (Reduced fee notification): Chemical other than polymer (more than 1 tonne per year) – Similar to a chemical that has been previously assessed by NICNAS

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, use details, import volume, identity of recipients.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: all physio-chemical and toxicological endpoints.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
Canada

European Union

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
CL 100-B in Safebrake 10M

MOLECULAR WEIGHT
< 600 Da

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

3. COMPOSITION

DEGREE OF PURITY
> 80%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Light-yellow, clear liquid

Property	Value	Data Source/Justification
Melting Point/Freezing Point	-55 °C	(M)SDS
Boiling Point	>300°C at 101.3 kPa	(M)SDS
Density	1080 kg/m^3 at 20 °C	(M)SDS
Vapour Pressure	0.12 kPa at 20 °C	(M)SDS
Water Solubility	Not determined	Highly soluble according to the notifier. This is consistent with the predominately hydrophilic chemical structure.
Hydrolysis as a Function of pH	$t_{½} \leq 10$ minutes at pH 4 – 9.	Measured according to OECD TG 111 (ECHA, 1999, EI).
Partition Coefficient (n-octanol/water)	log Pow = -4.37 at 20 °C	MSDS. Low Partition Coefficient is expected based on the predominantly hydrophilic chemical structure.
Adsorption/Desorption	Not determined	Expected not to partition to soil from the water based on the predominantly hydrophilic chemical structure.
Dissociation Constant	Not determined	Does not contain dissociable functional groups.
Flash Point	146 °C at 101.3 kPa	(M)SDS
Flammability	Not determined	Based on the flash point not classified as flammable
Autoignition Temperature	310 °C	(M)SDS
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
Reactivity
Ester groups are expected to hydrolyse in the presence of water.

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 as a component of finished brake fluid preparations at < 95% concentration.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	< 300	< 300	< 300	< 300	< 300

PORT OF ENTRY
Melbourne, Sydney

TRANSPORTATION AND PACKAGING
The finished products containing the notified chemical will be imported in 200 L steel or plastic drums or in 0.25, 0.5, 1.0, 20 or 40 L plastic packs. The 200 L drums will either be used to automatically fill brake fluid reservoirs or will be repackaged into the smaller pack sizes. These smaller packs will be distributed via a major petroleum company or wholesaler to retail outlets. These packs will be distributed within Australia by road.

USE
The notified chemical will be used as a component of finished brake fluid preparations at < 95% concentration.

OPERATION DESCRIPTION
The notified chemical will be imported as a component of finished brake fluids at < 95% concentration. Repackaging of the finished products into smaller containers for the after-care market (vehicle service stations or private individuals) will also take place.

Repackaging
Repackaging from the 200 L drums to smaller containers will be undertaken at one site using dedicated packing lines. This process will be automated and operators will attach and detach suction nozzles that pump the brake fluid directly into the filling line or into header tanks.

End-use
The brake fluids containing the notified chemical at < 95% concentration will be used in car manufacturing to fill brake fluid reservoirs on new cars. This is a one person operation where hoses are connected to a drum and fluid pumped via an automated system.

At vehicle service stations or with private users, brake fluid reservoirs will be refilled manually by pouring from a container. During routine service, brake or clutch repair, fluid in the entire system may be replaced.

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)*
Packaging operators	2-3	< 10
New vehicle production personnel	2-4	< 100
Service station/private users	1	< 50

EXPOSURE DETAILS
There may be some exposure to drips and spills of the notified chemical during repackaging and filling of hydraulic systems on new cars, but these processes occur under well-controlled conditions and the exposure would be expected to be limited by the use of protective equipment including gloves.

The most widespread source of occupational exposure to the notified chemical (at < 95% concentration) will be during servicing of automotive brake systems and other hydraulic parts, both during topping up of hydraulic fluids and during servicing of the lines containing the fluid. The conditions of exposure in automotive service centres will vary, and it is not likely that appropriate personal protective equipment will be used in all (or, indeed, most) cases. There may therefore be widespread and regular dermal exposure of workers to the notified chemical. Secondary ocular exposure, from contact with material on the hands, is also possible; direct ocular exposure may also occur.

6.1.2. Public Exposure

Public exposure to the notified chemical (at < 95% concentration) is expected to be almost completely restricted to persons who maintain their own vehicles. The more common exposure scenario is expected to be dermal contact with drips and spills while topping up hydraulic fluids, but there may be more extensive dermal and ocular exposure during servicing of hydraulic parts. As for occupational exposure during vehicle servicing, the use of personal protective equipment is expected to be variable; however the frequency of exposure is expected to be much lower for members of the public than for automotive service workers.

6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on the notified chemical, or a brake fluid formulation containing the notified chemical (concentration not reported), 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 > 2000 mg/kg bw; low toxicity
Rat, acute dermal toxicity*	LD50 > 2000 mg/kg bw; low toxicity
Rabbit, skin irritation	non-irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation – adjuvant test*	no evidence of sensitisation
Rat, repeat dose oral toxicity – 28 days*	NOAEL = 1000 mg/kg bw/day
Mutagenicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro chromosome aberration*	non genotoxic
Rat, reproductive and developmental toxicity*	NOAEL maternal and foetal = 1000 mg/kg bw/day

* Conducted on a brake fluid formulation containing the notified chemical (concentration not reported)

Toxicokinetics.

The notified chemical has a relatively low molecular weight (< 600 Da), hence there is potential for absorption across biological membranes. However, given the expected high water solubility and low partition coefficient (log Pow = -4.37 at 20 °C), dermal absorption is expected to be limited

Acute toxicity.

The notified chemical was found to be of low acute oral toxicity in a study in the rat. There are no studies on acute dermal toxicity for the notified chemical. However, a brake formulation containing the notified chemical (concentration not reported) was found to be of low acute dermal toxicity (IUCLID, 2000). This is consistent with the expected limited dermal adsorption of the notified chemical based on physico-chemical properties.

Irritation and sensitisation.

The notified chemical was found to be non-irritating to the skin and slightly irritating to the eye in studies conducted in rabbits. Conjunctivae redness was observed in all animals that persisted in two animals for at least 48 hours. A clear discharge was also observed in all three animals that cleared by 24 hours. All signs of irritation had resolved by 72 hours.

There are no sensitisation studies available for the notified chemical. However, a guinea pig maximisation study has been performed on a brake fluid formulation containing the notified chemical (concentration not reported) (IUCLID, 2000). The animals received 0.6% intradermal injections in water followed by application of the test substance one week later. Challenge was conducted using a 60% solution of the test substance. No animals showed a positive response at either 24 or 48 h after removal of the challenge patch. The result is consistent with the absence of structural alerts for sensitisation for the notified chemical.

Repeated Dose Toxicity.

There are no repeated dose toxicity studies for the notified chemical. However, a repeated dose oral toxicity study has been conducted in the rat with a formulated brake fluid containing the notified chemical (concentration

not reported) (IUCLID, 2000). Animals received daily doses of either negative control or test substance at 25, 150, or 1000 mg/kg bw. There were no treatment related deaths or overt signs of toxicity and body weight gains were not affected. There was a statistically significant decrease in food consumption in high-dose males in the first two weeks of the study. Haematology and blood clinical chemistry showed no treatment-related effects. There were no differences in organ weights or macroscopic abnormalities at necropsy. At microscopic examination it was noted that there was very slight hypertrophy of the liver in three females and all males in the high-dose group. Considering the mild nature of the finding, and in the absence of any other relevant treatment related effect, the NOAEL is therefore considered to be 1000 mg/kg bw/day.

Mutagenicity/Genotoxicity.
The notified chemical was non-mutagenic in a bacterial reverse mutation test. There are no additional *in vitro* genotoxicity studies conducted on the notified chemical; however, a chromosomal aberration study has been conducted with a brake fluid formulation containing the notified chemical (concentration not reported) (IUCLID, 2000). Although small effects were seen, these were concluded to not be test substance related due to lack of reproducibility and problems with controls. No data for *in vivo* toxicity was provided.

Toxicity for reproduction.
There are no developmental toxicity studies for the notified chemical. However, a developmental toxicity study has been conducted with a brake fluid formulation containing the notified chemical (concentration not reported) (IUCLID, 2000). The maximum dose tested was 1000 mg/kg bw/day and no test substance related effects were observed in either dams or pups. There were no overt signs of toxicity nor effects on body weights, food intake or pup loss at birth or viability. The maternal and foetal NOAEL was determined to be 1000 mg/kg bw/day.

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 greatest risk posed by the notified chemical is as a slight eye irritant. Workers most at risk of eye irritating effects will be those in automotive service centres when handling products containing the notified chemical at < 95% concentration that do not use PPE during vehicle servicing. However, the potential for accidental ocular exposure should be infrequent.

Based on the low hazardous nature of the notified chemical, the risk to workers is not considered unreasonable.

6.3.2. Public Health
The public may be at risk of slight eye irritating effects while servicing their own vehicles with products containing the notified chemical at up to 95% concentration through accidental ocular exposure. However, given the infrequent use of the products containing the notified chemical by the public and the low severity of eye irritation effects, the risk to the general public 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 be imported into Australia as a component of finished brake fluid products at < 95% in containers of up to 200 L in size. Environmental release of the notified chemical during importation, storage and transportation is not expected except in the event of accidental spills or leaks. Spills or leaks of a drum is expected to be collected with inert material and disposed of to landfill.

The brake products in the 200 L drums may be repackaged in Australia. To contain spills at the repackaging site, bunding is in place in all tank/drum areas, where collection of process spills occurs in onsite collection pits. Spilled material is not expected to be significant and will be either collected by licensed disposal firms or consigned to sewer under licence.

The 200 L drums when emptied will be sent to a drum recycler. The residues in the empty containers are estimated to be up to 100 kg per annum and are expected to be consigned to sewer from the cleaning/recycling process.

RELEASE OF CHEMICAL FROM USE

During end use, release of the notified chemical contained in the brake fluid may occur mainly through leakages from the hydraulic systems in vehicles, accidental spills during brake fluid changes, and during disposal of used fluids following changes. The notifier anticipates that users of the brake fluid formulation will include 70% professional after-care, 20% private after-care, 10% new car manufacturers. The notifier has provided the following estimates of releases for each of the these usage patterns:

(a) Professional after-care

Residues in drums, 30% of (70% of 300 t) with 0.1% residues = 63 kg/annum

Residues in small packaging, 40% of (70% of 300 t) with 0.1% residues = 84 kg/annum

Spills and leaks, <0.1% of (70% of 300 t) = 210 kg/annum

(b) Private after-care

Residues in small packaging, 20% of 300 t with <0.1% residues = 60 kg/annum

Spills and leaks, <0.1% of (20% of 300 t) = 60 kg/annum

(c) New car manufacturers

Residues in drums, 10% of 300 t with 0.1% residues = 30 kg/annum

The combined annual total of waste is approximately 507 kg brake fluid formulation, containing up to 482 kg notified chemical, which may be released to sewer for the worst case scenario. Car manufacturers recommend draining and refilling of brake fluid systems every two years. It is expected that most brake fluid removed from the reservoirs in vehicles at motor garages will be collected and mixed with waste oils, which would be sent for oil recycling for reuse or for further use of the calorific value. Minimal residues will be disposed of to sewer under licence.

RELEASE OF CHEMICAL FROM DISPOSAL

Material spilled during repackaging will be either collected by licensed disposal firms or consigned to sewer under licence, while residues from the cleaning and drum recycling process are consigned to sewer under licence.

Residues of the brake fluid in small empty containers are expected to be discarded to domestic garbage and disposed of to landfill. Used brake fluid remaining after oil changes is likely to be recycled for further reuse or for the use of the calorific value. The MSDS recommends disposal in accordance with government regulations for the disposal of special waste, which may include oil recycling or reuse of the calorific value.

7.1.2. Environmental Fate

The notified chemical is expected to be readily biodegradable. For the details of the environmental fate study on an acceptable analogue please refer to Appendix C. The notified chemical is also expected to hydrolyse rapidly. Since the components of the brake fluid are hygroscopic, it is likely that water would become absorbed during normal usage of the formulations containing the notified chemical, and consequently it is likely that some of the notified chemical will hydrolyse to boric acid and neutral organic chemicals to undergo further biodegradation.

A bioaccumulation study was not provided. The notified chemical is not expected to bioaccumulate given its high water solubility and low predicted log P_{OW}.

Most of the notified chemical is expected to be used as a component in the brake fluid, which may be recycled or reused for the calorific value. The associated notified chemical is expected to be either thermally decomposed during the recycling or to be reused for the calorific value as a component of the reused oil. In either case, the notified chemical is expected to be decomposed into water, oxides of carbon and boron.

A small amount of the notified chemical may also be sent to landfill as residues in empty containers. In landfill, the notified chemical may have potential to leach into public water due to the high water solubility. In water, the notified chemical is expected to hydrolyse rapidly followed with further degradation.

The notified chemical is expected to be released to sewer as residues from container cleaning and recycling, and spills from repackaging. Given the high water solubility, the notified chemical is expected to remain in the effluent water of the sewage treatment plants. In water, the notified chemical is expected to hydrolyse rapidly followed with further degradation.

In public water or landfill, the notified chemical is expected to undergo abiotic and biotic degradation processes, forming water, oxides of carbon and boron.

7.1.3. Predicted Environmental Concentration (PEC)

Up to 482 kg notified chemical may be released to the sewer from residue cleaning and spills, which is not considered to be significant. The notified chemical is expected to dissipate quickly via hydrolysis in water. In addition, the notified chemical is considered to be of low concern to aquatic organisms as shown below. Therefore, the calculation of Predicted Environmental Concentration (PEC) is not considered to be necessary.

7.2. Environmental Effects Assessment

The notifier provided the following endpoints for effects of the notified chemical on aquatic organisms (ECHA, 2013, for fish, daphnids and sludge microbial); IUCLID, 2000, for alga).

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity (96 h)	EC50 > 222.2 mg/L	Not harmful to fish
Daphnia Toxicity (48 h)	EC50 > 500 mg/L	Not harmful to aquatic invertebrates
Algal Toxicity (96 h)	EC50 = 430 mg/L	Not harmful to alga
Inhibition of Bacterial Respiration (30 min)	EC50 > 1000 mg/L	Not expected to be inhibitory to microbial activity

Under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS; United Nations, 2009) the notified chemical is considered not to be acutely harmful to fish, aquatic invertebrate, and algae. Based on the toxicity to aquatic organisms the notified chemical is not formally classified for acute toxicity and long-term hazard.

7.2.1. Predicted No-Effect Concentration

The Predicted No-Effect Concentration (PNEC) has not been calculated given no PEC was calculated and the expected low concern of the chemical to aquatic organisms.

7.3. Environmental Risk Assessment

The Risk Quotient (PEC/PNEC) has not been calculated since no PEC or PNEC was available. The potential for rapid hydrolysis and the ecotoxicity data of the notified chemical indicate that it is unlikely to reach ecotoxicologically significant concentrations in future waters based on its proposed use pattern. The notified chemical is expected to have a low potential for bioaccumulation. Therefore, on the basis of the assessed use pattern in brake fluid products, the notified chemical is not expected to pose an unreasonable risk to the environment.

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE Notified chemical

METHOD OECD TG 401 Acute Oral Toxicity – Limit Test.
Species/Strain Rat/Wistar
Vehicle None
Remarks - Method No significant protocol deviations

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	5M/5F	2000	0/10

LD50 > 2000 mg/kg bw
Signs of Toxicity No signs of toxicity were recorded
Effects in Organs No effects in organs were reported
Remarks - Results The notified chemical did not cause either deaths or symptoms of toxicity.

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

TEST FACILITY Hoechst (1995a)

B.2. Irritation – skin

TEST SUBSTANCE Notified chemical

METHOD OECD TG 404 Acute Dermal Irritation/Corrosion.
EC Directive 2004/73/EC B.4 Acute Toxicity (Skin Irritation).
Species/Strain Rabbit/New Zealand White
Number of Animals 3
Vehicle None
Observation Period 72 hours
Type of Dressing Semi-occlusive.
Remarks - Method No significant protocol deviations

Remarks - Results No signs of irritation were observed during the study.

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

TEST FACILITY Hoechst (1995b)

B.3. Irritation – eye

TEST SUBSTANCE Notified chemical

METHOD OECD TG 405 Acute Eye Irritation/Corrosion.
EC Directive 2004/73/EC B.5 Acute Toxicity (Eye Irritation).
Species/Strain Rabbit/New Zealand White
Number of Animals 3
Observation Period 72 hours
Remarks - Method No significant protocol deviations

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	0.3	1	0.7	2	< 72 h	0
Conjunctiva: chemosis	0	0	0	2	< 24 h	0
Conjunctiva: discharge	0	0	0	2	< 24 h	0
Corneal opacity	0	0	0	0	-	0
Iridial inflammation	0	0	0	0	-	0

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

Remarks - Results: Conjunctivae redness was observed in all animals that persisted in two animals for at least 48 hours. A clear discharge was also observed in all three animals and had cleared by 24 hours. Obvious swelling was observed one hour after application in one animal. All signs of irritation had cleared by 72 hours.

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

TEST FACILITY: Hoeschst (1995c)

B.4. Genotoxicity – bacteria

TEST SUBSTANCE: Notified chemical

METHOD: OECD TG 471 Bacterial Reverse Mutation Test.
Plate incorporation procedure and Pre incubation procedure

Species/Strain: *S. typhimurium*: TA1535, TA1537, TA98, TA100,
E. coli: WP2uvrA

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

Concentration Range in Main Test:
Plate incorporation study:
a) With metabolic activation: 50-5000 µg/plate
b) Without metabolic activation: 50-5000 µg/plate
Pre incubation procedure:
a) With metabolic activation: 230-5000 µg/plate
b) Without metabolic activation: 230-5000 µg/plate

Vehicle: Distilled water

Remarks - Method: The negative control was distilled water and positive controls were ICR 191, 4-nitro-o-phenylen-diamine, nitrofurantoine, sodium azide and 4-nitroquinoline-1-oxide 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 Main Test	*Precipitation*	*Genotoxic Effect*
Absent			
Test 1 (Plate incorporation)	> 5000	> 5000	Negative
Test 2 (Pre incubation)	> 5000	> 5000	Negative
Present			
Test 1 (Plate incorporation)	> 5000	> 5000	Negative
Test 2 (Pre incubation)	> 5000	> 5000	Negative

Remarks - Results: The test substance was tested up to the maximum recommended dose level of 5000 µg/plate. 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 notified chemical was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	Dr. U. Noack-Laboratorien (2007)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	Analogue
METHOD	OECD TG 301 E Ready Biodegradability: Modified OECD Screening Test.
Inoculum	Aqueous phase of non-adapted activated sludge
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	Dissolved Organic Carbon (DOC)
Remarks - Method	Duplicate samples containing concentrations of 60 mg/L of the test substance, corresponding to a TOC content of 0.475 mg C/mg test item and a carbon content of 28.5 mg C/L, were tested for ready biodegradability. Sodium acetate in a concentration of 130 mg/L was used as the functional control to check the activity of the test system. A test vessel containing both the test substance and the reference substances was used as a toxicity control. The amount of biodegradation of the test item over time was determined by measurement of DOC at regular intervals over the exposure period.

RESULTS

Test substance		*Sodium acetate*	
Day	*% Degradation*	*Day*	*% Degradation*
7	9	3	>10
17	>70	7	91
28	96	14	92

Remarks - Results	After 8 days, 10% of the test item was degraded. In the 10-d-window, beginning at day 7, 70% of the test item was degraded, while at day 28, 96% of the test item was degraded. The test substance attained a pass level (> 70%) of biodegradation after 17 days. The functional control attained 70% biodegradation after 3 days. In the toxicity control, biodegradation reached 64% after 14 days, indicating the test item had no inhibitory effect during the test. The validity criteria of the test were fulfilled according to the guideline.
CONCLUSION	The test substance is readily biodegradable.
TEST FACILITY	Dr. U. Noack Laboratorien (2000)

BIBLIOGRAPHY

Dr. U. Noack Laboratorien (2000) Analogue, Ready Biodegradability in the Modified OECD Screening Test (Study No. ASC71181; July, 2000). Sarstedt, Germany, Dr. U. Noack-Laboratorium für angewandte Biologie (Unpublished report submitted by the notifier).

Dr. U. Noack Laboratorien (2007) [Notified chemical] Bacterial reverse mutation test (Ames test) with *Salmonella typhimurium* and *Escherichia coli*. Sarstedt, Germany, Dr. U. Noack-Laboratorium für angewandte Biologie (Unpublished report submitted by the notifier).

ECHA (2013) Exempt Information

Hoechst (1995a) [Notified chemical] Test for acute oral toxicity in the male and female Wistar rat (Study no. 95.0103, March, 1995). Frankfurt, Hoechst Aktiengesellschaft (Unpublished report submitted by the notifier).

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Hoechst (1995c) [Notified chemical] Test for the primary eye irritation in the rabbit (Study no. 95.0105, April, 1995). Frankfurt, Hoechst Aktiengesellschaft (Unpublished report submitted by the notifier).

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