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May 2009

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Amines, bis (C11-14 branched and linear alkyl)

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

For the purposes of subsection 78(1) of the Act, this Full Public Report may be inspected at our NICNAS office by appointment only at 334-336 Illawarra Road, Marrickville NSW 2204.

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

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Director
NICNAS

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Amines, bis (C11-14 branched and linear alkyl)

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
BASF Australia Ltd (ABN 62 008 437 867)
500 Princes Highway, Noble Park, VIC 3174

and

The Shell Company of Australia (ABN 46 004 610 459)
8 Redfern Road, Hawthorn East VIC 3123

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:
Other Name, Impurities, Additives/Adjuvants and Use Details

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, Absorption/Desorption, Dissociation Constant, Explosive properties

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

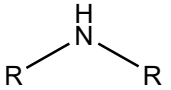
MARKETING NAME(S)
Ditridecylamine

CAS NUMBER
900169-60-0

CHEMICAL NAME
Amines, bis(C_{11-14}-branched and linear alkyl)

MOLECULAR FORMULA
(branched and linear $C_{11}H_{23} – C_{14}H_{29})_2NH$

STRUCTURAL FORMULA



R = branched and linear $C_{11}H_{23}$ - $C_{14}H_{29}$

MOLECULAR WEIGHT
< 500

ANALYTICAL DATA
Reference NMR, and GC/MS spectra were provided.

3. COMPOSITION

DEGREE OF PURITY > 90%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: Colourless to yellow liquid with an amine-like odour

Property	Value	Data Source/Justification
Melting Point	< -45°C	MSDS
Boiling Point	220-240°C at 0.1 kPa	MSDS
Density	836 kg/m^3 at 20°C	MSDS
Vapour Pressure	< 0.01 kPa at 50°C	MSDS
Water Solubility	0.1 g/L at 20°C	MSDS
Hydrolysis as a Function of pH	Not determined	No hydrolysable functionality present.
Partition Coefficient (n-octanol/water)	Log P_{OW} = 11.47	MSDS (calculated).
Adsorption/Desorption	Not determined	Expected to have a high affinity to organic carbon in soil and sludge based on the calculated log P_{OW}.
Dissociation Constant	Not determined	The notified chemical is a typical base that is expected to be protonated throughout the environmental pH range of 4 – 9.
Particle Size	Not determined	Liquid
Viscosity	32 mPa.s at 20°C	MSDS
Flash Point	138°C (pressure unknown)	MSDS (method DIN 51578)
Flammability	Upper: 3.5% Lower: 0.7%	MSDS
Autoignition Temperature	250°C	MSDS (method DIN 51794)
Explosive Properties	Not determined	Not expected to be explosive based on structure.

DISCUSSION OF PROPERTIES
Reactivity
Strong exothermic reaction with acids.

Dangerous Goods classification
Based on the available data the notified chemical is classified as follows according to the Australian Dangerous Goods Code (FORS, 1998):

Class 8 (Corrosive)

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will be introduced into Australia in two forms:

a) Imported as 100% notified chemical for formulation in Australia into lubricants (machine oils).
b) Imported as part of finished formulated machine oils containing the notified chemical at < 1%.

MAXIMUM INTRODUCTION VOLUME OF NOTIFIED CHEMICAL OVER NEXT 5 YEARS

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

PORT OF ENTRY
Sydney and Melbourne

IDENTITY OF RECIPIENTS
The Shell Company of Australia

TRANSPORTATION AND PACKAGING
The notified chemical and formulated machine oils will be imported into Australia in either 20L or 200L drums. After formulation process in Australia, the formulated machine oils are packaged in 18.9 L or 208 L pails for distribution to end users.

USE
Additive for lubricants.

OPERATION DESCRIPTION
The notified chemical will be transferred to the Shell formulation facility where it will be blended with base mineral oil and other additives in order to manufacture formulated machine oils. This will require plant operators to weigh, manufacture and pack the product in an industrial liquid blending facility.

The 20L or 200L drums of the notified chemical or the formulated product will be transferred to the respective warehouses. The formulated machine oils will be distributed to end users and will not require any further processing.

Formulated machine oils (containing < 1% of the notified chemical) will be used in industrial applications as a primary lubricant in metal working and machine tooling operations to prevent sticking and slippage in slide and table machine operations. Formulated machine oils are not sold to the consumer market. The formulated machine oils are used without dilution.

6. HUMAN HEALTH IMPLICATIONS

6.1 Exposure assessment

6.1.1 Occupational exposure

NUMBER AND CATEGORY OF WORKERS

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Transport and Warehouse	4-5	2-3 hours/day	25 days/year
Process Operator-Formulation	1-2	2-3 hours/day	25 days/year
Quality Control	1	1-2 hours/day	4-5 days/year
Packaging	1	2-3 hours/day	25 days/year
End Use	25-50	2-4 hours/day	250 days/year
Drum Recyclers	1	0.5 hours/day	48 days/year

EXPOSURE DETAILS
Transport and Warehouse
During transport and storage of both the notified chemical and formulated machine oils, workers are unlikely to be exposed to the notified chemical except when the packaging is accidentally breached. Should a spill occur, it is expected to be contained and collected using absorbent materials by workers using applicable personal protective equipment (PPE). The collected spill should be placed into suitable containers for recovery or disposal in accordance with the material safety data sheets (MSDS) and official state regulations.

Formulation – Weighing/Compounding and Filling/Packaging
While the blending of lubricants are done in an automated process in an enclosed "closed-loop" system, there is some potential for exposure of workers involved in blending operations using the notified chemical. However, typical blending facilities are designed to minimise exposures to employees and are generally well ventilated using cross-ventilation fans and exhaust fans.

Occupational exposure is possible in the event of a spill during weighing or formulation. Skin contact is possible by accidental contact with drips. Eye contact with the notified chemical may occur from leaks or splashes. Inhalation of the notified chemical is possible if any mists/aerosols/odours result from the handling process, particularly during weighing and compounding with the pure notified chemical.

Operators of the plants will wear goggles, chemically resistant gloves, boots, aprons or other protective clothing, and appropriate respirators as required.

Quality Control
Analysis of samples of formulated machine oils will occur in a controlled laboratory testing facility. Dermal and ocular exposure to the notified chemical is possible if there are splashes or spills during the analysis process. Laboratory workers will wear laboratory coats, safety goggles and nitrile gloves when analysing the sample.

End Use
Dermal or ocular exposure to the lubricants containing the notified chemical at < 1% may occur during machining processes, either through contact with lubricant on the machinery, or through accidental splashes as the formulated machine oils may be applied through an automated lubrication delivery system, or they may be applied manually by maintenance personnel. Respiratory exposure is also possible if vapour or aerosols are formed. Ventilation systems and exposure controls may be employed to minimise respiratory exposure.

D*rum Recyclers*
Worker exposure to small quantities from empty drums of the notified chemical and formulated machine oils may occur for short periods. Workers are expected to wear PPE during this process.

6.1.2. Public exposure
Public exposure to the notified chemical or the formulated machine oils containing the notified chemical at < 1% as a result of transportation within Australia is unlikely unless there is an accident during transport. The MSDS outlines proper instructions for clean-up and disposal of any accidental spills and therefore public exposure as a result of a transport accident is likely to be very low.

The lubricants containing the notified chemical will not be sold to the general public as a consumer product. Overall the public exposure to the notified chemical is expected to be very low.

6.2. Human health effects assessment

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

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	oral LD50 = 2700 mg/kg bw, low toxicity
Mice, acute intraperitoneal	intraperitoneal LD50 = 10 mg/kg bw, very toxic
Rat, acute inhalation toxicity	saturated vapour at 20^{o}C caused no mortality (dose not stated)
Rabbit, skin irritation (2 studies)	corrosive
Rabbit, eye irritation	corrosive
Mutagenicity – bacterial reverse mutation	non mutagenic

Acute toxicity
The notified chemical was of low acute toxicity *via* the oral route in a study carried out by an in-house method, however it was not clear whether the LD50 obtained was based on the notified chemical itself. It was very toxic via intraperitoneal administration. However, this exposure routine is not applicable to workers or public. Exposure to a saturated vapour of the notified chemical at room temperature caused no mortality. Signs of toxicity observed in the animals in these studies are likely to be related to the corrosive properties of the

chemical.

Irritation
The notified chemical was corrosive to rabbit skin and eyes in the studies provided, which were not to OECD guidelines. These observations are consistent with the structure of the chemical. (Hulzebos, et al. 2005).

Mutagenicity
The notified chemical tested was not mutagenic in a bacterial reverse mutation study performed to OECD guidelines.

Carcinogenicity
Together with nitrosating agents such as nitrites or nitrogen oxides, it is possible that carcinogenic nitrosamines could form in chemicals of this type, or products containing them (Ullmanns 2009). No information was supplied on possible occurrence of these impurities.

Health hazard classification
Based on the data provided the notified chemical is classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004) with the following risk phase:
R35 Causes severe burns

6.3. Human health risk characterisation

6.3.1. Occupational health and safety
Limited data were provided on the toxicological characteristics of the notified chemical. The notified chemical is corrosive as introduced. Lower concentrations such as those used in end-use products (<1%) are below the concentration cut-off for classification as a hazardous substance. The notified chemical may form carcinogenic nitrosamine impurities under certain conditions.

Worker exposure to the notified chemical at > 90% as introduced may occur during formulation. At this concentration it is corrosive. Dermal and ocular exposure to the pure notified chemical could occur during weighing/compounding operations and quality control analysis. Inhalation exposure could occur if aerosols were formed or significant quantities of the chemical were vapourised. However the formulation plant is largely automated, and is fitted with ventilation systems, reducing the potential exposure by all routes. Workers are also expected to wear PPE and have access to emergency showers. With these controls in place, exposure is low and the risk to workers is considered acceptable.

During end-use, worker dermal and ocular exposure to the notified chemical in formulated machine oils can occur to varying extents depending on the scenarios of use and the controls at the site of use. If oil mists, aerosols or vapours are formed, inhalation exposure could also occur, and this could result in some ingestion of the chemical. Exposure during end-use would be reduced by the low concentration in the products (< 1%). At these concentrations the chemical would not be corrosive or cause irritation. The risk would be reduced through workplace controls that reduce exposure, such as engineering controls, safe work practices, and PPE,

Data were not provided on the possible formation of carcinogenic nitrosamine impurities in the notified chemical or the lubricants containing the notified chemical. Based on experience with cutting fluids, these may occur in used oil. It is noted that nitrosamines can also be formed in the stomach if oil mist containing the notified chemical was inhaled and then ingested (Ullmanns 2009). The risk to workers using machine oils containing the notified chemical would be reduced by measures that prevent their formation or reduce worker exposure.

Transport and storage workers should not come in contact with the notified chemical except in the event of an accident involving rupture of drums, and the risk to this group of workers is considered low.

Overall, the risk to workers is considered to be acceptable if appropriate engineering controls, safe work practices, use of PPE, and communication of the hazards to workers through MSDS are in place. Measures to avoid formation of nitrosamines would further reduce the risk.

6.3.2. Public health

As the public is not exposed to the pure notified chemical as imported or the formulated machine oils containing the notified chemical at < 1% except for following accidental exposure from a spill, the risk to public health posed is considered to be very low.

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 either as part of finished formulated machine oils containing the notified chemical or as the notified chemical for formulation in Australia into lubricants (machine oils).

In the formulation process, blending of the formulated machine oils is done in an automated process in an enclosed "closed-loop" system. All spills or releases are quickly contained with absorbent materials, sand or earth to prevent spreading into nearby drains, ditches or waterways. Any absorbent material, sand or earth that has been used to contain a spill or release is then removed and placed in a clearly marked container for proper disposal within 24 hours of release in accordance with local or national regulations, which will most likely be sent to landfill. The total volume of all spills and releases at are expected to be less than 100 kg per annum.

RELEASE OF CHEMICAL FROM USE

Given the use pattern of the notified chemical in all commercial/industrial machine tool operations, the most likely release will be from unforseen accidental spills during the transfer of the formulated machine oils from the drum to the holding tank of the cutting machine. Since this is a closed loop operation, the potential release to the environment is very low. Any release resulting from a spill will be collected and disposed of in accordance with local environmental legislation.

RELEASE OF CHEMICAL FROM DISPOSAL

The machine oil containing the notified chemical will be used in workshops. Used oil will be likely be collected by professional operators, recycled or thermally decomposed for recovery of the calorific values.

7.1.2 Environmental fate

The notified chemical is not readily biodegradable according to the study result. For the details of the environmental fate studies please refer to Appendix C.

The chemical may have potential to bioaccumulate in aquatic organisms based on its properties of moderately water solubility (100 mg/L), low molecular weight (< 500) and high log P_{OW} (11.47). However, this is not a concern considering its low import volume and limited release to the aquatic environment.

The notified chemical will be either thermally decomposed to recover its calorific value or sent to landfill. In landfill, the notified chemical is not expected to leach due to the high log P_{OW}, and will undergo slow degradation processes via biotic and abiotic pathways. In either way, the notified chemical will finally be decomposed into small molecules of water and oxides of carbon and nitrogen.

7.1.3 Predicted Environmental Concentration (PEC)

The calculation of PEC is not necessary given the low import volume and the limited release of the notified chemical to the aqueous environment.

7.2. Environmental effects assessment

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

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity	LC50 = 10 – 21.5 mg/L	Harmful to fish

The notified chemical is considered harmful to aquatic life based on the ecotoxicity study for fish. In addition, the notified chemical contains secondary amine groups which are known to protonate in the aquatic environment where they are toxic to algae and aquatic invertebrates (Boethling and Nabholz, 1997).

7.2.1 Predicted No-Effect Concentration

The PNEC has not been calculated given the low imported volume and limited release of the notified chemical to the aquatic environment.

7.3. Environmental risk assessment

The calculation of the risk quotient (PEC/PNEC) has not been conducted since neither PEC nor PNEC has been calculated.

Given the low release of the notified chemical to the aquatic compartment, the risk posed by the notified chemical to the aquatic environment is expected to be acceptable.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

Based on the data provided the notified chemical is classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)] with the following risk phase:

R35 Causes severe burns

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

	Hazard category	***Hazard statement***
Skin irritation/corrosion	1a	Causes severe skin burns and eye damage
Environment	Acute Category 3 Chronic Category 3	Harmful to aquatic life with long lasting effects

Human health risk assessment

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

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

Environmental risk assessment

On the basis of the reported use pattern, the notified chemical is not considered to pose a risk to the environment.

Recommendations

REGULATORY CONTROLS

Hazard Classification and Labelling

- Safe Work Australia should consider the following health hazard classification for the notified chemical:
  - R35 Causes severe burns

- Use the following risk phrases for products/mixtures containing the notified chemical:
  - ≥10%: R35

- ≥ 5%: < 10%: R34
- ≥ 1%: < 5%: R36, R 38

- The following safety phases are recommended for workers:
  - S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
  - S36/37/39 Wear suitable protective clothing, gloves and eye/face protection.

- The notified chemical should be classified as follows under the ADG Code:
  - Class 8 (Corrosive)

Material Safety Data Sheet

- The MSDS for the notified chemical and products containing it should contain the following information or similar:
  - It is possible that carcinogenic nitrosamines could form under certain conditions in the presence of nitrosating agents such as nitrites or nitrogen oxides.

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following engineering controls
  to minimise occupational exposure to the notified chemical as introduced:
  - Automated chemical transfer apparatus and enclosed system for formulation.
  - Exhaust ventilation during formulation.

  to minimise occupational exposure to the notified chemical in the products:
  - Exhaust ventilation during end use if aerosols or mists are generated.

- Employers should implement the following safe work practices
  to minimise occupational exposure during handling of the notified chemical as introduced:
  - Procedures designed to minimise spillage during transfer operations together with adequate clean up and disposal.
  - Mandatory use of personal protective equipment.
  - Access to emergency showers and washing facilities.

  to minimise occupational exposure during handling of the notified chemical in the products:
  - Avoid contact with the lubricants.
  - Use of personal protective equipment.
  - Minimise spillage during end use.

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical as introduced and in the products:
  - Gloves, goggles or faceshield and chemical resistant clothing
  - Respiratory protection if aerosls or mists are generated

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

- A copy of the MSDS should be easily accessible to employees.

- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)] workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Control of impurities

- Preventive measures should be taken by the importer of the notified chemical, formulators and end users of lubricants to ensure control of any nitrosamine contamination and other hazardous impurities. Such measures would include where appropriate:
  - Monitoring of levels of impurities including nitrosamines in the imported chemical and lubricants. Monitoring should cover any changes during storage.
  - Avoidance of nitrosating agents in formulation and handling
  - Use of suitable inhibitors
  - Packaging in nitrite-free containers.

Environment

- Do not allow material or contaminated packaging to enter drains, sewers, or water courses.

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 additive for lubricants, or is likely to change 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 MSDS of the notified chemical and products containing the notified chemical provided by the notifier were reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.

APPENDIX A: TOXICOLOGICAL INVESTIGATIONS

A.1. Acute toxicity – oral

TEST SUBSTANCE	Notified chemical (only translated summary was provide)
METHOD	Not stated
Species	Rat
Vehicle	Emulsion with tragacanth gum
Comments	The chemical was administered as a 0.1-30% emulsion, and it is not clear whether the dosage was adjusted for concentration.
RESULTS	
LD50	2700 mg/kg bw (the doses tested were not provided)
Signs of Toxicity	Dyspnea, apathy and diarrhoea
Effects in Organs	Necropsy findings: sporadically, considerable injection of the gastric vessels
Remarks - Results	The study summary did not mention whether there was any morality but estimated the LD50 to be 2700 mg/kg bw.
CONCLUSION	The notified chemical is of low toxicity via the oral route.
TEST FACILITY	BASF (2006a) (study was carried out in 1970)

A.2 Acute toxicity – intraperitoneal

TEST SUBSTANCE	Notified chemical (only translated summary was provide)
METHOD	Not stated
Species	Mice
Vehicle	Emulsion with tragacanth gum
RESULTS	
LD50	10 mg/kg bw
Signs of Toxicity	Dyspnea, staggering, atony, apathy and slight twitching
Effects in Organs	Necropsy findings: sporadically, adhesions in the upper abdomen
CONCLUSION	The notified chemical is very toxic via the intraperitoneal route.
TEST FACILITY	BASF (2006b) (study was carried out in 1970)

A.3 Acute toxicity – inhalation

TEST SUBSTANCE	Notified chemical (saturated vapour at 20^{o}C) (only translated summary was provide)
METHOD	Not stated
Species/Strain	Rat
Remarks - Method	Twelve animals were exposed through inhalation to an atmosphere saturated with vapour at 20^{o}C (the doses tested were not provided). For saturation, air was conducted through a layer of about 5 cm of the product.
RESULTS	No deaths were recorded after an 8-hour exposure.
Signs of Toxicity	Moderate irritation to the mucosa.

Effects in Organs	Necropsy findings: no abnormalities were detected.
CONCLUSION	The notified chemical caused no moralities under the conditions of the test.
TEST FACILITY	BASF (2006c) (study was carried out in 1970)

A.4 Irritation – skin

TEST SUBSTANCE	Notified chemical (95%)
METHOD	The notified chemical was applied to the skin of the rabbit's back and ear for 1, 5 and 15 minutes, and 20 h.
Species/Strain	Rabbit/white Vienna
Number of Animals	5 M, 3F
Vehicle	None
Observation Period	8 days
Remarks - Method	After the short-term application (time test: 1, 5 and 15 minutes), the treated skin areas were washed first with undiluted PEG and subsequently with a 50% aqueous solution of PEG. After the 20-hour exposure, however, the test substance was not washed from the skin. The findings were recorded after 24 hours and after 8 days. Further comparative studies were carried out to evaluate the effect on irritation of washing with polyethylene glycol after the exposure period.

RESULTS

The acute skin irritation of the notified chemical
a) Local Irritation

Application site/exposure period	No. of animals	Findings after	
		24 hours	8 days
Dorsal Skin: 1 minute*	2	ER+++ extending far beyond the area of exposure; ED++	Parchment-like N+ extending far beyond the area of exposure; surroundings: ER++; ED++
5 minutes*	2	ER+++ extending far beyond the area of exposure; ED++	Parchment-like N+ extending far beyond the area of exposure; surroundings: ER++; ED++
15 minutes*	2	ER+++ extending far beyond the area of exposure; ED++	Parchment-like N+ extending far beyond the area of exposure; surroundings: ER++; ED++
20 hours	2	ER+++ extending far beyond the area of exposure; ED++	Parchment-like N+ extending far beyond the area of exposure; margin: ER++; ED++
Ear: 20 hours	2	ER++; brownish; ED++	Throughout in some cases'; anaemic in some cases; N++; ED++

*Washed with concentrated PEG and 50% in distilled water after application.
ER = erythema; ED = oedema; N = necrosis
+ = slight; ++ severe; +++ = very severe
b) No other signs of systemic toxicity were reported.

Remarks - Results	The same findings in qualitative terms were obtained after all four exposure periods on dorsal skin and also after the 20-hour exposure to the skin of the internal auricle: Severe to very severe erythema and oedema initially showed a severe inflammatory reaction which led to the formation of tissue defects (necroses) in the course of 8 days.

The intensity of the inflammatory reaction was not reduced noticeably by washing with PEG after 1-, 5- and 15-minute exposure periods.
No further detail was supplied on the anaemia noted at the 8-day observation.

CONCLUSION The notified chemical is corrosive to the skin.

TEST FACILITY BASF (2006d) (study was carried out in 1977)

A.5. Irritation – skin

TEST SUBSTANCE Notified chemical (100%) (only translated summary was provide)

METHOD Not stated
Species Rabbit
Vehicle None
Observation Period 8 days

RESULTS

	Time of exposure	Findings after 24 hours	Findings after 8 days
Dorsal skin	1 minute	ER+++ extending beyond the area of exposure/ED+	ER++/ED++/S+++ parchment-like
	5 minutes	ER+++ extending beyond the area of exposure/ED+	ER++/ED++/S+++ parchment-like
	15 minutes	ER+++ extending beyond the area of exposure/ED+	ER++/ED++/S+++ parchment-like
	20 hours	N++/margin: ER+++/ED++	N++/margin: ER+++/ED++
Ear	20 hours	N+++	Mummification

ER = erythema; ED = oedema; N = necrosis; S = scaling;
∅ = non-irritating; (+) = slight; + = distinct; ++ = severe; +++ = very severe

CONCLUSION The notified chemical is corrosive to the skin.

TEST FACILITY BASF (2006e) (study was carried out in 1970)

A.6 Irritation – eye

TEST SUBSTANCE Notified chemical (100%) (only translated summary was provide)

METHOD Application to the conjunctival sac of the eyelid
Species Rabbit
Observation Period 8 days

RESULTS

	Findings after 1 hour	Findings after 24 hours	Findings after 8 days
	R+/ED++/OP+	R++/ED+++/OP++/haemorrhage/suppuration	R++/ED+++/OP++/haemorrhage/staphyloma/suppuration
Compared with NaCl	∅	∅	∅

R = redness; ED = oedema; OP = opacity
∅ = non-irritating; (+) = slight; + = distinct; ++ = severe; +++ = very severe

CONCLUSION	The notified chemical is corrosive to the eye.
TEST FACILITY	BASF (2006f) (study was carried out in 1970)

A.7. 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 (Standard Plate Test, SPT) – Tests 1 and 2 Pre incubation procedure (Pre incubation Test, PIT) – Test 3
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100 *E. coli*: WP2uvrA
Metabolic Activation System	Aroclor-induced rat liver S-9 mix
Concentration Range in Main Test	1) With and without metabolic activation: 0, 20, 100, 500, 2500 and 5000 µg/plate (all strains) (SPT) 2) With and without metabolic activation: 0, 3, 6, 12, 25 and 50 µg/plate (*S. typhimurium* strains) (SPT) 3a) With and without metabolic activation: 0, 3, 6, 12, 25 and 50 µg/plate (*S. typhimurium* strains) (PIT) 3b) With and without metabolic activation: 0, 4, 20, 100, 500 and 2500 µg/plate (*E. coli* strain) (PIT)
Vehicle	Acetone
Remarks - Method	No preliminary testing was carried out.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:* *Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent			
Test 1 (*S. typhimurium* strains)	≥ 100	≥ 2500	negative
Test 1 (*E. coli* strain)	≥ 2500	≥ 2500	negative
Test 2	> 50	> 50	negative
Test 3a	≥ 6	> 50	negative
Test 3b	≥ 100	≥ 2500	negative
Present			
Test 1 (*S. typhimurium* strains)	≥ 100	≥ 2500	negative
Test 1 (*E. coli* strain)	≥ 2500	≥ 2500	negative
Test 2	> 50	> 50	negative
Test 3a	≥ 12	> 50	negative
Test 3b	≥ 100	≥ 2500	negative

Remarks - Results	A bacteriotoxic effect (reduced background growth, decrease in the number of revertants, reduction in the titer) was observed in the standard plate test and pre incubation test.
CONCLUSION	The notified chemical was not mutagenic to bacteria under the conditions of the test.

TEST FACILITY BASF (1999)

APPENDIX B: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

B.1 Environmental Fate

B.1.1 Ready biodegradability

TEST SUBSTANCE	Notified Chemical
METHOD	Not reported
Inoculum	Laboratory plant; municipal wastewater (Oppau)
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	Biochemical oxygen demand (BOD) tested for the determination of biodegradability
Remarks - Method	The test was conducted at concentrations of 50 (duplicate), 100 (triplicate) and 200 (duplicate) mg/L. Aniline was used as the reference substance. A blank control tests (duplicate), a control test containing aniline only (100 mg/L) and a toxicity control test containing both aniline and the notified chemical (100 mg/L for each) were also carried out.

RESULTS

Test substance		*Aniline*	
Day	*% Degradation*	*Day*	*% Degradation*
7	0	7	63.8
28	0	28	83.1

* Degree of biodegradation based on BOD values (reference chemical oxygen demand (COD)).

Remarks - Results	The biodegradation of the reference substance aniline reached 63.8% after 7 days. The average degree of biodegradation for all the test vessels for the notified chemical was -3.4% and is deemed as 0%.
CONCLUSION	The notified chemical is not considered to be readily biodegradable based on the test results.
TEST FACILITY	BASF (2006g)

B.2. Ecotoxicological Investigations

B.2.1 Acute toxicity to fish

TEST SUBSTANCE	Notified chemical
METHOD	The Guideline of Din 38 412 “Testverfahren Mit Wasserorganismen (Gruppie L). Allgemeine Hinweise Zur Planung, Durchfuehrung Und Auswertung Biologischer Test – Verfahren (L1)” Und “Bestimmung Der Wirkung Von Wasserinhaltsstoffen Auf Fische – Fischtest (L15) ”, June 1982 - Static
Species	Golden Orfe
Exposure Period	96 hours
Auxiliary Solvent	
Water Hardness	2.5 mmol/L
Analytical Monitoring	
Remarks – Method	Based on the results of a range finding study, the definitive test was conducted at 23˚C and concentrations of 1.00, 2.15, 4.64, 10.0, 21.5 and 46.4 mg/L. For each concentration 10 fish were used. Reconstituted

freshwater was used as the test water. Test solutions were prepared by directly adding the notified chemical to the test water without any pre-treatment.
A positive control test was carried out by using chloroacetamide.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*				
Nominal	*Actual*		*1 h*	*24 h*	*48 h*	*72 h*	*96 h*
1.00		10	0	0	0	0	0
2.15		10	0	0	0	0	0
4.64		10	0	0	0	0	0
10.0		10	0	0	1	3	4
21.5		10	0	0	0	10	10
46.4		10	0	1	10	10	10

LC50	10 – 21.5 mg/L at 96 hours.
NOEC	4.64 mg/L at 96 hours.
Remarks – Results	The 48-hour LC50 for the positive control test was determined to be 38 mg/L which was considered corresponds to the normal sensitivity. As only one partial response was obtained the data is not amenable to probit analysis. The LC50 lies between 10 – 21.5 mg/L.

CONCLUSION The notified chemical is harmful to fish.

TEST FACILITY BASF (1987)

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