File No: LTD/1666

July 2013

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Adogen 213

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:

Street Address:	Level 7, 260 Elizabeth Street, SURRY HILLS NSW 2010, AUSTRALIA.
Postal Address:	GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.
TEL:	+ 61 2 8577 8800
FAX	+ 61 2 8577 8888
Website:	www.nicnas.gov.au

Director
NICNAS

TABLE OF CONTENTS

SUMMARY

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

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
LTD/1666	BP Australia Pty Ltd	Adogen 213	Yes	≤ 1 tonne per annum	Ingredient in lubricant oils

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available information, the notified chemical is 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. The recommended hazard classification is presented in the table below.

Hazard classification	*Hazard statement*
Skin irritation/corrosion (Category 1)	H314 - Causes severe skin burns and eye damage

Based on the available information, the notified chemical is recommended for hazard classification according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004) with the following risk phrase:

R35: Causes severe burns

The environmental hazard classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals* (GHS) is presented below. Environmental classification under the GHS is not mandated in Australia and carries no legal status but is presented for information purposes.

Hazard classification	*Hazard statement*
Acute category 3	H402, Harmful to aquatic life

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 assessed use pattern, the notified chemical is not considered to pose an unreasonable risk to the environment.

Recommendations

REGULATORY CONTROLS
Hazard Classification and Labelling

- The notified chemical should be classified as follows:
  - H314 - Causes severe skin burns and eye damage

- The following should be used for products/mixtures containing the notified chemical:
  - Conc. ≥ 5% H314
  - ≥ 3% Conc. < 5%: H315, H318
  - ≥ 1% Conc. < 3%: H315, H319

H314 - Causes severe skin burns and eye damage
H315 - Causes skin irritation
H318 - Causes serious eye damage
H319 - Causes serious eye irritation

CONTROL MEASURES
Occupational Health and Safety

- 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(1) of the Act; if
  – the importation volume exceeds one tonne per annum notified chemical;
  – the notified chemical has begun to be introduced at >1% concentration;

or

(2) Under Section 64(2) of the Act; if
  – the function or use of the chemical has changed from ingredient in lubricant oils 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 (M)SDS 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 (M)SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
BP Australia Pty Ltd (ABN: 53 004 085 616)
132 McCredie Rd
GUILDFORD NSW 2161

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: use details and import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
No variation to the schedule of data requirements is claimed.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
No

NOTIFICATION IN OTHER COUNTRIES
USA

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Adogen 213

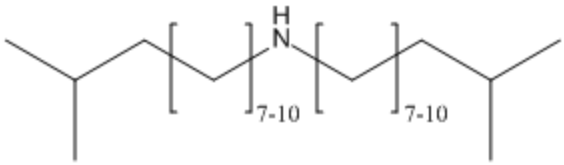
CAS NUMBER
1005516-89-1

CHEMICAL NAME
Amines, di-C11-14-isoalkyl, C13-rich

OTHER NAME(S)
Ditridecylamine

MOLECULAR FORMULA
Unspecified

STRUCTURAL FORMULA



MOLECULAR WEIGHT
325-409 Da (predominantly 381.7 Da)

ANALYTICAL DATA
Reference IR spectra were provided.

3. COMPOSITION

DEGREE OF PURITY > 90%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS

Chemical Name	Alcohols, C11-14-iso-, C13-rich		
CAS No.	68526-86-3	*Weight %*	< 6
Hazardous Properties	R36; R38		

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Clear colourless liquid

Property	Value	Data Source/Justification
Melting Point/Freezing Point	< -20 °C	Measured
Boiling Point	350-420 °C at 100.8 kPa	Measured
Density	831 kg/m^3 at 20 °C	Measured
Vapour Pressure	3.9 x 10^{-4} kPa at 25 °C	Measured
Water Solubility	< 2.0 × 10^{-3} g/L at 20 °C	Measured
Hydrolysis as a Function of pH	Not determined	Not expected as the notified chemical does not contain any readily hydrolysable functionalities
Partition Coefficient (n-octanol/water)	log Pow = 9.5-12.5	Estimated
Adsorption/Desorption	log K_{oc} = 4.4-7.7	Estimated
Dissociation Constant	Estimated in submission	The notified chemical contains potentially cationic functionality and is expected to be ionised under the environmental conditions
Flash Point	108 °C at 102.9 kPa	Measured
Flammability	Combustible liquid	Safety Data Sheet
Autoignition Temperature	262 °C	Measured
Explosive Properties	Not predicted to be explosive	Estimated
Oxidising Properties	Not determined	Contains no functional groups that imply oxidative 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. However, contact with strong oxidising agents should be avoided.

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 not be manufactured or reformulated in Australia. The notified chemical will be imported as a component of finished lubricant oils for aircraft engines at < 0.1%.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	< 0.5	< 0.5	< 0.9	< 0.9	< 1

PORT OF ENTRY
Brisbane

IDENTITY OF RECIPIENTS
BP Australia Pty Ltd
AMLC Pty Ltd

TRANSPORTATION AND PACKAGING
The finished product (containing the notified chemical at < 0.1%) will be imported into Australia in the final use containers in either 1 quart (0.95 L) cans or 5 gallon (18.9 L) pails. These will be packed in pallets and distributed within Australia by road.

USE
The notified chemical will be used as part of a lubricant oil at < 0.1% for aircraft turbine engines.

OPERATION DESCRIPTION
There will be no manufacture, reformulation or repackaging of the notified chemical in Australia.

End-use
The finished lubricant engine oils containing the notified chemical at < 0.1% will only be used by certified aircraft mechanics in commercial facilities. The engine oils will be poured or pumped through an oil delivery hose into engines of aircrafts through engine oil service ports. From this point onward the oil is contained within enclosed systems.

For oil sampling, engineers will open the oil sampling port and bleed off the engine oil into clean containers for laboratory testing.

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)*
Line Maintenance Engineer- Engine servicing	1	50
Line Maintenance Engineer- Oil sampling	0.5	25
Analytical/QC Worker	1	20
Product disposal worker- Includes airline customer and external waste management company	1	50

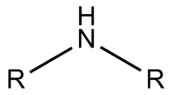
EXPOSURE DETAILS
Transport and storage
Transport and storage workers may come into contact with the notified chemical as a component of the finished products at < 0.1% concentration only in the event of an accidental rupture of containers.

End-use
Given the estimated low vapour pressure (3.9×10^{-4} kPa at 25 °C) of the notified chemical, inhalation exposure to the notified chemical is not expected. The potential for dermal and ocular exposure to the notified chemical at < 0.1% exists during draining of the lubricant oils to engine service ports as well as during oil sampling.

6.1.2. Public Exposure
The finished lubricant engine oils containing the notified chemical at < 0.1% will only be used by certified aircraft mechanics in commercial facilities. Therefore, members of the public are unlikely to be exposed to the notified chemical from the proposed uses.

6.2. Human Health Effects Assessment

There are no toxicological studies available for the notified chemical itself. Information on the expected health effects of the notified chemical are based on an analogue of the notified chemical, Amines, bis(C11-14-branched and linear alkyl) (CAS No. 900169-60-0). Both the analogue and the notified chemical are secondary amines with bis C_{11-14}-branched and linear alkyl chains. The only difference between the analogue and the notified chemical is that the notified chemical is a C13 rich chemical. This slight difference is not expected to significantly affect the physical-chemical properties or toxicology profile of the notified chemical. Thus, it is considered acceptable to use the analogue as a read-across substance for the notified chemical.



Analogue
R = Branched and linear $C_{11}H_{23}$ – $C_{14}H_{29}$
MW = < 500 Da

The results from toxicological investigations conducted on the analogue are summarised below.

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	LD50 = 2700 mg/kg bw; low toxicity
Mice, acute intraperitoneal	LD50 = 10 mg/kg bw; very toxic
Rat, acute inhalation toxicity	saturated vapour at 20 °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 analogue chemical was found to be of low acute toxicity via the oral route in a study carried out by an in-house method. In this study, however, it was not clear whether the LD50 was adjusted for the concentration of the analogue in the test substance. The analogue was very toxic via intraperitoneal administration. However, this exposure is not applicable to workers or public. Exposure to a saturated vapour of analogue 1 chemical at room temperature caused no mortalities. However, it should be noted that the concentration of analogue 1 was not stated. Signs of toxicity observed in the animals in these studies are likely to be related to the corrosive properties of the test substance.

Irritation

The analogue was found to be 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 analogue and the notified chemical, which contain structural alerts (aliphatic amines) for corrosion (Hulzebos, et al. 2005).

Mutagenicity

The analogue chemical was not mutagenic in a bacterial reverse mutation study.

Health hazard classification

Based on the available information, the notified chemical is 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. The recommended hazard classification is presented in the following table.

Hazard classification	***Hazard statement***
Skin irritation/corrosion (Category 1)	H314 - Causes severe skin burns and eye damage

Based on the available information, the notified chemical is recommended for hazard classification according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004), with the following risk phrase(s):

R35: Causes severe burns

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety

Based on the limited data for an analogue, the notified chemical is corrosive but is expected to be of low acute oral and inhalation toxicity and not mutagenic. Systemic toxicity from repeated exposure is not known.

Dermal and ocular exposure to the notified chemical (at < 0.1%) may occur during draining of the lubricant oils to engine service ports as well as during oil sampling. Given the low concentration in the end-use products, the risk of irritation and systemic toxicity effects is low. The expected use of PPE should further reduce these risks. Therefore, the risk to the health of professionals from use of the notified chemical under the occupational settings described is not considered to be unreasonable.

6.3.2. Public Health

The lubricant engine oils containing the notified chemical will only be used by professionals in commercial facilities and will not be sold to the public. Hence the risk to public health is not considered 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 part of lubricant oil for aircraft turbine engines. No release of the notified chemical to the environment is expected from manufacturing, reformulation or repackaging as these activities will not take place locally.

RELEASE OF CHEMICAL FROM USE

Given the final product containing the notified chemical will only be used in aircraft at commercial facilities, the most likely release will be from accidental spills during the transfer of the formulated lubricant oils into aircraft engines. Any spills are expected to be collected and disposed of in accordance with local environmental legislation.

RELEASE OF CHEMICAL FROM DISPOSAL

Used oil containing the notified chemical is anticipated to be collected by professional operators, recycled or thermally decomposed for recovery of the calorific values. The empty containers containing the notified chemical are expected to be disposed of by licensed waste management companies.

7.1.2. Environmental Fate

The notified chemical is not readily biodegradable based on the biodegradability result attained for an analogue. The analogue is chemically similar to the notified chemical. Therefore, it is considered to be scientifically reasonable to predict the environmental fate for the notified chemical using the analogue data. For the details of the environmental fate study conducted on the analogue, please refer to Appendix C.

The notified chemical is likely to be mainly disposed of by thermal decomposition as part of the process to recover the calorific value of used lubricants. Smaller amounts of the notified chemical may be consigned to landfill, or disposed of inappropriately to land or stormwater. On land or in landfill, the notified chemical is expected to associate strongly with the organic compartment based on its estimated high soil adsorption coefficient (log K_{oc} = 4.4-7.7) and cationic properties. The low water solubility (< 2.0 × 10-3 g/L), along with its high log K_{oc}, suggests that the notified chemical will not be environmentally mobile. The notified chemical may have potential to bioaccumulate in aquatic organisms based on the estimated high water/n-octanol partition coefficient (log Pow = 9.5-12.5). However, the notified chemical is expected to be ionised at the environmental pH range (4-9) and it is surface-active, which precludes the notified chemical from crossing the cell membrane to bioaccumulate. Furthermore, the notified chemical is not expected to be significantly released to the aquatic environment based on its use pattern. Either in landfill or through thermal decomposition, the notified chemical will finally be decomposed into 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 or the accepted analogue are summarised in the table below. The analogue is chemically similar to the notified chemical. Therefore, it is considered to be scientifically reasonable to predict the ecotoxicity endpoints for the notified chemical using the analogue data for the purpose of risk assessment. The Details of these studies can be found in Appendix C.

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity (*Golden Orfe*)	LC50 (96 h) = 10-21.5 mg/L*	Harmful to fish
Earthworm (*Eisenia fetida)*	LC50 (14 d) > 1000 mg/kg**	Very slightly toxic to earthworms

*Endpoint attained for the analogue
**Endpoint attained for the notified chemical

Based on the above results, it is concluded that the analogue is acutely harmful to fish. On this basis, the notified chemical is formally classified as "Acute Category 3: Harmful to aquatic life" under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS; United Nations, 2009).

While the notified chemical is not readily biodegradable, significant bioaccumulation is not expected due to its surface activity and the potential to be ionised. Based on the available acute endpoints for the analogue, the long-term hazard for the notified chemical is not classified under the GHS.

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 limited release of the notified chemical to the aquatic compartment and the expected low potential for bioaccumulation, the notified chemical is not expected to pose an unreasonable risk to the aquatic environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Melting Point/Freezing Point < -20 °C

Method	OECD TG 102 Melting Point/Melting Range. EC Council Regulation No 440/2008 A.1 Melting/Freezing Temperature.
Remarks	Determined using the pour point method
Test Facility	Harlan (2012a)

Boiling Point 350-420 °C at 100.8 kPa

Method	OECD TG 103 Boiling Point. EC Council Regulation No 440/2008 A.2 Boiling Temperature.
Remarks	Determined by differential scanning calorimetry
Test Facility	Harlan (2012a)

Density 831 kg/m^3 at 20 °C

Method	OECD TG 109 Density of Liquids and Solids. EC Council Regulation No 440/2008 A.3 Relative Density.
Remarks	Pycnometer method
Test Facility	Harlan (2012a)

Vapour Pressure 3.9 x 10^{-4} kPa at 25 °C

Method	OECD TG 104 Vapour Pressure. EC Council Regulation No 440/2008 A.4 Vapour Pressure.
Remarks	Determined using vapour pressure balance method
Test Facility	Harlan (2012b)

Water Solubility < 2.0 × 10^{-3} g/L at 20 °C

Method	OECD TG 105 Water Solubility.
Remarks	Flask Method. Test substance was mixed with water at three nominal concentrations of 2.0, 9.1 and 99.4 mg/L. The mixtures were shaken at approximately 30°C for 72 hours, following with standing for 24 hours at 20 °C. Water solubility of the test substance was visually examined. All solutions were clear and colourless with observed undissolved test substance inside the flasks. The pH of the test solution was determined to be 7.3-8.4.
Test Facility	Harlan (2012a)

Partition Coefficient (n-octanol/water) log Pow = 9.5 – 12.5

Method	Estimated using KOWWIN, v.1.68 (US Environmental Protection Agency, 2010)
Remarks	No determination method was applicable for the test substance according to OECD test guidelines as it is surface-active. Therefore, the partition coefficient (water/n-octanol) was calculated using the above estimation method.
Test Facility	Harlan (2012a)

Adsorption/Desorption – screening test log K_{oc} = 4.4-7.7

Method	Estimated using KOCWIN, v.2.00 (US Environmental Protection Agency, 2010)
Remarks	No determination method was applicable for the test substance according to OECD test guidelines as it is surface-active. Therefore, the adsorption coefficient was calculated using the above estimation software. The log Koc was calculated to be 6.2-7.7 based on molecular connectivity index (MCI) and a series of statistically derived fragment contributions. The calculated log Koc was 4.4-6.1 based on Kow method. However, as the test substance is anticipated to be fully

ionised in the environmental pH range, the mobility of the test substance in the environment may not be predominantly determined by the partition coefficient.
Test Facility Harlan (2012a)

Flash Point 108 °C at 102.9 kPa

Method EC Council Regulation No 440/2008 A.9 Flash Point.
Remarks Determined using a closed cup equilibrium method
Test Facility Harlan (2012c)

Autoignition Temperature 262 °C

Method EC Council Regulation No 440/2008 A.15 Auto-Ignition Temperature (Liquids and Gases).
Remarks The test flask was heated in a flask heater. Aliquots of the test item were injected into the flask and the flask observed for signs of ignition over a 300 second period. This procedure was repeated with varying sample size until the lowest temperature of ignition was observed.
Test Facility Harlan (2012c)

Explosive Properties

Method EC Council Regulation No 440/2008 A.14 Explosive Properties.
Remarks A statement provided by the testing laboratory indicates that the notified chemical does not contain chemical groups likely to lead to explosive properties.
Test Facility Harlan (2012c)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Analogue chemical (only translated summary was provided)
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 mortality but estimated the LD50 to be 2700 mg/kg bw.
CONCLUSION	The analogue and by inference, the notified chemical, is of low toxicity via the oral route.
TEST FACILITY	BASF (2006a) (study was carried out in 1970)

B.2 Acute toxicity – intraperitoneal

TEST SUBSTANCE	Analogue chemical (only translated summary was provided)
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 analogue and by inference, the notified chemical, is very toxic via the intraperitoneal route.
TEST FACILITY	BASF (2006b) (study was carried out in 1970)

B.3 Acute toxicity – inhalation

TEST SUBSTANCE	Analogue chemical (saturated vapour at 20 °C) (only translated summary was provided)
METHOD	Not stated
Species/Strain	Rat
Remarks - Method	Twelve animals were exposed through inhalation to an atmosphere saturated with vapour at 20 °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 analogue and by inference, the notified chemical, caused no mortalities under the conditions of the test.
TEST FACILITY	BASF (2006c) (study was carried out in 1970)

B.4 Irritation – skin

TEST SUBSTANCE	Analogue chemical (95%)
METHOD	The notified chemical was applied to the skin of the back and ear of the test animal 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 analogue 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 death (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 analogue and by inference, the notified chemical is corrosive to the skin.

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

B.5. Irritation – skin

TEST SUBSTANCE Analogue chemical (100%) (only translated summary was provided)

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 analogue and by inference, the notified chemical is corrosive to the skin.

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

B.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 analogue and by inference, the notified chemical is corrosive to the

eye.

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

B.7. Genotoxicity – bacteria

TEST SUBSTANCE Analogue 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 analogue and by inference, the notified chemical, was not mutagenic to bacteria under the conditions of the test.

TEST FACILITY BASF (1999)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	Analogue chemical
METHOD	Not reported
Inoculum	Laboratory plant; municipal wastewater (Oppau)
Exposure Period	28 Days
Auxiliary Solvent	None
Analytical Monitoring	Biochemical oxygen demand (BOD)
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 analogue and, by inference, the notified chemical are not considered to be readily biodegradable
TEST FACILITY	BASF (2006)

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	Analogue 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	None
Water Hardness	2.5 mg $CaCO_3$/L
Analytical Monitoring	Not reported
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*
1.0	N/A	10	0	0	0	0	0
2.15	N/A	10	0	0	0	0	0
4.64	N/A	10	0	0	0	0	
10.0	N/A	10	0	0	1	3	4
21.5	N/A	10	0	0	0	10	10
46.4	N/A	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 to correspond 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 analogue and, by inference, the notified chemical are harmful to fish

TEST FACILITY BASF (1987)

C.2.2. Acute toxicity to earthworm

TEST SUBSTANCE Notified chemical

METHOD OECD TG 207 Earthworms, Acute toxicity test
Species *Eisenia fetida*
Exposure Period 14 days
Auxiliary Solvent Acetone. The solvent was allowed to evaporate off prior to the commencement of the test.
Remarks - Method Based on the results of the preliminary range-finding test, a definitive test was conducted according to the test guideline above without significant deviation from the protocol. In the definitive test, 60 earthworms (six replicates of 10 worms) were exposed to a single concentration of 1000 mg/kg (dry weight) of soil for a period of 14 days at 21˚C to 25˚C. The test was conducted at pH 5.7-5.9 with the soil moisture content of 26%. The number of mortalities was determined after 7 and 14 days.

RESULTS

Concentration mg/L		*Number of D. magna*	*Mortality*	
Nominal	*Actual*		*7 d*	*14 d*
0	N/A	80	0	0
1000	N/A	60	0	0

LC50 > 1000 mg/kg at 14 days
NOEC 1000 mg/kg at 14 days
Remarks - Results There were no significant differences between the control, solvent control and the 1000 mg/kg test groups in terms of worm weight. Statistical analysis of the Day 14 worm weights indicated a significant difference in terms of worm weight between the solvent control and the test groups. A review of the data by the study author indicated that this was possibly due to the presence of a few slightly larger worms in the solvent control group at day 0. Given that no mortalities and no behavioural abnormalities were observed in the 1000 mg/kg test group, this slight difference in weight was not considered to be due to the test substance and was therefore, not

	considered to affect the interpretation of the results.
CONCLUSION	The notified chemical is considered very slightly toxic to earthworms
TEST FACILITY	Harlan (2012d)

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