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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Chemical in ProEco HE 801 Series Oils

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 Full Public Report may be inspected at our NICNAS office by appointment only at Level 7, 260 Elizabeth Street, Surry Hills NSW 2010.

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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FULL PUBLIC REPORT

Chemical in ProEco HE 801 Series Oils

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Cognis Australia Pty Ltd (ABN: 87 006 374 456)
4 Saligna Drive
Tullamarine, VIC 3043

NOTIFICATION CATEGORY
Standard: Chemical other than polymer (more than 1 tonne per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: chemical name, other names, CAS number, molecular and structural formulae, molecular weight, residual impurities 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, Adsorption/desorption, Dissociation constant, Flammability limits, Autoignition temperature, Explosive properties, toxicological and ecotoxicological endpoints.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
Canada (2009), USA (2010)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
ProEco HE 801-22/32/46/68 (up to 99% notified chemical)
ProEco HE 701

MOLECULAR WEIGHT
>500 Da

ANALYTICAL DATA
Reference IR and GC-MS spectra were provided.

3. COMPOSITION

DEGREE OF PURITY ≥85%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: Colourless-yellowish liquid

Property	Value	Data Source/Justification
Freezing Point	-52 to -33 °C	Measured
Boiling Point	389-454 °C at 100.9 kPa	Measured
Density	883 kg/m^3 at 20 °C	Measured
Vapour Pressure	1.9 x 10^{-6} kPa at 20 °C	Measured
Water Solubility	<4 × 10^{-6} g/L at 20 °C	Measured
Hydrolysis as a Function of pH	Not determined	Contains hydrolysable functions but is not expected to hydrolyse at environmental pH (4 – 9)
Partition Coefficient	log Pow >5.7 at 20 °C	Measured

(n-octanol/water)		
Adsorption/Desorption	log K_{oc} = 12.62	Calculated
Dissociation Constant	Not determined	Contains no dissociable functions
Flash Point	>200 °C	MSDS of ProEco HE 801-46 (>90% notified chemical)
Autoignition Temperature	Not determined	Not expected to autoignite based on the flash point
Explosive Properties	Not determined	Contains no functional groups that would imply explosive properties.

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

Reactivity
Expected to be stable under normal conditions of use.

Dangerous Goods classification
Based on the submitted physical-chemical data in the above table the notified chemical is not classified according to the Australian Dangerous Goods Code (NTC, 2007). However the data above do not address all Dangerous Goods endpoints. Therefore consideration of all endpoints should be undertaken before a final decision on the Dangerous Goods classification is made by the introducer of the chemical.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will be imported into Australia at up to 99% concentration in finished automotive and industrial oils.

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

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

PORT OF ENTRY
Sydney and Melbourne

IDENTITY OF MANUFACTURER/RECIPIENTS
Cognis Australia Pty Ltd

TRANSPORTATION AND PACKAGING
The products containing the notified chemical (at up to 99%) will be imported in 2 kg plastic drums or 180 kg steel drums suitable for sale. The containers will be packed on pallets and transported within Australia by road. Alternatively, the products may be supplied in 850 kg IBCs.

USE
The notified chemical is a synthetic lubricant that will be used in finished automotive and industrial oils.

The finished products containing the notified chemical will primarily be used in industrial environments for mobile hydraulic equipment. In addition, a small proportion (<5%) of the imported products containing the notified chemical may be available for do-it-yourself (DIY) applications.

OPERATION DESCRIPTION
The notified chemical will be imported at up to 99% concentration in finished oil products. It is not intended that reformulation will take place in Australia.

The finished products containing the notified chemical will be used to top-up or refill machinery. The majority of transfers at industrial sites will be conducted using a pump and hose. However, as expected with DIY users, manual addition will also occur.

6. HUMAN HEALTH IMPLICATIONS

6.1 Exposure assessment

6.1.1 Occupational exposure

EXPOSURE DETAILS
Transport and storage staff may come into contact with the imported products (up to 99% notified chemical) only in the event of accidental rupture of containers.

There is potential for dermal and ocular exposure to the notified chemical (up to 99%) during the transfer of oils containing it into industrial systems or machinery and during maintenance operations. Exposure is expected to be minimised by the use of personal protective equipment (PPE, e.g. gloves, goggles and protective clothing).

6.1.2. Public exposure
Products containing the notified chemical are primarily intended for use by industry and therefore public exposure to the chemical is expected to be low. However, exposure to the notified chemical (at up to 99%) may occur during the use of oil products containing it during DIY applications. In such cases, dermal and ocular exposure may occur. However, such applications are expected to occur infrequently.

6.2. Human health effects assessment

No toxicity data is available for the notified chemical. The results from toxicological investigations conducted on an acceptable analogue of the notified chemical are summarised in the table below. Details of these studies can be found in Appendix B. The analogue was acceptable based on structural similarity with the notified chemical, differing only by an additional CH_2 group.

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	LD50 >5,000 mg/kg bw; low toxicity
Rat, acute dermal toxicity	LD50 >2,000 mg/kg bw; low toxicity
Rabbit, skin irritation	slightly irritating
Rabbit, eye irritation	slightly irritating
Guinea pig, skin sensitisation – adjuvant test	no evidence of sensitisation (at 10% induction concentration)
Rat, repeat dose oral toxicity – 28 days.	NOAEL >1,000 mg/kg bw
Mutagenicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vivo mouse micronucleus assay	non genotoxic

While passive diffusion of the notified chemical across the gastrointestinal (GI) tract and dermal absorption may occur, it is expected to be limited by the low water solubility ($<4 \times 10^{-6}$ g/L at 20 ^{o}C) and relatively high molecular weight (≥500 Da) of the notified chemical.

A suitable analogue of the notified chemical was found to be of low acute oral and dermal toxicity in rats, was a slight skin and eye irritant in rabbits and was not a skin sensitiser in guinea pigs at up to 10% concentration (Magnus-Kligman method). In addition, a 28-day repeat dose oral toxicity study in rats established an NOAEL for the analogue chemical of 1,000 mg/kg bw/day. Administration at this dosage level did not result in mortality or any toxicologically significant behaviour and did not induce changes in the organs/tissues. The analogue chemical was not mutagenic in a bacterial reverse mutation study and was not clastogenic in an in vivo mouse micronucleus assay. There was no indication in the micronucleus test that the chemical had reached the bone marrow, implying that the chemical was absorbed minimally through the GI tract or that it has no toxicity at such high doses. Similar findings would be expected from studies conducted on the notified chemical.

Health hazard classification
Based on the data provided for a suitable analogue of the notified chemical, it is not classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human health risk characterisation

6.3.1. Occupational health and safety

Based on toxicological data provided for an analogue of the notified chemical, only slight irritancy effects may be expected from exposure to products containing the notified chemical during transfer processes. However, the skin sensitisation effect was tested at 10% concentration and workers will be handling the chemical at up to 99% concentration. The risk of worker exposure is expected to be minimised by the use of PPE.

Therefore, given the expected low exposure with the use of PPE, the risk to the health of workers from use of the notified chemical is not considered to be unacceptable.

6.3.2. Public health

Products containing the notified chemical are primarily intended for use in industrial applications. However, exposure to the notified chemical (at up to 99% concentration) may occur during infrequent DIY applications. As the skin sensitisation effect was only tested at 10% concentration, use of some PPE (single layer of clothing and gloves) is recommended to minimise exposure of the public to the notified chemical.

Therefore, when used in the proposed manner and provided that some PPE is worn, the risk to public health is not considered to be unacceptable, given the expected infrequent use of the notified chemical.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified chemical will be manufactured overseas and imported as a component of finished hydraulic oil and automotive (engine and transmission) oils. The notified chemical may also be imported as a raw material for local reformulation into the above end-use products. Minimal environmental release is expected from blending or repackaging. Release during transport is unlikely due to containerisation or the use of packaging designed to withstand impact. Any spills or residues are expected to be re-used to the extent practicable, or disposed of safely.

RELEASE OF CHEMICAL FROM USE

Hydraulic oils

The hydraulic oil containing the notified chemical will be used in sealed units, which may be topped up and refilled as required. The hydraulic oils are only available for industrial applications and as such the changing and topping up of the fluids will be conducted by trained tradespersons. No significant release of the notified chemical is expected from the removal of used hydraulic oil. During the use of lubricating fluid in sealed units, the notified chemical will be contained and its release is expected to be very low. The changed lubricating fluids are expected to be collected and stored for subsequent disposal. The release of the notified chemical from professional activities is expected to be limited by the requirements for appropriate disposal of waste oil according to State/Territory regulations.

The finished products are intended for use in topside marine hydraulic systems such as for the hydraulic power of drill floor equipment on drilling rigs and the hydraulic power and controls in cranes used on drilling rigs, ships, production platforms or harbour facilities. In these scenarios there is a very low risk of leakage or spillage into the marine environment. However, if hydraulic systems are correctly maintained and operated no discharges are expected to occur. Failure of a component such as a seal or hose is likely to result in a release of fluid which, because of the exposed location of the equipment, could result in the hydraulic fluid escaping into the marine environment. This will be above the water line and it is not envisaged that these products would be used in hydraulic systems located below the water line. It is estimated that ≤1% (100 kg) of notified chemical will be exposed to the marine environment due to accidental release.

Automotive Engine Oils

For engine oil applications, the majority of oil changes will take place in specialised automotive service centres, where release of the notified chemical from professional activities is expected to be limited by the requirement for appropriate disposal of waste oil according to State/Territory regulations. It is estimated that ≤5% of engine oil containing the notified chemical will be changed by 'do-it-yourself' (DIY) enthusiasts.

Automotive Transmission Oils

The industrial gear oil containing the notified chemical will be used in sealed units, which will be topped up or emptied and refilled at intervals depending on the application. In the case of automotive transmissions, gear oil will be used predominately in commercial garages. Gear oils are changed infrequently and it is assumed that skilled tradesmen will be undertaking almost all maintenance of equipment at mechanical workshops etc. Oils changed in such workshops are expected to be collected and stored for subsequent safe disposal. A very small proportion of gear oil is expected to be used in DIY applications. No significant release of gear oil containing the notified chemical is expected from the filling of new oil or the removal of used oil from gear boxes. During the use of the finished gear oil the product will be contained within enclosed gear boxes and the release of the chemical is expected to be very low.

RELEASE OF CHEMICAL FROM DISPOSAL

Hydraulic oil which has been used offshore will be collected and shipped back to shore and will be disposed of by the same methods as used for oils used on-shore and these are described below.

When lubricants containing the notified chemical are disposed of in accordance with State/Territory regulations, the notified chemical is expected to be recycled, re-refined or used as low grade burner fuel. It is likely that the notified chemical will be degraded into simpler compounds during re-refining with any residue partitioning to the heavy fractions such as lubricating oils or asphalt. If combusted, the notified chemical is likely to form oxides of carbon and water vapour. Similarly, during metal recycling of automotive components, the notified chemical will be completely combusted.

Although some transmissions require the fluid to be replaced during servicing, the trend for automatic transmissions is for sealed units which are filled for the life of the transmission. These are expected to be serviced only by professional mechanics and often do not require replacement of the automatic transmission fluid. The lubricants are expected to be collected either at the end of the useful life of the transmissions, or if required, during servicing. Since this will involve professionals, very little if any is likely to be changed and disposed of improperly. The lubricating fluid containing the notified chemical is expected to be collected at the end of the lifecycle of the sealed units and in the event of changing the fluid. As the notified chemical is for industrial use only, it is expected that the fluid will be collected and disposed according to State/Territory regulations.

The proportion of end-use products containing the notified chemical being used in engine oils was not provided. Apart from leaks to the marine environment, the only expected release of the notified chemical to the aquatic environment is via improper disposal by DIY users. Hence, a worst-case discharge scenario assumed that all of the import volume of notified chemical was used in engine oil. Of the 5% of engine oil, estimated to be disposed of by DIY practitioners, approximately 20% will be collected for recycling, 25% will be buried or disposed of in landfill, 5% [i.e. 0.25% of the total import volume (25 kg)] may be disposed of inappropriately into storm water drains and the remaining 50% will be used in treating fence posts, killing grass and weeds or disposed of in other ways.

7.1.2 Environmental fate

A study submitted by the notifier indicates the notified chemical is readily biodegradable. The notified chemical is not expected to be bioaccumulative or bioavailable to aquatic organisms due to its high molecular weight. Most of the notified chemical will be either thermally decomposed during use, recycling or refinement. A small amount of the notified chemical is expected to be sent to landfill as residues in containers or as a component of waste oil. The notified chemical is expected to be degraded into water and oxides of carbon by thermal decomposition in industrial facilities or by natural processes in landfill.

For the details of the environmental fate studies, refer to Appendix C.

7.1.3 Predicted Environmental Concentration (PEC)

The notified chemical is anticipated to be released to the aquatic environment through improper disposal by DIY users and by leaks to the marine environment. Assuming a worst-case scenario, the percentage of the imported quantity of notified chemical inappropriately disposed to stormwater drains is estimated to be 25 kg per annum, while the worst case release to the marine environment is estimated to be 100 kg per annum. In both cases the annual release is expected to be very low and, taking into account the low ecotoxicity of the notified chemical and its diffuse use nationwide, its release will not result in ecotoxicologically significant concentrations in the environment. Hence, a PEC has not been calculated. Based on its expected high log K_{oc} and low water solubility, the notified chemical released to the aquatic environment is expected to sorb to

particulates and sediment. The notified chemical is readily biodegradable and is therefore not anticipated to persist in the environment.

7.2. Environmental effects assessment

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

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity (96 hour)*	LL50 > 100 mg/L	Not harmful to fish up to the limit of its solubility in water
Algal Toxicity (72 hour)	E_rC50 > 0.29 mg/L	Not harmful to algae up to the limit of its solubility in water

*Analogue of notified chemical

The test substance, and by inference the notified chemical, is not harmful to fish and algae up to its limit of solubility in water. Furthermore, since the notified chemical is readily biodegradable, it is not classified for acute or long-term aquatic hazards under the Globally Harmonised System of Classification and Labelling of Chemicals (United Nations, 2009). The notified chemical is not expected to bioaccumulate based on its high molecular weight.

7.2.1 Predicted No-Effect Concentration

A Predicted No-Effect Concentration (PNEC) was not considered necessary since the PEC was estimated to be low.

7.3. Environmental risk assessment

The notified chemical is expected to have very low exposure to the aquatic environment, as the majority of the end-use products containing the notified chemical are expected to be disposed of according to State/Territory regulations. Ecotoxicity tests indicate the notified chemical is not harmful to aquatic life up to the limit of its solubility in water. Furthermore, the risk posed by the small amount of notified chemical potentially released to the environment is expected to be mitigated by its diffuse use, sorption to particulates and sediment and rapid biodegradation. Consequently, the notified chemical is not expected to pose a significant risk to the environment based on its proposed use pattern.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

Based on the data provided for a suitable analogue of the notified chemical, it is not classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)].

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 expected to pose a risk to the environment.

Recommendations

CONTROL MEASURES

Occupational Health and Safety

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical at >10% concentration in products:
  - *Coveralls*
  - *Gloves*

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.

Public Health

- The following measures should be taken by DIY users to minimise exposure to the notified chemical:
  - Wear a single layer of clothing and gloves during use of products containing the notified chemical at >10% concentration.

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(2) of the Act; if
  - the function or use of the chemical has changed from a component of finished automotive and industrial oils, or is likely to change significantly;
  - the amount of chemical being introduced has increased from 10 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 MSDS of 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: PHYSICAL AND CHEMICAL PROPERTIES

Melting Point/Freezing Point -52 to -33 ºC

Method	EC Directive 92/69/EEC A.1 Melting/Freezing Temperature.
Remarks	Determined by differential scanning calorimetry (DSC).
Test Facility	Henkel (2008a)

Boiling Point 389-454 ºC at 100.9 kPa

Method	EC Directive 92/69/EEC A.2 Boiling Temperature.
Remarks	Determined by differential scanning calorimetry (DSC).
Test Facility	Henkel (2008b)

Density 883 kg/m^3 at 20 ºC

Method	EC Directive 92/69/EEC A.3 Relative Density.
Remarks	Determined using a pycnometer.
Test Facility	Henkel (2008c)

Vapour Pressure 1.9 x 10^{-6} kPa at 20 ºC)

Method	EC Directive 92/69/EEC A.4 Vapour Pressure.
Remarks	The experimentally determined vapour pressure was not in the recommended range for DSC measurements. Therefore, the estimation procedure was used.
Test Facility	Henkel (2008d)

Water Solubility $< 4 \times 10^{-6}$ g/L at 20ºC

Method	OECD TG 105 Water Solubility. EC Directive 92/69/EEC A.6 Water Solubility.
Remarks	The flask method was used although the column elution method was more appropriate according to the guideline since the solubility was <0.01 g/L. The solubility of the test substance was found to be less than the limit of quantification (4 µg/L).
Test Facility	Dr. U. Noack-Laboratorien (2007a)

Partition Coefficient (n-octanol/water) log Pow > 5.7 at 20ºC

Method	OECD TG 117 Partition Coefficient (n-octanol/water): HPLC Method
Remarks	The test substance was dissolved in 100% methanol. Test substance eluted after 138 minutes which is after the retention time of the reference chemical. The test substance was therefore reported as having a log Pow greater than the reference chemical.
Test Facility	Henkel (2008e)

Adsorption/Desorption log K_{oc} = 12.62

Method	Calculated using KOCWIN v2.00
Test Facility	US EPA (2009)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Analogue chemical
METHOD	Similar to OECD TG 401 Acute Oral Toxicity – Limit Test.
Species/Strain	Rat/Wistar, 5M/5F
Vehicle	Peanut oil
Remarks - Method	No significant protocol deviations.
RESULTS	
Remarks - Results	There were no mortalities observed
LD50	>5,000 mg/kg bw
Signs of Toxicity	Slight pilo-erection was noted for all animals from 0.5-6 hours following administration of the test substance. In addition, weight reduction was noted for 1 female at the completion of the study.
Effects in Organs	None
CONCLUSION	The analogue chemical is of low toxicity via the oral route.
TEST FACILITY	Henkel (1986a)

B.2. Acute toxicity – dermal

TEST SUBSTANCE	Analogue chemical
METHOD	Similar to OECD TG 402 Acute Dermal Toxicity – Limit Test.
Species/Strain	Rat/Wistar, 5M/5F
Vehicle	None
Type of dressing	Occlusive
Remarks - Method	The test substance was applied to a 6 x 4 cm^2 linen cloth, which was then applied to the skin beneath a polyethylene film. Residual test substance was washed off following the 24-hour exposure period.
RESULTS	
Remarks - Results	There were no mortalities observed
LD50	>2,000 mg/kg bw
Signs of Toxicity	Hydrometra was noted in 1 female
Effects in Organs	None
CONCLUSION	The analogue chemical is of low toxicity via the dermal route.
TEST FACILITY	Henkel (1986b)

B.3. Irritation – skin

TEST SUBSTANCE	Analogue chemical
METHOD	OECD TG 404 Acute Dermal Irritation/Corrosion.
Species/Strain	Rabbit/small russian, Chbb: HM
Number of Animals	5 male
Vehicle	None
Observation Period	7 days
Type of Dressing	Occlusive
Remarks - Method	The test substance was applied to a 2.5 x 2.5 cm^2 linen cloth, which was then applied to the skin beneath a polyethylene film.

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Erythema/Eschar	0.4	2	<7 days	0
Oedema	0	0	-	0

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

Remarks - Results: No skin reactions were noted for 2/5 rabbits. Slight to obvious erythema was noted in the remaining 3 animals. All reactions were reversible within the observation period.

CONCLUSION: The analogue chemical is slightly irritating to the skin.

TEST FACILITY: Henkel (1986c)

B.4. Irritation – eye

TEST SUBSTANCE: Analogue chemical

METHOD: OECD TG 405 Acute Eye Irritation/Corrosion.
Species/Strain: Rabbit/small russian, Chbb: HM
Number of Animals: 4
Observation Period: 48 hrs
Remarks - Method: Observations were made at 1, 6, 24 and 48 hours post-instillation and were not conducted at 72 hours. After recording the observations at 24 hours, the eyes were further examined with the aid of fluorescein-Na.

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
Conjunctiva: redness	0.25	2	<48 hrs	0
Conjunctiva: chemosis	0	0	-	0
Conjunctiva: discharge	0.125	3	<48 hrs	0
Corneal opacity	0	0	-	0
Iridial inflammation	0	0	-	0

*Calculated on the basis of the scores at 24 and 48 hours for ALL animals.

Remarks - Results: Significant conjunctiva redness and discharge were noted in the first 24 hours post-instillation of the test substance. For two of the animals this cleared by the 24-hour observation mark, the remaining two exhibited slight reddening and/or discharge, which cleared within a further 24 hours.

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

TEST FACILITY: Henkel (1986d)

B.5. Skin sensitisation

TEST SUBSTANCE: Analogue Chemical

METHOD: Similar to OECD TG 406 Skin Sensitisation - Magnusson and Kligman guinea pig maximisation test.
Species/Strain: Guinea pig/Pirbright white
PRELIMINARY STUDY: Minimum Irritant Concentration:
intradermal: 0.5%
topical: 10%
MAIN STUDY
Number of Animals: Test Group: 20F Control Group: 20F

INDUCTION PHASE	Induction Concentration: intradermal: 0.5% topical: 10%
Signs of Irritation	Following the intradermal induction phase, skin reactions (unspecified) are noted for both the control and test group. Following the topical induction phase, reddening and necrotic skin alteration effects were observed at the application sites.
CHALLENGE PHASE	
1st challenge	topical: 5%
Remarks - Method	The vehicle for the test substance was liquid paraffin. The induction concentration was 10% although 100% of the chemical was found to be slightly irritating to the skin (Section B.3.). According to OECD TG 406, the concentration of test substance used for the induction exposure should be the highest to cause mild-to-moderate skin irritation.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after: 1st challenge*	
		24 h	*48 h*
Test Group	5%	0	0
Control Group	Liquid parrafin	0	0

Remarks - Results	Following the challenge phase, no signs of skin reaction are noted for animals in both the test and control groups.
CONCLUSION	There was no evidence of reactions indicative of skin sensitisation to the analogue chemical under the conditions of the test.
TEST FACILITY	Henkel (1986e)

B.6. Repeat dose toxicity

TEST SUBSTANCE	Analogue Chemical
METHOD	Similar to OECD TG 407 Repeated Dose 28-day Oral Toxicity Study in Rodents.
Species/Strain	Rat/Sprague-Dawley
Route of Administration	Oral – gavage
Exposure Information	Total exposure days: 28 days Dose regimen: 5 days per week Post-exposure observation period: 28 days
Vehicle	Peanut oil
Remarks - Method	No significant protocol deviations. Animals received 23 or 24 administrations of the test substance. An additional 10 animals each for the control and high-dose groups remained untreated for an extra 28 days following exposure.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw/day*	*Mortality*
control	10M/10F	0	0
low dose	10M/10F	100	0
mid dose	10M/10F	350	0
high dose	10M/10F	1000	0
control recovery	5M/5F	0	0

high dose recovery	5M/5F	1000	0

Clinical Observations
In very few animals, symptoms such as thin coat, localised alopecia and chromodacryorrhea were observed. These were not considered to be substance- or dosage-related.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis
Some slight variations were noted in the haematological examinations. These slight variations did not indicate toxic or dosage-related effects of the test substance. For the biochemical examinations, a significant decrease is noted for the glutamic-oxalacetic transaminase values. The variations in haematological and blood chemistry parameters were reported by the study authors to be not of toxicological significance.

Effects in Organs
No treatment-related macroscopic or microscopic findings were noted. For females in the mid dose group, an increase in the absolute liver weight without histological findings is noted.

Remarks – Results
Food consumption for the female animals was slightly increased in the mid (2^{nd}-4^{th} week) and high (1^{st}-2^{nd} and 4^{th} week) dose groups. Slightly increased body weights were noted for the female animals in the low (4^{th} week) dose group. Similarly, increased weight was noted for the mid-high dose groups (from week 3), with a clear increase after 4 weeks.

CONCLUSION
The No Observed (Adverse) Effect Level (NO(A)EL) was established as >1000 mg/kg bw/day in this study, based on the absence of any toxicologically significant effects at this dosage level.

TEST FACILITY Henkel (1986f)

B.7. Genotoxicity – bacteria

TEST SUBSTANCE Analogue Chemical

METHOD

	Similar to OECD TG 471 Bacterial Reverse Mutation Test. Plate incorporation procedure
Species/Strain	*S. typhimurium*: TA1538, TA1535, TA1537, TA98, TA100
Metabolic Activation System	Aroclor 1254-induced rat liver (S9 homogenate)
Concentration Range in Main Test	a) With metabolic activation: 8, 40, 200, 1000 and 5000 µg/plate b) Without metabolic activation: 8, 40, 200, 1000 and 5000 µg/plate
Vehicle	Tween 80/Bidistilled water
Remarks - Method	Positive controls: i) without S9: sodium azide (TA1535, TA100), 9-aminoacridine (TA1537) and 4-nitro-*o*-phenylenediamine (TA1538, TA98); ii) with S9: 2-aminoanthracene. Test 2 was conducted on separate day to Test 1.

RESULTS

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

Remarks - Results No significant increases in the frequency of revertant colonies were recorded for any of the bacterial strains up to and including the maximum dose of 5000 µg/plate, either with or without metabolic activation.

	The positive controls gave satisfactory responses, confirming the validity of the test system.
CONCLUSION	The analogue chemical was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	Henkel (1986g)

B.8. Genotoxicity – in vivo

TEST SUBSTANCE	Analogue Chemical
METHOD	OECD TG 474 Mammalian Erythrocyte Micronucleus Test.
Species/Strain	Mouse/CFW1
Route of Administration	Oral – gavage
Vehicle	Peanut oil
Remarks - Method	A preliminary maximum-dosage study was conducted using 2 male and 2 female mice at 3 dosage levels (5,000, 7,500 and 10,000 mg/kg bw). No symptoms were observed in any of the test animals up to 72 hours post-administration of the test substance.

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Sacrifice Time hours*
I (vehicle control)	7M/7F	-	24
II (low dose)	7M/7F	1,000	24
III (mid dose)	7M/7F	5,000	24
IV (high dose) x 3	7M/7F	10,000	24, 48, 72
V (positive control, CP)	7M/7F	10	24

CP=cyclophosphamide.

RESULTS	
Doses Producing Toxicity	There were no mortalities during the period of the study. For the mid-dose group, slightly reduced activity was noted for the test animals *ca*. 3 hours post-administration. For the high-dose group, slightly reduced activity and slightly bristled hair was noted for the test animals *ca*. 3 hours post-administration. After 20 hours these symptoms were no longer recognised.
Genotoxic Effects	A statistically significant increase in micronucleated PCEs was not observed at the high dose level. The positive control induced statistically significant increases in micronucleated PCEs.
Remarks - Results	Due to the absence of genotoxic effects for the high dose group, the low and mid-dose groups were not evaluated. There was no indication that the chemical had reached the bone marrow.
CONCLUSION	The analogue chemical was not clastogenic under the conditions of this in vivo Mammalian Erythrocyte Micronucleus Test.
TEST FACILITY	Henkel (1986h)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 301 B Ready Biodegradability: CO_2 Evolution Test.
Inoculum	Activated sludge from a domestic waste-water treatment plant
Exposure Period	28 days
Auxiliary Solvent	None reported
Analytical Monitoring	Evolved CO_2 was quantified by titrating unreacted $Ba(OH)_2$ in the CO_2 adsorption solution. Carbon concentrations of the test substance solutions were determined by elemental analysis.
Remarks - Method	The test substance was added at nominal concentrations of 37.5 – 37.6 mg/L to inoculated mineral medium. The test solutions were aerated with CO_2-free air and incubated at 20.0 – 21.0°C and mixed with magnetic stirrers for 28 days. Degradation was determined by measuring the amount of CO_2 produced, corrected with the blank inoculum, and expressed as % of theoretical amount of CO_2 ($ThCO_2$). Sodium benzoate was used as a reference substance control. The results are presented below.

RESULTS

Test substance		*Sodium Benzoate*	
Day	*% Degradation**	*Day*	*% Degradation**
0	0	0	0
7	-3.1	7	77.5
14	59.9	14	92.0
21	80.0	21	97.1
28	78.3	28	99.6
28 (after acidification)	81.5	28 (after acidification)	99.6

*Mean of 3 replicates

Remarks - Results	All validity criteria for the test guideline were satisfied and hence the test is considered valid. The reference substance reached the pass level for ready biodegradability within 4 days indicating a suitable aerobic activated sludge inoculum was used. The test material attained > 60% degradation within the 10-day window and can therefore be classified as readily biodegradable.
CONCLUSION	The notified chemical is readily biodegradable
TEST FACILITY	Hydrotox GmbH (2005)

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE	Analogue of the notified chemical
METHOD	Method proposed by the UBA (German Federal Environment Office): "Lethal effects on the zebra barbel *Brachydanio rerio"* of June 01, 1982 (LC_0, LC_{50}, LC_{100}; 48-96 h) – Semi static
Species	Zebra barbel (*Brachydanio rerio*)
Exposure Period	96 hours
Auxiliary Solvent	None reported
Water Hardness	Not reported
Analytical Monitoring	Gas chromatography on DB 5 column using flame ionisation detection

Remarks – Method	Ultrasound (5 min) and Ultraturrax (5 min) were applied to give a fine suspension of the test substance. After 24 hours slight deposits of the test substance were observed together with some flocs. The turbidity of the solution remained unaltered over the course of the test. The number of fish used in the test was not reported. The test facility was inspected for GLP.

RESULTS

Concentration mg/L		*Number of Fish*	*Mortality*			
Nominal	*Actual**		*0 h*	*24 h*	*48 h*	*96 h*
0	0	Not reported	0	0	0	0
100	62 (fresh solution) 90 (old solution)	Not reported	0	0	0	0

*The nominal concentration was used to determine the toxicity endpoints since the notified chemical water solubility is << 62 mg/L

LL50	> 100 mg/L at 96 hours
NOEL	100 mg/L at 96 hours
Remarks – Results	The measured concentration of the test substance was approximately 100 times greater than that expected according to the water solubility of the notified chemical. This indicated that a dispersion of the notified chemical was being detected. Since the turbidity remained over the course of the test it is likely that the concentration of the test substance was maintained over the entire test. The results of this test should be treated with caution as the number of fish used was not reported.

CONCLUSION The test substance, and by inference the notified chemical, is not harmful to fish up to the limit of its solubility in water

TEST FACILITY Henkel (1986i)

C.2.2. Acute toxicity to aquatic invertebrates – Study 1

TEST SUBSTANCE Notified chemical

METHOD OECD TG 202 Daphnia sp. Acute Immobilisation Test and Reproduction Test - Static
EC Directive 92/69/EEC C.2 Acute Toxicity for Daphnia - Static

Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	None reported
Water Hardness	251 mg $CaCO_3$/L
Analytical Monitoring	LC-MS (LOQ = 2 µg notified chemical / L)
Remarks - Method	A preliminary range finding test was conducted. In the definitive test a stock solution was prepared by loading 100 mg/L of test substance in dilution one day prior to application. The stock solution was shaken with 20 rpm for 24 h with a rotating shaker. Undissolved particles were removed by centrifugation with 3000 rpm for 20 min. Twenty animals were used per dilution level and control, divided into 4 groups of 5 animals each.

RESULTS

Concentration mg/L		*Number of D. magna*	*% Immobilised**	
Nominal	*Actual*		*24 h*	*48 h*
	0	20	0	0
0.410	0.008	20	0	0
1.22	0.014	20	0	0
3.57	0.034	20	0	0
10	0.033	20	100	100
25	0.110	20	95	100
50	0.222	20	90	100

*Mean value of 4 replicates

EC50	Could not be determined
NOEC	Could not be determined
Remarks - Results	All validity criteria were satisfied. The toxic response of daphnia to the reference compound $K_2Cr_2O_7$ gave an EC50 (24 h) of 1.98 mg/L which was in the prescribed range of the daphnia. In the definitive test, all the daphnia observed to be immobile were trapped on the surface of the water and stuck together. Hence, the immobilisation was considered to be due to physical effects. Therefore the test is considered invalid (EPHC, 2009).

CONCLUSION The test is considered invalid and therefore the notified chemical cannot be classified.

TEST FACILITY Dr. U. Noack-Laboratorien (2007b)

C.2.3. Acute toxicity to aquatic invertebrates – Study 2

TEST SUBSTANCE Analogue of the notified chemical

METHOD Method proposed by the UBA (German Federal Environment Office): "Determination of the swimming ability of the water flea *Daphnia magna*" of May 1984.

Species	*Daphnia magna*
Exposure Period	Not reported
Auxiliary Solvent	None reported
Water Hardness	Not reported
Analytical Monitoring	None reported
Remarks - Method	A preliminary test found that there was 100% mortality of daphnia with 500 mg/L of test substance. Ultrasound (5 min) and Ultraturrax (5 min) were applied to give a fine suspension of the test substance. After 24 hours slight deposits of the test substance were observed. The turbidity of the solution remained unaltered over the course of the test. The number of daphnids used in the test was not reported. The facility was inspected for GLP.

RESULTS

Nominal Concentration mg/L	*% Mortality*
0	0
5.6	0
8.0	0
11.0	15
16.0	20
22.0	25
32.0	30

45.0	35
64.0	50
90.0	60
100.0	75

LC50	Could not be determined
NOEC	Could not be determined
Remarks - Results	The toxic response of daphnia to the reference compounds $K_2Cr_2O_7$ and chloroactamide gave LC50s of 1.1 and 9.5 mg/L, respectively. Effects were observed at a nominal concentration of 11 mg/L and above. The observed mortality was expected to be due to physical effects. Therefore the test is considered invalid (EPHC, 2009).
CONCLUSION	The test is considered invalid and therefore the notified chemical cannot be classified
TEST FACILITY	Henkel (1986j)

C.2.4. Algal growth inhibition test

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 201 Alga, Growth Inhibition Test. EC Directive 92/69/EEC C.3 Algal Inhibition Test.
Species	*Desmodesmus subspicatus*
Exposure Period	72 hours
Concentration Range	Nominal: 0 – 100 mg/L Actual: 0 – 290 µg/L
Auxiliary Solvent	None reported
Water Hardness	Not reported
Analytical Monitoring	LC/MS-MS
Remarks - Method	The test substance was added to dilution water at a loading rate of 100 mg/L and shaken at 20 rpm for 24 hours at room temperature and centrifuged at 3000 rpm for 20 min.

RESULTS

Biomass		*Growth*	
E_bC50	*NOEC*	*E_rC50*	*NOEC*
mg/L at 72 h	*mg/L at 72 h*	*mg/L at 72 h*	*mg/L at 72 h*
> 0.29	*0.29*	*> 0.29*	*0.29*

Remarks - Results	All validity criteria for the test guideline were satisfied. The toxic response of *Desmodesmus subspicatus* to the reference compound $K_2Cr_2O_7$ gave an E_rC50 (72 h) of 0.92 mg/L. No inhibiting effects on specific growth rate and yield were found in the saturated solution of the test substance. It is noted that the actual concentration is much greater than the water solubility of the notified chemical.
CONCLUSION	The notified chemical is not harmful to algae up to the limit of its solubility in water
TEST FACILITY	Dr. U. Noack-Laboratorien (2007c)

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