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**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME
(NICNAS)**

PUBLIC REPORT

Additiv 309

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

For the purposes of subsection 78(1) of the Act, this Public Report may be inspected at our NICNAS office by appointment only at Level 7, 260 Elizabeth Street, Surry Hills NSW 2010.

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

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**Director
NICNAS**

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SUMMARY

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

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS SUBSTANCE	INTRODUCTION VOLUME	USE
LTD/1508	BP Australia Pty Ltd	Amides from N1-(9Z)-9-octadecenyl-1,3-propanediamine and tall oil	ND*	≤1000 kg	Anti-corrosion and lubricant additive in grease formulations for use in the mining, steel and printing industries

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

Based on the available data the notified chemical cannot be classified as hazardous according to the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

The classification of the notified chemical using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations 2009) is presented below.

	<i>Hazard category</i>	<i>Hazard statement</i>
Aquatic environment	Acute Category 3	Harmful to aquatic life
	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 unreasonable risk to the health of workers.

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

Environmental risk assessment

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

Recommendations

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical:
 - Avoid contact with skin and eyes
 - Do not inhale vapours/mists
 - Avoid contact with uncured coatings or overspray
- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical:
 - Respirators
 - Coveralls
 - Gloves
 - Goggles

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

- Where not already contained in the MSDS for products containing the notified chemical, appropriate engineering controls, safe work practices and personal protective equipment to reduce exposure should be recommended on the product MSDS.
- 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.

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;
 - the function or use of the chemical has changed from a component of grease formulations at up to 4%.or
- (2) Under Section 64(2) of the Act; if
 - the function or use of the chemical has changed from a component of grease formulations for industrial use, 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.

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.

ASSESSMENT DETAILS

This notification has been conducted under the cooperative arrangement with the United States Environmental Protection Agency (US EPA). Information pertaining to the assessment of the notified chemical by the US EPA was provided to NICNAS and, where appropriate, used in this assessment report. The other elements of the risk assessment, including the recommendations on safe use of the notified chemical, were carried out by NICNAS.

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: molecular and structural formulae, molecular weight, analytical data and import volume,

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed as follows: water solubility, hydrolysis as a function of pH, adsorption/desorption, dissociation constant, partition coefficient and flammability.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

US EPA PMN: P-04-297

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Optimol Paste White T (imported product containing 3.6% notified chemical)
Optimol Paste White T Spray (imported product containing 1.7% notified chemical)

CAS NUMBER

628723-38-6

CHEMICAL NAME

Amides from N1-(9Z)-9-octadecenyl-1,3-propanediamine and tall oil

OTHER NAME(S)

Optimol Additiv 309 (>90% notified chemical)
Additiv 309 (>90% notified chemical)
Fatty amide derivative (generic name on MSDS)

MOLECULAR WEIGHT

>500 Da.

ANALYTICAL DATA

Reference IR spectrum was provided.

3. COMPOSITION

DEGREE OF PURITY >90%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS

Chemical Name 1,3-propanediamine N1-(9Z)-9-octadecen-1-yl
 CAS No. 7173-62-8 Weight % ≤ 5%
 Hazardous Properties R22, R34, R48/25

Chemical Name Tall Oil
 CAS No. 8002-26-4 Weight % ≤ 5%
 Hazardous Properties R43

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (>1% by weight) None

ADDITIVES/ADJUVANTS None

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Brown liquid

Property	Value	Data Source/Justification
Melting Point/Freezing Point	-17 ±3 °C	Measured
Boiling Point	>400°C at 101.04 kPa	Measured
Density	922 kg/m ³ at 20±0.5°C	Measured
Vapour Pressure	7.7 x10 ⁻⁶ kPa at 25 °C	Measured
Water Solubility	≤2.4 × 10 ⁻¹³ g/L at 25°C	Estimated using WSKOWWIN v1.41a (USEPA 2008)
Hydrolysis as a Function of pH	Not Determined	Expected to be hydrolytically stable in environmental pH range (4-9)
Partition Coefficient (n-octanol/water)	log Pow ≥ 13.5	Estimated using KOWWIN v1.67a (US EPA 2008)
Adsorption/Desorption	Log Koc ≥ 10.0 (MCI Method) Log Koc ≥ 8.3 (Kow Method)	Estimated using KOCWIN v2.00 from MCI and Kow (US EPA 2008)
Dissociation Constant	pKa ~ 9 – 10	Estimated from analogous compounds
Particle Size	Not determined	Liquid
Flash Point	>300 °C	Measured
Flammability	Not highly flammable	Based on measured flash point
Autoignition Temperature	370 ±5°C	Measured
Explosive Properties	Predicted negative	Based on chemical structure
Oxidising Properties	Predicted negative	Based on chemical structure

DISCUSSION OF PROPERTIES

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

Reactivity

The notified chemical is stable under normal conditions of use in air and water.

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 not be manufactured in Australia, but will be imported as a component in finished lubricant grease or spray. It will be present in grease product formulation (product name: Optimol Paste White T) at 3.6% and in the spray product formulation at 1.7% (product name: Optimol Paste White T Spray).

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

<i>Year</i>	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>
<i>Tonnes</i>	<1	<1	<1	<1	<1

PORT OF ENTRY
Sydney

TRANSPORTATION AND PACKAGING

The notified chemical will be imported as a component of finished product formulations in 400 mL (spray), 500g and 5 kg containers and transported by road to end user sites.

USE

The notified chemical will be used as an anti-corrosion and lubricant additive in grease formulations for use in the mining, steel and printing industries. The notified chemical will be present in finished products at <4%. Anti-fretting greases will be used to lubricate press-fitted parts, and allow disassembly when required. The spray formulation containing the notified chemical will be used on printing press frames, to prevent printing ink adhering to the frames.

OPERATION DESCRIPTION

The imported finished products containing the notified chemical at <4% will be distributed only to industrial customers and will only be used on equipment onsite.

For anti-fretting applications the grease product containing the notified chemical will be applied to equipment using a grease gun or lint-free cloth.

In printing press applications, the product will be sprayed onto the printing press frame and any excess will be wiped off with a lint-free cloth.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

<i>Category of Worker</i>	<i>Exposure Duration (hours/day)</i>	<i>Exposure Frequency (days/year)</i>
Import/dock/warehouse workers	1-2	50-100
Pack drivers	2-4	50-100
End users (mining, steel and printing)	2-5	150-200

EXPOSURE DETAILS

Dermal and ocular exposure to the notified chemical at concentrations of <4% in grease products could occur during application and in case of a spill. However, workers in the mining, steel and printing industry are expected to use personal protective equipment (PPE) including gloves, safety goggles and coveralls to minimise the potential for dermal and ocular exposure.

Inhalation exposure is expected during application of the notified chemical in spray products. Product labels and MSDS for products containing the notified chemical advise the use of ventilation and respiratory protection to prevent exposure to other components of the product with occupational exposure limits. Inhalation exposure would be minimised when ventilation and respiratory protection are used.

6.1.2. Public Exposure

The grease products containing the notified chemical and the equipment to which they are applied are not intended for use by the general public. Therefore, the potential for public exposure to the notified chemical is unlikely.

6.2. Human Health Effects Assessment

Based on the molecular weight (>500 Da.), estimated low water solubility ($\leq 2.4 \times 10^{-10}$ mg/L) and estimated high

partition coefficient (≥ 13.5) of the notified chemical, the potential of the notified chemical to cross the gastrointestinal (GI) tract by passive diffusion or to be absorbed dermally or by inhalation is limited.

An acute oral toxicity (fixed dose method) study was conducted on the notified chemical in rats which determined the LD50 > 2000 mg/kg bw (Harlan Laboratories, 2010). There were no mortalities or systemic effects reported in the study.

The notified chemical contains functional groups (secondary amines) that are associated with burns and irritation (Hulzebos et al., 2005). The notified chemical has been classified by the notifier with R41 Risk of serious eye damage and R38 Irritating to skin.

In addition, the notified chemical contains a hazardous residual monomer/impurity (tall oil) at a concentration up to 5%, which may result in sensitisation by skin contact.

Health hazard classification

Based on the available data the notified chemical cannot be 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

The main risks to workers using products containing the notified chemical at <4% are expected to be the potential for skin sensitisation and irritation. However, these risks are expected to be minimised by the use of ventilation and PPE, including respiratory protection, gloves, safety goggles and coveralls. The risk of irritation is expected to be further minimised by the low concentration of the notified chemical in the products workers will be exposed to.

Provided that control measures are in place to minimise worker exposure, including the use of ventilation and the wearing of PPE when using products containing the notified chemical, the risk to the health of workers from use of the notified chemical is not considered to be unreasonable.

6.3.2. Public Health

Products containing the notified chemical and equipment which the products will be applied to are not intended for use by the general public. Therefore, given the unlikely potential for exposure, the risk to public health from the notified chemical is not considered to be unreasonable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified chemical will not be manufactured in Australia but will be imported as a component of finished products including grease and spray for use in the mining, steel and printing industries. The notified chemical will be present in the finished products at <4% concentration. There will not be any repackaging or reformulation of the notified chemical in Australia. Therefore, no release of the notified chemical to the environment from these activities is expected.

RELEASE OF CHEMICAL FROM USE

During the application of the grease product formulation to equipment, there is possibility of accidental spillage. Any spilled products containing the notified chemical would be highly viscous and easily cleaned up. There is a possibility of release of the notified chemical during spray application to printing press frames. Any overspray or excess spray will be wiped off with a lint-free cloth. It is unlikely that any significant amount will be released to the environment during use in industrial settings. The majority of notified chemical is expected to share the same fate as equipments and frames and eventually be disposed of to landfill at the end of their useful lives.

RELEASE OF CHEMICAL FROM DISPOSAL

Residual amount of the notified chemical in the empty drums or containers is estimated to be <1% of the

imported volume and is expected to be removed by washing with mineral oil at the industrial facilities for proper disposal or reuse. Waste product on lint-free cloth would be disposed of to landfill. Any collected wastes are expected to be disposed of in accordance to local and national regulations.

7.1.2. Environmental Fate

One study submitted by the notifier indicates the notified chemical is not readily biodegradable. The notified chemical is not expected to be bio-available to aquatic organisms due to its low water solubility. The notified chemical is not expected to bioaccumulate based on its very high partition coefficient ($\log K_{ow} > 12$) and high molecular weight. Most of the notified chemical will be either decomposed during use as a grease formulation or when disposed of to landfill by association with greased articles at the end of their useful life. A small amount of the notified chemical is expected to be sent to landfill as residues in containers or as a component of waste product. Notified chemical sent to landfill or spilt on the ground is expected to sorb strongly to soil and sediment. It is anticipated to ultimately be degraded into water and oxides of carbon and nitrogen by decomposition in industrial settings or by natural processes in landfill. Details of the environmental fate study are included in Appendix C.

7.1.3. Predicted Environmental Concentration (PEC)

A predicted environmental concentration (PEC) was not determined since, based on the reported use pattern, the notified chemical is not expected to be released to the aquatic environment.

7.2. Environmental Effects Assessment

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

<i>Endpoint</i>	<i>Result</i>	<i>Assessment Conclusion</i>
Daphnia Toxicity	48 h EL50 >10 and <100 mg/L	The notified chemical is harmful to aquatic invertebrates

Under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS; United Nations, 2009) the notified chemical is harmful to aquatic invertebrates based on the ecotoxicity study for *Daphnia magna*, and is formally classified as 'Acute Category 3: Harmful to aquatic life'.

The notified chemical is considered harmful with long lasting effects to aquatic invertebrates. On the basis of its acute toxicity to daphnia with $EL50 \leq 100$ mg/L and not being readily biodegradable, the notified chemical is formally classified under the GHS as 'Chronic Category 3: Harmful to aquatic life with long lasting effects'.

7.2.1. Predicted No-Effect Concentration

The predicted no-effect concentration (PNEC) has not been calculated for the notified chemical as, based on its assessed use pattern, ecotoxicologically significant quantities are not expected to be released to the aquatic environment.

7.3. Environmental Risk Assessment

A Risk Quotient ($Q = PEC/PNEC$) has not been calculated since neither a PEC nor PNEC has been determined. The notified chemical is not expected to be released to the aquatic environment in ecotoxicologically significant concentrations based on its low import volume and its reported use pattern as a component in grease formulation. The notified chemical is not expected to be readily biodegradable, but it is not expected to bioaccumulate. Based on the low import volume and assessed use pattern, the notified chemical is not expected to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Melting Point/Freezing Point $-17 \pm 3^{\circ}\text{C}$

Method OECD TG 102 Melting Point/Melting Range.
 Remarks BS 2000: Part 15 (equivalent to ISO 3016) designed to be compatible with OECD TG 102
 Test Facility Harlan Laboratories (2011a)

Boiling Point 400°C at 101.04 kPa

Method OECD TG 103 Boiling Point.
 Remarks Determined by differential scanning calorimetry
 Test Facility Harlan Laboratories (2011a)

Density 922 kg/m^3 at $20 \pm 0.5^{\circ}\text{C}$

Method OECD TG 109 Density of Liquids and Solids.
 Remarks Determined by pycnometer
 Test Facility Harlan Laboratories (2011a)

Vapour Pressure $7.7 \times 10^{-6} \text{ kPa}$ at 25°C

Method EC Council Regulation No 440/2008 A.4 Vapour Pressure.
 Remarks Determined by vapour pressure balance
 Test Facility Harlan Laboratories (2011b)

Water Solubility $\leq 2.4 \times 10^{-13} \text{ g/L}$ at 25°C

Method EPI Suite WSKOWWIN, version 1.41
 Remarks No determination was possible according to OECD Method 105 as the notified chemical is a complex reaction mixture and viscous liquid. In an attempt of the flask method, final sample filtrates were unsuitable for analysis due to presence of a significant suspension of excess, undissolved notified chemical. Therefore, water solubility was estimated for the least hydrophobic component of the UVCB substance by WSKOWWIN, version 1.41 (US EPA 2008)
 Test Facility Harlan Laboratories Ltd (2011a)

Hydrolysis as a Function of pH Estimated as stable

Method OECD TG 111 Hydrolysis as a Function of pH.
 Remarks No determination was possible according to OECD TG111 method due to poor water solubility of the notified chemical. The hydrolysis was estimated for the least hydrophobic component of the UVCB substance by HYDROWIN, version 2.00 (US EPA 2008)
 Test Facility Harlan Laboratories Ltd (2011a)

Partition Coefficient (n-octanol/water) $\log \text{Pow} \geq 13.5$ at 20°C

Method OECD TG 107 Partition Coefficient (n-octanol/water): Shake Flask Method
 OECD TG 117 Partition Coefficient (n-octanol/water). HPLC Method
 Remarks No determination was possible according to OECD Methods TG 107 or 117 due to poor water solubility and the surfactant nature of the notified chemical. The limit value was estimated for the least hydrophobic component of the UVCB substance by KOWWIN, version 1.67 (US EPA 2008)
 Test Facility Harlan Laboratories Ltd (2011a)

Adsorption/Desorption $\log K_{oc} \geq 10.0$ at 20°C (MCI Method) $\log K_{oc} \geq 8.3$ at 20°C (Kow Method)

Remarks No determination was possible according to OECD Method 121 because the notified chemical was insoluble in water. The limit value was estimated for the least hydrophobic component of the UVCB substance by KOCWIN, version 2.00 (US EPA 2008)

Test Facility Harlan Laboratories Ltd (2011)

Dissociation Constant Estimated pKa ~9 - 10

Remarks No determination was possible according to OECD Method 112 because OECD Method 112 is not appropriate for complex reaction mixtures. Therefore, predicted pKa value of ~9.9-10.4 was calculated using ACD/1-Lab Web Service. The estimated pKa is consistent with analogous chemicals containing the same functional group (pKa ~9 - 10).

Test Facility Harlan Laboratories Ltd (2011a)

Flash Point >300°C

Method EC Council Regulation No 440/2008 A.9 Flash Point.

Remarks Determined by closed cup equilibrium method

Test Facility Harlan Laboratories (2011b)

Autoignition Temperature 370 ±5°C

Method EC Council Regulation No 440/2008 A.15 Auto-Ignition Temperature (Liquids and Gases).

Test Facility Harlan Laboratories (2011b)

Explosive Properties Not predicted to be explosive

Method Method compatible with EC Council Regulation No 440/2008 A.14 Explosive Properties.

Test Facility Harlan Laboratories (2011b)

Oxidizing Properties Not predicted to be oxidizing

Method Method compatible with EC. 440/2008 A.21 Oxidizing Properties (Liquids)

Test Facility Harlan Laboratories (2011b)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS**B.1. Acute toxicity – oral**

TEST SUBSTANCE	Notified chemical														
METHOD	OECD TG 420 Acute Oral Toxicity – Fixed Dose Procedure. EC Council Regulation No 440/2008 B.1 bis Acute toxicity (oral) fixed dose method.														
Species/Strain	Rat/Female Wistar (HsdRccHan [®] TM;WIST [®] TM)														
Vehicle	Arachis oil														
Remarks - Method	The test substance was administered via oral gavage.														
RESULTS	<table> <tr> <th><i>Group</i></th><th><i>Number and Sex of Animals</i></th><th><i>Dose mg/kg bw</i></th><th><i>Mortality</i></th></tr> <tr> <td>I</td><td>1 female</td><td>300</td><td>0</td></tr> <tr> <td>II</td><td>5 female</td><td>2000</td><td>0</td></tr> </table>			<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Dose mg/kg bw</i>	<i>Mortality</i>	I	1 female	300	0	II	5 female	2000	0
<i>Group</i>	<i>Number and Sex of Animals</i>	<i>Dose mg/kg bw</i>	<i>Mortality</i>												
I	1 female	300	0												
II	5 female	2000	0												
LD50	2000 mg/kg bw														
Signs of Toxicity	No signs of systemic toxicity were observed.														
Effects in Organs	No abnormalities were noted at necropsy/														
Remarks - Results	At 2000 mg/kg 4 animals displayed hunched posture at the day of dosing, 1 animal displayed pale faeces.														
CONCLUSION	The notified chemical is of low toxicity via the oral route.														
TEST FACILITY	Harlan Laboratories (2010)														

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 domestic sewage treatment plant
Exposure Period	47 days
Auxiliary Solvent	None
Analytical Monitoring	CO ₂ evolution
Remarks - Method	Conducted in accordance with the guidelines above. No significant deviations were recorded. The test concentration was added to inoculated culture medium to give a final concentration of 13 mg carbon/L. The test was carried out in a temperature controlled room at approximately 21°C in low light conditions. A sodium benzoate control and toxicity control were run in parallel

RESULTS

<i>Test substance</i>		<i>Sodium Benzoate</i>	
<i>Day</i>	<i>%Degradation</i>	<i>Day</i>	<i>%Degradation</i>
8	8 (7)*	8	73
14	20 (20)	14	80
28	34 (38)	28	96
42	40 (55)	42	100
47	41 (66)	47	100
48	43 (69)	48	100

*second replicate

Remarks - Results	The notified chemical is not readily biodegradable. The 60% pass rate was reached in the 2 nd replicate after 46 days, but not reached in the first replicate. The mean biodegradation rate after 47 days was 56%. The total CO ₂ evolution in the inoculum control at the end of the test was 40.9 mg CO ₂ /L after 28 days and 86.3 mg CO ₂ /L after 47 days (validity criterion: <70 mg CO ₂ /L after 28 days). The validity criteria were fulfilled as the degradation of functional control reached the pass level of ≥60% by day 14.
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CONCLUSION	The notified chemical cannot be classified as ready biodegradable.
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TEST FACILITY	Dr. U. Noack-Laboratorien (2009a)
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C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 202 <i>Daphnia</i> sp. Acute Immobilisation Test and Reproduction Test – 48 h, static, fresh water EC Directive 92/69/EEC C.2 Acute Toxicity for <i>Daphnia</i>
Species	<i>Daphnia magna</i>
Exposure Period	48 hours
Auxiliary Solvent	None reported

Water Hardness	250 mg CaCO ₃ /L
Analytical Monitoring	None
Remarks - Method	<p>Due to low water solubility and complex nature of the notified chemical, the Water Accommodated Fraction (WAF) of the required concentration was used. The WAF is prepared by weighing of each nominal load, 24 hour shaking with the required amount of dilution water for testing and subsequent membrane filtration. The test organisms were exposed to the WAF. Exposures are expressed in terms of the original concentration of the notified chemical in water at the start of the mixing period (loading rate) irrespective of the actual concentration of notified chemical in the WAF.</p> <p>Daphnia (20 = 4 replicates of 5 animals) were exposed to a WAF of the notified chemical, at nominal loading rate of 1, 10 and 100 mg/L for 48 h. Test conditions were: 20°C±2°C, pH 7.6 -7.8 under static test conditions. Immobilisation and any adverse reactions to exposure were recorded after 24 hours.</p>

RESULTS

Concentration mg/L		Number of <i>D. magna</i>	Number Immobilised in	
Nominal	Actual		24 h [%]	48 h [%]
Control	ND	20	0	5
1	ND	20	0	0
10	ND	20	0	0
100	ND	20	50	100

ND = Not detectable

EL50	>10 and <100 mg/L at 48 h
NOEL	10 mg/L at 48 h (WAF)
Remarks - Results	For the validity criteria to be fulfilled, 24h EC50 of the reference substance, potassium dichromate should be between 0.6 to 2.1 mg/L. In this reference test, 24 h EC50 of potassium dichromate was 1.8 mg/L.

CONCLUSION The notified chemical is harmful to *Daphnia magna*.

TEST FACILITY LAUS Gmbh – Prüfbericht (2009)

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- Harlan Laboratories Ltd (2010) Additiv 309: Acute Oral Toxicity in the Rat – Fixed Dose Method. Project Number: 0334/0177. Derbyshire, UK (21 April 2010) (Unpublished report submitted by notifier.)
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