File No: LTD/1831

October 2015

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Chemical in Kauropal 936 Liquid

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (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 conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of the Environment.

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

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

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Director
NICNAS

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SUMMARY

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

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
LTD/1831	BASF Australia Ltd	Chemical in Kauropal 936 Liquid	Yes	≤ 1 tonne per annum	Component of decorative panels

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available information, the notified chemical is recommended for classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia. The hazard classification is presented in the table below.

Hazard classification	*Hazard statement*
Skin corrosion / irritation Category 2	H315 - Causes skin irritation
Serious eye damage / eye irritation Category 2A	H319 - Causes serious eye irritation

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

R38: Irritating to skin
R36: Irritating to eyes

The environmental hazard classification according to the *Globally Harmonised System of 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 Toxicity (Category 2) Chronic Aquatic Toxicity (Category 3)	H401 - Toxic to aquatic life H412 – 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 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:
  - Skin corrosion / irritation (Category 2): H315 – Causes skin irritation

- Serious eye damage / eye irritation (Category 2A): H319 – Causes serious eye irritation

The above should be used for products/mixtures containing the notified chemical, if applicable, based on the concentration of the notified chemical present and the intended use/exposure scenario.

CONTROL MEASURES

Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical as introduced:
  - Avoid skin contact
  - Avoid eye contact

- A person conducting a business or undertaking at a workplace should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical as introduced, if skin or eye contact is likely to occur:
  - Safety goggles
  - Gloves

  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 of 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

- Where reuse or recycling are unavailable or impracticable, dispose of the chemical in an environmentally sound manner in accordance with relevant Commonwealth, State, Territory and local government legislation.

Emergency procedures

- Spills or accidental release of the notified chemical should be handled by containment, physical 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;
  - further information becomes available regarding the eye irritation potential of the notified chemical.

or

(2) Under Section 64(2) of the Act; if

- the function or use of the chemical has changed from a component of decorative panels, or is likely to change significantly;
- the amount of chemical being introduced has increased, 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.

(Material) Safety Data Sheet

The (M)SDS of the product containing the notified chemical provided by the notifier was reviewed by NICNAS. The accuracy of the information on the (M)SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
BASF Australia Ltd (ABN: 62 008 437 867)
Level 12, 28 Freshwater Place,
Southbank, VIC 3006

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: chemical name, other names, CAS number, molecular and structural formulae, molecular weight, analytical data, degree of purity, residual/impurities, site of reformulation and import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed for hydrolysis as a function of pH, particle size, dissociation constant and explosive and oxidising properties.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
Europe, China and Japan.

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Kauropal 936 Liquid (product containing the notified chemical)

MOLECULAR WEIGHT
< 500 Da

ANALYTICAL DATA
Reference NMR, IR, GC, GC-MS, UV spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
>90 %

ADDITIVES/ADJUVANTS
None

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: White powder or granules

Property	Value	Data Source/Justification
Melting Point	48-164 °C	Measured
Boiling Point	Evaporates or decomposes from 203°C	Measured
Density	1135 kg/m^3 at 20 °C	Measured
Vapour Pressure	≤ 19x10^{-3} kPa at 20 °C	Measured
Water Solubility	46.61 g/L at 20 °C	Measured

Hydrolysis as a Function of pH	Not Determined.	The notified chemical contains hydrolysable functionality, although hydrolysis is expected to occur very slowly within the environmental pH range of 4-9
Partition Coefficient (n-octanol/water)	log Pow = -0.69 at 20 °C	Calculated. The notified chemical is a surfactant and will tend to accumulate at the phase interface of octanol and water
Adsorption/Desorption	log K_{oc} = 3.515 – 3.912 at 25 °C	Calculated
Dissociation Constant	Not Determined.	The notified chemical is a salt and is expected to be ionised in the environmental pH range of 4 – 9.
Surface Tension	34.5 mN/m	Measured
Particle Size	Not determined	The notified chemical will not be isolated from solution.
Solid Flammability	Not flammable	Measured
Autoignition Temperature	278 °C	Measured
Explosive Properties	Not determined	Based on the structure, the notified chemical is not expected to be explosive
Oxidising Properties	Not determined	Based on the structure, the notified chemical is not expected to have oxidising 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.

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 of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will be imported as an aqueous solution at < 0.5% concentration.

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

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

PORT OF ENTRY
Melbourne

IDENTITY OF MANUFACTURER/RECIPIENTS
BASF Australia Ltd
Level 12, 28 Freshwater Place
Southbank VIC 3006

TRANSPORTATION AND PACKAGING
The notified chemical will not be manufactured in Australia. It will be imported as a component of an aqueous solution by sea in 1000 litre intermediate bulk containers (IBC) and transported by road for storage at a third party contracted warehouse in Laverton North for storage. The product containing the notified chemical will then be transported by road to the customer for reformulating and end use.

USE
The notified chemical will be used as an additive for the production of decorative panels.

OPERATION DESCRIPTION
The notified chemical will not be manufactured in Australia. It will be imported in solution at < 0.5% and delivered to end-users for reformulation.

At the end-use site, the plant operators will transfer the imported product to the bulk storage tank using a hose system. The product containing the notified chemical will be pumped from this bulk storage tank to a large bath which is kept under negative pressure by an exhaust canopy, where it will be mixed with other ingredients. Operators will take a sample that has < 0.05 % of the notified chemical for testing. Decorative paper is dipped into the bath and then hot pressed onto fibreboard which will be used in domestic (kitchen) and commercial (office furniture) applications. In the hot press, the product is reacted and solidifies to create an inert plastic decorative surface. The final laminated panel products will be sold to furniture fabricators across the country, who will convert the decorative sheets into kitchen or commercial furniture.

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)*
Storage and transport personnel	1	12
Warehouse personnel	1	20
Plant operators	0.5-1	50-70
Furniture fabricators	4-8	100-200

EXPOSURE DETAILS
Transport and storage
Dermal and ocular exposure of transport, warehouse, and storage workers to the notified chemical at < 0.5% is not expected except in the event of accidental spill or breach of packaging.

Formulation
Dermal and ocular exposure to the notified chemical (concentration < 0.5%) is possible from direct contact with drips, spills and splashes during the connection and disconnection of the IBC to the hose transfer system to the bulk storage tank. However, exposure to the notified chemical will be minimised as workers are expected to wear personal protective equipment (PPE) including gloves and goggles. Inhalation exposure to the notified chemical it is not expected as the notified chemical is not volatile and aerosols are not expected to be generated.

Workers may be exposed to the product in the bath at very low concentration only (< 0.05%). Operator exposure to the notified chemical after the hot pressing of decorative paper to the fibreboard is expected to be negligible as the inert plastic decorative coating containing the notified chemical is cured.

End-Use
Furniture fabricators will have potential dermal exposure to the notified chemical when handling and cutting the laminated panels containing the notified chemical, prior to installation in domestic (kitchen) and industrial (office furniture) applications. As the notified substance is part of the cured decorative panel coating, there is likely to be negligible exposure.

6.1.2. Public Exposure
The product containing the notified chemical will only be for industrial use and not be sold to the general public. The general public may have contact with final laminated surfaces containing the notified chemical (such as

doors, kitchen benchtops or furniture) However the notified chemical will be trapped within the final resin mass which will be cured and therefore it is not expected to be bioavailable.

6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on analogues of the notified chemical are summarised in the following table. For full details of the studies, refer to Appendix B.

Endpoint	*Analogue*	*Result and Assessment Conclusion*
Rat, acute oral toxicity	2	LD50 >5000 mg/kg bw; low toxicity
Rat, acute dermal toxicity	3	LD50 >2000 mg/kg bw; low toxicity
Rabbit, skin irritation	4	irritating
Bovine Corneal Opacity and Permeability Test (BCOP), eye irritation	1	severely irritating
BCOP Modified surfactant protocol versus surfactant protocol, eye irritation	1	not severely irritating
Guinea pig, skin sensitisation	4	no evidence of sensitisation
Mutagenicity – bacterial reverse mutation	4	non mutagenic
Genotoxicity – in vivo micronucleus	1	non genotoxic

No toxicity data were submitted on the notified chemical. The notified chemical contains a functional group indicating a structural alert for corrosion/irritation.

Acute toxicity

Based on the analogue acute toxicity results, the notified chemical is expected to be of low acute oral and dermal toxicity.

Skin irritation

Based on a skin irritation study on an analogue, the notified chemical is expected to be irritating to the skin, and to meet the criteria for classification.

Eye irritation

The BCOP studies described in Appendix B were carried out using varying protocols and concentrations of Analogue 1. This test method can be used to classify chemicals as severe eye irritants (Category 1). However, using the protocol considered most relevant for the notified chemical (the surfactant method for solids as described in OECD TG437) the analogue did not meet the criteria for this classification.

Analogue 1 showed eye irritation potential at 100% but not at 25% in an EpiOcular study. This test method does not differentiate between different classification classes. The study authors stated that the results showed an eye irritation potential, and that the result of this test does not exclude a serious eye irritation potential. Analogue 1 at 55% was described in an IUCLID summary as not irritating to eyes based on an *in vivo* (OECD TG 405) study on two animals only. Detailed scores were not provided.

Based on available information on analogues (including some data that is considered exempt information), the notified chemical is expected to be irritating to eyes, and to warrant classification at least as Category 2A. The potential for classification as a Class 1 eye irritant cannot be ruled out.

The notifier has classified the chemical under the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)* as Eye Damage Category 1 and under the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004) as R41 (Risk of serious damage to eyes).

Other endpoints

Based on studies on analogues, the notified chemical is not expected to be a skin sensitiser and not to be mutagenic or genotoxic.

Health hazard classification
Based on the available information, the notified chemical is recommended for hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)*, as adopted for industrial chemicals in Australia. The hazard classification is presented in the table below.

Hazard classification	*Hazard statement*
Skin corrosion / irritation Category 2	H315 - Causes skin irritation
Serious eye damage / eye irritation Category 2A	H319 - Causes serious eye irritation

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 phrases:
R38: Irritating to skin
R36: Irritating to eyes

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety
The notified chemical is expected to be a skin and eye irritant. However, at the low concentration in the introduced product (<0.5%) these effects are expected to be very much reduced. The notifier has stated that formulation workers are expected to wear personal protective equipment to limit skin and eye contact. In addition, safe work practices are recommended in the product (M)SDS. Once incorporated in the final decorative board, worker exposure is not expected. Therefore the risk to workers presented by the notified chemical is not considered to be unreasonable.

6.3.2. Public Health
The product containing the notified chemical will not be available to the general public. The general public may have contact with final laminated surfaces containing the notified chemical at very low concentration, however in this form the notified chemical will be incorporated into the final resin mass and is not expected to be bioavailable. Therefore the risk to the public from use of 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; therefore, there will be no release from this activity. Environmental release during importation, transport and distribution may occur as a result of accidental spills. In the event of a spill, the notified chemical is expected to be contained and collected and is expected to be sent to a licensed off site waste disposal centre which is most likely to be disposed of to landfill.

Resin containing the notified chemical will be recycled back into the paper treating process, therefore, none of the notified chemical is sent to waste. Wash-down water will be captured on site and evaporated, with any solids disposed of via a licensed waste contractor.

After the product containing the notified chemical is pumped into storage tanks for production use, any residual chemical (< 0.1%) will be washed out. The wash-down water will be pumped into evaporative ponds. Any solids left after evaporation will be taken off-site by a licensed waste contractor. The empty washed out product IBCs are expected to be used to store waste resin (notified chemical is not present in this resin) for contractor disposal.

RELEASE OF CHEMICAL FROM USE
The end use for the product containing the notified chemical is expected to be an additive in paper impregnating resins. The resin impregnated decorative paper will be hot pressed onto fibreboard and the panels are expected to be used in domestic (kitchen) and commercial (office furniture) applications. In the hot press, the product

will react with paper saturating resin and the total resin mass solidifies to create an inert plastic decorative surface.

No release of the notified chemical is anticipated once the resin mass solidifies and is incorporated into the inert plastic decorative surface. Domestic and commercial furniture articles are most likely to end up in landfill at the end of their useful life.

RELEASE OF CHEMICAL FROM DISPOSAL
The empty IBCs will be rinsed out and then used to store waste resin (does not contain the notified chemical) before disposal via licensed waste disposal contractor. Waste domestic and commercial furniture articles containing the notified chemical in the cured resin will be disposed of to landfill.

7.1.2. Environmental Fate

The product containing the notified chemical is expected to be readily biodegradable based on a biodegradation study provided for an acceptable analogue. Therefore, the notified chemical is expected to rapidly biodegrade and is not expected to persist in the environment. Bioaccumulation of the notified chemical in organisms is not expected due to the expected water solubility and hydrophilicity of the notified chemical. For the details of the environmental fate study, please refer to Appendix C.

The majority of the notified chemical is expected to adhere to the surface to which it is applied. Treated articles and other dried residues containing the notified chemical are expected to ultimately be disposed of to landfill. When associated with the article to which the product containing the notified chemical has been applied, the notified chemical is not likely to be mobile or bioavailable in landfill.

However, some of the notified chemical may be released to sewer during reformulation, use and disposal. In general, surfactants have the potential to be removed from influent in sewage treatment plants (STP) via partitioning to phase boundaries. Notified chemical released to surface waters is expected to partition to suspended solids and organic matter, or to disperse and degrade. Consequently, the notified chemical is not expected to be significantly bioavailable. The potential for the notified chemical to bioaccumulate is low based on its surfactant properties and degradability. Due to the expected dispersibility and solubility of the notified chemical in water, there is a potential of leaching in landfill. However, most of the notified chemical is expected to be disposed of to landfill after being dried or cured into solids and trapped in the paint matrix, in which case leaching is unlikely to occur. In landfill, the notified chemical is expected to ultimately undergo biotic or abiotic degradation, forming water and oxides.

7.1.3. Predicted Environmental Concentration (PEC)

The calculation of the PEC is not considered necessary since no significant release of the notified chemical to the aquatic environment is expected.

7.2. Environmental Effects Assessment

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

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity (96 h)	LC50 = 5.2 mg/L	Toxic to fish
Algal Toxicity (72 h)	E_rC50 = 30-34 mg/L	Harmful to algae
Daphnia Toxicity	7 d NOEC = 0.2 mg/L	Harmful to aquatic invertebrates

Under the Globally Harmonised System of Classification and Labeling of Chemicals (United Nations, 2009) the notified chemical, based on its similarity to the analogue chemical, is expected to be toxic to aquatic invertebrates. Therefore, the notified chemical is formally classified as “Acute Category 2; Toxic to aquatic life” under the GHS. The notified chemical is expected to be readily biodegradable. Therefore, based on the chronic test result for daphnia, the notified chemical is formally classified as “Chronic category 3; Harmful to aquatic life with long lasting effects” under the GHS.

7.2.1. Predicted No-Effect Concentration

It is not considered necessary to calculate the PNEC since no significant release of the notified chemical to the aquatic environment is expected from the proposed use pattern.

7.3. Environmental Risk Assessment

The Risk Quotient (Q = PEC/PNEC) has not been calculated since no significant release of the notified chemical to the aquatic environment is expected from the assessed use pattern.

The majority of the imported notified chemical will be trapped in the inert coating matrix after application to decorative paper that will be hot pressed onto fibreboard and the panels expected to be used in domestic and commercial applications. In this form the notified chemical is not expected to leach or be bioavailable. Therefore, on the basis of limited aquatic exposure and the assessed use pattern, the notified chemical is not considered to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Melting Point 48-164 °C

Method	OECD TG 102 Melting Point/Melting Range. EC Council Regulation No 440/2008 A.1 Melting/Freezing Temperature.
Remarks	DSC (differential scanning calorimetry) method. The test substance shows a melting area of crystalline components between 48 and 164 °C in the 1st to 4th heating run. The mean value was 48-164 °C. From 210 °C the test substance showed evaporation and/or thermal decomposition.
Test Facility	Henkel AG & Co. KGaA (2009a)

Boiling Point 203 °C at 103.8 kPa

Method	OECD TG 103 Boiling Point. EC Council Regulation No 440/2008 A.2 Boiling Temperature.
Remarks	DSC (differential scanning calorimetry) method which was confirmed by the thermos gravimetric analyses (TGA). The boiling and/or thermal decomposition occurred at approximately 203 °C.
Test Facility	Henkel AG & Co. KGaA (2009b)

Density 1135 kg/m3 at 20 °C

Method	OECD TG 109 Density of Liquids and Solids. EC Council Regulation No 440/2008 A.3 Relative Density.
Remarks	The relative density was determined using the pycnometer method.
Test Facility	Henkel AG & Co. KGaA (2015)

Vapour Pressure $\leq 19 \times 10^{-3}$ kPa at 20 °C

Method	OECD TG 104 Vapour Pressure. EC Council Regulation No 440/2008 A.4 Vapour Pressure.
Remarks	The vapour pressure was measured according to the dynamic method. As the experimentally determined pressure was not in the recommended range, an estimation method was used instead. The calculation was based on the lowest possible boiling temperature (203 °C).
Test Facility	Henkel AG & Co. KGaA (2009c)

Water Solubility 46.61 g/L at 20 °C

Method	OECD TG 105 Water Solubility.
Remarks	Flask Method. The pH value of the aqueous solutions varied from 10.01 to 10.05. Samples were placed in an incubator (30°C) /shaker and were removed after 24, 48, and 72 hours. Samples were then placed at room temperature storage for at least 24 hours to equilibrate prior to analysis by HPLC. Each study sample were analysed in duplicate.
Test Facility	Henkel AG & Co. KGaA (2012)

Solid Flammability Not flammable

Method	EC Council Regulation No 440/2008 A.10 Flammability (Solids).
Remarks	In the preliminary test, there was propagation over a distance of 200 mm during 222 seconds, therefore a full burning test was performed. In 6 runs of the full test, the shortest time to propagate burning for a 100 mm powder train was 85 seconds. As this is longer than the limit of 45 seconds, the test substance was not considered to be flammable.
Test Facility	Henkel AG & Co. KGaA (2012b)

Autoignition Temperature 278 °C

Method	EC Council Regulation No 440/2008 A.16 Relative Self-Ignition Temperature for Solids.
Remarks	The test substance reached 400 °C by self heating.

Test Facility	Henkel AG & Co. KGaA (2012c)

Surface Tension 34.5 mN/m at 21 °C

Method	OECD TG 115 Surface Tension of Aqueous Solutions. EC Council Regulation No 440/2008 A.5 Surface Tension.
Remarks	Concentration was 1000 mg/L in accordance with the test method and the water solubility (45 g/L). The sample was dissolved in water at 20 °C. The measurement was initiated and completed after 264 seconds.
Test Facility	Henkel AG & Co. KGaA (2012d)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE: Analogue 2

METHOD
- Species/Strain: Rat/Wistar
- Vehicle: Suspension in water
- Remarks - Method: A translation of the test report was provided. The calculation of the test results was performed according to the method of J.T. Litchfield and F. Wilcoxon, J. Pharm. Exptl. Ther. 96, 99-108 (1949).
  The chemical was supplied as a 50% solution. This was taken into account in calculating dosage.
  Observation period: 14 Days after administration.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	10 M	3980	1/10
2	10 M	5010	3/10
3	10 M	5320	5/10
4	10 M	5630	6/10
5	10 M	6250	7/10

- LD50: 5500 mg/kg bw
- Signs of Toxicity: In all test groups diarrhoea, vocalisation, piloerection and accelerated breathing were observed after two hours of the treatment but cleared after 24 hours, except diarrhoea remained
- Effects in Organs: No abnormality was detected in the necropsy findings in all dose groups except a mild oedema in one animal in the 3980 mg/kg bw dose group.
- Remarks - Results

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

TEST FACILITY: BASF SE (1982)

B.2. Acute toxicity – dermal

TEST SUBSTANCE: Analogue 3

METHOD: OECD TG 402 Acute Dermal Toxicity.
EC Council Regulation No 440/2008 B.3 Acute Toxicity (Dermal).
- Species/Strain: Rat/Wistar
- Vehicle: Solution in deionised water (35 g/L)
- Type of dressing: Semi-occlusive.
- Remarks - Method: A limit test was used. A single application was made to the clipped epidermis (dorsal and dorsolateral parts of the trunk) covered with semi-occlusive dressing for 24 hours. After removal of the semi-occlusive dressing, the application site was rinsed with warm water.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	5 M	2000	0
2	5 F	2000	0

- LD50: >2000 mg/kg bw

Signs of Toxicity - Local	No local effects were observed
Signs of Toxicity - Systemic	No mortality occurred. No systemic clinical signs were observed.
Effects in Organs	None
Remarks - Results	Mean body weight of the male animals increased normally throughout the study period. The mean body weight of the female animals did not significantly change during the first post-exposure observation week (the author considered that this was probably due to the bandage procedure), but increased during the second week within the normal range.

CONCLUSION The chemical is of low toxicity via the dermal route.

TEST FACILITY Bioassay (2012)

B.3. Irritation – skin

TEST SUBSTANCE Analogue 4 (at 88.7%)

METHOD OECD TG 404 Acute Dermal Irritation/Corrosion.
EC Directive 2004/73/EC B.4 Acute Toxicity (Skin Irritation).

Species/Strain	Albino Rabbit/New Zealand White
Number of Animals	3 M
Vehicle	The powder was ground and moistened with distilled water before application.
Observation Period	1, 24, 48 and 72 hours and 7 and 14 days after the removal of the test substance.
Type of Dressing	Occlusive.
Remarks - Method	

RESULTS

Lesion	*Mean Score* Animal No.*			*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3			
Erythema/Eschar	2	3	4	4	<14 days	0
Oedema	1.7	2.3	3.0	3	<14 Days	0

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

Remarks - Results A maximum of grade 2 was observed in one animal for erythema and oedema during the course of the study. The skin irritation was resolved within 7 days after exposure in this animal. In the other two animals signs of necrosis (grey/brown discolouration of the treated skin became apparent within 24 hours and erythema grade 4 and oedema grade 3 had developed within 24-72 hours after exposure. The skin reactions resulted in reduced flexibility and fissuring of the skin in one animal. Scaliness was noted in one animal at 7 days, resolving by 14 days. Erythema and oedema had resolved within 14 days after exposure in both animals. However bald skin remained in one animal at the end of the observation period.

The study authors stated that there was no evidence of corrosion effects on the skin.

CONCLUSION The chemical is irritating to the skin.

TEST FACILITY Notox B.V. (1994)

B.4. Irritation – eye (in vitro)

TEST SUBSTANCE Analogue 1 (20%)

METHOD OECD TG 437 Bovine Corneal Opacity and Permeability Test Method for Identifying Ocular Corrosives and Severe Irritants

Vehicle Deionised water

Remarks - Method Assessment of the potential test substance to cause serious damage to isolated bovine corneas.
Two tests were performed as the prediction was not clearly identified in all corneas in test one.
Deionised water was used as negative control and 20% imidazole in deionised water as positive control.
Three corneas per test run were treated with a 20% test substance in deionised water for an exposure of four hours (protocol for non-surfactant solids).

RESULTS

Test 1

Test material	*Mean opacities of triplicate tissues (SD)*	*Mean permeabilities of triplicate tissues (SD)*	*IVIS (SD)*
Vehicle control	1.4 (1.0)	0 (0.005)	1.4 (1.1)
*Test substance**	1.6 (0.8)	4.476 (1.479)	68.8 (21.7)
*Positive control**	65.6 (10.7)	2.666 (0.745)	105.6 (3.3)

SD = Standard deviation; IVIS = in vitro irritancy score
*Corrected for background values

Test 2

Test material	*Mean opacities of triplicate tissues (SD)*	*Mean permeabilities of triplicate tissues (SD)*	*IVIS (SD)*
Vehicle control	4.4 (2.7)	-0.004 (0.002)	4.4 (2.7)
*Test substance**	-1.7 (1.4)	5.980 (0.579)	88.0 (7.4)
*Positive control**	59.6 (8.0)	2.725 (1.036)	100.5 (8.2)

SD = Standard deviation; IVIS = in vitro irritancy score
*Corrected for background values

Remarks - Results

CONCLUSION The test substance is a severe eye irritant under the conditions of the test.

TEST FACILITY BASF (2012a)

B.5. Irritation – eye (in vitro)

TEST SUBSTANCE Analogue 1 (10% and 25%)

METHOD OECD TG 437 Bovine Corneal Opacity and Permeability Test Method for Identifying Ocular Corrosives and Severe Irritants

Vehicle Deionised water

Remarks - Method Assessment of the potential test substance to cause serious damage to isolated bovine corneas in comparative study using the surfactant protocol for solids as laid out in the test method (OECD TG 437), and also a modified surfactant protocol.
Deionised water was used as negative control and 1% NaOH or ethanol in deionised water as positive control.
Standard protocol:
Three corneas per test run were treated with a 10% (1st test) or a 25% (2nd

test) test substance in deionised water for 10 minutes followed by a two hours post incubation period.
Modified surfactant protocol:
Three corneas per test run were treated with a 10% (1st test) or a 25% (2nd test) test substance in deionised water for one hour followed by a one hours post incubation period.

RESULTS

Standard Surfactant Protocol
Test 1 (10%)

Test material	*Mean opacities of triplicate tissues (SD)*	*Mean permeabilities of triplicate tissues (SD)*	*IVIS (SD)*
Vehicle control	0.9 (1.4)	-0.003 (0.003)	0.9 (1.4)
*Test substance**	0.2 (0.2)	0.381 (0.369)	6.0 (5.3)
*Positive control**	155.5 (15.5)	2.733 (0.283)	196.5 (11.9)

SD = Standard deviation; IVIS = in vitro irritancy score
*Corrected for background values

Test 2 (25%)

Test material	*Mean opacities of triplicate tissues (SD)*	*Mean permeabilities of triplicate tissues (SD)*	*IVIS (SD)*
Vehicle control	1.3 (0.9)	-0.004 (0.002)	1.3 (0.9)
*Test substance**	-0.2 (1.6)	0.231 (0.198)	3.3 (2.3)
*Positive control**	132.8 (17.4)	3.102 (0.232)	179.3 (20.5)

SD = Standard deviation; IVIS = in vitro irritancy score
*Corrected for background values

Modified Surfactant Protocol
Test 1 (10%)

Test material	*Mean opacities of triplicate tissues (SD)*	*Mean permeabilities of triplicate tissues (SD)*	*IVIS (SD)*
Vehicle control	-0.7 (0.2)	-0.006 (0.003)	-0.8 (0.2)
*Test substance**	3.5 (2.5)	2.295 (0.723)	38.0 (13.3)
*Positive control**	72.3 (6.8)	1.910 (0.134)	101.0 (8.5)

SD = Standard deviation; IVIS = in vitro irritancy score
*Corrected for background values

Test 2 (25%)

Test material	*Mean opacities of triplicate tissues (SD)*	*Mean permeabilities of triplicate tissues (SD)*	*IVIS (SD)*
Vehicle control	0.8 (1.1)	-0.010 (0.005)	0.6 (1.1)
*Test substance**	0.1 (1.2)	1.337 (0.247)	20.1 (2.8)
*Positive control**	59.2 (2.7)	1.413 (0.104)	80.4 (2.0)

SD = Standard deviation; IVIS = in vitro irritancy score
*Corrected for background values

Remarks - Results

Using the standard surfactant protocol (OECD TG 437) test or the modified surfactant protocol, and based on the *In Vitro* Irritancy scores (IVIS) of <55, no serious eye damage potential of the test substance was noted.

Histopathological evaluation of the corneas under the surfactant protocol (10% and 25%) indicated minimal eye damage. Under the modified surfactant protocol, histopathological evaluation of the corneas indicated mild to severe damage at 10% and mild damage in one cornea at 25%. Histology of the other two corneas treated with 25% of the test substance could not be evaluated due to artifacts.

CONCLUSION The test substance was not a severe eye irritant under the conditions of the test.

TEST FACILITY BASF (2012b)

B.6. Skin sensitisation

TEST SUBSTANCE Analogue 4

METHOD OECD TG 406 Skin Sensitisation - Buehler test.
EEC Guideline "EEC92/69 part B.6 Skin Sensitisation - Buehler test.

Species/Strain Albino Guinea pig/SPF

PRELIMINARY STUDY A preliminary study was carried out to determine irritation potential, and was used to select the concentration for induction and challenge. The procedures for this test were stated to be identical to those in the main study.

MAIN STUDY

Number of Animals Test Group: 20 Control Group: 10

INDUCTION PHASE Induction Concentration:
topical: A paper patch saturated with 0.2 mL of test substance at 12.5% concentration was placed on the shaved skin of the left flank animal for 6 hours (closed patch). The procedure was repeated on days 7 and 14. The control group were treated similarly but with the vehicle only (sterile distilled water).

Signs of Irritation No skin reactions were noted.

CHALLENGE PHASE

challenge topical: Four weeks after the first induction, a paper patch was saturated with 0.2 mL of test substance at 6.25% concentration which was placed on the anterior right flank of the animal for 6 hours (closed patch). In the same way a paper patch was placed posterior on the right flank but saturated with 0.2 mL of the vehicle.

Remarks - Method Skin reactions were evaluated 24 and 48 hours after the challenge application.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after: challenge*	
		24 h	*48 h*
Test Group	6.25%	4/20	2/20
Control Group	0%	1/10	0

Remarks - Results One death in the test group was attributed to stress rather than any effect of the test substance. None of the remaining animals showed ill health. Body weight gain was as expected.
After 24 h a slight skin reaction (defined as slight or discrete erythema) was noted in 4/20 of the test animals and 1/10 of the control animals after challenge. The same reaction was seen after application with distilled water in one animal from the test group.
After 48 h a slight skin reaction was seen two animals from the test group (including one animal that showed a reaction at 24 h).

The study authors considered the scores to be marginal and not related to sensitisation, and noted that one of the reactions was prompted by the vehicle alone.

CONCLUSION There was no evidence of reactions indicative of skin sensitisation to the chemical under the conditions of the test.

TEST FACILITY Scantox Germany (1996)

B.7. Genotoxicity – bacteria

TEST SUBSTANCE Analogue 4

METHOD OECD TG 471 Bacterial Reverse Mutation Test.
Species/Strain *S. typhimurium*: TA1538, TA1535, TA1537, TA98, TA100

Metabolic Activation System Aroclor 1254-induced rat liver S9
Concentration Range in Main Test a) With metabolic activation:
test 1: 8-5000 µg/plate;
test 2: 11.1-600 µg/plate
b) Without metabolic activation:
test 1: 8-5000 µg/plate
test 2: 11.1-600 µg/plate
Vehicle Bi-distilled water and buffer were both used as negative controls.
Remarks - Method No preliminary study was performed.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	-	≥200	-	Negative
Test 2	-	≥300	-	Negative
Present				
Test 1	-	≥200	-	Negative
Test 2	-	≥300	-	Negative

Remarks - Results The positive controls induced the appropriate responses in the corresponding strains in the presence and absence of S9.

CONCLUSION The chemical was not mutagenic to bacteria under the conditions of the test.

TEST FACILITY Henkel KGaA Toxikologie (1991)

B.8. Genotoxicity – in vivo

TEST SUBSTANCE Analogue 1

METHOD OECD TG 474 Mammalian Erythrocyte Micronucleus Test.

Species/Strain Albino mice/CFW 1
Route of Administration Oral – gavage
Vehicle Bi-distilled water
Remarks - Method Dosages for the main test were determined through a range finding toxicity study with the test substance at 2000 – 10000 mg/kg bw
Mortality occurred at dosages ≥5000 mg/kg bw. Signs of toxicity such as reduced activity were seen at the lower doses but had resolved by 45 h after administration.

In the main test, the bone marrow cells of the low and mid dose groups were not examined (based on the results of the high dose groups).

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Sacrifice Time hours*
I (vehicle control)	7M, 7F	10	24
II (low dose)	7M, 7F	400	24
III (mid dose)	7M, 7F	2000	24
IV (high dose)	7M, 7F	4000	24, 48 & 72
V (positive control CP)	7M, 7F	10	24

CP=cyclophosphamide.

RESULTS

Doses Producing Toxicity	There was no mortality at the highest tested dose (4000 mg/kg bw). All animals at this dose were found to have reduced activity, ruffled fur and diarrhoea two hours after administration with the test substance. A slight reduced activity and ruffled fur were still observed at about 24 hours but cleared by 46 hours after administration. The test substance at this dose did not induce change in the ratio polychromatic to normochromatic erythrocytes in male and female mice at 24, 48 or 72 hours after administration, indicating no toxic effect on the bone marrow.
Genotoxic Effects	No significant increases in the number of micronucleated cells were observed in male or female animals at the high dose of 4000 mg/kg bw at any of the sacrifice intervals. Doses of 2000 and 400 mg/kg bw at 24 hours after administration were not evaluated for genotoxicity.
Remarks - Results	The clinical signs noted after administration suggest that the chemical was systemically distributed. As there was no change in the ratio of polychromatic and normochromatic erythrocytes, it is not clear whether the test substance reached the bone marrow. The positive control cyclophosphamide showed significant increases in micronucleated cells, confirming the validity of the test system.
CONCLUSION	The chemical was not clastogenic under the conditions of the test.
TEST FACILITY	Henkel KGaA Toxikologie (1986)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE Analogue 1

METHOD OECD TG 301 D Ready Biodegradability: Closed Bottle Test.

Inoculum	Activated sludge
Exposure Period	28 days
Auxiliary Solvent	None Reported
Analytical Monitoring	Chemical oxygen demand (COD)
Remarks - Method	The test was conducted in accordance with the test guideline above with no significant deviation from the protocol reported.

RESULTS

Test substance		*Sulfuric acid,mono dodecyl ester sodium salt*	
Day	*% Degradation*	*Day*	*% Degradation*
5	52	5	59
15	78	15	88
30	77	30	94

Remarks - Results	Under the test conditions 77% of the test substance was degraded within 30 days test period. Since the pass level (=60% ThoD for respirometric methods according to the OECD 301) was reached within the 14-day time window and in conformity with the evaluation of the substance can be regarded as "readily biodegradable"

CONCLUSION The notified chemical is readily biodegradable.

TEST FACILITY Henkel AG & Co. KGaA (2001a)

C.2. Ecotoxicological Investigations

C.2.1. Acute toxicity to fish

TEST SUBSTANCE Analogue 1

METHOD OECD TG 203 Fish, Acute Toxicity Test – Semi Static.

Species	Zebrafish *(Brachydanio rerio)*
Exposure Period	96 hours
Auxiliary Solvent	None
Water Hardness	250 mg $CaCO_3$/L
Analytical Monitoring	High performance liquid chromatography (HPLC)
Remarks – Method	The test was conducted in accordance with the test guideline without significant deviations. Good Laboratory Practice (GLP) was followed. The test substance was tested in a concentration range of 2.8 to 22 mg product/ 1 (nominal).

RESULTS

Concentration mg/L	*Number of Fish*	*Mortality%*				
Actual		*6 h*	*24 h*	*48 h*	*72 h*	*96 h*
2.8	10	0	0	0	n.d	0
4.0	10	0	0	0	n.d	0

8.0	10	0	0	0	n.d	0
11	10	0	10	100	n.d	100
16	10	0	100	100	n.d	100
22	10	0	100	100	n.d	100

LC50 5.2 mg/L at 96 hours.

Remarks – Results All validity criteria were within acceptable limits, no mortality and therefore the study is considered valid.

CONCLUSION The analogue is toxic to fish

TEST FACILITY Henkel AG & Co. KGaA (2001b)

C.2.2. Algal growth inhibition test

TEST SUBSTANCE Analogue 1

METHOD OECD TG 201 Alga, Growth Inhibition Test - Static.
Species *Scenedesmus subcapitata*
Exposure Period 72 hours
Concentration Range Nominal: 100 mg/L
Auxiliary Solvent None
Water Hardness Not reported
Analytical Monitoring High performance liquid chromatography (HPLC)
Remarks - Method Test organisms were exposed to different concentrations of the test substance in a defined mineral nutrient media during period of 72 hours over several generations. At several times (24, 48, 72h) the algae concentrations were determined.

The test was conducted in accordance with the test guideline without significant deviations. Good Laboratory Practice (GLP) was followed.

RESULTS

Biomass	*Growth*
E_bC50 *mg/L at 72 h*	*E_rC50* *mg/L at 72 h*
30	34

Remarks - Results All validity criteria were within acceptable limits, therefore the study is considered valid.

CONCLUSION The analogue is harmful to algae.

TEST FACILITY Henkel AG & Co. KGaA (2001c)

C.2.3. Chronic toxicity to aquatic invertebrates

TEST SUBSTANCE Analogue chemical

METHOD EPA-600/489/001: Short term methods for measuring the chronic toxicity of effluents and receiving waters to freshwater organisms. Deviations, reliability and validity evaluated against USEPA OPPTS 850.1300 (Daphnid Chronic Toxicity Test).
Species *Ceriodaphnia dubia*
Exposure Period 7 d

Auxiliary Solvent	Not reported
Water Hardness	Not reported
Analytical Monitoring	UV-Vis and MS
Remarks - Method	In a 7-day chronic toxicity study, *Ceriodaphnia dubia* were exposed to the analogue chemical at nominal concentrations of 0, 0.05, 0.10, 0.50, 1.0 and 2.0 mg/L, and measured concentrations of 0, 0.02, 0.08, 0.20, 0.80 and 1.29 mg/L under flow-through conditions.
7 day NOEC (Reproduction)	0.204 mg/L
7 day NOEC (Mortality)	1.3 mg/L
Remarks - Results	The test validity criteria were met (80% or greater survival in controls, 15 or more young per surviving female). The test substance is considered as an acceptable analogue for the notified polymers.
CONCLUSION	The 7-day NOEC based on measured concentrations was 0.20 mg/L, based on the most sensitive endpoint (reproduction). The toxicity study is classified as acceptable and satisfies the validity critieria as stated in the study protocol. The test substance and, by inference, the notified chemical is harmful to *Ceriodaphnia dubia* on a chronic basis.
TEST FACILITY	Summary from IUCLID 5 report

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