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September 2020

AUSTRALIAN INDUSTRIAL CHEMICALS INTRODUCTION SCHEME (AICIS)

PUBLIC REPORT

Nonadecane, 9-methylene-, mixed with 1-decene, dimers and trimers, hydrogenated

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals Act 2019 (the IC Act) and Industrial Chemicals (General) Rules 2019 (the IC Rules) by following the Industrial Chemicals (Consequential Amendments and Transitional Provisions) Act 2019 (the Transitional Act) and Industrial Chemicals (Consequential Amendments and Transitional Provisions) Rules 2019 (the Transitional Rules)*. The legislations are Acts of the Commonwealth of Australia. The Australian Industrial Chemicals Introduction Scheme (AICIS) 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 Agriculture, Water and the Environment.

This Public Report is available for viewing and downloading from the AICIS website. For enquiries please contact AICIS at:

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Executive Director
AICIS

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SUMMARY

The following details will be published on the AICIS website:

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
STD/1725	Amochem Pty Ltd	Nonadecane, 9-methylene-, mixed with 1-decene, dimers and trimers, hydrogenated	Yes	≤ 100 tonnes per annum	Component of motor oil, automatic transmission fluid, and industrial lubricants

CONCLUSIONS AND REGULATORY OBLIGATIONS

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

Hazard Classification	*Hazard Statement*
Aspiration hazard (Category 1)	H304 – May be fatal if swallowed and enters airways

Human Health Risk Assessment
Under the conditions of the occupational settings described, the assessed chemical is not considered to pose an unreasonable risk to the health of workers.

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

Environmental Risk Assessment
On the basis of the low hazard and the reported use pattern, the assessed chemical is not considered to pose an unreasonable risk to the environment.

Recommendations

REGULATORY CONTROLS

Hazard Classification and Labelling

- The assessed chemical should be classified as follows:
  - Aspiration hazard (Category 1): H304 – May be fatal if swallowed and enters airways

  The above should be used for products/mixtures containing the assessed chemical, if applicable, based on the concentration of the assessed chemical present.

CONTROL MEASURES

Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following engineering controls to minimise occupational exposure to the assessed chemical as introduced or during reformulation:
  - Enclosed, automated processes, where possible
  - Local exhaust ventilation if aerosols or mists are generated

- 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 assessed chemical as introduced or during reformulation and use:
  - Avoid contact with skin and eyes
  - Avoid inhalation
  - Avoid ingestion/aspiration

- 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 assessed chemical as introduced or during reformulation:
  - Respiratory protection if inhalation exposure may occur

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

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

- If products and mixtures containing the assessed 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.

Public Health

- As liquid hydrocarbons are included in Schedule 5 of the SUSMP, any labelling and/or packaging requirement for products containing the assessed chemical, which are available to the public, should be adhered to.

Storage

- The handling and storage of the assessed chemical should be in accordance with the Safe Work Australia Code of Practice for *Managing Risks of Hazardous Chemicals in the Workplace* (SWA, 2012) or relevant State or Territory Code of Practice.

Emergency procedures

- Spills or accidental release of the assessed chemical should be handled by physical containment, collection and subsequent safe disposal.

Disposal

- Where reuse or recycling are not appropriate, dispose of the assessed chemical in an environmentally sound manner in accordance with relevant Commonwealth, state, territory and local government legislation.

Regulatory Obligations

Specific Requirements to Provide Information
This risk assessment is based on the information available at the time of the application. The Executive Director may initiate an evaluation of the chemical based on changes in certain circumstances. Under Section 101 of the IC Act the applicant of the assessed chemical has post-assessment regulatory obligations to provide information to AICIS when any of these circumstances change. These obligations apply even when the assessed chemical is listed on the Australian Inventory of Industrial Chemicals (the Inventory).

Therefore, the Executive Director of AICIS must be notified in writing within 20 working days by the applicant or other introducers if:

- additional information has become available to the person on the reproductive/developmental toxicity of the assessed chemical;

- the chemical is proposed to be used in spray products;
- the function or use of the chemical has changed from a component of motor oil, automatic transmission fluid, and industrial lubricants, 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 human health, or the environment.

The Executive Director will then decide whether an evaluation of the introduction is required.

Safety Data Sheet
The SDS of the assessed chemical provided by the applicant was reviewed by AICIS. The accuracy of the information on the SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND APPLICATION DETAILS

APPLICANT(S)
Amochem Pty Ltd (ABN: 48 095 713 269)
40 Myrna Road
STRATHFIELD NSW 2135

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

PROTECTED INFORMATION (SECTION 38 OF THE TRANSITIONAL ACT)
Data items and details taken to be protected information include: structural formulae, molecular weight, analytical data, import volume and identity information of analogue chemicals.

VARIATION OF DATA REQUIREMENTS (SECTION 6 OF THE TRANSITIONAL RULES)
Variation to the schedule of data requirements is claimed for all physico-chemical (except autoignition temperature), toxicological and ecotoxicological endpoints.

PREVIOUS APPLICATION IN AUSTRALIA BY APPLICANT(S)
None

APPLICATION IN OTHER COUNTRIES
Canada (2020)
USA (2020)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Durasyn 136 polyalphaolefin

CAS NUMBER
1000172-32-6

CHEMICAL NAME
Nonadecane, 9-methylene-, mixed with 1-decene, dimers and trimers, hydrogenated

OTHER NAME
Hydrogenated oligomers of C20vd + C10α

MOLECULAR FORMULA
Unspecified

MOLECULAR WEIGHT
Number average molecular weight (Mn) is < 500 g/mol.

ANALYTICAL DATA
Reference FTIR spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
≥ 85%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS

Chemical Name	1-Propanol		
CAS No.	71-23-8	*Weight*	< 10 ppm
Hazardous Properties	H225 (Highly flammable liquid and vapour) H336 (May cause drowsiness or dizziness) H318 (Causes serious eye damage) AUH066 (Repeated exposure may cause skin dryness and cracking)		
Chemical Name	1-Butanol		
CAS No.	71-36-3	*Weight*	< 10 ppm
Hazardous Properties	H226 (Flammable liquid and vapour) H302 (Harmful if swallowed) H335 (May cause respiratory irritation) H315 (Causes skin irritation) H318 (Causes serious eye damage) H336 (May cause drowsiness or dizziness)		
Chemical Name	Acetic acid, butyl ester		
CAS No.	123-86-4	*Weight*	< 10 ppm
Hazardous Properties	H226 (Flammable liquid and vapour) H336 (May cause drowsiness or dizziness) AUH066 (Repeated exposure may cause skin dryness and cracking)		

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (> 1% BY WEIGHT)

Chemical Name	Oligomers from olefins other than α-decene (C10) or Nonadecane, 9-methylene-		
CAS No.	Unknown	*Weight %*	< 2
Chemical Name	Unsaturated oligomers of α-decene (α-C10) or Nonadecane, 9-methylene- (C20vd)		
CAS No.	Unknown	*Weight %*	< 2
Chemical Name	Oligomers and unsaturated oligomers of 1-decene		
CAS No.	Unknown	*Weight %*	< 5
Chemical Name	1-Decene		
CAS No.	872-05-9	*Weight %*	< 2
Chemical Name	Nonadecane, 9-methylene-		
CAS No.	37624-31-0	*Weight %*	< 2
Chemical Name	Hydrogen		
CAS No.	1333-74-0	*Weight %*	< 2

ADDITIVES/ADJUVANTS
None

4. PHYSICAL AND CHEMICAL PROPERTIES

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

Property	***Value***	***Data Source/Justification***
Pour Point	-65 °C	SDS
Boiling Point	263 °C	SDS
Density	820 kg/m^3 at 15.6 °C	SDS
Kinematic viscosity	14.5 mm^2/s at 40 °C 3.6 mm^2/s at 100 °C	SDS
Vapour Pressure	< 1.3 × 10^{-1} kPa at room temperature	SDS
Water Solubility	< 0.61 × 10^{-3} g/L at 20 °C	Provided by the applicant

Property	*Value*	*Data Source/Justification*
Hydrolysis as a Function of pH	Not measured	Contains no hydrolysable functionalities
Partition Coefficient (n-octanol/water)	log P_{ow} > 6 log P_{ow} > 8 at 20 °C	Measured on analogue chemicals Estimated (Epi Suite KOWWIN (US EPA, 2012))
Adsorption/Desorption	log K_{oc} = 6.58	Calculated by the applicant based on empirically derived relation between K_{oc} and P_{ow}
Dissociation Constant	Not measured	Contains no dissociable functionalities
Flash Point	204 °C	SDS
Flammability	Not determined	Not expected to be highly flammable based on flash point
Autoignition Temperature	362 °C	Measured
Explosive Properties	Not determined	Contains no functional groups that would imply explosive properties
Oxidising Properties	Not determined	Contains no functional groups that would imply oxidative properties

DISCUSSION OF PROPERTIES
The viscosity provided for the assessed chemical is 14.5 mm^2/s at 40 °C. According to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)*, hydrocarbon substances with viscosity < 20.5 mm^2/s at 40 °C should be classified for aspiration hazard. See Section 6.2 for further details regarding the health hazard classification.

For details of measured physical and chemical properties, refer to Appendix A.

Reactivity
The assessed chemical is expected to be stable under normal conditions of use.

Physical Hazard Classification
Based on the physico-chemical data depicted in the above table, the assessed 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.

The assessed chemical has a flash point of 204 ºC which is greater than 93 °C. Based on *Australian Standard AS1940* definitions for combustible liquid, the assessed chemical may be considered as a Class C2 combustible liquid if the chemical has a fire point below the boiling point.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF ASSESSED CHEMICAL (100%) OVER NEXT 5 YEARS
The assessed chemical will be imported into Australia in the neat form for the formulation of motor oils, transmission fluids, and industrial lubricants.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	1-20	1-20	20-100	20-100	20-100

PORT OF ENTRY
Sydney

IDENTITY OF RECIPIENTS
Amochem Pty Ltd

TRANSPORTATION AND PACKAGING
The assessed chemical will be imported into Australia in either 200 L drums or iso-containers. The assessed chemical is expected to be primarily transported from the dockside to the customers or contract warehouses via trucks, but rail transport may be possible. The assessed chemical is then stored until required for despatch to

customers for reformulation. The finished lubricant products may be packaged in drums (200 L) or bottles (1 L or bigger).

USE
The assessed chemical will be used as a base component of motor oil, automatic transmission fluid, and industrial lubricants at 10-98% concentration. These products will be used industrially (at ≤ 98% concentration) and by Do-It-Yourself (DIY) users (at ≤ 70% concentration).

OPERATION DESCRIPTION
Formulation of the motor oil, automatic transmission fluid and industrial lubricants will occur at blending facilities of lubricant manufacturers.

At the blending sites, the assessed chemical will be pumped via dedicated hard pipes to blending tanks. After blending with other components, the finished lubricant products containing the assessed chemical at ≤ 98% concentration will be pumped via dedicated hard pipes to bulk storage tanks for subsequent packaging into 200 L drums and bottles (1 L or larger). The reformulation process is expected to be largely enclosed and automated. Samples will be collected at various stages for quality control testing.

The finished lubricant products will be supplied to industrial and commercial end-users, and retail stores. They will be used industrially and in automotive applications by motor mechanics and DIY users.

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)*
Formulation:		
Taking samples	5	350
Analysing samples	1	350
Maintaining equipment	3	350
Continuous blending operation	20	350
Filling packaging	10	250
Quick lube employees	7	140
Industrial oil exchangers	0.5	10-15

EXPOSURE DETAILS

Transport and storage
Transport and storage workers may come into contact with the assessed chemical at ≤ 100% concentration only in the unlikely event of a spill or accidental rupture of containers.

Formulation of lubricants
Dermal and ocular exposure of workers to the assessed chemical at ≤ 100% concentration may occur during quality control analysis, and cleaning and maintenance of equipment. Exposure to the assessed chemical at other times is expected to be negligible given the formulation process will be largely enclosed and automated.

According to the applicant, dermal and ocular exposure to workers would be mitigated through the use of personal protective equipment (PPE), including protective clothing, impervious gloves and goggles. Inhalation exposure is not expected given the use of enclosed systems for formulation and low vapour pressure of the assessed chemical.

End-use
Workers may be exposed to lubricants containing the assessed chemical at ≤ 98% concentration during use, for example, at automotive car dealerships or automotive service centres during transfer, charging or top-up activities, or during plant maintenance activities at industrial sites.

Given the low vapour pressure of the assessed chemical, inhalation exposure is not expected. According to the applicant, dermal and ocular exposure to workers would be mitigated through the use of PPE, including protective clothing, impervious gloves and goggles.

6.1.2. Public Exposure

Finished motor oil and automatic transmission fluid containing the assessed chemical at ≤ 70% concentration may be sold through the retail market to DIY users to replace or top-up automotive lubricants, for example, engine and gearbox oils. Therefore, incidental dermal exposure to the assessed chemical at ≤ 70% concentration may occur to DIY users. Given the low vapour pressure of the assessed chemical, inhalation exposure to the assessed chemical is not expected. Accidental ocular exposure may be possible.

6.2. Human Health Effects Assessment

No toxicological data were submitted for the assessed chemical. The results from toxicological investigations conducted on analogues (identities are protected information) that are considered likely to have similar toxicological characteristics to the assessed chemical are summarised in the following table. For details of the studies, refer to Appendix B.

Endpoint	*Test substance*	*Result and Assessment Conclusion*
Acute oral toxicity – rat (4 studies)	Analogue chemicals 1-4	LD50 > 5,000 mg/kg bw; low toxicity
Acute dermal toxicity – rat	Durasyn 125	LD50 > 2,000 mg/kg bw; low toxicity
Skin irritation – rabbit (4 studies)	Analogue chemicals 1-4	slightly irritating (based on 24 hours exposure)
Eye irritation – rabbit (4 studies)	Analogue chemicals 1-4	slightly irritating
Skin sensitisation – guinea pig, adjuvant test (2 studies)	Analogue chemicals 1-2	no evidence of sensitisation
Skin sensitisation – guinea pig, adjuvant test	Analogue chemical 3	limited evidence of sensitisation
Repeat oral dose toxicity – rat, 91 days	Analogue chemical 3	NOAEL = 1,000 mg/kg
Mutagenicity – bacterial reverse mutation	Analogue chemical 2	non mutagenic
Genotoxicity – *in vitro* chromosomal aberrations in human lymphocytes	Analogue chemical 5	non genotoxic
Genotoxicity – *in vitro* mammalian cell gene mutation test	Analogue chemical 5	non genotoxic
Genotoxicity – *in vivo* mouse micronucleus test	Analogue chemical 6	non genotoxic
Two-generation reproduction toxicity study – rat[#]	Durasyn 164X	NOEL for systemic and reproductive/developmental toxicity = 1,000 mg/kg bw/day*

***** Established by the study authors
[#] Not included in Appendix B

Toxicokinetics

Given the low molecular weight of the assessed chemical (< 500 g/mol), absorption across biological membranes may occur, but would be limited by the low water solubility (< 0.61×10^{-3} g/L) and high partition coefficient (log Pow > 6). The assessed chemical may also be taken up by micellular solubilisation due to its high lipophilicity.

Acute Toxicity

Based on analogue data, the assessed chemical has low acute oral toxicity (LD50 > 5,000 mg/kg bw) and low acute dermal toxicity (LD50 > 2,000 mg/kg bw).

No inhalation toxicity data were submitted for the assessed chemical. An analogue chemical, 1-tetradecene, homopolymer, hydrogenated (CAS No. 1857296-89-9) was not considered to be classified for acute inhalation toxicity (NICNAS, 2020).

Irritation and Sensitisation

Some skin irritation was reported in four *in vivo* studies on analogue chemicals where the exposure time was 24 hours rather than the 4 hours exposure specified in the OECD Test Guideline. It is expected that the extended

timeframe in these studies would have resulted in increased irritation effects. Based on these results, the assessed chemical is not considered to be classified for skin irritation.

Based on *in vivo* eye irritation studies in rabbits on four analogue chemicals, the assessed chemical is likely to be slightly irritating to the eyes.

One of three guinea pig maximisation skin sensitisation studies carried out on analogues showed limited evidence of skin sensitisation. Responses occurred in a small percentage of the test group, were higher at 24 hours than at 48 hours after challenge and were attributed to irritation rather than sensitisation by the study authors. The two other studies were negative. Overall, the assessed chemical is not considered to be sensitising to the skin.

Repeated Dose Toxicity
In a 91-day oral toxicity study in rats (with an in utero phase) with doses of 100, 500, 1,000 mg/kg bw/day of analogue 3, significant systemic effects were not seen in the F0 or F1 generations. A slight increase in prothrombin time in males at the highest dose (1,000 mg/kg bw/day) was not associated with other haematological changes. Minor clinical signs were attributed to the vehicle, and a 'No Observed Effect Level' (NOEL) of 1,000 mg/kg bw/day was established by the study authors for systemic toxicity.

Mutagenicity/Genotoxicity
Analogue chemicals were non mutagenic or non-genotoxic in a range of studies: bacterial reverse mutation, *in vitro* chromosomal aberration test in human lymphocytes, *in vitro* mammalian cell gene mutation test using Chinese hamster ovary cells and an *in vivo* mouse micronucleus test. Overall the assessed chemical is not expected to be mutagenic or genotoxic.

Toxicity for Reproduction
A two-generation reproduction oral gavage study on an analogue (Durasyn 164X) was carried out on rats according to OECD TG 416 at dose levels of 100, 300 and 1,000 mg/kg bw/day. A control group was dosed with vehicle alone (Arachis oil BP). The No Observed Effect Level (NOEL) for adult toxicity and reproductive and developmental toxicity for both F0 and F1 generations and offspring was considered by the study authors to be 1,000 mg/kg bw/day.

A NOEL of 1,000 mg/kg bw/day for reproductive/developmental effects was established by the study authors in a 91-day oral combined repeated dose/developmental study (described above in the repeat dose toxicity section) on analogue 3. Treatment-related effects on fertility, length of gestation, pregnancy status, parturition or lactation were not identified, except that one high dose female had total litter loss.

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

Hazard Classification	***Hazard Statement***
Aspiration hazard (Category 1)	H304 – May be fatal if swallowed and enters airways

6.3. Human Health Risk Characterisation
The assessed chemical is classified as an aspiration hazard. Based on analogue data, it is a slight skin and eye irritant and it may have irritant effects on the respiratory tract. Adverse effects after repeated inhalation exposure were reported for an analogue chemical, 1-tetradecene, homopolymer, hydrogenated (CAS No. 1857296-89-9) (NICNAS, 2020).

6.3.1. Occupational Health and Safety
Ingestion/aspiration is unlikely to occur in the proposed use of the chemical, except in case of an accident. There is the possibility of skin and eye irritation to lubricant blenders and end users as the lubricant contains up to 98% of assessed chemical. The risk would be reduced by the controlled environment in which some of the processes occur, by safe work practices, and further reduced by the stated use of PPE by workers. Inhalation exposure and risk is likely to be low in the scenarios described, unless aerosols or mists are generated.

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

6.3.2. Public Health

Exposure of the public to the assessed chemical will be minimal during transport, storage, blending and industrial use, except in the event of an accidental spill.

The risk to DIY users from manual addition of products containing the assessed chemical (up to 70%) to automobiles or other machinery is not considered unreasonable as only incidental exposure is expected and the frequency of use is expected to be low. Protective gloves may not necessarily be used by DIY users during applications (up to 70% concentration), however, users may have access to the SDS of the lubricant, which contains adequate information to warn users regarding the hazards of the lubricant.

The assessed chemical is a liquid hydrocarbons. Liquid hydrocarbons are included in Schedule 5 of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP), with packaging/labelling requirements for products containing liquid hydrocarbons available to the public.

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

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified chemical will be imported into Australia for the formulation of motor oils, automatic transmission fluids, and industrial lubricants. The formulation process involves blending operations in closed systems, followed by automatic filling of the formulated products into end-use containers. Any waste generated from the formulation process is expected to be recycled or disposed of by an approved waste management facility. Bulk shipments of the finished lubricants containing the notified chemical for industrial uses may be moved by truck, train, or barge. Material trapped in transfer hoses is collected or goes back into the truck, railcar, or cargo hold. Empty trucks, railcars, or cargo holds are drained and cleaned. The wastewater is collected and treated at onsite wastewater treatment plant before being discharged to the environment. Accidental spills of the notified chemical during import, transport, formulation or storage are expected to be collected for recycling or disposal of, in accordance with local government regulations.

RELEASE OF CHEMICAL FROM USE

The finished motor oils/lubricants containing the notified chemical will be available to industry, motor mechanics and public consumers. According to the notifier, about 30% of the notified chemical will be consumed during use and the remainder will be drained from the equipment or engine during oil changes. Minor accidental spills could occur during use and are expected to be collected on suitable absorbent material for disposal of, in accordance with local government regulations.

Some of the notified chemical will be used by Do-It-Yourself (DIY) users. In a recent Australian survey it was found that only 4% of households disposed of motor oil and approximately 30% of them was incorrectly disposed of (Aither, 2013). For ATF, the trend for these types of transmissions is “fill for life”, with no scheduled servicing (drain and refill). Therefore the amount of transmission fluid likely to be disposed of by DIY users will be less than that for motor oil. Therefore a small amount of used motor oils/lubricants containing the notified chemical may be incorrectly disposed by DIY users.

RELEASE OF CHEMICAL FROM DISPOSAL

Empty containers containing residues of the notified chemical will be disposed of to landfill in accordance with local government regulations. The used oil containing the notified chemical is expected to be collected and re-refined or disposed of by approved waste management contractors, in accordance with local government regulations.

7.1.2. Environmental Fate

The notified chemical is not readily biodegradable (degradation of only 9.3% after 28 d in OECD 301 B test), but can be considered inherently biodegradable due to continue to biodegrade over time.

According to the notifier, 30% of the notified chemical is consumed during use and the remainder will be drained from the equipment or engine during oil changes. The used oil containing the notified chemical is expected to be re-refined or disposed of by approved waste management contractors. It is likely that the notified chemical will be degraded into simpler compounds during refining. The wastewater containing the notified chemical released at site will be treated at onsite wastewater treatment plant. Based on its low solubility and high log P_{ow} (> 6), the notified chemical is expected to be removed effectively through adsorption to sludge at the treatment plant. A proportion of this may be applied to land when sludge from wastewater treatment facilities is used for soil remediation, or disposed of to landfill. Minor amounts of the notified chemical may also be disposed of to landfill as collected spills. Based on its low water solubility and high log K_{oc} (= 6.58), the notified chemical is expected to have low mobility in soil. The notified chemical in the environment is expected to eventually degrade into water and oxides of carbon via biotic and abiotic pathways.

7.1.3. Predicted Environmental Concentration (PEC)

The predicted environmental concentration (PEC) has not been calculated for the assessed chemical, as no significant release to the aquatic compartment is expected from the proposed use pattern.

7.2. Environmental Effects Assessment

Study summaries of the ecotoxicological investigations conducted on the assessed chemical and its analogues (Analogues 5, 7 and 8; identities are protected information) were provided and are summarised in the table below. The results are presented as nominal concentrations. For details of the study on the assessed chemical, refer to Appendix C. Studies marked * are available in a NICNAS assessment report (NICNAS, 2020).

Endpoint	*Test chemical*	*Result*	*Assessment Conclusion*
Fish Acute Toxicity	Analogue 8	96 h LL0 > 5002 mg/L	Not harmful to fish
	Analogue 7	96 h LL0 = 5010 mg/L	Not harmful to fish
	Analogue 1*	NOEC = 1000 mg/L (WAF)	Not harmful to fish
Fish Chronic Toxicity	Analogue 5	NOEC = 1000 mg (WAF)	Not harmful to fish
Aquatic Invertebrate Acute Toxicity	Analogue 8	96 h LL0 > 5002 mg/L (Mysid shrimp)	Not harmful to aquatic invertebrate
	Analogue 7	48 h EL0 = 5220 mg/L (Daphnia magna)	Not harmful to aquatic invertebrate
	Analogue 5 and Analogue 6*	NOEC ≥ 1000 mg/L (WAF) (Daphnia magna)	Not harmful to aquatic invertebrate
Chronic Daphnia Toxicity	Analogue 1* and Analogue 4*	21 d EL50 > 125 mg/L (WAF) 21 d NOEL ≥ 125 mg/L (WAF)	No adverse effect on the survival, reproduction and growth
Algal Toxicity	Analogue 7	NOEC ≥ 1000 mg/L	Not harmful to algae
	Analogue 5 and Analogue 6*	NOEC ≥ 1000 mg/L (Growth rate)	Not harmful to algae
Inhibition of Bacterial Respiration	Assessed chemical	3 h EC50 > 1000 mg/L (WAF)	Not inhibitory to microbial respiration
	Analogue 5 and Durasyn 164E*	3 h EC50 > 1000 mg/L	Not inhibitory to microbial respiration
	Analogue 1*	16 h EC50 > 10000 mg/L	Not harmful to bacteria up to its water solubility limit

WAF = Water Accommodated Fraction

Based on the above ecotoxicological information, the assessed chemical is not expected to be harmful to aquatic life. Therefore, the assessed chemical is not formally classified under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) (United Nations, 2009) for acute and chronic toxicities.

7.2.1. Predicted No-Effect Concentration

The predicted no-effects concentration (PNEC) has not been calculated, as the submitted ecotoxicological studies indicate that the assessed chemical is not expected to be harmful to aquatic life.

7.3. Environmental Risk Assessment

The Risk Quotient (Q = PEC/PNEC) for the aquatic compartment has not been calculated, as release to the aquatic compartment is not expected and the notified chemical is not expected to be harmful to aquatic life. The notified

polymer is not readily biodegradable but does not bioaccumulate. Therefore, on the basis of the low hazard, low expected 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

Partition Coefficient (n-octanol/water) log Pow > 6

Method	OECD TG 117 Partition Coefficient (n-octanol/water).
Remarks	HPLC Method. The column temperature was maintained at 30 °C. The test was done on five polyalphaolefins. None were eluted from the column after 1 hour and the log Pow values were determined to be > 6.
Test Facility	PTRL (2006)

Autoignition Temperature 362 °C

Method	ASTM E 659 - Standard Test Method for Autoignition Temperature of Chemicals
Remarks	Flask heater procedure
Test Facility	Ineos Oligomers (2016a)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute Oral Toxicity – Rat

B.1.1. Analogue chemical 1

TEST SUBSTANCE	Analogue chemical 1
METHOD	Similar to OECD TG 401 Acute Oral Toxicity – Limit Test (1987)
Species/Strain	Rat/Sprague-Dawley derived, albino
Vehicle	None
Remarks – Method	One male rat weighed slightly below the specified weight in the protocol. Study authors stated that this deviation did not compromise the results of the study.

RESULTS

Group	*Number and Sex of Animals*	*Dose (mg/kg bw)*	*Mortality*
1	5/sex	5000	0/10

LD50	> 5,000 mg/kg bw
Signs of Toxicity	Shortly after administration of the analogue chemical, all animals appeared to be mildly depressed and had scruffy oily fur, which persisted until Day 3 or 4 observation. All animals appeared to be normal from the Day 5 observation until the end of the observation period.
Effects in Organs	No abnormalities were observed at necropsy.
Remarks – Results	All animals showed expected body weight gains during the study period.
CONCLUSION	The analogue chemical is of low acute toxicity via the oral route.
TEST FACILITY	Hill Top Biolabs (1998a)

B.1.2. Analogue chemical 2

TEST SUBSTANCE	Analogue chemical 2
METHOD	Similar to OECD TG 401 Acute Oral Toxicity – Limit Test (1987)
Species/Strain	Rat/Sprague-Dawley derived, albino
Vehicle	None
Remarks – Method	No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose (mg/kg bw)*	*Mortality*
1	5 per sex	5000	0/10

LD50	> 5,000 mg/kg bw
Signs of Toxicity	Shortly after administration of the analogue chemical, all animals appeared to be mildly depressed and had scruffy oily fur, which persisted until Day 3 or 4 observation. All animals appeared to be normal from the Day 5 observation until the end of the observation period.
Effects in Organs	One female rat appeared to have a small spleen and thickened stomach lining filled with clear liquid containing a bright yellow substance at necropsy. No abnormalities were observed at necropsy in the remaining animals.
Remarks – Results	All animals showed expected body weight gains during the study period.
CONCLUSION	The analogue chemical is of low acute toxicity via the oral route.

TEST FACILITY Hill Top Biolabs (1998b)

B.1.3. Analogue chemical 3

TEST SUBSTANCE Analogue chemical 3

METHOD Similar to OECD TG 401 Acute Oral Toxicity – Limit Test (1987)
Species/Strain Rat/Sprague-Dawley derived, albino
Vehicle None
Remarks – Method No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose (mg/kg bw)*	*Mortality*
1	5 per sex	5000	0/10

LD50 > 5,000 mg/kg bw
Signs of Toxicity Shortly after administration of the analogue chemical, all animals appeared to be mildly depressed and had an oily hair coat, which persisted until the Day 4 observation. All animals appeared to be normal from the Day 5 observation until the end of the observation period.
Effects in Organs Necropsy revealed that one female rat had a yellow-brown spot on the stomach lining. No abnormalities were observed at necropsy in the remaining animals.
Remarks – Results All animals showed expected body weight gains during the study period.

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

TEST FACILITY Hill Top Biolabs (1998c)

B.1.4. Analogue chemical 4

TEST SUBSTANCE Analogue chemical 4

METHOD Similar to OECD TG 401 Acute Oral Toxicity – Limit Test (1987)
Species/Strain Rat/Sprague-Dawley derived, albino
Vehicle None
Remarks – Method No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose (mg/kg bw)*	*Mortality*
1	5 per sex	5000	0/10

LD50 > 5,000 mg/kg bw
Signs of Toxicity Shortly after administration of the analogue chemical, all animals appeared to be mildly depressed and had an oily hair coat, which persisted until the Day 3 observation. All animals appeared to be normal from the Day 4 observation until the end of the observation period.
Effects in Organs No abnormalities were observed at necropsy.
Remarks – Results All animals showed expected body weight gains during the study period.

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

TEST FACILITY Hill Top Biolabs (1998d)

B.2. Acute Dermal Toxicity – Rat

TEST SUBSTANCE Durasyn 125

METHOD	OECD TG 402 Acute Dermal Toxicity U.S. EPA Health Effects Guidelines, OPPTS 870.1200 (1998)
Species/Strain	Rat/Sprague-Dawley derived, albino
Vehicle	None
Type of dressing	Occlusive
Remarks – Method	No significant protocol deviations.

RESULTS

Group	*Number and Sex of Animals*	*Dose (mg/kg bw)*	*Mortality*
1	5 per sex	2000	0/10

LD50	> 2,000 mg/kg bw
Signs of Toxicity – Local	No signs of local skin effects were observed.
Signs of Toxicity – Systemic	No signs of systemic effects were observed.
Effects in Organs	No gross abnormalities were noted for any of the animals when necropsied at the conclusion of the 14-day observation period.
Remarks – Results	All animals showed expected body weight gains during the study period.

CONCLUSION The analogue chemical is low acute toxicity via the dermal route.

TEST FACILITY Product Safety Laboratories (2006)

B.3. Skin Irritation – Rabbit

B.3.1 Analogue chemical 1

TEST SUBSTANCE Analogue chemical 1

METHOD	US 16 CFR 1500 Hazardous Substances Labelling Act
Species/Strain	Rabbit/New Zealand White
Number of Animals	6 F
Vehicle	None
Observation Period	72 hours
Type of Dressing	Semi-occlusive
Remarks – Method	Gauze patch was applied for 24 hours. Scoring was conducted at 24 and 72 hours only.

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at 72-Hour Observation Period*
Erythema/Eschar	2	3	> 72 hours	3
Oedema	1	2	> 72 hours	1

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

Remarks – Results	The Primary Irritation Index was found to be 3.1 out of 8 based on erythema and oedema. No evidence of tissue damage was found.

CONCLUSION The analogue chemical is slightly irritating to the skin.

TEST FACILITY Hill Top Biolabs (1988e)

B.3.2 Analogue chemical 2

TEST SUBSTANCE Analogue chemical 2

METHOD	US 16 CFR 1500 Hazardous Substances Labelling Act
Species/Strain	Rabbit/New Zealand White
Number of Animals	6 F

Vehicle	None
Observation Period	72 hours
Type of Dressing	Semi-occlusive
Remarks – Method	Gauze patch was applied for 24 hours. Scoring was conducted at 24 and 72 hours only.

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at 72-Hour Observation Period*
Erythema/Eschar	0.67	3	> 72 hours	1
Oedema	0.42	2	> 24 hours	0

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

Remarks – Results	The Primary Irritation Index was found to be 1.3 out of 8 based on erythema and oedema. No evidence of tissue damage was found.

CONCLUSION The analogue chemical is slightly irritating to the skin.

TEST FACILITY Hill Top Biolabs (1988f)

B.3.3 Analogue chemical 3

TEST SUBSTANCE Analogue chemical 3

METHOD US 16 CFR 1500 Hazardous Substances Labelling Act

Species/Strain	Rabbit/New Zealand White
Number of Animals	3 per sex
Vehicle	None
Observation Period	72 hours
Type of Dressing	Semi-occlusive
Remarks – Method	Gauze patch was applied for 24 hours. Scoring was conducted at 24 and 72 hours only.

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at 72-Hour Observation Period*
Erythema/Eschar	0.42	2	> 24 hours	0
Oedema	0	0	-	-

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

Remarks – Results	The Primary Irritation Index was found to be 0.5 out of 8 based on erythema and oedema. No evidence of tissue damage was found.

CONCLUSION The analogue chemical is slightly irritating to the skin.

TEST FACILITY Hill Top Biolabs (1988g)

B.3.4 Analogue chemical 4

TEST SUBSTANCE Analogue chemical 4

METHOD US 16 CFR 1500 Hazardous Substances Labelling Act

Species/Strain	Rabbit/New Zealand White
Number of Animals	3 per sex
Vehicle	None
Observation Period	72 hours
Type of Dressing	Semi-occlusive

Remarks – Method Gauze patch was applied for 24 hours. Scoring was conducted at 24 and 72 hours only.

RESULTS

Lesion	*Mean Score**	*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at 72-Hour Observation Period*
Erythema/Eschar	0.42	1	> 24 hours	0
Oedema	0.17	1	> 24 hours	0

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

Remarks – Results The Primary Irritation Index was found to be 0.5 out of 8 based on erythema and oedema. No evidence of tissue damage was found.

CONCLUSION The analogue chemical is slightly irritating to the skin.

TEST FACILITY Hill Top Biolabs (1988h)

B.4. Eye Irritation – Rabbit

B.4.1 Analogue chemical 1

TEST SUBSTANCE Analogue chemical 1

METHOD US 16 CFR 1500 Hazardous Substances Labelling Act
Species/Strain Rabbit/New Zealand White
Number of Animals 6 F
Observation Period 72 hours
Remarks – Method No protocol deviations were noted.

RESULTS

Lesion	*Mean Score**						*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3	4	5	6			
Conjunctiva: Redness	0.33	0.67	1	0.67	0.33	1	1	> 72 hours	1
Conjunctiva: Chemosis	0	0	0.33	1	0.33	0.33	2	> 72 hours	1
Conjunctiva: Discharge	0	0	0	0	0	0	0	-	0
Corneal Opacity	0	0	0	0	0	0	0	-	0
Iridial Inflammation	0	0	0	0	0	0	0	-	0

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

Remarks – Results The eyes of all the rabbits were found to show evidence of conjunctival changes. Irritation scores in individual rabbits ranged from 0 to 2.

CONCLUSION The analogue chemical is slightly irritating to the eye.

TEST FACILITY Hill Top Biolabs (1988i)

B.4.2 Analogue chemical 2

TEST SUBSTANCE Analogue chemical 2

METHOD US 16 CFR 1500 Hazardous Substances Labelling Act
Species/Strain Rabbit/New Zealand White
Number of Animals 6 F
Observation Period 72 hours
Remarks – Method No protocol deviations were noted.

RESULTS

Lesion	*Mean Score**						*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3	4	5	6			
Conjunctiva: Redness	0.67	0	0	0	0	0.33	1	> 72 hours	1
Conjunctiva: Chemosis	0	0	0	0	0	0	0	-	0
Conjunctiva: Discharge	0	0	0	0	0	0	0	-	0
Corneal Opacity	0	0	0	0	0	0	0	-	0
Iridial Inflammation	0	0	0	0	0	0	0	-	0

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

Remarks – Results: The eyes of two of the rabbits were found to show evidence of conjunctival changes. Irritation scores in individual rabbits ranged from 0 to 1.

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

TEST FACILITY: Hill Top Biolabs (1988j)

B.4.3 Analogue chemical 3

TEST SUBSTANCE: Analogue chemical 3

METHOD: US 16 CFR 1500 Hazardous Substances Labelling Act
Species/Strain: Rabbit/New Zealand White
Number of Animals: 3 per sex
Observation Period: 72 hours
Remarks – Method: No protocol deviations were noted.

RESULTS

Lesion	*Mean Score**						*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3	4	5	6			
Conjunctiva: Redness	1	1	0	0.67	0.33	0.67	1	> 72 hours	1
Conjunctiva: Chemosis	0.33	0	0	0.33	0	1	1	> 72 hours	1
Conjunctiva: Discharge	0	0	0	0	0	0	0	-	0
Corneal Opacity	0	0	0	0	0	0	0	-	0
Iridial Inflammation	0	0	0	0	0	0	0	-	0

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

Remarks – Results: The eyes of five rabbits were found to show evidence of conjunctival changes. Irritation scores in individual rabbits ranged from 0 to 1.

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

TEST FACILITY: Hill Top Biolabs (1988k)

B.4.4 Analogue chemical 4

TEST SUBSTANCE: Analogue chemical 4

METHOD: US 16 CFR 1500 Hazardous Substances Labelling Act
Species/Strain: Rabbit/New Zealand White
Number of Animals: 3 per sex

Observation Period	72 hours
Remarks – Method	No protocol deviations were noted.

RESULTS

Lesion	*Mean Score**						*Maximum Value*	*Maximum Duration of Any Effect*	*Maximum Value at End of Observation Period*
	1	2	3	4	5	6			
Conjunctiva: Redness	1	1	0	0.67	0.33	0	1	> 72 hours	1
Conjunctiva: Chemosis	0.67	0.67	0	0	0	0	1	> 72 hours	1
Conjunctiva: Discharge	0	0	0	0	0	0	0	-	0
Corneal Opacity	0	0	0	0	0	0	0	-	0
Iridial Inflammation	0	0	0	0	0	0	0	-	0

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

Remarks – Results	The eyes of three rabbits were found to show evidence of conjunctival changes. Irritation scores in individual rabbits ranged from 0 to 1.

CONCLUSION The analogue chemical is slightly irritating to the eye.

TEST FACILITY Hill Top Biolabs (1988l)

B.5. Skin Sensitisation – Guinea Pig

B.5.1 Analogue chemical 1

TEST SUBSTANCE Analogue chemical 1

METHOD Similar to OECD TG 406 Skin Sensitisation –Maximisation Test (1981)
Magnusson & Kligman (1969)

Species/Strain	Guinea pig/Dunkin-Hartley
PRELIMINARY STUDY	Maximum non-irritating concentration: Intradermal: slight erythema at 0.5% Topical: slight erythema at 10% in 1/4 animals
MAIN STUDY	
Number of Animals	Test Group: 10 per sex Control Group: 10 per sex
Vehicle	Mineral oil
Positive Control	0.1% 1-chloro-2,4 dinitrobenzene (DNCB) in petrolatum
INDUCTION PHASE	Induction concentration: Intradermal: 5% Topical: 10%
Signs of Irritation	None noted.
CHALLENGE PHASE	
Challenge	Topical: 10%
Remarks – Method	No significant protocol deviations.

RESULTS

Remarks – Results	No animals in either the control or treated groups exhibited signs of erythema.

CONCLUSION There was no evidence of reactions indicative of skin sensitisation to the analogue chemical at 10% concentration under the conditions of the test.

TEST FACILITY Pharmakon (1992a)

B.5.2 Analogue chemical 2

TEST SUBSTANCE	Analogue chemical 2
METHOD	Similar to OECD TG 406 Skin Sensitisation –Maximisation Test (1981) Magnusson & Kligman (1969)
Species/Strain	Guinea pig/Dunkin-Hartley
PRELIMINARY STUDY	Maximum non-irritating concentration: Intradermal: 5% Topical: 100%
MAIN STUDY	
Number of Animals	Test Group: 10 per sex Control Group: 10 per sex
Vehicle	Mineral oil
Positive Control	0.1% 1-chloro-2,4 dinitrobenzene (DNCB) in petrolatum
INDUCTION PHASE	Induction concentration: Intradermal: 5% Topical: 100%
Signs of Irritation	None noted
CHALLENGE PHASE	
Challenge	Topical: 100%
Remarks – Method	No significant protocol deviations.
RESULTS	
Remarks – Results	No animals in either the control or treated groups exhibited signs of erythema.
CONCLUSION	There was no evidence of reactions indicative of skin sensitisation to the analogue chemical under the conditions of the test.
TEST FACILITY	Pharmakon (1992b)

B.5.3 Analogue chemical 3

TEST SUBSTANCE	Analogue chemical 3
METHOD	OECD TG 406 Skin Sensitisation – Maximisation Test (1992) EC Directive 96/54/EC B.6 Skin Sensitisation – Maximisation Test (1992)
Species/Strain	Guinea pig/Dunkin-Hartley
PRELIMINARY STUDY	Maximum non-irritating concentration: Intradermal: < 1% Topical: 100%
MAIN STUDY	
Number of Animals	Test Group: 20 females Control Group: 10 females
Vehicle	Maize oil
Positive Control	Not conducted in parallel with the test substance, but had been conducted previously in the test laboratory using 2-mercaptobenzothiazole (MBT).
INDUCTION PHASE	Induction concentration: Intradermal: 10% Topical: 25-100%
Signs of Irritation	Slight erythema was observed in one control animal at an intradermal induction site after 1 hour of patch removal and persisted at up to 24 hours. Slight erythema was observed in most animals after topical induction. Dry, flaking and cracking skin was also noted at all sites of all control and test group animals after 24 hours of topical application.
CHALLENGE PHASE	
1st Challenge	Topical: 100%
2nd Challenge	Topical: 50%, 100%
Remarks – Method	No significant protocol deviations.

RESULTS

Animal	*Challenge Concentration*	*Number of Animals Showing Skin Reactions after:*			
		1st Challenge		*2nd Challenge*	
		24 h	*48 h*	*24 h*	*48 h*
Test Group	100%	2/20	1/20	1/20	0/20
	50%	-	-	0/20	0/20
Control Group	100%	0/10	0/10	0/10	0/10
	50%	-	-	0/10	0/10

Remarks – Results

Challenge
Positive responses were noted in 2/20 test group animals at 24 hours after patch removal, lasting to 48 hours after patch removal in one animal.

Rechallenge
A positive response was observed in 1/20 of the test group animals challenged with 100% of the analogue chemical, at 24 hours after patch removal only. The effect resolved at the 48 h observation.

Based on the results, the authors suggested that if the initial response seen in the 1st challenge was a true sensitisation response, this animal would have been expected to respond in the same way at rechallenge; however, no such response was noted. The authors suggested that this positive result may be due to the fact that the chemical is a mild irritant.

No positive responses were noted in any of the animals of the control group.

CONCLUSION

There was limited evidence of reactions indicative of skin sensitisation to the analogue chemical under the conditions of the test.

TEST FACILITY

Inveresk Research (1997a)

B.6. Repeat Dose Oral Toxicity – Rat

TEST SUBSTANCE

Analogue chemical 3

METHOD

In-house repeat oral dose toxicity protocol (not specified)

Species/Strain
Rat/Sprague-Dawley

Route of Administration
Oral – gavage

Exposure Information
Total exposure days: 90 days
Dose regimen: 7 days per week
F0 generation males and females were dosed four weeks prior to mating. For the males, dosing continued until scheduled euthanasia (at the end of the breeding period). For the females dosing continued through gestation and through lactation day 20 or until euthanasia for females without evidence of mating and/or failure to deliver. Dams that delivered and weaned their offspring were euthanised on lactation day 21. The F1 generation was dosed from Day 21 to Day 90.

Vehicle
Polyethylene Glycol 400

Remarks – Method
Minor deviations from protocol were noted but appeared to be unlikely to affect the outcome of the study.

RESULTS

Group	*Number and Sex of Animals*		*Dose (mg/kg bw/day)*	*Mortality*	
	F0	F1		F0	F1
Control	30 per sex	20 per sex	0	4 F	0
Low Dose	30 per sex	20 per sex	100	5 F	1 F
Mid Dose	30 per sex	20 per sex	500	7 F	1 M

High Dose	30 per sex	20 per sex	1,000	3 F	1 M

Mortality and Time to Death

F0

One control female was euthanised (moribund during an incomplete delivery) and one low dose female died accidentally. Four low dose, seven mid dose and three high dose females were euthanised post breeding day 25 after they produced no evidence of littering. One high dose female was euthanised due to total litter loss.

F1

There were no apparent test article effects on pup viability, live litter size, mean pups per litter and male to female ratio. One male in each of the mid and high dose groups and 1 low dose female were found dead on days 94, 54 and 27, respectively.

Clinical Observations

F0

A range of clinical observations was recorded as minor and likely to be due the vehicle. The study authors reported that none were attributed to the test article.

No changes in body weights or body weight gain due to treatment was found for F0 males. For the females the only observation related to treatment was a significant decrease in body weight gain for high dose females.

The only treatment related changes to food consumption were in high dose females over days 1 – 7 and 7 – 14 of lactation. These changes were statistically significant in terms of weight(g)/animal/day but not when calculated as g/kg bw/day.

There were no test article related effects on fertility, length of gestation, pregnancy status, parturition or lactation except that one high dose female had total litter loss.

F1

A number of incidental clinical findings were noted but were reported as not related to the test article. Significant increases in body weight in high dose animals were noted in males over weeks 11 and 12 and in females over weeks 3 to 4 but were reported as not ascribed to the test article. Food consumption decreased in mid dose females over weeks 6 to 7, in the low, mid and high dose groups over weeks 12 to 13 and in the low and mid dose groups over weeks 13 to 14. These changes were not considered to be biologically significant due to a lack of dose response or an abnormally increased control value.

Laboratory Findings – Clinical Chemistry, Haematology, Urinalysis

F1

Clinical Chemistry: No test article related changes.
Haematology: Elevated prothrombin time in high dose males; no dose related changes in females.

Effects in Organs

F0

No macroscopic changes were observed in the F0 males and female that were test article related.

F1

No test article related macroscopic or microscopic findings were noted.

Remarks – Results

Treatment of F0 rats with analogue 3 at the designated dosage levels did not produce significant organ toxicity or effects on fertility nor did the F1 pups exhibit toxic effects during the parturition and lactation phases. In the F1 rats during the 91-day toxicity phase, no organ toxicity could be attributed to the test article. A significant increase in prothrombin time in high dose males was not considered to be biologically meaningful as it did not correlate with a decrease in platelets, gross necropsy or microscopic findings according to the study authors. Effects observed for clinical observations, clinical chemistry and in organs were considered by the study authors to be vehicle- related and not test substance-related.

CONCLUSION

A No Observed Effect Level (NOEL) of 1,000 mg/kg bw/d was established by the study authors.

TEST FACILITY Springborn (1994)

B.7. Genotoxicity – Bacteria

TEST SUBSTANCE Analogue chemical 2

METHOD OECD TG 471 Bacterial Reverse Mutation Test
Species/Strain *Salmonella typhimurium*: TA1535, TA1537, TA98, TA100
Escherichia coli: WP2uvrA
Metabolic Activation System Aroclor 1254 induced rat liver S9 fraction
Concentration Range in Main Test a) With metabolic activation: 156.25 - 5000 µg/plate
b) Without metabolic activation: 156.25 - 5000 µg/plate
Vehicle Sorbitan stearate and Polysorbate 60
Remarks – Method No significant protocol deviations

Positive controls:
With metabolic activation: 2-aminoanthracene
Without metabolic activation: methyl methanesulphonate (TA100); N-ethyl-N-nitro-N-nitrosoguanidine (TA1535, WP2 uvrA); 2-nitrofluorene (TA98); 9-aminoacridine (TA1537)

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*		
	Cytotoxicity in Main Test	*Precipitation*	*Genotoxic Effect*
Absent	> 5000	≥ 5000	negative
Present	> 5000	≥ 5000	negative

Remarks – Results No significant increases in the frequency of revertant colonies were observed for any of the bacterial strains, with any dose of the test substance, either with or without metabolic activation.

The positive and negative controls gave a satisfactory response confirming the validity of the test system.

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

TEST FACILITY Inveresk Research (1997a)

B.8. Genotoxicity – *In Vitro* Mammalian Cell Gene Mutation

TEST SUBSTANCE Analogue Chemical 5

METHOD OECD TG 476 *In vitro* Mammalian Cell Gene Mutation Test (1997)
EC Directive 2000/32/EC B.17 Mutagenicity – *In vitro* Mammalian Cell Gene Mutation Test
Species/Strain Chinese hamster
Cell Type/Cell Line Chinese hamster ovary (CHO)
Metabolic Activation System Aroclor 1254 induced rat liver S9 fraction
Vehicle Ethanol
Remarks – Method Two protocol deviations were described, that were considered by the study author to have no effect on the validity of the test results. The activated portion of test 1 was lost due to contamination and was repeated. In the confirmatory assay the number of cells seeded in the solvent control and all the test substance-treated cultures, except for one replicate at the highest concentration of 5,000 µg/mL, was less than 2×10^5 cells/plate.

Positive control:
Without metabolic activation: ethyl methanesulfonate (EMS)

With metabolic activation:7,12-dimethylbenz[a]anthracene (DMBA)

Metabolic Activation	*Test Substance Concentration (μg/mL)*	*Exposure Period*	*Expression Time*	*Selection Time*
Absent				
Test 1	313, 625, 1,250, 2,500, 5,000	4 hrs	8 days	7 days
Test 2	313, 625, 1,250, 2,500, 5,000	4 hrs	8 days	7 days
Present				
Test 1	313, 625, 1,250, 2,500, 5,000	4 hrs	8 days	7 days
Test 2	313, 625, 1,250, 2,500, 5,000	4 hrs	8 days	7 days

RESULTS

Metabolic Activation	*Test Substance Concentration (μg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	> 5,000	> 5,000	> 5,000	negative
Test 2	-	> 5,000	> 5,000	negative
Present				
Test 1	> 5,000	≥ 625	> 5,000	negative
Test 2	-	≥ 2,500	> 5,000	negative

Remarks – Results

In Test 1 (without metabolic activation), a statistically significant increase in the frequencies of mutants was noted at the 313 μg/mL concentration; however, the study authors did not consider these results to be biologically relevant as the observed values were not greater than or equal to two fold of the solvent control.

In Test 1 (with metabolic activation), a statistically significant increase in the frequencies of mutants was noted at the 625 μg/mL concentration. When this was repeated in Test 2, this increase in mutants was not observed at the same dose level (with metabolic activation), but at 2500 μg/mL. Despite the increase in mutants at these concentrations, the study authors did not consider these results to be biologically relevant as the increase was within the range of the historical control data and no dose-dependency via trend test was observed.

Apart from these observations, the analogue chemical did not induce a statistically or biologically significant increase in the mutant frequencies either with or without metabolic activation.

The positive and negative controls gave a satisfactory response confirming the validity of the test system.

CONCLUSION

The analogue chemical was not clastogenic to Chinese hamster ovary cells treated *in vitro* under the conditions of the test.

TEST FACILITY

SITEK (2001)

B.9. Genotoxicity – *In Vitro* Mammalian Chromosome Aberration Test

TEST SUBSTANCE

Analogue Chemical 5

METHOD

OECD TG 473 *In vitro* Mammalian Chromosome Aberration Test
EC Directive 2000/32/EC B.10 Mutagenicity – *In vitro* Mammalian Chromosome Aberration Test

Species/Strain	Human
Cell Type/Cell Line	Peripheral lymphocytes
Metabolic Activation System	Aroclor 1254 induced rat liver S9 fraction
Vehicle	Ethanol

Remarks – Method: No significant protocol deviations.

Positive control:
Without metabolic activation: ethyl methanesulfonate
With metabolic activation: cyclophosphamide

Metabolic Activation	*Test Substance Concentration (μg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	39, 78.1, 156.25, 312.5, 625, 1,250*, 2,500*, 5,000*	4 hrs	20 hrs
Test 2	625, 1,250*, 2,500*, 5,000**	4 hrs	20, 44 hrs
Present			
Test 1	39, 78.1, 156.25, 312.5, 625, 1,250*, 2,500*, 5,000*	4 hrs	20 hrs
Test 2	625, 1,250*, 2,500*, 5,000**	4 hrs	20, 44 hrs

*Cultures selected for metaphase analysis. ** Cultures selected for metaphase analysis at both harvest times

RESULTS

Metabolic Activation	*Test Substance Concentration (μg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1	-	> 5,000	> 5,000	negative
Test 2	-	> 5,000	> 5,000	negative
Present				
Test 1	-	> 5,000	> 5,000	negative
Test 2	-	> 5,000	> 5,000	negative

Remarks – Results: No statistically significant increases in the frequency of cells with structural or numerical chromosome aberrations were observed in the presence or absence of metabolic activation.

The results of the negative controls were within historical limits and the positive controls demonstrated the sensitivity of the test. In test 2 one of the positive control cultures was negative due to excessive toxicity but this did not negate the conclusions of the experiment.

CONCLUSION: The analogue chemical was not clastogenic to human lymphocytes treated *in vitro* under the conditions of the test.

TEST FACILITY: Safepharm (1995a)

B.10. Genotoxicity – *In Vivo* Erythrocyte Micronucleus Test

TEST SUBSTANCE: Analogue chemical 6

METHOD: OECD TG 474 Mammalian Erythrocyte Micronucleus Test
EC Directive 2000/32/EC B.12 Mutagenicity – Mammalian Erythrocyte Micronucleus Test
Species/Strain: Mouse/CD-1
Route of Administration: Intraperitoneal injection
Vehicle: Arachis Oil
Remarks – Method: No significant protocol deviations

Group	*Number and Sex of Animals for each sacrifice time*	*Dose (mg/kg bw)*	*Sacrifice Time (hours)*
I (vehicle control)	5 per sex	0	24, 48, 72 hrs
II (low dose)	5 per sex	1,250	24, 48, 72 hrs
III (mid dose)	5 per sex	2,500	24, 48, 72 hrs
IV (high dose)	5 per sex	5,000	24, 48, 72 hrs
V (positive control, CP)	5 per sex	50	24 hrs

CP = cyclophosphamide.

RESULTS	
Doses Producing Toxicity	No clinical signs of toxicity were noted. As there was no indication of toxicity at any dose level, it is not possible to confirm that the test substance reached the bone marrow.
Genotoxic Effects	There was no statistically significant increase in micronucleated PCEs in any test group when compared to vehicle control. There were no differences in the PCE/NCE ratio in any dose group as compared to the vehicle control.
Remarks – Results	Vehicle and positive controls performed as expected, confirming the validity of the test system.
CONCLUSION	The analogue chemical was not clastogenic under the conditions of this *in vivo* mouse micronucleus test.
TEST FACILITY	Safepharm (1995b)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Ecotoxicological Investigations

C.1.1. Inhibition of Microbial Activity

TEST SUBSTANCE	Assessed chemical
METHOD	OECD TG 209 Activated Sludge, Respiration Inhibition Test
Inoculum	Activated Sludge
Exposure Period	3 hours
Concentration Range	Nominal: 10, 1000 and 1000 mg/L
Remarks – Method	No major deviations from the test guidelines were reported. The test substance was added to the test medium and stirred for 3 hours before testing. A reference test with 3,5-dichlorophenol was run.
RESULTS	
IC50	> 1000 mg/L
NOEC	1000 mg/L
Remarks – Results	The validity criteria for the test were satisfied. The mean control oxygen uptake rate was not lower than 20 mg oxygen per one gram of activated sludge in an hour. Dissolved oxygen concentration was >60% saturation during the test. No significant toxic effect was observed at the highest concentration. The reference item gave a 3 h IC50 of 4.7 mg/L, which was within the acceptable range of 2 to 25 mg/L for total respiration.
CONCLUSION	The assessed chemical does not inhibit microbial respiration.
TEST FACILITY	CRL (2018)

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