



Australian Government
Department of Health and Ageing
NICNAS

Existing Chemical
Secondary Notification Assessment
NA/486S

Infineum C9350

November 2006

National Industrial Chemicals Notification and Assessment Scheme
GPO Box 58, Sydney NSW 2001, Australia www.nicnas.gov.au

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Preface

This assessment was carried out under the National Industrial Chemicals Notification and Assessment Scheme (NICNAS). This Scheme was established by the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act), which came into operation on 17 July 1990.

The principal aim of NICNAS is to aid in the protection of people at work, the public and the environment from the harmful effects of industrial chemicals.

NICNAS assessments are conducted in conjunction with the Australian Government Department of the Environment and Heritage, which carries out the environmental assessment.

NICNAS has two major programs: the assessment of the health and environmental effects of new industrial chemicals prior to importation or manufacture; and the other focussing on the assessment of chemicals already in use in Australia in response to specific concerns about their health and/or environmental effects.

Chemicals that have been assessed as new or existing chemicals may require a reassessment of the risk of the chemical under the secondary notification provisions of the Act.

This assessment report has been prepared by the Director of NICNAS, in accordance with the secondary notification provisions of the Act. Under the Act manufacturers/importers of the chemical are required to notify the Director of new information and apply for assessment. New information can include a significant increase in quantity imported, the commencement of Australian manufacture, increased environmental exposure, and/or additional information becoming available on hazards.

Applicants for assessment are given a draft copy of the report and 28 days to advise the Director of any errors. Following the correction of any errors, the Director provides applicants and other interested parties with a copy of the draft assessment report for consideration. This is a period of public comment lasting for 28 days during which requests for variation of the report may be made. Where variations are requested the Director's decision concerning each request is made available to each respondent and to other interested parties (for a further period of 28 days). Notices in relation to public comment and decisions made appear in the *Commonwealth Chemical Gazette*.

In accordance with the Act, publication of this report revokes the declaration of this chemical for secondary assessment, therefore manufacturers and importers wishing to introduce this chemical in the future need not apply for assessment unless further secondary notification is required under S65 of the Act. Manufacturers and importers need to be aware of their duty to provide any new information to NICNAS, as required under Section 64 of the Act.

For the purposes of Section 78(1) of the Act, copies of assessment reports for new and existing chemical assessments are freely available from the web (www.nicnas.gov.au) and may be inspected by the public at the ASCC Library (Office of the Australian Safety and Compensation Council), Department of Employment and Workplace Relations (formerly known as the National Occupational Health and Safety Commission (NOHSC) library). Summary Reports are published in the *Commonwealth Chemical Gazette* (<http://www.nicnas.gov.au/publications/#gazette>), which are also available to the public at the ASCC library.

Copies of this and other assessment reports are available on the NICNAS website. Hardcopies are available from NICNAS directly from the following address:

GPO Box 58, Sydney, NSW 2001, AUSTRALIA

Tel: +61 (02) 8577 8800

Freecall: 1800 638 528

Fax: +61 (02) 8577 8888

Other information about NICNAS (also available on request) includes:

- NICNAS Service Charter;
- NICNAS Community Engagement Charter
- Information sheets on NICNAS Registration;
- Information sheets on Priority Existing Chemical and New Chemicals assessment programs;
- Safety information sheets on chemicals that have been assessed as Priority Existing Chemicals;
- Details for the NICNAS Handbook for Notifiers; and
- Details for the *Commonwealth Chemical Gazette*.

More information on NICNAS can be found at the NICNAS web site:

<http://www.nicnas.gov.au>

Other information on the management of workplace chemicals can be found at the following web site:

<http://www.ascc.gov.au>

Overview and Recommendations

Overview

Background

Infineum C9350 was declared for secondary notification by notice published in the *Chemical Gazette* as a result of new toxicity data becoming available and a new use being identified.

Infineum C9350 was assessed as a new chemical in 1999 in the standard notification category. The New Chemicals Assessment Report (NA/486) was published in September 1999 and the chemical was classified as R43, “may cause sensitisation by skin contact” at concentrations $\geq 1\%$ and R38, “irritating to skin at concentrations $\geq 20\%$ ”.

This current report involved a more complete assessment of experimental human data on the sensitisation potential of Infineum C9350 and reconsidered the environmental impact based on the changed use pattern. A previously submitted Buehler test in guinea pigs was also reassessed together with the human data so as to obtain a more complete picture of the chemical’s sensitisation potential.

Infineum C9350 is not a pure chemical entity and is described as calcium long chain alkyl benzene sulphonate. It is not manufactured in Australia . It is a non-flammable, non-explosive, viscous brown liquid with a faint petroleum odour and low water solubility.

Uses

Infineum C9350 was previously assessed as a new chemical under the name Parabar 9350 for use as a detergent additive in crankcase motor oils. It is now intended that the majority of import of Infineum C9350 will be as an additive to oils used as lubricants in the cutting of metals with small amounts imported for crankcase oils.

Exposure

The assessment of Infineum C9350 as a new chemical in 1999 indicated that the import of the chemical could expose workers during the following activities:

- unloading the additive blend at the port for storage or road transport
- transportation of the bulk additive blend to commercial customers for blending
- storage sites at the importer’s or oil blenders’ storage tanks
- blending operations at the lubricant oil blending plants
- maintenance of pump, blending, and associated equipment at plants or
- during transport.

Dermal contact was seen as the main route of exposure however it was expected that this would be minimised because of automated handling procedures, engineering controls and workers using personal protective equipment. Workers in the automotive service industry such as mechanics and their assistants doing regular maintenance and repair work on motors are unlikely to use protective clothing apart from overalls in their daily work and facilities are unlikely to have engineering controls in place to minimise exposure. Therefore, repeated dermal exposure to concentrations of Infineum 9350 of up to 2% in the final lubricating oil mixture can occur for these workers.

In terms of the new use, occupational exposure would be unchanged during delivery, transport and formulation of oils but because of decreased volumes of Infineum C9350 being used, exposure during vehicle and ship maintenance would also decrease. Exposure to workers in the metalworking industries is potentially significant but, based on information provided to NICNAS, it is expected these workers will wear appropriate PPE so occupational exposure will be minimal. NICNAS has not independently examined the use of PPE in any industry for the purposes of this report. It must be remembered that PPE is the least preferred risk control measure and in some cases the work being performed mitigates against wearing of PPE. For example, in metalworking, factors such as loss of grip strength, loss of manual dexterity and increased risk of entanglement with machinery can work against glove usage. Infineum C9350 is classified as a skin sensitiser. Reliance on PPE alone is unlikely to provide sufficient protection against skin sensitisation.

Public exposure is considered to be low for the use in metalworking fluids. For use in crankcase oils the previous report determined low public exposure during formulation of the oils. For do-it-yourself oil changes users may be dermally exposed for short durations at infrequent intervals. As volumes for use in crankcase oils will be lower than previously notified public exposure from this use will be below what was previously determined.

No new environmental data were provided for this assessment. Release to the atmosphere is likely to be negligible. Accidental release during blending will be contained and removed for disposal. Environmental exposure is expected to be minimal from accidental spills or leaks from storage tanks or in landfills as the chemical is expected to bind strongly to soil due to its low water solubility.

Health effects

Previous assessment as a new chemical found that Infineum C9350 showed low acute oral and dermal toxicity in animals. In rabbits it was a slight eye irritant but did not show any potential for skin irritation. The chemical was however found to be a skin sensitiser in a Buehler test. Repeat dosing of rats showed mild to moderate skin irritation and minor histopathological changes all of which appeared reversible, and in vitro testing did not demonstrate the chemical to be mutagenic nor inductive of structural chromosomal aberrations. A human repeat insult patch test was found to be insufficiently reported such that no conclusions regarding sensitisation could be drawn, but the study did show Infineum C9350 to be a skin irritant in human volunteers.

Reassessment of the Buehler test showed that the chemical had significant sensitisation potential in animal studies and confirmed the conclusions reached in the new chemical assessment. The human repeat insult patch test (HRIPT) was considered by this reassessment to have been poorly performed and poorly reported with a number of inconsistencies. Consequently it is considered that no reliable conclusions can be drawn from the HRIPT. Based on the animal data and noting the study in humans is inconclusive, the classification of Infineum C9350 as a skin sensitiser is confirmed.

Infineum C9350 is classified as a hazardous substance under the NOHSC's *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

Infineum C9350 is classified as a hazardous substance under the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) (UNECE, 2005) and would require appropriate labelling when this system is adopted in Australia.

Risk

Except in the event of a spill, occupational risk during transport of the imported additive package is expected to be low. Use of automated transfer systems and PPE by workers during blending is expected to result in low risk (based on information supplied to NICNAS). Occupational risk from use of products containing Infineum C9350 in heavy metal working is moderate due to the higher concentrations of the chemical used in these types of products, however based on information supplied to NICNAS, workers in these industries generally use PPE, though it should be noted that PPE alone is not sufficient to provide protection against hazardous substances. No significant risk is expected from light duty metal working lubricants because the concentration of Infineum C9350 will be below 1%. Engineering controls to minimise exposure to lubricating fluids are unlikely to be in place in all automotive repair workshops. Workers involved in the automotive repair industry are unlikely to use PPE and are expected to be repeatedly exposed to the chemical. Because of the additive nature of exposure these workers are at risk of skin sensitisation.

The public is at low risk from use of products containing Infineum C9350 as it is likely hobbyists working with metal would use products containing less than 1% of the chemical and the infrequent nature of DIY oil changes in motor vehicles means that the public are unlikely to be continuously exposed.

On the basis of data previously supplied, Infineum C9350 is considered non-toxic to aquatic organisms up to the limit of its solubility. The chemical is unlikely to pose an environmental risk to aquatic organisms from use in motor vehicles or metal cutting fluids.

Recommendations

This section provides the recommendations arising from the secondary notification assessment of Infineum C9350. Recommendations are directed principally at regulatory bodies and importers and formulators of Infineum C9350. Implicit in these recommendations is that best practice is implemented to minimise occupational and public exposure and environmental impact.

Recommendations for regulatory bodies:

Australian Safety and Compensation Council

Calcium long chain alkyl benzene sulphonate (Infineum C9350) is not currently listed in the ASCC's *Hazardous Substances Information System (HSIS)*.

In accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004) Infineum C9350 is classified as:

R43 **May cause sensitisation by skin contact**

R38 **Irritating to skin**

The concentration cut-offs for mixtures containing calcium long chain alkyl benzene sulphonate are:

Risk Phrases*	Concentration Cut-off
Xi, R43	Conc \geq 1%
Xi, R38	Conc \geq 20%

*Xi, Irritant

The following safety phrases are also recommended:

S24/25	Avoid contact with skin and eyes
S28	After contact with skin, wash immediately with plenty of soap suds
S36/37/39	Wear suitable protective clothing, gloves and eye/face protection

This classification should be reflected in the ASCC's HSIS.

Recommendations for importers and State and Territory Authorities:

Hazard communication – Material Safety Data Sheet

Under the *National Model Regulations for the Control of Workplace Hazardous Substances* (NOHSC, 1994) and the Commonwealth, State and Territory regulations introduced in accordance with these national model regulations, employees shall have ready access to Material Safety Data Sheets (MSDS) for hazardous substances at their workplace. MSDS provide information to those who use the hazardous substance.

It is recommended that importers of Infineum C9350 review their MSDS for compliance with the *National Code of Practice for the Preparation of Material Safety Data Sheets 2nd Edition*, paying particular attention to the hazard classification in Recommendation 13.1.1

Hazard communication – Labels

In accordance with the *National Code of Practice for the Labelling of Workplace Substances* (NOHSC 1994a) it is recommended that importers of Infineum C9350 review their labels for compliance and pay particular attention to the following:

In addition to the hazard classification risk phrases it is recommended the following safety phrases be incorporated on labels of Infineum C9350 or products containing Infineum C9350 in concentrations greater than or equal to 1%:

S24/25	Avoid contact with skin and eyes
S28	After contact with skin, wash immediately with plenty of soap suds
S36/37/39	Wear suitable protective clothing, gloves and eye/face protection

Recommendation to importers and users:

Classification

The above classification should be adopted by industry on publication of this report.

Occupational controls

The risk of adverse effects from occupational use of Infineum C9350 is low. This assessment supports the control measures recommended in the original new chemical assessment report NA/486. The control measures for Infineum C9350 are as follows:

- local exhaust ventilation at the refinery/terminal facility when the petrol additive is blended with petrol;
- avoidance of spillage and splashing of the chemical. Spillages should be cleaned up promptly and put into containers for disposal;
- if engineering controls and safe work practices are insufficient to reduce exposure, employers should ensure that personal protective equipment such as gloves, safety glasses and overalls are used by workers to minimise occupational exposure. The personal protective equipment used should be in accordance with Australian, Australian/New Zealand or other approved standards.

Disposal

Accidental leaks and spillages should be cleaned up promptly with absorbents and put into containers for disposal. The empty drums and their residues should be disposed in accordance with government regulations.

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Acronyms and Abbreviations

ACGIH	American Conference of Governmental Industrial Hygienists
ADG Code	Australian Dangerous Goods Code
ADI	acceptable daily intake
ai	active ingredient
AICS	Australian Inventory of Chemical Substances (NICNAS)
AS	Australian Standard
ASCC	Australian Safety and Compensation Council
BEI	Biological Exposure Index
BOD	biochemical oxygen demand
BUN	blood urea nitrogen
bw	bodyweight
CAS	Chemical Abstracts Service
CHO	Chinese hamster ovary
CNS	central nervous system
COD	chemical oxygen demand
conc.	concentration
d	day
DOL	dissolved oxygen level
EASE	estimation and assessment of substance exposure

EC50	median effective concentration
EC	European Community, or European Commission
EU	European Union
h	hour
HRIPT	human repeat insult patch test
HSIS	Hazardous Substances Information System (ASCC)
id	intra-dermal
im	intra-muscular
ip	intra-peritoneal
iv	intra-venous
IC(NA) Act	<i>Industrial Chemicals (Notification and Assessment) Act 1989</i> (Cwlth)
IUPAC	International Union of Pure and Applied Chemistry
IR	infrared
K_{oc}	organic carbon partition coefficient
K_{ow}	octanol/water partition coefficient
LC50	median lethal concentration
LD50	median lethal dose
LDH	lactate dehydrogenase
LEV	local exhaust ventilation
LL50	lethal loading rate resulting in 50% mortality

LLR	lethal loading rate
LOAEL	lowest-observed-adverse-effect level
LOEL	lowest-observed-effect level
mg/kg bw/d	milligram per kilogram bodyweight per day
MOE	margin of exposure
MRL	maximum residue limit
MTD	maximum tolerated dose
MSDS	material safety data sheet
ND	New data. In this report these initials are used to highlight the fact that data under discussion is new data submitted for this assessment. Data submitted for the original assessment and summarised in this report is not highlighted in this way.
NICNAS	National Industrial Chemicals Notification and Assessment Scheme
NIOSH	National Institute of Occupational Safety and Health
NOEC	no-observed-effect concentration
NOAEL	no-observed-adverse-effect level
NOEL	no-observed-effect level
NOHSC	National Occupational Health and Safety Commission
OECD	Organisation for Economic Cooperation and Development
pKa	dissociation constant
ppm	parts per million
ppb	parts per billion

PEC	predicted environmental concentration
PPE	personal protective equipment
sc	subcutaneous
SAR	structure-activity relationship
SCE	sister chromatid exchange
STP	sewage treatment plant
SUSDP	Standard for the Uniform Scheduling of Drugs and Poisons
TOD	total oxygen demand
TLV	Threshold Limit Value (ACGIH)
TSCA	Toxic Substances Control Act (US)
TWA	time-weighted average (NOHSC)
UDS	unscheduled DNA synthesis
VOC	volatile organic compound
v/v	volume per volume
w/v	weight per volume
w/w	weight per weight
WAF	water accommodated fraction
WHO	World Health Organization
WSF	water soluble fraction

Glossary

In this report, NICNAS used the IPCS Risk Assessment Terminology (WHO, 2004) glossary which includes Part 1: IPCS/OECD Key Generic Terms used in Chemical Hazard/Risk Assessment and Part 2: IPCS Glossary of Key Exposure Assessment Terminology. The IPCS Terminology can be accessed at: <http://www.who.int/ipcs/methods/harmonization/areas/ipcsterminologyparts1and2.pdf>

Adverse effect	Change in the morphology, physiology, growth, development, reproduction, or life span of an organism, system or (sub) population that results in an impairment of functional capacity, an impairment of the capacity to compensate for additional stress, or an increase in susceptibility to other influences.
Assessment	Evaluation of appraisal of an analysis of facts and the inference of possible consequences concerning a particular object or process.
Assessment endpoint	Quantitative/qualitative expression of a specific factor with which a risk may be associated as determined through an appropriate risk assessment.
Concentration	Amount of a material or agent dissolved or contained in unit quantity in a given medium or system.
Dose	Total amount of an agent administered to, taken up or absorbed by an organism, system or (sub) population.
Dose rate	Dose per unit time
Dose-related effect	Any effect to an organism, system or (sub) population as a result of the quantity of an agent administered to, taken up or absorbed by that organism, system or (sub) population.
Dose-response relationship	Relationship between the amount of an agent administered to, taken up or absorbed by an organism, system or (sub) population and the change developed in that organism, system or (sub) population in reaction to the agent. Related Terms: <i>Dose-Effect Relationship</i> , <i>Effect Assessment</i> , <i>Concentration-Effect Relationship</i> .

Effect	Change in the state or dynamics of an organism, system or (sub) population caused by the exposure to an agent.
Exposure	Concentration or amount of a particular agent that reaches a target organism, system or (sub) population in a specific frequency for a defined duration.
Exposure assessment	Evaluation of the exposure of an organism, system or (sub) population to an agent (and its derivatives). Exposure Assessment is the third step in the process of Risk Assessment.
Exposure period	The time of continuous contact between an agent and a target.
Exposure route	The way an agent enters a target after contact (<i>e.g.</i> , by ingestion, inhalation, or dermal absorption).
Fate	Pattern of distribution of an agent, its derivatives or metabolites in an organism, system, compartment or (sub) population of concern as a result of transport, partitioning, transformation or degradation.
Hazard	Inherent property of an agent or situation having the potential to cause adverse effects when an organism, system or (sub) population is exposed to that agent.
Hazard assessment	A process designed to determine the possible adverse effects of an agent or situation to which an organism, system or (sub) population could be exposed. The process includes hazard identification and hazard characterization. The process focuses on the hazard in contrast to risk assessment where exposure assessment is a distinct additional step.
Hazard characterization	The qualitative and, wherever possible, quantitative description of the inherent properties of an agent or situation having the potential to cause adverse effects. This should, where possible, include a dose-response assessment and its attendant uncertainties. Hazard Characterisation is the second stage in the process of Hazard Assessment, and the second step in Risk Assessment. Related terms: <i>Dose-Effect Relationship, Effect Assessment, Dose-Response Relationship, Concentration -Effect Relationship.</i>

Hazard identification	<p>The identification of the type and nature of adverse effects that an agent has inherent capacity to cause in an organism, system or (sub) population.</p> <p>Hazard identification is the first stage in hazard assessment and the first step in process of Risk Assessment</p>
Risk assessment	<p>A process intended to calculate or estimate the risk to a given target organism, system or (sub)population , including the identification of attendant uncertainties, following exposure to a particular agent, taking into account the inherent characteristics of the agent of concern as well as the characteristics of the specific target system.</p> <p>The Risk Assessment process includes four steps: hazard identification, hazard characterization (related term: dose-response assessment), exposure assessment, and risk characterization. It is the first component in a risk analysis process.</p>
Risk characterization	<p>The qualitative and, wherever possible, quantitative determination, including attendant uncertainties, of the probability of occurrence of known and potential adverse effects of an agent in a given organism, system or population, under defined exposure conditions.</p> <p>Risk Characterization is the fourth step in the Risk Assessment process.</p>
Risk management	<p>Decision-making process involving considerations of political, social, economic, and technical factors with relevant risk assessment information relating to a hazard so as to develop, analyse, and compare regulatory and non-regulatory options and to select and implement appropriate regulatory response to that hazard.</p> <p>Risk management comprises three elements: risk evaluation; emission and exposure control; risk monitoring.</p>
Toxicity	<p>Inherent property of an agent to cause an adverse biological effect.</p>
Uptake (absorption)	<p>The process by which an agent crosses an absorption barrier.</p>

1. Introduction

The chemical Parabar 9350 was assessed as a new chemical under Section 23 of the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act) under the standard notification category. Parabar 9350 is now known as Infineum C9350 and will be referred to as Infineum C9350 throughout this report.

The New Chemicals Assessment Report (NA/486) was published in September 1999. From the limited data provided at the time, a hazard classification was conducted in accordance with the National Occupational Health and Safety Commission's (NOHSC) *Approved Criteria for Classifying Hazardous Substances*. Infineum C9350 was considered to be a skin sensitiser and skin irritant and classified as R43, "may cause sensitisation by skin contact" at concentrations \geq 1% and R38, "irritating to skin" at concentrations \geq 20%. Readers are referred to the New Chemicals Full Public Report on Parabar 9350 available at the NICNAS website

<http://www.nicnas.gov.au/PUBLICATIONS/CAR/NEW/NA/NASUMMR/NA040OSR/na486.asp>

Recommendations were made relating to engineering controls, use of personal protective equipment, safe work practices and Material Safety Data Sheet (MSDS). These recommendations were based on the intended use of Infineum C9350 as a detergent additive in crankcase oils.

The chemical was classified as a sensitiser, based on a positive sensitisation study in animals. A human repeat insult patch test was also provided however the data presented were insufficient to negate the positive animal data. Infineum Australia Pty Limited later provided complete experimental human data on Infineum C9350 which warranted a re-assessment of the skin sensitisation potential of the chemical. A new use and increased import volume were also foreshadowed.

Infineum C9350 was originally assessed for use as a detergent in crankcase oils and has been imported into Australia in low quantities for use in passenger motor vehicle crankcase oils. It is now intended that the majority of import of Infineum C9350 will be as an additive to oils used as lubricants in the cutting of metals. Use in marine crankcase oils will be limited and these products will only be imported as necessary for bunkering of ships and as a consequence will almost immediately be re-exported in the ships' engines. Use as an additive in crankcase oils for passenger motor vehicles is to continue as a minor import.

As five years have elapsed since the original assessment, this chemical is now being assessed as an existing chemical (Secondary Notification). The new data (toxicity and new use) warranted reassessment which has been carried out under Section 68A of the Act, covering secondary notifications of existing chemicals.

Data submitted for the original assessment on use, exposure, animal and human toxicity are summarised in this report in the relevant sections. New data submitted for this assessment are discussed in detail and identified by the abbreviation ND.

1.1 Declaration and secondary notification

A notice was published in the *Chemical Gazette* of 5 July 2005 requiring all persons who introduce Infineum C9350 into Australia either by manufacture or import, to apply for secondary notification, based on the proposed new use and new hazard data becoming available.

1.2 Objectives

The objectives of this assessment were to review the new data made available since the publication of the 1999 New Chemical Assessment, and where appropriate, revise the original assessment to:

- characterise the hazards of Infineum C9350 to human health and the environment;
- characterise potential occupational, public and environmental exposure to Infineum C9350;
- characterise the risks of adverse effects resulting from exposure to workers, the general public and the environment; and
- make appropriate recommendations to control exposures and/or reduce potential risks for workers, the general public and the environment.

1.3 International perspective

The chemical has been notified to the United States, Canada, Korea and the Philippines. It is not classified as a sensitiser in any of those countries.

1.4 Peer review

During all stages of preparation, this report has been subject to internal peer review by NICNAS.

2. Applicants

Two companies applied for secondary notification assessment of this chemical. New toxicity data on skin sensitisation and new use/volume data were supplied by one applicant only. Under Section 36 of the Act, the applicants were provided with a draft copy of the report for correction of errors and variation of content.

Applicant details are:

INFINEUM AUSTRALIA PTY LIMITED

Level 2, 6 Riverside Quay

Southbank VIC 3006

MOBIL OIL AUSTRALIA PTY LIMITED

12 Riverside Quay

Southbank VIC 3006

3. Chemical Identity and Composition

No new data were provided for this assessment on chemical identity and composition

Chemical Name:	calcium long chain alkyl benzene sulphonate
CAS Number	Confidential
Trade name:	Infineum C9350
Average Molecular Weight	Confidential
Degree of purity:	80% –85% minimum
Additives/Adjuvants	Infinium C9350 is supplied in a blend, approximately 40%-60% w/w active ingredient in mineral oil

4. Physical and Chemical Properties

No new data were provided for this assessment on chemical and physical properties.

Infineum C9350 is a viscous brown liquid with a faint petroleum odour. It is not a pure chemical entity and is supplied blended in mineral oil.

Boiling point:	Initial 114.2°C; Final 522.1°C (boiling temperature range estimates)
Density:	Not available
Specific gravity:	0.9045 at 15.5°C
Vapour pressure:	1.61×10^{-5} kPa at 24°C
Water solubility:	5.755 mg/L at 20°C
Partition co-efficient (n-octanol/water):	$\text{Log } P_{\text{ow}} > 6$
Hydrolysis as a function of pH:	Not determined as it does not contain hydrolysable function groups and is poorly soluble in water
Dissociation constant:	pK_a 6.70
Flash point:	> 150°C
Autoignition temperature:	340°C (as for the diluent oil)
Explosive properties:	None indicated by the molecular structure
Flammability limits:	Upper Explosive Limit = 5.0% (as for the diluent oil) Lower Explosive Limit = 1.0% (as for the diluent oil)
Reactivity/stability:	Stable viscous liquid at room temperature
Fat solubility	> 1,000 g/L

Tests were performed at facilities complying with OECD Principles of Good Laboratory Practice (Organisation for Economic Co-operation and Development, 1995-1996).

Concentrations of Infinium C9350 in water were determined by the total organic carbon (TOC) analysis of the equilibrated solutions. Percent carbon information and results of the TOC analysis were used to calculate the test substance concentration in water.

A partition coefficient test reported that Infinium C9350 eluted several discrete chromatographic components when analysed by HPLC. The majority of these components were estimated to have log K_{OW} values greater than 6. There was one minor component with an estimated log K_{OW} of < 1.7 .

After 16 h of equilibration testing three different soils in duplicate, the following sorption of the water-soluble fraction occurred: 0% in Freehold soil, approximately 11% in Colorado soil and approximately 24% in Snyder soil. These results did not meet the guideline for desorption determination and no further desorption testing was conducted. On the basis of these results, it was concluded that sorption of the water soluble components of Infinium C9350 did not occur at any appreciable extent in these soils. The resultant K_{OC} s indicate that this fraction of Infinium C9350 would exhibit very high mobility within soils. However, the remainder of the chemical is expected to be far less mobile.

Infinium C9350 is completely soluble in fat, indicating its potential to migrate and be stored in biological tissues.

5. Manufacture, Importation and Use

5.1 Use

The original assessment indicated the the chemical was to be used as a detergent additive to engine crankcase oils in concentrations of < 5% w/w. Data provided for this secondary notification states that in addition to the crankcase oil use Infineum C9350 will also be used as an additive to metalworking lubricating fluids in concentrations ranging from less than 1% to 10%.

5.2 Manufacture and importation

Infineum C9350 is not manufactured in Australia. Data for the original assessment showed that it would be imported as a bulk lubricating oil additive package containing 1% to 15% w/w of the chemical.

Following the original assessment, import has been in 205L drums for use as a crankcase oil additive in passenger motor vehicles. Import, since 2003, of Infineum C9350 for this use has been as part of an additive package where the chemical has been present in concentrations of between 1% to 10% w/w. Import volume has been up to 5 tonnes/year, which is expected to increase to around 60 tonnes/year.

For use in metalworking fluids the chemical will be imported blended in mineral oil as part of an additive package in 205 L drums at concentrations ranging from 40% to 60% w/w. Over the next five years it is estimated that up to 50 tonnes will be imported annually for this use.

6. Exposure

Occupational, public and environmental exposures are considered below.

6.1 Occupational exposure

6.1.1 Use in crankcase oils

At the time of the original assessment Infineum C9350 was to be imported in bulk as part of a lubricant additive package then transported by road tanker to customer blending facilities for formulation into products which would be transported to retail outlets and industrial users throughout Australia. Exposure was expected for workers involved in transferring the bulk additive package from ship to the customer, blending and transporting the final product and for workers in the automotive service industry. Worker exposure from current imports for crankcase oil use is discussed in the section on metalworking fluids below.

6.1.2 Use in metalworking fluids (ND)

Dockside and transport

The chemical is imported in drums and it is estimated 2 workers would be involved in receiving the import. Occupational exposure is not expected except in the event of a spill. No repackaging of drums is required, as these are delivered directly to the customer site by road transport, which is likely to involve a further 1 – 2 workers. It is estimated that there will be 10 –15 deliveries of chemical per year.

Refinery/terminal facility

At the customer facility Infineum C9350 is blended with other ingredients according to the specific end use of the product. For general soluble oil concentrates, the chemical will be blended in batches of 250 – 5000 L having a concentration of Infineum C9350 of less than 1% w/w. For production of neat oil products and deformation products (e.g cold rolling and milling), Infineum C9350 is similarly blended but the concentration of the chemical is between 1% and 10% w/w. For crankcase oils the final concentration of Infineum C9350 is up to 2% w/w of the blended lubricant.

Automated enclosed processes are used for blending which would typically involve 1 – 4 workers for about 10 minutes per batch. Exposure is expected to be minimal and confined to skin and eye contact occurring as a result of drips and spills during the connection and disconnection of transfer lines and equipment. This is expected to amount to release of millilitre quantities of the chemical. Other workers who may come into contact with the chemical at the customer facility include those associated with quality assurance and maintenance. In total it is estimated that less than 10 workers could potentially come into contact with the chemical per delivery and that potential exposure for each worker would be a maximum of 10 minutes.

The blended fluids are repackaged into small containers or drums in volumes ranging from 2 to 200 L and transported to end users by road transport. Packaging is carried out on an automated filling line. Containers are automatically filled then sealed – usually with a screwcap. Operator involvement is restricted to packaging of the filled containers for distribution.

In all operations workers wear appropriate personal protective equipment and mechanical ventilation is provided.

End use

The end uses of products containing Infineum C9350 are varied. For light metalworking tasks such as drilling, where cooling is important, the soluble cutting oil concentrate (containing Infineum C9350 at a concentration of < 1%) is diluted at a rate of 5% concentrate to 95% water. In applications such as heavy duty metalworking operations, the blended neat oil concentrate (containing Infineum C9350 at a concentration of between 1% and 10%) would be used without further dilution, and for rolling and milling work the blended deformation product would be used without further dilution.

It is anticipated there would be a high number of metalworking facilities that would use products containing Infineum C9350 and hence a large number of workers could potentially be exposed to Infineum C9350 at concentrations of <1% to 10%. It is not possible to estimate the number of workers in metal working facilities. It is expected however that appropriate engineering controls will be in place and workers would wear appropriate personal protective equipment to minimise contact. It must be noted that PPE by itself is not sufficient to protect against the risks of exposure to hazardous substances and engineering controls should be in place as a first measure, to minimise exposure. PPE is an adjunct to engineering controls, not a substitute.

In most cases in the automotive service industry engineering controls are unlikely to be in place at all workplaces and workers such as mechanics and their assistants doing regular maintenance and repair work on motors are unlikely to use protective clothing apart from overalls in their daily work. Therefore, repeated dermal exposure to Infineum C9350 in concentrations of up to 2% in the final lubricating oil mixture can occur for these workers.

6.2 Public exposure

Potential for public exposure at the time of the original assessment was considered to be low.

From this assessment, potential for public exposure from use of Infineum C9350 in metalworking is considered to be low. Products containing Infineum C9350 could be purchased by the general public however the end-use pattern of products mean they will be confined to machinery which incorporates a fluid sump such as lathes and certain metal cutting machinery. It is likely such equipment would be in minimal use by the public.

Lubricating oil containing the chemical will be available to the public through retailers. Public exposure can occur during do-it-yourself (D-I-Y) oil changes. The user may be dermally exposed to Infineum C9350 and its decomposition products in oils, but dermal contact would be short and infrequent. From this assessment, potential for public exposure from use of Infineum C9350 in crankcase lubricants is considered to be low.

6.3 Environmental exposure

6.3.1 Release

During transport and blending, fugitive emissions are considered to be negligible given the chemical is imported in sealed drums and blending is carried out in a closed system. The low vapour pressure and high viscosity indicate that release of Infineum C9350 to the atmosphere will also be negligible. Accidental spillage and leakage during blending will be contained, absorbed with earth or sand and transported off-site to an appropriate disposal facility.

Metal cutting fluids (ND)

In use the products containing Infineum C9350 will be contained within sumps of metalworking machines and circulated from the sump to lubricate the metal being cut then returned to the sump. It is not expected that the lubricant will be released to the atmosphere although depending on the particular operation being performed some splashing of fluid could occur. Once used the lubricant will be removed from the sump and disposed of by recycling, burning or re-refining. It is anticipated that virtually all of the imported chemical will be disposed of in this way.

However, limited information is available on Australian metal working industry practices, particularly those for small and medium enterprises, relating to disposal of waste fluids (NICNAS 2004). The problem for environmental exposure, as identified in the NICNAS report, is the potential for inappropriate disposal of the Infineum C9350 by small metal working companies. According to the EU Technical Guidance Document (EC 2003) worst case release figures to waste water for metal working fluid additives are 18.5% from oil-based fluids and 31.6% from water-based fluids in these industries. As there are believed to be no significant differences in industry practices between Europe and Australia, this will be assumed in the initial worst case Predicted Environmental Concentration (PEC) calculation for Australia for risk.

Crankcase oils

The majority of the chemical will be used as lubricants in the cutting of metals. Use in marine crankcase oils and for passenger motor vehicles will be limited. For the latter, some minor and diffuse exposure will result from spills during addition of oil to vehicles. However, the greatest potential for exposure is through disposal of waste oil containing the additive.

A survey by the Australian Institute of Petroleum (AIP 1995) indicates that of the annual sales of automotive engine oils in Australia, some 60% are potentially recoverable (i.e. not burnt in the engines during use). This report also indicates that around 86% of oil changes take place in specialised automotive service centres, where old oil drained from crankcases could be expected to be disposed of responsibly - either to oil recycling or incineration. The remaining 14% are removed by "do it yourself" (DIY) enthusiasts, and in these cases some of the used oil would be either incinerated, left at transfer stations where it is again likely to be recycled, or deposited into landfill. A recent report estimated that DIY activities account for between 7% to 10% of the unaccounted for quantities of used oil (Meinhardt, 2002).

According to a survey tracing the fate of used lubricating oil in Australia (Snow, 1997) only around 20% of used oil removed by enthusiasts is collected for recycling, approximately 25% is buried or disposed of in landfill, 5% is disposed of into stormwater drains and the remaining 50% is used in treating fence posts, killing grass and weeds or disposed of in other ways.

Consequently, assuming that oil removed by professional mechanics is disposed of appropriately (i.e. burning as workshop heating oil or sent for recycling), negligible release of Infineum C9350 should result from these professional activities. Assuming a worst case scenario of 14% of the used oil removed by the DIY enthusiasts it is possible to have 20%, 25%, 5% and 50% of this oil to be collected for recycling, buried or disposed of in landfill, disposed into stormwater drains and used in treating fence posts, to kill weeds or disposed of in other ways, respectively.

If we assume a maximum of 10 tonnes used for passenger motor vehicle oil, the amount disposed of to the stormwater is $14\% \times 5\% \times 10 \text{ tonnes} = 70 \text{ kg}$. Since the use of lubricating oils will occur throughout Australia, all releases resulting from use or disposal of used oil will be very diffuse, and release of Infineum C9350 in high concentrations is very unlikely except as a result of transport accidents.

Empty containers are either washed and reconditioned or disposed of. It is estimated that empty containers will have approximately 1% unused residues. Washings are either incinerated with unwashed containers disposed of to landfill.

6.3.2 Fate

The following section is reproduced from the original 1999 NICNAS report and will apply to the anticipated use pattern.

Infineum C9350 will be used as automotive and industrial lubricants and will share their fate. Therefore, most spent oil will be combusted (if used for fuel value) or recycled. Incineration products are expected to include oxides of carbon and sulfur, and calcium salts (in the ash). A minor component will be released to the environment from spills and leaks, but this would be widely dispersed. If the chemical were washed off road surfaces, the majority would adsorb to the soil and sediments adjacent to the road. However, the water-soluble components are expected to be more mobile.

Collection of waste lubricants is easier to accomplish from industrial and commercial users than from the small but significant D-I-Y market (Australian and New Zealand Environment Council, 1991). Infineum Australia Pty Limited estimates that greater than 10% of cars are not serviced at garages, which may lead to “used oil” not being collected. This could potentially lead to a release of used oil to the environment. It has been estimated from an ANZEC Report (Australian and New Zealand Environment Council, 1991) that 35% of oil used for automotive purposes will not be collected and could be disposed of in an inappropriate manner, such as dust suppression, vegetation control, uncontrolled burial and incomplete combustion.

The chemical was found not to be readily biodegradable (calculated as the ratio of the amount of CO₂ produced to the theoretical carbon dioxide (ThCO₂), and expressed as a percentage). Biodegradation amounted to 9.08% at the end of the 28 d exposure to activated sludge from a domestic sewage treatment facility in the CO₂ Evolution (Modified Sturm Test) for ready biodegradability (Organisation for Economic Co-operation and Development, 1995-1996). The inherent biodegradability of Infineum C9350 was not measured.

The potential for bioaccumulation was not determined. Due to the partition coefficient ($\log K_{OW} > 6$), water solubility (4.506 mg/L) and high fat solubility, bioaccumulation of the substance may be perceived as an issue of concern (Connell, 1989). However, biological membranes are not permeable to chemicals of very large molecular size. Therefore, bioaccumulation of the substance is not expected (Australian and New Zealand Environment Council, 1991; Connell, 1989; Anliker, 1988).

7. Evaluation of Animal Toxicological Data

Data submitted for the original new chemical assessment included animal studies on acute toxicity, skin irritation, eye irritation, skin sensitisation in guinea pigs, repeat dose toxicity, genotoxicity, micronucleus assay and chromosomal aberration. Summaries of the original data is presented below for completeness.

No new animal data has been provided, however since this secondary notification assessment focused on sensitisation it is felt prudent to re-assess the animal data for this end point so that a full picture of the sensitisation potential on Infineum C9350 is presented.

7.1 Acute toxicity

Table 7.1 - Summary of the acute toxicity of Infineum C9350 or analogue from the original new chemical assessment

Test	Species	Outcome
acute oral toxicity	rat	LD ₅₀ > 2000mg/kg
acute dermal toxicity	rabbit	LD ₅₀ > 2000mg/kg
skin irritation	rabbit	non irritant
eye irritation*	rabbit	slight irritant
skin sensitisation	guinea pig	moderate sensitisation

* data were from an analogue product

7.1.1 Acute oral

In a study using a method similar to OECD Guidelines, 5 male and 5 female Crl:CDBR rats were administered 2000 mg/kg Infineum C9350 by oral intubation and observed for 14 d. No signs of clinical toxicity were noted and all animals survived. The acute oral LD₅₀ was determined to be > 2000 mg/kg.

7.1.2 Acute dermal

Infineum C9350 was applied under occlusive dressing, using a method similar to OECD Guidelines, to the clipped skin of 5 male and 5 female New Zealand white rabbits at a dose of 2000 mg/kg. The patch was removed after 24 h and animals observed for 14 d. On day 1 slight to moderate/severe erythema was seen in all animals and slight oedema in 8 animals. By day 7, 4 animals showed slight erythema and no animals showed oedema. No erythema or oedema was present in any animal by day 14. The acute dermal LD₅₀ was determined to be > 2000 mg/kg.

7.1.3 Skin irritation

Infineum C9350 was non irritant to New Zealand white rabbits. Using a method similar to OECD Guidelines, 0.5 ml of the chemical was applied to the clipped skin of 6 male New Zealand white rabbits under occlusive dressing. The patch was removed after 4 h and animals observed for 3 d. No erythema or oedema were noted in any animal throughout the observation period and all animals survived.

7.1.4 Eye irritation

Using a method similar to OECD Guidelines, 0.1 ml of an analogue of Infineum C9350 which differed in calcium carbonate content, was introduced into the right eye of 2 male and 4 female New Zealand white rabbits. The chemical was not washed out and animals were observed for 14 d. After 24 h redness and/or chemosis and/or discharge was observed in all animals. After 72 h slight redness persisted in 5 animals and by 14 d no clinical signs of toxicity were apparent. Based on analogue data, Infineum C9350 was considered to be a slight eye irritant, though it did not meet the criteria for classification as an eye irritant.

7.1.5 Skin sensitisation

In a Buehler study (Oswald, 1995), 20 female Hartley guinea pigs were employed in the treated and control groups. Induction and challenge concentrations were determined from the results of an irritancy test. At induction, 100% Infineum C9350 was applied topically, for 6 h a day on day 0, 7 and 14. At challenge on day 28 a concentration of 100% Infineum C9350 was applied to the test animals and 10 control animals for 6 h and readings taken 24 h (day 29) and 48 h (day 30) after patch removal. A re-challenge was conducted using the same concentration and methodology on day 35 on the test animals and the remaining 10 control animals. The study included a positive control group of 10 guinea pigs that received 50% 2-mercaptobenzothiazole (MBT) in peanut oil during induction and were challenged and re-challenged with 20% MBT in peanut oil.

No skin reactions were seen in any animal during induction. At challenge, erythema was seen in 19/20 (95%) treated animals 24 h after patch removal and in 15/20 animals (75%) at 48 h. Oedema was seen in 2 animals at 24 h but was absent in all animals at 48 h. No erythema or oedema was seen in control animals. At re-challenge, erythema was seen in 20/20 (100%) treated animals at 24 h and in 15/20 (75%) animals at 48 h. Erythema (very slight) was seen in 1/10 control animals (10%) at 24 h but was absent in all control animals at 48 h. No oedema was seen in treated and control animals. The challenge and re-challenge results in treated animals, indicating the severity and incidence of the observed erythema and oedema are presented in Table 7.2. The results with the positive control at challenge and re-challenge are presented in Table 7.3.

Focusing on erythema seen at challenge, as oedema was only seen in 2 treated animals at day 29 only, 95% and 75% treated animals exhibited erythema at 24 h and 48 h respectively. No erythema (or oedema) was seen in control animals. The report authors state however, that 75% of animals were not sensitised, on the basis that reactions that fade in severity between 24 and 48 h indicate that the reaction may be due to irritation. When such skin reactions are excluded, sustained erythema was observed in 25% treated animals. It is then stated that

because of the disparity in the sensitisation potential when the data were evaluated either by taking the percentage of animals exhibiting a skin reaction at 48 h or by calculating the number of animals whose skin reactions do not diminish between 24 h and 48 h a re-challenge was undertaken. At re-challenge erythema was seen in 100% and 75% treated animals at 24 and 48 h, and 10% control animals at 24 h only.

In comparison, erythema was seen in 100% animals at 24 h and 48 h for both the challenge and re-challenge with the positive control. Sustained or increased erythema was seen in 70% of animals at the initial challenge and 0% of animals at re-challenge (with sustained oedema seen in 0% animals at challenge and 10% animals at re-challenge).

Therefore, while different methods of interpretation of the data can result in different incidences in sensitisation, overall, a significant number of animals have shown skin reactions at challenge and re-challenge, and the observed pattern of responses are similar to that seen with the positive control MBT. Thus, Infineum C9350 is considered to have shown a significant skin sensitisation potential in this study.

Table 7.2 - Challenge (day 29 and 30) and re-challenge (day 36 and 37) dermal scores in treated animals

		Dermal Scores					
		0	1	2	3	4	
Day 29	Erythema	1	6	11	2	0	N = 20
	Oedema	18	2	0	0	0	N = 20
Day 30	Erythema	5	10	5	0	0	N = 20
	Oedema	20	0	0	0	0	N = 20
Day 36	Erythema	0	5	11	4	0	N = 20
	Oedema	20	0	0	0	0	N = 20
Day 37	Erythema	5	14	1	0	0	N = 20
	Oedema	20	0	0	0	0	N = 20

Erythema scores: 0 = no erythema, 1 = very slight, 2 = well-defined, 3 = moderate to severe, 4 severe, to slight eschar formation

Oedema scores: 0 = no oedema, 1 = very slight, 2 = slight, 3 = moderate, 4 = severe

Table 7.3 - Challenge (day 29 and 30) and re-challenge (day 36 and 37) dermal scores in positive control animals

		Dermal Scores					
		0	1	2	3	4	
Day 29	Erythema	0	4	5	1	0	N = 10
	Oedema	8	2	0	0	0	N = 10
Day 30	Erythema	0	3	7	0	0	N = 10
	Oedema	10	0	0	0	0	N = 10
Day 36	Erythema	0	0	5	5	0	N = 10
	Oedema	4	6	0	0	0	N = 10
Day 37	Erythema	0	7	3	0	0	N = 10
	Oedema	9	1	0	0	0	N = 10

Erythema scores: 0 = no erythema, 1 = very slight, 2 = well-defined, 3 = moderate to severe, 4 severe, to slight eschar formation

Oedema scores: 0 = no oedema, 1 = very slight, 2 = slight, 3 = moderate, 4 = severe

7.2 Repeat dose toxicity

7.2.1 Repeat dose dermal toxicity

Using a method similar to OECD guidelines, groups of Crl:CDBR rats (5/sex/group) were exposed to 100, 300 and 1000 mg/kg of Infineum C9350 topically onto clipped skin under occlusive bandage for a minimum of 6 h per day for 28 d. Clinically there was no changes in body weight or food consumption, slight erythema without oedema was observed sporadically in control and treated rats with increasing incidences with dose. No other adverse signs were noted. No changes in haematology, serum chemistry or clotting factors were seen. Histopathologically there was thickening of the epidermis, sebaceous gland hyperplasia, and focal dermal inflammation in all groups including controls however severity increased in all treated male rats and in the 300 mg/kg and 1000 mg/kg treated female rats. All changes appeared reversible and a NOAEL of > 1000 mg/kg was determined.

7.3 Genotoxicity

Five different strains of *salmonella typhimurium* were exposed to Infineum C9350 in concentrations of 250, 500, 1000, 2500 and 5000 µg/plate using a method similar to OECD test guidelines. The chemical was not mutagenic to the bacterial strains tested either in the presence or absence of metabolic activation. Five CD-1

mice were each administered increasing doses of 500, 1000 and 2000 µg/kg of Infineum C9350 by gavage once a day for three days (total of 3 doses) in a micronucleus bone marrow cell study using a method similar to OECD guidelines. There was no increase in micronucleated polychromatic erythrocytes and no induced cytotoxicity.

In a chromosomal aberration assay in Chinese Hamster ovary (CHO) cells using a method similar to OECD guidelines, CHO/WBL cells were exposed to 10, 20 or 40 µg/ml of Infineum C9350 for 16 and 40 h. The chemical did not induce structural chromosomal aberrations either in the presence or absence of metabolic activation.

8. Evaluation of Human Toxicological Data

Data submitted for the original new chemical assessment consisted of a human repeat insult patch test which was considered to be incomplete for full assessment. The reportedly complete study report of the HRIPT was assessed for this secondary notification. The same data were used to assess skin irritancy and skin sensitisation.

8.1 Human repeat insult patch test

Eight chemicals were simultaneously tested in volunteers in a human repeat insult patch test (Kenney, 1993). Of these eight, Infineum Australia advised that two (samples F and H) were analogues of Infineum C9350. Infineum C9350 was not tested. The induction phase consisted of a 24h topical application of 0.1 mL of the test material as provided (semi-occlusive dressing) to the same site 3 times per week for 3 successive weeks. The concentration of the test material ‘as provided’ cannot be reliably determined. Ten to seventeen days after the last induction challenge patches containing 0.1 mL of 10% of the test material (as provided) in mineral oil (semi-occlusive dressing) were applied to the test site and a naive site on the arm or lower back for 24 h and readings taken 48 h and 96 h after application. If required, a re-challenge using the same methodology was undertaken approximately 11 to 13 weeks later with 0.1 mL of 5% of the test material (as provided) in mineral oil. No justification was provided for the challenge concentrations used. Additionally, the justification provided for the use of Infineum C9350 analogues was based on chemical similarity. Due to conflicting information on the identity of the test samples the chemicals tested cannot be reliably determined. However, this assessment assumed that samples F and H are analogues of Infineum C9350.

Text reporting those specific volunteers (i.e. subject number) that did not complete the study was sometimes not consistent to the data presented in tabulated format. The results summarised below relate to the data presented in the table, which included a comprehensive listing of the type of skin reactions observed.

Of the initial 123 volunteers, who were 21 years of age or older, 14 volunteers did not complete the test due to reasons unrelated to the study. Of the remaining volunteers, mild to moderate erythema often with papules present was seen at least once in 38 volunteers during induction with sample F and at least once in 34 volunteers during induction with sample H. Seven volunteers reacted to sample F but not to sample H, three reacted to sample H but not to sample F with 31 volunteers reacting to both sample F and H. Furthermore, it is reported that there was evidence of the skin reactions spreading beyond the test area in 25 volunteers with sample F and 23 volunteers with sample H. Adverse skin reactions resulted in 13 volunteers (who reacted to both sample F and H) not receiving a patch at challenge. For these 13 volunteers whose participation in this study was discontinued, the consulting dermatologist for the study determined that in 2 of the volunteers the skin reactions were definitely related to the test products, and were probably related to the test products in 11 volunteers. Therefore in this study, 96

volunteers were challenged with a 10% solution of the sponsor supplied solutions of two chemicals said to be Infineum C9350 analogues in mineral oil, of which over half were only challenged at a naive site.

At challenge, skin reactions were seen in 6 volunteers at the 96 h reading only to sample F. These results are presented below in Table 8.1. Reactions to sample H at challenge were seen in 10 subjects, all but one being at the 96 h reading (Table 8.2).

Table 8.1 – Skin reactions seen at challenge with 10% of a sponsor supplied solution of Sample F

Volunteer Number	Test site 48h	Naive site 48h	Test site 96h	Naive site 96h
12	NP	0	NP	1P
18	0	0	0	1P
27	NP	0	NP	1P
34	NP	0	NP	1P
76	0	0	1P	0
104	0	0	0	1

NP = Not patched. 0 = No visible reaction and/or erythema. 1 = Mild reaction – macular erythema (faint, but definite pink). P = Papules – red, solid, pinpoint elevation, granular feeling.

Table 8.2 – Skin reactions seen at challenge with 10% of a sponsor supplied solution of Sample H

Volunteer Number	Test site 48h	Naive site 48h	Test site 96h	Naive site 96h
3	NP	0	NP	1P
10	NP	0	NP	1P
12	NP	0	NP	1P
17	0	0	0	1P
18	0	0	0	1P
20	0P	1P	0	0
27	NP	0	NP	1P
34	NP	0	NP	1P
74	NP	0	NP	1P
85	NP	0	NP	1P
87	NP	0	NP	1P

NP = Not patched. 0 = No visible reaction and/or erythema. 1 = Mild reaction – macular erythema (faint, but definite pink). P = Papules – red, solid, pinpoint elevation, granular feeling.

Seventeen subjects who were considered to have had ‘questionable’ responses to test products at challenge, were asked to participate in a re-challenge with a 5% solution of the sponsor supplied solutions of test chemicals in mineral oil. However, subjects 27 and 76 (Table 8.1) and subjects 85 and 87 (Table 8.2), were unable to participate hence 13 subjects were actually re-challenged. At re-challenge subjects were not patched with all test compounds (compared with the challenge phase)

Of the 6 subjects who reacted to sample F at challenge (Table 8.1) volunteers 12 and 18 were re-challenged. These subjects exhibited erythema with papules at the initial challenge. At re-challenge, it is reported that a single volunteer (subject 12) exhibited mild erythema with minimal papular reaction at the 48h observation period. This response resolved by 96 h, suggesting the observed skin reaction was probably due to irritation rather than sensitisation.

Of the 11 subjects who reacted to sample H at challenge (Table 8.2) volunteers 3, 10, 12, 17 and 18 were re-challenged. All these subjects exhibited erythema with papules at the initial challenge and at re-challenge, no reactions to sample H are reported.

Overall, the results for sample H showed similar responses to those seen with sample F. Mild to moderate erythema was seen to sample H in 34 subjects at least once (often with papules present) at induction, and of these, spreading skin reactions were seen in 23. Furthermore, of these 34 subjects, 31 also showed skin reactions to sample F at induction. At challenge, mild erythema with papules was seen in 1 subject 48 h after challenge with sample H and in 10 subjects 96 h after challenge with sample H, compared with sample F where mild erythema with papules was seen in 6 subjects and mild erythema without papules in 1 subject.

Although similar results to sample F were seen with sample H and no skin reactions were seen at re-challenge with either chemical, that indicated a skin sensitisation response, there are a number of experimental limitations with this study, such as:

- no reliable information on the concentrations employed.
- for the 13 subjects whose participation in the study was discontinued, clinical notes are provided for 8 volunteers, of these, skin reactions were considered likely to be due to sensitisation in 5 subjects, though it is not reported which test product or products was/were the causative agent (i.e. no clinical testing to determine such appears to have been undertaken)
- not all the volunteers who exhibited questionable skin reaction at challenge with the chemical were re-challenged.
- six subjects wore the patch for less time than required by the protocol but there is no discussion by the study authors on whether this protocol deviation was significant

Overall, it is considered that no reliable conclusions can be drawn from the HRIPT on the skin sensitisation potential of the chemical.

9. Hazard Classification

This section discusses the classification on the end point of skin sensitisation of Infineum C9350 according to the NOHSC's *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004). The Approved Criteria are cited in the NOHSC *National Model Regulations for the Control of Workplace Hazardous Substances* (NOHSC, 1994) and provide mandatory criteria for determining whether a workplace chemical is hazardous.

The classification for health effects is based on experimental data (animal and in vitro) and human data. Infineum C9350 was determined to be irritating to the skin in concentrations $\geq 20\%$ (R38) and causing sensitisation by skin contact at concentrations $\geq 1\%$ (R43) when assessed as a new chemical.

Classification of Infineum C9350 in accordance with the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) (UNECE, 2005) can be found in Appendix 1. This is provided for guidance only, is not mandatory and has no legal status in Australia at present.

9.1 Skin sensitisation

According to the NOHSC Approved Criteria, a substance shall be classified as sensitising by skin contact and assigned the risk phrase R43 if the following criteria are met:

- if practical experience shows the substance or preparation to be capable of inducing sensitisation by skin contact in a substantial number of persons, or;
- where there are positive results from an appropriate animal test.

In the only available animal study, a Buehler test in guinea pigs, erythema was seen in 100% test animals at the initial 24 h reading following challenge and re-challenge and in 75% animals thereafter. For these test animals, sustained erythema (i.e. severity did not diminish between readings) was seen in 25% and 10% animals at challenge and re-challenge respectively. No sustained oedema was seen in test animals. No sustained skin reactions were seen in control animals. Therefore, while different methods of interpretation of the data can result in different incidences in sensitisation, all the evaluations with the exception of sustained erythema at re-challenge, resulted in incidence rates greater than the 15% which is considered a positive response in the Buehler test. Furthermore, the pattern of responses was similar to that seen with the positive control (2-mercaptobenzothiazole), though a greater incidence of erythema was seen in Infineum C9350 treated animals at re-challenge. Therefore, Infineum C9350 is considered to have shown a significant skin sensitisation potential in this study.

Although a human repeat insult patch test is available that reports no skin sensitisation in the re-challenged volunteers there are a number of limitations with this study, including inconsistencies in the reporting of data, discontinued participation of subjects due to adverse skin reactions, and not all subjects who exhibited questionable skin reactions to Infineum C9350 at challenge were re-challenged. Consequently, no reliable conclusions can be drawn from this study on the skin sensitisation potential of Infineum C9350.

Classification: Based on the available data Infineum C9350 meets the Approved Criteria (NOHSC, 2004) for classification as ‘May cause sensitisation by skin contact’ (risk phrase R43).

10. Environmental Assessment

The following discussion is taken from the original new chemical assessment report and is included for completeness.

10.1 Environmental effects

The ecotoxicity studies presented in Table 10.1 have been supplied by the importer. The tests were carried out to OECD Test Methods.

The supplied acute algal toxicity test was conducted on CMA 604, a calcium long chain alkyl sulfonate, synthetic, high molecular weight chemical, which the importer claims is representative of the same class as the notified substance. The precise chemical identity of this product was not supplied, as it is proprietary information not privileged to the importer. CMA 604 is claimed to be the latest commercial predecessor of Infineum C9350. The importer claims that Environment Canada and the United States' Environmental Protection Agency have both accepted this closely related material as representative of the notified substance. The algal toxicity data of CMA 604 was accepted to represent that of Infineum C9350.

Table 10.1 Ecotoxicity of an analogue of Infineum C9350 (CMA 604)

Test	Species	Results (Nominal Concentrations of WAF [#])
Acute Toxicity Static system [OECD TG 203]	Rainbow trout (<i>Oncorhynchus mykiss</i>)	96 h LL ₅₀ > 1 000 mg/L*
Acute Immobilisation Static system [OECD TG 202]	Water flea (<i>Daphnia magna</i>)	48 h EL ₅₀ > 1 000 mg/L**
Growth Inhibition [†] [Wilbury Test 73-CM ^Δ]	F/W Green Algae (<i>Scenedesmus capricornutum</i>)	96 h EbC ₅₀ = 1 000 mg/L 96 h EμC ₅₀ > 1 000 mg/L 96 h NOEC = 1 000 mg/L

Water accommodated fraction - see text below; * LL₅₀: Lethal Loading; ** EL₅₀: Effect Loading; † Inhibition to CMA 604 - see text above; and Δ T.R Wilbury test protocol number 73-CM (Acute Toxicity of the Water Accommodated Fraction [WAF] of Lubricant Additive to the Freshwater Algae, *Scenedesmus capricornutum*) based on the procedures of the US EPA and OECD.

Due to the low water solubility of Infineum C9350, the studies were performed to determine the toxicity of the water accommodated fraction (WAF). A 1000 mg/L treatment was prepared and stirred for 24 h. After settling for 1 h, the WAF was removed and used as the treatment solution. The WAF was slightly cloudy.

Infineum C9350 can be classed as non-toxic to rainbow trout, water fleas and algae, up to its limit of solubility (the WAF).

Conclusion

No new environmental data were provided for this assessment. On the basis of the ecotoxicological data provided in the original assessment, it is considered that Infineum C9350 is non-toxic to aquatic organisms up to its limit of water solubility (~6 mg/L based on WAF).

The Predicted No Effect Concentration (PNEC) is > 60 µg/L, using a safety factor of 100 as three trophic levels are available and the acute 48 h EC50 for *Daphnia magna* of > 6 mg/L.

11. Risk Characterisation

Infineum C9350 is a viscous brown liquid. The molecular structure does not suggest the chemical will be explosive. Its water solubility is 5.755 mg/L.

The data provided in the original assessment indicated that Infineum C9350 had low acute oral and dermal toxicity in rats and rabbits respectively (LD50 > 2000 mg/kg). The chemical was not a skin irritant in rabbits and an analogue substance was a slight eye irritant in rabbits. However the chemical was a skin irritant in a HRIPT.

A NOAEL of > 1000 mg/kg was determined in a 28 day repeat dose study in rats which showed mild to moderate skin irritation and some histopathological changes, all of which appeared to be reversible.

The chemical was negative in a reverse mutation assay in *Salmonella typhimurium*. There was no increase in micronucleated polychromatic erythrocytes and no induced cytotoxicity in the micronucleus assay in bone marrow cells of the mouse and it did not induce structural chromosomal aberrations in Chinese Hamster Ovary cells.

Infinium C9350 was a skin irritant and a skin sensitiser.

Based on the data provided for the Secondary Notification, Infineum C9350 is re-confirmed as a skin irritant and a skin sensitiser and is classified as a hazardous substance according to NOHSC Approved Criteria.

The following occupational, public and environmental risk characterisation takes into account the proposed new use and exposure.

11.1 Occupational risk

Raw material

The chemical is imported in drums mixed with mineral oil at concentrations of between 1% and 10% w/w or 40% to 60% w/w depending on the product.

Worker exposure during transport is unlikely except in the event of a spill. The MSDS supplied by Infineum Australia Pty Limited provides instructions for clean-up following a spill. These instructions are considered adequate.

Handling of lubricant products at refineries and terminals may result in dermal and ocular exposure to chemicals if adequate precautions are not taken. However, based on information supplied to NICNAS, workers at these sites are required to wear personal protective equipment. The use of automatic transfer lines and enclosed, automated blending will reduce the likelihood of exposure to the additive package. Therefore, no significant health risks are expected for these workers.

Products containing Infineum C9350

Metal working lubricants

Exposure for metal workers is not likely to be significant however exposure from spills and splashes is possible. Generally though, metal working machines incorporate guards to protect users. Because of the concentration (up to 10% w/w depending on the particular product) of Infineum C9350 present in heavy duty lubricants there is a risk to workers during use of metal cutting fluids and adequate precautions need to be taken. For light duty use such as drilling, small section cutting and lathe use the concentration of the chemical is less than 1%. No significant health risks are expected for workers using products containing Infineum C9350 in concentrations of less than 1%.

Automotive repair

There is potential for dermal and ocular exposure to Infineum C9350 for automotive repairers involved in changing engine (crankcase) oils in motor vehicles from spills and splashes. Significant splashing of oil during changes and therefore skin and eye contact, is unlikely but possible. Workers are unlikely to wear gloves during oil changes so skin contact can occur and care needs to be taken. Workers are expected to be repeatedly exposed to Infineum C9350 and the additive nature of exposure results in a risk of skin sensitisation in such workers.

11.1.1 MSDS

One MSDS was submitted for Infineum C 9350 raw material. It is noted that under the *National Code of Practice for the Preparation of Material Safety Data Sheets 2nd Edition* [NOHSC:2011 (2003)] (NOHSC, 2003) (the MSDS Code) data on Hazard Identification is in section 2 of the MSDS and data on Composition/Information on Ingredients is in section 3. The supplied MSDS reversed this order. A review of the information on health hazards shows the risk phrase for skin irritation (R38 irritating to skin) is missing. Though part of the risk phrase for skin sensitisation (R43) is given, the remainder of the risk phrase (may cause sensitisation by skin contact) is missing.

For clarity it is suggested the following appear under the heading "CLASSIFICATION/SYMBOL":

R43 - may cause sensitisation by skin contact

R38 - irritating to skin

Page 3 of 6 of the supplied MSDS refers to an ACGIH TLV for mineral oil mist, not the relevant NOHSC national exposure standard for oil mist, refined mineral. The NOHSC national exposure standard should be referred to instead of, or in addition to the ACGHI TLV.

The MSDS code classifies substances assigned the risk phrase R43 as Type I ingredients. Under the MSDS Code, the full chemical name of Type I ingredients must be disclosed on MSDSs. The submitted MSDS uses a generic name for the chemical.

11.2 Public risk

The public may be exposed through skin and eye contact during DIY oil changes and use of drills, small metal cutting machinery and lathes. Members of the public are unlikely to use drilling equipment that requires the use of lubricants but use of small metal cutting machinery and lathes by hobbyists would not be unusual. The concentration of Infineum C9350 in light duty metal working fluids is low (< 1%) and minimal risk is expected in using these products. The potential for exposure during DIY changing of engine oil carries the same exposure risk as for automotive workers, but the duration of contact would be smaller and less frequent than for mechanics. However home mechanics are unlikely to possess a hoist and proper oil draining equipment as would be found in an automotive workshop so the risk of spills and splashes would be greater. Based on the low potential for public exposure to Infineum C9350, it is considered that the chemical will not pose a risk to public health.

11.3 Environmental risk

Fugitive release to the environment during transport and blending is considered unlikely. In the event of spills, the MSDS of the additive package containing Infineum C9350 contains instructions to prevent entry of the chemical to drains and waterways, to contain spills with inert material such as sand or earth and to dispose of recovered material according to local regulations. This information on clean up operations would minimise release to the environment and is considered adequate.

Limited information is available on Australian metal working industry practices relating to disposal of waste fluids. Based on the EU Technical Guidance Document (European Communities, 2003) a worst-case release to water could amount to 31.6% of the water-based chemical used in the metal working industries. This value will be assumed in the initial worst-case PEC calculation for Australia.

A calculated worst-case scenario daily PEC in the sewer effluent is 10.8 µg/L as a continental release in Australia. In calculating the PEC, the following were assumed: (1) usage of the maximum import volume of 50 tonnes is evenly distributed over a 365 day period; (2) usage is nationwide, with a population of 20 million contributing 200 L of water per person per day to the sewer, (3) there is no adsorption or degradation in the sewer prior to release and (4) all will be released from small operators with a worst case release to sewer of 31.6% or 15.8 tonnes per year.

Based on the respective dilution factors of 1 and 10 for rural areas and coastal discharges of effluents, the PECs of Infineum C9350 in rural areas and coastal water may approximate 10.8 and 1.08 µg/L, respectively.

The worst-case PECs and Risk Quotients for the aquatic environment based on a maximum usage of 50 tonnes are summarised below:

	PEC	Q
Sewage effluent/coastal city:	1.08 µg/L	$1.08 / >60 = < 0.018$
Sewage effluent/rural areas:	10.8 µg/L	$10.8 / >60 = < 0.18$

The risk quotients for use in metal cutting fluids indicate an acceptable risk ($Q < 1$) for both fresh water and marine organisms.

The amount released (70 kg from motor vehicle used oil) to stormwater drains can enter the aquatic compartment and could be expected to become associated with suspended organic material (due to the calculated high P_{ow}), settle out into the sediments and eventually be biodegraded.

It is difficult to estimate the PEC of Infineum C9350 released into the stormwater drains, which have the potential to directly enter the aquatic environment. However, a worst case estimated PEC might be calculated if it is assumed that all of the chemical that is expected to be released into the stormwater drains into a single metropolitan area with a geographical footprint of 500 square kilometres and an average annual rainfall of 50 cm. With a maximum annual release into this localised stormwater system of 70 kg and the annual volume of water drained from this region estimated to be approximately $250 \times 10^6 \text{ m}^3$, the resultant PEC is approximately $0.28 \text{ } \mu\text{g/L}$. It should be stressed that this result is very much a worst case scenario, and that in reality releases of the chemical would be very much more diffuse than indicated here, and also at significantly reduced levels.

It is apparent that at a lower PEC of $0.28 \text{ } \mu\text{g/L}$, as compared to that of metal cutting fluids, the chemical is unlikely to pose an environmental risk to the aquatic organisms from use in motor vehicle oils.

12. Discussion and Conclusions

Infineum C9350 is not manufactured in Australia, and is imported as a component in lubricant additive packages at various concentrations in mineral oil depending on the final use of the lubricants to which it is added. Concentrations for imported additive range from less than 10% w/w up to 60% w/w. The additive package is blended with other components, again depending on the products' use, to give a final concentration of less than 1% or between 1% and 10% for metalworking fluids and between 1% and 10% for crankcase oils. The estimated import volume of Infineum C9350 is up to 50 tonnes/year. The major use of Infineum C9350 will be as a detergent additive in metalworking fluids.

Infineum C9350 is a brown viscous liquid having a faint petroleum odour. It is not a pure chemical entity but is supplied blended in mineral oil. It is stable at room temperature, partially soluble in water, is not explosive nor flammable however the diluent oil is flammable and could be explosive. Infineum C9350 is not listed in the *Australian Code for the Transport of Dangerous Goods by Road and Rail* (FORS, 1998).

12.1 Health hazards

The chemical has low acute oral and dermal toxicity in animals. It is not a skin irritant in animal tests but human data indicates it to be a moderate skin irritant. It is a skin sensitiser in guinea pigs. An analogue showed slight eye irritant properties in rabbits. Repeat dose toxicity was confined to skin irritation and reversible histopathological changes and a NOAEL of > 1000 mg/kg was determined. It is not genotoxic.

Infineum C9350 is confirmed to be a mild to moderate skin sensitiser and skin irritant. Infineum C9350 is classified as a hazardous substance under the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004) as:

- 'May cause sensitisation by skin contact' (risk phrase R43 Conc \geq 1%)
- and
- 'Irritating to skin' (risk phrase R38 Conc \geq 20%)

For comparison purposes, Infineum C9350 is classified as a hazardous substance under the Globally Harmonized System of Classification and Labelling of Chemicals (GHS), and would require appropriate labelling when this system is adopted in Australia.

12.2 Occupational health risk

Infineum C9350 is imported as a bulk lubricating oil additive package. Occupational exposure is low during importation, transport and storage and hence risks to importation and distribution workers are low. Occupational exposure is not expected during blending due to the automated nature of the process when using

the additive package of which the chemical is a part, except in the event of spills or leakages.

In products, Infineum C9350 will be present in concentrations of < 1% up to 10%. During use in metal working applications, worker exposure is expected to be low. Risk in these occupations is also considered to be low.

Exposure and risk to workers in the automotive repair industry is expected to be low.

12.3 Public health risk

The public will only be exposed to products containing Infineum C9350 and not the raw material. Products containing Infineum C9350 that will be available to the public will contain the chemical in concentrations of < 1% and < 10%. Public exposure during use in metal work is possible, however because of the low (< 1%) concentration of the chemical in light duty metal working fluids likely to be used by the public, risk will be minimal. During DIY oil changes, exposure and risk will be low because of the short and infrequent nature of exposure.

12.4 Environmental hazard and risk

The chemical is non-toxic to aquatic organisms up to its limit of water solubility. The Predicted No Effect Concentration is > 60 µg/L.

Environmental exposure is expected to be minimal from accidental spills or leaks from storage tanks or in landfills as the chemical is expected to bind strongly to soil due to its low water solubility. A worst-case environmental risk assessment based on the proposed new use as metal cutting fluid indicates that there is unlikely to be an environmental risk under the proposed use pattern. It is expected there will be negligible release of Infineum C9350 to the environment from oil changes by professional mechanics. Environmental exposure from DIY oil changes is likely as home mechanics may not dispose of used oil appropriately. Disposal however will be diffuse hence release of high concentrations of Infineum C9350 to the environment is very unlikely except in the event of a transport accident. The chemical is unlikely to pose an environmental risk to aquatic organisms from its use in motor vehicle oils.

13. Recommendations

This section provides the recommendations arising from the assessment of Infineum C9350. Recommendations are directed principally at regulatory bodies and importers and formulators of Infineum C9350. Implicit in these recommendations is that best practice is implemented to minimise occupational and public exposure and environmental impact.

13.1 Recommendations for regulatory bodies

13.1.1 Australian Safety and Compensation Council

Calcium long chain alkyl benzene sulphonate (Infineum C9350) is not currently listed in the ASCC's *Hazardous Substances Information System (HSIS)*.

In accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004) Infineum C9350 is classified as:

R43 May cause sensitisation by skin contact

R38 Irritating to skin

The concentration cut-offs for mixtures containing calcium long chain alkyl benzene sulphonate are:

Risk Phrases*	Concentration Cut-off
XiR43	Conc \geq 1%
Xi, R38	Conc \geq 20%

*Xi, Irritant

The following safety phrases are also recommended:

S24/25 Avoid contact with skin and eyes

S28 After contact with skin, wash immediately with plenty of soap suds

S36/37/39 Wear suitable protective clothing, gloves and eye/face protection

This classification should be reflected in the ASCC's HSIS.

13.2 Recommendations for importers and State and Territory Authorities

13.2.1 Hazard communication – Material Safety Data Sheet

Under the *National Model Regulations for the Control of Workplace Hazardous Substances* (NOHSC, 1994) and the Commonwealth, State and Territory regulations introduced in accordance with these national model regulations, employees shall have ready access to Material Safety Data Sheets (MSDS) for hazardous substances at their workplace. MSDS provide information to those who use the hazardous substance.

It is recommended that importers of Infineum C9350 review their MSDS for compliance with the *National Code of Practice for the Preparation of Material Safety Data Sheets 2nd Edition*, paying particular attention to the hazard classification in Recommendation 13.1.1.

13.2.2 Hazard communication – Labels

In accordance with the *National Code of Practice for the Labelling of Workplace Substances* (NOHSC 1994a) it is recommended that importers of Infineum C9350 review their labels for compliance and pay particular attention to the following:

In addition to the hazard classification risk phrases it is recommended the following safety phrases be incorporated on labels of Infineum C9350 or products containing Infineum C9350 in concentrations greater than or equal to 1%:

- | | |
|-----------|--|
| S24/25 | Avoid contact with skin and eyes |
| S28 | After contact with skin, wash immediately with plenty of soap suds |
| S36/37/39 | Wear suitable protective clothing, gloves and eye/face protection |

13.2.3 Recommendation to importers and users

Classification

The classification in section 13.1.1 (above) should be adopted by industry on publication of this report.

Occupational controls

The risk of adverse effects from occupational use of Infineum C9350 is low. This assessment supports the control measures recommended in the original new chemical assessment report NA/486. The control measures for Infineum C9350 are as follows:

- local exhaust ventilation at the refinery/terminal facility when the oil additive is blended with oil;
- avoidance of spillage and splashing of the chemical. Spillages should be cleaned up promptly and put into containers for disposal;

- if engineering controls and safe work practices are insufficient to reduce exposure, employers should ensure that personal protective equipment such as gloves, safety glasses and overalls are used by workers to minimise occupational exposure. The personal protective equipment used should be in accordance with Australian, Australian/New Zealand or other approved standards.

Disposal

Accidental leaks and spillages should be cleaned up promptly with absorbents and put into containers for disposal. The empty drums and their residues should be disposed in accordance with government regulations.

14. Secondary Notification

Under Section 65 of the Act, the Secondary Notification of Infineum C9350 may be required where an applicant or other introducer (importer) or new manufacturer of Infineum C9350, becomes aware of any circumstances that may warrant a reassessment of its hazards and risks. Specific circumstances include:

- a. The use of Infineum C9350 has changed, or is likely to change significantly.
- b. The amount of Infineum C9350 introduced into Australia has increased, or is likely to increase significantly.
- c. Manufacture of Infineum C9350 has begun, or is likely to begin in Australia.
- d. Additional information has become available on the adverse health and/or environmental effects of Infineum C9350.

Under Section 64 of the Act the Director must be notified within 28 days of the introducer becoming aware of any of the above circumstances.

Appendix 1

Classification under the Globally Harmonized System of Classification and Labelling of Chemicals (GHS).

In this report, Infineum C9350 has been classified against the NOHSC *Approved Criteria for Classifying Hazardous Substances* (Approved Criteria) (NOHSC, 2004). However, classifications under the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) (UNECE, 2005) will come into force when the GHS is adopted by the Australian Government and promulgated into Commonwealth legislation. GHS documentation is available at:

<http://www.unece.org/trans/danger/danger.htm>


GHS classification for Infineum C9350.


Physical hazards – not classifiable

Environmental hazards

Environmental Hazard	Classification	Hazard Communication
Acute toxicity	Not classifiable	Symbol: no symbol Signal Word: no signal word Hazard Statement: no hazard statement
Chronic toxicity	Chronic 4	Symbol: no symbol Signal Word: no signal word Hazard Statement: may cause long lasting harmful effects to aquatic life

Health hazards

Health Hazard	Classification	Hazard Communication
Skin Sensitisation	Category 1	Symbol:  Signal Word: Warning Hazard Statement: May cause an allergic skin reaction

Skin Irritation	Category 2	Symbol:  Signal Word: Warning Hazard Statement: Causes skin irritation
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Appendix 2

This MSDS was provided by Infineum Australia Pty Limited. It is reproduced here as a matter of public record. The format of this MSDS is acceptable, however the contents require updating in line with the recommendations in Section 13.2.1 of this report. Introducers should note the comments in section 11.1.1 of this report.

MATERIAL SAFETY DATA SHEET



1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product Name: Infineum C9350 (Australia)
Description: Lubricant additive
Supplier: Infineum AUSTRALIA PTY. LTD
Level 2, 6 Riverside Quay
Southbank Vic 3006
Melbourne, Australia
Telephone: 1-800-815-297 / 0418 178 449 after hours
Facsimile: 61-3-9686-6851
EMERGENCY TELEPHONE NUMBER: 1800 033 111 (Within Australia)
0800 222 002 (Within New Zealand)
+65-6867-1939 (Regional)

2. COMPOSITION/INFORMATION ON INGREDIENTS

<i>Hazardous Components</i>	<i>Symbol/R-phrase or OEL</i>	<i>Mass %</i>
Calcium long chain alkaryl sulphonate	Xi, R43	50.0 – 70.0

CLASSIFIED AS HAZARDOUS ACCORDING TO CRITERIA OF NOHSC

AICS STATUS: LISTED

3. HAZARD IDENTIFICATION

CLASSIFICATION/SYMBOL: IRRITANT/XI
R43

Health Hazards

- May cause sensitisation by skin contact

Environmental Hazards

- This product does not require classification on the basis of environmental hazard

Physical And Chemical Hazards / Fire And Explosion Hazards

- Low hazard. Material can form flammable mixtures or can burn only upon heating to temperatures at or above the flash point
- Toxic gases will form on combustion

4. FIRST AID MEASURES

Inhalation:

- Using proper respiratory protection, immediately remove the affected victim from exposure. Administer artificial respiration if breathing is stopped. Keep at rest. Call for prompt medical attention

Skin Contact:

- Immediately flush with large amounts of water; use soap if available. Remove contaminated clothing, including shoes, after flushing has begun.
- If irritation persists, get medical attention

Eye Contact:

- Flush eyes with large amounts of water until irritation subsides. If irritation persists, get medical attention

Ingestion:

- If swallowed, **DO NOT** induce vomiting. Keep at rest. Get prompt medical attention

Advice to Doctor:

- Treat according to symptoms.

5. FIRE-FIGHTING MEASURES

Extinguishing Media:

- Use alcohol type foam or dry chemical

Protective Equipment:

- Respiratory and eye protection required for fire fighting personnel

Special Fire Precautions:

- Avoid spraying water directly into storage containers due to danger of boilover

Hazardous Combustion Products:

Fumes, smoke, carbon dioxide, carbon monoxide, oxides of sulphur

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions:

- Wear eye and skin protection

Environmental Precautions:

- Do not allow to enter drains or watercourses

Methods for cleaning up:

- Contain spills immediately with inert materials such as sand and earth
- Consult an expert on disposal of recovered material and ensure conformity to local disposal regulations

7. HANDLING AND STORAGE

Storage temp	Handling temp	Transport temp	Fire & Explosion Prevention
60.0 °C. maximum	55.0 – 60.0 °C Recommended range	60.0 °C. maximum	Keep away from potential ignition sources. Use proper grounding procedures to prevent electrostatic

discharge.

- Container remains hazardous when empty. Continue to observe all precautions.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Engineering controls:

- The usual precautionary measures for handling chemicals should be observed. Laboratory samples should be handled in a lab hood. Provide mechanical ventilation of confined spaces. Use explosion-proof ventilation equipment.
- Contact should be avoided by people with known hypersensitivity to:

CALCIUM LONG CHAIN ALKARYL SULPHONATE

Occupational Exposure Limits:

This product contains mineral oil. Under certain conditions (open heating and/or mechanical shear), the following component(s) with a recognised or recommended OEL value may be released:

Mineral oil mist; TWA 5 mg/ m³ STEL 10mg/ m³, for oil mist, vapour excluded, ACGIH (2002)

Personal protection:

RESPIRATORY PROTECTION

Where concentrations in air may exceed the limits given in this section it is recommended to use a half face filter mask to protect from overexposure by inhalation. Suitable filter material depends on the amount and type of chemicals being handled in the workplace, but filter material of type "P" or similar may be considered for use.

<i>Hand Protection</i>	<i>Eye Protection</i>	<i>Skin/Body Protection</i>
PVC or nitrile gloves	Goggles or face shield	Chemical resistant clothing

9. PHYSICAL AND CHEMICAL PROPERTIES – Typical values

<i>Physical state</i>	Liquid	
<i>Odour</i>	Mild hydrocarbon	
<i>Flash point</i>	> 150° C	PMCC ASTM D93
<i>Freezing/melting point</i>	0.0, below	Pour Point ASTM D97
<i>Viscosity (100° C)</i>	130.0 cSt	D445
<i>Density (15° C)</i>	938 kg/ m ³	D4052
<i>Viscosity (40° C)</i>	2300.0 cSt	D445
<i>Boiling point range</i>	315 ° C	IBP
<i>Autoignition temperature</i>	> 360 ° C	Diluent oil
<i>Solubility in water</i>	Negligible	

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Coeff. of thermal expansion 0.00071 Deg C.
(Liquid)

Vol/Vol/Deg.C

10. STABILITY AND REACTIVITY

<i>Stability</i>	Stable
<i>Conditions to avoid</i>	Heat, flames and sparks, temperatures > 60 °C
<i>Materials and conditions to avoid</i>	Strong oxidising agents

11. TOXICOLOGICAL INFORMATION

Inhalation:

- Negligible hazard at ambient (-18 to 38 °C) or recommended blending temperature.
- Avoid breathing vapours or mists.
- Repeated and prolonged overexposure to oil mists may result in droplet deposition, oil granuloma formation, inflammation and increased incidence of infection

Skin contact:

- Low order of toxicity
- Frequent or prolonged contact may cause mild skin discomfort
- May cause skin sensitisation, an allergic reaction which becomes evident on re-exposure to this material

Eye contact:

- Will cause slight eye discomfort; but will not injure eye tissue

Ingestion:

- Minimal toxicity

12. ECOLOGICAL INFORMATION

Mobility:

- This is a preparation and environmental assessment is based on component data and that of similar products. A mineral oil component of this preparation floats and can migrate from water to land. This preparation contains a substance or substances classified as Dangerous for the Environment

Biodegradation:

- This preparation is not expected to be "readily" biodegradable. A component(s) of this preparation is expected to be "inherently" biodegradable according to OECD guidelines

Ecotoxicity and bioaccumulation:

- Low acute toxicity to aquatic organisms is expected.

13. DISPOSAL CONSIDERATIONS

<i>Product</i>	According to local regulations (most probably controlled incineration).
<i>Contaminated packaging</i>	According to local regulations

14. TRANSPORT INFORMATION

Australian Dangerous Goods (railroad/road) This product is not regulated for land transport

IMO This product is not regulated for sea transport

IATA This product is not regulated for air transport

15. REGULATORY INFORMATION

Classification and labelling according to NOHSC Codes:

Classification/Symbol: IRRITANT/XI

Label Name: CALCIUM LONG CHAIN ALKARYL SULPHONATE

R(isk) phrase(s) R43 May cause sensitisation by skin contact

S(afety) phrase(s) S24 Avoid contact with skin
S37 Wear suitable gloves

Governing Directive:
Approved Criteria for Classifying Hazardous Substances NOHSC:1008 (1999)

16. OTHER INFORMATION

Library of Risk phrases listed in this document:

R43 May cause sensitisation by skin contact

MATERIAL SAFETY DATA SHEET



Contact Name: Des Shaw
Title: MSDS Coordinator
Phone: 1800-815297

This information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process. The information and recommendations contained herein are to the best of Infineum's knowledge and belief accurate and reliable as of the date indicated. However, no representation, warranty or guarantee is made with regards to accuracy, reliability or completeness. Conditions of use of the material are under the control of the user; therefore, it is the user's responsibility to satisfy himself as to the suitability and completeness of such information for his own particular use.

Print Date: 26 August, 2004

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