



Australian Government
Department of Health and Ageing
NICNAS

Existing Chemical
Secondary Notification Assessment NA/752S

Polymer in E7581

November 2005

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 (DEH), 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 an increase in quantity imported, the commencement of Australian manufacture, increased environmental exposure, and/or additional information becoming available on hazards, as is the case of Polymer in E7581.

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. However, 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 either by using the prescribed application form at the back of this report or 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;
- 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.nohsc.gov.au>

Overview and Recommendations

Overview

Background

Polymer in E7581 was assessed as NA/752 under the NICNAS New Chemicals program in 1999 in the limited notification category. As a result of new data on skin and eye irritation and reproduction/developmental effects becoming available, Polymer in E7581 has now been reassessed under the Secondary Notification provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act) relevant to existing chemicals, as more than five years has elapsed since the original assessment.

Polymer in E7581 is an amber viscous liquid, stable under normal conditions. For commercial purposes, it is prepared in solvent, and never isolated. It is a flammable liquid as formulated, with oxides of carbon, hydrogen and nitrogen being produced. Its water solubility is < 10.0 mg/L and flash point 41⁰C, as it exists in solvent. Its boiling point has not been determined.

Uses

Polymer in E7581 is not manufactured in Australia, but is imported as a component in fuel additive packages. The major use of Polymer in E7581 is as a detergent additive in gasoline. The use pattern in Australia has not changed since its introduction as a new chemical. Approximately 200-250 tonnes of the chemical is imported annually.

Exposure

The assessment of Polymer in E7581 as a new chemical in 1999 indicated that exposure from drips and spills is possible when the additive package is added to the fuel, using automated processes and dedicated delivery lines and equipment. However, the exposure is expected to be confined to skin contamination which may occur during the connection and disconnection of transfer lines and equipment. The polymer is a minor component in petrol.

The polymer and additive package is not directly marketed to the public, but preblended into the petrol sold at service stations, hence, direct contact with the polymer by members of the public is unlikely.

Health effects

No toxicology data were provided for the chemical substance during assessment as a new chemical. Data on acute toxicity, repeated dose toxicity, and genotoxicity were provided on a polymeric substance similar in composition and molecular weight distribution to Polymer in E7581. A reassessment of this data has not been conducted. In this report, new eye and skin irritation studies and a reproduction/developmental study conducted on the Polymer in E7581 (without solvent) are assessed.

The assessment conducted in 1999 on a substance analogous to Polymer in E7581 indicated very low acute oral toxicity in rats (LD50 >5000 mg/kg bw). It is not a skin sensitiser. In a 28-day repeated-dose gavage study in rats, the NOAEL was identified as 1250 mg/kg bw/day based on the absence of systemic toxicity or pathological effects at this level. An in vitro and in vivo genotoxicity test were performed with Polymer in E7581. The chemical was negative in the *Salmonella*/Mammalian Microsome Plate Incorporation Mutagenicity Assay and in the in vivo mouse micronucleus test. Overall the chemical is not considered genotoxic.

Assessment of current data indicate that Polymer in E7581 is a skin irritant, not an eye irritant, and is not a substance toxic to reproduction.

Polymer in E7581 is classified as a hazardous chemical under the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004). Polymer in E7581 is classified as a hazardous substance under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), (OECD, 2003) and would require appropriate labelling when this system is adopted in Australia. The classification of the fuel additive package in which the polymer will be contained is a Class 3 Flammable Liquid, Packaging Group III listed in the Australian Code for the Transport of Dangerous Goods by Road and Rail (FORS, 1998).

The use of dedicated and automatic transfer lines and enclosed, automated injection into fuel reduces the risk of exposure to the additive package. The risk to service station workers and mechanics is expected to be low, as exposure for these workers is negligible because of the very low concentration (< 0.1%) of polymer in the fuel.

Based on the use pattern, Polymer in E7581 will not pose a significant risk to public health.

Environmental effects

Based on the use pattern resulting in the majority of the chemical being bound in a polymer matrix, environmental exposure is expected to be minimal. Potential release to the environment would only be through accidental spills. The empty drums and their residues are sent to a certified drum recycler where they are rinsed and the rinsate disposed in accordance with government regulations. Polymer released to soil through either a spill or leak from a storage tank is expected to bind strongly to soil due to its low water solubility. Polymer released to an aquatic environment would tend to partition out of water and into sediment.

Ecotoxicological data for Polymer in E7581 were obtained from information provided with the earlier submission (NA/752). The polymer is unlikely to be mobile given the very low water solubility and high binding affinity to soil. The polymer's large molecular size and very low water solubility should prevent bioaccumulation. However, the product contains components which may be persistent in the environment. Based on the above, environmental exposure and risk are expected to be low.

Recommendations

This section provides the recommendations arising from the assessment of Polymer in E7581. Recommendations are directed principally at regulatory bodies and importers and formulators of Polymer in E7581. Implicit in these recommendations is that best practice is implemented to minimise occupational and public exposure and environmental impact.

Recommendations to Regulatory Bodies

NOHSC

Polymer in E7581 is classified as hazardous in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004), with the following risk phrase:

- R38 – Irritating to Skin;

The following safety phrase is also recommended for Polymer in E7581:

- S24 – Avoid contact with skin

Products containing Polymer in E7581 at concentrations ≥ 20 % are determined to be hazardous.

It is recommended that this classification be included in the *List of Designated Hazardous Substances* contained in the Hazardous Substances Information System (HSIS).

Recommendations to 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.

In accordance with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC 2003) it is recommended that importers of Polymer in E7581 review their MSDS for compliance and pay particular attention to the following points:

- risk phrases and hazard information should be updated to reflect the hazard classification in Recommendation 12.1.1.
- safety phrases should be included as noted in Recommendation 12.1.1.

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 Polymer in E7581 review their labels for compliance and pay particular attention to the following points:

- risk phrases and hazard information should be updated to reflect the hazard classification in Recommendation 12.1.1; and

- safety phrases should be included as noted in Recommendation 12.1.1.

It is recommended that the State and Territory Occupational Health and Safety authorities review compliance with the above information, in the workplace.

Recommendation to Importers and Users

Occupational controls

The risk of adverse effects from occupational use of Polymer in E7581 is low. This assessment supports the control measures recommended in the original new chemical assessment report NA/752. The control measures for Polymer in E7581 are as follows:

- local exhaust ventilation at the refinery/terminal facility, if the petrol additive is blended with petrol in an enclosed area;
- avoidance of spillage and splashing of the chemical. Spillages should be cleaned up promptly using chemical-resistant impervious gloves;
- if engineering controls and safe work practices are insufficient to reduce exposure, employers should ensure that personal protective equipment (PPE) 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

CAS	Chemical Abstracts Service
CO	carbon monoxide
DEH	Australian Government Department of the Environment and Heritage
FORS	Federal Office of Road Safety
GLP	good laboratory practice
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
HC	hydrocarbon
HPLC	high performance liquid chromatography
IPCS	International Programme on Chemical Safety
LD50	median lethal dose
MSDS	Material Safety Data Sheet
NAMW	number average molecular weight
ND	new data
NICNAS	National Industrial Chemicals Notification and Assessment Scheme
NOAEL	no-observed-adverse-effect level
NOHSC	National Occupational Health and Safety Commission
ISO	International Organization for Standardization
OECD	Organisation for Economic Cooperation and Development
PMN	premanufacture notice
PPE	personal protective equipment
TG	test guidelines
US EPA	United States Environment Protection Authority
US TSCA	United States Toxic Substances Control Act
WAMW	weight-average molecular weight
WHO	World Health Organization

Glossary

In this report, NICNAS used the IPCS Risk Assessment Terminology (IPCS, 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 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	<p>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.</p> <p>Related Terms: <i>Dose-Effect Relationship, Effect Assessment, Concentration-Effect Relationship.</i></p>
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	<p>Evaluation of the exposure of an organism, system or (sub) population to an agent (and its derivatives).</p> <p>Exposure Assessment is the third step in the process of Risk Assessment.</p>
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	<p>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.</p>
Hazard characterization	<p>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.</p> <p>Hazard Characterisation is the second stage in the process of Hazard Assessment, and the second step in Risk Assessment.</p> <p>Related terms: <i>Dose-Effect Relationship, Effect Assessment, Dose-Response Relationship, Concentration -Effect Relationship.</i></p>
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 (sub)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 Polymer in E7581 (CAS Number not assigned) was assessed as a new chemical under Section 23 of the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act) under the limited notification category.

The New Chemicals Assessment Report (NA/752) was published in October 1999. From the limited data provided at the time, a hazard classification was conducted in accordance with the National Occupational Health and Safety Commission (NOHSC) *Approved Criteria for Classifying Hazardous Substances*, and Polymer in E7581 was considered to be non-hazardous. 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 Polymer in E7581 as a detergent additive in unleaded petrol.

In September 2004, additional toxicity data on skin and eye irritation and reproduction/developmental effects were provided for Polymer in E7581. As five years have elapsed since the original assessment, this chemical is now being assessed as an existing chemical (Secondary Notification). The new data warranted reassessment which has been carried out under Section 68A of the Act, covering secondary notifications of existing chemicals.

Polymer in E7581 is imported into Australia as part of an additive package.

1.1 Declaration and secondary notification

Declaration as a Secondary Notification was initiated when NICNAS received further studies conducted on Polymer in E7581 without solvent that were not available during its assessment as a new chemical. The studies are:

1. Dermal Irritation/Corrosivity
2. Primary Eye Irritation
3. Reproduction/Developmental Toxicity Screening Test

A notice was published in the *Chemical Gazette* of 7 December 2004 requiring all persons who introduce Polymer in E7581 into Australia either by manufacture or import, to apply for secondary notification.

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 Polymer in E7581 to human health;
- characterise potential occupational, and public exposure to Polymer in E7581;

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

1.3 International perspective

USA: In February 1999 a Premanufacture Notification (PMN) for Polymer in E7581 was made to the United States Environmental Protection Agency (US EPA). Following the PMN, the US EPA determined that additional information was required in order to complete their human risk assessment on Polymer in E7581. An outcome of the PMN review was a Consent Order requiring a Reproductive/Developmental Toxicity Screening Test to be conducted in accordance with OECD Guidelines.

Other data which became available since the original assessment were:

Dermal Irritation/Corrosivity Study

Primary Eye Irritation Study

These studies were conducted by Afton Chemical Corporation as part of their evaluation of chemical hazards for employee and customer risk management.

In 2001, the US EPA revoked the PMN consent order based on the results of the testing.

Canada: A New Substance Notification submission was made to the Canadian authorities in 1999, and the assessment commenced. No action was taken by the Canadian Government prior to completion of the assessment, and the applicant was allowed to import this product into Canada for commerce.

Korea: Submission to the Korean authorities for nomination to the Korean Inventory of Chemical Substances was made in 2000. No comments were received after the 90-day review period, and therefore the applicant was allowed to import the product into Korea for commercial purposes.

1.4 Peer review

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

2. Applicant

One company applied for secondary notification assessment of this chemical. The applicant supplied additional toxicity data. Under Section 36 of the Act, the applicant was provided with a draft copy of the report for correction of errors and variation of content.

Applicant details are:

AFTON CHEMICAL ASIA PACIFIC LLC

Level 9, 20 Berry Street (P.O. Box 285)

North Sydney, NSW 2059

3. Chemical Identity and Composition

Chemical Name:	Formaldehyde, reaction products with an alkylated phenol and an aliphatic amine
Trade name:	Polymer in E7581
USA Premanufacture Notice Number (PMN):	P99-531
Number-Average Molecular Weight (NAMW):	1019
Weight-Average Molecular Weight (WAMW):	1530
Maximum percentage of low molecular weight species:	
Molecular Weight < 500	6
Molecular Weight < 1000	38
Maximum content of hazardous residual monomers:	No hazardous residual monomers are present in the polymer
Degree of purity:	Very high
Loss of monomers, additives, impurities:	None expected
Additives/Adjuvants:	Petroleum solvent naphtha; not classifiable as a hazardous substance in terms of benzene or PNA content or measured kinematic viscosity

4. Physical and Chemical Properties

Polymer in E7581, as formulated in solvent, is an amber viscous liquid. Unless otherwise indicated, the data below represents that of the notified polymer in petroleum solvent naphtha.

Boiling point:	Not determined
Density:	0.908 g/cm ³ at 15.6 °C
Particle size:	Not applicable
Vapour pressure:	Not determined; expected to be low due to high molecular weight
Water solubility:	< 10.0 mg/L (see comments below)
Partition co-efficient (n-octanol/water):	Not determined
Hydrolysis as a function of pH:	Not determined (in the pH range of 4-9)
Adsorption/desorption:	Not determined
Dissociation constant:	Not determined
Flash point:	41°C (Closed Cup)
Autoignition temperature:	Not determined
Explosive properties:	None
Flammability limits:	Combustible as formulated. Oxides of carbon, hydrogen and nitrogen are produced
Reactivity/stability:	Stable under normal conditions
Kinematic viscosity	193 x 10 ⁻⁶ m ² /s at 40 °C (target) 20 x 10 ⁻⁶ m ² /s at 100 °C (typical)

5. Manufacture, Importation and Use

No new information was provided on use during the secondary notification. The use of the chemical is as originally notified for assessment as a new chemical.

5.1 Manufacture and importation

Polymer in E7581 is not manufactured in Australia. It is not imported as a polymer but as part of an additive package. The amounts of the additive package varies from year to year. Of the total amount imported, approximately 80% is imported in ISO (International Organization for Standardization) containers and 20% in drums. The containers are sent to the customer refineries directly after importation.

The volume imported is in the range of 200-250 tonnes/year.

5.2 Use

No new use pattern data have been provided. The polymer is currently used as a detergent additive in unleaded petrol which in conjunction with a polymeric carrier reduces the formation of deposits in carburettors, fuel injectors and intake valves as well as reduces combustion chamber deposits in petrol engines.

At the refinery/terminal facility, the petrol additive is typically blended with petrol immediately just prior to transport of the fuel to the petrol station. The additive package is injected automatically as the fuel is pumped into the delivery tanker. The additive is injected into unleaded petrol on a volumetric basis that will result in less than 0.1% w/w notified polymer in the final fuel.

6. Exposure

Occupational, public and environmental exposures are considered below.

6.1 Occupational exposure

According to information provided by the applicant, a total number of 20 workers are involved in import and transportation, 24 plant operators and maintenance workers in the storage facility, and 100 plant operators and maintenance workers in the refinery/terminal facility.

Dockside and transport

The notified polymer is imported in drums or ISO containers. Occupational exposure is not expected except in the event of a spill. No repackaging of drums or ISO containers is required, as these are delivered directly to the customer site.

Refinery/terminal facility

Exposure is possible from drips and spills when the additive package is added to the fuel. Automated processes and dedicated delivery lines and equipment are used for this activity. Exposure is expected to be confined to skin contamination which may occur during the connection and disconnection of transfer lines and equipment. Workers use chemical goggles and chemical resistant gloves when handling the additive package. Engineering controls in the form of automated delivery systems already in place at the refineries will minimise the potential for exposure during blending.

End use - service stations

Exposure to very low concentrations of the notified polymer in the final fuel by mechanics and service station personnel may occur.

6.2 Public exposure

The polymer is used as a minor component in petrol. Hence, direct contact with the polymer by members of the public is unlikely.

6.3 Environmental exposure

6.3.1 Release

The polymer is transported via road in closed containers. Potential release would only be through accidental spills. The Material Safety Data Sheet (MSDS) details procedures to protect the environment in these cases.

The ISO containers used to transport and store the fuel additive are continually reused without rinsing. The applicant estimates that a maximum of 4% of the fuel additive package will remain as residues in empty drums. This corresponds to

< 5kg of the polymer in each 200 L drum. At a maximum import volume of < 60 tonnes of the polymer in drums, < 1 tonne of the polymer waste will be generated per year. The empty drums and their residues are sent to a certified drum recycler where they are rinsed and the rinsate disposed in accordance with government regulations.

The applicant expects that a maximum of 1500 service stations may store fuel containing the polymer. The probable number of spills for 1500 service stations would be 4.05 per year. If each spill was 200 L, this would result in a total of < 5kg of the polymer being lost. These figures are based on a research project carried out at the University of British Columbia, Canada, which investigated the incidents of petrol spills at service stations in the Greater Vancouver region. These figures do not take into account frequent minor spills (< 1 L) that would occur at petrol bowsers as customers fill their vehicles with fuel. Given the low percentage in fuel, the amount of polymer lost in these spills would be expected to be very low.

The polymer and additive package is not directly marketed to the public, but preblended into the petrol sold at service stations.

6.3.2 Fate

Polymer released to soil in either a spill or leak from a storage tank is expected to bind strongly to soil due to its low water solubility. Polymer released to an aquatic environment would tend to partition out of water and into sediment. Once adsorbed to soil/sediment, the fate of the polymer is unknown. The polymer is not expected to cross biological membranes due to the low solubility and high molecular weight, and should not bioaccumulate (Connell, 1989).

Less than 1 tonne of the polymer waste from drum recycling enters an aqueous treatment plant. The polymer waste is part of the solid wastes from the plant and is consigned to landfill.

The applicant has indicated that tail pipe emission data on the notified polymer are unavailable. However, the applicant supplied data on an analogue. The only structural difference between the notified polymer and the analogue is the absence of an alkyl group.

Test results provided show no statistical difference in HC, CO and NO_x emissions between test fuel with and without the additive. The long term effect of using detergent fuel additives is to reduce the formation of engine deposits, ie “keep clean”, and “clean up” existing engine deposits leading to reduced levels of tail pipe emissions. The analogue in conjunction with its polymeric carrier has been shown to reduce port fuel injector plugging after ~ 500 miles to less than 5% from levels as high as 25%.

The analogue is listed on the US TSCA inventory and, in combination with certain carrier/dispersant additives, is said to be registered for use with US EPA and the California Air Resources Board as a fuel additive.

The polymer needs to meet the criteria in the Australian Standard - AS 4430.2-2004 - Evaluation of devices, additives and processes which claim to improve vehicle performance-spark ignition engine system.

7. Evaluation of Animal Toxicological Data

Data submitted for the original new chemical assessment included data on a similar polymeric substance for acute oral, repeated-dose toxicity and genotoxicity studies. New data (denoted by ND) for skin and eye irritation and reproductive/developmental toxicity conducted on the Polymer in E7581 without solvent was provided for the Secondary Notification. Summaries of the original data, and assessment of the new studies are presented in the following chapters.

7.1 Acute toxicity

7.1.1 Acute oral

Polymer in E7581 has very low oral toxicity with an LD50 of >5000 mg/kg in rats.

7.1.2 Skin irritation (ND)

A Dermal Irritation/Corrosivity Study in rabbits (Bonnette KL, Springborn Laboratories, 2001), conducted on the Polymer in E7581 without solvent was submitted for assessment during the Secondary Notification. The study was conducted to assess the potential irritant and/or corrosive effects of the test substance, Polymer in E7581 without solvent, in New Zealand white rabbits, when administered by a single dermal dose. The study was conducted in compliance with Good Laboratory Practice (GLP), and in accordance with the OECD TG 404, and the US Consumer Products Safety Commission, Federal Hazardous Substances Act Regulations, 1988.

Six New Zealand white rabbits (3 male and 3 female) approximately 11 weeks of age weighing 2.4-2.5 kg and 2.5 kg respectively were chosen for the study. On the day before the test (day-1), the animals had the fur removed from the dorsal area of the trunk with care being taken to avoid abrading the skin during the clipping procedure. On the following day (day-0), each animal received 0.5 mL of the test substance as a single dermal application. The test substance was held in contact with the skin under a semi-occlusive binder for 4 h. Following the 4-h exposure period, the binder was removed and the test material removed from the skin using alcohol (first rinse) and mineral oil (second rinse). Each rinse was followed by soap, water and dry gauze. Test sites were examined for signs of erythema and oedema, and the responses scored according to the OECD TG 404, 1 h after patch removal and 24, 48 and 72 h, and up to 7 days after patch application.

Additional dermal findings of desquamation (scaling and flaking) were noted in three animals at 48 h and in all six animals at the end of 7 days. Superficial lightening was noted in four animals at 24 h, which resolved in three out of four animals at 48 h, and in all animals at 72 h. Transient incidences of dark material around the mouth were noted in three out of six animals during the study.

The individual dermal irritation scores at the end of 24, 48 and 72 h are presented in Table 7.1. The individual dermal irritation scores at the end of 1 h are not included in the table.

Table 7.1: Individual dermal irritation scores at 24, 48 and 72 h after exposure to Polymer in E7581 without solvent

Animals	Erythema			Oedema		
	24 h	48 h	72 h	24 h	48 h	72 h
1	2	2	2	0	0	0
2	2	2	2	1	0	0
3	2	2	2	2	0	0
4	2	2	2	2	2	1
5	2	2	1	2	0	0
6	2	2	2	2	0	1

Following the grading of erythema and oedema for individual animals at the end of 24, 48 and 72 h, the mean scores of individual and all animals for erythema and oedema at the end of 72 h were determined. These are presented in Table 7.2.

Table 7.2: Mean scores of individual, and all animals for erythema and oedema at the end of 72 h

Clinical findings	Mean scores of individual animals*						Mean scores of all animals**
	1	2	3	4	5	6	
Erythema	2	2	2	2	1.7	2	1.95
Oedema	0	0.3	0.7	1.7	0.7	1	0.73

*based on scores for each animal at the end of 72 h according to the Draize scoring method.

**after 72 h for all animals

The mean scores of all animals were 1.95 for erythema, and 0.73 for oedema.

7.1.3 Eye irritation (ND)

A Primary Eye Irritation Study in Rabbits (Bonnette KL, Springborn Laboratories, 2001), conducted with the Polymer in E7581 without solvent was submitted during the Secondary Notification.. The study was conducted to assess the irritant and/or corrosive effects of Polymer in E7581 without solvent when administered by a single ocular dose. The study was conducted in compliance with GLP and in accordance with the OECD TG 405, and the US Consumer Products Safety Commission, Federal Hazardous Substances Act Regulations, 1988.

Six New Zealand white rabbits (3 male and 3 female) were chosen, with each animal receiving a detailed pretest observation prior to dosing. On day 0 prior to dosing, both eyes of each animal selected for the test were examined macroscopically for ocular irritation. In addition, the corneal surface was examined using fluorescein sodium dye. Following an approximately 15 second exposure, the eyes were rinsed and the corneal surface examined for dye retention. Animals exhibiting ocular irritation or pre-existing corneal injury were not used in the test. One hour after the preliminary ocular examination, 0.1 mL of the test substance Polymer in E7581 without solvent was instilled in the conjunctival sac of the right eye of each rabbit. Following instillation, the eyelids were held together for approximately one second in order to limit the test article loss. The contralateral eye of each animal remained untreated and served as a control.

Following application of the test substance, the test and control eyes were examined for signs of irritation at 1, 24, 48 and 72 h and up to 14 days, and the effects on the cornea, iris and conjunctiva noted. The results were graded according to the OECD Ocular Grading System (TG 405), and the data classified according to the NOHSC Approved Criteria (NOHSC, 2004). The ocular irritation scores for all animals are presented in Table 7.3.

Table 7.3: Ocular Irritation Scores according to the OECD Ocular Grading System

Animals	Corneal opacity	Iris	Conjunctival redness	Chemosis	Conjunctival discharge
1					
24 h	0	0	2	2	0
48 h	0	0	1	1	0
72 h	0	0	0	0	0
2					
24 h	0	0	1	1	0
48 h	0	0	0	0	0
72 h	0	0	0	0	0
3					
24 h	2	1	2	2	0
48 h	1	1	1	1	0
72 h	0	1	1	1	0
4					
24 h	0	0	1	1	0
48 h	0	0	1	1	0
72 h	0	0	0	0	0
5					
24 h	1	1	2	2	0
48 h	0	0	1	1	0
72 h	0	0	1	1	0
6					
24 h	0	0	2	1	0
48 h	0	0	1	1	0
72 h	0	0	1	1	0

Based on the results of the Ocular Grading System, the mean ocular irritation score at the end of 72 h for all animals for corneal opacity was (0.2), iris lesion (0.2), conjunctival redness (1.1) conjunctival oedema (0.9) and conjunctival discharge (0).

7.2 Skin sensitisation

No skin sensitisation data were presented in the original submission. No new data were submitted with this application.

7.3 Repeated-dose toxicity

In an oral (gavage) study conducted according to OECD TG 407, Sprague-Dawley rats were given 0, 325, 625 and 1250 mg/kg of the test substance for 28 consecutive days in corn oil vehicle. No changes in body weight, weight gain and food consumption were observed in any group. No toxicologically-significant changes were noted. Significant dose-related increases in absolute and relative liver weights in both sexes were observed, but no microscopic changes were noted in the rats given the highest dose.

The No-Observed-Adverse-Effect level (NOAEL) of the substance was determined to be 1250 mg/kg bw/d, based on the absence of systemic toxicity or pathological effects at this level.

7.4 Genotoxicity

One in vitro study and one in vivo study were submitted with the original application.

In a study conducted according to OECD TG 471 using direct plate incorporation (San and Krueel, 1989), *S.typhimurium* strains TA 98, TA 100, TA 1535 and TA 1537 were exposed to the test substance at concentrations of up to 10 000 µg/plate with metabolic activation, and concentrations of up to 6667 µg/plate without metabolic activation. No positive response with any of the tester strains was noted either in the presence or absence of metabolic activation.

The test substance did not induce mutation in the bacterial strains tested.

In an in vivo study conducted according to OECD TG 474, ICR mice were given 0, 363, 1815 and 3630 mg/kg of the test substance by a single intraperitoneal injection. Results indicated that the ratio of polychromatic erythrocytes to total erythrocytes was not changed in treated mice of both sexes, indicating that the substance did not induce bone marrow toxicity. A statistically significant increase in micronucleated polychromatic erythrocytes was noted at the 72 h point in male mice at the low dose only, but was considered to be related to the low background rate in the control group at this time point, rather than a real increase in the treated group. When compared to the vehicle controls at 24 or 48 h, no statistically significant increases were noted. No changes were observed at 24 and 48 h at all doses.

The test substance did not show evidence of genotoxic activity in vivo in the mouse micronucleus assay.

7.5 Reproductive effects (ND)

A Reproduction/Developmental Toxicity Screening Test in the Rat (CTL/RR0844/Regulatory/Report), conducted with Polymer in E7581 without solvent was submitted during the Secondary Notification. The study was conducted to determine the effects of Polymer in E7581 without solvent on male and female reproductive organs. The study was conducted in compliance with GLP, and in accordance with the OECD TG 421.

The study consisted of four groups, one control and three treatment groups each containing 10 male and 10 female Wistar-derived rats. The test substance, Polymer in E7581 without solvent, was a light amber liquid, and was tested as a formulation in corn oil. The control substance was corn oil. Prior to the study, the rats were examined to determine that they were normal. Body weights and clinical changes were recorded daily. Food consumption for each cage of rats was recorded during the 2-week pre-mating period and calculated on a weekly basis. Doses administered prior to mating and during gestation and lactation were based on individual animal body weights.

The rats were dosed orally by gavage with 0 (control), 20, 100 or 500 mg/kg bw/day Polymer in E7581 without solvent in corn oil, with dosing continuing for 2 weeks pre-mating and during mating. Dosing of males continued to day 30/31 (after mating was completed) until termination, on day 31 of the study. Dosing of females continued throughout gestation until day 4 of lactation. Females were terminated on day 5 of lactation.

Litters were weighed and examined on days 1 and 5, post partum. The sexes of the pups and any clinical abnormalities were recorded at the same time. Dead or moribund pups were subjected to a post-mortem examination, and abnormalities recorded.

Males dosed with 500 mg/kg bw/day showed poorer growth than the controls (approximately 11% below those of the control group). Food consumption in males was also slightly less than the control group during the pre-mating period in the 500 mg/kg bw/day group. One male in this group was killed for humane reasons, which included weight loss and clinical effects such as stained nose, eye discharge and reduced limb function on day 31. There were no effects in males dosed with Polymer in E7581 at 20 or 100 mg/kg bw/day.

Females dosed with Polymer in E7581 without solvent had similar weights as controls during the pre-mating period and for most of the gestation period. However, in the 500 mg/kg bw/day group, bodyweights were low during late gestation, with the overall gestation weight gain being 14% below the control group. There was a decrease of bodyweight during lactation. One female from each of the 100 and 500 mg/kg bw/day groups was found to have difficulty giving birth (dystocia), and were killed to investigate this clinical effect.

There was no effect on the length of gestation. The number of litters produced in the 20, 100 and 500 mg/kg bw/day groups was 9, 10 and 8 respectively, and 7 in the control group. There were two total litter losses in the 500 mg/kg bw/day group and one in the control group. Toxic findings indicated by low body weights, diminished or no food consumption, and clinical findings such as wet area around the anus, or urine staining were noted during the lactation period in dams in the 500 mg/kg bw/day group. Therefore, the litter losses in this group could be related to the toxic effects noted in dams at this dose. There were no whole litter losses, and pup survival was 100% and 97.5% in the 20 and 100 mg/kg bw/day groups.

The mean pup body weights in the 500 mg/kg bw/d group were reduced (15%) compared to controls. There were no effects on pups in the 20 or 100 mg/kg bw/day groups.

Macroscopic post-mortem findings in the single female in the 100 and 500 mg/kg bw/day groups was dystocia. The findings in the deceased male rat in the 500 mg/kg /day group were non-specific.

Macroscopic findings indicative of possible hepatotoxicity (accentuated lobular pattern, pale spots/areas) were observed at termination in 1 of 10 and 4 of 10 male and female animals respectively. No histological examination was conducted.

No microscopic changes in the ovaries, testes or epididymis which could be related to treatment were observed in the study.

No structural abnormalities were identified in the live pups examined, or the pups examined macroscopically at post mortem.

The No-Observed-Adverse-Effect-level (NOAEL) in females was determined to be 100 mg/kg bw/day based on an overall reduction in body weight gain of 14% when compared to controls, and possible hepatotoxicity in the 500 mg/kg bw/day treated group.

The NOAEL in males was determined to be 100 mg/kg bw/day based on a significant reduction (>10%) in body weight and feed consumption at 500 mg/kg bw/day.

The NOAEL for developmental toxicity was determined to be 500 mg/kg bw/day. A reduction in pup weight (15%) and litter losses were reported at 500 mg/kg bw/d. Pup survival was low in the 500 mg/kg bw/day treatment group with two whole litter losses. No macroscopic structural deformities, adverse clinical signs, litter weight changes, or effects on sex distribution were observed in pups, at this dose. The reduction in pup body weight and litter losses were observed at maternally toxic doses and are therefore considered to be secondary to maternal toxicity and not a direct effect of Polymer in E7581.

The NOAEL for fertility was determined to be 500 mg/kg bw/day based on the absence of effects on reproductive organs, pre-coital interval, length of gestation and production of viable litters at dose levels up to and including 500 mg/kg bw/day.

There was no evidence of developmental toxicity due directly to Polymer in E7581 or effects on reproductive organs in male and female rats exposed to Polymer in E7581 at doses up to, and including 500 mg/kg/day.

8. Hazard Classification

This section discusses the classification of the health effects of Polymer in E7581 according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004). The NOHSC 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.

No human data are available. The classification for health effects is based on experimental studies (animal and in vitro tests). Polymer in E7581 was determined to be non-hazardous based on acute oral toxicity, repeated-dose toxicity and genotoxicity data provided with the original submission.

The hazard classification for the new data (ND) provided for the Secondary Notification for skin and eye irritation and reproductive/developmental effects are presented below.

Classification of Polymer in E7581 in accordance with the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) (OECD, 2003) can be found in Appendix 1. This is provided for guidance only, is not mandatory and has no legal status at present.

8.1 Skin irritation (ND)

According to the NOHSC Approved Criteria, substances and preparations which cause significant inflammation of the skin, that persists for at least 24 h after an exposure period of up to 4 h are classified as skin irritants.

Inflammation of the skin is significant if the mean value of the scores for either erythema, eschar formation or oedema formation, calculated over all the animals tested is 2 or more. All scores at each of the reading times (24, 48 and 72 h) for an effect should be used in calculating respective mean values. Inflammation of the skin is also significant if it persists in at least two animals at the end of the observation time. Particular effects e.g., hyperplasia, scaling, discolouration, fissures, scabs and alopecia should be taken into account.

In the Dermal Irritation/Corrosivity Study provided, skin inflammation was noted after an exposure period of 4 h that persisted for 24 h. Significant inflammation was seen in 5 of the 6 animals with individual scores for erythema of 2 at the end of 72 h. One animal had significant inflammation at the end of 48 h (score of 2) with slight erythema (score of 1) at the end of 72 h resulting in a mean score for all animals of 1.95 at the end of 72 h.

Additional dermal findings of desquamation (scaling and flaking) were noted in three animals at 48 h and in all six animals at the end of 7 days.

Although the mean score of all animals for erythema did not meet the criteria for significant skin inflammation (≥ 2) according to the Approved Criteria, based on the borderline score of 1.95 for erythema, in conjunction with the additional findings of scaling and flaking noted in all six animals that persisted at the end of 7 days, Polymer in E7581 without solvent meets the Approved Criteria for classification as a skin irritant.

Classification

Polymer in E7581 meets the NOHSC Approved Criteria (NOHSC, 2004) for classification as a skin irritant.

8.2 Eye irritation (ND)

According to the NOHSC Approved Criteria, substances and preparations which cause significant ocular lesions that occur within 72 h after exposure, and which persist for at least 24 h, are classified as eye irritants.

All scores at each of the reading times (24, 48 and 72 h) for an effect should be used in calculating the respective mean values.

Ocular lesions are considered significant if the mean scores of the eye irritation test on two or more animals are equivalent to any of the following:

- cornea opacity equal to or greater than 2 but less than 3;
- iris lesion equal to or greater than 1 but greater than 2;
- redness of the conjunctivae equal to or greater than 2.5;
- oedema of the conjunctivae (chemosis) equal to or greater than 2.

All scores at each of the reading times (24, 48 and 72 h) for an effect should be used in calculating the respective mean values.

In the Primary Eye Irritation Study in Rabbits, the mean value of the scores for corneal opacity, iris lesions and redness and oedema of the conjunctivae at each of the reading times (24, 48 and 72 h) were < 2 for cornea opacity, < 1 for iris lesions, and < 2 and < 2.5 for oedema and redness of the conjunctivae respectively.

Classification

Polymer in E7581 does not meet the NOHSC Approved Criteria (NOHSC, 2004) for classification as an eye irritant.

8.3 Reproductive toxicity (ND)

According to the NOHSC Approved Criteria, reproductive toxicity includes impairment of male and female reproductive functions or capacity, and the induction of non-heritable harmful effects on the progeny. Reproductive toxicity may be classified as:

Effects on male or female fertility

Developmental toxicity

In the Reproduction/Developmental Toxicity Screening Test in the rat, no treatment-related changes were observed in the pre-coital interval, gestation length, litter size, number of implantation sites, and post-implantation losses. The number of litters produced in the 20, 100 and 500 mg/kg bw/day groups was 9, 10 and 8 respectively, and 7 in the control group. There were no whole litter losses, and pup survival was 100% and 97.5% in the 20 and 100 mg/kg bw/day groups.

There were no effects on testes or epididymis weights. No microscopic changes in the ovaries, testes or epididymis which could be related to treatment were observed in the study.

Three pups in one litter in the 500 mg/kg bw/day treatment group were observed to be small on day 5 post partum. All other pup observations were related to pups found dead or missing presumed cannibalised by the dam. Mean individual male and female pup body weights in this group were reduced, though not statistically significant as compared to controls. There were no effects on mean individual pup weights in the 100 mg/kg bw/day treatment groups when compared to controls. No structural abnormalities were noted in any of the pups examined macroscopically, or at post mortem.

Classification

Polymer in E7581 does not meet the Approved Criteria (NOHSC, 2004) for classification as a substance toxic to reproduction.

9. Environmental Effects Assessment

Ecotoxicological data were not provided. The intended use pattern of the polymer in the fuel additive is not expected to result in a significant release to the environment, as it is claimed that the polymer is completely destroyed by combustion within the petrol engine, producing oxides of carbon and hydrogen. There are no direct data to support the claim of complete combustion of the polymer to oxides of carbon and hydrogen when the fuel is burnt within the combustion chamber of petrol engines. However, it is evident that the polymer which is made up of hydrocarbon, nitrogen and oxygen, the normal constituents of petrol, will not survive the temperatures at which the fuel explodes within the internal combustion engine. The analogue data indicates that the notified polymer will not increase tailpipe emissions.

In the event of spills, the MSDS of the additive package containing the polymer contains information on procedures to enable clean up operators to reduce release to the environment. Minor spills and leaks of the polymer may occur during customer fill ups at petrol service stations. However, given its low percentage in fuel, the loss of the polymer in these spills would be expected to be low.

Less than 1 tonne of the polymer waste from drum recycling enters an aqueous treatment plant, where polymer waste will be part of the solid wastes from the plant that is consigned to landfill. The polymer is unlikely to be mobile given the very low water solubility and high binding affinity to soil. The polymer's large molecular size and very low water solubility should prevent bioaccumulation.

Given the above, environmental exposure and risk are expected to be low.

10. Risk Characterisation and Management

Polymer in E7581 in solvent is an amber viscous liquid, stable under normal conditions. It is combustible as formulated, with oxides of carbon, hydrogen and nitrogen being produced. Its water solubility is < 10.0 mg/L and flash point 41°C in solvent. Its boiling point has not been determined.

The data provided in the original assessment indicated that Polymer in E7581 had very low acute toxicity (LD50 > 5000 mg/kg). It was not a skin sensitiser. In a 28-day repeat-dose testing by gavage, a NOAEL of 1250 mg/kg bw/d was established, based on increased liver weights. It is not genotoxic.

Based on the data provided for the Secondary Notification, Polymer in E7581 is a skin irritant. It is not an eye irritant, and has no reproductive effects.

Polymer in E7581 is classified as a hazardous substance according to NOHSC Approved Criteria.

10.1 Occupational

The product is imported fully formulated. Worker exposure during transport is unlikely except in the event of a spill. The MSDS supplied by Afton Chemical Corporation provides instructions for clean-up following a spill.

The handling of fuel and fuel products at refineries and terminals in general may cause a transitory irritation if adequate precautions are not taken. However, workers at these sites are required to wear personal protective equipment to control exposure. The use of dedicated and automatic transfer lines and enclosed, automated injection into fuel, will reduce the likelihood of exposure to the additive package. Therefore, no significant health risks are expected for these workers.

Exposure for service station workers and mechanics is likely to be negligible because of the very low concentration (less than 0.1% w/w) of polymer present in the final fuel. Therefore, the risk of adverse health effects arising from exposure to the notified polymer is negligible.

10.2 Public

Based on the negligible potential for public exposure to Polymer in E7581 arising from its intended use, it is considered that the Polymer in E7581 will not pose a significant hazard to public health when used in the proposed manner.

10.3 Environmental

Release to the environment is not expected to be significant as the polymer in the fuel additive is completely destroyed by combustion within the petrol engine, producing oxides of carbon, nitrogen, and hydrogen. It is also evident that the polymer which is made up of hydrocarbon, nitrogen and oxygen which are the normal constituents of petrol will not survive the temperatures within the internal combustion engine.

In the event of spills, the MSDS of the additive package containing the polymer contains information on clean up operations which minimise release to the environment. The release of the polymer in minor spills and leaks at petrol service stations is not expected to be significant, due to the low percentage of the polymer in the fuel.

The polymer is unlikely to be mobile given the very low water solubility and high binding affinity to soil. Due to the polymer's large molecular size and very low water solubility, bioaccumulation is unlikely.

The empty drums and their residues are sent to a certified drum recycler where they are rinsed, and the rinsate disposed in accordance with government regulations.

Ecotoxicological data for Polymer in E7581 were not provided.

11. Discussion and Conclusions

Polymer in E7581 is not manufactured in Australia, and is imported as a component in fuel additive packages at 38% w/w in solvent naphtha (petroleum) with polybutene and other additives. The additive package is added to the unleaded petrol at a rate that will result in approximately 0.005% w/w of the notified polymer in the final fuel. The estimated import volume of the polymer is in the range of 200-250 tonnes/year. The major use of Polymer in E7581 is as a detergent additive in gasoline. No new use/exposure data were provided.

Polymer in E7581, as formulated, is an amber viscous liquid, stable under normal conditions. It is combustible as formulated, with oxides of carbon, hydrogen and nitrogen being produced. Its water solubility is < 10.0 mg/L and flash point 41^oC as formulated. Its boiling point has not been determined.

Polymer in E7581 has very low acute oral toxicity in rats (LD50 >5000 mg/kg bw). It is a skin but not an eye irritant or a skin sensitiser. In a 28-day repeated-dose gavage study in rats, the NOAEL was identified as 1250 mg/kg bw/day based on the absence of systemic toxicity or pathological effects at this level. The chemical was negative in the *Salmonella*/Mammalian Microsome Plate Incorporation Mutagenicity Assay and in the in vivo mouse micronucleus test. The chemical is not considered genotoxic. Polymer in E7581 is not toxic to reproduction.

Occupational exposure may occur during addition of the additive package to the fuel. However, due to the use of automated processes and dedicated delivery lines, exposure is expected to be low, except in the event of spills or leakages. Public exposure is unlikely as the polymer will not be directly marketed to the public, and is also unlikely at petrol service stations. Environmental exposure is expected to be minimal from accidental spills or leaks from storage tanks or in landfills, as the polymer is expected to bind strongly to soil due to its low water solubility. Polymer released to an aquatic environment would tend to partition out of water and into sediment.

Polymer in E7581 is classified as a hazardous chemical under the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004). For comparison purposes, Polymer E7581 is classified as a hazardous substance under the Globally Harmonised System for Hazard Classification and Labelling of Chemicals (GHS) (OECD, 2003), and would require appropriate labelling when this system is adopted in Australia. Polymer in E7581 is not listed in the *Australian Code for the Transport of Dangerous Goods by Road and Rail* (FORS, 1998). The classification of the fuel additive package in which the polymer will be contained is a Class 3 Flammable Liquid, Packaging Group III.

12. Recommendations

This section provides the recommendations arising from the assessment of Polymer in E7581. Recommendations are directed principally at regulatory bodies and importers and formulators of Polymer in E7581. Implicit in these recommendations is that best practice is implemented to minimise occupational and public exposure and environmental impact.

12.1 Recommendations to regulatory bodies

12.1.1 NOHSC

Polymer in E7581 is classified as hazardous in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004), with the following risk phrase:

- R38 – Irritating to Skin;

The following safety phrase is also recommended for Polymer in E7581:

- S24 – Avoid contact with skin

Products containing Polymer in E7581 at concentrations $\geq 20\%$ are determined to be hazardous.

It is recommended that this classification be included in the *List of Designated Hazardous Substances* contained in the Hazardous Substances Information System (HSIS).

12.2 Recommendations to Importers and State and Territory Authorities

12.2.1 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.

In accordance with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC 2003) it is recommended that importers of Polymer in E7581 review their MSDS for compliance and pay particular attention to the following points:

risk phrases and hazard information should be updated to reflect the hazard classification in Recommendation 12.1.1.

safety phrases should be included as noted in Recommendation 12.1.1.

12.2.2 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 Polymer in E7581 review their labels for compliance and pay particular attention to the following points:

risk phrases and hazard information should be updated to reflect the hazard classification in Recommendation 12.1.1; and

safety phrases should be included as noted in Recommendation 12.1.1.

It is recommended that State and Territory Occupational Health and Safety authorities review compliance with the above information, in the workplace.

12.2.3 Recommendation to importers and users

Occupational controls

The risk of adverse effects from occupational use of Polymer in E7581 is low. This assessment supports the control measures recommended in the original new chemical assessment report NA/752. The control measures for Polymer in E7581 are as follows:

- local exhaust ventilation at the refinery/terminal facility, if the petrol additive is blended with petrol in an enclosed area;
- avoidance of spillage and splashing of the chemical. Spillages and splashes should be cleaned up promptly using chemical-resistant impervious gloves;
- if engineering controls and safe work practices are insufficient to reduce exposure, employers should ensure that personal protective equipment (PPE) 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.

13. Secondary Notification

Under Section 65 of the Act, the Secondary Notification of Polymer in E7581 may be required where an applicant or other introducer (importer) or new manufacturer of Polymer in E7581, becomes aware of any circumstances that may warrant a reassessment of its hazards and risks. Specific circumstances include:

- a. The use of Polymer in E7581 has changed, or is likely to change significantly.
- b. The amount of Polymer in E7581 introduced into Australia has increased, or is likely to increase significantly.
- c. Manufacture of Polymer in E7581 has begun, or is likely to begin in Australia.
- d. Additional information has become available on the adverse health and/or environmental effects of polymer in E7581.

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, Polymer in E7581 has been classified against the NOHSC *Approved Criteria for Classifying Hazardous Substances* (Approved Criteria) (NOHSC, 2004) and, in the case of physicochemical hazards, the *Australian Dangerous Goods Code* (ADG Code) (FORS, 1998). However, classification under the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) (OECD, 2003) 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 Polymer in E7581.

Health Hazard	Classification	Hazard Communication
Skin Irritation	Category 3	Symbol: No symbol Signal Word: Warning Hazard Statement: Causes mild skin irritation

Appendix 2

This MSDS was provided by Afton Chemical Corporation. It is reproduced here as a matter of public record. The format of this MSDS is acceptable under the NOHSC's *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC, 2003). However the contents require updating as outlined in Recommendation 12.1.1. The accuracy of the information remains the responsibility of the applicant.



Polymer in E7581

MSDS No. E7581

1. Product and Company Identification

Chemical Family: Petrochemical.
Product Use:
CAS No.: Mixture.
Validation Date: 14 December 2004
In Case of Emergency:

02-9923-1588 (Australia)
1-800-403-0044 (US & Canada)
1-804-648-7727 (International)
32-2-507-20-94 (Europe)

Manufacturer / Supplier

Afton Chemical/Asia Pacific Company
Level 9, 20 Berry Street
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Australia
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2. Composition and Information on Ingredients

Note: See section 8 for occupational exposure limits and section 11 for LC50/LD50 information.

Substance/Preparation	Preparation			
Ingredient Name	CAS No.	Conc. (% w/w)	EU Classification	WHMIS Regulated?
Polyolefin alkyl phenol alkyl amine	Proprietary	60-100	Xi; R36/38	Yes.

3. Hazards Identification

Notice to Reader

Afton operates a world-wide system for hazard communication. Please see Section 2 and 15 for country specific classification information and Section 11 for additional details. This product is hazardous according to criteria of NOHSC Australia.

The preparation is classified as dangerous according to Directive 1999/45/EC and its amendments.

Note: See section 1 for emergency contact information and section 13 for waste disposal.

Primary Hazards and Critical Effects: WARNING!
CAUSES EYE AND SKIN IRRITATION.

Physical/Chemical Hazards: Not applicable.

Environmental Hazards: Not classified as dangerous for the environment according to EC criteria.

**Hazardous Material Information
System (U.S.A.)**



4. First Aid Measures

Inhalation: If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention immediately.

Ingestion: If affected person is fully conscious, give one glass of water to drink. Never give anything by mouth to an unconscious person. Get medical attention if symptoms appear.

Skin Contact: In case of contact, immediately flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Get medical attention immediately.

Eye Contact: In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention immediately.

5. Fire Fighting Measures

Extinguishing Media: In case of fire, use water spray (fog), foam, dry chemicals, or CO₂.

Fire-Fighting Procedures: Fire fighters should wear positive pressure self-contained breathing apparatus (SCBA) and full turnout gear.

Hazardous Decomposition

Products: These products are carbon oxides (CO, CO₂), NO, NO₂

Flash point: Closed cup: >95°C (104°F). (Minimum Pensky-Martens.)

6. Accidental Release Measures

Personal Precautions: Immediately contact emergency personnel. Eliminate all ignition sources. Keep unnecessary personnel away. Use suitable protective equipment (Section 8). Follow all fire fighting procedures (Section 5). Do not touch or walk through spilled material.

Environmental Precautions and Clean-up Methods : If emergency personnel are unavailable, contain spilled material. For small spills add absorbent (soil may be used in the absence of other suitable materials) and use a non-sparking or explosion proof means to transfer material to a sealed, appropriate container for disposal. For large spills dike spilled material or otherwise contain material to ensure runoff does not reach a waterway. Place spilled material in an appropriate container for disposal. Minimize contact of spilled material with soils to prevent runoff to surface waterways.

Note: See section 1 for emergency contact information and section 13 for waste disposal.

7. Handling and Storage

Handling : Avoid contact with eyes, skin and clothing. Wash thoroughly after handling.

Storage : Keep container tightly closed. Keep container in a cool, well-ventilated area.

8. Exposure Controls and Personal Protection

Engineering Controls : Provide exhaust ventilation or other engineering controls to keep the airborne concentrations of vapors below their respective threshold limit value.

**Personal Protective Equipment
Respiratory System:** Use appropriate respiratory protection if there is the potential to exceed the exposure limit(s).

Skin and Body: Where contact is likely, wear chemical resistant gloves, a chemical resistant suit, and boots. Additional body garments should be used based upon the task being performed.

Hands: Use chemical resistant, impervious gloves.

Eyes: Safety goggles are considered minimum protection. Goggles with a face shield may be necessary depending on quantity of material and conditions of use.

Occupational Exposure Limits

Ingredient Name OEL United States OEL Canada OEL Europe

No NOHSC exposure standard established.

9. Physical and Chemical Properties

Physical State and Appearance Color Odor	: Liquid.
Color	: Clear. (Light)
Vapor Density	: Not determined.
Density	: Not determined.
Specific Gravity	: 0.9203 at 15.6/15.6C (target).
Odor	: Aromatic. to Ammoniacal. (Slight.)
Solubility	: Insoluble in cold water.
Viscosity	: Not determined.
Auto-Ignition Temperature Flash Point	: Not determined.
Flash Point	: Closed cup: >95°C (104°F). (Minimum Pensky-Martens.)

10. Stability and Reactivity

Stability :	The product is stable.
Materials to avoid :	Strong oxidizing and reducing agents.
Conditions to avoid :	High temperatures, sparks, and open flames.

11. Toxicological Information

Routes of Entry :	Eyes. Absorbed through skin.
Target Organs:	Contains material which may cause damage to the following organs: skin, eyes

Acute Effects

Inhalation:	Not determined
Ingestion:	Not determined
Skin Contact:	Irritating to skin.
Eye Contact:	Irritating to eyes.

Chronic Effects

Adverse Effects:	Not determined.
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Carcinogenic Effects:	Not classified or listed by IARC, NTP, OSHA, EU and ACGIH.
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Toxicity Data

<u>Inredient Name</u>	<u>Test</u>	<u>Result</u>	<u>Route</u>	<u>Species</u>
Not Determined.				

12. Ecological Information

Environmental Hazards : Not classified as dangerous to the environment according to EC criteria.
Environmental Fate : This product contains components which may be persistent in the environment.
Germany water class : Not Available

13. Disposal Consideration

Waste Handling and Disposal: Waste must be disposed of in accordance with federal, state and local environmental control regulations.

14. Transport Information

Regulatory Information	UN Number	Proper Shipping Name	Class	Packing Group	Label	Additional Information
ADG Classification	Not Regulated	-	-	-	-	-
TDG Classification	Not Regulated	-	-	-	-	-
ADR/RID Class	Not Regulated	-	-	-	-	-
IMDG Class	Not Regulated	-	-	-	-	-
IATA-DGR Class	Not Regulated	-	-	-	-	-

15. Regulatory Information

EU Regulations

Hazard Symbol(s):



Irritant

Risk Phrases:

Safety Phrases:

US Regulations:

R36/38-Irritating to eyes and skin.

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

No SARA 313 chemicals are present above the reporting threshold

State:

California prop. 65: The following statement is made order to comply with the California Safe Drinking Water and Toxic Enforcement Act of 1986. This product is not known to cause cancer.

Canadian Regulations WHMIS (Classification): Not determined.

International Inventory Status

United States :	All components on TSCA Inventory
Canada :	All components on DSL
Europe :	All components on EINECS
Japan :	All components on MITI or MOL
Australia:	One or more components not found on NICNAS
Korea :	All components on ECL
China :	All components on IECSC
Philippines:	All components on PICCS

16. Other Information

PREPARATION INFORMATION

Validated by HS&E Department (Tel: +1 804 788 5800) on 12/14/2004.
Version: 1

Date of Printing: 12/14/2004.

▣ Indicates information that has changed from previously issued version.

Notice to Reader

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*** END OF MSDS ***

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