

File No.: STD/1737

April 2021

**AUSTRALIAN INDUSTRIAL CHEMICALS INTRODUCTION SCHEME
(AICIS)**

PUBLIC REPORT

Chemical in Envirotemp™ 360

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals Act 2019* (the IC Act) and *Industrial Chemicals (General) Rules 2019* (the IC Rules) by following the *Industrial Chemicals (Consequential Amendments and Transitional Provisions) Act 2019* (the Transitional Act) and *Industrial Chemicals (Consequential Amendments and Transitional Provisions) Rules 2019* (the Transitional Rules). The legislations are Acts of the Commonwealth of Australia. The Australian Industrial Chemicals Introduction Scheme (AICIS) is administered by the Department of Health, and conducts the risk assessment for human health. The assessment of environmental risk is conducted by the Department of Agriculture, Water and the Environment.

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

Street Address:	Level 7, 260 Elizabeth Street, SURRY HILLS NSW 2010, AUSTRALIA.
Postal Address:	GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.
TEL:	+ 61 2 8577 8800
Email:	assessments@industrialchemicals.gov.au
Website:	www.industrialchemicals.gov.au

**Executive Director
AICIS**

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SUMMARY

The following details will be published on our website:

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
STD/1737	Cargill Australia Limited	Chemical in Envirottemp™ 360	ND*	< 1,000 tonnes per annum	Component of industrial transformer fluid

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard Classification

As only limited toxicity data were provided, the assessed chemical cannot be classified according to the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia.

Human Health Risk Assessment

Provided that the recommended controls are being adhered to, under the conditions of the occupational settings described, the assessed chemical is not considered to pose an unreasonable risk to the health of workers.

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

Environmental Risk Assessment

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

Recommendations

CONTROL MEASURES

Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following engineering controls to minimise occupational exposure to the assessed chemical during transfer and maintenance processes:
 - Automated processes where possible
- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure during handling of the assessed chemical during transfer and maintenance processes:
 - Avoid contact with skin and eyes
 - Avoid inhaling mists or aerosols
 - Clean up spills promptly
- A person conducting a business or undertaking at a workplace should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the assessed chemical during transfer and maintenance processes:
 - Gloves
 - Goggles
 - Protective clothing
 - Respiratory protection if inhalation of mists or aerosols may occur

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

- A copy of the SDS should be easily accessible to employees.
- If products and mixtures containing the assessed chemical are classified as hazardous to health in accordance with the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)* as adopted for industrial chemicals in Australia, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation should be in operation.

Emergency procedures

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

Disposal

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

Regulatory Obligations

Specific Requirements to Provide Information

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

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

- the function or use of the chemical has changed from a component of industrial transformer fluid, or is likely to change significantly;
- the chemical has begun to be manufactured in Australia;
- additional information has become available to the person as to an adverse effect of the chemical on human health, or the environment.

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

Safety Data Sheet

The SDS of the product containing the assessed chemical provided by the applicant was reviewed by AICIS. The accuracy of the information on the SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

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

1. APPLICANT AND APPLICATION DETAILS

APPLICANT(S)

Cargill Australia Limited (ABN: 42 004 684 173)
Level 11
28 Freshwater Place
SOUTHBANK VIC 3006

APPLICATION CATEGORY

Standard (reduced fee application): Chemical other than polymer (more than 1 tonne per year) – Assessed by Comparable Agency

PROTECTED INFORMATION (SECTION 38 OF THE TRANSITIONAL ACT)

Data items and details taken to be protected information include: chemical name, other names, CAS number, molecular and structural formulae, molecular weight, analytical data, degree of purity, impurities, additives/adjuvants, use details, import volume, identity of manufacturer and identity of analogue.

VARIATION OF DATA REQUIREMENTS (SECTION 6 OF THE TRANSITIONAL RULES)

Schedule data requirements are varied for all physical and chemical properties, toxicological endpoints and ecotoxicological endpoints.

PREVIOUS APPLICATION IN AUSTRALIA BY APPLICANT(S)

None

APPLICATION IN OTHER COUNTRIES

United States (2018)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Envirotemp™ 360 (product containing the assessed chemical at > 99% concentration)

MOLECULAR WEIGHT

500 – 1,000 g/mol (UVCB)

ANALYTICAL DATA

Reference NMR, IR and GC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY

> 99%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: clear liquid

<i>Property</i>	<i>Value</i>	<i>Data Source/Justification</i>
Freezing Point	-54 °C (pour point)	Measured* (ISO 3016/D97)
Boiling Point	> 300 °C at 101.3 kPa	Calculated (EPI v4.11)
Density	957.3 kg/m ³ at 20 °C	Measured* (ISO 3675)
Viscosity	34.49 mm ² /s at 40 °C	Measured* (ISO 3104/D445)
Vapour Pressure	1.33 × 10 ⁻⁹ kPa at 25 °C	Calculated (EPI v4.11)

Property	Value	Data Source/Justification
Water Solubility	1.8×10^{-10} mg/L	Calculated (US EPA 2012)
Hydrolysis as a Function of pH	Not determined	Contains hydrolysable functional groups, however significant hydrolysis is not expected in the environmental pH range
Partition Coefficient (n-octanol/water)	log Pow = 13.5	Calculated (US EPA 2012)
Adsorption/Desorption	log Koc = 9.8	Calculated (US EPA 2012)
Dissociation Constant	Not determined	Does not contain any dissociable functional groups
Flash Point	258 °C	Measured* (ISO 2719/D93)
Autoignition Temperature	Not determined	-
Explosive Properties	Not determined	Contains no functional groups that imply explosive properties.
Oxidising Properties	Not determined	Contains no functional groups that imply oxidative properties.

*Full report not provided

DISCUSSION OF PROPERTIES

A summary report (Doble 2019) was provided for the physical and chemical properties freezing point, density, viscosity, and flash point. The report outlines the results and protocol used, but full details of the studies conducted were not described.

Reactivity

The assessed chemical is expected to be stable at ambient temperatures, however hydrolysis may occur at high temperatures.

Physical Hazard Classification

Based on the submitted physico-chemical data depicted in the above table, the assessed chemical is not recommended for hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)*, as adopted for industrial chemicals in Australia.

5. INTRODUCTION AND USE INFORMATION

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

The assessed chemical will not be manufactured or reformulated in Australia. It will be imported at > 99% concentration in an industrial transformer fluid.

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

<i>Year</i>	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>
<i>Tonnes</i>	10 – 100	100 – 1,000	100 – 1,000	100 – 1,000	100 – 1,000

PORT OF ENTRY

Melbourne, Sydney, Fremantle

IDENTITY OF MANUFACTURER/RECIPIENTS

Cargill Australia Ltd

TRANSPORTATION AND PACKAGING

The assessed chemical at > 99% concentration will be introduced into Australia by sea in 20 kg drums, 200 kg drums, or 1,000 L IBCs/totes. It will be transported to manufacturers and distributors across Australia by road or by rail, typically as a project-by-project order.

USE

The assessed chemical will be used as a dielectric fluid for the manufacture of new power and distribution transformers, across the electricity network. The quantity of the assessed chemical used will be dependent on the size of the transformer being manufactured, ranging from 100 L to 75,000 L.

OPERATION DESCRIPTION

The assessed chemical will not be manufactured or reformulated in Australia. At the end use site the product containing the assessed chemical will be transferred from IBCs or drums into storage tanks. The transfer will be carried out using special equipment such as positive suction pumps, positive displacement pumps, diaphragm air-operated drum or centrifugal pumps. Dedicated oil resistant hoses of minimum length are used for the transfer process. Quality control and laboratory testing will be carried out on the assessed chemical at this time. The product containing the assessed chemical will then be transferred into transformers with similar pumps and hoses. The filling process will be carried out within a closed oil handling system. After the assessed chemical has been transferred into the transformer, empty containers will be sent to waste handlers for cleaning, re-use or recycling. During the life cycle of the transformer, which will be typically be 20 – 40 years, some maintenance work, such as top-ups or reprocessing the fluid, might occasionally be required. These would be carried out by qualified technicians.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

<i>Category of Worker</i>	<i>Exposure Duration (hours/day)</i>	<i>Exposure Frequency (days/year)</i>
Transport and storage	1	5 – 10
QA laboratory	1 – 2	5 – 10
Transformer workers and fillers	1	52

EXPOSURE DETAILS

Transport and storage

Transport, storage and warehouse workers may come into contact with the assessed chemical at > 99% concentration only in the event of accidental breaching of containers.

End-use

Workers may be exposed to the assessed chemical at > 99% concentration at the transformer manufacturing site. Dermal and ocular exposure to the assessed chemical may occur during the transfer of the liquid into storage tanks and transformers, and during maintenance and servicing of equipment, and end of life processes. Inhalation exposure to the assessed chemical is not expected due to the predicted low vapour pressure of the assessed chemical, unless aerosols are generated. If decomposition of the assessed chemical occurs at high temperatures, workers would also be potentially exposed to the breakdown products. Exposure to the assessed chemical is not expected when the transformer is in use.

Exposure to the assessed chemical will be minimised during transfer processes through the use of closed systems and appropriate personal protection equipment such as chemical resistant impervious gloves, safety glasses, protective clothing, and respirators if inhalation exposure is possible.

6.1.2. Public Exposure

The assessed chemical is intended only for use within transformers, in industrial settings. Public exposure to the assessed chemical is not expected, as these transformers will be kept within an enclosed system during use. Public access to these transformers is prohibited, and access is restricted to qualified technicians.

6.2. Human Health Effects Assessment

No toxicological study data were provided for the assessed chemical. Some information on the expected health effects of the assessed chemical is based on studies conducted on an analogue chemical, which is one of the components of the assessed chemical.

The results from toxicological investigations conducted on an analogue of the assessed chemical are summarised in the following table.

<i>Endpoint</i>	<i>Result and Assessment Conclusion</i>
Acute oral toxicity – rat	LD50 > 2,000 mg/kg bw; low toxicity*

<i>Endpoint</i>	<i>Result and Assessment Conclusion</i>
Combined repeat dose/reproductive developmental toxicity – rat	NOAEL = 1,000 mg/kg bw/day [^]
Mutagenicity – bacterial reverse mutation	Non mutagenic*
Genotoxicity – <i>in vitro</i> chromosome aberration	Non genotoxic*

*Summarized report by Biosafety Research Centre

[^]Summarized report by Hatano Research Institute

Toxicokinetics, Metabolism and Distribution

No information on toxicokinetics of the assessed chemical was provided. Based on the high molecular weight (> 500 g/mol), low water solubility (1.8×10^{-10} mg/L) and high partition coefficient (log Pow = 13.5), the assessed chemical is expected to have limited potential for dermal absorption.

Acute Toxicity

No acute toxicity studies were provided for the assessed chemical.

An acute oral toxicity study following OECD TG 423 was conducted on rats using the analogue chemical at 300 and 2,000 mg/kg bw. No deaths or adverse effects were observed, except for diarrhoea seen in one animal at 300 mg/kg bw. The analogue chemical was considered to be of low acute oral toxicity.

Irritation and Sensitisation

No data were provided on eye, skin or respiratory irritation. The assessed chemical contains functional groups which are known to have potential to cause skin irritation (Hulzebos *et al*, 2005). In addition, the SDS of the assessed chemical indicated that similar material may cause slight skin irritation and moderate eye irritation upon contact. Therefore, the potential for the assessed chemical to cause irritation effects cannot be ruled out.

The assessed chemical does not contain any functional groups expected to have skin sensitisation potential (Confidential, 2012a).

Repeated Dose, Reproductive and Developmental Toxicity

No repeated dose toxicity studies were provided for the assessed chemical.

A combined repeated dose and reproductive/developmental toxicity screening study following OECD TG 422 was conducted on rats using the analogue chemical. No changes related to the compound were observed with regard to general condition, body weights and food consumption during the treatment period. No treatment-related effects were observed in the haematology, biochemistry, organ weights or pathology data. No adverse effects on any of the fertility parameters were noted, and no abnormalities were observed in any pups. Under the conditions of this study, the NOAEL for systemic, reproductive and developmental toxicity was considered by the study authors to be 1,000 mg/kg/day for repeated dose toxicity and reproductive/developmental toxicity.

The US EPA also evaluated a 90-day repeated dose oral study conducted on rats using the analogue chemical. Increased blood clotting time, increases in neutrophils, decreased red blood cells, increased platelets, decreased serum potassium and phosphorus, vacuolated lung macrophages, and thyroid hypertrophy were observed at 1,000 mg/kg bw/day. The NOAEL for this study was established to be 300 mg/kg/day.

A possible hydrolysis product and metabolite of the assessed chemical is a developmental toxicant, with a LOAEL of 100 mg/kg bw/day (Confidential, 2012b).

Mutagenicity/Genotoxicity

No data were provided for the assessed chemical on genotoxicity.

A bacterial reverse mutation study following OECD TG 471 was conducted on the analogue chemical using the pre-incubation method. A maximum concentration of 2,500 µg /plate was used in the main study, based on a preliminary test. No increase in revertant colonies was observed, in the presence or absence of metabolic activation. In a chromosome aberration test on the analogue chemical following OECD TG 473 using Chinese hamster lung cells, no chromosome aberrations were observed, in the presence or absence of metabolic activation, after short-term and long-term treatment up to a maximum concentration of 5,000 µg/mL. The study authors concluded that the analogue chemical was not mutagenic and did not induce chromosome aberrations, under the conditions of the studies.

Health Hazard Classification

As only limited toxicity data were provided, the assessed chemical cannot be classified according to the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia.

6.3. Human Health Risk Characterisation

A potential hydrolysis product and metabolite of the assessed chemical is a developmental toxicant. Based on available information, the assessed chemical may be a slight irritant and have systemic effects after repeated exposure.

6.3.1. Occupational Health and Safety

Workers may come into contact with the assessed chemical at > 99% concentration during the transfer of transformer liquid into storage tanks and transformers, during maintenance or servicing of equipment and during end of life processes. The main route of exposure would be dermal and incidental ocular exposure may occur. Inhalation exposure to the assessed chemical is not expected unless aerosols are generated. Exposure to breakdown products may also occur. Exposure and risk would be mitigated by use of control measures, such as the use of automated equipment, safe work practices and the PPE as stated by the applicant.

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

6.3.2. Public Health

Products containing the assessed chemical will not be available to the public. The assessed chemical is intended only for use in industrial settings, and public exposure to the assessed chemical is not expected.

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

7. ENVIRONMENTAL IMPLICATIONS**7.1. Environmental Exposure & Fate Assessment****7.1.1. Environmental Exposure****RELEASE OF CHEMICAL AT SITE**

The assessed chemical is not manufactured in Australia. Any release will be due to accidental spills during transport or storage which is expected to be collected for disposal, in accordance with local government regulations.

RELEASE OF CHEMICAL FROM USE

The assessed chemical will be used in closed transformer systems which are filled by automatic processes. The transformer fluid is expected to last the whole service life of the transformer, only being drained during disposal of the transformer. No release is expected from this activity.

RELEASE OF CHEMICAL FROM DISPOSAL

The assessed chemical will be drained out of the transformer at the end of its service life. The drained oil will be disposed of by approved waste contractors which is expected to be recycled, re-refined or possibly used as low-grade burner fuel in accordance with local government regulations.

The applicant estimates that up to 2% of the import volume of the assessed chemical may remain as residues in the empty drums and containers which are expected to be disposed of to landfill in accordance with local government regulations.

7.1.2. Environmental Fate

Most of the assessed chemical is expected to be disposed of by approved waste contractors as a part of the waste oil recycling process. It is likely that the assessed chemical will be degraded into simpler compounds during refining. In the environment, the assessed chemical is expected to sorb to soil due to its high calculated log K_{oc} (log K_{oc} = 9.8). The US EPA has determined that the assessed chemical is expected to be ultimately biodegradable.

The assessed chemical will eventually be degraded by biotic and abiotic processes to form water and oxides of carbon.

7.1.3. Predicted Environmental Concentration (PEC)

A Predicted Environmental Concentration was not calculated as release of the assessed chemical into the aquatic environment is expected to be limited based on the proposed use as a dielectric fluid in transformers.

7.2. Environmental Effects Assessment

No measured ecotoxicity data were submitted for the assessed chemical. The aquatic hazard of the assessed chemical has been estimated using EPIWIN 4.11 software (US EPA, 2012) and the calculated endpoints are detailed below.

<i>Endpoint</i>	<i>Result</i>	<i>Assessment Conclusion</i>
Fish Toxicity	LC50 > limit of solubility	Assessed chemical is not expected to be harmful up to the limit of its solubility in water
Daphnia Toxicity	EC50 > limit of solubility	Assessed chemical is not expected to be harmful up to the limit of its solubility in water
Algal Toxicity	EC50 > limit of solubility	Assessed chemical is not expected to be harmful up to the limit of its solubility in water

Based on the above calculated ecotoxicological endpoints for the assessed chemical, it is not expected to be harmful to aquatic organisms up to its limit of solubility. Therefore, the assessed chemical is not formally classified under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) for acute and chronic toxicities (United Nations, 2017).

7.2.1. Predicted No-Effect Concentration (PNEC)

A Predicted No-Effect Concentration was not calculated as the assessed chemical is not expected to exhibit toxicity to aquatic organisms at the limit of its solubility in water.

7.3. Environmental Risk Assessment

A risk quotient ($Q = \text{PEC}/\text{PNEC}$) was not calculated as the assessed chemical is not expected to be toxic at its limit of solubility in water and aquatic exposure is not expected from the proposed use pattern.

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

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