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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Polycarboxylic acid in Palene 810W

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NICNAS

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Henkel Australia Pty Ltd (ABN 82 001 302 996)
135-141 Canterbury Road
KILSYTH VIC 3137

NOTIFICATION CATEGORY
Limited-small volume: Chemical other than polymer (1 tonne or less per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication:

- Chemical name
- CAS number
- Molecular and structural formula
- Spectral data
- Purity
- Exact import volume
- Detailed use

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
No variation to the schedule of data requirements is claimed.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
The notified chemical is introduced as a ingredient of a finished product Palene 810W

METHODS OF DETECTION AND DETERMINATION

METHOD	Infrared (IR)
Remarks	A reference IR spectrum was provided.

3. COMPOSITION

DEGREE OF PURITY
High

4. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will not be manufactured in Australia but will be imported as a component of a finished product, Palene 810W, at <2%. Formulation of this product may occur in the future.

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

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

USE
As a corrosion inhibitor for use in the immersion coating industry.

5. PROCESS AND RELEASE INFORMATION

PORT OF ENTRY
Melbourne

IDENTITY OF MANUFACTURER/RECIPIENTS
Palene 810W containing the notified chemical will be stored (or potentially reformulated in the future) at Henkel Australia Pty Ltd before distribution to a single end user in the immersion coating industry.

TRANSPORTATION AND PACKAGING
The imported formulation Palene 810W containing <2% of the notified chemical will be shipped and transported by road in 200 L steel drums or 1000 L IBCs directly from dockside to the notifier's warehouse. No repackaging occurs before Palene 810W is distributed by truck or rail to end users in the immersion coating industry.

5.2. Operation description

Potential future reformulation
The notified chemical (~10%) will be transferred into a mixer by an automated transfer pump and blended with other ingredients to produce the final product (<2%% of notified chemical). After blending the product is filtered, packaged and stored in a warehouse for distribution. Formulation is carried out under exhaust ventilation in a fully enclosed mixing vessel. Samples for quality control testing are taken from the batch before filling, using a sampling cup with extension handle and transferred to the laboratory in sealed plastic bottles.

Immersion coating:
During surface treatment for aluminium, Palene 810W containing <2% of the notified chemical will be diluted in an immersion coating bath with water to a concentration of <1% of the notified chemical using an enclosed metering pump system. The diluted end product is then applied to aluminium by an automated bath line technique. The metal for coating is attached to conveyor system and is cleaned and rinsed prior to being immersed in the enclosed bath containing the notified chemical. The applied coating is not rinsed off but dried in place to allow at least 90% transfer to the coated metal. Chemicals not transferred onto the aluminium from the solution are recycled and reused. After drying to evaporate residual water, the coated strip is cured by baking in an oven. The coating process is expected to occur in an effective filtered exhaust system.

End uses:
The coated aluminium may be used for air-conditioning units for motor vehicles.

5.3. Occupational exposure

Number and Category of Workers

Category of Worker	*Number*	*Exposure Duration*	*Exposure Frequency*
Transport and Warehousing	10	4	220
Potential reformulation – make up	2	2	10
Potential reformulation – QC testing	1	1.25	10
Potential reformulation – filling	2	2	10
Immersion Coating	30	4	220

Exposure Details

Transport and Warehousing
The drums and IBCs will be transported from the dockside to the notifier's warehouse. Exposure during transport and storage is not expected, except in the event of an accident. Workers are expected to wear coveralls, long sleeved clothing and impervious gloves. In the event of an accident, workers will wear impervious gloves, rubber apron and shoes, coveralls, goggles and organic vapour respirators to control exposure.

Potential Reformulation
Dermal and to a lesser extent ocular exposure to the notified chemical (~10%) may occur as result of drips and spills during connecting and disconnecting pipelines and transfer hoses. Dermal and to a lesser extent ocular exposure to the notified chemical (< 2%) may occur as result of drips and spills during the QC sampling and testing process and during the connection and disconnection of filling lines. Workers are expected to wear protective personal equipment such as coveralls, impervious gloves and goggles.

Immersion Coating
Palene 810W (< 2% notified chemical) is mixed with water in an enclosed bath after being introduced into the bath using a metered pump system. The final concentration of the notified chemical in the bath will be < 1%. Dermal exposure through drips and spill may occur during the connection and disconnection of lines to the pump. Once it is added to the bath, exposure to the notified chemical should not occur. The coating area is fitted with a filtered exhaust system. The applied coating is not rinsed but dried in place once the metal is removed from the bath. Therefore, worker's exposure during coating is limited. This is further reduced by use of PPE such as coveralls, long sleeve clothing, goggles, and impervious gloves. In case of spills, rubber shoes and aprons, and organic vapour respirators will be used.

5.4. Release

RELEASE OF CHEMICAL AT SITE
Potential Reformulation
The notified chemical is added to a high-speed mixer where it is blended with other ingredients to produce the final product (<2%% of notified chemical). After blending the product is filtered, packaged and stored in a warehouse for distribution. Formulation is carried out under exhaust ventilation in a fully enclosed mixing vessel. Containment of any spillages is through existing bunding. It is estimated that approximately 1% of waste per year is generated by cleaning up minor spills, cleaning out equipment and rinsing and recycling drums. The wastewater will be disposed of to sewer prior to pre-treatment in the manufacturing wastewater treatment plant. Incineration of waste may also occur.

Immersion Coating
Immersion coating in Australia occurs at one industrial facility. With the exception of rail and road transfer, all handling of the notified chemical happens at fully bunded facilities. Only a single customer has been identified for distribution of the corrosion inhibitor product. The product is applied to aluminium as a solution containing < 1% of the notified chemical. The applied coating is not subsequently rinsed off but dried in place giving greater than 90% transfer to the coated metal. The notified chemical remains unchanged throughout the application process and any material not transferred is recycled back into the coating solution and re-used. There is no release of the notified chemical into the aquatic environment during the coating process. All solution lines are periodically cleaned and this rinsate is utilised as a diluent for the coating solution, such that it is recycled back into the process and re-used. During application, all waste, including rinsate is collected in drums and disposed of via a licensed waste operator. A small amount of spillage may occur during application (0.5%), which is collected and disposed of via a licence waste operator to landfill.

RELEASE OF CHEMICAL FROM USE
After its lifecycle the coated aluminium is likely to be disposed to landfill or recycled

5.5. Disposal

Disposed of by licensed waste contractors to landfill.

5.6. Public exposure

The notified chemical is intended for use in the coating industry only. After application and once dried, the notified chemical is cured into an inert matrix and hence is unavailable for exposure. Public exposure to the notified chemical therefore will only occur in the event of a transport accident or spillage.

6. PHYSICAL AND CHEMICAL PROPERTIES

The notified chemical is not separated from solution. Limited physical and chemical properties were supplied for the solution containing the notified chemical. The properties of the notified chemical were estimated by the notifier using modelling techniques (quantitative structure activity relationships). Results are presented below.

Appearance at 20ºC and 101.3 kPa Pale yellow-brown liquid (for Palene 810W)

Melting Point/Freezing Point 196 ºC

Remarks Modelled using EPIWIN v3.12

Boiling Point 465 ºC

Remarks Modelled using EPIWIN v3.12

Specific gravity 1.020– 1.03 at 20 ºC (for Palene 810W)

Remarks Taken from the MSDS.

Vapour Pressure 4.5×10^{-10} kPa at 25ºC

Remarks Modelled using EPIWIN v3.12

Water Solubility 1.18×10^{2} g/L at 19ºC

Remarks Beilstein; Handbook of Organic Chemistry (on-line database).

Hydrolysis as a Function of pH Not determined

Remarks The chemical has no functional groups expected to hydrolyse under normal environmental pH (4 to 9).

Partition Coefficient (n-octanol/water) log Pow = -1.41

Method Modelled using EPIWIN v3.12

Adsorption/Desorption log K_{oc} = 2.73

METHOD Modelled using EPIWIN v3.12 (PCKOCWIN v1.66)

Dissociation Constant Not determined

Remarks The chemical contains functional groups that will undergo dissociation

Flash Point Not determined

Remarks The notified chemical is predicted to be a low volatility solid and hence is not expected to form a flammable air/vapour mixture under normal conditions of use.

Flammability Limits Not determined

Remarks The notified chemical is expected to be a low volatility solid. The notified chemical does not react upon contact with water.

Autoignition Temperature Not determined

Remarks The notified chemical is expected to be a low volatility solid and is not expected to autoignite under normal conditions of use.

Explosive Properties Not determined

Remarks The notified chemical contains no functional groups that would infer explosive properties.

Reactivity

Remarks Expected to be stable under normal conditions of use and in the environmental pH range.

7. TOXICOLOGICAL INVESTIGATIONS

No toxicological data (full study reports) are available for the notified chemical. A toxicity profile for the notified chemical was obtained from a published reference and the National Toxicology Program (NTP) website (http://ntp.niehs.nih.gov). These reports contained toxicity information from various unpublished US EPA reports. No original study reports were cited.

The toxicity endpoints are tabulated below:

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral	harmful, LD50 1620 mg/kg bw (females), 1740 mg/kg bw (males)
Rabbit, acute dermal	low toxicity, LD 50 >8000 mg/kg bw
Rat, acute inhalation	low toxicity, LC50 >8.19 mg/L/1 hour
Rabbit, skin irritation	slightly irritating
Rabbit, eye irritation	severely irritating
Rabbit, skin sensitisation	inadequate evidence of sensitisation
Genotoxicity – bacterial reverse mutation	Genotoxic, mutagenic to bacteria
Developmental effects	Maternal NOAEL 500 mg/kg bw/day. Developmental NOAEL $\geq$ 1000 mg/kg bw/day

7.1. Acute toxicity – oral

TEST SUBSTANCE — Notified chemical

METHOD

Species/Strain	Rat/COX-SD
Vehicle	Deionised water
Remarks - Method	No significant deviations from OECD TG 401 Acute Oral Toxicity.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	5 per sex	800	Not reported
II	5 per sex	1260	1/10
III	5 per sex	1590	2/10
IV	5 per sex	2000	8/10
V	5 per sex	3170	10/10

LD50	1740 mg/kg bw (male), 1620 mg/kg bw (female)
Signs of Toxicity	All animals at the two highest doses (group IV and V) exhibited gross signs of chemical-induced toxicity, and 20/30 animals showed signs of toxicity at the three lowest dose levels (group I-III). Group I and II animals had pronounced or severe diarrhoea less than 24 hours after dosing (4/10 and 7/10, respectively). Group III animals exhibited hypoactivity (3/10), diarrhoea (9/10), piloerection (1/10), and malaise (3/10) within 24 or 48 hours of dosing. Group IV animals exhibited hypoactivity (10/10), hypersalivation (1/10), diarrhoea (4/10), unkempt pelage (2/10), piloerection (2/10), malaise (9/10), and proneness (3/10) within 24 or 48 hours. Toxicological signs seen in group V animals in less than 24 hours included hypoactivity (10/10), hypersalivation (2/10), malaise (7/10), and proneness (10/10). Surviving animals returned to normal within 24 and 96 hours following treatment. Body weights of surviving animals remained constant or showed a slight decrease (0.0 to -9.0 g) in four animals seven days after treatment, and a slight decrease (-3.4%) in one animal fourteen days after treatment. All other survivors

showed normal gains. Animals that succumbed during the experiment exhibited weight losses at the time of death, with the exception of two animals that showed essentially constant weights.

Effects in Organs: Necropsy of animals that died during the fourteen-day observation period revealed several abnormalities. Group II and III animals that died had moderate to severe congestion of the adrenals, kidneys, liver, and lungs, and erosion and blanching of the stomach mucosa. The group II animal also had moderate congestion of the intestines, and severe blanching of the small intestine. All of the 8 group IV animals that died during the study exhibited moderate to severe congestion of the adrenals, kidneys, liver, and lungs, and erosion of the stomach mucosa. Other abnormalities seen in these animals included moderate congestion of the intestines (4/8), brownish-grey coloration of the lungs (1/8), severe blanching of the small intestine (5/8), blanching of the stomach mucosa (7/8), and lesions on the stomach mucosa (1/8). All group V animals exhibited moderate to severe congestion of the adrenals, kidneys, liver, and lungs, and blanching and erosion of the stomach mucosa. Other abnormalities seen in this group included moderate congestion of the intestines (6/10), a paleness of the liver (2/10), a brownish-grey coloration of the lungs (1/10), and blanching of the small intestine (9/10). Necropsy of surviving animals showed no abnormalities, with the exception of three rats that exhibited a hollowing of the renal pelvises.

CONCLUSION: The notified chemical is harmful via the oral route.

7.2. Acute toxicity – dermal

TEST SUBSTANCE: Notified chemical

METHOD

Species/Strain: Rabbit/New Zealand

Vehicle: Isotonic saline (50% suspension)

Type of dressing: Not reported

Remarks - Method: Deviations from OECD TG 402 Acute Dermal Toxicity.

- Only 2 animals/sex used per group (compared with 5 per group)
- Two animals in each group were further prepared by making epidermal abrasions over the area of exposure, significantly deep enough to penetrate the stratum corneum, but not disturb the dermis.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
I	2 per sex	2000	0/4
II	2 per sex	4000	0/4
III	2 per sex	8000	1/4

LD50: > 8000 mg/kg bw

Signs of Toxicity - Local: At all dose levels, the rabbits exhibited moderate to severe erythema with chemical burns and/or blanching, especially along the abrasions. The intensity of the reactions increased with the dose level. On days 7 and 14, desquamation and drying were also observed

Signs of Toxicity - Systemic: In group III, one animal exhibited generalised weakness for 72 hours, and three animals were observed to be thin after 72 hours and until day 10 of the study. Wry neck was seen in two group I animals. Two animals in this dose group also exhibited a generalised weakness for 24-48 hours. No other signs of systemic toxicity were observed.

Final body weight data of surviving animals at day 14 revealed that three

	group I animals (two with intact skin, one with abraded skin) had significant (10% or greater) weight gains. One group II animal (abraded skin) had a significant weight gain. Other surviving animals had weight gains or losses that were less than 10%.
Effects in Organs	From gross necropsy of animals that died, the skin was observed to have severe erythema of the sides and ventrum with severe congestion of the subcutaneous tissue. The stomachs were blanched with severe erosion of the mucosal surface, and the small intestines showed severe scattered congestion. No other abnormalities were observed. Gross necropsy of the animals sacrificed at day 14 showed no remarkable abnormalities, with the exception of one group III animal that showed an approximate 90% loss of fat tissue.
CONCLUSION	The notified chemical is of low toxicity via the dermal route.

7.3. Acute toxicity – inhalation

TEST SUBSTANCE	Notified chemical
METHOD	
Species/Strain	Rat/COX-SD
Vehicle	Test substance administered undiluted
Method of Exposure	Not specified
Exposure Period	1 hour
Physical Form	solid aerosol (particulate)
Particle Size	Not specified (administered in dust form)
Remarks - Method	Deviations from OECD TG 403 Acute Inhalation Toxicity – Exposure period 1 hour only (compared with 4 hours in the protocol) Equipment/atmosphere deviations could not be verified

RESULTS

Group	*Number and Sex of Animals*	*Concentration mg/L*		*Mortality*
		Nominal	*Actual*	
I	5 per sex	-	8.19	0/10

LC50	> 8.19mg/L/1 hour
Signs of Toxicity	No gross toxicological effects were seen in any animal during the test period. Weight gains were within the expected limits.
Effects in Organs	Moderate congestion of the lungs was observed in three of the ten animals and slightly mottled lungs in three other animals, however, this type of congestion is reported to be often observed as a sacrifice artefact in rats. No other abnormalities were found in the remaining animals.
Remarks - Results	An LC50 based on 4 hours exposure is required for classification under NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2004).
CONCLUSION	The notified chemical is of low toxicity via inhalation under the conditions of this test.

7.4. Irritation – skin

TEST SUBSTANCE	Notified chemical
METHOD	
Species/Strain	Rabbit/New Zealand White

Number of Animals	Six
Vehicle	Isotonic suspension (50% w/v)
Observation Period	7 day
Type of Dressing	Not specified
Remarks - Method	Deviations from OECD TG 404 Acute Dermal Irritation/Corrosion – Exposure period was 24 hours (compared to 4 hours in the protocol) – The chemical was applied to two sites on each animal. Two sets of abrasions were made on one site over the area of exposure, significantly deep enough to penetrate the stratum corneum, but not disturb the dermis.

RESULTS

At 24 hours, 5 animals showed a barely perceptible erythema (score=1) with no oedema formation, and one animal showed moderate erythema (score=2) with a slight oedema (score=1). Steady reduction of the response was noted throughout the 7-day observation period, and with the exception of slight erythema along the abrasions in one animal, all reactions disappeared completely by day seven. Also, none of the usual sequelae to irritation, such as desquamation and drying, were observed during the course of the study. No essential differences were seen between reactions on intact and abraded skin areas.

Remarks - Results: A primary irritation index of 0.9 was reported.

CONCLUSION

The notified chemical is slightly irritating to the skin.

7.5. Irritation – eye

TEST SUBSTANCE

Notified chemical

METHOD

Species/Strain	Rabbit/New Zealand White
Number of Animals	Nine
Observation Period	14 days
Remarks - Method	Fluorescein dye was used to facilitate corneal observations Deviations from OECD TG 405 Acute Eye Irritation/Corrosion – An observation period of 14 days was used (compared to 21 days in the protocol) – The treated eyes of three animals were rinsed 20 seconds after application, for one minute. Treatment for six animals was per the protocol

RESULTS

Remarks - Results

<u>Eyes rinsed after 20 seconds (3 animals)</u>

Slight to moderate erythema of the bulbar and palpebral conjunctivae, a moderate to severe chemosis of the lids, a slight to moderate accumulation of watery-mucoid discharge, and a slight to moderate corneal opacity involving 1/4 to 1/2 of the corneal surface was observed within 24 hours. At 48 hours, the reaction of the conjunctivae became more intense for each animal, while the corneal reaction in one animal disappeared, was decreased in another, and became more intense in the third. By 96 hours, only slight improvement was noted. At 7 days, two animals showed only slight erythema and the third continued to have corneal opacity. At the 14-day observation point, two animals were reaction-free, and the third exhibited erythema, chemosis, and corneal opacity. Vascularization was noted in two animals at 96 hours that continued through day 14.

<u>Without rinsing (six animals)</u>

Severe ocular damage including slight to moderate erythema of the bulbar and palpebral conjunctivae, severe chemosis of the lids, a moderate to marked accumulation of watery-mucoid discharge, and moderate to marked corneal opacity involving 1/4 or the entire corneal surface, was observed after 24 hours. The reactions were more severe at 48 and 72 hours, with 5/6 animals developing iritis. The maximum reaction was noted at 72 hours but only slight improvement was noted throughout the 14-day test period. Vascularization of the cornea was observed initially at 96 hours that continued to increase through day 14.

CONCLUSION The notified chemical severely irritating to the eye.

7.6. Genotoxicity – bacteria

TEST SUBSTANCE Notified chemical

METHOD

Species/Strain	*S. typhimurium*: TA100, TA98
Metabolic Activation System	Induced Sprague Dawley rat liver S9 and induced male Syrian hamster liver S9.
Concentration Range in Main Test	With and without metabolic activation: 0 - 10000 µg/plate
Vehicle	Not specified
Remarks - Method	Preincubation method used.

Limited method information was provided and hence a comparison with the OECD TG471 Bacterial Reverse Mutation Test protocol was not possible. However, only two strains were tested, compared with five recommended in the protocol.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent	-			
Test 1		> 10000	> 10000	Positive
Test 2		> 10000	> 10000	Negative
Test 3		> 10000	> 10000	Positive
Present (rat liver)	-			
Test 1		10000*	> 10000	Positive
Test 2		10000*	> 10000	Positive
Present (hamster liver)	-			
Test 1		3333*	> 10000	Not valid test
Test 2		10000*	> 10000	negative

* slight toxicity

Remarks - Results No information was provided regarding the different tests or why certain tests were not valid.

<u>Absence of activation</u>

TA 100: A two-fold and three-fold increase in the number of revertants per plate was observed at a dose of 10000 µg/plate in two tests. No increase was observed in a third test.

TA98: A six-fold and 32-fold increase in the number of revertants was observed at 3333 µg/plate and 10000 µg/plate respectively in one test. In a second test a 10-fold and 42-fold increase was observed at these doses.

Rat liver activation
TA100: Only one test was valid. No increase in the number of revertants was observed.

TA98: A three-fold and four-fold increase in the number of revertants per plate was observed at a dose of 10000 µg/plate in two tests

Hamster liver activation
TA100: Only one test was valid. No increase in the number of revertants was observed.

TA98: Only one test was valid. No increase in the number of revertants was observed.

CONCLUSION The notified chemical was mutagenic to bacteria under the conditions of the test.

7.7. Developmental toxicity

TEST SUBSTANCE Notified chemical

METHOD

Species/Strain	Rat/ Sprague Dawley
Route of Administration	Oral – gavage
Exposure Information	Exposure days: gestational days 6-19
Vehicle	Deionised/distilled water
Remarks - Method	No significant deviations from OECD 414 Teratogenicity

RESULTS

Group	*Number of Animals*	*Dose mg/kg bw/day*	*Mortality*
I	25	0	0/25
II	25	250	0/25
III	25	500	0/25
IV	25	1000	1/24*

*one animal removed due to misdirected gavage dose.

Mortality and Time to Death
One group IV female was found dead on gestational day 17.

Effects on Dams
Maternal body weight was significantly reduced in group IV animals on gd 12, 15, 18, 19 and 20. Maternal body weight gain during treatment (gd 6 to 20) (18%, $p<0.05$) and gestation (gd 0 to 20) (16%, $p<0.05$) and corrected weight gain (30%, $p <0.05$) also showed significant reductions at this dose. Maternal relative water intake was increased in group IV (gd 12 to 15, 18 to 19, 19 to 20, and the treatment period as a whole (16%, $p<0.05$)). Piloerection was noted in less than or equal to 4 group IV females/day. Rooting in the cage bedding after dosing suggested an aversion to the sensory properties of the dose formulations (less than or equal to 3 females/day in group III and less than or equal to 5 females/day in group IV). Gravid uterine weight and maternal relative liver weight were not affected.

Necropsy of the female that died revealed dark red, mottled lungs and pink discharge from the vagina, but no direct evidence of a misdirected dose.

Effects on Foetus
Prenatal mortality and average live litter size did not differ among groups. Average foetal body weight per litter in treated groups was 97-103% of the control weight, and no significant trends were found. No statistically significant differences were observed in the incidences of foetal malformations or variations.

CONCLUSION

The No Observed (Adverse) Effect Level (NO(A)EL) for maternal toxicity was established as 500 mg/kg bw/day in this study, based on the decreased bodyweight gain and mortality observed at 1000 mg/kg bw/day. The developmental toxicity NOAEL is $\geq$ 1000 mg/kg bw/day.

8. ENVIRONMENT

8.1. Environmental fate

8.1.1. Ready biodegradability

The behaviour of the chemical in wastewater predicted by the EPIWIN v3.12 model is summarised below. The results suggest that greater than 92% of the notified chemical may be removed during wastewater treatment.

	Biowin/EPA Draft Method	*10000 hr Bio P, A, S Method*
Total removal (%)	92.06	1.85
Total biodegradation (%)	91.72	0.09
Total sludge sorption (%)	0.33	1.75
Total to air (%)	0.00	0.00

Using the estimated partition coefficient, assuming ready biodegradation (based on EPIWIN) and Henrys Law constant the Simpletreat model predicts that 67% will be degraded, none will partition to air or sludge resulting in a total removal of 67% with 33% remaining in water.

8.1.2. Bioaccumulation

A Log BCF of 0.5 (BCF = 3.16) estimated using EPIWIN v3.12 from log Kow, indicates that the notified chemical is not bioaccumulative.

8.2. Ecotoxicological investigations

No ecotoxicity data were submitted

9.1. Environment

9.1.1. Environment – exposure assessment

Potential reformulation

During reformulation, it is estimated that approximately 1% of waste per year is generated by cleaning up minor spills, cleaning out equipment and rinsing and recycling drums. The waste will be disposed of to sewer prior to pre-treatment in the manufacturing wastewater treatment plant. Incineration of waste may also occur.

Assuming that the total volume of waste produced (1%) during reformulation is released to STP during maximum of 30 days per year. Based on the typical use per day, worst-case predicted environmental concentration (PEC) values are estimated for discharging into a large sewage treatment works assuming no partitioning to sludge within the sewage treatment works.

Process or Dilution Factor	Reformulation Release to Large STP
Concentration of notified chemical per year	10 kg
Typical notified chemical use expected per day	0.04 kg
Number of day per year used during formulation	30 days
Australian population	Large City
STP daily Volume	395 ML
Concentration in effluent from sewage treatment plant	0.84 µg/L
Predicted environmental concentrations (PECs) in receiving waters	
Ocean (Dilution Factor 1:10)	
PEC	0.08 µg/L
River (Dilution Factor 1:1)	

PEC	0.84 µg/L

Immersion Coating
During application, all waste, including rinsate is collected in drums and disposed of via a licensed waste operator. Rinsate and waste coating is re-worked by coating suppliers into further coating products. A small amount of spillage may occur during application (0.5%), which is collected and disposed of via a licence waste operator to landfill.

After its lifecycle the aluminium products are likely to be disposed to landfill or recycled. If disposed to landfill, the notified chemical is likely to remain bound to the coating and be degraded by abiotic process to oxide of carbon. During recycling the aluminium products are likely to go high temperature recovery during which the chemical will be release as oxide of carbon.

9.1.2. Environment – effects assessment

No ecotoxicity data were provided for the notified chemical. However, toxicity will be limited due to the high water solubility and very low partitioning coefficient values. Additionally, the quantity of the notified chemical released to the aquatic compartment is low suggesting that its potential for bioaccumulation is also low.

9.1.3. Environment – risk characterisation

The notified chemical water solubility and Kow values indicate that the notified chemical should stay in the water column and not sorb into solid phases. Modelling prediction indicates a minimum of 67% removal during treatment and during formulation the notified chemical will be released to an ocean discharge STP. Therefore, due to it physico-chemical properties and low PEC the notified chemical poses a low risk to the environment.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Transport and Warehousing
Exposure to waterside, transport and storage workers is expected to be negligible considering the handling of sealed containers containing the notified chemical and should only occur in the event of an accident resulting in rupture of containers.

Potential reformulation
The reformulation of the notified chemical into products is for the most part described as automated and enclosed minimising the potential for exposure. The potential sources of exposure during reformulation occur during the connection and disconnection of transfer lines and QC sampling and testing. Dermal and potentially ocular exposure will be limited by the concentration of the notified chemical (10% and < 2% (pre and post reformulation) and the use of PPE. Inhalation exposure of workers involved in reformulation of the corrosion inhibitor solution should be precluded by the low vapour pressure and high solubility of the notified chemical.

Immersion Coating
Dermal exposure to coating workers should be limited by the notified chemical's low concentration (< 2%) in the reformulated corrosion inhibitor solution and limited opportunity for exposure while connecting and disconnecting containers to the immersion coating machine. The immersion coating machine is designed for continuous operation but there may be intermittent exposure from cleaning operations or maintenance. Inhalation exposure of workers should be precluded by the low vapour pressure and high solubility of the notified chemical.

9.2.2. Public health – exposure assessment

The notified chemical is intended for use in the immersion coating industry only. After application and once dried, the notified chemical is cured into an inert matrix and hence is unavailable for exposure. Public exposure to the notified chemical is expected to be negligible and will only occur in the event of a transport accident or spillage.

9.2.3. Human health – effects assessment

Acute toxicity.

The notified chemical is harmful via the oral route but is of low toxicity via dermal and inhalation routes.

Irritation and Sensitisation.

The notified chemical was slightly irritating in a skin irritation test but caused moderate to severe skin irritation in an acute dermal toxicity study. The notified chemical is considered to be severely irritating to the eye causing irreversible damage. No data on sensitisation is available. The notified chemical does not contain a structural alert for sensitisation (Barratt (1994).

Mutagenicity.

The notified chemical was mutagenic to bacteria. The genotoxicity profile of the notified chemical has not been established.

Developmental toxicity

In a developmental toxicity study in rabbits, the Maternal No Observed Adverse Effect Level (NOAEL) was established as 500 mg/kg bw/day in this study, based on reduced bodyweight gain and a mortality observed at 1000 mg/kg bw/day. No developmental effects were observed and a developmental NOAEL of $\geq$ 1000 mg/kg bw/day was established.

Hazard classification for health effects.

Based on the available data, the notified chemical is classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2004).

9.2.4. Occupational health and safety – risk characterisation

The notified chemical is harmful via the oral route but of low toxicity via the dermal route which is expected to be the primary route of exposure.

The notified chemical is also a skin and severe eye irritant. However, the notified chemical will be introduced at less than 10%, and will be less than 2% for use in metal treatment. These low concentrations will reduce the irritation effects. Exposure to the notified chemical during reformulation and the preparation of immersion coating baths may occur; however, both processes are mostly automated and the use of PPE during handling, reformulation and addition to the immersion coating machines, will ensure adequate protection and low exposure. Hence the risk posed to workers is considered to be low provided the controls are maintained.

9.2.5. Public health – risk characterisation

The risk to the public from importation of the notified polymer is considered to be negligible based on the negligible exposure predicted.

10. CONCLUSIONS – ASSESSMENT LEVEL OF CONCERN FOR THE ENVIRONMENT AND HUMANS

10.1. Hazard classification

Based on the available data the notified chemical is classified as hazardous under the NOHSC *Approved Criteria for Classifying Hazardous Substances*. The classification and labelling details are:

R22 Harmful if swallowed

R41 Risk of serious damage to eyes

Due to differences from standard protocols (24 hour exposure time, use of abraded test sites) it is not possible to classify the skin irritation effects using the NOHSC *Approved Criteria for Classifying Hazardous Substances*. Based on the effects observed in the acute dermal toxicity

study a precautionary risk phrase of 'R38 Irritating to skin' may be appropriate. The notified chemical is introduced at ≤ 10%, which is below the cut-off concentration for application of this risk phrase to mixtures.

As a comparison only, the classification of notified chemical using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations 2003) is presented below. This system is not mandated in Australia and carries no legal status but is presented for information purposes.

	Hazard category	*Hazard statement*
Acute toxicity	4	Harmful if swallowed (oral)
Serious eye damage	1	Causes serious eye damage

10.2. Environmental risk assessment

The chemical does not pose a risk to the environment based on the notified use pattern.

10.3. Human health risk assessment

10.3.1. Occupational health and safety

There is Low Concern to occupational health and safety under the conditions of the occupational settings described.

10.3.2. Public health

There is Negligible Concern to public health when used under the conditions of the environmental, workplace and occupational settings described.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the product containing the notified chemical provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Preparation of Material Safety Data Sheets* (NOHSC 2003). It is published here as a matter of public record. The accuracy of the information on the MSDS remains the responsibility of the applicant.

11.2. Label

The label for the product containing the notified chemical provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC 1994). The accuracy of the information on the label remains the responsibility of the applicant.

12. RECOMMENDATIONS

REGULATORY CONTROLS
Hazard Classification and Labelling

- The Office of the ASCC, Department of Employment and Workplace Relations (DEWR), should consider the following health hazard classification for the notified chemical:
  - R22 Harmful if swallowed
  - R41Risk of serious damage to eyes

- Use the following risk phrases for products/mixtures containing the notified chemical:
  ≥25%: R22; R38*; R41
  20% ≤ Conc < 25%: R38*; R41

10% ≤ Conc < 20%: R41
5% ≤ Conc < 10%: R36

* precautionary

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified chemical as introduced and as diluted for use:
  - Use of automated processes where practicable

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified chemical as introduced and as diluted for use:
  - Avoid skin and eye contact

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical as introduced and as diluted for use.

  - Coveralls; and
  - eye protection; and
  - impervious gloves

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

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

- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances*, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation. Particular note should be taken of the hazards of the chemical solution Palene 810W to be imported and the corrosion inhibitor product produced by dilution of this solution.

Disposal

- The notified chemical should be disposed of by combustion or landfill application.

Emergency procedures

- Spills or accidental release of the notified chemical should be handled by sweep up and collect for disposal.

12.1. Secondary notification

The Director of Chemicals Notification and Assessment must be notified in writing within 28 days by the notifier, other importer or manufacturer:

(1) Under Section 64(1) of the Act; if
  - the importation volume exceeds one tonne per annum notified chemical; or
  - the notified chemical is introduced at a concentration > 10%

or

(2) Under Section 64(2) of the Act:
  - if any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.

13. BIBLIOGRAPHY

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