File No: LTD/1884

March 2016

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Manganese(2+), bis(octahydro-1,4,7-trimethyl-1*H*-1,4,7-triazonine-κN^1,κN^4,κN^7)tri-μ-oxodi-, hexafluorophosphate(1-) (1:2)

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the Department of Health, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of the Environment.

This Public Report is available for viewing and downloading from the NICNAS website or available on request, free of charge, by contacting NICNAS. For requests and enquiries please contact the NICNAS Administration Coordinator 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
FAX:	+ 61 2 8577 8888
Website:	www.nicnas.gov.au

Director
NICNAS

TABLE OF CONTENTS

SUMMARY

The following details will be published in the NICNAS *Chemical Gazette:*

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
LTD/1884	Procter & Gamble Australia Pty Ltd	Manganese(2+), bis(octahydro-1,4,7-trimethyl-1*H*-1,4,7-triazonine-κN^1,κN^4,κN^7)tri-μ-oxodi-, hexafluorophosphate(1-) (1:2)	ND	≤ 1 tonne per annum	Component of automatic dishwashing detergents

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
As no toxicity data were provided, the notified chemical cannot be classified according to the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

The environmental hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS) is presented below. Environmental classification under the GHS is not mandated in Australia and carries no legal status but is presented for information purposes.

Hazard classification	*Hazard statement*
Acute Category 2	H401 – Toxic to aquatic life
Chronic Category 2	H411 – Toxic to aquatic life with long lasting effects

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

Based on the available information, when used in pre-packaged automatic dishwashing detergent products, the notified chemical is not considered to pose an unreasonable risk to public health

Environmental risk assessment
On the basis of the PEC/PNEC ratio and the reported use pattern, the notified chemical is not considered to pose an unreasonable risk to the environment.

Recommendations

CONTROL MEASURES

Occupational Health and Safety

- A copy of the (M)SDS should be easily accessible to employees.
- If products and mixtures containing the notified 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.

Disposal

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

Emergency procedures

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

Regulatory Obligations

Secondary Notification
This risk assessment is based on the information available at the time of notification. The Director may call for the reassessment of the chemical under secondary notification provisions based on changes in certain circumstances. Under Section 64 of the *Industrial Chemicals (Notification and Assessment) Act (1989)* the notifier, as well as any other importer or manufacturer of the notified chemical, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified chemical is listed on the Australian Inventory of Chemical Substances (AICS).

Therefore, the Director of NICNAS 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;
- the notified chemical is to be imported in a form other than as an ingredient in automatic dishwashing detergent pouches;

or

(2) Under Section 64(2) of the Act; if
- the function or use of the chemical has changed from component of automatic dishwashing detergents, or is likely to change significantly;
- the amount of chemical being introduced has increased, or is likely to increase, significantly;
- the chemical has begun to be manufactured in Australia;
- additional information has become available to the person as to an adverse effect of the chemical on occupational health and safety, public health, or the environment.

The Director will then decide whether a reassessment (i.e. a secondary notification and assessment) is required.

(Material) Safety Data Sheet
The (M)SDS of the products containing the notified chemical provided by the notifier were reviewed by NICNAS. The accuracy of the information on the (M)SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Procter & Gamble Australia Pty Ltd (ABN: 91 008 396 245)
Level 4, 1 Innovation Road
MACQUARIE PARK NSW 2113

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: use details and import volume

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: all physico-chemical endpoints.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
EU and Switzerland

2. IDENTITY OF CHEMICAL

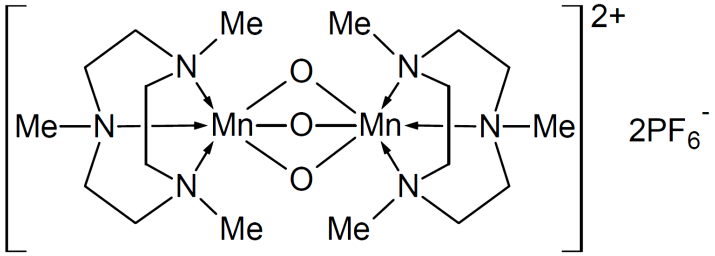
MARKETING NAME(S)
Peractive Mn-TACN
Fairy All in One – Original (product containing the notified chemical)
Fairy Platinum All in One – Lemon (product containing the notified chemical)

CAS NUMBER
116633-52-4

CHEMICAL NAME
Manganese(2+), bis(octahydro-1,4,7-trimethyl-1H-1,4,7-triazonine-κN^1,κN^4,κN^7)tri-μ-oxodi-, hexafluorophosphate(1-) (1:2)

MOLECULAR FORMULA
$C_{18}H_{42}Mn_2N_6O_3.2F_6P$

STRUCTURAL FORMULA



MOLECULAR WEIGHT
790.4 Da

ANALYTICAL DATA
Reference UV-Vis spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
> 95.8 %

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS
None

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (> 1% BY WEIGHT)
None

ADDITIVES/ADJUVANTS
None

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Brown powder

Property	Value	Data Source/Justification
Melting Point/Freezing Point	> 160-170 °C (decomposes below the melting point)	(M)SDS
Boiling Point	> 300 °C	(M)SDS
Density	500-800 kg/m^3	(M)SDS
Vapour Pressure	< 1 × 10^{-8} kPa at 25 °C	(M)SDS
Water Solubility	10.8 g/L at pH 7-7.2 at 20 °C	(M)SDS
Hydrolysis as a Function of pH	$t_{½}$ ≤ 1 year at pH 4 $t_{½}$ > 1 year at pH 7 and 9	(M)SDS
Partition Coefficient (n-octanol/water)	log Pow < -2.71 at pH 7-7.3 at 20°C	(M)SDS
Adsorption/Desorption	log K_{oc} = 3.861	(M)SDS
Dissociation Constant	Not determined	Expected to be ionised under environmental conditions (pH 4-9)
Particle Size	16 µm	(M)SDS
Solid Flammability	Not flammable	(M)SDS
Autoignition Temperature	150 °C	(M)SDS
Explosive Properties	Not explosive	(M)SDS
Oxidising Properties	Not oxidising	(M)SDS

DISCUSSION OF PROPERTIES

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

Physical hazard classification
Based on the submitted physico-chemical data depicted in the above table, the notified 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 NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will not be manufactured or reformulated within Australia. The notified chemical will be imported into Australia as a component of dishwashing detergents contained in pouches.

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

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

PORT OF ENTRY
Sydney

IDENTITY OF RECIPIENTS
Procter & Gamble Australia Pty Ltd

TRANSPORTATION AND PACKAGING
Dishwashing detergent pouches containing the notified chemical (at < 0.1% concentration) will be imported into Australia in packaging suitable for retail sale. The products will be transported in the same form in which they are imported and will be distributed to commercial warehouses and retail stores within Australia by road.

USE
The notified chemical will be used at < 0.1% concentration in automatic dishwashing detergents, as a bleach catalyst.

OPERATION DESCRIPTION
The notified chemical will not be manufactured or reformulated in Australia. It will be imported into Australia as a component of dishwashing detergents contained in pouches. During end use, consumers will remove a dishwashing pouch from the outer packaging and place it into the detergent reservoir in the automatic dishwasher. The pouch containing the detergent will dissolve in the dishwasher, releasing the contents. The notified chemical will be discharged into the wastewater at the end of the dishwashing cycle.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure
Transport, storage and retail workers may come into contact with the notified chemical only in the event of accidental rupture of packages. Exposure would be limited to dermal or ocular contact and is expected to be limited by the notified chemical being contained within the individual pouches.

Exposure of professional kitchen workers is expected to be of a similar extent to that experienced by consumers using automatic dishwashing detergents containing the notified chemical.

6.1.2. Public Exposure
Consumer exposure to the notified chemical while adding the detergent to the dishwashing machine is not expected to occur as detergent is contained in sealed pouches. Exposure to the notified chemical from washed dishes is expected to be very low because it is present at a very low concentration (< 0.1%) in the detergent, it will be further diluted in the wash water, and is expected to be rinsed off from the washed articles prior to drying.

If the pouch ruptures, incidental dermal and possibly ocular exposure of the public to dishwashing detergents containing the notified chemical may occur through spills and splashes. It is expected that any spilt material would be washed off promptly.

6.2. Human Health Effects Assessment
No toxicity data were submitted. However information on toxicity from a (M)SDS for the notified chemical is reported below.

Acute toxicity.
The (M)SDS of the notified chemical provided with the application stated that the notified chemical was of low toxicity via the oral and dermal routes in rats. The LD50 values in rat were >2000 mg/kg bw for oral exposure (Directive 67/548/EEC, Annex V, B.1 method) and >2000 mg/kg bw for dermal exposure (Directive 67/548/EEC, Annex V, B.3 method).

Irritation and sensitisation.
The (M)SDS provided with the application stated that the notified chemical was not an irritant to skin and eye when tested in rabbits, and was non-sensitising in a guinea pig Maximisation test. The studies were carried out to EEC Directive methods.

Repeated dose toxicity.
The (M)SDS provided with the application stated a NOAEL of 15 mg/kg in rats for the notified chemical (oral, 30 days exposure time followed by 14 days observation period).

Genotoxicity.
The (M)SDS provided with the application stated that the notified chemical was non mutagenic, based on an overall evaluation of mutagenicity tests. The Ames test (*in-vitro*, *Salmonella typhimurium)* was negative with and without metabolic activation, and positive results were seen in a chromosome aberration test (*in vitro*, OECD test guideline 473) with and without metabolic activation. The *in vivo* micronucleus test (mouse, oral) and unscheduled DNA synthesis test (rat, oral) were stated to be negative.

Health hazard classification
As no toxicity data were provided, the notified chemical cannot be classified according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)*, as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety
As worker exposure to the notified chemical will be very low and limited to spills due to an accident, the risk to these workers is not considered to be unreasonable.

6.3.2. Public Health
Based on expected very low exposure, the risk to the public from the notified chemical is not considered to be unreasonable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE
The notified chemical will be imported as a component of finished pouches containing detergent for domestic dishwashing applications. Therefore, release of the notified chemical to the environment prior to end-use is not expected, as manufacturing and reformulation of the dishwashing formulations containing the notified chemical will not take place in Australia. Environmental release of the notified chemical during importation, transport and storage is likely to be limited to accidental spills and leaks, which are unlikely given the imported product containing the notified chemical is pre-packaged. In the event of spills, the product containing the notified chemical is expected to be collected with adsorbents, and disposed of to landfill in accordance with local government regulations.

RELEASE OF CHEMICAL FROM USE
The majority of the notified chemical in dishwashing formulations is expected to be released to sewers nationwide in wastewaters following use.

RELEASE OF CHEMICAL FROM DISPOSAL
A minor amount of the notified chemical may be disposed of to landfill as domestic waste if unused detergent pouches are discarded.

7.1.2. Environmental Fate
Following its use in dishwashing formulations, the majority of the notified chemical is expected to enter the sewer system via domestic wastewater, before potential release to surface waters nationwide. Based on the results of a biodegradability study in the submitted (M)SDS (carried out in accordance with OECD 301 B test guidelines), the notified chemical is not considered to be readily biodegradable (12% in 29 days). However, as the full study report for these data has not been submitted, the results should be treated with caution. Based on its molecular structure and high adsorption coefficient (log K_{OC} = 3.86), release to surface waters is not expected as the notified chemical is expected to adsorb strongly to sludge and sediment. Although the notified chemical has low molecular weight < 1000, it is not expected to bioaccumulate due to its low partition coefficient (log P_{OW} < -

2.71). Therefore, in surface waters the notified chemical is expected to disperse and degrade through biotic and abiotic processes to form water and oxides of carbon and inorganic salts.

The majority of the notified chemical will be released to sewer after use. A small proportion of the notified chemical may be applied to land when effluent is used for irrigation, when sewage sludge is used for soil remediation, or disposed of to landfill as collected spills and solid wastes. The notified chemical residues in landfill, soil and sludge are expected to eventually degrade to form water and oxides of carbon and inorganic salts.

7.1.3. Predicted Environmental Concentration (PEC)

The predicted environmental concentration (PEC) has been calculated to assume a worst case scenario, with 100% release of the notified chemical into sewer systems nationwide and no removal within sewage treatment plants (STPs).

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	1,000	kg/year
Proportion expected to be released to sewer	100%	
Annual quantity of chemical released to sewer	1,000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	2.74	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	22.613	million
Removal within STP	0%	
Daily effluent production:	4,523	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	0.606	µg/L
PEC - Ocean:	0.061	µg/L

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1000 L/m^2/year (10 ML/ha/year). The notified chemical in this volume is assumed to infiltrate and accumulate in the top 10 cm of soil (density 1500 kg/m^3). Using these assumptions, irrigation with a concentration of 0.61 µg/L may potentially result in a soil concentration of approximately 4.039 µg/kg. Assuming accumulation of the notified chemical in soil for 5 and 10 years under repeated irrigation, the concentration of the notified chemical in the applied soil in 5 and 10 years may be approximately 20.19 µg/kg and 40.39 µg/kg, respectively.

7.2. Environmental Effects Assessment

The results from ecotoxicological investigations conducted on the notified chemical in the submitted (M)SDS are summarised in the table below. However, as the full study reports have not been provided, these results should be treated with caution.

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity	96 h LC50 > 100 mg/L	Not harmful to fish
Daphnia Toxicity	48 h EC50 > 100 mg/L	Not harmful to *Daphnia*
Algal Toxicity	96 h E_rC50 = 8.7 mg/L	Toxic to algae
	96 h E_bC50 = 3.2 mg/L	
Inhibition of Bacterial Respiration	16 h IC50 = 26.06 mg/L	Inhibitory to microbial respiration

Based on the above ecotoxicological endpoints, the notified chemical is expected to be toxic to algae, but is not expected to be harmful to fish and aquatic invertebrates. Therefore, under the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)* (United Nations, 2009), the notified chemical is formally classified as “Acute Category 2; Toxic to aquatic life”. Based on its lack of ready biodegradability and acute toxicity, the notified chemical is formally classified as “Chronic Category 2; Toxic to aquatic life with long lasting effects” under the GHS.

7.2.1. Predicted No-Effect Concentration

The predicted no-effects concentration (PNEC) has been calculated from the most sensitive endpoint for algae. A conservative assessment factor of 250 was used given acute endpoints for three trophic levels are available, although the full study reports for these data are not available.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
E_rC50 (Algae, 96 h)	8.7	mg/L
Assessment Factor	250	
Mitigation Factor	1.00	
PNEC:	34.8	µg/L

7.3. Environmental Risk Assessment

The Risk Quotient (Q = PEC/PNEC) has been calculated based on the predicted PEC and PNEC.

Risk Assessment	PEC µg/L	PNEC µg/L	Q
Q - River	0.606	34.8	**0.017**
Q - Ocean	0.061	34.8	**0.002**

The risk quotient for discharge of treated effluents containing the notified chemical to the aquatic environment indicates that the notified chemical is unlikely to reach ecotoxicologically significant concentrations in surface waters, based on its maximum annual importation quantity. Although the notified chemical is not readily biodegradable, it is expected to have a low potential for bioaccumulation. On the basis of the PEC/PNEC ratio, maximum annual importation volume and assessed use pattern in domestic dishwashing detergents, the notified chemical is not expected to pose an unreasonable risk to the environment.

BIBLIOGRAPHY

NOHSC (2004) Approved Criteria for Classifying Hazardous Substances, 3rd edition [NOHSC:1008(2004)]. National Occupational Health and Safety Commission, Canberra, AusInfo.

United Nations (2009) Globally Harmonised System of Classification and Labelling of Chemicals (GHS), 3rd revised edition. United Nations Economic Commission for Europe (UN/ECE), <http://www.unece.org/trans/danger/publi/ghs/ghs_rev03/03files_e.html >.