File No: LTD/1963

March 2017

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Manganese(2+), bis(octahydro-1,4,7-trimethyl-1H-1,4,7-triazonine-kN¹,kN⁴,kN⁵)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 and Energy.

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:

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Director NICNAS

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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/1963	Reckitt	Manganese(2+),	ND*	≤ 1 tonne per	Component of
	Benckiser	bis(octahydro-1,4,7-		annum	automatic
	(Australia) Pty	trimethyl-			dishwashing
	Ltd	$1H$ -1,4,7-triazonine- kN^1 , kN^4 , kN^7)tri- μ -			detergents
		oxodi-,			
		hexafluorophosphate(1-			
) (1:2)			

^{*}ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

Based on the available information, the notified chemical is not recommended for classification according to the Globally Harmonised System of Classification and Labelling of Chemicals (GHS), as adopted for industrial chemicals in Australia.

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 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 physical containment, 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 a component of automatic dishwashing detergent pouches or capsules;

or

- (2) Under Section 64(2) of the Act; if
 - the function or use of the chemical has changed from a 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 notified chemical and product 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)

Reckitt Benckiser (Australia) Pty Ltd (ABN: 17 003 274 655)

44 Wharf Road

WEST RYDE NSW 2114

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: other names, use details, site of manufacture and identity of manufacturer.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed for all physico-chemical endpoints.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

Notification in Other Countries EU (2015)

2. IDENTITY OF CHEMICAL

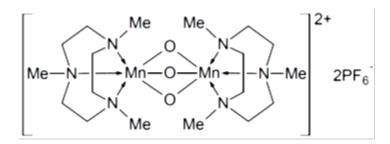
CAS NUMBER 116633-52-4

CHEMICAL NAME

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

 $\begin{array}{l} MOLECULAR\ FORMULA\\ C_{18}H_{42}Mn_2N_6O_3.2F_6P \end{array}$

STRUCTURAL FORMULA



Molecular Weight 790.4 Da

ANALYTICAL DATA

Reference NMR, IR, HPLC, GC, GPC, UV spectra were provided.

3. COMPOSITION

Degree of Purity > 98%

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	> 360 °C	Measured (the notified chemical
		decomposes below the melting point).*
Boiling Point	Not determined	The notified chemical is a solid and did
		not melt above 360 °C
Relative Density	$1,710 \text{ kg/m}^3 \text{ at } 21^{\circ}\text{C}$	Measured*
Vapour Pressure	$5.0 \times 10^{-9} \text{ kPa at } 25 ^{\circ}\text{C}$	Measured*
Water Solubility	10.8 g/L at 20 °C	Measured*
Hydrolysis as a Function of	$t_{\frac{1}{2}} > 1$ year at pH 4	Measured*
pН		
Partition Coefficient	$\log P_{\rm OW}$ < - 2.71 at 20 °C	Measured*
(n-octanol/water)		
Adsorption/Desorption	$\log K_{OC} = 3.86$ at 20 °C	Measured*
Dissociation Constant	Not determined	Expected to be ionised under
		environmental conditions
Particle Size	$> 200 \ \mu m$: $< 1\%$.	Measured*
	> 150 μm: < 15%.	
	$> 50 \ \mu \text{m} \ \& < 150 \ \mu \text{m} : < 74\%.$	
	$< 50 \ \mu m$: $< 11\%$.	
	< 10 μm: < 3%	
Flash Point	Not determined	The notified chemical is a solid.
Flammability	Not flammable	Measured*
Autoignition Temperature	385 °C	Measured*
Explosive Properties	Not explosive	Measured*
Oxidising Properties	Not oxidising	Measured*

^{*} ECHA, 2016.

DISCUSSION OF PROPERTIES

For full details of tests on physical and chemical properties, refer to Appendix A.

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 or capsules at a concentration of < 0.1%.

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 MANUFACTURER/RECIPIENTS Reckitt Benckiser (Australia) Pty Limited

TRANSPORTATION AND PACKAGING

The automatic dishwasher detergent products containing the notified chemical (at < 0.1% concentration) will be imported into Australia in the final packaging for retail sale to consumers (pouches or capsules). The imported products will be transported within Australia by road.

Use

The notified chemical will be used as a component of automatic dishwashing detergents at a concentration of < 0.1%.

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 or capsules. During end use, consumers will remove the dishwashing pouch or capsule from the outer packaging and place it into the detergent reservoir in the automatic dishwasher. The detergent pouch or capsule containing the notified chemical will dissolve in the dishwasher, releasing the contents. At the end of the dishwashing cycle, the notified chemical will be discharged into the wastewater.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

Category of Worker	Exposure Duration (hours/day)	Exposure Frequency (days/year)
Transport and Storage	4	12
Store Persons	4	12
End Users	0.5	365
Workers using the product in professional kitchens	0.5	200

EXPOSURE DETAILS

Transport, storage and retail workers may come into contact with the notified chemical only in the event of accidental rupture of packages. Dermal and ocular exposure is expected to occur, however, this will be limited by the notified chemical being contained within the individual sealed pouches or capsules and present at low concentrations (< 0.1%).

Exposure of professional kitchen workers to the notified chemical is expected to be of a similar extent to that experienced by consumers using automatic dishwashing detergents containing the notified chemical (see section 6.1.2).

Inhalation exposure of the notified chemical which has a very low vapour pressure (5.0×10^{-9} kPa) and is contained in sealed water soluble pouches or capsules is not expected.

6.1.2. Public Exposure

Public 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 or capsules. However, dermal and or ocular exposure of the

public to dishwashing detergents containing the notified chemical at concentrations of < 0.1% may occur through spills and splashes if the pouches or capsules are damaged during handling. Exposure to the notified chemical from washed dishes is expected to be very low as a further dilution in the wash water is expected.

6.2. Human Health Effects Assessment

The toxicological tests results conducted on the notified chemical are summarised in the following table.

 Endpoint	Result and Assessment Conclusion
Rat, acute oral toxicity	LD50 > 2000 mg/kg bw; low toxicity*
Rat, acute dermal toxicity	LD50 > 2000 mg/kg bw; low toxicity*
Rabbit, skin irritation	slightly-irritating*
Rabbit, eye irritation	slightly-irritating*
Guinea pig, skin sensitisation – adjuvant test -	no evidence of sensitisation*
Magnusson & Kligman / Maximisation test	
Rat, repeat dose oral toxicity – 28 days.	NOAEL = 15 mg/kg bw/d*
Rat, repeat dose oral toxicity – 90 days.	NOAEL = 5 mg/kg bw/d*
Mutagenicity – bacterial reverse mutation	non mutagenic*
Genotoxicity - in vitro Mammalian Chromosome	genotoxic*
Aberration Test Human Lymphocyte and Chinese	
hamster Ovary cells	
Genotoxicity - in vivo Unscheduled DNA Synthesis	non genotoxic*
Test	
Genotoxicity - in vivo Mammalian Bone Marrow	non genotoxic*
Chromosome Aberration Test	
Genotoxicity - in vivo Mammalian Erythrocyte	non genotoxic*
Micronucleus Test	
*ECHA 2016	

^{*}ECHA, 2016.

Toxicokinetics, metabolism and distribution

A basic toxicokinetics study (OECD Guideline 417) showed that the ¹⁴C from the labelled notified chemical was extensively absorbed from the intestinal tract of both male and female rats and both excreted the ¹⁴C rapidly mainly via the urine and traces (2%) of ¹⁴C remained in the carcass at 96 hours after dosing. The expired air contained approximately 9% of the ¹⁴C in male rats and 5% in female rats (ECHA, 2016).

The whole body autoradiography (WBA) indicated widespread tissue distribution of ¹⁴C with liver, kidney, salivary glands and thyroid as principle organs of ¹⁴C accumulation which was quickly removed from these organs (ECHA, 2016).

The thin layer chromatography (TLC) examination of urinary ¹⁴C indicated breakdown of the notified chemical probably to the ligand which was excreted extensively in the urine. Instability of the chemical in the presence of rat urine was demonstrated by UV absorption spectroscopy. The ¹⁴CO₂ produced indicated a slight degree of N-demethylation of the ligand (ECHA, 2016).

A skin absorption test showed that after topical application of ¹⁴C labelled notified chemical to rat skin under conditions of occlusion, up to 17% of the ¹⁴C dose was absorbed through the rat skin (ECHA, 2016).

Acute toxicity

The notified chemical was of low toxicity via the oral and dermal routes in rats with LD50 values > 2000 mg/kg bw. There was no available data on the acute toxicity of the notified chemical from inhalation exposure (ECHA, 2016).

Irritation and sensitisation

The notified chemical was a slight skin and eye irritant when tested in rabbits, and was non-sensitising in a guinea pig Maximisation test (ECHA, 2016).

Repeated dose toxicity

The NOAEL of 5 mg/kg bw/day was resulted from a 90 Day Repeated Dose Oral (Gavage) Toxicity test in rats (OECD Guideline 409) (Test dose: 0, 0.01, 0.1, 1, 5, and 500 mg/kg bw /day) (ECHA, 2016). Faecal analysis, urinalysis, haematology and clinical chemistry examination revealed changes in rats from the 500 mg/kg bw /day

dose group. In addition, histological changes were identified in the pituary of male rats and in the thyroid of male and female rats of the top dose group. Following an eight week recovery period most of these changes regressed or reverted to normal levels. All the males and five out of 10 of the females treated with 500 mg/kg/day showed an increase in the number of thyroid follicles.

In a Repeated Dose 28-Day Oral (Gavage) Toxicity test in Rats (OECD Guideline 407), a NOAEL of 15 mg/kg bw/day was established (Test doses: 0, 1, 15, 40, 200, and 1000 mg/kg bw/day dosed for 4 weeks), based on the observed histopathological changes in the thyroid gland of rats in the 40, 200 and 1000 mg/kg/day dose groups (ECHA, 2016). Following a two week recovery period many of these observed changes regressed and some reverted to control levels.

Mutagenicity/Genotoxicity

The notified chemical was not mutagenic in a bacterial reverse mutation assay (EU Method B.13/14) but showed evidence of clastogenic activity in *in vitro* Mammalian Chromosome Aberration Tests (OECD Guideline 473) in Human Lymphocyte and Chinese hamster Ovary cells with and without metabolic activation (ECHA, 2016). The notified chemical did not elicit any evidence of DNA-damaging activity in an *in vivo* unscheduled DNA synthesis test (OECD Guideline 482), an *in vivo* Mammalian Erythrocyte Micronucleus Test (EU method B.12) or an *in vivo* Mammalian Bone-Marrow Chromosome Aberration Test (EU method B.11) (ECHA, 2016).

Health hazard classification

Based on the available information, the notified chemical is not recommended for classification 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

6.3.1. Occupational Health and Safety

The notified chemical is not an irritant or sensitiser, but showed a range of systemic toxicity effects following repeated oral exposure in both 28 and 90 day studies with a NOAEL of 5 mg/kg bw/day. Transport, storage, retail, and professional kitchen workers exposure to the notified chemical (at < 0.1%) is expected to be very low and limited to accidental spills and splashes from rupture of the sealed capsules or pouches. Therefore, the risk to workers from the use of sealed capsules or pouches containing the notified chemical is not considered to be unreasonable.

6.3.2. Public Health

Based on expected very low exposure of the public to the notified chemical contained in the dishwashing detergent capsules or pouches, the risk to the public from the use of 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 professional kitchen and 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 absorbents, 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 (ECHA, 2016), the notified chemical is not considered to be readily biodegradable (12% in 29 days). Based on its high adsorption coefficient (log $K_{\rm OC} = 3.86$) and cationic properties, the notified chemical is expected to adsorb strongly to sludge and sediment, and release to surface waters is not expected. The inorganic moiety of the notified chemical (manganese) is redox sensitive and may undergo biochemical oxidation and reduction in aqueous and soil environments (Cerrato et al 2010).

A small proportion of the notified chemical may be applied to land when effluent is used for irrigation; sewage sludge is used for soil remediation, or disposed of to landfill as collected spills and solid wastes. An organic moiety of the notified chemical is not expected to bioaccumulate based on its low partition coefficient ($logP_{OW}$ < - 2.71). A bioavailable fraction of an inorganic moiety (manganese) has high potential to bioconcentrate in lower trophic organisms (plankton, aquatic plants and some fish) but has low potential for biomagnification from lower trophic levels to higher (Williams et al 2012). In surface waters, landfill, soil and sludge the notified chemical is expected to transform and degrade through biotic and abiotic processes to form water and oxides of carbon, nitrogen and manganese.

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:	0.61	$\mu g/L$
PEC - Ocean:	0.06	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 $0.61~\mu g/L$ may potentially result in a soil concentration of approximately $4.039~\mu g/kg$. 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 $20.19~\mu g/kg$ and $40.38~\mu g/kg$, respectively.

7.2. Environmental Effects Assessment

The results from ecotoxicological investigations conducted on the notified chemical are summarised in the table below (ECHA, 2016). 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 EC50 = 8.7 mg/L	Toxic to algae
	96 h NOEC = 3.2 mg/L	
Pseudomonas cell multiplication	17 h IC 50 = 26.06 mg/L	Inhibitory to microbial growth
inhibition test§	_	

[§] ISO draft method 10712

Based on the above ecotoxicological endpoints, the notified chemical is expected to be toxic to algae and inhibitory to microbial growth, 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. An assessment factor of 100 was used given acute endpoints for three trophic levels are available.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment				
NOEC (Algae)	3.2	mg/L		
Assessment Factor	100.00			
Mitigation Factor	1.00			
PNEC:	32.00	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:	0.61	32.0	0.019
Q - Ocean:	0.06	32.0	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 import quantity. On the basis of the PEC/PNEC ratio, maximum annual import volume and assessed use pattern in domestic dishwashing detergents, the notified chemical is not expected to pose an unreasonable risk to the environment.

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