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**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME
(NICNAS)**

FULL PUBLIC REPORT

Polyquaternium-76

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (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 Ageing, 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, Water, Heritage and the Arts.

For the purposes of subsection 78(1) of the Act, this Full Public Report may be inspected at our NICNAS office by appointment only at 334-336 Illawarra Road, Marrickville NSW 2204.

This Full Public Report is also 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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This notification has been carried out under the approved foreign scheme provisions (Canada) of Section 44 of the Act. The health and environment hazard assessment of the Canadian report was provided to NICNAS and where appropriate used in this assessment report. The other elements of the risk assessment and recommendations on safe use of the notified polymer were carried out by NICNAS.

Polyquaternium-76

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)

Rhodia Chemicals Pty Ltd (ABN: 80 004 449 870)
44 Real Avenue Norman
Park QLD 4170

AND

Procter and Gamble Australia Pty Ltd (ABN: 91 008 396 245)
1 Innovation Road
Macquarie Park NSW 2113

NOTIFICATION CATEGORY

Limited: Synthetic polymer with $M_n \geq 1000$ Da.

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication:

Chemical name; Other names; CAS number; Purity; Impurities; Polymer constituents; Molecular weight; Import volume; Use details.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed as follows:

Melting point; Boiling point; Density; Vapour pressure; Partition coefficient; Hydrolysis as function of pH; Particle size; Flash point; Flammability limits; Auto-ignition

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

Canada (2008)

2. IDENTITY OF CHEMICAL

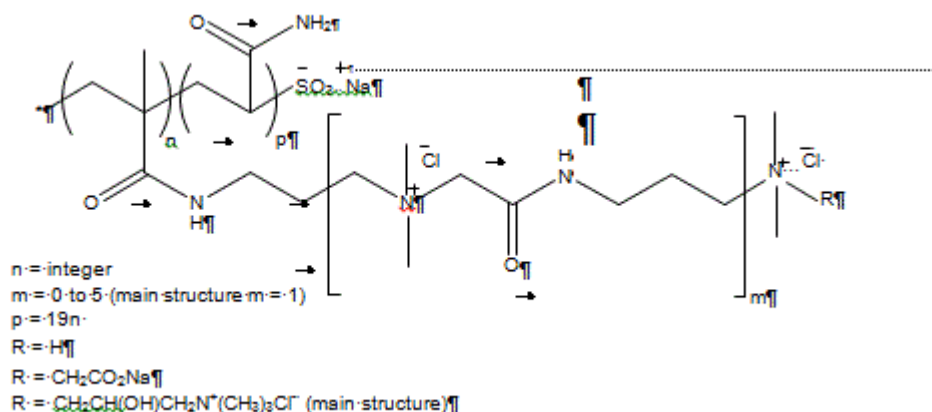
MARKETING NAME(S)

Mirapol AT-1 (containing approximately 10% notified polymer)

MOLECULAR FORMULA

(C₉H₁₈N₂O . C₆H₁₅ClNO . Cl . C₅H₁₄N₂ . C₃H₅ClO₂ . C₃H₅NO)

STRUCTURAL FORMULA

**MOLECULAR WEIGHT**

>10000 Da

ANALYTICAL DATA

Reference NMR, IR, GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY > 95%

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (>1% by weight) None

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES

None expected during use. Low levels of residual monomers and other additives are present with the notified polymer and may be lost from the solution in which they are contained.

DEGRADATION PRODUCTS

None expected under normal conditions of storage and use.

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: Slightly yellow solid

Property	Value	Data Source/Justification
Melting Point/Freezing Point	Not determined	Decomposition is expected to occur prior to melting.
Density	Not determined	Test could not be performed as the solid was found to be hygroscopic.
Vapour Pressure	< 1.3×10^{-9} kPa	Estimated based on high molecular weight (> 1000 Da) (USEPA, 2007).
Water Solubility	at pH 2 >10.07 g/L at 19.8°C at pH 7 >10.8 g/L at 19.8°C	Measured. OECD 120, ~93 wt% notified polymer. 100% water extractability.
Hydrolysis as a Function of pH	Not determined	Due to the nature of the polymer and unsuccessful attempts to perform the hydrolysis test, it was deemed not to be technically feasible to conduct the test. The polymer contains functional groups that are potentially hydrolysable in the environmental pH range of 4 – 9.

Partition Coefficient (n-octanol/water)

log Kow <-2 at 20°C Estimated. Modified Kow based on OECD 105 and OECD 120, ~93 wt%

Adsorption/Desorption	Not determined.	notified polymer. Despite the low K _{OW} and high water solubility of the notified polymer, the K _{OC} may be high due to the presence of quaternary ammonium groups in the structure.
Dissociation Constant	Not determined	Predicted to be ionised in the environmental pH range of 4 – 9 due to the presence of ionisable functional groups in the structure.
Particle Size	Not determined.	Notified polymer is imported in aqueous solution.
Flash Point	Not determined	Low vapour pressure solid.
Flammability Limits	Not determined	Not expected to be flammable and imported in aqueous solution.
Autoignition Temperature	Not determined	Not expected to undergo autoignition under normal conditions of use.
Explosive Properties	Not expected to be explosive	Contains no groups with known explosive properties.

DISCUSSION OF PROPERTIES

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

Reactivity

Under normal conditions of use and storage the notified polymer is stable.

5. INTRODUCTION AND USE INFORMATION

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

The notified polymer will be introduced in aqueous solution at approximately 10% concentration or imported as a component of finished hair care products (up to 0.5% concentration).

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

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

PORT OF ENTRY

Melbourne

IDENTITY OF MANUFACTURER/RECIPIENTS

Manufacturers of hair care products

TRANSPORTATION AND PACKAGING

The product containing the notified polymer (approx. 10%) will be imported in 205 L plastic drums and transported by road to the warehouse of Rhodia Australia at Clayton, Victoria for storage prior to transportation to personal care product manufacturers. Alternatively, it will be imported as a component of finished shampoo products (up to 0.5%). The finished shampoo products (those formulated in Australia or imported) will be packaged into 250 – 1000 mL plastic bottles and then packed in cardboard cartons before being transported by road to retail outlets.

USE

The notified polymer will be used as a conditioning agent in hair shampoos at concentrations of up to 0.5%.

OPERATION DESCRIPTION

At customer sites, drums containing the notified polymer will be stored on racks and, after quality control analysis by laboratory technicians, will be transferred via forklifts to the formulation area. The solution containing the notified polymer at approx. 10% will be manually added under vacuum to a stainless steel

blender. Other ingredients will also be added and mechanically mixed under local exhaust ventilation whilst the vessel is sealed. Batches of 10,000 L will be produced. Prior to packaging, sampling and quality testing of the preparation will be carried out. The formulated shampoo products will then be transferred to a hopper with a multiple head filler machine and automatically poured into 250 - 1000 mL plastic bottles. The finished hair care products containing up to 0.5% of the notified polymer will be purchased by consumers at retail outlets.

6. HUMAN HEALTH IMPLICATIONS

6.1 Exposure assessment

6.1.1 Occupational exposure

NUMBER AND CATEGORY OF WORKERS

<i>Category of Worker</i>	<i>Number</i>	<i>Exposure Duration (hours/day)</i>	<i>Exposure Frequency (days/year)</i>
Transportation from docks	2-4	2-3	4 – 6
Storemen	2	0.5	50
Laboratory technicians	2	1-2	50
Formulation, filling containers, cleaning and maintenance	6	4	50
Transport and storage of products	10-20	2-3	100
Retail workers	5000+	0.5-1.0	50

EXPOSURE DETAILS

Formulation of shampoo products

Dermal and ocular exposure of workers to the notified polymer at concentrations of approx. 10% may occur during manual charging of the mixer, and cleaning and maintenance operations. Dermal and ocular exposure may also occur to concentrations of up to 0.5% of the notified polymer during quality control operations, and dispensing of the reformulated product into end use containers. Exposure is expected to be lowered by the local exhaust ventilation systems in place, the enclosed mixing vessel, the automated systems used for dispensing, and the wearing of personal protective equipment (PPE), including overalls, safety glasses, safety shoes and gloves.

Retail sales

Retail workers will only be exposed to products containing up to 0.5% of the notified polymer in the event of damage or leakage of containers.

6.1.2. Public exposure

End-use products are designed to be sold to consumers. The general public will be repeatedly exposed to the notified polymer through the use of hair shampoos (typical levels up to 0.5%). Dermal and accidental ocular exposure of consumers to the notified polymer may occur during application of shampoo products to the scalp and hair using the hands, and to other parts of the body during rinsing off of the product. A small quantity of the notified polymer may be retained on the scalp after rinsing. In addition, the notified polymer is expected to be sorbed by the hair and retained after rinsing, as quaternary ammonium compounds are designed to bind to the anionic binding sites present on the hair fibre at normal pH ranges. They are intended to be removed following subsequent shampooing. As such, dermal contact with small quantities of the notified polymer may occur during hair styling, etc.

6.2. Human health effects assessment

The results from toxicological investigations conducted on the notified polymer are summarised in the table below.

<i>Endpoint</i>	<i>Result and Assessment Conclusion</i>
Rat, acute oral toxicity	low oral toxicity LD50 >2000 mg/kg bw

Acute oral toxicity

The acute oral toxicity of the notified polymer to Sprague-Dawley rats was determined according to OECD Guideline for Testing of Chemicals 425. Rats were fasted overnight prior to dosing with the notified polymer

(purity 93%), but were offered water with 10% glucose during the fasting period to minimize stress. The first rat was dosed with 2,000 mg/kg, since this rat survived, 4 additional rats were sequentially dosed at approximately 48 to 72 hours intervals. All doses were administered orally using a feeding cannula inserted into the stomach of the rats. Rats were weighed on days 0, 7, 13 and 14 and were observed daily for 14 days after dosing. No effects of toxicity or mortalities were observed post-dosing and during the 14-day observation period in any of the 5 animals. All animals gained body weight by Day 7 and at the end of the 14-day observation period. No gross pathological findings were observed at the time of necropsy. The LD50 is > 2,000 mg/kg which may be considered a low acute toxicity concern.

The notified polymer is not expected to be significantly dermally absorbed due to its high molecular weight, low proportion of low molecular weight species, and low partition coefficient. As such, systemic toxicity following dermal exposure to the notified polymer is expected to be low.

The notified polymer contains quaternary ammonium groups that may be considered to be structural alerts for skin sensitisation and corrosion (though perhaps not strictly within the defined limits specified) (Barratt 1994, Gerner 2004). The possibility of sensitisation or corrosion/irritation effects cannot be ruled out, even at high molecular weight.

Health hazard classification

Based on the limited data provided the notified polymer cannot be classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human health risk characterisation

6.3.1. Occupational health and safety

Dermal and ocular exposure of workers to the notified polymer at concentrations of approximately 10% may occur during handling of the notified polymer, particularly during manual charging of the mixer. The risk of corrosion effects resulting from contact with the notified polymer is expected to be low, given that the concentrations present in the product are at similar levels to the cut off concentration for classification for corrosivity, and there are measures in place to reduce exposure. At such concentrations, workers involved in these operations could potentially be at risk of skin sensitisation. However, the use of engineering controls and personal protective equipment is expected to minimise exposure and reduce the risk of such effects.

Dermal and ocular exposure of workers to the notified polymer at concentrations of up to 0.5% may occur mainly during handling of the finished products containing the notified polymer. Corrosivity and/or skin sensitisation is unlikely to occur given that the concentrations present are below the cut off concentrations for classification for these effects.

In conclusion, the occupational health and safety risk associated with the notified polymer is not considered to be unacceptable.

6.3.2. Public health

The general public will be repeatedly exposed to the notified polymer by use of hair shampoo products containing it. However, the rinse off nature of the products should reduce exposure to the notified polymer, as only a small proportion is expected to be retained on the scalp or other areas of the skin.

Whilst the notified polymer has the potential to cause sensitisation or corrosion/irritation, such effects may not occur at the proposed use concentrations (up to 0.5%) and are expected to be concentration dependent. In addition, it is likely that anionic surfactants will be present in the shampoo formulations with the notified polymer (which is a cationic surfactant) and combinations of this sort are known to mitigate the irritant effects that may be experienced when the cationic surfactant is used in isolation (Mitsui, 1997). Therefore, the risk of skin or eye irritancy to consumers is not expected. In addition, the risk of sensitisation is not expected, given the relatively low concentrations of the notified polymer present in end use products.

No toxicological data for repeated exposure to the notified polymer is available. However, based on the expected low absorption of the notified polymer the risk to the public from repeated exposure would not be considered unacceptable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE

Release to the environment may occur in the unlikely event of an accident during transport or an accidental spill. The notified polymer will be transported to Australia by ship in 205 L plastic drums and will be transported by road to the importer's warehouse and then to the customer's formulation site.

During the formulation of the hair care products up to 1% per annum of the imported volume of notified polymer will be released into the environment as a result of residuals in import containers, spills and equipment cleaning. Subsequent water washes will pass to interceptor pits where the settled material will be collected and disposed of to landfill. Wastewater will be used for gardening or recycled in the plant for other processing activities. The rinsate will be collected and disposed of to a liquid waste facility by licensed contractors.

RELEASE OF CHEMICAL FROM USE

As the notified polymer is used in shampoo products it is expected that the entire import volume will be released to the environment via consumer use and end up in sewers. Some residues will remain in imported plastic drums and end user plastic shampoo bottles.

RELEASE OF CHEMICAL FROM DISPOSAL

After rinsing, imported plastic drums will be sent to licensed landfill sites by licensed contractors. End use containers will be disposed of to domestic garbage and end up in landfill sites.

7.1.2 Environmental fate

Information on the biodegradation of the notified polymer was not provided. Based on its chemical structure, the notified polymer is expected to undergo biodegradation at a slow rate. However, in acclimated biological treatment systems such as sewage treatment plants, removal of quaternary ammonium compounds is generally expected to exceed 90% as a result of sorption and biodegradation (Boethling, 1984), however, studies of quaternary ammonium compounds often do not distinguish between removal due to biodegradation and removal by sorption.

Based on the positive charge and the molecular size of the notified polymer, it is not likely to cross biological membranes and thus absorption is expected to be minimal and bioaccumulation is not expected to occur.

7.1.3 Predicted Environmental Concentration (PEC)

<i>Predicted Environmental Concentration (PEC) for the Aquatic Compartment</i>		
Total Annual Import Volume	5,000	kg/year
Proportion expected to be released to sewer	100 %	
Annual quantity of chemical released to sewer	5,000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	13.70	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	21.161	million
Removal within STP	90%	Mitigation
Daily effluent production:	4,232	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	0.32	µg/L
PEC - Ocean:	0.03	µg/L

The notified polymer contains quaternary ammonium functional groups. In the calculation of PEC, 90% removal

of the notified polymer in STP is assumed, which is the default value for cationic polymers with $M_n > 1,000$ (Boethling and Nabholz, 1997). Assuming all of the imported volume of the notified polymer is released to the sewer, the PEC of the notified polymer is calculated to be 0.32 $\mu\text{g/L}$ in river and 0.03 $\mu\text{g/L}$ in ocean.

7.2. Environmental effects assessment

The results from ecotoxicological investigations conducted on the notified polymer are summarised in the table below.

<i>Endpoint</i>	<i>Result</i>	<i>Assessment Conclusion</i>
Algal Toxicity	E_bC_{50} (72 h) = 0.649 mg/L	Very toxic to algae

The acute toxicity of the notified polymer to green algae (*Selenastrum capricornutum*) was examined in accordance with the OECD Guideline for Testing of Chemicals 201. A range-finding test was conducted with concentrations of 0.01, 0.1, 1, 10, 100, and 1000 mg/L. Based on the outcome of the range-finding test, algae were exposed to the following doses of the notified polymer (purity 93%) for 72 hours: 0.01024, 0.0256, 0.064, 0.16, 0.40, 1.00, and 2.50 mg/L. Four replicates per dose were exposed to the notified polymer under static conditions and continuous light. The test was validated as the biomass in the control cultures increased by a factor of at least 16. At 24, 48 and 72 hours, cells looked normal and solutions were green at all doses except 1.00 and 2.50 mg/L. In these 2 groups, the cells were enlarged and abnormally shaped. At 72 hours, the 1.00 mg/L flasks were either clear with large green clumps or slightly green with small green clumps. The 2.50 mg/L flasks were clear with small green clumps. The E_bC_{50} (72h) is 0.649 mg/L (95% confidence limit: 0.558-0.686 mg/L), and the E_rC_{50} (0-72h) is 1.021 mg/L (95% confidence limit: 0.545-1.771 mg/L). The NOEC is 0.40 mg/L. These results can be considered a high acute toxicity hazard to green algae for both growth inhibition and biomass reduction.

7.2.1 Predicted No-Effect Concentration

<i>Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment</i>	
EC50 (Alga)	0.649 mg/L
Assessment Factor	1,000
PNEC:	0.649 $\mu\text{g/L}$

For the calculation of the PNEC, an assessment factor (AF) of 1000 is proposed since only one ecotoxicology test (on alga) was conducted.

7.3. Environmental risk assessment

<i>Risk Assessment</i>	<i>PEC $\mu\text{g/L}$</i>	<i>PNEC $\mu\text{g/L}$</i>	<i>Q</i>
Q - River:	0.32	0.649	0.499
Q - Ocean:	0.03	0.649	0.050

The Q value (Risk Quotient, PEC/PNEC) to river water has been calculated to be 0.499, based on the worst scenario of assuming all the notified polymer will be released to the aquatic environment. Therefore, the notified polymer is not considered to pose an unacceptable risk to aquatic ecosystems based on predicted low PEC/PNEC.

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1000 L/m²/year (10 ML/ha/year). The notified polymer in this volume is assumed to infiltrate and accumulate in the top 10 cm of soil (density 1300 kg/m³). Using these assumptions, irrigation with a concentration of 0.324 $\mu\text{g/L}$ may potentially result in a soil concentration of approximately 2.49 $\mu\text{g/kg}$. Assuming accumulation of the notified polymer in soil for 5 and 10 years under repeated irrigation, the concentration of notified polymer in the applied soil in 5 and 10 years may be approximately 12.45 $\mu\text{g/kg}$ and 24.9 $\mu\text{g/kg}$, respectively.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

Based on the available data the notified polymer cannot be classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)].

As a comparison only, the classification of the notified polymer 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.

	<i>Hazard category</i>	<i>Hazard statement</i>
Environment	Acute Category 1	Very toxic to aquatic life

Human health risk assessment

Under the conditions of the occupational settings described, the notified polymer is not considered to pose an unacceptable risk to the health of workers.

When used in the proposed manner, the notified polymer is not expected to pose an unacceptable risk to public health.

Environmental risk assessment

On the basis of the PEC/PNEC ratio and the reported use pattern, the notified polymer is not considered to pose a risk to the environment.

Recommendations

CONTROL MEASURES

Occupational Health and Safety

- Employers should implement the following engineering controls to minimise occupational exposure to the notified polymer:
 - Local exhaust ventilation
 - Automated dispensing machines.
- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer:
 - Avoid contact with eyes and skin.
- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer:
 - Gloves, safety glasses, protective clothing.

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 polymer are classified as hazardous to health in accordance with the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)] workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Material Safety Data Sheet

- The MSDS provided by the notifier for the imported product containing the notified polymer at approximately 10% should contain the following:
 - Mention of the potential for irritancy and sensitisation effects of the notified polymer and appropriate exposure controls.

Public Health

- Any adverse effects in consumers from use of formulations containing the notified polymer should be reported to NICNAS.

Disposal

- The notified chemical should be disposed of to landfill.

Emergency procedures

- Spills and/or accidental release of the notified polymer should be handled by 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 polymer has a number-average molecular weight of less than 1000;
 - additional information becomes available as to the sensitisation or corrosion/irritation potential of the notified polymer;
 - the notified polymer is imported at concentrations $\geq 20\%$.

or

- (2) Under Section 64(2) of the Act; if
 - the function or use of the chemical has changed from a component of hair shampoos at concentrations $>0.5\%$, or is likely to change significantly;
 - the amount of chemical being introduced has increased from 5 tonnes per annum, 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 MSDS of the imported product containing the notified polymer provided by the notifier was reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.

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