File No: LTD/1846

September 2015

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Polymer in Milliguard® AOX-1

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:

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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/1846	Milliken Design, Inc.	Polymer in Milliguard® AOX-1	ND*	≤ 1 tonnes per annum	A thermoset and thermoplastic polymer additive

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
As no toxicity data were provided, the notified polymer 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).

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

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

Environmental risk assessment
Based on the reported use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

Recommendations

CONTROL MEASURES

Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer as introduced in the product:
  - Avoid contact with skin and eyes

- A person conducting a business or undertaking at a workplace should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified polymer as introduced in the product:
  - Chemical goggles
  - Impervious gloves
  - 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 (M)SDS should be easily accessible to employees.

- If products and mixtures containing the notified polymer 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 polymer 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 polymer 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 polymer 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 polymer;

or

(2) Under Section 64(2) of the Act; if
  - the function or use of the polymer has changed from a thermoset and thermoplastic polymer additive, or is likely to change significantly;
  - the amount of polymer being introduced has increased, or is likely to increase, significantly;
  - the polymer has begun to be manufactured in Australia;
  - additional information has become available to the person as to an adverse effect of the chemical/polymer 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 product containing the notified polymer provided by the notifier was reviewed by NICNAS. The accuracy of the information on the (M)SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

This notification has been conducted under the cooperative arrangement with Canada. The health and environmental hazard assessment components of the Canadian report were 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.

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Milliken Design, Inc. (ABN: 58 142 096 759)
Level 14, 380 St. Kilda Road
MELBOURNE VIC 3004

NOTIFICATION CATEGORY
Limited-small volume (reduced fee notification): Synthetic polymer with Mn < 1,000 Da (1 tonne or less per year) – Assessed by comparable agency

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: chemical name, CAS number, molecular and structural formulae, molecular weight, degree of purity, polymer constituents, residual monomers, impurities, additives/adjuvants and use details

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
Canada (2011)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Milliguard® AOX-1 (containing the notified polymer at < 50%)

MOLECULAR WEIGHT
> 500 Da

ANALYTICAL DATA
Reference IR and GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
> 60%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: liquid (light yellow, orange)*

Property	Value	Data Source/Justification
Boiling Point*	210 °C (pressure unknown)	(M)SDS
Density*	1,090 kg/m^3 (temperature unknown)	(M)SDS
Vapour Pressure*	3.48×10^{-2} kPa at 25 °C	Estimated using the boiling point
Water Solubility	$\leq 5.94 \times 10^{-8}$ g/L	Calculated using WSKOW v1.42, EPI Suite v4.1 (US EPA, 2010)
Hydrolysis as a Function of pH	Not determined	Not expected as the notified polymer does not contain any readily

		hydrolysable functionalities.
Partition Coefficient (n-octanol/water)	log Pow > 5.09	Estimated based on data on a component of the notified polymer
Adsorption/Desorption	log Koc > 4.17	Estimated based on data on a component of the notified polymer
Dissociation Constant	Not determined	Does not contain ionisable functionalities
Flash Point*	252 °C (open cup)	(M)SDS
Flammability*	Not determined	Not expected to be flammable based on the flash point
Autoignition Temperature*	Not determined	Not expected to autoignite based on the flash point
Explosive Properties	Not determined	Contains no functional groups that would imply explosive properties
Oxidising Properties	Not determined	Contains no functional groups that would imply oxidative properties

*For Milliguard® AOX-1 (containing the notified polymer at < 50%)

DISCUSSION OF PROPERTIES

Reactivity
The notified polymer 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 polymer 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 polymer will not be manufactured in Australia. It will be imported at < 50% concentration in a blend.

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 and Melbourne

TRANSPORTATION AND PACKAGING
Product containing the notified polymer at < 50% will be imported in 208 L steel or poly drums and transported by road or rail.

USE
The notified polymer is a thermoset and thermoplastic polymer additive used at < 1% by weight as a carbon centred radical scavenger to protect various polymers from oxidation during the manufacture of polyurethane foam slabstock.

OPERATION DESCRIPTION
There will be no repackaging of the import product (Milliguard® AOX-1) containing the notified polymer at < 50%.

Milliguard® AOX-1 will be transferred into dedicated tank with pumping system to meter it directly into the polyol manifold during the manufacture of polyurethane foam slabstock. Milliguard® AOX-1 will be charged into enclosed reactors to mix with other ingredients and the finished foam will be shipped to customers for the end use.

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)*
Shipping/Receiver	0.5	12
Process workers	1	20

EXPOSURE DETAILS
Process workers are not expected to have significant exposure to the notified polymer at < 50% as the dilution process and manufacture of polyurethane foam slabstock are carried out using a closed system. Ocular and dermal exposure is possible when manually connecting and disconnecting hoses during transfer processes.

Based on the notifier's statement, workers are also expected to use personal protective equipment (PPE) to minimise exposure when transferring products containing the notified polymer into storage tanks and during the manufacture of polyurethane foam slabstock and clean-up operations.

When the polyurethane foam slabstock is in solid phase, the notified polymer will be encapsulated within the polymer matrix and will not be readily available for further exposure.

6.1.2. Public Exposure
Members of the public may come into contact with polyurethane foam slabstock containing the bound notified polymer at < 1% concentration; however, significant exposure as a result of casual contact during handling is not expected as the notified polymer is expected to be incorporated in the plastic matrix where it is non-extractable or has very low extractability. However as the notified polymer will not be chemically bound, it may be released from products in low levels over time.

6.2. Human Health Effects Assessment

No toxicity, toxicokinetics, metabolism or distribution studies were submitted for the notified polymer. In the absence of toxicological information, no conclusion regarding the hazard potency of the notified polymer can be made. However, due to the moderately high molecular weight (Mn > 500 Da With < 15% molecules < 500 Da), the calculated relatively high partition coefficient (log Pow = 5.09) and low water solubility (5.94×10^{-8} g/L) of the notified polymer, its dermal absorption is expected to be low (ECHA, 2014). In addition, the notified polymer does not contain any structural alerts of concern.

Although not considered in this risk assessment, NICNAS notes that the notified polymer contains a residual impurity that is classified as hazardous according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia. This impurity, classified as H315 – causes skin irritation and H318 – causes serious eye damage based on ECHA dossier, may present in the notified polymer as introduced above the cut off concentrations for classification.

Health hazard classification
As no toxicity data were provided, the notified polymer 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
There is no toxicological data available on the notified polymer; however, the polymer does not contain structural alerts for toxicity and the physico-chemical properties of the polymer indicate that dermal absorption is likely to be limited. Exposure to the notified polymer, at concentrations < 50%, by workers may occur during the transfer, manufacture and clean up processes. Exposure to the notified polymer will be limited by the controls in place and PPE used to protect the workers against hazardous component of the imported product.

Once the notified polymer is incorporated in the polyurethane foam, it is non-extractable or has very low extractability over time. Therefore based on the expected low exposure the risk to workers is not considered to be unreasonable.

6.3.2. Public Health

The notified polymer will be used in industrial settings only and will not be sold to the public. The public may come into contact with polyurethane foam slabstock containing the bound notified polymer at < 1% concentration; however, significant exposure as a result of casual contact during handling is not expected as the notified polymer is expected to be incorporated in the plastic matrix where it is non-extractable or has very low extractability over time. Therefore, when used in the proposed manner, the risk to public health 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 polymer is a thermoset and thermoplastic polymer additive. Products containing the notified polymer will not be manufactured or repacked in Australia. Accidental release of products containing the notified polymer may occur during transport accidents. However, the capacity and specifications of the import containers are likely to minimise the extent of any such releases. Releases that do occur as a result of accidents are expected to be physically contained, absorbed by inert material and sent for disposal to landfill.

RELEASE OF CHEMICAL FROM USE

During use, products containing the notified polymer at < 50% will be transferred into a dedicated tank with a pumping system to meter it directly into a manifold during the manufacture of polyurethane slabstock foam under industrial settings. The product will be charged into enclosed reactors to mix with other ingredients and the finished foam will be shipped to customers for the end use. Products containing the notified polymer are designed to be incorporated into the polyurethane foam where it is either non-extractable or has very low extractability. A significant release of the notified polymer from use is not expected.

RELEASE OF CHEMICAL FROM DISPOSAL

Any spilled or waste product is expected to be collected for disposal by a licensed disposal company. Most of the notified polymer will be incorporated into the polyurethane foam which is expected to be disposed of to landfill at the end of its service life.

7.1.2. Environmental Fate

No environmental fate data were submitted. Due to the low water solubility and low molecular weight (< 1,000 Da), the notified polymer may have a potential to bioaccumulate in aquatic organisms. However, this is not considered to be of concern given the low release to the aquatic environment expected based on the proposed use pattern. Most of the notified polymer will be incorporated into the polyurethane foam which is expected to be disposed of to landfill at the end of its service life. A small amount of the notified polymer is expected to be sent to landfill from collected spills during manufacturing of polyurethane slab stock foam. In landfill, the notified polymer will undergo slow degradation processes via biotic and abiotic pathways eventually forming water and oxides of carbon.

7.1.3. Predicted Environmental Concentration (PEC)

No significant concentrations of the notified polymer are expected in the aquatic environment based on the proposed use pattern of the notified polymer. The Predicted Environmental Concentration for the notified polymer has therefore not been calculated.

7.2. Environmental Effects Assessment

No ecotoxicity data were submitted. Polymers without significant ionic functionality are of low concern to the aquatic environment.

7.2.1. Predicted No-Effect Concentration

The predicted no-effect concentration (PNEC) for the notified polymer has not been calculated as no ecotoxicological data for the notified polymer were submitted, and no significant aquatic exposure is expected based on its reported use pattern.

7.3. Environmental Risk Assessment

The risk quotient (Q = PEC/PNEC) for the notified polymer has not been calculated as no PEC or PNEC was calculated. A significant release of the notified polymer to the aquatic environment is not expected based on its reported use pattern. The notified polymer will be bound into polyurethane foam, and is unlikely to be bioavailable in this form. Therefore, on the basis of the assessed use pattern, the notified polymer is not expected to pose an unreasonable risk to the environment.

BIBLIOGRAPHY

ECHA (2014) Guidance on Information Requirements and Chemical Safety Assessment Chapter R.7c: Endpoint specific guidance, November 2014, version 2.0. European Chemicals Agency, http://echa.europa.eu/documents/10162/13632/information_requirements_r7c_en.pdf.

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

NTC (National Transport Commission) 2007 Australian Code for the Transport of Dangerous Goods by Road and Rail (ADG code), 7th Edition, Commonwealth of Australia

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 >.

US EPA (2010) Estimations Program Interface Suite™ for Microsoft® Windows, v 4.10. United States Environmental Protection Agency. Washington, DC, USA.