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November 2020

AUSTRALIAN INDUSTRIAL CHEMICALS INTRODUCTION SCHEME (AICIS)

PUBLIC REPORT

Additive for KM-1 HS101

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals Act 2019* (the IC Act) and *Industrial Chemicals (General) Rules 2019* (the IC Rules) by following the *Industrial Chemicals (Consequential Amendments and Transitional Provisions) Act 2019* (the Transitional Act) and *Industrial Chemicals (Consequential Amendments and Transitional Provisions) Rules 2019* (the Transitional Rules). The legislations are Acts of the Commonwealth of Australia. The Australian Industrial Chemicals Introduction Scheme (AICIS) is administered by the Department of Health, and conducts the risk assessment for human health. The assessment of environmental risk is conducted by the Department of Agriculture, Water and the Environment.

This Public Report is available for viewing and downloading from the AICIS website. For enquiries please contact AICIS 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
Email:	assessments@industrialchemicals.gov.au
Website:	www.industrialchemicals.gov.au

Executive Director
AICIS

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SUMMARY

The following details will be published on our website:

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
LTD/2153	Konica Minolta Business Solutions Australia Pty Ltd	Additive for KM-1 HS101	ND*	≤ 1 tonne per annum	Component of UV-cured inks for commercial printing

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard Classification
As no toxicity data were provided, the assessed polymer cannot be classified according to the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia.

Human Health Risk Assessment
Provided that the recommended controls are being adhered to, under the conditions of the occupational settings described, the assessed polymer is not considered to pose an unreasonable risk to the health of workers.

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

Environmental Risk Assessment
On the basis of the low import volume, and the assessed use pattern, the assessed 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 assessed polymer during use:
  - 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 assessed polymer during use:
  - Impervious gloves
  - Safety glasses or goggles
  - Respiratory protection if aerosols are generated
  - 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 SDS should be easily accessible to employees.

- If products and mixtures containing the assessed 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.

Emergency procedures

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

Disposal

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

Regulatory Obligations

Specific Requirements to Provide Information
This risk assessment is based on the information available at the time of the application. The Executive Director may initiate an evaluation of the polymer based on changes in certain circumstances. Under section 101 of the IC Act the introducer of the assessed polymer has post-assessment regulatory obligations to provide information to AICIS when any of these circumstances change. These obligations apply even when the assessed polymer is listed on the Australian Inventory of Industrial Chemicals (the Inventory).

Therefore, the Executive Director of AICIS must be notified in writing within 20 working days by the applicant or other introducers if:

- the importation volume exceeds one tonne per annum of the assessed polymer;
- the function or use of the polymer has changed from a component of UV-cured inks for commercial printing, or is likely to change 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 polymer on human health, or the environment.

The Executive Director will then decide whether an evaluation of the introduction is required.

Safety Data Sheet
The SDS of products containing the assessed polymer provided by the applicant were reviewed by AICIS. The accuracy of the information on the SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND APPLICATION DETAILS

APPLICANT(S)
Konica Minolta Business Solutions Australia Pty Ltd (ABN: 50 001 065 096)
4 Drake Ave
MACQUARIE PARK NSW 2113

APPLICATION CATEGORY
Limited-small volume: Synthetic polymer with Mn < 1,000 g/mol (1 tonne or less per year)

PROTECTED INFORMATION (SECTION 38 OF THE TRANSITIONAL ACT)
Data items and details taken to be protected information include: chemical name, other name(s), CAS number, molecular and structural formulae, molecular weight, analytical data, degree of purity, polymer constituents, residual monomers, impurities, additives/adjuvants, use details and identity of manufacturer.

VARIATION OF DATA REQUIREMENTS (SECTION 6 OF THE TRANSITIONAL RULES)
Schedule data requirements are varied for hydrolysis as a function of pH, partition co-efficient, absorption/desorption and dissociation constant.

PREVIOUS APPLICATION IN AUSTRALIA BY APPLICANT(S)
None

APPLICATION IN OTHER COUNTRIES
Korea (2017) Korea Chemicals Management Association

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Additive for KM-1 HS101

MOLECULAR WEIGHT
Number average molecular weight (Mn) is > 500 g/mol.

ANALYTICAL DATA
Reference NMR, IR, HPLC, GPC, UV spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
> 70%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: clear liquid, low odour

Property	*Value*	*Data Source/Justification*
Freezing Point	-25 °C	Measured
Boiling Point	173.6 °C at 102.15 kPa	Measured
Density	1,128.9 kg/m^3 at 20 °C	Measured
Vapour Pressure	9.59×10^{-5} kPa at 25 °C	Measured
Water Solubility	Insoluble	Measured
Hydrolysis as a Function of pH	Not determined	The assessed polymer contains hydrolysable functionality but is not expected to hydrolyse due to insolubility in water.
Partition Coefficient (n-octanol/water)	Could not be determined	Insoluble in water
Adsorption/Desorption	Not determined	Based on its low water solubility, the assessed polymer is expected to adsorb strongly to soil, sediment and sludge.
Dissociation Constant	Not determined	Does not contain dissociable functionalities
Flash Point	> 93 °C at 100.7 kPa	Measured
Autoignition Temperature	≥ 422 °C	Measured
Explosive Properties	Not explosive	Measured
Oxidising Properties	Not considered an oxidiser	Measured

DISCUSSION OF PROPERTIES
For details of tests on physical and chemical properties, refer to Appendix A.

Reactivity
The assessed 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 assessed 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.

The assessed polymer has a flash point of greater than 93 °C. Based on *Australian Standard AS1940* definitions for combustible liquid, the assessed polymer may be considered as a Class C2 combustible liquid if the polymer has a fire point below the boiling point.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF ASSESSED CHEMICAL (100%) OVER NEXT 5 YEARS
The assessed polymer will be imported into Australia as an additive at < 10 % in a UV ink product.

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

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

PORT OF ENTRY
Sydney

TRANSPORTATION AND PACKAGING
The UV ink products containing the assessed polymer in the enclosed aluminium pack within cardboard boxes will be imported into Australia by ships or planes. In Australia, the UV ink product will be transported interstate by truck, and by van to deliver locally. Each individual package size is 22.9 cm × 20.6 cm × 16.7 cm in 5 kg boxes.

USE
The assessed polymer will be used in UV-cured inks for commercial printing at < 10% concentration.

OPERATION DESCRIPTION
The assessed polymer will not be reformulated or repackaged in Australia.

The UV ink products which include the assessed polymer are set in industrial printing machine and used as printing ink for inkjet printer. The inks are cured by UV light in the printer in printing process.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

Category of Worker	*Exposure Duration (per day)*	*Exposure Frequency (days/year)*
Stevedore, Transport and Storage	4 – 8 hours	50
Operator – ink exchange	10 minutes	200
Operator – printing	8 hours	200
Operator – waste tank exchange	5 minutes	12
Operator – maintenance	15 minutes	40

EXPOSURE DETAILS

Stevedore, Transport and Storage workers

Stevedore, transport and storage workers are not expected to be exposed to the assessed polymer except in the unlikely event of an accident, when the packaging of the ink product is breached.

Operator – ink exchange

Workers carry the ink product from a storage place and set them in the printing machine, i.e. exchange the printing inks.

Operator – printing

When workers manipulate the printing machine to print publications, minimal dermal and ocular exposure to the product is expected.

Operator – waste tank exchange

Workers exchange the waste tank set on the printing machine when it is full.

Operator – maintenance

Workers periodically maintain the printing machine or repair it when it is broken, faulty or non-functional.

Dermal and incidental ocular exposure to the product may occur during the above operations; however, exposure is expected to be infrequent or incidental, given that the workers will be given instructions on safe handling through training, education and reading the printing machine user manual and the SDS for the assessed polymer. Occasional dermal exposure may occur when the printed material is handled while it is wet, or if the ink-stained parts of the printer are touched. Dermal and ocular exposure will be minimised by wearing personal protective equipment (PPE) such as impervious gloves, goggles and protective clothing during the above operations. Workers in the printing place wear normal uniform in the work place.

During the above operations, inhalational exposure is not expected due to the low volatility of the assessed polymer.

After the ink product is cured, the assessed polymer will be bound to the matrix of the substrates and is not expected to be available for exposure.

6.1.2. Public Exposure

The UV-curable printing inks containing the assessed polymer will not be made available to the general public. Therefore, direct public exposure to the assessed polymer is not expected.

Members of the public may come into contact with printed materials. However, once the ink is cured, the assessed polymer will be reacted and bound to the matrix of the substrates and is not expected to be available for exposure.

6.2. Human Health Effects Assessment

No toxicity data were submitted.

No information on the toxicokinetics of the assessed polymer was provided. For dermal absorption, molecular weights below 500 g/mol are favourable for absorption and molecular weights above 1,000 g/mol do not favour absorption (ECHA, 2017). Absorption of the assessed polymer through the skin, gastrointestinal tract and respiratory tract is not expected to occur to a significant extent based on its relatively high molecular weight (> 500 g/mol). However, the assessed polymer contains an amount (< 20 %) of low molecular weight species (< 500 g/mol) that may be absorbed through the skin if exposed.

The assessed polymer contains a structural alert indicative of possible toxicity concerns associated with skin irritation, and skin and respiratory sensitisation.

Health Hazard Classification

As no toxicity data were provided, the assessed polymer cannot be classified 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

Based on the structure of the assessed polymer, it may have the potential to cause skin and eye irritation, and skin and respiratory sensitisation. Systemic effects are not expected due to limited absorption of the assessed polymer.

Workers may come into contact with the assessed polymer at a concentration < 10 % via dermal and to a lesser extent, ocular and inhalation routes. The use of appropriate PPE (impervious gloves, goggles and protective clothing) will be used to limit worker exposure. Furthermore, precautions taken to avoid exposure to the other hazardous ingredients of the product would also reduce exposure to the assessed polymer.

Once the inks are cured and dried, the assessed polymer will be reacted and bound within a polymer matrix and is not expected to be available for exposure.

Provided that the recommended controls are being adhered to, under the conditions of the occupational settings described, the assessed polymer is not considered to pose an unreasonable risk to the health of workers.

6.3.2. Public Health

Public exposure to the assessed polymer is expected to be very low, as they will only contact it as part of a dried ink matrix. Therefore, when used in the proposed manner, the assessed polymer is not considered to pose an unreasonable risk to public health.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The assessed polymer will be imported as a component of finished UV-curable ink products. The containers are placed directly into the machine and no spillage is expected unless packaging is breached. Any spills will be collected for disposal, in accordance with local government regulations.

RELEASE OF CHEMICAL FROM USE

The assessed polymer will be used as a component of UV-curable printing inks for industrial printing processes on various substrates. These printing processes are expected to be automated. The cured ink will be bound onto the substrate matrix, and no environmental exposure of the uncured product is expected. Any waste ink containing the assessed polymer will be collected for disposal, in accordance with local government regulations.

RELEASE OF CHEMICAL FROM DISPOSAL

Most of the assessed polymer will be cured as part of the ink product. This is expected to share the fate of the printed substrates to which it has been applied, either subjected to substrate recycling processes, or being disposed of to landfill at the end of their useful lives. Exposure of the assessed polymer to the environment is not expected

after curing of its ink products. Empty ink containers containing the assessed polymer are also expected to be disposed of either by recycling or to landfill.

7.1.2. Environmental Fate

No environmental fate data were submitted for the assessed polymer. As a result of its use pattern, most of the assessed polymer is expected to be cured, with insignificant amounts of the assessed polymer remaining in the cured product. The cured ink product will share the fate of the substrates to which it has been applied, either subjected to the substrate recycling processes, or being disposed of to landfill at the end of their useful lives. In landfill, the assessed polymer is expected to eventually degrade via biotic and abiotic processes to form water and oxides of carbon.

7.1.3. Predicted Environmental Concentration (PEC)

A Predicted Environmental Concentration (PEC) has not been calculated for the assessed polymer, as no significant release to the aquatic compartment is expected from the proposed use pattern.

7.2. Environmental Effects Assessment

No ecotoxicity data were provided for the assessed polymer.

7.2.1. Predicted No-Effect Concentration

A Predicted No-Effect Concentration (PNEC) could not be calculated as no ecotoxicity endpoints were provided.

Due to the lack of ecotoxicity data, the assessed polymer cannot be classified under the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)* for acute and chronic toxicities (United Nations, 2009).

7.3. Environmental Risk Assessment

A risk quotient (Q = PEC/PNEC) was not calculated as a PNEC was unable to be determined.

However, on the basis of the low import volume, and the assessed use pattern, the assessed polymer is not considered to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Freezing Point -25 °C

Method	OECD TG 102 Melting Point/Melting Range
Test Facility	Shenyang Research Institute of Chemical Industry Co., Ltd. (2018a)

Boiling Point 173.6 °C at 102.15 kPa

Method	OECD TG 103 Boiling Point
Remarks	Capillary method was used.
Test Facility	Shenyang Research Institute of Chemical Industry Co., Ltd. (2018b)

Density 1,128.9 kg/m^3 at 20 °C

Method	OECD TG 109 Density of Liquids and Solids
Remarks	Pycnometer was used.
Test Facility	Shenyang Research Institute of Chemical Industry Co., Ltd. (2018c)

Vapour Pressure 9.59×10^{-5} kPa at 25 °C

Method	OECD TG 104 Vapour Pressure
Remarks	The isothermal thermo gravimetric method was used.
Test Facility	Shenyang Research Institute of Chemical Industry Co., Ltd. (2018d)

Water Solubility Insoluble

Method	OECD TG 105 Water Solubility EC Council Regulation No 440/2008 A.6 Water Solubility
Remarks	Flask Method was used.
Test Facility	Citox (2019)

Flash Point > 93 °C at 100.7 kPa

Method	European Economy Community (EEC) Directive 92/69, Part A, A.9 Flash Point
Remarks	Closed cup flash point tester was used.
Test Facility	Shenyang Research Institute of Chemical Industry Co., Ltd. (2018e)

Autoignition Temperature ≥ 422 °C

Method	ASTM E659-2015 – Standard Test Method for Autoignition Temperature of Chemicals
Remarks	The autoignition temperatures of 100 µL, 150 µL and 200 µL of the test substance at a pressure of 100.42 kPa were 431 °C, 428 °C and 422 °C, respectively.
Test Facility	Shenyang Research Institute of Chemical Industry Co., Ltd. (2018f)

Explosive Properties Not explosive

Method	EEC Directive 92/69, Part A, A.14 Explosive Properties.
Remarks	No explosion occurred during any of thermal sensitivity and mechanical (shock) sensitivity test.
Test Facility	Shenyang Research Institute of Chemical Industry Co., Ltd. (2018g)

Oxidizing Properties Not considered an oxidiser

Method	EEC Directive 92/69, Part A, A.21 Oxidizing Properties (Liquids)
Remarks	Oxidising liquid tester was used with 65 % (w/w) aqueous nitric acid as the reference substance. Time taken for the pressure to rise from 690 kPa to 2,070 kPa was tested 5 times using the test substance, but the pressure of 2,070 kPa was not reached during any of the tests.
Test Facility	Shenyang Research Institute of Chemical Industry Co., Ltd. (2018h)

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