File No: LTD/1997

November 2017

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Lumogen® UV 560

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:

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/1997	BASF Australia Ltd	Lumogen® UV 560	ND*	≤ 1 tonne per annum	Component of UV-cured inks for commercial printing

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the limited available information, 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.

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

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

Environmental risk assessment
On the basis of the assessed use pattern, the notified chemical is not considered to pose an unreasonable risk to the environment.

Recommendations

REGULATORY CONTROLS

Safety data Sheet

- If the hazardous impurity of the notified chemical is present at or above the cut-off concentration for classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)*, as adopted for industrial chemicals in Australia, this impurity should be included on the SDS, along with appropriate control measures.

CONTROL MEASURES

Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following engineering controls to minimise occupational exposure to the notified chemical as introduced in powder form:
  - Exhaust ventilation during weighing and reformulation.

- 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 chemical during reformulation and end-use:
  - Impervious gloves and goggles
  - Coveralls or apron
  - Respiratory protection if exposure to dust is expected

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 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 concentration of the notified chemical exceeds or is intended to exceed 1% in final products;

or

(2) Under Section 64(2) of the Act; if
  - the function or use of the chemical has changed from component of UV-cured inks for commercial printing, 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.

Safety Data Sheet
The SDS of the notified chemical provided by the notifier was reviewed by NICNAS. The accuracy of the information on the SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
BASF Australia Ltd (ABN: 62 008 473 867)
Level 12, 28 Freshwater Place
SOUTHBANK VIC 3006

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: chemical name, other names, CAS number, molecular and structural formulae, molecular weight, analytical data, degree of purity, residual impurities, import volume and site of manufacture.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
No variation to the schedule of data requirements is claimed.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
Canada (2015), China (2015), Japan (2017) and USA (2015)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Lumogen® UV 560

MOLECULAR WEIGHT
> 500 g/mol

3. COMPOSITION

DEGREE OF PURITY
> 95%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: The notified chemical is a colourless to yellowish powder with product specific odour.

Property	Value	Data Source/Justification
Melting Point	> 315°C (decomposition)	Measured
Boiling Point	Not applicable	-
Density	1429.1 kg/m^3 at 20°C	Measured
Vapour Pressure	< 1×10^{-7} kPa at 20°C	Measured
Water Solubility	5×10^{-5} g/L at 20 °C	Measured
Hydrolysis as a Function of pH	Not determined	Contains hydrolysable functional groups. However, due to its low water solubility significant hydrolysis is not expected in the environment at pH range of 4 – 9.
Partition Coefficient (n-octanol/water)	Not determined	Could not be determined due to its low solubility in both water and n-octanol.

Property	Value	Data Source/Justification
Adsorption/Desorption	Not determined	Expected to adsorb to soil and sediment based on its high molecular weight and low water solubility.
Dissociation Constant	Not determined	Contains no dissociable functionalities.
Particle Size	Inhalable fraction (<100 µm): 29.01% Respirable fraction (<10 µm): 3.00 %	Measured
Solid Flammability	Not considered highly flammable	Measured
Autoignition Temperature	391°C	Measured
Explosive Properties	Not considered to be explosive	Based on low exothermic decomposition energy
Oxidising Properties	Not considered to be oxidising	Measured

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.

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 be imported into Australia by sea from the port of Melbourne. It will also be imported as a component of printing inks at ≤ 1% concentration.

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
Melbourne

TRANSPORTATION AND PACKAGING
The notified chemical will be imported in neat form in 1 kg plastic bottles and 5 kg open head steel drums. The metal drums will be stored in a third party contracted warehouse. Within Australia, the products containing the notified chemical will be distributed by road to the sites of use.

USE
The notified chemical will be used in UV-cured inks for commercial printing on paperboard materials. The final concentration of the notified chemical in end-use inks will be ≤ 1%.

OPERATION DESCRIPTION

Reformulation
Where reformulation into printing ink occurs in Australia, this will involve a batch size of less than 100 kg and will occur every 2 – 4 months. Weighing is normally conducted under local exhaust ventilation, prior to addition to a pre-mix vessel containing medium for complete 'wetting out' of the particles. This is normally conducted under local exhaust ventilation and takes 30 minutes after which stirring is continued for 15 – 30 minutes. Dispersion of particles is then accomplished using a mill or attritor following which the dispersion is pumped to mixing tanks for blending with additives, solvent and resin. The final concentration of the notified substance in the printing inks is up to 1%. After blending, the operators will drain the end-use product from the production vessel into containers for trade sale.

Formulations are first established on a laboratory scale using less than 1 kg of the notified chemical, about once per year. The laboratory staff will also be involved in testing the imported chemical every 2 - 4 months for about an hour. The laboratory staff will also perform quality control checks on inks during manufacture.

End-use
The formulated inks containing up to 1% of the notified chemical will be transported to printing works. In small scale works, the ink will be poured or scooped out of small tubs into the ink reservoir of the printing machine, before being applied to the substrates. During the printing operation the ink will be replenished in the machine in the same manner as the initial charging.

In larger scale printing works, the ink will be pumped from larger containers directly to the ink reservoir of the printing machine, and automatically replenished as required during operation. The ink container will be changed regularly, often daily. This will involve transferring the dip tube from the empty drum to the full drum.

At the end of each day, or at the end of a printing job, the machine will be cleaned. Typically the ink contaminated parts of the machine will be wiped with rags, with or without solvents.

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 warehouse	4	20
Quality control laboratory staff	1.5	10
Printing (decanting and cleaning)	1.5	240

EXPOSURE DETAILS

Transport and warehousing
Transport and warehouse workers may come into dermal and ocular contact with the notified chemical through accidental leaks and spillages of the drums and containers.

Plant operators
During formulation, operators will transfer the notified chemical from the imported containers and add it to a pre-mix vessel, where it is mixed with other components. Inhalation exposure can occur during the weighing and loading processes as the product containing the notified chemical is a powder with inhalable and respirable components. These processes are expected to be conducted under local exhaust ventilation. Spills and splashes during the blending process can lead to dermal and ocular exposure. During transfer of the ink, workers may have exposure to the notified chemical at up to 1%.

Laboratory staff
Laboratory staff may have exposure to limited quantities of the notified chemical during formulation trials, and during sampling and testing of the chemical and inks.

Printing
Workers involved in printing processes may be dermally exposed to ink containing up to 1% notified chemical when decanting containers of ink into the reservoir of a printing machine, and when replenishing the reservoir of the ink pump. Ocular exposure is possible in the event of accidental splashing. The notifier stated that it is usual for the machine operator to wear goggles, rubber gloves and overalls for this operation. The operator may also wear an apron if the risk of ink splashing is greater for a lower viscosity ink formulation. Once dried, the ink will be incorporated into the ink matrix, and is expected to be unavailable for further exposure.

Dermal exposure is also possible during cleaning of the printing machine, however, goggles, gloves and overalls will be worn during this operation.

6.1.2. Public Exposure

Public exposure to the notified chemical as a result of contact with end-use printed products is not expected to occur as it will be embedded in the resin/polymer matrix of the print materials. The notifier has stated that negligible potential for migration of the chemical from finished products is expected.

6.2. Human Health Effects Assessment

Only one genotoxicity assay was provided. For full details of the study, refer to Appendix B.

Endpoint	*Result and Assessment Conclusion*
Mutagenicity – bacterial reverse mutation	non mutagenic

Toxicokinetics, metabolism and distribution

No data have been provided on toxicokinetics and metabolism of the notified chemical. The relatively high molecular weight (> 500 g/mol) and low solubility of the notified chemical in water and octanol are expected to limit its absorption across biological membranes.

Mutagenicity/Genotoxicity

The notified chemical was negative in an *in vitro* bacterial reverse mutation assay.

Impurities

Based on the analytical data, the notified chemical contains a hazardous impurity (Category 1 reproductive toxicity, Category 2 eye damage/irritation and Category 4 acute inhalation toxicity), however the level of the impurity was not quantified.

Health hazard classification

Based on the limited available information, 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.

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety

Limited toxicological data are available for the notified chemical. If appropriate controls are used to reduce worker exposure, such as exhaust ventilation during handling of the chemical in powder form and use of PPE, the notified chemical is not considered to pose an unreasonable risk to the health of workers.

6.3.2. Public Health

Public exposure to the notified chemical 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 notified chemical is not considered to pose an unreasonable risk to public health.

ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified chemical will be imported into Australia in neat form in 1 kg plastic bottles and 5 kg open head steel drums for reformulation into UV-cured inks for commercial printing on fibreboard materials. Environmental release of the notified chemical is unlikely to occur during importation, storage and transportation as containers are designed to minimise release. In the event of an accidental spill the ink or paint containing the notified chemical is expected to be collected and disposed of via a licensed waste contractor.

RELEASE OF CHEMICAL FROM USE

The notified chemical will be imported and it is expected that < 1% of the annual import volume of the notified chemical may be spilt. If leakage or spillage does occur, the ink is expected to be physically contained with absorbent material and disposed of to landfill. The ink will be contained within the printer reservoir until the contents are consumed. The empty tubes and containers are estimated to contain < 1% of the annual import

volume of notified chemical, will be removed and disposed of to landfill or sent to the manufacturer for recycling.

RELEASE OF CHEMICAL FROM DISPOSAL

The majority of notified chemical used in ink preparations will be bound to printed paper board materials and, once the ink dries, will be contained in an inert matrix. It is assumed that 24% of the waste paper will end up in landfill and the rest will undergo paper recycling processes (APC 2015). During recycling processes, waste paper will be repulped using a variety of chemical agents which, amongst other things, enhance detachment of ink from the fibres. Based on its low water solubility, the notified chemical is expected to partition to sludge generated during the recycling process and this is expected to be sent to landfill for disposal.

7.1.2. Environmental Fate

No environmental fate data were provided. The majority of the notified chemical is expected to be disposed of to landfill where it will degrade by biotic and abiotic processes to form water and oxides of carbon, nitrogen and sulfur.

Approximately 76% of the paper to which the ink containing the notified chemical is applied to will be recycled. During recycling processes, waste paper is repulped using a variety of chemical agents which, amongst other things, enhance detachment of ink from the fibres. However, the notified chemical is cured into the ink matrix and is unlikely to be released into the supernatant waters during recycling processes. The majority of the cured notified chemical is anticipated to sorb to sludge and sediment. Notified chemical in landfilled sludge is expected to degrade biotically and abiotically.

7.1.3. Predicted Environmental Concentration (PEC)

The predicted environmental concentration (PEC) has been calculated to assume a worst case scenario, with 76% of the paper products containing the notified chemical undergoing recycling and the notified chemical to be released into sewers with no removal during recycling or STP processes. As the notified chemical bound to paper substrates is to be processed at paper recycling facilities located throughout Australia, it is anticipated that such releases will occur over 260 working days per annum into the Australian effluent volume.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	1,000	kg/year
Proportion expected to be released to sewer	76%	
Annual quantity of chemical released to sewer	760	kg/year
Days per year where release occurs	260	days/year
Daily chemical release:	2.92	kg/day
Water use	200	L/person/day
Population of Australia (Millions)	24.386	million
Removal within STP	0%	
Daily effluent production:	4,877	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	0.6	µg/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 1,000 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 1,500 kg/m^3). Using these assumptions, irrigation with a concentration of 0.6 µg/L may potentially result in a soil concentration of approximately 4 µg/kg. Assuming accumulation of the notified chemical in soil for 5 and 10 years under repeated irrigation, the concentration of notified chemical in the applied soil in 5 and 10 years may be approximately 20 µg/kg and 40 µg/kg, respectively.

7.2. Environmental Effects Assessment

No ecotoxicity data were submitted. Due to its measured low water solubility, the notified chemical is not anticipated to cross biological membranes due to its poor solubility in both water and n-octanol and is therefore not expected to be bioavailable or bioaccumulate.

7.2.1. Predicted No-Effect Concentration

Since no ecotoxicity data were submitted, the predicted no effect concentration (PNEC) was not calculated.

7.3. Environmental Risk Assessment

The potential for exposure of the notified chemical to the aquatic environment is very low because the majority will be disposed to landfill. The risk for harm to aquatic organisms due to washings to the sewer, as a result of paper recycling, is mitigated by the notified chemical's lack of potential to bioaccumulate, insolubility in water and high propensity to adsorb to particulate matter. Taking into account the low exposure to aquatic organisms, the notified chemical is therefore not expected to pose an unreasonable risk to the environment based on its proposed use pattern.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Melting Point/Boiling Point > 315°C

Method	OECD TG 102 Melting Point/Melting Range
Remarks	Differential scanning calorimetry method The test item has no melting point between -20°C and vaporisation/decomposition of the test item at about 315°C.
Test Facility	BASF (2014a)

Density 1429.1 kg/m^3 at 20°C

Method	OECD TG 109 Density of Liquids and Solids
Remarks	Gas pycnometer method
Test Facility	BASF (2014a)

Vapour Pressure < 1 × 10^{-7} kPa at 20°C

Method	OECD TG 104 Vapour Pressure
Remarks	Effusion method
Test Facility	BASF (2014a)

Water Solubility 5 × 10^{-5}g/L at 20 °C

Method	OECD TG 105 Water Solubility EC Council Regulation No 440/2008 A.6 Water Solubility
Remarks	Flask Method
Test Facility	BASF (2013)

Particle Size Inhalable fraction (< 100 µm): 29.01%
Respirable fraction (< 10 µm): 3.00 %

Method	ISO 13320 Particle Size Distribution
Remarks	Laser diffraction method according to ISO 13320
Test Facility	BASF (2014a)

Solid Flammability Not considered highly flammable

Method	EC Council Regulation No 440/2008 A.10 Flammability (Solids)
Remarks	Brief burning and rapid extinction was seen in the preliminary test. Based on the result of the preliminary test, a main test was not performed.
Test Facility	BASF (2014b)

Autoignition Temperature 391°C

Method	EC Council Regulation No 440/2008 A.16 Relative Self-Ignition Temperature for Solids
Remarks	
Test Facility	BASF (2014b)

Explosive Properties Not considered to be explosive

Method	EC Council Regulation No 440/2008 A.14 Explosive Properties.
Remarks	A test for explosive properties was not carried out because the exothermic decomposition energy, determined by a DSC, was less than 500 J/g.
Test Facility	BASF (2014b)

Oxidizing Properties Not considered to be oxidising

Method	EC Council Regulation No 440/2008 A.17 Oxidizing Properties (Solids)
Remarks	The maximum burning rate of the mixtures tested was lower than the maximum burning rate of the reference mixture.
Test Facility	BASF (2014b)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Genotoxicity – bacteria

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 471 Bacterial Reverse Mutation Test Plate incorporation procedure (Test 1) Pre incubation procedure (Test 2)
Species/Strain	*Salmonella typhimurium*: TA1535, TA1537, TA98, TA100, *Escherichia coli*: WP2uvrA
Metabolic Activation System	Liver S9 mix from phenobarbital/ β-naphthoflavone induced rats
Concentration Range in Main Test	Test 1 (with and without metabolic activation): 33 – 5000 µg/plate Test 2 (with and without metabolic activation): 33 – 5000 µg/plate
Vehicle	Dimethyl sulphoxide (DMSO)
Remarks - Method	No deviations from the standard test protocol. Six doses of the test substance were tested in triplicates for all test groups. Dose selection and evaluation in repeat studies (Test 2) were based on the findings of Test 1.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1		> 5000	> 333	Negative
Test 2		≥ 1000	≥ 333	Negative
Present				
Test 1		> 5000	> 333	Negative
Test 2		≥ 1000	≥ 333	Negative

Remarks - Results	The test substance did not lead to a dose-related and reproducible increase in the number of revertant colonies in any strain, either with or without S9 mix in two experiments carried out independently of each other. The results of the negative and positive controls were within the range of the historical control data and confirmed the validity of the test system. One positive control value was at the lower end of the historical controls, but still met the acceptance criteria of the test.
CONCLUSION	The notified chemical was not mutagenic to bacteria under the conditions of the test.
TEST FACILITY	BASF (2015)

BIBLIOGRAPHY

BASF (2013) Water solubility of the [notified chemical] (Project No. 14L00324, October 2013) Ludwigshafen, Switzerland, Competence Center Analytics, BASF SE (Unpublished report submitted by the notifier).

BASF (2014a) Physico-chemical properties of the [notified chemical] (Project No. 14L00037, May 2014) Ludwigshafen, Switzerland, Competence Center Analytics, BASF SE (Unpublished report submitted by the notifier).

BASF (2014b) Evaluation of physical and chemical properties for planned production/marketing of the [notified chemical] (Project No. SKI-Nr.14/0412, April 2014) Ludwigshafen, Switzerland, Competence Center Analytics, BASF SE (Unpublished report submitted by the notifier).

BASF (2015) Salmonella Typhimurium / Escherichia Coli reverse Mutation Assay (Study No. 40M0076/13M313, May 2015) Ludwigshafen, Germany, BASF SE Experimental Toxicology and Ecology (Unpublished report submitted by the notifier)

SWA (2012) Code of Practice: Managing Risks of Hazardous Chemicals in the Workplace, Safe Work Australia, https://www.safeworkaustralia.gov.au/doc/model-code-practice-managing-risks-hazardous-chemicals-workplace.

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 >