File No.: LTD/2102

October 2019

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Amines, bis(hydrogenated palm-oil alkyl)hydroxy

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

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SUMMARY

The following details will be published in the NICNAS *Chemical Gazette:*

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
LTD/2102	BASF Australia Ltd	Amines, bis(hydrogenated palm-oil alkyl)hydroxy	Yes	≤ 1 tonne per annum	Additive for plastics

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard Classification
Based on the available information, the notified chemical is a hazardous chemical according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia. The hazard classification applicable to the notified chemical is presented in the following table.

Hazard Classification	*Hazard Statement*
Skin Sensitiser (Category 1B)	H317 – May cause an allergic skin reaction

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.

As the notified chemical will be used in materials with direct food contact, the public report of this assessment will be forwarded to Food Standards Australia New Zealand (FSANZ) for their consideration.

Environmental Risk Assessment
Based on the low hazard and reported use pattern, the notified chemical is not considered to pose an unreasonable risk to the environment.

Recommendations

REGULATORY CONTROLS

Hazard Classification and Labelling

- The notified chemical should be classified as follows:
  – Skin Sensitiser (Category 1B): H317 – May cause an allergic skin reaction

  The above should be used for products/mixtures containing the notified chemical, if applicable, based on the concentration of the notified chemical present.

Health Surveillance

- As the notified chemical is a skin sensitiser, employers should carry out health surveillance for any worker who has been identified in the workplace risk assessment as having a significant risk of skin sensitisation.

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 during reformulation:
  - Enclosed/automated processes
  - Local exhaust ventilation

- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure of the notified chemical during reformulation:
  - Avoid contact with skin and eyes
  - Avoid inhalation of dust
  - Avoid formation of dust clouds
  - Avoid sources of ignition around reformulation area

- 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:
  - Impervious gloves
  - Protective clothing
  - Safety glasses or goggles
  - Respiratory protection if dusts or aerosols are 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.

Storage

- The handling and storage of the notified chemical should be in accordance with the Safe Work Australia Code of Practice for *Managing Risks of Hazardous Chemicals in the Workplace* (SWA, 2012) or relevant State or Territory Code of Practice.

Emergency procedures

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

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.

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 final use concentration of the notified chemical exceeds 0.1% in food packaging;

or

(2) Under Section 64(2) of the Act; if
- the function or use of the chemical has changed from an additive for plastics, 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: 62 008 437 867)
Level 12, 28 Freshwater Place
SOUTHBANK VIC 3006

NOTIFICATION CATEGORY
Limited (Reduced fee notification): Chemical other than polymer (1 tonne or less per year) – Similar to a chemical that has been previously assessed by NICNAS (NA/592).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
No details are exempt from publication.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Schedule data requirements are varied for boiling point, vapour pressure, adsorption/desorption, dissociation constant, flash point and oxidising property.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
USA (2019)
Canada (2019)
China (2012)
Europe (2019)
Japan
Philippines (2019)

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Irgastab® FS 042-V

CAS NUMBER
1374859-51-4

CHEMICAL NAME
Amines, bis(hydrogenated palm-oil alkyl)hydroxy

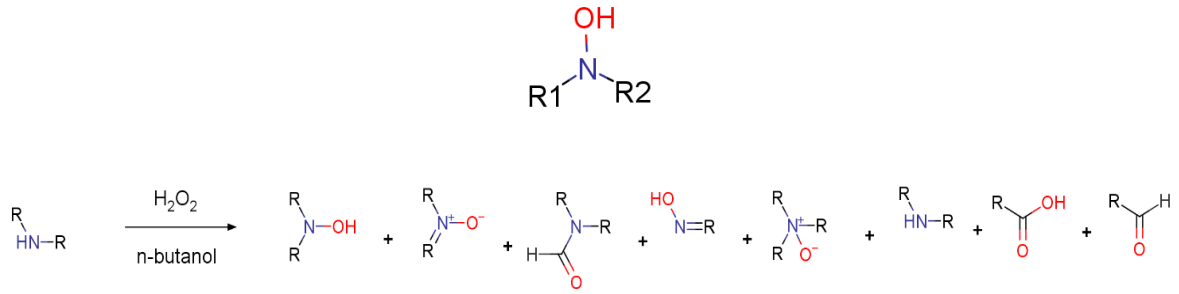
OTHER NAME(S)
Irgastab® FS 042-VEG

MOLECULAR FORMULA
Unspecified

STRUCTURAL FORMULA

R1 = primarily C14 – C18 fatty acids from palm oil
R2 = one carbon less in the fatty acid chain compared to R1

Representative structure of the main constituents of the notified chemical



R = primarily C14 – C18 fatty acids from palm oil

Reaction scheme provided by the notifier

MOLECULAR WEIGHT
481.9 – 538.0 g/mol

ANALYTICAL DATA
Reference NMR, IR, UV, SFC/MS, HPLC and LC/MS/MS spectra were provided.

3. ANALOGUE CHEMICAL

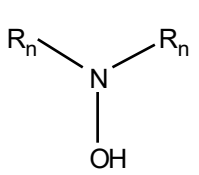
CHEMICAL NAME
Amines, bis(hydrogenated tallow alkyl), oxidised

CAS NUMBER
143925-92-2

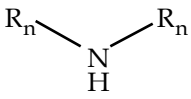
MOLECULAR FORMULA
Unspecified

Molecular formula
$HON(Rn)_2$ where n = C16 – 18 as the main component in the mixture

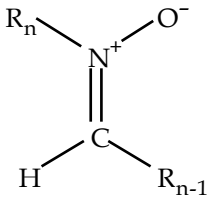
STRUCTURAL FORMULA



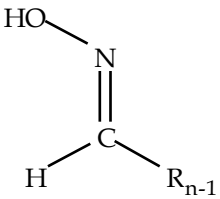
CG 25-067
Hydroxylamine
(67.1 – 67.4%)



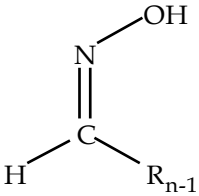
Armeen 2 HT
Amine
(13.9 – 14.4%)



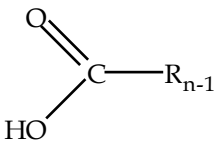
CA 26-0154
Nitrone
(5.1 – 5.6%)



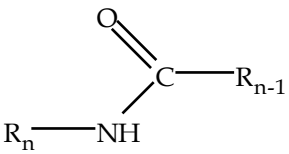
CA 27-0119
Anti-oxime
(1.8 – 1.9%)



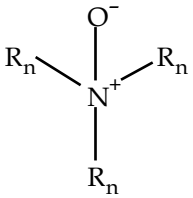
CA 27-0119
Syn-oxime
(1.7%)



Carboxylic acid
(3.0 – 3.2%)



Secondary amide
(4.3 – 4.7%)



Trialkylene N-oxide
(2.1 – 2.2%)

R_n = C16 – C18

JUSTIFICATION

The analogue chemical is a hydroxylamine based, phenol-free antioxidant used as a processing stabiliser for the plastics industry. The synthesis of both the notified chemical and analogue chemical follow the same procedure. However, the triglyceride starting material used are different. For the notified chemical palm oil (primarily C14 – 18 fatty acids) is used while for the analogue chemical tallow (primarily C16 – 18 fatty acids) is used as the starting material. Therefore, the composition of the individual substances is expected to be very similar. Analytical investigations of batches of the palm oil and the tallow versions demonstrate that the composition of the two versions are very similar (table below).

The toxicological data obtained on the analogue chemical is considered applicable for the notified chemical, since the slight difference in fatty acid chain length and saturation is not expected to influence the overall toxicological properties of the notified chemical.

4. COMPOSITION

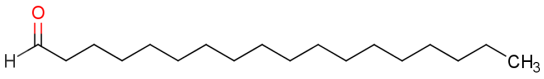
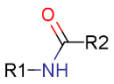
DEGREE OF PURITY

The notified chemical is a UVCB substance.

CHEMICAL CONSTITUENTS

The notified chemical consists of a mixture of starting material and reaction products, all of which are considered to be part of the notified chemical (stated by the notifier).

Based on the analytical reports submitted, the following constituents for the notified chemical were identified using NMR, FTIR, SFC/MS, HPLC and LC/MS/MS (BASF, 2016a).

Constituent	*Structure*	*Weight %*	
		Notified chemical	*Analogue chemical* *
Hydroxylamine		67.6 ± 4.0	67.1 – 67.4
Amine		9.6 ± 3.6	13.9 – 14.4
Nitrone		5.6 ± 3.2	5.1 – 5.6
Aldehyde		2.3 ± 0.8	< 1
Secondary amide		2.1 ± 0.8	4.3 – 4.7
Anti-oxime		1.0 ± 0.2 **	1.8 – 1.9
Syn-oxime		1.0 ± 0.2 **	1.7
Trialkylene N-oxide		– #	2.1 – 2.2

Constituent	*Structure*	*Weight %*	
		Notified chemical	*Analogue chemical* *
Carboxylic acid		ND ^	3.0 – 3.2

R1 = primarily C14 – C18 fatty acids
R2 = one carbon less in the fatty acid chain compared to R1
* Values taken from NICNAS assessment NA/592
** Anti- and syn-oxime listed as oxime
# Detected in NMR analysis. Analysis by SFC/MS and LC/MS/MS not provided.
^ Not detected (below limit of detection). Stearic acid content was analysed

5. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: White to cream crystalline powder with no odour

Property	***Value***	***Data Source/Justification***
Melting Point	95.8 °C	Measured
Boiling Point	Not determined	The notified chemical decomposes in nitrogen atmosphere at > 150 °C
Density	930 kg/m^3 at 20 °C	Measured
Vapour Pressure	5.58 × 10^{-10} kPa at 25 °C	Calculated using MPBPWIN (part of EPI Suite version 4.11 from the US EPA)
Water Solubility	< 3 × 10^{-4} g/L at 20 °C	Measured
Hydrolysis as a Function of pH	Not determined	The notified chemical contains constituents with hydrolysable functionalities but these constituents are unlikely to hydrolyse due to very low water solubility.
Partition Coefficient (n-octanol/water)	log Pow > 10	Calculated for the main constituent
Adsorption/Desorption	Not determined	All constituents of the notified chemical are expected to strongly adsorb to soil/sediment based on their low water solubilities and high partition coefficients.
Dissociation Constant	Not determined	The notified chemical contains constituents with dissociable functionalities (carboxylic acid) but these constituents are insoluble in water.
Particle Size	< 100 µm: 49.8% (Inhalable fraction) < 10 µm: 5.1% (Respirable fraction) < 4 µm: 0.19%	Measured D_{90} = 985 µm D_{50} = 101 µm D_{10} = 14.6 µm
Flash Point	Not determined	–
Flammability	Not flammable	Measured
Autoignition Temperature	Not self-igniting	Measured
Explosive Properties	Not explosive	Measured
Oxidising Properties	Not determined	Contains no functional groups that would imply oxidative properties
Thermal Stability	Stable up to 150 °C	Measured
Minimum Ignition Energy	< 10 mJ	Measured

DISCUSSION OF PROPERTIES

Reactivity
The notified chemical contains constituents with hydrolysable and dissociable functionalities. However, these constituents are unlikely to hydrolyse or dissociate due to the low water solubility of the constituents and the use of the notified chemical as a stabiliser for plastics.

A minimum ignition energy (MIE) test, which measures the ignition sensitivity for the formation of a suspended dust cloud, was conducted on the notified chemical. The ignition energy of the notified chemical was less than 10 mJ. Low MIE values (< 10 mJ) are of concern, because weak ignition sources such as electrostatic discharges may lead to ignition of suspended dust clouds. A number of factors affect MIE including particle size, particles size distribution and moisture content. Therefore, it is recommended to avoid situations where formation of dust clouds during the formulation process can occur. Avoiding sources of ignition around the formulation area will further prevent the risk of ignition of dust.

Physical Hazard Classification
Based on the submitted physico-chemical data depicted in the above table, the notified chemical is not recommended for hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia.

6. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will not be manufactured in Australia. The notified chemical in neat form will be imported into Australia for reformulation into polyolefin fibres.

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 and Sydney

TRANSPORTATION AND PACKAGING
The notified chemical will be imported in neat form in 50 kg polyethylene-lined fibre drums. It will be transported by road to warehouses for storage, and then delivered to customer sites for reformulation. The drums containing the neat chemical will be stored in bunded areas.

USE
The notified chemical (at up to 0.2% concentration) will be formulated into polyolefin fibres for use in applications including carpeting, carpet backing, fabrics, disposable nappies, disposable hospital gowns and packaging.

The notified chemical (at up to 0.1% concentration) is also intended to be used in packaging materials with food contact.

OPERATION DESCRIPTION
The notified chemical will be imported as a component of a polymer stabiliser at up to 100% concentration in sturdy polyethylene-lined fibre drums.

It is expected that up to five reformulation sites in Australia may be involved in preparing masterbatches, a process where the notified chemical is blended together with other additives and then mixed with polymer granules. The batching operation consists of weighing out the notified chemical and then transferring it to a blender. The weighing is carried out in a dispensary, equipped to handle very fine particles and equipped with exhaust ventilation facilities.

Once weighed, the masterbatch containing the notified chemical (at concentrations of 30 – 50%) is taken to the dry powder blender and added to other polymer powder/granules. The addition to the blender is under the control of local exhaust or through a closed system of transfer. The blended masterbatch is discharged into a tote bin, usually via a closed transfer system or under the control of local exhaust ventilation and taken to melt processing equipment, such as fibre spinners. In melt processing equipment the granules are melted, extruded or moulded, and allowed to cool. At this stage the notified chemical (up to 0.2% concentration) will be encapsulated in the polymer matrix.

7. HUMAN HEALTH IMPLICATIONS

7.1. Exposure Assessment

7.1.1. Occupational Exposure

CATEGORY OF WORKERS

Category of Worker	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Transport and storage	1 – 2	30 – 50
Reformulation	2 – 4	30 – 50
Fibre spinning / extrusion / moulding	6 – 8	80 – 100

EXPOSURE DETAILS

Transport and Storage
Worker exposure to the notified chemicals in neat form during the importation, transport and storage is not expected, except in the unlikely event of an accident where the packaging may be breached.

Reformulation – Masterbatch formulation
During reformulation, dermal, ocular and inhalation exposure of workers to the notified chemical (at ≤ 100%) in powder form may occur during weighing, transfer, blending, quality control analysis, cleaning and maintenance of equipment. The use of engineering controls including local exhaust ventilation and enclosed systems, and the use of personal protective equipment (PPE) by workers such as coveralls, goggles, impervious gloves and appropriate respiratory protection if required, is expected to minimise exposure to the notified chemical during reformulation.

Fibre spinning / extrusion / moulding
During fibre spinning / extrusion / moulding, the notified chemical is expected to be encapsulated in the polymer matrix in the masterbatch pellets. Dermal and ocular exposures of workers to the notified chemical at concentrations of ≤ 0.2% is expected to be minimal due to the use of control measures such as local exhaust ventilation and the use of PPE (including impervious gloves, coveralls and safety goggles) by workers.

7.1.2. Public Exposure
Although widespread public contact with fibres containing the notified chemical at concentrations of ≤ 0.2% will occur, the notified chemical is expected to be encapsulated in the polymer matrix of polymer fibres in finished articles. Hence exposure of the general public is likely to be negligible, especially since the polymer fibres are reported to be resistant to degradation.

Migration into foods
The public will also be exposed to various plastic articles containing the notified chemical at a concentration of up to 0.1%, such as packaging with food contact.

The analogue chemical previously assessed by NICNAS has undergone migration testing studies using various food simulants under different storage conditions. Migration of the analogue chemical from polyolefins (polypropylene, high-density polyethylene and low-density polyethylene) and polyethylene terephthalates was analysed. The analogue chemical was present in polypropylene and high-density polyethylene at 0.1% concentration and in low-density polyethylene at 0.05% concentration. The migration of the transformation products of the analogue chemical from polyolefins were detected in 95% ethanol (max. 1.86 ppm oxime, 1.14 ppm amine, 1.00 ppm aldehyde, respectively), except for the hydroxylamine constituent. Migration from polyethylene terephthalate containing 0.25% concentration of the analogue chemical in aqueous food simulants was not detectable at a level of 0.5 mg/kg (SCF, 2003).

The migration analysis of the analogue chemical indicates that the notified chemical is expected to be bound into the polyolefin or polyethylene terephthalate matrix. Therefore, significant migration into the food it comes in contact with is not expected and the notified chemical is not expected be available for further exposure.

Based on the available information, secondary public exposure to the notified chemical from migration into food that is in contact with packaging containing ≤ 0.1% concentration of the notified chemical is expected to be negligible.

7.2. Human Health Effects Assessment

No toxicological data on the notified chemical were submitted. The results from toxicological investigations conducted on the analogue chemical previously assessed by NICNAS are summarised in the following table. Details of these studies can be found in the NA/592 public report available on the NICNAS website.

Endpoint	*Result and Assessment Conclusion*
Acute oral toxicity – rat	LD50 > 2,000 mg/kg bw; low toxicity
Acute dermal toxicity – rat	LD50 > 2,000 mg/kg bw; low toxicity
Skin irritation – rabbit	slightly irritating
Eye irritation – rabbit	slightly irritating
Skin sensitisation – guinea pig, maximisation test	evidence of sensitisation
Repeat dose oral toxicity – rat, 90 days	NOAEL = 50 mg/kg bw/day *
Mutagenicity – bacterial reverse mutation	non mutagenic
Genotoxicity – *in vitro* chromosomal aberration assay	non clastogenic

* Study authors concluded that the NOEL and NOAEL were equal for the analogue chemical.

Toxicokinetics, Metabolism and Distribution

No toxicokinetic data on the notified chemical were submitted. Given the notified chemical is a UVCB with low molecular weight (< 500 g/mol) chemical constituents and has a log Pow of 5.5 – 25, absorption across biological membranes may occur.

Acute Toxicity

The analogue chemical was of low acute oral and dermal toxicity in the rat with both LD50 values exceeding 2,000 mg/kg bw. No inhalation toxicity information was available for the notified chemical or a suitable analogue.

Irritation and sensitisation

When the analogue chemical was applied to the skin of rabbits, slight eschar/erythema were produced, but no oedema. These effects had disappeared by the end of the observation period (7 days). Likewise, application of the analogue chemical to the eyes of rabbits produced reversible effects in the conjunctiva of the animals. No iridal or corneal effects were noted.

The analogue chemical was found to be a moderate skin sensitiser to guinea pigs in an adjuvant-type test, with 40% of the test animals scoring a positive response during challenge. The analogue chemical was classified as hazardous according to the National Occupational Health and Safety Commission's *Approved Criteria for Classifying Hazardous Substances.* The analogue chemical meets the criteria for classification as a skin sensitiser (Category 1B) according to the GHS.

It is also noted that the notified chemical contains a constituent with an aldehyde functional group which is associated with a protein binding alert for skin sensitisation (OECD QSAR Toolbox V 4.2). This constituent is present at a higher concentration compared to the analogue. The notified chemical also has a structural alert for corrosion due to the presence of constituents with aliphatic amines.

Based on the sensitisation data on the analogue chemical, the chemical composition similarities (refer to Section 4 for details) of the notified chemical and analogue, and protein binding alert for skin sensitisation, the notified chemical is classified as a skin sensitiser (Category 1B) according to the GHS criteria.

Repeated Dose Toxicity

In a 90-day oral repeated-dose study on the analogue chemical in rats (OECD TG 408), specific organ toxicity was observed in the treated animals at ≥ 200 mg/kg bw/day. The organs affected were the liver, the mesenteric lymph nodes and kidney. The liver suffered necrosis of hepatocytes and granuloma formation, while the kidney developed tubular lesions. The no observed effect level (NOEL) was considered to be 50 mg/kg bw/day. The authors noted in the report that the NOEL for the analogue chemical was "equal to the no observed adverse effect level (NOAEL)" (NICNAS NA/592).

A 90-day oral repeated-dose study on the analogue chemical in dogs was also conducted. The authors established a no observed effect level (NOEL) of 200 mg/kg bw/day (ECHA, 2019).

Mutagenicity/Genotoxicity
The analogue chemical was found not to be mutagenic in bacterial or mammalian cells. The analogue chemical was also found to be non-clastogenic in an *in vitro* chromosomal aberration assay using Chinese hamster lung cells.

Health Hazard Classification
Based on the available information on the analogue chemical, the notified chemical is a hazardous chemical according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia. The hazard classification applicable to the notified chemical is presented in the following table.

Hazard Classification	***Hazard Statement***
Skin Sensitiser (Category 1B)	H317 – May cause an allergic skin reaction

7.3. Human Health Risk Characterisation
According to the toxicological data on the analogue chemical, the notified chemical is a skin sensitiser. The notified chemical may also cause slight eye and skin irritation at high concentrations.

7.3.1. Occupational Health and Safety
Worker exposure and risk during transport and storage of the notified chemical is negligible given the packaging in sturdy polythene-lined fibre drums.

Reformulation
Reformulation workers may come into contact with the notified chemical at ≤ 100% concentration. When used in powder form, the main routes of exposure are expected to be dermal and inhalation, with accidental ocular exposure also possible. Skin sensitisation and irritation effects are possible if workers are exposed to the notified chemical at high concentrations.

The notified chemical is a powder with particles in the respirable size range (< 10 μm: 5.29%) and no data on the inhalation toxicity of the notified chemical is available. Therefore, caution should be exercised by workers when handling the notified chemical. The use of automated/enclosed processes (where possible), ventilated areas and PPE (such as gloves, coveralls, googles and respiratory protection) should minimise the potential for exposure.

Fibre spinning / extrusion / moulding
The notifier has also indicated that the fibre spinning / extrusion / molding operation, where the notified chemical and other additives are mixed with polymer powder/granules, is performed under local exhaust or through a closed system of transfer. Therefore, exposure and the risk of any adverse health effects are likely to be negligible for blending operators.

Finally, the workers exposed to cooled polymer fibres are not expected to have exposure to the notified chemical, as it will be encapsulated in the polymer matrix and unlikely to be leached out.

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.

7.3.2. Public Health
Members of the public may come into contact with articles containing the notified chemical (≤ 0.2% concentration). However, the notified chemical is expected to be bound into the inert polymer matrix and is not expected to be available for further exposure.

The public will be frequently exposed to plastic articles such as food packaging containing ≤ 0.1% concentration of the notified chemical. However, the notified chemical will be trapped in the inert matrix and will, therefore, not be available for further exposure. Furthermore, migration studies on the analogue chemical indicate that migration of the notified chemical from food package materials to the food in contact in any notable concentrations is not expected. Thus, considering the stability and very low end use concentration of the notified chemical, the risk to the general public is not considered to be unreasonable.

The Scientific Committee on Food reviewed the analogue chemical in 2003 for suitability for use in various food contact packaging materials. The committee concluded that the analogue chemical can be used in materials with food contact with the following restrictions: "(1) in polyolefins at 0.1% (w/w) and not for fatty food with a simulant

D Reduction Factor less than 3 and (2) in PET at 0.25% (w/w) and only for food for which simulant D is not required" (SCF, 2003).

The public report of this assessment will be forwarded to Food Standards Australia New Zealand (FSANZ) for their information.

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

8. ENVIRONMENTAL IMPLICATIONS

8.1. Environmental Exposure & Fate Assessment

8.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified chemical will be imported into Australia as a solid which is added as a component to a polymer masterbatch. A masterbatch is a solid mixture of one or more compounds in a suitable carrier polymer. The concentration of the notified chemical in masterbatches is expected to be 30 – 50%. The process for formulating a masterbatch consists of weighing and blending the notified chemical with other compounding ingredients. The blending is carried out in closed/sealed mixers. This pre-blending process is followed by a melting and extrusion process that completely dissolves and encapsulates the notified chemical into the polymer (polyolefin fibres) in a process known as 'melt spinning'. The notifier has estimated that up to 5% waste may be generated by the fibre spinning process. This corresponds to a maximum of 50 kg of the notified chemical per annum at the maximum import volume. This material is expected to be disposed of to landfill, bound within the polyolefin matrix.

Wastes from masterbatch formulations, consisting of dirty spilt material or purging material, will be recycled. Empty import containers will be disposed of to landfill. The notifier has indicated that there will be approximately 0.4 kg of notified chemical remaining in containers as residues per annum at the maximum import volume.

RELEASE OF CHEMICAL FROM USE

Polyolefin fibres containing the notified chemical (at concentrations of $\leq 0.2\%$) will have a wide range of applications including carpeting, carpet backing, disposable nappies, disposable hospital gowns and packaging. In each of these applications, the notified chemical is expected to be bound within the polymer matrix and will not be released.

RELEASE OF CHEMICAL FROM DISPOSAL

The majority of the notified chemical is expected to share the fate of the substrates to which it has been applied and be disposed of to landfill at the end of their useful lives. Material which is spilt during fibre spinning will be disposed of to landfill.

8.1.2. Environmental Fate

The notified chemical is not readily biodegradable (0.3% over 28 days) based on data for an analogous chemical (previously assessed as NA/592). A bioaccumulation study on this analogue chemical (not previously assessed in NA/592) indicated that the notified chemical has limited potential to bioaccumulate; however, not all constituents were considered. For the details of the environmental fate study refer to Appendix B. Any potential for bioaccumulation would be mitigated by the very low exposure to the aquatic compartment.

As a result of its use pattern, most of the notified chemical is expected to share the fate of the substrates/articles to which it has been applied and be disposed of to landfill. The notified chemical will be crosslinked into a solid polymer matrix as part of its normal use pattern and is therefore not expected to be mobile or bioavailable. In landfill, the notified chemical is expected to eventually degrade via biotic and abiotic processes to form water and oxides of carbon and nitrogen.

8.1.3. Predicted Environmental Concentration (PEC)

The Predicted Environmental Concentration (PEC) has not been calculated as release of the notified chemical to the aquatic environment will be limited based on its reported use pattern.

8.2. Environmental Effects Assessment

The results from ecotoxicological investigations conducted on an acceptable analogue of the notified chemical are summarised in the table below. Details of these studies can be found in the assessment report for NA/592.

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity	96 h LL50 > 100 mg/L	Not harmful to fish up to its water solubility limit
Daphnia Toxicity	48 h EL50 > 100 mg/L	Not harmful to aquatic invertebrates up to its water solubility limit
Algal Toxicity	72 h ErL50 > 100 mg/L	Not harmful to algae up to its water solubility limit
Inhibition of Bacterial Respiration	3 h EC50 > 100 mg/L	Not inhibitory to microorganisms in STPs up to its water solubility limit

Based on the ecotoxicological test results of the analogue chemical, the notified chemical is not expected to be toxic to aquatic organisms up to its water solubility limit.

8.2.1. Predicted No-Effect Concentration

The Predicted No-effect Concentration (PNEC) has not been calculated as the notified chemical is not expected to be harmful to aquatic organisms up to its water solubility limit.

Based on the above ecotoxicological data, the notified chemical is not formally classified under the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS) for acute and chronic toxicities (United Nations, 2009). Currently available information indicates that degradation of the notified chemical is limited under environmentally relevant conditions.

8.3. Environmental Risk Assessment

The risk quotient (Q = PEC/PNEC) for the notified chemical has not been calculated as the notified chemical is not expected to be harmful to aquatic organisms up to its water solubility limit. The majority of the notified chemical will be disposed of to landfill along with the articles to which it has been applied. In landfill, the notified chemical is bound to these articles and is unlikely to be bioavailable or mobile.

On the basis of the assessed use pattern, and the low hazard to the aquatic environment, the notified chemical is not considered to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Melting Point 95.8 °C

Method OECD TG 102 Melting Point/Melting Range
Remarks Determined by differential scanning calorimetry (DSC) in nitrogen
Test Facility BASF (2016b)

Density 930 kg/m^3 at 20 °C

Method OECD TG 109 Density of Liquids and Solids
Remarks Determined using gas comparison pycnometer
Test Facility BASF (2016b)

Water Solubility < 3 × 10^{-4} g/L at 20 °C

Method OECD TG 105 Water Solubility
Remarks Column Elution Method. The total solubility of the notified UVCB was less than the detection limit of 0.3 mg/L.
Test Facility BASF (2016b)

Partition Coefficient (n-octanol/water) log Pow > 10

Method KOWWIN v1.68 (US EPA 2012)
Remarks The three most water soluble constituents of the notified UVCB have a calculated log Pow = 6.67, 6.96 and 7.69; however these are minor constituents, comprising ~ 5% w/w of the notified chemical. All other constituents of the notified UVCB have a calculated log Pow >> 10. The calculated log Pow of the major constituent (67% w/w) is 14.18.

Particle Size

Method OECD TG 110 Particle Size Distribution/Fibre Length and Diameter Distributions

Range (μm)	*Mass (%)*	*Diameter and Volume-weighted Mean Diameter*
< 4	0.19	–
< 10	4.86	D_{10} = 14.6 μm
< 100	49.79	D_{50} = 101 μm
		D_{90} = 985 μm

Remarks Determined by laser diffraction. A dry powder sample and a sample dispersed in pentanone were analysed. The particle size distribution values above are from the dry sample of the notified chemical.

Crystals of the notified chemical were also imaged using optical microscopy.
Test Facility BASF (2016b)

Stability Testing Stable up to 150°C

Method OECD TG 113 Screening Test for Thermal Stability and Stability in Air
Remarks Determined by thermogravimetric analysis
Test Facility BASF (2016b)

Minimum Ignition Energy Test < 10 mJ

Method ASTM E2019 – Standard Test Method for Minimum Ignition Energy of a Dust Cloud in Air

Remarks	Determined using MIKE-3 Apparatus
Test Facility	BASF (2016b)

APPENDIX B: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

B.1. Environmental Fate

B.1.1 Bioaccumulation

TEST SUBSTANCE	^{14}C-labelled analogue
METHOD	Bioconcentration: Flow-through Fish Test
Species	*Cyprinus carpio* (Carp)
Exposure Period	Exposure: eight weeks
Auxiliary Solvent	THF, HCO-20 dispersant
Concentration Range	Nominal: 0.01, 0.001 µg/L Measured: 0.010, 0.0011 µg/L
Analytical Monitoring	HPLC, LSC
Remarks – Method	The test was not conducted according to the prescribed OECD method (OECD TG 305). The test substance contained three ^{14}C-radiolabelled constituents which are suitable chemical analogues for three of the major constituents of the notified chemical. The relative concentrations of the radiolabelled constituents in the test substance were comparable to the concentrations of their representative constituents in the notified chemical. A stock feed solution containing the test substance was prepared by dispersing the test substance in water with the aid of low concentrations of the dispersing agent HCO-20 and THF (≤ 0.2 µg/mL and 40 ppm respectively). The feed stock was diluted and pumped into the test media daily. The net bioconcentration factor was determined periodically throughout the eight week study by measuring the total radioactivity with a liquid scintillation counter (LSC) in the test media and in the fish biomass.
RESULTS	
Bioconcentration Factor	The maximum bioconcentration factor was 153 (0.0011 µg/L, week 6).
Remarks – Results	The net bioconcentration factor was measured from the LSC data. The bioconcentration factors for the individual constituents were not considered. No lethal or sub-lethal effects were observed in any of the fish during the eight week study.
CONCLUSION	The test substance shows limited potential for bioaccumulation
TEST FACILITY	MCSI Ltd. (1999)

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