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

**PUBLIC REPORT**

**Benzamide, 2-Amino**

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:

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**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/2110	TCL Australia Pty Ltd	Benzamide, 2-Amino	ND*	≤ 1 tonne per annum	Component of articles for food contact

\*ND = not determined

## CONCLUSIONS AND REGULATORY OBLIGATIONS

### **Hazard Classification**

As no toxicity data were provided, 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.

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**

On the basis of the reported use pattern, the notified chemical 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 isolation and engineering controls to minimise occupational exposure to the notified chemical during reformulation:
  - Enclosed/automated processes if possible
  - Local exhaust ventilation
- 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 chemical during reformulation:
  - Avoid contact with skin and eyes
  - Avoid inhalation of dust
- 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
  - Respiratory protection if inhalation exposure may occur

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;or
- (2) Under Section 64(2) of the Act; if
  - the function or use of the chemical has changed from a component of articles for food contact, 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 a product containing 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)

TCL Australia Pty Ltd (ABN: 39 091 773 330)  
150 Woodlands Drive  
BRAESIDE VIC 3195

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 exempt from publication include: analytical data and degree of purity.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Schedule data requirements are not varied.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

Canada (1998), China (2013), EU (1990), Japan (2004), New Zealand (2006), Philippines (2000), South Korea (2014) and USA (2019)

### 2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Global Triple A-1 (product contains 25-50% notified chemical)

CAS NUMBER

88-68-6

CHEMICAL NAME

Benzamide, 2-amino

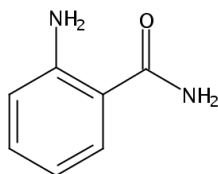
OTHER NAME(S)

Anthranilamide

MOLECULAR FORMULA

C<sub>7</sub>H<sub>8</sub>N<sub>2</sub>O

STRUCTURAL FORMULA



MOLECULAR WEIGHT

136.15 g/mol

ANALYTICAL DATA

Reference IR spectra were provided.

### 3. COMPOSITION

DEGREE OF PURITY

> 95%

#### 4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Off white powder

<i>Property</i>	<i>Value</i>	<i>Data Source/Justification</i>
Melting Point/Freezing Point	111.8 °C	Measured
Boiling Point	300 °C	HSDB, 2019
Density	1,300.9 kg/m <sup>3</sup> at 20 °C	Measured
Vapour Pressure	4.6 × 10 <sup>-7</sup> kPa at 20 °C 9.5 × 10 <sup>-7</sup> kPa at 25 °C 2.6 × 10 <sup>-5</sup> kPa at 50 °C	Measured
Water Solubility	19.076 g/L at 20 °C	Measured
Hydrolysis as a Function of pH	t <sub>1/2</sub> > 1 year at pH 4, pH 7, pH 9 and 50 °C	Measured
Partition Coefficient (n-octanol/water)	log Pow < 0 at 20°C	Measured
Adsorption/Desorption	log Koc < 1.32 at 25 °C	Measured
Dissociation Constant	pKa = 3.1	Measured
Particle Size	Inhalable fraction (< 100 µm): < 50% Respirable fraction (< 10 µm): < 10% Median particle size = 118.613 µm	Measured
Flammability	Not classified as flammable solid	Measured
Autoignition Temperature	No self-ignition up to 401 °C	Measured
Explosive Properties	Not determined	Contains no functional groups that imply explosive properties
Oxidising Properties	Not determined	Contains no functional groups that imply oxidising properties

#### DISCUSSION OF PROPERTIES

For 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.

#### 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.

#### 5. INTRODUCTION AND USE INFORMATION

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

The notified chemical will not be manufactured in Australia. It will be imported into Australia as a component (< 35% concentration) of colourant formulations for incorporation into polyethylene terephthalate (PET) beverage bottles.

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

<i>Year</i>	<i>1</i>	<i>2</i>	<i>3</i>	<i>4</i>	<i>5</i>
<i>Tonnes</i>	1	1	1	1	1

#### PORT OF ENTRY

Sydney, Melbourne, Brisbane and Perth

**TRANSPORTATION AND PACKAGING**

The notified chemical will be imported by air or sea as a component of formulations packed in 15 L cubitainers and will be transported by rail or road to customer's facilities.

**USE**

The notified chemical will be used as a component of colourants for manufacture of PET beverage bottles. The concentration of the notified chemical in finished articles will be ~0.033%.

**OPERATION DESCRIPTION**

The notified chemical will be imported into Australia as a component of colourants for incorporation into polyethylene terephthalate (PET) beverage bottles.

*Reformulation*

The colourant containing the notified chemical is mixed with other materials to form the melted coloured resin which is then formed into articles via injection or blow moulding.

*End-use*

The PET bottles containing the notified chemical will be filled with beverages at bottling facilities.

**6. HUMAN HEALTH IMPLICATIONS****6.1. Exposure Assessment****6.1.1. Occupational Exposure****CATEGORY OF WORKERS**

<i>Category of Worker</i>	<i>Exposure Duration (hours/day)</i>	<i>Exposure Frequency (days/year)</i>
Stevedore	1	1-2
Article manufacture	2	6-8
Quality control	2	6-8
Transport	10-20	6-8

**EXPOSURE DETAILS***Transport and storage*

Transport and storage workers may come in contact with the notified chemical at < 35% concentration in the event of an unlikely accidental rupture of containers.

*Reformulation*

During reformulation into PET bottles, dermal, ocular and inhalation exposure of workers to the notified chemical at < 35% concentration may occur. According to the notifier, exposure is expected to be minimised through the use of exhaust ventilation and/or automated/enclosed systems as well as through the use of personal protective equipment (PPE) such as coveralls, eye protection, impervious gloves and respiratory protection (as appropriate).

*End use*

Exposure to the notified chemical during the bottling of beverages is not expected, given the notified chemical will be contained in the inert matrix of the bottles.

**6.1.2. Public Exposure**

The product containing the notified chemical is intended for industrial use only and will not be sold or made available to the public. Dermal, ocular and inhalation exposure of the public to the notified chemical is not expected, given the notified chemical will be contained in the inert matrix of beverage bottles.

The notified chemical will be used as acetaldehyde scavenging agent in polyethylene terephthalate (PET) blends that will be used to manufacture beverage bottles, and subsequently beverages could be a source of public exposure. The notified chemical will be encapsulated within the PET matrix of the bottles and is not expected to migrate into the beverage at high levels. The diffusion coefficients for the notified chemical from PET bottles into water or water with 20% ethanol have been measured and were  $4.2 \times 10^{-16} \text{ cm}^2 \cdot \text{s}^{-1}$  and  $4.7 \times 10^{-16} \text{ cm}^2 \cdot \text{s}^{-1}$  for water and water with 20% ethanol respectively at a temperature of 23 °C (Franz *et al.* 2016). At the higher temperature

of 40 °C the diffusion coefficients for the notified chemical were  $4.2 \times 10^{-15} \text{ cm}^2 \cdot \text{s}^{-1}$  and  $7.7 \times 10^{-15} \text{ cm}^2 \cdot \text{s}^{-1}$  for water and water with 20% ethanol respectively (Franz *et al.* 2016). The concentration of the notified chemical in water after storage at 23 °C was  $10.6 \pm 1.2 \mu\text{g} \cdot \text{L}^{-1}$  and  $12.4 \pm 0.3 \mu\text{g} \cdot \text{L}^{-1}$  after 40 days and 60 days respectively (Franz *et al.* 2016). When stored at 40 °C the concentration of the notified chemical in water after 40 days was  $32.1 \pm 1.8 \mu\text{g} \cdot \text{L}^{-1}$  (Franz *et al.* 2016). The concentration of the notified chemical in water containing 20% ethanol that was stored at 23 °C was  $10.8 \pm 0.3 \mu\text{g} \cdot \text{L}^{-1}$  and  $11.7 \pm 0.5 \mu\text{g} \cdot \text{L}^{-1}$  after 40 days and 60 days respectively; and when stored at 40 °C was  $39.7 \pm 1.5 \mu\text{g} \cdot \text{L}^{-1}$  after 40 days (Franz *et al.* 2016). All of the above concentrations were based on a bottle wall concentration of the notified chemical of  $197.6 \pm 2.7 \text{ mg/kg}$  (Franz *et al.* 2016).

The notifier has stated that the notified chemical will be added to PET beverages at a concentration of ~0.033%, which will lead to a nominal concentration of the notified chemical in the bottle wall of ~330 mg/kg. Franz *et al.* (2016) reported that the concentration of the notified chemical in the bottle wall when measured was only about 2/5 of the nominal concentration due to it reacting with acetaldehyde. Hence the final concentration of the notified chemical in the PET bottles is expected to be about 130 mg/kg.

The European Union commission regulation number 10/2011 of the 14<sup>th</sup> January 2011 on plastic materials and articles intended to come into contact with food allows the use of the notified chemical only in PET bottles for water and beverages with a specific migration limit of  $50 \mu\text{g} \cdot \text{L}^{-1}$  (EU, 2011). The notified chemical is listed on the U.S. Food and Drug Administration (FDA) Inventory of Effective Food Contact Substance (FCS) Notifications with a restriction that it must not exceed 500 mg/kg (ppm) in bottles used to hold water or 250 mg/kg (ppm) in bottles used for non-water, aqueous, acidic, and low-alcohol food applications (U.S. FDA, 2001). Based on the migration coefficients for the notified chemical, measured by Franz *et al.* (2016), and the proposed use concentration (~0.033%) the notified chemical is not expected to exceed the allowable concentrations for food and packaging set by the EU and U.S. FDA respectively.

## 6.2. Human Health Effects Assessment

No toxicity data were submitted for the notified chemical.

The notifier has classified the notified chemical as acute toxicity (Category 4), skin irritation (Category 2), eye irritation (Category 2A), skin sensitisation (Category 1) and specific target organ toxicity (respiratory tract irritation) (Category 3), consistent with the classifications in ECHA C&L Inventory.

### Health Hazard Classification

As no toxicity data were provided, 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

Based on the hazard classifications provided by the notifier, the notified chemical is expected to be a skin and eye irritant. The notified chemical is potentially a skin sensitiser and may cause irritation to the respiratory tract.

Workers handling colourants containing the notified chemical may come into contact with the chemical at < 35% concentration during reformulation. According to the notifier, the exposure is expected to be limited by the use of enclosed, automated systems and PPE (impervious gloves, safety glasses, protective clothing and respiratory protection if inhalation may occur).

Once formulated into PET bottles, the notified chemical will be bound within an inert solid matrix and will not be available for exposure.

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.

### 6.3.2. Public Health

The colourant product containing the notified chemical will be only used in industrial settings and will not be sold to the public. The public may have dermal contact with PET beverage bottles containing the notified chemical at a concentration of ~0.033%. However, dermal exposure to the notified chemical is not expected from the beverage bottles.



Therefore, the notified chemical is not considered to pose an unreasonable risk to the health of the public.

As the notified chemical will be incorporated in beverage bottles, this assessment report will be forwarded to Food Standards Australia New Zealand (FSANZ) for their information and to consider any public exposure through food and beverages.

## **7. 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 as a component of colourant formulations for incorporation into PET beverage bottles. Release of the notified chemical during the automatic bottle production process is not expected. Empty containers containing residual notified chemical are expected to be reused or disposed of, in accordance with local government regulations. Accidental spills of the notified chemical during import, transport, storage or bottle production are expected to be collected for reuse to the extent practicable or disposal, in accordance with local government regulations.

##### **RELEASE OF CHEMICAL FROM USE**

The PET bottles will be filled with beverages at bottling facilities. Release of the notified chemical during the bottling of beverages is not expected as the notified chemical is contained in the inert matrix of the bottles.

##### **RELEASE OF CHEMICAL FROM DISPOSAL**

The notified chemical will share the fate of the beverage bottles in which they have been incorporated. They may enter recycling streams, but will ultimately end up in landfill at the end of their useful lives.

#### **7.1.2. Environmental Fate**

No environmental fate data were submitted. The majority of the notified chemical will share the fate of the beverage bottles in which they have been incorporated. They may enter recycling streams, but will ultimately end up in landfill at the end of their useful lives. A minor amount of the notified chemical may also be disposed of to landfill as collected spills and empty container residues. In landfill, most of the notified chemical will be present as cured solids and will be neither bioavailable nor mobile. The notified chemical is not expected to bioaccumulate based on its low log Pow. The notified chemical is expected to eventually degrade via biotic and abiotic processes to form water and oxides of carbon and nitrogen.

#### **7.1.3. 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 from the reported use pattern.

### **7.2. Environmental Effects Assessment**

No ecotoxicity data were submitted.

#### **7.2.1. Predicted No-Effect Concentration**

A predicted no-effect concentration (PNEC) for the aquatic compartment has not been calculated as no ecotoxicity data were submitted.

### **7.3. Environmental Risk Assessment**

The Risk Quotient ( $Q = \text{PEC}/\text{PNEC}$ ) has not been calculated as release of the notified chemical to the aquatic environment will be limited based on its reported use pattern. Therefore, based on the reported use pattern, the notified chemical is not expected to pose an unreasonable risk to the environment.

## APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

**Melting Point** 111.8 °C

Method OECD TG 102 Melting Point/Melting Range  
Remarks Determined using a heating apparatus.  
Test Facility Eurofins (2019a)

**Density** 1,300.9 kg/m<sup>3</sup> at 20 °C

Method OECD TG 109 Density of Liquids and Solids  
Remarks Gas comparison pycnometer method  
Test Facility Eurofins (2019b)

**Vapour Pressure** 4.6 × 10<sup>-7</sup> kPa at 20 °C  
9.5 × 10<sup>-7</sup> kPa at 25 °C  
2.6 × 10<sup>-5</sup> kPa at 50 °C

Method OECD TG 104 Vapour Pressure  
Remarks Effusion method  
Test Facility Siemens (2019a)

**Water Solubility** 19.076 g/L at 20 °C

Method OECD TG 105 Water Solubility  
EC Council Regulation No 440/2008 A.6 Water Solubility  
Remarks Flask Method; the notified chemical was determined by HPLC with UV detection  
Test Facility Eurofins (2019c)

### Hydrolysis as a Function of pH

Method OECD TG 111 Hydrolysis as a Function of pH  
EC Council Regulation No 440/2008 C.7 Degradation: Abiotic Degradation: Hydrolysis as a Function of pH

<i>pH</i>	<i>T (°C)</i>	<i>t</i> <sub>1/2</sub> ( <i>year</i> )
4	50	> 1
7	50	> 1
9	50	> 1

Remarks The degradation of the notified chemical was < 10% at pH 4, pH 7, pH 9 and 50 °C over 120 hours; the notified chemical was determined by HPLC with UV detection  
Test Facility Eurofins (2019d)

**Partition Coefficient (n-octanol/water)** log Pow < 0 at 20°C

Method OECD TG 117 Partition Coefficient (n-octanol/water)  
EC Council Regulation No 440/2008 A.8 Partition Coefficient  
Remarks HPLC Method; the column temperature was 20°C  
Test Facility Eurofins (2019e)

**Adsorption/Desorption** log Koc < 1.32 at 25 °C

Method OECD TG 121 Estimation of Adsorption Coefficient using HPLC  
Remarks The column temperature was 25 °C  
Test Facility Eurofins (2019f)

**Dissociation Constant**

pKa = 3.1

Method OECD TG 112 Dissociation Constants in Water  
 Remarks The notified chemical was analysed by UV/VIS  
 Test Facility Siemens (2019b)

**Particle Size**

Median particle size = 118.613 µm

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

<i>Range (µm)</i>	<i>Mass (%)</i>
Inhalable fraction (< 100 µm):	< 50%
Respirable fraction (< 10 µm):	< 10%

Remarks Determined using laser diffraction method with dry dispersion.  
 Test Facility Eurofins (2019g)

**Flammability**

Not classified as a flammable solid

Method EC Council Regulation No 440/2008 A.10 Flammability (Solids)  
 Remarks No independent burning or glowing over the length of the pile of the test item was observed in a preliminary test.  
 Test Facility Eurofins (2019h)

**Autoignition Temperature**

No self-ignition temperature up to 401 °C

Method EC Council Regulation No 440/2008 A.16 Relative Self-Ignition Temperature for Solids  
 Remarks No self-ignition temperature was observed up to the maximum test temperature of 401 °C.  
 Test Facility Siemens (2019c)

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