File No: STD/1339

November 2009

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

1,4-Benzenediamine, N1-(1-methylheptyl)-N4-phenyl-

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (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 Ageing, 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, Water, Heritage and the Arts.

For the purposes of subsection 78(1) of the Act, this Full Public Report may be inspected at our NICNAS office by appointment only at 334-336 Illawarra Road, Marrickville NSW 2204.

This Full Public Report is also 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:334 - 336 Illawarra Road MARRICKVILLE NSW 2204, AUSTRALIA.Postal Address:GPO Box 58, SYDNEY NSW 2001, AUSTRALIA.TEL:+ 61 2 8577 8800FAX+ 61 2 8577 8888Website:www.nicnas.gov.au

Director NICNAS

TABLE OF CONTENTS

| FULL PU | UBLIC REPORT | . 3 |
|---------|--|-----|
| 1. | APPLICANT AND NOTIFICATION DETAILS | . 3 |
| 2. | IDENTITY OF CHEMICAL | . 3 |
| 3. | COMPOSITION | .4 |
| 4. | PHYSICAL AND CHEMICAL PROPERTIES | .4 |
| 5. | INTRODUCTION AND USE INFORMATION | . 5 |
| 6. | HUMAN HEALTH IMPLICATIONS | . 5 |
| 7. | ENVIRONMENTAL IMPLICATIONS | .9 |
| 8. | CONCLUSIONS AND REGULATORY OBLIGATIONS | 10 |
| BIBLIO | GRAPHY | 13 |

FULL PUBLIC REPORT

1,4-Benzenediamine, N1-(1-methylheptyl)-N4-phenyl-

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S) The Shell Company of Australia Limited (ABN 46 004 610 459) 8 Redfern Road East Hawthorn, VIC 3123

NOTIFICATION CATEGORY Standard: Chemical other than polymer (more than 1 tonne per year).

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

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT) Variation to the schedule of data requirements is claimed as follows: melting point, vapour pressure, hydrolysis as a function of pH, partition co-efficient, adsorption/desorption, dissociation constant, flash point, flammability limits, autoignition temperature, spectral data and the use of analogue data for toxicological and ecotoxicological endpoints.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S) None

NOTIFICATION IN OTHER COUNTRIES USA, Canada, EU, Korea and Japan

2. IDENTITY OF CHEMICAL

MARKETING NAME(S) NU-400 (contains 3% notified chemical)

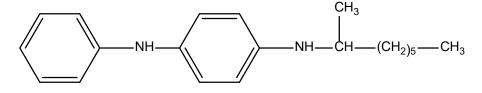
CAS NUMBER 15233-47-3

CHEMICAL NAME 1,4-Benzenediamine, N1-(1-methylheptyl)-N4-phenyl-

OTHER NAME(S) N-1-Methylheptyl-N'-phenyl-p-phenylenediamine

 $\begin{array}{l} Molecular \ Formula \\ C_{20}H_{28}N_2 \end{array}$

STRUCTURAL FORMULA



MOLECULAR WEIGHT

NICNAS

Unknown

296.45

ANALYTICAL DATA Reference spectra were not provided.

3. COMPOSITION

DEGREE OF PURITY >95%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS Unknown

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (>1% by weight)

ADDITIVES/ADJUVANTS None

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: Liquid

| Property | Value | Data Source/Justification |
|--|------------------------------------|---|
| Melting Point/Freezing Point | Not determined | Will be imported in solution |
| Boiling Point | 431°C at 101.3 kPa | IUCLID (2001) |
| Density | 1003 kg/m ³ at 15.6°C | IUCLID (2001) |
| Vapour Pressure | 6.7×10^{-8} kPa at 25°C | Estimated with EPIWIN (US EPA, 2003) |
| Water Solubility | ≤ 1.1 ppm | Estimated based on the water solubility of 1.1 ppm for an analogue (6PPD) that contains two less carbon atoms in the aliphatic chain (IUCLID, 2000). |
| Hydrolysis as a Function of pH | $t\frac{1}{2} = 3-4$ hours at pH 7 | Estimated based on the analogue 6PPD. The notified chemical may react rapidly with the oxygen in water (IUCLID, 2000). |
| Partition Coefficient (n-octanol/water) | $\log P_{\rm OW} \!\geq \! 5.4$ | Estimated based on the calculated value of 5.4 for the analogue chemical 6PPD (IUCLID, 2000). |
| Adsorption/Desorption | Not determined | Expected to absorb strongly to soil from water based on the high P_{OW} and the presence of the amine groups in the molecule. |
| Dissociation Constant | Not determined | The notified chemical contains aromatic amines which are expected to show their typical basicity within the environmental pH range of 4-9. |
| Flash Point | Not determined | Imported as a component (0.3 ppm) of an extremely flammable solution. |
| Flammability | Not determined | Imported as a component (0.3 ppm) of an extremely flammable solution. |
| Autoignition Temperature | Not determined | Imported as a component (0.3 ppm) of an extremely flammable solution. |
| Explosive Properties | Not expected to be explosive | The structural formula contains no explosophores. |
| Fat Solubility | 100% | Measured OECD 116 (IUCLID, 2001) |

DISCUSSION OF PROPERTIES

The melting point was estimated using EPIWIN (US EPA, 2003) as 146°C, however it was also reported to be a liquid at room temperature (IUCLID, 2001).

Reactivity

Stable under normal conditions of use apart from during combustion when it will be converted to water and oxides of carbon and nitrogen. The analogue 6PPD is an antiozonant and as such necessarily reacts very quickly with oxygen. Therefore, fast oxidation in dilute aqueous solutions, where oxygen is readily available, is to be expected. The initial oxidation product is believed to be quinondiimine, which itself is a very reactive species. The quinondiimine can hydrolyze or form a polymer by further oxidation giving very complicated mixtures of products usually involving loss of the alkyl group (IUCLID, 2000). The notified chemical is expected to react similarly.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS The notified chemical will not be manufactured or reformulated within Australia. The notified chemical will be imported as a component of unleaded petrol at a concentration of 0.3 ppm.

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 Throughout Australia

IDENTITY OF RECIPIENTS The Shell Company of Australia Limited

TRANSPORTATION AND PACKAGING

The unleaded petrol containing the notified chemical (0.3 ppm) will be brought into Australia by ship. The petrol will then be pumped into storage tanks prior to being transferred to service stations by road tankers. At the service stations, the petrol will be transferred to underground tanks for storage.

USE

The notified chemical will be used as an antioxidant in unleaded petrol at a concentration of up to 0.3 ppm.

OPERATION DESCRIPTION

The unleaded petrol containing the notified chemical (0.3 ppm) will be transferred from the ship to the terminal storage tanks by closed pipes, and when unloaded at refinery terminals, transferred to storage sites by fixed closed pipes. Sampling and analysis of the imported unleaded petrol will be undertaken at the storage sites. The petrol will then be transferred by fixed closed pipes to road tankers for delivery to minor depots or directly to service station storage tanks. When required, the petrol will be pumped directly into automobile fuel tanks.

6. HUMAN HEALTH IMPLICATIONS

6.1 Exposure assessment

6.1.1 Occupational exposure

EXPOSURE DETAILS

Worker exposure to the notified chemical at concentrations of 0.3 ppm could occur during connection and disconnection of pipes involved in the transfer of the petrol. Exposure to the notified chemical is also likely during the handling and fuelling of vehicles or equipment that are powered by unleaded petrol that contains the notified chemical.

The main route of exposure is expected to be dermal, although ocular exposure to splashes is possible. Inhalation exposure is expected to be negligible based on the predicted low vapour pressure $(6.7 \times 10^{-8} \text{ kPa at})$

25°C). Exposure is expected to be minimized by the low concentration (0.3 ppm) of the notified chemical in the finished petrol and through good hygiene practices. Use of PPE is expected during the connection and disconnection of pipes involved in the transfer of the petrol.

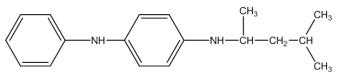
6.1.2. Public exposure

The public may be directly exposed (dermal and ocular) to the notified chemical when filling vehicles and equipment with petrol containing it. Inhalation exposure is expected to be negligible based on the predicted low vapour pressure (6.7×10^{-8} kPa at 25°C). Overall, direct exposure to the notified chemical in petrol is expected to be low due to the low concentration (0.3 ppm).

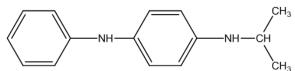
6.2. Human health effects assessment

The results from toxicological investigations conducted on the notified chemical and analogues considered acceptable by NICNAS are summarised in the table below.

The structurally related analogues were the phenylenediamines;



1,4-Benzenediamine, N1-(1,3-dimethylbutyl)-N4-phenyl- (6PPD) (CAS No. 793-24-8) and;



1,4-Benzenediamine, N1-(1-methylethyl)-N4-phenyl (IPPD) (CAS No. 101-72-4).

| Endpoint | Test Substance | Result and Assessment Conclusion | Source |
|--------------------------|-------------------|---------------------------------------|--------------|
| Rat, acute oral toxicity | notified chemical | LD50 4.3 mg/kg bw, very toxic | IUCLID, 2001 |
| | 6PPD | LD50 500-1000 mg/kg bw (females) and | UNEP, 2004 |
| | | 1000-2000 mg/kg bw (males); harmful | |
| | IPPD | LD50 800-900 mg/kg bw; harmful | UNEP, 2000 |
| Mouse, acute oral | IPPD | LD50 1122-3592 mg/kg bw; harmful | UNEP, 2000 |
| toxicity | | | |
| Rat, acute dermal | notified chemical | LD50 > 2000 mg/kg bw; low toxicity | IUCLID, 2001 |
| toxicity | 6PPD | LD50 > 3000 mg/kg bw; low toxicity | UNEP, 2004 |
| | IPPD | LD50 > 7500 mg/kg bw; low toxicity | UNEP, 2000 |
| Rabbit, skin irritation | notified chemical | slightly irritating | IUCLID, 2001 |
| | 6PPD | slightly irritating | UNEP, 2004 |
| | IPPD | slightly irritating | UNEP, 2000 |
| Rabbit, eye irritation | notified chemical | slightly irritating | IUCLID, 2001 |
| - | 6PPD | slightly irritating | UNEP, 2004 |
| | IPPD | slightly irritating | UNEP, 2000 |
| Sensitisation – human | notified chemical | no evidence of sensitisation | IUCLID, 2001 |
| patch test | | | |
| Guinea pig, skin | 6PPD | evidence of sensitisation | UNEP, 2004 |
| sensitisation – adjuvant | IPPD | evidence of sensitisation | UNEP, 2000 |
| test | | | |
| Mouse, skin | IPPD | evidence of sensitisation | UNEP, 2000 |
| sensitisation – Local | | | |
| lymph node assay | | | |
| Rat, repeat dose oral | 6PPD | NOAEL = 6 mg/kg bw/day | UNEP, 2004 |
| (gavage) toxicity – 48 | | LOAEL = 25 mg/kg bw/day | |
| days. | | | |
| Rat, repeat dose oral | 6PPD | NOAEL > 75 mg/kg bw/day highest dose | UNEP, 2004 |
| (diet) toxicity – 24 | | | , |
| months. | | | |

| Rat, repeat dose oral (diet) toxicity – 28 | IPPD | NOAEL > 223 mg/kg bw/day highest dose | UNEP, 2000 |
|---|-------------------|---|--------------|
| days. Rat, repeat dose oral (diet) toxicity – 90 days. | IPPD | NOAEL > 57 mg/kg bw/day highest dose | UNEP, 2000 |
| Mutagenicity – | notified chemical | non mutagenic | IUCLID, 2001 |
| bacterial reverse | 6PPD | non mutagenic | UNEP, 2004 |
| mutation | IPPD | non mutagenic | UNEP, 2000 |
| Genotoxicity – in vitro | 6PPD | genotoxic | UNEP, 2004 |
| Chinese Hamster lung | 0112 | 5-10-10-10 | 01(21,200) |
| cells | | | |
| Genotoxicity - in vitro | IPPD | three separate studies on CHO cells, two | UNEP, 2000 |
| Chinese Hamster ovary | | were positive (sister chromatid exchange) | |
| (CHO) cells | | and one negative (hprt gene mutation assay) | |
| Genotoxicity – in vitro | 6PPD | non genotoxic | UNEP, 2004 |
| rat hepatocytes | IPPD | Two studies one positive for genotoxicity and one negative | UNEP, 2000 |
| Genotoxicity – in vitro mouse lymphoma L5178Y cells | IPPD | non genotoxic | UNEP, 2000 |
| Genotoxicity – in vivo cytogenetic assay in rats | 6PPD | non genotoxic | UNEP, 2004 |
| Genotoxicity – in vivo cytogenetic assay in mice | 6PPD | non genotoxic | UNEP, 2004 |
| Genotoxicity – in vivo micronucleus assay in mice | 6PPD | two studies both non genotoxic | UNEP, 2004 |
| Developmental and | IPPD | NOAEL Parental > 125 mg/kg bw/day | UNEP, 2000 |
| reproductive effects | | NOAEL offspring = $62.5 \text{ mg/kg bw/day}$ | |
| Reproductive effects | 6PPD | NOAEL > 100 mg/kg bw/day | UNEP, 2004 |
| Developmental effects | 6PPD | NOAEL (rats) > 250 mg/kg bw/day | UNEP, 2004 |
| | v 2 | NOAEL (rabbits) $> 30 \text{ mg/kg bw/day}$ | ,,, |
| Carcinogenicity | 6PPD | non carcinogenic | UNEP, 2004 |

Toxicokinetics, metabolism and distribution.

There is no toxicokinetic data on the notified chemical. However, based on the low molecular weight (296.45 Da) and the lipophilicity of the notified chemical (water solubility ≤ 1.1 ppm; log Pow ≥ 5.4) dermal absorption may occur, but the transfer from the stratum corneum into the epidermis is expected to be slow. Absorption of the notified chemical across the gastrointestinal tract was confirmed by the observation of toxic effects after acute oral exposure. While no evidence for acute toxic effects was observed in the acute dermal toxicity study, the possibility of dermal absorption of the notified chemical cannot be ruled out.

Acute toxicity.

The notified chemical is considered to be very toxic (LD50 4.3 mg/kg bw) via the oral route based on tests conducted in rats. The notified chemical is considered to be of low toxicity via the dermal route based on tests conducted in rabbits. The analogous chemicals 6PPD and IPPD were found to be harmful via the oral route and of low toxicity via the dermal route.

Irritation and Sensitisation.

The notified chemical is slightly irritating to the skin based on a primary irritation index (PII) score of 1.5 in a study conducted in rabbits (IUCLID, 2001). A PII of ≥ 2.0 is considered positive for an irritant. The notified chemical is slightly irritating to the eye based on tests in rabbits. The analogous chemicals 6PPD and IPPD were also found to be slightly irritating to skin and eyes.

A human patch test using 15 subjects was conducted to determine the sensitisation potential of the notified chemical. However the number of subjects used was too low to reliably detect sensitisation (McNamee et al., 2008). In LLNA and Guinea Pig maximisation tests the analogue IPPD was found to be sensitising at a

concentration of 0.5%. The analogue chemical 6PPD was also found to be a medium sensitiser at a concentration of 0.05% and a very strong sensitiser at a concentration of 0.5%. Based on the analogue data there is significant potential for the notified chemical to present as a sensitiser.

Repeated Dose Toxicity.

No repeat dose toxicity studies have been conducted on the notified chemical. In repeat dose oral toxicity studies conducted in rats exposed with the analogues 6PPD and IPPD in the diet, no adverse effects were observed at the highest doses tested (up to 223 mg/kg bw/day). However, a NOAEL of 6 mg/kg bw/day was obtained when rats were exposed to 6PPD by gavage. The lower NOAEL value seen in the gavage study was attributed to increased bioavailability due to the lipophilic vehicle. Based on these results and the systemic toxicity observed after acute exposure, the notified chemical may cause systemic toxicity after repeated exposure.

Mutagenicity.

The notified chemical was found to be non mutagenic using a bacterial reverse mutation test as were the two analogues 6PPD and IPPD. The analogue 6PPD showed clastogenic activity in Chinese Hamster lung cells but did not induce unscheduled DNA synthesis in rat hepatocytes. However, in four in vivo studies involving 6PPD no genotoxic effects were noted and therefore it is unlikely that 6PPD will cause chromosome aberrations in humans. A range of in vitro studies on the analogue IPPD showed both positive and negative results for genotoxicity, in vivo studies on IPPD were not available. Based on the analogue data the potential for genotoxicity by the notified chemical can not be ruled out.

Carcinogenicity.

Studies on the notified chemical are not available. A number of long term studies with the analogue 6PPD gave no indication of carcinogenic potential.

Reproduction and Developmental Toxicity.

Developmental and reproductive studies on the notified chemical are not available. The analogue 6PPD had no effect on the fertility of rats at doses up to 100 mg/kg bw/day and produced no indication of teratogenic or developmental effects at doses up to 250 and 30 mg/kg bw/day for rats and rabbits respectively. There are no studies available on the reproductive effects of IPPD. There is one developmental study where ossification in bones was seen in the high dose group but was considered insufficient evidence to determine if IPPD is a developmental toxicant. Based on the analogue data the notified chemical is of low concern as a reproductive and developmental toxicant.

Health hazard classification

Based on the acute oral toxicity in the notified chemical and the evidence of sensitisation seen in animal studies with the analogues 6DDP and IDDP the notified chemical is classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

R28 Very toxic if swallowed

R43 May cause sensitisation by skin contact

6.3. Human health risk characterisation

6.3.1. Occupational health and safety

The notified chemical is very toxic through oral exposure, a slight skin and eye irritant and also based on analogue data has strong potential for being a skin sensitiser. However, workers will only be exposed to the notified chemical in petrol where it will be present at a concentration of 0.3 ppm. Due to the very low concentration of the notified chemical in the petrol significant exposure is not expected and therefore the risk to the workers is not considered unacceptable.

6.3.2. Public health

The public will only be exposed to the notified chemical in petrol where it will be present at a concentration of 0.3 ppm. Therefore although the notified chemical is very toxic and a potential skin sensitiser the very low concentration of the notified chemical in the petrol means that significant exposure is not expected and the risk to the public is not considered unacceptable.

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 as a component in petrol. After importation by sea the petrol containing the notified chemical will be transferred to product storage tanks. The petrol will then be pumped into the road tanker trucks to be transported to fuel stations and rural depots in various retail sites across Australia. Releases will be expected only from the unlikely event of spills during the transportation. Any large spillages would be collected in underground spill tanks before being reprocessed or reblended into product. Small spills would be immediately soaked up using absorbent material and presumably disposed of to landfill.

RELEASE OF CHEMICAL FROM USE

At service stations, the road tankers will be emptied via their own 2-2.5 metre flexible hose into underground storage tanks. Potential release would mainly be resulting from accidental spills.

The notifier has not indicated the losses that may be expected during this procedure but the amount of petrol lost due to spills and leaks is likely to be less than 5 L per load, which is 0.15 mg of the notified chemical. The notifier has also not provided any data that takes into account the frequent minor spills (< 1 L) that would occur at petrol bowsers as customers fill their vehicles with fuel. However, given the low percentage in fuel, the loss of notified chemical in these spills would be expected to be very low. Any spills will be treated in the same way as stated above.

RELEASE OF CHEMICAL FROM DISPOSAL

The majority of the notified chemical is expected to be consumed together with the petrol in auto-engines. Any small spills will be disposed of to landfill.

7.1.2 Environmental fate

The notified chemical is not considered to be readily biodegradable, however, it is expected to be readily degraded via reaction with oxygen in water (IUCLID, 2001). It is also predicted to be moderately concentrating in aquatic organisms (IUCLID, 2001).

Most of the notified chemical will be decomposed in engines, while small amount from spillage will be sent to landfill and strongly absorb to soil to undergo abiotic or biotic degradation processes. In either way, the notified chemical will be finally decomposed into water and oxides of carbon and nitrogen.

7.1.3 Predicted Environmental Concentration (PEC)

The calculation of PEC is not considered necessary due to the low exposure predicted from the reported use pattern for the notified chemical as a component in petrol.

7.2. Environmental effects assessment

The results from ecotoxicological investigations conducted on the notified chemical are summarised in the table below.

| Endpoint | Result | Assessment Conclusion | Reference |
|-----------------------|----------------------------|-----------------------------|----------------|
| Fish Toxicity | LC50 = 0.067 - 0.094 mg/L | Very toxic to fish | (IUCLID, 2001) |
| Invertebrate Toxicity | EC50 = 0.00134-0.093 mg/L | Very toxic to invertebrates | (IUCLID, 2001) |
| Algal Toxicity | EC50 = 0.072 mg/L | Very toxic to Algae | (IUCLID, 2001) |

The notified chemical is expected to be very toxic based on the predicted toxicity endpoints. As these data are modelled they do not take into account the probable degradation of the notified chemical through the reaction of oxygen in water.

Measured data is available for the acceptable analogue 6PPD. In fish, the lowest acute toxicity was observed in *Oryzias latipes* during a test in accordance with OECD TG 203. A 96 h LC50 of 0.028 mg/l (effective concentration) was measured. In daphnids, the lowest effective LC50/EC50 was a 48 h EC50 of 0.23 mg/l

measured with Daphnia magna in a Guideline study according to OECD TG 202. In a "degradation toxicity" test with Daphnia magna, it was shown that analogue solution aged shortly (24 h) lost its toxicity towards Daphnia magna. Freshly prepared analogue solution exhibited a nominal 48 h NOEC of 0.25 mg/l and a 48 h LC50 of 0.51 mg/. Stirring for 24 h under aerobic conditions at room temperature, decreased the toxicity of the test solution (containing analogue and degradation products) significantly. The 48 h NOEC of aged analogue was larger than 1 mg/l (highest exposure concentration). In a study according to the Algal Assay Procedure: Bottle Test of the US EPA with the green alga *Selenastrum capricornutum*, a 96 h EC50 of 0.6 mg/l (nominal) and a 96 h EC10 in the range of 0.2 mg/l were obtained (UNEP 2004). Consequently, fresh solutions of the notified chemical should be considered highly toxic to aquatic organisms.

7.2.1 Predicted No-Effect Concentration

The calculation of PNEC has not been conducted since no significant release of the notified chemical to the aquatic environment is expected based on the use pattern.

7.3. Environmental risk assessment

The risk quotient (RQ) has not been calculated due to the low exposure expected based on the reported use pattern of the notified chemical as a component in petrol products.

The notified chemical is not expected to pose an unacceptable risk to the environment based on the reported use pattern.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

Based on the available data the notified chemical is classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)]. The classification and labelling details are:

- T+: R28 Very toxic if swallowed
- Xi: R43 May cause sensitisation by skin contact

and

As a comparison only, the classification of the notified chemical using the Globally Harmonised System for the Classification and Labelling of Chemicals (GHS) (United Nations 2003) is presented below. This system is not mandated in Australia and carries no legal status but is presented for information purposes.

| | Hazard category | Hazard statement |
|--------------------|-----------------|---|
| Environment | Category 1 | Very Toxic to Aquatic life With long lasting effects |
| Acute Toxicity | Category 1 | Fatal if swallowed |
| Skin Sensitization | Category 1 | May cause an allergic skin reaction |

Human health risk assessment

Under the conditions of the occupational settings described, the notified chemical is not considered to pose an unacceptable risk to the health of workers.

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

Environmental risk assessment

On the basis of the reported use pattern, the notified chemical is not considered to pose a risk to the environment.

Recommendations

REGULATORY CONTROLS Hazard Classification and Labelling

- The Office of the ASCC, Department of Employment and Workplace Relations (DEWR), should consider the following health hazard classification for the notified chemical:
 - T+: R28 Very toxic if swallowed
 - Xi: R43 May cause sensitisation by skin contact
- Use the following risk phrases for products/mixtures containing the notified chemical:
 - Conc \geq 7%: R28; R43
 - $\geq 1\%$ Conc < 7%: R25; R43
 - $\geq 0.1\%$ Conc < 1%: R22

CONTROL MEASURES Occupational Health and Safety

• No specific engineering controls, work practices or personal protective equipment are required for the safe use of the notified chemical as introduced in very low concentrations (0.3 ppm), however, these should be selected on the basis of all ingredients in the formulation.

Guidance in selection of personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

- A copy of the MSDS should be easily accessible to employees.
- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)] workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Disposal

• The notified chemical should be disposed of to landfill.

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 concentration of the notified chemical in the imported petrol exceeds 0.3 ppm.

or

(2) Under Section 64(2) of the Act; if

- the function or use of the chemical has changed from an additive in petrol at a concentration of up to 0.3 ppm, or is likely to change significantly;
- the amount of chemical being introduced has increased from 1 tonne, 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.

Material Safety Data Sheet

The MSDS of products containing the notified chemical provided by the notifier were reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.

BIBLIOGRAPHY

- IUCLID (International Uniform Chemical Information Database) (2001) 1,4-Benzenediamine, N-(1methylheptyl)-N'-phenyl- (CAS No. 15233-47-3): Dataset. European Commission-European Chemicals Bureau, 19 pp, 09 November 2001.
- IUCLID (International Uniform Chemical Information Database) (2000), N-1,3-dimethylbutyl-N'-phenyl-pphenylendiamine (CAS No. 793-24-8): Dataset. European Commission-European Chemicals Bureau, 40 pp, 19 February 2000.
- McNamee et al., (2008) A review of critical factors in the conduct and interpretation of the human repeat insult patch test. Regul. Toxicol. Pharmacol., **52**:24–34.
- NOHSC (1994) National Code of Practice for the Labelling of Workplace Substances [NOHSC:2012(1994)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.
- NOHSC (2003) National Code of Practice for the Preparation of Material Safety Data Sheets, 2nd edition [NOHSC:2011(2003)]. National Occupational Health and Safety Commission, Canberra, Australian Government Publishing Service.
- NOHSC (2004) Approved Criteria for Classifying Hazardous Substances, 3rd edition [NOHSC:1008(2004)]. National Occupational Health and Safety Commission, Canberra, AusInfo.
- NTC (National Transport Commission) 2007 Australian Code for the Transport of Dangerous Goods by Road and Rail (ADG code), 7th Edition, Commonwealth of Australia
- UNEP (2000) SIDS Initial Assessment Report for N-Isopropyl-N' –phenyl-p-phenylenediamine (IPPD) CAS No. 101-72-4, 37 pp, Prepared for SIAM 10, Tokyo Japan, 15-17 March. UNEP Publications.
- UNEP (2004) SIDS Initial Assessment Report for N-(1,3-Dimethylbutyl)-N'-phenyl-1,4-phenylenediamine CAS No. 793-24-8, 144 pp, Prepared for SIAM 18, Paris France, 20-23 April. UNEP Publications.
- United Nations (2003) Globally Harmonised System of Classification and Labelling of Chemicals (GHS). United Nations Economic Commission for Europe (UN/ECE), New York and Geneva.
- US EPA (2003) High Production Volume (HPV) Challenge Program. Substituted p-Phenylenediamines Category Justification and Testing Rational (Revised). United States Environmental Protection Agency.