File No: STD/1487

December 2013

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Residues (petroleum), Thermal Cracked Vacuum

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 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.

For the purposes of subsection 78(1) of the Act, this Public Report may be inspected at our NICNAS office by appointment only at Level 7, 260 Elizabeth Street, Surry Hills NSW 2010.

This 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:

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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
STD/1487	The Shell Company of Australia Ltd	Residues (petroleum), thermal cracked vacuum	ND*	≤ 16000 tonnes per annum	Component of bitumen for road paving

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available information, the notified chemical is not recommended for classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

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

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

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

Recommendations

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:
  - Enclosed, automated systems where possible during reformulation
  - Handling of the notified chemical in heated form should be carried out under well-ventilated conditions

- 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 in the heated form:
  - Avoid contact with eyes and skin
  - Avoid inhalation of fumes/mists
  - Minimise the generation of fumes/mists where possible

- 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 in the heated form or its degradation products:
  - Eye protection
  - Protective clothing
  - Gloves
  - Respiratory protection if inhalation of fumes/mists is expected
  - Respiratory protection where hydrogen sulphide may accumulate

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

- The level of bitumen fumes should be maintained as low as possible. The Safe Work Australia exposure standard for bitumen fumes is 5 mg/m^3 (time weighted average).

- A copy of the (M)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 for the Classification and Labelling of Chemicals (GHS)* as adopted for industrial chemicals in Australia, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation should be in operation.

Disposal

- The notified chemical should be disposed of to landfill.

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.

- The following precautions should be taken regarding storage of the notified chemical:
  - Avoid exceeding the recommended storage and handling temperature
  - Monitor hydrogen sulphide levels where vapours may accumulate

Emergency procedures

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

Transport and Packaging

- The transport and packing of the notified chemical should be in accordance with State and Territory laws based on the requirements under the *Australian Code for the Transport of Dangerous goods by Road and Rail* (ADG Code) (NTC, 2007).

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(2) of the Act; if
  - the function or use of the chemical has changed from a component of bitumen for road paving, 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.

No additional secondary notification conditions are stipulated.

(Material) Safety Data Sheet
The (M)SDS of the notified chemical and products containing the notified chemical provided by the notifier were reviewed by NICNAS. The accuracy of the information on the (M)SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
The Shell Company of Australia Ltd (ABN: 46 004 610 459)
8 Redfern Road
HAWTHORN EAST VIC 3123

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

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Details of a reference are claimed exempt from publication.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed for all physicochemical and (eco)toxicological endpoints.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
Europe and Philippines

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Shell Bitumen 60/70 (contains ~7% notified chemical)
Shell Bitumen 60/100 (contains ~7% notified chemical)
Shell Multiphate 1000/320 (contains 4-5% notified chemical)
Shell Multiphate 600/170 (contains 4-5% notified chemical)
Shell Bitumen Class 600 (contains 4-5% notified chemical)
Shell Bitumen Class 170 (contains 4-5% notified chemical)
Shell Bitumen Class 320 (contains 4-5% notified chemical)
Shell Bitumen AR450 (contains 4-5% notified chemical)
Shell Bitumen HMB (contains 4-5% notified chemical)
Shell Bitumen Class 240 (contains 4-5% notified chemical)

CAS NUMBER
92062-05-0

CHEMICAL NAME
Residues (petroleum), thermal cracked vacuum

OTHER NAME(S)
Residues, thermal cracked vacuum
Vacuum flash bottoms
Vacuum flashed cracked residue

MOLECULAR FORMULA
Unspecified

STRUCTURAL FORMULA
Unspecified

MOLECULAR WEIGHT
Unspecified

ANALYTICAL DATA
Reference SIMDIS-GC and TLC-FID spectra were provided.

3. COMPOSITION

CHEMICAL COMPOSITION
The notified chemical is recognised as an Unknown or Variable compositions, Complex reaction products and Biological materials (UVCB) substance derived from the refining of crude oil (petroleum). It is a complex combination of hydrocarbons obtained from the vacuum distillation of the products from a thermal cracking process. It is made up mainly of hydrocarbons with a number of carbon atoms predominantly greater than C_{34} and a boiling point above ~495 °C. The composition of the crude petroleum may vary between oil fields and even within the same oil field (at different locations) and therefore the exact chemical composition of the notified chemical may vary. Further information about bitumen (asphalt) can be found in several literature sources (CICAD, 2004; HPV, 2006).

SIMDIS-GC analysis indicates that the notified chemical contains hydrocarbons covering the C_{21} to > C_{110} range corresponding with initial and final boiling points of 389 °C and > 750 °C respectively, with 90% of the hydrocarbons having a boiling point above 515 °C.

TLC-FID analysis shows the notified chemical contains 12.7% (m/m) saturates, 48.2% (m/m) aromatics, 18.6% (m/m) resins and 20.5% (m/m) asphaltenes.

DEGREE OF PURITY
100 %

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Black to dark brown solid.

Property	Value	Data Source/Justification
Softening Point	128 °C	CONCAWE, 2010
Boiling Point	> 350 °C at 101.3 kPa	(M)SDS
Density	973 kg/m^3 at 15 °C	CONCAWE, 2010
Vapour Pressure	Not determined	Expected to be << 0.1 kPa at 20 °C (CONCAWE, 2013)
Water Solubility	Not determined	Expected to have low solubility due to the hydrophobic structure of the notified chemical.
Hydrolysis as a Function of pH	Not determined	Does not contain hydrolysable functionalities and the notified chemical is not expected to be soluble in water.
Partition Coefficient (n-octanol/water)	log Pow ≥ 10.7 at 25 °C	Calculated for a representative structure (KOWWIN v1.68; US EPA, 2012).
Adsorption/Desorption	log K_{oc} ≥ 9.3 at 25 °C	Calculated for a representative structure (KOWWIN v2.00; US EPA, 20112).
Dissociation Constant	Not determined	Not expected to contain dissociable functionalities.
Particle Size	Not determined	The notified chemical is a high viscosity solid and will not be used in granular form.
Flash Point	> 220 °C (Pensky-Martens closed cup)	MSDS
Flammability	Not determined	Not expected to be flammable based on low vapour pressure
Autoignition Temperature	430 °C	(CONCAWE, 2010)
Explosive Properties	Not determined	Not considered explosive based on structural and oxygen balance

		considerations (CONCAWE, 2013).
Oxidising Properties	Not determined	Incapable of reacting exothermically with combustible materials based on chemical structure (CONCAWE, 2013).

DISCUSSION OF PROPERTIES

Reactivity
The notified chemical is stable under normal conditions of use. Heating above the maximum recommended storage and handling temperature will cause degradation and evolution of flammable vapours. The notified chemical reacts with strong oxidising agents. When in contact with water or liquids, molten notified chemical can cause violent eruptions, splatter hot material or ignite flammable material.

Incomplete combustion may produce a complex mixture of airborne solid and liquid particulates and gases (smoke) including hydrogen sulphide, carbon monoxide, sulphur oxides, sulphuric acid and unidentified organic and inorganic compounds.

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 for the Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will be imported into Australia as a component of Shell Bitumen 60/70 and Shell Bitumen 60/100 at a concentration of approximately 7%.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	8000-16000	8000-16000	8000-16000	8000-16000	8000-16000

PORT OF ENTRY
Brisbane and Sydney

IDENTITY OF MANUFACTURER/RECIPIENTS
Manufacturer: Shell Eastern Petroleum (Pet) Ltd (Singapore)
Recipient: The Shell Company of Australia Ltd

TRANSPORTATION AND PACKAGING
The products Shell Bitumen 60/70 and Shell Bitumen 60/100 containing the notified chemical at ~7% concentration will be imported as a hot liquid. The products will be directly received from the import vessel at the Brisbane port or Port Botany (Sydney) into the bulk storage tanks at Pinkenba (Brisbane) or Vopak (Sydney) via steel pipelines that are heated with hot oil tracing and insulated and will be stored as received. After local reformulation, the final products will be transported via road tankers of capacity ≥ 20 tonnes to end users.

USE
The notified chemical will be used as a component of bitumen for road paving.

OPERATION DESCRIPTION
Reformulation
The imported products Shell Bitumen 60/70 and Shell Bitumen 60/100 containing ~7% notified chemical will be transferred in steel pipelines to bulk storage tanks (ranging from 200 tonnes to ≥ 5000 tonnes) where will be blended with other materials to form new finished grade bitumen containing 4-5% notified chemical. The finished grade bitumen will be loaded into road tankers as a hot liquid via enclosed pipelines.

End-use
The finished grade bitumen will be mixed with other components to form asphalt which will be spread on roads by asphalt pavers. The manufacture, transport and placement of asphalt will be carried out in accordance with the accepted operational procedures on the Austroads asphalt guide (Austroads, 2007) or Australian Standard 2150-2005 (AS 2150-2005, 2005).

The notified chemical and products containing the notified chemical will not be sold to the public.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

Category of Worker	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Road paving contractor	10	300
Port operator (ship to shore discharge)	24	12
Distribution (transport)	10	300
Plant operator (storage and handling)	24	365

EXPOSURE DETAILS
Transport and storage
Transport and storage workers may come into contact with the notified chemical in heated form only in the event of accidental rupture of the connection points of enclosed pipelines and tanks. The exposure is expected to be further mitigated through the use of personal protective equipment (PPE) in accordance with appropriate standards for bitumen handling.

Reformulation
As reformulation will occur within enclosed tanks and transferred via enclosed pipelines, workers may come into contact with the notified chemical in heated form only in the event of accidental rupture of the connection points of pipelines and tanks. The exposure is expected to be further mitigated through the use of PPE in accordance with appropriate standards for bitumen handling.

Dermal, ocular and inhalation exposure of workers to the notified chemical (at up to 7% concentration) may occur during quality control and equipment maintenance. The exposure should be minimised through correct handling and the use of PPE in accordance with appropriate standards for bitumen handling.

End-use
At the end-use sites, dermal, ocular and inhalation exposure to the heated notified chemical (at up to 5% concentration) and fumes and mists generated by the notified chemical may occur. Several studies have been carried out to examine construction workers' exposure to bitumen (asphalt), many of which have been summarised in the CICAD document on asphalt (CICAD, 2004). The results of these studies are somewhat mixed.

Dermal, ocular and inhalation exposure is expected to be minimised through correct handling and the use of PPE in accordance with appropriate standards for bitumen handling.

Once the bitumen (asphalt) product containing the notified chemical is cooled down to the room temperature, the notified chemical will become a solid and will be strongly bound within a solid matrix together with other components of the asphalt product and on the road. The notified chemical bound to the paved roads will not be available for exposure under normal use conditions.

6.1.2. Public Exposure
The notified chemical will be handled by professional road paving workers and will not be sold to the public.

There is potential for the public to be exposed to fumes of the notified chemical during road paving. However, exposure is expected to be negligible given the low concentration (up to 5%) of the notified chemical in the finished grade bitumen, and the short duration and infrequent nature of any potential exposure.

Once the paved roads are ready for public use, the notified chemical will become a solid bound within the asphalt matrix and will not be available for exposure under normal use conditions.

6.2. Human Health Effects Assessment

No toxicological data was provided for the notified chemical. Information on the expected health effects of the notified chemical are therefore based on other bitumen analogue substances (i.e. petroleum vacuum residues (CAS No. 64741-56-6) and asphalt (CAS No. 8052-42-4)) due to their similarity in chemical composition and physicochemical properties (CONCAWE, 2013). Toxicological studies on bitumen fume condensates have also been considered for read-across, as appropriate, based on consideration of the endpoint and physicochemical properties of the substance. In some cases, fumes and fume condensates of oxidised asphalt (CAS No. 64742-93-4) have also been used to read-across to the notified chemical as the substance is similar in terms of the type and range of structures present in fumes of the notified chemical (CONCAWE, 2013). However, it is important to recognise that toxicity studies involving exposure to bitumen fumes represent only the volatile fraction of the whole material.

The results from toxicological investigations conducted on the bitumen substances and oxidised asphalt are summarised in the following table (CONCAWE, 2013).

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	LD50 > 5000 mg/kg bw; low toxicity
Rabbit, acute dermal toxicity	LD50 > 2000 mg/kg bw; low toxicity
Rat, acute inhalation toxicity	LC50 > 0.094 mg/L/4 hr
Skin irritation	non-irritating
Eye irritation	slightly irritating
Guinea pig, skin sensitisation – non-adjuvant test	no evidence of sensitisation
Rat, repeat dose dermal toxicity –28 days	NOAEL = 200 mg/kg bw/day (local); NOAEL = 2000 mg/kg bw/day (systemic)
Rat, repeat dose inhalation toxicity	28 day NOAEC = 0.03 mg/L; 2 year NOAEC (systemic) = 0.17 mg/L
Mutagenicity/Genotoxicity	evidence of mutagenicity/genotoxicity
Carcinogenicity	no evidence of carcinogenicity

Toxicokinetics, metabolism and distribution.

Mixtures do not lend themselves to kinetic analysis. The notified chemical is a complex mixture and therefore the properties and interactions of the individual constituents will influence its toxicokinetics, metabolism and distribution. Studies in kinetics, metabolism and distribution of some bitumen (asphalt) components have been summarised (CICAD, 2004; CONCAWE, 2013; IARC, 2013). These studies have shown some constituents, including polycyclic aromatic hydrocarbons (PAHs), can be absorbed through the skin and be taken up via the lungs. Dermal uptake was shown to be a function of viscosity and the bioavailability of neat bitumen is deemed to be negligible. Based on the data, the amounts of PAHs becoming available from the bitumen itself are too low to pose a carcinogenic hazard. Experiments also show that PAHs in condensed fume from bitumen are bioavailable when the condensate is directly applied to the skin. Studies in human volunteers showed that under rather extreme experimental conditions, the uptake through the skin of 3- and 4-ring PAH from fumes from bitumen could account for about half of the total exposure. Studies in workers, under normal conditions as they occur during paving, gave evidence of dermal absorption and subsequent systemic availability of 2- to 4-ring PAHs through the determination of urinary metabolites (CONCAWE, 2013).

Acute toxicity.

In two acute oral toxicity studies on two samples of petroleum vacuum residues (CAS No 64741-56-6) using a method similar to OECD TG 401, 5 male and 5 female rats (per study) were administered with 5000 mg/kg bw test substance by gavage. No mortalities were observed and the acute oral LD50 was reported as > 5000 mg/kg bw for both samples (CONCAWE, 2013). Based on the read-across data, the notified chemical is expected to be of low acute oral toxicity.

In two acute dermal toxicity studies on two samples of petroleum vacuum residues (CAS No 64741-56-6) using a method similar to OECD TG 402, 4 male and 4 female rabbits (per study) were treated under an occlusive

patch with 2000 mg/kg bw test substance for 24 hours. No toxicity was observed in the animals with intact skin or in the animals with abraded skin during the study period of 14 days. The acute dermal LD50 was reported as > 2000 mg/kg bw for both samples (CONCAWE, 2013). Based on the read-across data, the notified chemical is expected to be of low acute dermal toxicity.

In an acute inhalation toxicity study on fume (volatile fraction) from oxidised (air-rectified) asphalt using a method similar to OECD TG 403, 5 males and 5 females Wistar rats (per study) were exposed to the generated fume nose-only at a concentration of 94.4 ± 7.7 mg/m^3 for 4.5 hours (0.5 hours longer to achieve the desired exposure concentration during 4 hours). No clinical signs of toxicity and no effects on the reflexes tested were observed during the exposure and the subsequent observation period of 2 weeks. The toxic inhalation LC50 was reported as > 94.4 mg/m^3/4 h (CONCAWE, 2013).

Irritation and sensitisation.
In two primary skin irritation studies on two samples of petroleum vacuum residues (CAS No 64741-56-6), skin of 6 male white rabbits (per study) was treated with the test substance (occlusive conditions) for 24 hours (rather than 4 hours recommended by current OECD guidelines). The mean erythema and oedema scores for 24 and 72 hours for both samples ranged from 0 to 0.1 (CONCAWE, 2013). Based on the read-across data, the notified chemical is not expected to be irritating.

In two primary eye irritation studies on two samples of petroleum vacuum residues (CAS No 64741-56-6), the test substance was placed in eyes of 4 male and 4 female white rabbits (per study) for 30 seconds, with 3 of them being eye washed for 1 minute after application. The primary eye irritation scores indicated the test substance was only slightly irritating (CONCAWE, 2013). Based on the read-across data, the notified chemical is only expected to be slightly irritating to the eye.

In two skin sensitisation studies on two samples of petroleum vacuum residues (CAS No 64741-56-6) using a method similar to OECD TG 406, 10 male albino guinea pigs (per study) were tested using a closed patch technique (Buehler assay). Very slight erythema was observed in most animals during the induction phase and no erythema or oedema was observed in the challenge phase (CONCAWE, 2013). Based on the read-across data, the notified chemical is not expected to be sensitising.

Repeated Dose Toxicity.
No repeated dose toxicity via the oral route was provided; however, this endpoint is considered not appropriate since the main exposure routes in humans are dermal and inhalation.

In two 28-day dermal studies on two samples of petroleum vacuum residues (CAS No 64741-56-6), skin of 5 male and 5 female rabbits was treated with the test substance (occlusive conditions) at doses of 200, 1000 or 2000 mg/kg bw once per day, 3 days per week for 4 weeks. In both studies the NOAEL for local toxicity was established as 200 mg/kg bw/day based on skin irritation and the NOAEL for systemic effects was 2000 mg/kg bw/day (CONCAWE, 2013).

A combined repeated dose/reproductive/developmental screening test and a chronic inhalation study have been conducted with fumes of oxidised (air-rectified) asphalt (CONCAWE, 2013).

In a combined repeat dose/reproductive/developmental screening study, rats were exposed nose-only to roofing (oxidised) asphalt fume condensate at target concentrations of 30, 100 and 300 mg/m^3 total hydrocarbons, for 6 hours per day, 7 days per week. There were no treatment-related effects on clinical signs, mortality, neurological tests, haematology or clinical chemistry parameters. However, body weight gain and food consumption were significantly reduced in the high-dose males and increased relative lung weights were observed in females in the mid- and high-dose groups and in males in the high dose group only. The low dose 30 mg/m^3 was determined as the systemic NOAEC for the study, although it was noted the changes observed were in the absence of any associated histopathological findings (CONCAWE, 2013).

In a chronic inhalation study, 50 male and 50 female rats were exposed nose-only to fumes regenerated from the fume condensate at target concentrations of 0, 4, 20 and 100 mg/m^3 total hydrocarbon concentration for 6 hours per day, 5 days per week for 104 weeks. The NOAEC for systemic effects following inhalation was 100 mg/m^3 (172.5 mg/m^3 adjusted) based on the absence of any histopathological changes or alterations in clinical chemistry or haematology. The LOEC for local effects was 20 mg/m^3 (34.4 mg/m^3 adjusted), based on slight irritation effects in the nasal passages noted in the mid- and high-dose groups (CONCAWE, 2013).

Mutagenicity/Genotoxicity.
Genotoxicity studies of bitumen-fume samples have given mixed results that have been ascribed to the differing compositions of the bitumen samples used, the temperature at which fumes are generated, and experimental conditions used to collect fume condensates (IARC, 2013). Results of studies have included DNA-adduct formation, bacterial mutagenicity, DNA damage and chromosomal effects. Bitumen fume contains polycyclic aromatic hydrocarbons (PAHs) many of which are mutagenic and carcinogenic and have produced many of the same genotoxic activities as those reported for bitumen-fume condensates (IARC, 2013).

Carcinogenicity.
The International Agency for Research on Cancer (IARC) has recently evaluated the carcinogenic hazard to humans of bitumens and bitumen emissions (IARC, 2013). As a result of this review, oxidised asphalt (CAS No. 64742-93-4) has been classified as a Category 2A carcinogen (the agent is probably carcinogenic to humans) and petroleum vacuum residues (CAS No 64741-56-6) and asphalt (CAS No. 8052-42-4) have been classified as Category 2B carcinogens (the agent is possibly carcinogenic to humans). However, the notified chemical has not been classified as the only study available for the notified chemical (a skin-painting study in mice) was considered to be inadequate for the evaluation of carcinogenicity.

Given the similarity in chemical composition of the above bitumen substances to the notified chemical and the potential role of PAHs (common in all bitumen substances) in causing genotoxicity, the potential for carcinogenicity cannot be ruled out for the notified chemical.

Toxicity for reproduction.
No reproductive study on bitumen has been performed. However, some indication of the likely effect of a test substance on reproductive organs can be gained from the results of the repeated-dose toxicity studies where the weights and histopathology of reproductive organs were not affected following dermal exposure to bitumen at doses up to 2000 mg/kg (CONCAWE, 2013).

Degradation products
The notified chemical may decompose and release hydrogen sulphide (CAS No. 7783-06-4) when heated. Hydrogen sulphide is a colourless, flammable gas with a characteristic odour of rotten eggs and has a broad portfolio of effects on humans, many of which have been summarised in the CICAD document on hydrogen sulphide (CICAD, 2003). It is classified as R26 very toxic by inhalation.

Health hazard classification
Based on the available information, the notified chemical is not recommended for classification according to the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety
Based on the available information for other bitumen analogue substances, the notified chemical may pose a concern for carcinogenicity. The greatest concern is expected from exposure to fumes/mists of the notified chemical which contain PAHs, common to bitumen emissions, many of which are mutagenic and carcinogenic. The concentration and composition of PAHs in bitumen emissions varies according to application temperature (IARC, 2013). There is strong evidence that higher application temperatures are associated with higher exposures. The highest concentration of bitumen emissions have been measured during mastic-asphalt application and for roofers applying hot bitumen, while asphalt mixing plant workers and pavers are exposed to lower concentrations. The notified chemical is intended to be used in road paving equivalent to the lowest expected concentration of PAHs in bitumen emissions.

The greatest potential risk of exposure to fumes/mists of the notified chemical will be during road-paving as reformulation will be conducted using automated and enclosed systems. However, as the notified chemical is present at low concentrations (up to 5%) in the finished grade bitumen for use in road paving applications in outdoor areas, exposure to high concentrations of the notified chemical fumes/mists is expected to be negligible. Furthermore, the expected use of PPE to minimise exposure to the hot bitumen is also expected to further reduce exposure.

Although there is not an exposure standard for the notified chemical, there is a Safe Work Australia exposure standard of 5 mg/m^3 (time weighted average) for bitumen fumes for one of the bitumen analogue substances

with CAS No. 8052-42-4. Given the similarity in chemical composition in bitumen emissions, this exposure standard provides appropriate guidance for the notified chemical.

There is also the potential risk of exposure to the very toxic gas hydrogen sulphide formed from decomposition of the notified chemical. The levels of hydrogen sulphide should therefore be monitored and respiratory protection worn in places where hydrogen sulphide vapours may accumulate.

Overall, provided control measures are in place to limit exposure to fumes/mists of the notified chemical and its decomposition product hydrogen sulphide, the risk to the health of workers under the proposed use of the notified chemical is not considered unreasonable.

6.3.2. Public Health

The public may be exposed to fumes/mists of the notified chemical during road paving; however, exposure is expected to be negligible, largely due to the outdoor nature of the paving activities. Therefore, the risk to public health under the proposed use of the notified chemical is not considered unreasonable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified chemical will not be manufactured in Australia. Therefore, release of the notified chemical from this activity is not expected. However, the notified chemical will be reformulated in Australia. Significant release of the notified chemical to the environment is not expected during transport and storage. The reformulation of the notified chemical will be carried out in closed chambers. Therefore, spills of the notified chemical during reformulation are expected to be limited. Should a spill occur, it would be allowed to cool and solidify. The solid wastes are expected to be collected in clearly marked containers for disposal or reclamation in accordance with local regulations. Spills are expected to be prevented from spreading by making a barrier with sand, earth or other containment material.

RELEASE OF CHEMICAL FROM USE

No environmental release of the notified chemical is expected when used as a component of bitumen for road paving. Accidental spills are expected to be prevented from spreading by making a barrier with sand, earth or other containment material, for disposal in accordance with local regulations.

RELEASE OF CHEMICAL FROM DISPOSAL

No environmental release of the notified chemical is expected from disposal as once the bitumen product containing the notified chemical is cooled down to the room temperature, it is bound within a solid matrix. Solid wastes are expected to be disposed of in accordance with local regulations.

7.1.2. Environmental Fate

No environmental fate data were submitted. The majority of the notified chemical in bitumen (asphalt) product is expected to be strongly bound within a solid matrix together with other components of the product. Hence, in bituminous surfaces, the notified chemical is not expected to be bioavailable or biodegradable. With a high adsorption/desorption coefficient of log $K_{OC} \geq 9.3$, and high partition coefficient of log Pow ≥ 10.7, the notified chemical is expected to associate with organic matter, and is therefore considered highly immobile within the bitumen product. The notified chemical is not expected to be released to the aquatic environment according to the reported use pattern. The notified chemical in solid waste disposed of to landfill is expected to remain in situ and is expected to slowly degrade to form predominantly water and oxides of carbon.

7.1.3. Predicted Environmental Concentration (PEC)

The predicted environmental concentration (PEC) has not been calculated for the notified chemical as, based on its reported use pattern, ecotoxicologically significant quantities are not expected to be released to the aquatic environment.

7.2. Environmental Effects Assessment

No experimental data were submitted. The notified chemical is expected to have limited solubility and is not likely to be bioavailable based on its very high predicted log $K_{ow} \geq 10.7$. Therefore, no effects on aquatic biota

are predicted for the notified chemical at its water saturation concentration (ECOSAR (v1.00), US EPA, 2012). Classification should only be based on toxic responses observed in the soluble range and, therefore, the notified chemical cannot be formally classified under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) (United Nations, 2009).

7.2.1. Predicted No-Effect Concentration

A PNEC has not been calculated as the notified chemical is not expected to be bioavailable, based on its estimated log K_{ow} of $\geq$ 10.7, and is predicted to have no effect on aquatic biota at its water saturation concentration (ECOSAR (v1.00), US EPA, 2012).

7.3. Environmental Risk Assessment

A Risk Quotient (RQ = PEC/PNEC) is unable to be quantified as a PEC and PNEC were not calculated. Aquatic release of the notified chemical is not anticipated based on the reported use pattern. The notified chemical is also not expected to be bioavailable to aquatic organisms in surface waters based on its intrinsic hydrophobicity. On the basis of the assessed use pattern, the notified chemical is not expected to pose an unreasonable risk to the environment.

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