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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Liquitint Brilliant Orange

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FULL PUBLIC REPORT

Liquitint Brilliant Orange

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)

Walk Off Mats Asia Pacific P/L, ABN: 14 002 708 830

U7/95 O'Sullivan Beach Rd., Lonsdale

South Australia, 5160

and

Albright & Wilson, ABN: 36 004 234 137

22 Davis Rd, Wetherill Park, New South Wales, 2164

NOTIFICATION CATEGORY

Limited: Polymer with NAMW ≥ 1000 (greater than 1 tonne per year).

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication:

Chemical Name

Other Name

CAS Number

Molecular Formula

Structural Formula

Molecular Weight (NAMW and WAMW)

Spectral Data

Composition

Import Volume

Use Details

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Melting Point/Boiling Point

Specific Gravity/Density

Vapour Pressure

Flash Point

Flammability Limits

Autoignition Temperature.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

Yes

NOTIFICATION IN OTHER COUNTRIES

United States TSCA (1986), Korea (1999), China (2002), New Zealand (1998) and Brazil – Consumer (1999).

2. IDENTITY OF CHEMICAL

MARKETING NAME(S) Liquitint Brilliant Orange

3. COMPOSITION

DEGREE OF PURITY High

ADDITIVES/ADJUVANTS

None

4. INTRODUCTION AND USE INFORMATION

Mode of Introduction of Notified Polymer (100%) Over Next 5 Years

The notified chemical will be imported as a liquid (<60% notified chemical) by sea in 18 kg high-density polyethylene pails or 210 L drums.

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

| Year | 1 | 2 | 3 | 4 | 5 |
|--------|-----|-----|-----|-----|-----|
| Tonnes | < 1 | < 1 | < 1 | < 1 | < 1 |

USE

The notified chemical will be used as a colorant (<1% notified chemical) in industrial and household cleaners.

5. PROCESS AND RELEASE INFORMATION

5.1. Distribution, transport and storage

PORT OF ENTRY

Sydney, New South Wales or Melbourne, Victoria

IDENTITY OF RECIPIENTS

The product containing the notified chemical will be warehoused at site(s) located in Sydney New South Wales.

TRANSPORTATION AND PACKAGING

The imported liquid product Liquitint Brilliant Orange (<60% notified chemical) will be imported in 18 kg high density polyethylene pails or 210 L drums and transported by road to the warehouse(s) for storage until required. The end-use products (<1% notified chemical) will be typically transported in by road in 1-2 L plastic containers to retail outlets and industrial users Australia-wide.

5.2. Operation description

The notified chemical is not manufactured in Australia. Blending or packaging of the product containing the notified chemical occurs in Australia. Retail workers will handle the finished products containing the notified chemical.

Blending and packing

The 20 L pails or 210 L drums of liquid product containing the notified chemical (up to 60%) will be transported by forklift or manually as required from the warehouse to the production area. At the blending plant the imported liquid product containing the notified chemical is transferred manually from the drum to the blending tank. This is typically achieved by manually opening the drum and measuring out the product containing the notified chemical. In some operations this may occur by automated means whereby by the drum is lanced and the contents automatically transferred by transfer lines to the blending tank. During the blending process, the product containing the notified chemical is pumped automatically through to the blending tank (closed system) to formulate a variety of cleaning products that contains the notified chemical (<1%). The end-use products containing the notified chemical are characteristically packed by means of automated and enclosed filling systems into 1–2 L plastic containers.

5.3. Occupational exposure

Number and Category of Workers

| Category of Worker | Number | Exposure Duration | Exposure Frequency |
|--------------------------|---------|-------------------|--------------------|
| Transport | unknown | unknown | < once per week |
| Warehouse and Storage | 5 | 0.5 hour | once per week |
| Reformulation (Blending) | 10 | 8 hours per day | 50 days per year |
| Maintenance and Cleaning | 5 | < 8 hours per day | < 50 days per year |
| Ouality Control | 0 | 0 | 0 |

Exposure Details

Transport and warehousing

Transport, warehouse and stores personnel will wear protective equipment (overalls/ industrial clothing and gloves as appropriate) when receiving and handling consignments of the imported product containing the notified chemical (<60% notified chemical). The product will be handled in the warehouse by forklift handling of pails or drums or manual handling of individual packages. During transport and warehousing, workers are unlikely to be exposed to the notified chemical except when packaging is accidentally breached.

Blending and packing

The main routes of exposure to the notified chemical (<60% notified chemical) are dermal and accidental ocular exposure during manual measuring and transferring of the imported product) to the blending tank.

It is possible that dermal and accidental ocular exposure may also occur if manual intervention is required during the automated blending and packaging operations and if the packaging is accidentally breached. Maintenance workers will have intermittent dermal and the potential for accidental ocular exposure to the notified chemical when performing maintenance/cleaning of the equipment in general.

All workers involved in handling the imported product and blended product will wear personal protective equipment (PPE) such as safety glasses, safety boots, PVC/latex gloves, protective clothing, if necessary. The blending operations occur in a closed system under local exhaust ventilation (LVE). All production operators are trained in the appropriate operational procedures and precautions. All workers have access to the MSDS.

Once the formulated cleaning products are packaged for distribution, no further worker exposure is expected except when packaging is accidentally breached.

End-use

While the notifier gives no details, it is estimated that a large number of retail and cleaning workers may potentially be exposed to the notified chemical (<1%) by means of end-use cleaning products. Such exposure may include spray-cleaning products that have the potential to form aerosols. It is expected that use of the end-use products by cleaning workers would be similar (albeit more frequent) to the pattern of public exposure. The level of PPE used by cleaning workers is likely to vary and would include gloves in a number of cases.

Retail workers would only be exposed to the notified chemical (<1%) in the case of inadvertent breach of the packaging. In the event of an accident, spills will be removed in accordance with the manufacturers instructions.

5.4. Release

RELEASE OF CHEMICAL AT SITE

The notified chemical is manufactured overseas and will be imported and transported by road to the distributor(s). From here, it is then transported to the reformulation site, again by road. During the transport and handling operations, only accidental release through mishap is expected. Any spilt notified chemical is expected to be physically contained, collected and subsequently disposed of to secure landfill.

At the reformulation site, the notified chemical is removed from the import containers and held in a

storage tank. The import containers are then rinsed, with water and the rinsate will be emptied into the storage container, also. Rinsed import containers, with negligible residual notified chemical are then expected to be disposed of to secure landfill.

From the storage tank, the notified chemical is then fed into a closed mixer/blender and incorporated with other ingredients. From here it is subsequently bottled using an automatic filling machine. Release to the environment may occur at this time from the unlikely event of spills and from the routine cleaning and maintenance operations. Large spills are expected to be contained by standard physical engineering means, and collected using absorbent pads, which would then be disposed of to secure landfill. Small spills and releases from equipment cleaning and maintenance operations are expected to be disposed of to sewer as trade waste.

RELEASE OF CHEMICAL FROM USE

The notified chemical is proposed to be used primarily as a colourant in household and industrial cleaners. As such, it is expected that apart from the very small quantity that is disposed of to landfill, as residual in containers or from major spills, effectively the entire quantity of imported notified chemical will be disposed of after use to sewer.

5.5. Disposal

The major route for disposal of the notified chemical will be to the sewer after use. A very small proportion of the total imported quantity is expected to be disposed of to landfill, as residual in containers.

5.6. Public exposure

The notified chemical will be incorporated into household cleaning products at up to 1% that will be used widely by consumers. There is the potential for low level albeit regular dermal and accidental ocular contact by the public with the notified chemical during use of cleaning products. This may include products used in spray bottles leading to potential aerosol formation.

There could be incidental dermal exposure to detergent liquid itself through splashes or contamination of the outside of the packaging. Dermal exposure may also occur through inadvertent use of products to wash hands. Inhalation exposure is considered unlikely either from the cleaning products or from water containing it as the notified chemical has low volatility and aerosols are unlikely to form due to the typical high viscosity of the intended cleaning products.

Oral exposure could occur from residues of the cleaning products if used to wash food containers and utensils and if these articles are not rinsed after washing. It is expected that residues would be low, and transfer to ingested food would be even lower. Accidental oral exposure of young children to cleaning products is also possible.

It is expected that some consumers would wear gloves for certain cleaning tasks while others would not. However, exposure to the notified chemical will be minimized by the low concentration (<1%) of the notified chemical in the consumer products.

The public would only be exposed to concentrations up to 60% notified chemical in the event of an accident during transport involving extensive breakage of the imported product.

6. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa

Dark red liquid with a faint vinegar-like odour

Freezing Point -7°C

METHOD In-house procedure.

Remarks None

TEST FACILITY Milliken Chemical (1999)

Boiling Point >100°C at 101.3 kPa

METHOD In-house procedure.

Remarks None

TEST FACILITY Milliken Chemical (1999)

Density $1.02 \text{ kg/m}^3 \text{ at } 20 \text{ }^{\circ}\text{C}$

METHOD In-house procedure.

Remarks None.

TEST FACILITY Milliken Chemical (1999)

Vapour Pressure This has not been measured for the notified chemical, but it

is expected to be very low due to the chemicals relatively

high molecular weight.

Remarks Test not conducted.

Water Solubility The polymer is completely soluble in water

No test result has been provided, but product (up to 60% notified chemical) is imported as an aqueous solution. The notifier provided a modelled result using WKSOW v1.41 using a log $K_{OW} = -4.54$, giving a water solubility of 14.78 mg/L, with the estimate using fragments being 1 x 10^6 mg/L. Further modelling done by the Department of the Environment and Heritage, using the experimental log Pow

the Department of the Environment and Heritage, using the experimental log Pow = 1.322, as reported below, and using Kenaga and Goring's regression equation (log S = -0.922 log Kow + 4.184) in Lyman *et al* (1990), results in a water solubility of 24465 mg/L, indicating high variability in model results, possibly due

to surfactant properties.

Hydrolysis as a Function of pH

Remarks

METHOD OECD TG 111 Hydrolysis as a Function of pH.

| рН | $T(\mathcal{C})$ | t _½ days |
|----|------------------|--------------------------|
| 4 | 50 | <10% hydrolysis observed |
| 7 | 50 | <10% hydrolysis observed |
| 9 | 50 | <10% hydrolysis observed |

Remarks Preliminary test performed at 50°C for 6 days showed less than 10% hydrolysis

thus no further studies were conducted.

TEST FACILITY Milliken Chemical (1997a)

Partition Coefficient (n-octanol/water) Pow = 21.0 at 20°C, log Pow = 1.322 at 20°C

METHOD ASTM TG E1147-92, under the guidance and conditions of OECD TG 117

Remarks Analytical Method. Detector used for HPLC was a Waters 996 Photodiode Array.

The notified chemical eluted before the six reference chemicals.

TEST FACILITY Milliken Chemical (1997b)

Adsorption/Desorption $\log K_{oc} = 8.059$ (Estimated)

METHOD Estimated using QSAR. This value should be treated with great caution as it is

based on an estimated log P_{OW} = -4.54. Further modelling done by the Department of the Environment and Heritage, using the experimental log Pow = 1.322, as reported below, and using Kenaga and Goring's regression equation (log K_{OC} = 0.544 log K_{OW} + 1.3477) in Lyman *et al* (1990), results in a log K_{OC} = 2.096, indicating high variability in model results, possibly due to surfactant properties.

TEST FACILITY PCKOWIN V1.66 US EPA.

Dissociation ConstantNot expected to dissociate throughout the environmental pH range of 4-9.

Remarks Based on the closely related polymer submitted by the notifier as PLC/588 with a

measured pKa = 2.48.

Particle Size

Remarks Test not conducted. The notified chemical is a liquid.

Flash Point >200°C at 101.3 kPa

METHOD EC Directive 92/69/EEC A.9 Flash Point.

Remarks None

TEST FACILITY Milliken Chemical (1999)

Flammability Limits

Remarks Test not conducted. The notified chemical is imported only as an aqueous

solution.

Autoignition Temperature

Remarks Test not conducted. The notified chemical is imported only as an aqueous

solution.

Explosive Properties

Remarks Test not conducted. There are no chemical groups that would infer explosive

properties. Hence the result has been predicted negative by expert determination.

Reactivity

The notified chemical is stable under normal conditions of use

Remarks None

7. TOXICOLOGICAL INVESTIGATIONS

| Endpoint and Result | Assessment Conclusion |
|---|-----------------------|
| Rat, acute oral LD50 >5000 mg/kg bw | low toxicity |
| Rabbit, skin irritation | non-irritating |
| Genotoxicity – bacterial reverse mutation | non mutagenic |

7.1. Acute toxicity – oral

TEST SUBSTANCE Liquitint Brilliant Orange

METHOD Unspecified. An acute oral toxicity dose range finding and a single dose

study.

Species/Strain Rat/ Sprague-Dawley Vehicle Distilled water

Remarks - Method Statement of GLP. No protocol deviations reported.

Each animal was observed for signs of toxic and pharmacologic effects. In the dose range finding study, the animals were observed at 1, 2, 4, 24 and 48 hours post dose (oral gavage). Body weights were taken at initiation. In the single dose study, the animals were observed at 1, 2 and 4 hours post dose and once daily thereafter for 14 days. Body weights were taken prior to test material administration, on Day 7 and at death or termination. Mortality/moribundity was recorded twice daily. No pathology was undertaken in the dose range finding study. Necropsies

were performed on all Single Dose Study animals.

RESULTS

| Group | Number and Sex | Dose | Mortality |
|------------------|----------------|----------|-----------|
| | of Animals | mg/kg bw | |
| Dose Range Study | | | |
| I | 1 per sex | 500 | 0/2 |

| II | 1 per sex | 1000 | 0/2 |
|-------------------|-----------------------|----------------------------------|-----------------------------|
| III | 1 per sex | 1500 | 0/2 |
| IV | 1 per sex | 2500 | 0/2 |
| V | 1 per sex | 5000 | 0/2 |
| Single Dose Study | • | | |
| | 5 per sex | 5000 | 0/10 |
| 1070 | 7 000 // 1 | | |
| LD50 | >5000 mg/kg bw | | |
| Signs of Toxicity | | ived in the dose range | |
| | observations consis | sted of soft faeces, urine stair | ns and compound coloured |
| | faeces at the 1, 2 ar | nd 4 hour post dose period. | All findings cleared by the |
| | 24-hour interval an | d all remaining animals appe | eared normal. All animals |
| | | hroughout the single Dose | |
| | | ermination. No observable g | |
| | in any of the anima | - | gross pathology was noted |
| Eff4- :- O | • | is upon necropsy. | |
| Effects in Organs | nil | | |
| Remarks - Results | nil | | |
| | | | |

7.4. Irritation – skin

CONCLUSION

TEST FACILITY

TEST SUBSTANCE Liquitint Brilliant Orange

METHOD United States Environmental Protection Agency Guidelines for Federal

Insecticide Fungicide Rodenticide Act (FIFRA) and Toxic Substances Control Act (TSCA, Environmental Protection Agency No 158. 81-5

The notified chemical is of low toxicity via the oral route.

Acute dermal irritation.

Milliken Chemical (1986a)

Species/Strain Rabbit/New Zealand White

Number of Animals
Vehicle
Observation Period
Type of Dressing
Ogenstation
3 per sex
nil
72 h
Occlusive

Remarks - Method Statement of GLP. No protocol deviations reported.

RESULTS

| Lesion | | an Sco nimal N | - | Maximum Value | Maximum Duration of Any Effect | Maximum Value at End of Observation Period |
|-----------------|---|-------------------|---|------------------|--------------------------------|--|
| | 1 | 2 | 3 | | | |
| Erythema/Eschar | 0 | 0 | 0 | 0 | _ | 0 |
| Oedema | 0 | 0 | 0 | 0 | _ | 0 |

^{*}Calculated on the basis of the scores at 24, 48, and 72 hours for EACH animal.

sites during the study.

CONCLUSION The notified chemical is non-irritating to the skin.

TEST FACILITY Milliken Chemical (1986b)

7.8. Genotoxicity – bacteria

TEST SUBSTANCE Liquitint Brilliant Orange

METHOD OECD TG 471 Bacterial Reverse Mutation Test.

EC Directive 2000/32/EC B.13/14 Mutagenicity - Reverse Mutation Test

using Bacteria.

Plate incorporation procedure

Species/Strain Metabolic Activation System

Concentration Range in

Main Test Vehicle

Remarks - Method

S. typhimurium: TA1535, TA1537, TA98, TA100, TA012

S9 fraction from phenobarbitone and $\beta\mbox{-naphthoflavone}$ induced rat liver

a) With metabolic activation: 50-5000 μg/plate

b) Without metabolic activation: 50-5000 μg/plate

Sterile distilled water

Statement of GLP. No protocol deviations reported.

RESULTS

| Metabolic | Test | Test Substance Concentration (µg/ | ion (μg/plate) Resultii | ng in: |
|------------|------------------|-----------------------------------|-------------------------|------------------|
| Activation | Cytotoxicity in | Cytotoxicity in | Precipitation | Genotoxic Effect |
| | Preliminary Test | Main Test | • | |
| Absent | · | | | |
| Test 1 | >5000 | >5000 | >5000 | Negative |
| Test 2 | >5000 | >5000 | >5000 | Negative |
| Present | | | | Negative |
| Test 1 | >5000 | >5000 | >5000 | Negative |
| Test 2 | >5000 | >5000 | >5000 | Negative |

Remarks - Results

The vehicle control plates gave counts of revertant colonies generally within the normal range. All of the positive control chemicals used in the test induced marked increases in the frequency of the revertant colonies, both with and without metabolic activation. Thus, the sensitivity of the assay and the efficacy of the S-9 mix were validated.

The test material caused no visible reduction in the growth of the bacterial background lawn at any dose level. The test material, therefore, was tested up to a maximum does level of $5000~\mu g/plate$. An orange colour was observed at and above $50~\mu g/plate$, however, this did not prevent the scoring of revertant colonies. No test material precipitate was observed on the plates at any dose treated in either the presence or absence of the S-9 mix. No significant increases in the frequency of revertant colonies were recorded for any of the bacterial strains with any dose of the test material either with or without metabolic activation.

CONCLUSION

The notified chemical was not mutagenic to bacteria under the conditions of the test.

8. ENVIRONMENT

8.1. Environmental fate

No environmental fate data were submitted. It is assumed that the notified chemical will not be readily biodegradable.

8.2. Ecotoxicological investigations

Only modelled ecotoxicity data were provided, based on a less-soluble analogue, using the "Neutral Organics" model of ECOSAR v 0.99g and an estimated log $K_{\rm OW}=0.40$. The Department of the Environment and Heritage attempted to model the notified chemical using ECOSAR and log $K_{\rm OW}=-4.54$, however only one test result (chronic fish 14 d LC50 = 8.4×10^8 mg/L) was given due to possible surfactant properties.

| Endpoint and Result | Assessment Conclusion |
|---|-----------------------|
| Fish 96 h LC50 = 11038 mg/L | Very Slightly toxic. |
| Daphnid 48 h LC $50 = 10590 \text{ mg/L}$ | Very Slightly toxic. |
| Green Algae 96 h EC50 = 6038 mg/L | Very Slightly toxic. |

9. RISK ASSESSMENT

9.1. Environment

9.1.1. Environment – exposure assessment

The notified chemical will be imported then reformulated with other ingredients to form household and industrial cleaners, of which the notified chemical is a colourant. Nearly all of the notified chemical will be disposed of to sewer after use, with only small quantities, including that proportion remaining as residual in containers and from major spills, being disposed of to landfill.

In sewer, some of the notified chemical is expected to associate with suspended particles and sediment. In landfill, the notified chemical is not expected to be mobile and should adsorb to sediment, where over time it should slowly degrade through biotic and abiotic processes to simple carbon and nitrogen-based compounds.

Based on the worst-case scenario of 100% notified chemical being released to the aquatic environment via the sewer, with nil removal, a predicted environmental concentrations (PECs) of the notified chemical have been calculated:

Amount entering sewer per year Number of days per year 365
National population 20.1 million
Litres per person 200 L
PEC_{River} 0.682 µg/L.
PEC_{Ocean} 0.068 µg/L.

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be $1000~L/m^2/year$ (10~ML/ha/yr). The notified chemical in this volume is assumed to infiltrate and accumulate in the top 0.1~m of soil (density $1000~kg/m^3$). Using these assumptions, irrigation with a concentration of $0.682~\mu g/L$ may potentially result in a soil concentration of approximately $6.82~\mu g/kg$. Assuming accumulation of the notified chemical in soil for 5 and 10 years under repeated irrigation, the concentration of notified chemical in the applied soil in 5 and 10 years may be approximately 0.03~and~0.07~mg/kg respectively.

The potential for the notified chemical to bioaccumulate is low due to its high level of water solubility and will be limited due to the diffused release to sewer Australia wide.

9.1.2. Environment – effects assessment

The results of the modelled ecotoxicological studies based on an analogue indicate that the notified chemical is only slightly toxic to aquatic organisms. A PNEC has therefore, been calculated based on the green algae modelled end point (6038 mg/L) using a safety factor of 1000 due to modelled data for an analogue and so resulting in PNEC 6038 μ g/L.

9.1.3. Environment – risk characterisation

The Risk quotient (RQ) values, where RQ = PEC/PNEC, for freshwater and marine receiving environments have been calculated for the "worst case" scenario, as shown in the table below.

| Worst Case: PNEC & 0% Removal | PEC | PNEC | RQ |
|-------------------------------|-----------------|----------------|-------------------------|
| River | 0.682 μg/L | 6038 μg/L | 1.13 X 10 ⁻⁴ |
| Marine | $0.068 \mu g/L$ | $6038 \mu g/L$ | 1.13 X 10 ⁻⁵ |

As the RQ for both river and marine receiving waters are significantly below 1.0, the proposed diffuse use of the notified chemical at current expected import volumes is unlikely to pose an unacceptable risk to the aquatic environment.

9.2. Human health

9.2.1. Occupational health and safety – exposure assessment

Skin contact will be the main route of exposure although eye contact by means of inadvertent splashes is also possible. Given the molecular weight range of the notified chemical, absorption through intact skin is not expected to be significant. The notified chemical is a non-volatile polymeric liquid consequently inhalation exposure is not expected.

Transport, Warehouse and Storage

The notified chemical is imported as a solution (<60% notified chemical) in high-density polyethylene pails and steel drums and is warehoused at distributor(s) prior to supply to manufacturer(s) as required. Consequently, exposure to the notified chemical (<60% notified chemical) is not expected during transport, warehousing and storage provided the pails and drums containing the imported product remain intact.

Blending and packaging

Due to the largely automated, controlled and enclosed nature of the blending and packaging process, minimal occupational exposure to the notified chemical (at a concentration up to 60%) is expected. However, dermal and accidental ocular exposure to the notified chemical could occur from inadvertent drips, splashes and spills during the manual addition of the imported product to the automated blending machine at a concentration up to 60% or via incidental leaks from the blending and packaging machine transfer hoses, fittings, and/or pumps (at a concentration less than 1%). Inhalation exposure is expected to be low given the predicted low vapour pressure for the notified chemical.

Potential exposure during blending and packaging operations will be of short duration and will not occur on a daily basis. Such exposure is further limited by the use of PPE such as latex gloves, safety glasses, helmet and safety boots. All workers will undergo routine education training in chemical handling and have access to the Material Safety Data Sheet (MSDS).

End-use

Retail workers are unlikely to be exposed to the notified chemical (<1%) provided the end-use plastic containers containing the end-use products remain intact. In the event of an accident, spills will be removed in accordance with the manufacturers instructions.

Cleaning workers will be potentially exposed daily to the notified chemical however such exposure will be limited by the low level of the notified chemical (<1%) in the products and the use of gloves as required.

Overall, on the basis of the engineering controls, industrial hygiene, safe work practices and personal protective equipment (and low concentration of the notified chemical in the end-use product), occupational exposure to the notified chemical is determined to be low.

9.2.2. Public health – exposure assessment

The notified chemical will be available to the public by means of household cleaning products – including by way of spray applications. The public will be exposed potentially daily to <1% notified chemical during household cleaning tasks.

While members of the public will make dermal contact and possibly accidental ocular and inhalation (by means of spray applications) contact, such exposure is assessed as low. This is on the basis that the notified chemical is present at low concentrations in the end-use product (<1% notified chemical) and will typically be contained in high viscosity household cleaning products (that limit potential inhalation exposure). In addition, given the molecular weight of the notified chemical, absorption through intact skin is not expected.

Overall, public exposure to the notified chemical is determined to be low.

9.2.3. Human health – effects assessment

Toxicological data for the notified chemical for the following health end points were submitted:

• Acute toxicity.

- Irritation
- Mutagenicity

An acute oral toxicity study in the rat indicated the notified chemical is of low toxicity via the oral route. A primary dermal irritation test in rabbits showed the notified chemical is non-irritating to skin with no erythema, oedema or other dermal effects noted at any of the test sites during the study. A reverse mutation test in *Salmonella typhimurium* (*in vitro*) indicated the notified chemical was not mutagenic to bacteria under the conditions of the test. While no skin irritation data was submitted, the notifier advises that the notified chemical may cause slight eye irritation however no hazard is expected in normal industrial use.

Based on the available data, the notified chemical is not classified as a hazardous substance in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC 2004).

9.2.4. Occupational health and safety – risk characterisation

Dermal contact will be the main route of exposure with the potential for accidental ocular exposure. The notified chemical is unlikely to be acutely toxic, irritating or genotoxic. The imported and end-use products are not classified hazardous on the basis of the content of the notified chemical which is up to 60% and <1% of the imported and end-use products, respectively.

Blending and packaging

The OHS risk presented by the notified chemical is expected to be low, given the automated process and engineering controls implemented at blending and packaging facilities, the industrial hygiene, good work practices and safety measures including use of appropriate personal protective equipment by workers. Moreover, the notified chemical will be used at blending and packaging sites where operatives are familiar in using such products and good handling procedures and good housekeeping is the norm and workers wear personal protective equipment.

End Use

Large numbers of retail and cleaning workers will be potentially exposed on a regular basis to cleaning products containing very low levels of notified chemical. However, dermal exposure will be limited by the very low level of the notified chemical (<1%) in the products. In addition, industrial users will typically wear as required impervious gloves and protective clothing to minimise skin contact, if required.

Risk from repeated exposure is considered to be low given the molecular weight of the notified chemical is such that absorption through intact skin is not expected to be significant. While the vapour pressure of the notified chemical is predicted to be low and consequently risk of inhalation exposure is expected to be low, inhalation by means of spray-cleaners cannot be discounted. However, the risk of such exposure is assessed as low due to the low concentration of the notified chemical in the end-use products.

The notified chemical may be present in formulations containing hazardous ingredients. If these formulations are classified as hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances*, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

The adverse health risk for workers handling the notified chemical is assessed as low under the current circumstances.

9.2.5. Public health – risk characterisation

There will be no significant public exposure to the notified chemical given the low concentration of the notified chemical in the household cleaning products (<1%). Given the typical viscous nature of the spray cleaning products (combined with the low concentrations of the notified chemical used therein), the risk to public health from inhalation exposure to the notified chemical is considered low. Consequently, there is unlikely to be any significant public health

risk posed by the notified chemical.

There is a very slight chance of ingestion of the notified chemical due to accidental ingestion of household cleaning products. As a worst-case scenario, a 10 kg child ingesting 5 mL of a liquid formulation containing 1% v/v notified chemical would receive a dose of approximately no more than 0.05 mg/kg bw which is significantly below the lethal dose (LD₅₀ > 2000 mg/kg). The notified chemical has a low acute oral toxicity and the quantities consumed would be minimal, so the notified chemical is unlikely to pose a significant risk to human health.

Therefore, based on the very low concentration and hence low potential for exposure, the risk to public health from exposure to the notified chemical is considered low.

10. CONCLUSIONS – ASSESSMENT LEVEL OF CONCERN FOR THE ENVIRONMENT AND HUMANS

10.1. Hazard classification

Based on the available data the notified chemical is not classified as hazardous under the NOHSC Approved Criteria for Classifying Hazardous Substances.

As a comparison only, the classification of 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 |
|----------------|-----------------|-----------------------------|
| Acute toxicity | 5 | May be harmful if swallowed |

10.2. Environmental risk assessment

On the basis of the PEC/PNEC ratio the chemical is not considered to pose a risk to the environment based on its reported use pattern and volume.

10.3. Human health risk assessment

10.3.1. Occupational health and safety

There is Low Concern to occupational health and safety under the conditions of the occupational settings described.

10.3.2. Public health

There is No Significant Concern to public health when used in household cleaning products as described.

11. MATERIAL SAFETY DATA SHEET

11.1. Material Safety Data Sheet

The MSDS of the notified chemical provided by the notifier was in accordance with the NOHSC National Code of Practice for the Preparation of Material Safety Data Sheets (NOHSC 2003). It is published here as a matter of public record. The accuracy of the information on the MSDS remains the responsibility of the applicant.

11.2. Label

The label for the notified chemical provided by the notifier was in accordance with the NOHSC *National Code of Practice for the Labelling of Workplace Substances* (NOHSC 1994). The accuracy of the information on the label remains the responsibility of the applicant.

12. RECOMMENDATIONS

CONTROL MEASURES

Occupational Health and Safety

- Employers should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the notified chemical as introduced:
 - Wear suitable protective clothing
 - Wear suitable gloves
 - Wear safety glasses

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 NOHSC *Approved Criteria for Classifying Hazardous Substances*, workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Public Health

- The following measures should be taken by consumers to minimise public exposure to the notified chemical in spray applications:
 - Do not breathe spray

Disposal

• The notified chemical should be disposed of to landfill.

Emergency procedures

• Spills/release of the notified chemical should be handled by physical containment, collection and subsequent disposal to landfill.

12.1. Secondary notification

The Director of Chemicals Notification and Assessment 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, then a full set of aquatic toxicity data should be provided, given the uncertainty with modelled physico-chemical results;
 - a change in the manufacturing process or purity of the notified chemical
 - health and/or environmental data becomes available on potential degradation products

or

- (2) Under Section 64(2) of the Act:
 - if any of the circumstances listed in the subsection arise.

The Director will then decide whether secondary notification is required.

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