

23 April 2020

**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION
AND ASSESSMENT SCHEME**

FULL PUBLIC REPORT

DESMORAPID Trial Product PU 59IF05

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT**DESMORAPID Trial Product PU 59IF05****1. APPLICANT**

Thermoformable Foam Australia Pty Ltd of 12 Brand Drive THOMASTOWN, VIC 3074 (ACN 077 849 720) has submitted a **limited** notification statement in support of their application for an assessment certificate for DESMORAPID Trial Product PU 59IF05.

2. IDENTITY OF THE CHEMICAL

The chemical name, CAS number, molecular and structural formulae, molecular weight, spectral data and details of the chemical composition have been exempted from publication in the Full Public Report and the Summary Report.

Marketing name: DESMORAPID Trial Product PU 59IF05

Imported product:
BAYNAT Trial Product PU 80IF04

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C & 101.3 kPa: Colourless to yellowish liquid with an amine-like odour.

Melting Point/Boiling Point: 190°C.

Specific Gravity/Density: 1.04 g/cm³.

Vapour Pressure: 0.3 kPa at 20°C.
1.1 kPa at 50°C.

Water Solubility: Not miscible in water. Solubility calculated to be 0.036 g/L using ACD software.

Partition Co-efficient (n-octanol/water): Log P_{ow} = 4.32 ± 0.73 (Calculated using ACD software).

Hydrolysis as a Function of pH: The chemical contains ester groups, which may undergo hydrolysis under extreme conditions.

Adsorption/Desorption:	$K_{oc} = 5\ 315$ (Calculated using ACD software).
Particle size:	Not relevant as the chemical is introduced as a liquid.
Dissociation Constant:	The typical range of pK_a for the following components of the notified chemical calculated using the ACD software are as follows: tertiary aminium ion 9.0-11.0 alkenyl (alkyl) aminium ion 6.0-10.0 alcohols 13.0-16.0.
Flash Point:	173°C.
Flammability Limits:	Not flammable.
Autoignition Temperature:	370°C.
Explosive Properties:	Not explosive.
Reactivity/Stability:	Stable under normal conditions of use.

3.1 Comments on Physico-Chemical Properties

Test reports were not provided with the submission.

The water solubility of the chemical calculated as 0.036 g/L by ACD software (based on the calculated value of $\log P_{OW}$ where $n=3$) seems low considering that the notifier indicates that the notified chemical has high polarity and the presence of amino groups which are likely to be charged in water, and the large number of polar oxygens, suggests that the notified chemical should be soluble.

Hydrolysis as a function of pH was not determined. The notifier notes that the chemical contains ester groups that may undergo hydrolysis under extreme conditions. In addition, the chemical contains an enamine/imine tautomer. This functionality is known to undergo hydrolysis in aqueous acid or base, regenerating the parent ketone and amine. However, it is not known to what extent hydrolysis would occur in the environmental pH range of 4 to 9 and would depend in part on the actual water solubility.

The $\log P_{OW}$ was estimated using ACD software. The value obtained seems high given the expected polarity of the molecule.

Adsorption/desorption was estimated from ACD software using the estimated value of $\log P_{OW}$. The value obtained indicates that the chemical should not be mobile in soils, but again there is uncertainty as to how this substance would behave in the environment, as there is no measured water solubility.

The dissociation constants for the main components of the chemical were estimated using ACD software. The values obtained are not relevant because they are textbook values for those functionalities rather than representing any unique properties of the notified chemical.

Additionally, the dissociation constant value for the alkenyl aminium ion is not necessarily representative of the enamine functionality.

The results calculated from ACD software have not been substantiated by reference to published data from similar compounds; hence the results obtained are questionable. The calculations were conducted on an uncharged species, not taking into account the likely effect of environmental conditions on the molecule. Quateranisation of the amino functionality would render the molecule more water-soluble. Additionally, the calculations were conducted using $n=3$ while the molecular weight information provided suggests that $n=1$.

4. PURITY OF THE CHEMICAL

High purity. Contains some hazardous impurities and adjuvants, but all are below their cut-off concentrations.

5. USE, VOLUME AND FORMULATION

The notified chemical acts as a catalyst in the reaction between polyols and diisocyanates to form polyurethanes. It will be used in the production of semi-rigid thermoformable polyurethane foams. These foams will be used as internal headliners in car roofs.

The notified chemical will be imported into Australia in liquid form as a constituent (1 to <5%) of a product, Baynat Trial Product PU 80IF04 in 180 kg drums. The notifier has estimated that about 1000 kg/year of the notified chemical will be imported in the next five years. The imported product will be used directly in foam production.

6. OCCUPATIONAL EXPOSURE

Transport and storage

The imported product contained in 180 kg drums will be unloaded at the docks and transported by trucks to a warehouse where it will be stored until required. From the warehouse, the product drums on wooden pallets will be transported by road to the notifier's production site. Waterside workers, transport drivers and warehouse personnel (5-10 workers) will handle the packed product (2-3 hours/day, 10-20 days/year) and would only be exposed to the notified chemical if packaging were breached.

Foam manufacture

At the production site, plant operators will open the drum caps and add a measured amount of a pigment to the viscous liquid. Mixing is achieved by inserting a variable speed impeller into the drums. Exposure due to splashing during mixing is prevented by covering the drum opening with a lid. It is unlikely that workers will be exposed to the notified chemical during this procedure. Two to five workers will handle the product containing the notified chemical for 3 hours/day, 220-240 days/year. The notifier states that the area where the pigment is added to and mixed with the imported product is subject to general ventilation. Workers wear safety glasses, gloves and a half-face respirator.

Drums are then wheeled to the foaming machine and the liquid from the drums is transferred

to the foaming machine using an air pump via a 1.5 m length of pipe. Dermal exposure to the notified chemical is possible when attaching the tubing to the drums. The foaming machine combines the mixture containing the notified chemical with methylene bisphenyl isocyanate (MDI) stored in a tank attached to the foaming machine. The mixture is then immediately discharged into a mould through a pouring tube. The concentration of the notified chemical in the final mixture is around 0.7%.

The foaming machine is a closed system and vapour pressure of the notified chemical is low. Hence inhalation exposure is not likely. Splashing could occur during pouring of the mixture into the mould. However, the pourer is positioned 75 mm above the floor of the mould and the foaming machine discharges the viscous mixture under low pressure. This is expected to minimise splashing. The foaming machine is subject to local exhaust ventilation with two movable hoods.

After 30 minutes in the mould, the foam solidifies and is partially cured. It is then dragged out on to a pallet, labelled and stored on a rack for three days to complete the curing process. Workers involved in this process may be subjected to dermal exposure to the notified chemical in the partially cured foam. During the pouring operation and while removing the foam from the mould, the workers wear safety glasses, gloves and a half-face respirator.

The cured foam is then sized to customer-required dimensions using a bandsaw and a horizontal slicer. Workers may be exposed to the product dust generated during cutting the cured blocks. Workers wear safety glasses, a dust mask and hearing protection whilst sizing the foam blocks.

End-use

At the customer site for car manufacture, the foam will be sealed behind the velure, heat pressed onto a sheet of foam and used in headliner of car roofs. As the notified chemical is cured in the foam, no exposure occurs during this process.

7. PUBLIC EXPOSURE

The imported product containing the notified chemical will not be sold to the general public and will only be used at industrial sites. The notified chemical will be fully reacted and cured during the foam production process. The foam will be sealed behind the velure on the headliner of car roofs. Hence, the general public will not come into contact with the notified chemical.

8. ENVIRONMENTAL EXPOSURE

8.1 Release

The imported product is transported and stored in 180 L drums in a temperature-controlled environment. The only mechanism for release is through accidental spills. Spills from drums at the storage warehouse will be contained by bunding. At the industrial site, the product is

stored away from exits and in the event of a spill, will be contained with absorbent material. The application states that the spill residues will be disposed of to landfill while the material safety data sheet (MSDS) supplied recommends disposal by incineration. It is estimated that up to 20 L per annum of the imported material might be lost this way (0.4 L of the notified chemical per annum).

There is potential for release of the notified chemical during foam production. Following every pour, the foaming machine head and pouring tube are rinsed with dichloromethane and the rinsate collected. Empty import drums are rinsed with dichloromethane and collected by drum recyclers. Drum rinsate is placed in a drum containing the washings from the foaming machine and empty MDI drums. The solvent is allowed to evaporate and the solid (foam) residue remaining is disposed to landfill.

Foam residues are generated during resizing of the final product. Foam trimmings are disposed to landfill. Total solid waste is estimated to account for 20% of production volume i.e. 200 kg per annum of the notified chemical.

There should be no release to sewers.

8.2 Fate

Any spills of the product containing the notified polymer will be collected with absorbent material and disposed either to landfill or by incineration. The fate of the uncured chemical in landfill is unknown. Due to the polarity of the chemical, it may be mobile. However, estimates of the physico-chemical properties provided by the notifier suggest that the chemical may partition to soils and sediments. The notified chemical contains an enamine/imine functionality, which may readily hydrolyse under some environmental conditions, although the extent of the possible hydrolysis is not known. Hydrolysis of the notified chemical will regenerate the parent chemical and an amino species. When incinerated, it is anticipated that the notified chemical will form water vapour and oxides of carbon and nitrogen.

Drum residues and equipment washings will be reacted with residual MDI to form solid waste that will be disposed to landfill.

The majority of the notified chemical will be incorporated into the foam lining the interior roof of cars. Therefore, the notified chemical will share the fate of the foam, which is most likely to landfill, although incineration is an option.

Information on the fate of the foam in landfill was not provided, but it is anticipated to slowly degrade over time. The notified chemical will share the fate of the foam and is unlikely to be liberated from it. It will be degraded by slow biological and abiotic processes.

The notifier has determined a bioconcentration factor of 1125 from ACD calculations, which indicates that the notified chemical has the potential to bioaccumulate. This is consistent with chemicals of moderate molecular weight and high log Pow (Connell, 1990) but does not consider the polarity, hence water solubility of the notified chemical. There will also be very low exposure to the aquatic compartment in the proposed use.

9. EVALUATION OF TOXICOLOGICAL DATA

No toxicological data has been submitted on the notified chemical. The submission and MSDS for the notified chemical provide very brief health hazard information. It is reported as irritating to eyes and skin and a skin sensitiser. Hence, the imported product containing the notified chemical would also be considered to be a skin sensitiser.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

A summary of a fish ecotoxicity study was provided for assessment. The test was carried out on the notified chemical in accordance with EEC guidelines.

Test	Species	Results
Acute Toxicity for fish	<i>Brachydanio rerio</i> (HAMILTON-BUCHANAN)	96 h LC ₀ = 3.1 g/L (nominal concentration) 96 h LC ₁₀₀ = 10 g/L (nominal concentration)

The ecotoxicity data for the notified chemical indicate that it is practically non-toxic to fish. However, the summary noted that undissolved test particles were removed by filtration before starting the test suggesting that the exact exposure level is unclear.

There is the possibility for hydrolysis of the notified chemical to the parent chemical and an amine. Amines are of concern due to their high ecotoxicity (Boethling and Nabholz, 1997). In this instance, no information has been supplied indicating the possibility of hydrolysis or, if it was to occur, the fate and effect of the amine in the environment. It is possible that the amine will display toxicity towards aquatic organisms, however exposure to water from the proposed use will be low.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The environmental hazard posed by the notified chemical is expected to be low.

There is no anticipated release to sewer as the residual chemical is mixed with residual MDI forming a solid residue that will be disposed to landfill. As the polymer will be firmly incorporated into the foam matrix, leaching is not expected.

A small amount of the uncured chemical may be released to landfill where its fate and effects are unknown. Although the notified chemical may display some toxicity towards aquatic organisms and a propensity to bioaccumulate, the low volume released is not likely to pose a significant risk to the environment.

The majority of the notified chemical will share the fate of the foam, namely, disposal to landfill or incineration at the end of the useful life of the vehicle. The chemical is unlikely to leach from the foam and should degrade slowly through biological and abiotic processes. Incinerated polymer in foam is likely to form water vapour and oxides of carbon and nitrogen.

The main environmental hazard would arise if spillage in transport accidents released substantial quantities of the chemical to drains and waterways. Adverse effects from an accident of this nature should be mitigated as the chemical is transported in drums at low concentration and if the recommendations outlined for accidental release measures and disposal in the MSDS are followed. The behaviour of the notified chemical in the natural aquatic environment is difficult to predict, but it may be toxic to aquatic organisms.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

No toxicological data have been provided for the notified chemical. However, the submission and the MSDS state that the notified chemical is irritating to eyes and skin and is a skin sensitiser. Hence, the imported, product containing 1-<5% notified chemical, is considered a skin sensitiser. Based on the above information, the notified chemical and the imported product are classified as hazardous according to the Approved Criteria for Classifying Hazardous Substances (National Occupational Health and Safety Commission (NOHSC) 1999). The following risk phrases are required for the notified chemical as well as the product, Baynat Trial Product PU 80IF04: R36/38 'irritating to eyes and skin' and R43 'may cause sensitisation by skin contact'.

Occupational health and safety

The notified chemical will be imported at a low concentration (1 - <5%) within the product, Baynat Trial Product PU 80IF04. Transport and storage workers will handle packaged product infrequently and will be exposed to the notified chemical only if packaging were breached or spillage occurred. The likelihood of exposure and therefore the risk of adverse health effects in these workers are low.

Workers involved in adding pigment to the imported product and transferring the product to the foaming machine may be exposed to the notified chemical when opening the drum lids, inserting or withdrawing the variable speed impeller and attaching air pump tubing to the drums. Skin and eye contact may occur; therefore there is a risk of skin and eye irritation during these operations. Allergic dermatitis may result if skin contamination is regular.

Mixing within the foaming machine is an enclosed process. Pouring of the mixture is not a closed system, but the notifier states that the pouring tube is positioned approximately 75 mm above the floor of the mould and the mixture is poured under low pressure to prevent splashing of the viscous mixture. These measures, combined with local exhaust ventilation, are expected to minimise worker exposure to the notified chemical. However, workers monitoring the process may be exposed dermally to the notified chemical in dilute form (0.7%) if splashing or overfilling occurs. Workers may also be exposed when adjusting the sides of the mould. Exposure may be low, however it can occur, so workers are at some risk of skin and eye irritation and sensitisation.

Some exposure to the partially cured foam may occur, however, once the foam is fully cured any risk from exposure is minimal as the chemical is fully reacted.

Workers involved in cutting the foam into thin sheets will be exposed to product dust and should wear overalls, gloves, eye/face protection and dust masks to prevent exposure.

Workers who become sensitised to the notified chemical in products used in the workplace should no longer continue to handle the chemical or products containing it.

Public health

As the general public will not come into contact with the notified chemical, it is considered that the notified chemical will not pose a significant hazard to public health when used in the proposed manner.

13. RECOMMENDATIONS

The following regulatory action is recommended:

Nomination of the notified chemical to the National Occupational Health and Safety Commission for consideration for inclusion in the NOHSC List of Designated Hazardous Substances.

To minimise occupational exposure to Desmorapid Trial Product PU 59IF05 the following guidelines and precautions should be observed:

- Workplaces handling the notified chemical should be sufficiently ventilated to ensure that respiratory exposure to workers does not occur;
- Eye/face protection, dust mask, chemical resistant industrial clothing and footwear and impermeable gloves should be used during occupational use of the notified chemical;
- Spillages of the notified chemical should be avoided. Spillages should be cleaned up promptly with absorbents which should be put into containers for disposal;
- A copy of the MSDS should be easily accessible to employees.

Due to the risk of skin and respiratory sensitisation, workers potentially exposed to the notified chemical should be subject to health surveillance in accordance with State and Territory hazardous substances regulations.

If products containing the notified chemical are hazardous to health in accordance with the NOHSC *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 1999b), workplace practices and control procedures consistent with State and Territory hazardous substances regulations must be in operation.

Guidance in selection of goggles may be obtained from Australian Standard (AS) 1336 (Standards Australia, 1994) and Australian/New Zealand Standard (AS/NZS) 1337 (Standards Australia/Standards New Zealand, 1992); for industrial clothing, guidance may be found in AS 3765.2 (Standards Australia, 1990); for impermeable gloves or mittens, in AS 2161.2 (Standards Australia/Standards New Zealand, 1998); for occupational footwear, in AS/NZS 2210 (Standards Australia/Standards New Zealand, 1994).

14. MATERIAL SAFETY DATA SHEET

The MSDS for the notified chemical was provided in a format consistent with the *National Code of Practice for the Preparation of Material Safety Data Sheets* ((NOHSC, 1994).

This MSDS was provided by the applicant as part of the notification statement. It is reproduced here as a matter of public record. The accuracy of this information remains the responsibility of the applicant.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the Act, secondary notification of the notified chemical may be required if any of the circumstances stipulated under subsection 64(2) of the Act arise. No other specific conditions are prescribed.

16. REFERENCES

Boethling, R. S. and Nabholz, J. V. (1997). Environmental Assessment of Polymers under the U.S. Toxic Substances Control Act. In *Ecological Assessment of Polymers*, Hamilton, J. D. and Sutcliffe, R. (Eds), Van Nostrand Reinhold, New York, USA.

Connell, D.W., (1990). General Characteristics of Organic Compounds Which Exhibit Bioaccumulation. In *Bioaccumulation of Xenobiotic Compounds*, DW Connell (Ed), CRC Press, Boca Raton, USA.

National Occupational Health and Safety Commission (1994) National Code of Practice for the Preparation of Material Safety Data Sheets [NOHSC:2011(1994)]. Australian Government Publishing Service, Canberra.

National Occupational Health and Safety Commission (1999) Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(1999)]. Canberra, Australian Government Publishing Service.

Standards Australia (1987) Australian Standard 2919-1987, Industrial Clothing. Standards Association of Australia, Sydney.

Standards Australia (1990) Australian Standard 3765.2-1990, Clothing for Protection against Hazardous Chemicals Part 2 Limited protection against specific chemicals. Standards Association of Australia.

Standards Australia (1994) Australian Standard 1336-1994, Eye protection in the Industrial Environment. Standards Association of Australia.

Standards Australia/Standards New Zealand (1992) Australian/New Zealand Standard 1337-1992, Eye Protectors for Industrial Applications. Standards Association of Australia/Standards Association of New Zealand.

Standards Australia/Standards New Zealand (1994) Australian/New Zealand Standard 2210-1994, Occupational Protective Footwear. Standards Association of Australia/Standards Association of New Zealand.

Standards Australia/Standards New Zealand (1998) Australian/New Zealand Standard 2161.2-1998, Occupational protective gloves, Part 2: General requirements. Standards Association of Australia/Standards Association of New Zealand.