



Environmental
Protection Authority
Te Mana Rauhi Taiao

STAFF ADVICE

APP204043 – NPD 100 PLUS

August 2020

1. Executive Summary

- 1.1 NPD 100 PLUS is a pre-mixed fuel containing 2% to 3% anti-knock additives¹, plus other components. It is intended for use as a fuel in domestic and commercial engines and vehicles.
- 1.2 The hazard classifications of NPD 100 PLUS determined by the EPA are: 3.1A, 6.1E (oral), 6.1E (aspiration), 6.3B, 6.7B, 6.9B (oral, dermal, inhalation), 9.1B and 9.3C.
- 1.3 With the full suite of controls in place, the risks associated with the use of NPD 100 PLUS can be adequately managed.

2. Application Context

Background

- 2.1 As the substance is a fuel and therefore does not contain an 'active ingredient', the term 'primary component' has been used.
- 2.2 NPD 100 PLUS is a pre-mixed fuel containing 2% to 3% anti-knock additives, plus other components. It is intended for use as a fuel in domestic and commercial engines and vehicles.
- 2.3 The formulation of NPD 100 PLUS is considered confidential by the applicant.
- 2.4 The primary component, unleaded petrol, is already present in various approved substances and in varying concentrations to NPD 100 PLUS. These substances are used as fuels. The main additive, N-methylaniline has an individual approval (HSR003020).
- 2.5 NPD 100 PLUS has the same primary component, petrol (unleaded), which is already present in various approved substances at similar and lower concentrations to NPD 100 PLUS. These substances are intended to be used in similar ways. The hazards of the main additive, N-methylaniline, as well as the other components of the substance, have been well described. Accordingly, the risks to human health and the environment are not likely to be significantly higher from the use of NPD 100 PLUS compared to other approved substances containing the same primary petrol (unleaded) component. Therefore, the assessment of risks to human health and the environment for NPD 100 PLUS has been limited to a qualitative assessment.

Primary component

- 2.6 To allow evaluation of NPD 100 PLUS, key aspects of petrol (unleaded) regulation have been summarised below.

¹ An anti-knock additive is used to improve the fuel's octane rating, which suppresses the "knocking" in the engine. Knocking, sometimes known as 'pinking' is when fuel is unable to burn in a stable way, detonating, causing the characteristic knocking sound and potentially damaging the engine.

- 2.7 Petrol (unleaded) is approved in New Zealand for use as a fuel. It has also been approved internationally for this use
- 2.8 An assessment of the risks that petrol (unleaded) poses to human health and the environment was carried out under the approval number HSR001445, this approval number was given when the substance was transferred on 1 April 2004 by way of the Dangerous Goods and Scheduled Toxic Substances Transfer Notice 2004.
- 2.9 Petrol (unleaded) has been reassessed as part of the application RES06002 (grounds for reassessment) and HRC07001 (reassessment). The reassessment aimed at replacing the approved handler control by the certified handler control administered by WorkSafe when the petrol (unleaded) was stored and used on farms. A further qualitative assessment was undertaken as part of the reassessment (HRC07001), giving the substance a new approval number HRC000003. This reassessment may not have direct implications on the risk assessment of NPD 100 PLUS. However, there may be implications if there was intent for the substance to be stored or used in bulk on farmlands or other similar workplaces.
- 2.10 There are existing formulations of petrol (unleaded) which are approved under the Act and are highly similar to NPD 100 PLUS in that they share similar concentrations of petrol (unleaded).
- 2.11 The formulation of NPD 100 PLUS is considered confidential by the applicant.

Regulatory parameters of primary component

Impurities and or restrictions on purity or composition

- 2.12 The following composition limits for petrol (unleaded) set by EPA are:
- Benzene: 1% volume;
 - Additives (azo dyes, antioxidants, metal deactivators, corrosion inhibitors): 0.1% each;
 - Detergent additives: <0.5% each.

Concentration and maximum application rate

- 2.13 The concentration of petrol (unleaded) in NPD 100 PLUS is similar to other approved substances with a similar use pattern.
- 2.14 A maximum application rate has not been previously been set for petrol (unleaded) as this is not appropriate for its use pattern.

Physical form and use pattern

- 2.15 NPD 100 PLUS is formulated as a liquid fuel.
- 2.16 The intended use of NPD 100 PLUS is as a pre-mixed fuel containing 2% to 3% anti-knock additives, plus other components. It is intended for use as a fuel in domestic and commercial engines and vehicles. The use pattern is summarised in Table 2.

Table 2: Summary of use pattern for NPD 100 PLUS

Substance category	Wide dispersive use?	Home use?	Remarks
Fuel	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	Intended for use as a fuel in domestic and commercial engines and vehicles.

3. Hazard Assessment

Hazard classification of NPD 100 PLUS

- 3.1 The hazard classifications of NPD 100 PLUS determined by the EPA are: 3.1A, 6.1E (oral), 6.1E (aspiration), 6.3B, 6.7B, 6.9B (oral, dermal, inhalation), 9.1B and 9.3C. Table 3 shows the method used for classification and indicates the main component that contributes to each hazard classification.
- 3.2 The EPA classification of NPD 100 PLUS differed from that of the applicant in that the EPA classified the substance as a 9.3C, while the applicant did not.

Table 3: Hazard classification of NPD 100 PLUS

Hazard Class/Subclass	Mixture classification		Method of classification			Remarks
	Applicant's classification	EPA classification	Mixture data	Read across	Mixture rules ¹	
Class 1 Explosiveness	ND	ND	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Class 2, 3 & 4 Flammability	3.1A	3.1A	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Petrol (unleaded)
Class 5 Oxidisers/Organic Peroxides	ND	ND	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
8.1 Metallic corrosiveness	ND	ND	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
6.1 Acute toxicity (oral)	6.1E	6.1E	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	N-Methylaniline
6.1 Acute toxicity (dermal)	ND	ND	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
6.1 Acute toxicity (inhalation)	ND	ND	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
6.1 Aspiration hazard	6.1E	6.1E	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Petrol (unleaded)
6.3/8.2 Skin irritancy/corrosion	6.3B	6.3B	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Petrol (unleaded)
6.4/8.3 Eye irritancy/corrosion	ND	ND	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

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Hazard Class/Subclass	Mixture classification		Method of classification			Remarks
	Applicant's classification	EPA classification	Mixture data	Read across	Mixture rules ¹	
6.5A Respiratory sensitisation	ND	ND	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
6.5B Contact sensitisation	ND	ND	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
6.6 Mutagenicity	ND	ND	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
6.7 Carcinogenicity	6.7B	6.7B	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Petrol (unleaded)
6.8 Reproductive/ developmental toxicity	ND	ND	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
6.8 Reproductive/ developmental toxicity (via lactation)	ND	ND	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
6.9 Target organ systemic toxicity	6.9B (unspecified)	6.9B (oral, dermal, inhalation)	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	N-Methylaniline
9.1 Aquatic ecotoxicity	9.1B	9.1B	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Petrol (unleaded), N-Methylaniline
9.2 Soil ecotoxicity	ND	ND	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
9.3 Terrestrial vertebrate ecotoxicity	ND	9.3C	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	N-Methylaniline
9.4 Terrestrial invertebrate ecotoxicity	ND	ND	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

-: No information provided by the applicant

NA: Not Applicable. For instance, testing for a specific endpoint may be omitted if it is technically not possible to conduct the study as a consequence of the properties of the substance e.g. highly volatile, highly reactive or unstable substances cannot be tested; mixing of the substance with water may cause danger of fire or explosion; or the radio-labelling of the substance required in certain studies may not be possible.

ND: Not Determined. Data were unavailable for one or more components.

No: Data are available for the formulation or for all components and classification is not triggered.

¹ Use of mixture rules may not adequately take into account interactions between different components in some circumstances and must be considered of lower reliability than data on the mixture itself.

² Klimisch, H-J., Andrear, M., & U. Tillmann, 1997. A systematic approach for evaluating the quality of experimental toxicological and ecotoxicological data. Reg. Toxicol. Pharmacol. 25, 1-5 (1997)

Identification of components of concern (CMRs, vPBTs etc)

3.3 The following component that is present in NPD 100 PLUS has been identified to be of concern as it is a suspected carcinogen, mutagen or reproductive/developmental toxicant (CMR).

Petrol (unleaded)

3.4 Petrol (unleaded) is a suspected carcinogen, with a classification of 6.7B.

3.5 Petrol (unleaded) is the primary component in the NPD 100 PLUS, as such, the substance cannot be re-formulated. Furthermore, other similar substances also contain this component of concern.

3.6 Given the use pattern and exposure routes, we consider that the risks can be mitigated provided proposed controls are followed.



4. Risk Assessment

- 4.1 It is considered that there is potential for significant exposure to people and the environment during the use phase of the lifecycle. Therefore, a qualitative risk assessment was undertaken to understand the likely exposures to the substance under the use conditions proposed by the applicant.
- 4.2 During the manufacture, transportation, storage and disposal of this substance it is considered that the proposed controls and other legislative requirements will sufficiently mitigate risks to a negligible level.
- 4.3 This assessment takes into account the existing EPA Notices controls around packaging, identification and disposal of hazardous substances. In addition, the Land Transport Rule 45001, Civil Aviation Act 1990, Maritime Transport Act 1994 and New Zealand's Health and Safety at Work (Hazardous Substances) (HSW (HS)) requirements all have provisions for the safe management of hazardous substances.

Physical hazard risk assessment

- 4.4 NPD 100 PLUS is classified as a flammable liquid and as such there is the potential for adverse effects on human health and the environment.
- 4.5 It is **highly unlikely** that an event of this nature will occur during the lifecycle of the substance as the prescribed controls and other relevant legislation specifically address risks associated with the flammability of this substance during storage, transport, use, disposal and in the event of an emergency. Accordingly, there are **negligible** risks associated with the physical hazards of NPD 100 PLUS, provided that the prescribed controls are in place. The flammability risks associated with NPD 100 PLUS are similar to other commonly available fuels.

Human health risk assessment

- 4.6 NPD 100 PLUS is intended to be supplied to the domestic and professional markets. It is likely that users will be exposed to the substance during the loading (fuelling) stages. Risks during other phases of the lifecycle are mitigated by the prescribed controls.
- 4.7 Petrol is a widely used substance. The use of NPD 100 PLUS is not likely to generate more adverse effects than other similar petrol substances.

Acute oral toxicity (6.1E)

- 4.8 It is **very unlikely** that oral exposure will occur during the use of this substance, but any effect is expected to be **minor and reversible**. The prescribed controls include requirements for the use of Personal Protective Equipment (PPE) for professionals when working with class 6 and 8 substances to limit exposure to the substance. Furthermore, the transfer and use of NPD 100 PLUS occurs in a series of controlled, closed systems. The substance will be stored in underground tanks and dispensed via a nozzle into the fuel tanks of vehicles or fuel containers for at-home use to refuel petrol-powered equipment. As such, the risk from acute oral toxicity is assessed as being **negligible**.

Aspiration hazard (6.1E)

4.9 It is **unlikely** that an aspiration hazard will occur during the use of this substance. The prescribed controls include requirements for the use of PPE for professionals when working with class 6 and 8 substances to limit exposure to the substance. Furthermore, the transfer and use of NPD 100 PLUS occurs in a series of controlled, closed systems. The substance will be stored in underground tanks and dispensed via a nozzle into the fuel tanks of vehicles or fuel containers for at-home use to refuel petrol-powered equipment. As such, the risk of aspiration hazard is **negligible**.

Skin irritancy (6.3B)

4.10 It is **likely** that skin exposure will occur during the use of this substance, but any effect is expected to be **minor and reversible**. The prescribed controls include requirements for the use of PPE for professionals when working with class 6 and 8 substances to limit exposure to the substance. Furthermore, the transfer and use of NPD 100 PLUS occurs in a series of controlled, closed systems. The substance will be stored in underground tanks and dispensed via a nozzle into the fuel tanks of vehicles or fuel containers for at-home use to refuel petrol-powered equipment. As such, the risk from the skin irritancy hazard is assessed as **negligible**.

Carcinogenicity (6.7B)

4.11 Given the use pattern, it is considered **very unlikely** that users will be exposed to or ingest the substance in sufficient quantities for chronic exposure to occur during the use of the substance. Any effect is expected to be **major**. The prescribed controls include requirements for the use of PPE for professionals when working with class 6 and 8 substances to limit exposure to the substance. Furthermore, the transfer and use of NPD 100 PLUS occurs in a series of controlled, closed systems. The substance will be stored in underground tanks and dispensed via a nozzle into the fuel tanks of vehicles or fuel containers for at-home use to refuel petrol-powered equipment. Therefore, the risk is assessed as **negligible**.

Target organ toxicity via the oral route (6.9B)

4.12 It is considered **very unlikely** that the substance could be ingested during the use of this substance in sufficient quantities for chronic exposure to occur. Any effect is expected to be **moderate**. The prescribed controls include requirements for the use of PPE for professionals when working with class 6 and 8 substances to limit exposure to the substance. Furthermore, the transfer and use of NPD 100 PLUS occurs in a series of controlled, closed systems. The substance will be stored in underground tanks and dispensed via a nozzle into the fuel tanks of vehicles or fuel containers for at-home use to refuel petrol-powered equipment. Therefore, the risk is assessed as **negligible**.

Target organ toxicity via the dermal route (6.9B)

4.13 It is considered **likely** that dermal exposure will occur during the use of this substance, however, it is **unlikely** this will be in sufficient quantities for chronic exposure to occur. Any effect is expected to be **moderate**. The prescribed controls include requirements for the use of PPE for professionals when

working with class 6 and 8 substances to limit exposure to the substance. Furthermore, the transfer and use of NPD 100 PLUS occurs in a series of controlled, closed systems. The substance will be stored in underground tanks and dispensed via a nozzle into the fuel tanks of vehicles or fuel containers for at-home use to refuel petrol-powered equipment. Therefore, the risk is assessed as **negligible**.

Target organ toxicity via the inhalation route (6.9B)

4.14 It is considered **unlikely** that the substance would be inhaled during the use of the substance in sufficient quantities for chronic exposure to occur. Any effect is expected to be **moderate**. The prescribed controls include requirements for the use of PPE for professionals when working with class 6 and 8 substances to limit exposure to the substance. Furthermore, the transfer and use of NPD 100 PLUS occurs in a series of controlled, closed systems. The substance will be stored in underground tanks and dispensed via a nozzle into the fuel tanks of vehicles or fuel containers for at-home use to refuel petrol-powered equipment. Therefore, the risk is assessed as **negligible**.

WorkSafe Assessment

4.15 WorkSafe are proposing a Safe Work Instrument (SWI) to remove a tracking requirement for the substance. The SWI would add this substance to Table 3 of Schedule 26 of the (HSW HS) Regulations for substances that do not require tracking.

Environmental risk assessment

4.16 NPD 100 PLUS is a pre-mixed fuel that is intended for use in domestic and commercial engines and vehicles and therefore has the potential to affect aquatic organisms and terrestrial vertebrates if significant exposure occurs during spillage.

Aquatic ecotoxicity (9.1B)

4.17 It is **unlikely** that aquatic organisms will be exposed to NPD 100 PLUS as exposure is only likely to occur from spillage or leakage that results in the substance entering waterways.

4.18 NPD 100 PLUS is classified as ecotoxic to aquatic organisms, and as such, it is expected that exposure may result in **moderate** effects to organisms. Transfer and use of NPD 100 PLUS occurs in a series of controlled, closed systems. The substance will be stored in underground tanks and dispensed via a nozzle into the fuel tanks of vehicles or fuel containers for at-home use to refuel petrol-powered equipment. Therefore, the risk is assessed as **negligible**.

Toxicity to terrestrial vertebrates (9.3C)

4.19 It is **unlikely** that terrestrial vertebrates will be exposed to NPD 100 PLUS as exposure is only likely to occur from spillage or leakage of the substance.

4.20 NPD 100 PLUS is classified as ecotoxic terrestrial vertebrates, and as such, it is expected that exposure may result in **moderate** effects to organisms. Transfer and use of NPD 100 PLUS occurs in

a series of controlled, closed systems. The substance will be stored in underground tanks and dispensed via a nozzle into the fuel tanks of vehicles or fuel containers for at-home use to refuel petrol-powered equipment. Therefore, the risk is assessed as **negligible**.

Risk assessment conclusion

- 4.21 Risks during other phases of the lifecycle are considered to be mitigated by the prescribed controls.
- 4.22 With the proposed controls in place, the residual risks of the use of NPD 100 PLUS are negligible.

5. Benefit Assessment

5.1 The applicant has stated the following benefits of NPD 100 PLUS being available:

- the substance, and other similar substances, would be created in New Zealand. These formulations could be created so they are useful for New Zealand conditions and requirements. This also allows the creation of more efficient products that other countries may wish to use;
- allows tuned engines to perform optimally, reducing fuel consumption and harmful emissions;
- NPD 100 PLUS is usually dispensed with a different filter from what comes standard in other retail spaces. These high performance filters in the dispensers are 'absolute rated' with an efficiency rating of 99.5% for high performance engines as opposed to the efficiency rating of approximately 75% on standard filters used with 98 Unleaded currently;
- NPD PLUS 100 enables modern high compression or low emission engines to reach their full potential, as well as showing improved cleaning of the engine and fuel system to further reduce harmful emissions and reduce maintenance costs;
- the fuel economy is also improved compared to other products currently in use and the shelf life of the petrol has been shown to be extended, with tests carried out in New Zealand show that the Octane rating was maintained for an excess of 12 months.

5.2 No information was provided that would allow the EPA to quantify the benefits of the substance. The substance consists of petrol (unleaded) and anti-knock additives, including N-methylaniline. Other similar substances are already approved for commercial and domestic use. Additionally, end users would not be required to premix the petrol and fuel additives prior to use. The substance will be stored in underground tanks and dispensed via a nozzle into the fuel tanks of vehicles or fuel containers for at-home use to refuel petrol-powered equipment, thereby reducing potential exposure to humans or the environment.

5.3 The overall conclusion is that, with the proposed controls, the risks are expected to be negligible.

6. Controls

Prescribed controls (EPA Notice controls)

- 6.1 The hazard classifications of NPD 100 PLUS determine a set of prescribed controls specified by the EPA Notices. There are also requirements in the Health and Safety at Work (Hazardous Substance, HSW (HS)) Regulations under the HSW Act.
- 6.2 The prescribed controls set the baseline for how the substance should be managed and include specifications on how the substance is to be packaged, labelled, stored, disposed of, transported, handled and used. The prescribed controls also set information requirements (eg Safety Data Sheets), signage and emergency management.

Variations to prescribed controls

Exposure limits

- 6.3 Tolerable Exposure Limits (TELs) have previously been set for petrol based upon the substances benzene, toluene and xylene when they are components of petrol, and therefore apply to NPD 100 PLUS. The following TELs are recommended for NPD 100 PLUS.

Table 4: Petrol components exposure thresholds

Petrol components	Acceptable Daily Exposure (ADE) – mg/kg bw/d	Potential Daily Exposure (PDE) – mg/kg bw/d	Tolerable Exposure Limit (TEL) mg/L (water) mg/kg (soil) mg/m ³ (air)
Benzene	Not applicable	Not applicable	TEL _{air} 10 µg/m ³ TEL _{water} 10 µg/L
Toluene	Not applicable	Not applicable	TEL _{air} 400 µg/m ³ TEL _{water} 800 µg/L
Xylene	Not applicable	Not applicable	TEL _{air} 870 µg/m ³ TEL _{water} 600 µg/L

- 6.4 Environmental Exposure Limits (EELs) have been set previously for benzene, toluene and xylene and therefore apply to NPD 100 PLUS. The EEL values set are:

- EEL_{water} benzene 2000 µg/L
- EEL_{water} toluene 330 µg/L
- EEL_{water} o-xylene 640 µg/L
- EEL_{water} m/p- xylene 340 µg/L.

Labelling and identification

6.5 The name and concentration of the following components need to be specified on the label and SDS:

Table 5: List of components requiring identification

Label	SDS
Petrol (unleaded) (6.1E [aspiration], 6.7B)	Petrol (unleaded) (6.1E [aspiration], 6.7B, 9.1B, WES) N-Methylaniline (6.9B, 9.1B, WES)

Restriction to workplaces

- 6.6 Clause 13 of the Hazardous Property Controls (HPC) Notice requires certain substances to be restricted to workplaces only. This control is triggered for NPD 100 PLUS as part of the prescribed controls for the 3.1A flammable hazard. However, this classification is drawn from the primary petrol (unleaded) component which is excluded from this control under Schedule 1, Table 2 of the HPC notice.
- 6.7 The components which make up NPD 100 PLUS are not restricted to a workplace so can be mixed and used by domestic users. Therefore, it is recommended that NPD 100 PLUS be excluded from this restriction and the prescribed control be removed. The risks to the substance in storage are managed by other controls.

Tracking control

- 6.8 The prescribed regulations under the HSW Act include requirements for NPD 100 PLUS to be tracked due to the physical hazards of the substance.
- 6.9 Due to the use of NPD 100 PLUS as domestic use fuel, it is expected that home users will purchase and keep small quantities of this substance in their home. As the risks associated with these quantities are considered to be **negligible**, it is recommended that the tracking requirements are modified by WorkSafe using a Safe Work Instrument (SWI).

Management if large quantities of certain substances to be in accordance with HSW (HS) regulations

- 6.10 Clause 19 of the HPC Notice applies to petrol at more than 50 L in accordance with Schedule 3 of the HPC notice. In keeping with the alignment with the controls applied to petrol, and to ensure that large quantities of the substance stored domestically or in any other non-workplace are restricted, it is proposed that clause 19 should apply as if NPD 100 PLUS was listed in Schedule 3 of the notice at the same quantity as petrol (50 L).

Additional controls

Restriction on petrol composition

- 6.11 The primary component in NPD 100 PLUS, petrol (unleaded), is associated with the toxicologically significant subcomponents and additives as part of its composition as a complex mixture substance. When present in high enough concentrations, these impurities can cause adverse effects to people or the environment. There are restrictions listed in the approval for petrol which should be imposed on the petrol content of NPD 100 PLUS. Imposing a restriction on the maximum amount of these components will prevent them from occurring in concentrations sufficient to cause adverse effects to people or the environment.
- 6.12 Accordingly, the following limitations apply to the composition of the component petrol (unleaded):
- Aromatic hydrocarbons: maximum 55% (volume)
 - Benzene: maximum 1% (volume)
 - Additives: (each < 0.1% w/w)
 - azo dyes
 - antioxidants
 - metal deactivator
 - corrosion inhibitor
 - Detergent additives: (each < 0.5% w/w)

7. Conclusion

- 7.1 After taking into account the prescribed controls and any proposed variations and additions to these controls, it was concluded that the residual level of risk of any potentially significant adverse effects is negligible.