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# NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

# **FULL PUBLIC REPORT**

Troika SS

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Director
Chemicals Notification and Assessment

# **FULL PUBLIC REPORT**

### **TROIKA SS**

#### 1. **APPLICANT**

Exxon Chemical Australia Ltd of 636 St Kilda Road Melbourne VIC 3004 has submitted a standard notification for the assessment of the UVCB compound Troika SS.

#### 2. **IDENTITY OF THE CHEMICAL**

Based on the nature of the chemical and the data provided, Troika SS, is considered to be non-hazardous. Therefore, the details relating to exempt information have been exempted from publication in the Full Public Report and the Summary Report.

Trade name: Troika SS

#### 3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa: Pale yellow to amber liquid

33°C **Pour Point:** 

1090 kg/m<sup>3</sup> Density:

6.67 x 10<sup>-5</sup> KPa at 30°C **Vapour Pressure:** 

0.194 g/L at 20°C **Water Solubility:** 

**Partition Co-efficient** 

(n-octanol/water) log Pow: Not provided

The OECD method applies only to watersoluble, pure or commercial grade substances. Due to the complex nature of the reaction product, it is not technically, nor economically feasible to obtain

analytical data for each possible chemical

species.

Hydrolysis as a function of pH: Not provided

The OECD method applies only to water-

soluble, pure or commercial grade

substances. Due to the complex nature of the reaction product, it is not technically, nor economically feasible to obtain

analytical data for each possible chemical

species.

Adsorption/Desorption: Not provided

The OECD method applies only to water-

soluble, pure or commercial grade

substances. Due to the complex nature of the reaction product, it is not technically, nor economically feasible to obtain analytical data for each possible chemical

species.

**Dissociation Constant** 

pK<sub>a</sub>: Not provided

Flash Point: 61°C

Flammability Limits: Not provided

**Combustion Products:** Toxic fumes, smoke, oxides of phosphorus,

oxides of sulphur and carbon monoxide may be

released upon combustion

**Autoignition Temperature:** Not provided

May form flammable mixtures at or above the **Explosive Properties:** 

flash point

Reactivity/Stability: May form combustible mixtures at or above the

flash point

Comments on physico-chemical properties

The above comments provided by the notifier are adequate

#### 4. **PURITY OF THE CHEMICAL**

Degree of purity: >99%

#### 5. **INDUSTRIAL USE**

Troika SS will be imported into Australia as a component (~2.5%) of the liquid product, Parabar 9400. Parabar will be reformulated in Australia for use in automatic transmission fluids.

It is estimated that 25 to 125 tonnes of notified compound will be imported over the first five years.

#### **OCCUPATIONAL EXPOSURE** 6.

The oil based product, Parabar 9400 (containing 2.5% notified chemical), will be imported in 200 L drums and 18 MT bulk liquid containers and transported to one customer for blending into automatic transmission fluids. The automatic transmission fluids (containing 15% Parabar 9400 and 85% base oil, ie 0.375% notified chemical) will be transported to gearbox manufacturers (90%) as well as car service workshops, oil company retail sites, and large commercial fleet operators, eg bus fleets (10%).

Transport and storage personnel are unlikely to be exposed to the notified chemical as the imported product is handled in sealed drums or bulk containers and stored in "sealed areas with adequate spill containment". Exposure should only result in the event of accidental spills or mishaps.

The applicant estimates that, based on the importation of 5 tonnes of additive package per annum, approximately 9 workers will be involved in product reformulation at the customer site. These workers will include 2 blending personnel involved in blending the additive package with base oil (~2 h/day, 12 days/annum), 1 quality control staff member involved in product testing (~1 h/day, 12 days/annum), 2 maintenance personnel involved in routine maintenance tasks (~2 h/day, 4 days/annum) and 4 packaging workers involved in storage of the packaged final product (~4 h/day, 12 days/annum). Blending processes will be conducted in a fully automated closed system. The final product will be packaged into drums and/or small containers via an automated filling line. Local exhaust ventilation will be located at the sampling and blending sites as well as at the packaging station. The potential for exposure will be greatest during the connection and disconnection of transfer hoses from the imported containers to the customer transfer lines. Other sources of exposure will be residues remaining in drums/storage containers, transfer piping and blending tanks.

Workers potentially exposed to the finished product include operators assembling transmission components (~8 h/day, 40 days/annum) and supervisory personnel (~1 h/day, 20 days/annum) at the gearbox manufacturing sites. Other workers with potential for exposure include mechanics involved in repairs and servicing of cars and other vehicles. Exposure of these workers will be limited to diluted product (0.375% notified chemical).

### 7. PUBLIC EXPOSURE

The notified chemical will constitute < 0.4% of the formulated transmission fluid which will be sold to gearbox manufacturers, car service workshops, oil company retail sites and large commercial fleets (eg. bus fleets). The public is unlikely to be exposed to the chemical during importation, distribution and storage.

Reformulation of Parabar 9400 will be conducted in essentially closed systems. Minimal waste is expected to occur, as any residues of the chemical will be recycled. Due to the low vapour pressure, inhalational exposure levels are expected to be negligible. Public exposure during formulation of the transmission fluid is not expected to occur.

Some dermal public exposure to the notified chemical is expected to occur during the replacement of transmission fluid.

#### 8. ENVIRONMENTAL EXPOSURE

# . Release

The potential for environmental release of the notified chemical from the blending site is considered to be negligible. Blending of the new chemical is conducted in essentially closed systems. Release to the atmosphere is unlikely as the material has a low vapour pressure and a high molecular weight.

During the blending process product losses from transfer piping and blend tank residues are minimal. Residual material is recycled into the next blend. The residue is flushed with mineral baseoil to clear the pipeline and tank, ready for the next blend batch. The resultant mixture is stored at the site until the next blend process, when the mixture is added to the tank. Losses of the notified chemical incurred in the connection/disconnection of transfer hoses are also recycled.

The notifier estimates that product losses of Troika SS from bulk liquid containers and drums would be 14 kg and 7 kg per year, respectively. For sample residues, the volume loss is estimated to be ~50 g per year. Residue at the bottom of a bulk liquid container is washed by a licensed transport agent. The washings are passed to on-site wastewater treatment plant before disposal in accordance with water authority regulations by the licensed agent. Drum reconditioners collect the drums, which are cleaned and the washings passed to an on-site wastewater treatment plant before disposal in accordance with water authority regulations. On-site waste water treatment plants are said to include a API separator and biological oxidation features, induced air flotation and sand filtration. Water thus cleaned is then sent to sewers.

The automatic transmission fluid normally lasts the life of the modern automotive transmission and is not normally replaced. However, should fluid replacement be necessary, it would occur in appropriate workshops and disposed in accordance with local disposal regulations. The other possible environmental releases are from leaks or accidents. Leaks of transmission oils are most often minor in nature and will be diffuse. Release in accidents will be random events and uncommon

#### . Fate

No fate studies (eg bioaccumulation and biodegradation) were provided due to the negligible amounts of the notified chemical released to the environment. The potential for environmental exposure is low, as losses of the notified chemical during the blending process are recycled and the notified chemical is contained within the transmission for the life of the engine. At the end of the engine-life lubricants are usually drained from engines and disposed of to a liquid waste facility. Most of this used transmission oil will be collected and reused as fuel or incinerated.

The UVCB nature of notified substance precludes estimation of biodegradation potential by QSAR methods.

### 9. EVALUATION OF TOXICOLOGICAL DATA

Limited toxicological data were provided for the notified chemical, Troika SS. However, the applicant supplied data on a chemically similar compound, P-88-1628.

# 9.1 Acute Toxicity

Table 1 Summary of the acute toxicity of Troika SS

Test	Species	Outcome	Reference
Acute dermal toxicity	Rat	LD <sub>50</sub> >2000 mg/kg	(2)

Table 2 Summary of the acute toxicity of P-88-1628

Test	Species	Outcome	Reference
Acute oral toxicity	Rat	LD <sub>50</sub> >2000 mg/kg	(1)
Skin Irritation	Rabbit	Severe, possibly corrosive	(4)

# **9.1.1 Oral Toxicity (1)**

A single dose of P-88-1628 (2000 mg/kg) was administered by gavage to 5 male and 5 female Sprague-Dawley rats. Clinical observations were made at 1, 2, 4 and 6 hours and once per day for 14 days. Body weights were recorded on day 0, 7 and 14. Animals found dead during the study were necropsied at the time of death. All surviving animals were necropsied at 14 days.

One animal died during the first 24 hours. All other animals survived until the study end. Clinical signs of toxicity were observed during the first 3 days only. These included low incidences of wet and dry rales, ano-genital staining, soft stool, and dyspnea. No body weight effects were observed in the surviving animals. Postmortem findings revealed gastro-intestinal tract, urinary bladder, adrenal, brain and skin abnormalities in the animal which died. Necropsy of the surviving animals revealed abnormalities in one animal only (lung discolouration).

The study suggests that P-88-1628 has an oral  $LD_{50} > 2000$  mg/kg.

### 9.1.2 Dermal Toxicity (2)

This study was conducted in accordance with OECD guidline No: 402 (3).

A single dose of Troika SS (2000 mg/kg) was administered to the clipped backs of 5 male and 5 female New Zealand White rabbits. The test sites were covered with a gauze patch and a plastic sleeve. Dressings were removed after 24 hours (day one). Clinical observations were made at 2 and 4 hours and once per day for 14 days. Dermal responses were scored on days 1 (60 minutes after dressing removal), 3, 7, 10 and 14 by the Draize method. Body weights were recorded on day 0, 7 and 14. Terminal necropsy was performed on all animals at 14 days.

There were no mortalities during the study. Clinical signs included decreased food consumption in one animal and vocalisation in another. There were no body weight effects observed during the study. Skin effects included severe erythema and slight to moderate edema, observed in all animals up to at least day 10. Postmortem findings were reported as being limited to skin abnormalities at the treatment sites of all animals (no results were reported for other organs).

The study suggests that Troika SS has a dermal LD<sub>50</sub> >2000 mg/kg.

# 9.1.3 Inhalation Toxicity

No data provided. This is acceptable as inhalational exposure is not considered a probable route of exposure for the notified chemical. It has very low vapour pressure and will be available in Australia in a diluted liquid form (<2.5%) only.

# 9.1.4 Skin Irritation (4)

Undiluted P-88-1628 (0.5 ml) was applied to the clipped dorsa of 2 male and 4 female New Zealand White rabbits. The test sites were covered with gauze and a semi-occlusive dressing for 4 hours after which they were wiped clean with distilled water and paper towelling. Dermal responses were scored by the Draize method approximately 1, 20, 44 and 72 hours after patch removal as well as on day 7.

All animals survived until the study termination. All animals showed well-defined to severe erythema from 20 hours until the last observation, day 7 (1 well-defined; 5 severe). Very slight to slight oedema was observed in all animals over the same observation interval. Other skin effects noted throughout the study included atonia (6/6), leathery skin (6/6), desquamation (2/6), eschar formation (6/6), fissuring (2/6), necrosis (5/6), exfoliation (2/6) and blanching (2/6).

The results of this study suggest that P-88-1628 is a severe skin irritant. The incidence of necrosis suggests the chemical is corrosive.

### 9.1.5 Eye Irritation

No data were provided however the notified chemical is expected to be corrosive to the eyes.

#### 9.1.6 Skin Sensitisation

No data were provided. The chemical is expected to cause severe and possible permanent skin damage. This will necessitate the use of protective clothing and gloves which will reduce the likely levels of dermal exposure.

# 9.2 Subchronic Oral Toxicity

# 9.2 Subchronic Oral Toxicity Study in the Rat (5)

P-88-1628 was administered by the oral route, via gavage, 5 days per week for 4 weeks. Group I was used as a control which was used as a control which received vehicle only. Group 2,3,4 and 5 received 5, 50, 100 and 250 mg/kg/day fo p-88-197, respectively, at a dose volume of 21 ml/kg. Observations were made as to the nature, onset, severity and duration of toxicological signs daily for the duration of the study. Body weights were recorded prior to dosing, at dosing initiation, and on days of dosing during the test period.

Dose Group	Dose mg/kg	Total Animals M F
1 '	0	10 10
2	5	5 5
3	50	5 5
4	100	5 6a
5	250	10 11a

a=Due to problems with dosing accidents on the first day of study one female was added to both the 100 mg/kg and the 250 mg/kg groups. These animals were handled in the same manner as the other animals, but all actions were one day behind the other seventy animals.

*Mortality:* 11 animals died prior to study termination, 1 animal from group 3, and 4 and 6 animals from Group 4 and 5 respectively. Based on the results of postmortem and histopathologic examinations, the following deaths discussed above appear to be related to dosing trauma.

Clinical observations: Clinical observations noted during the study were minimal, intermittent and most prevalent in those animals which succumbed prior to termination. Observations noted for animals which succumbed included but were not limited to nasal discharge, oral discharge, dyspnea, wet and dry rales, red nasal dischage, and red ocular discharge. Observations noted for surviving animals included but were not limited to staining of the fur, soft and mucoidal stool, abdominal griping, little sign of stool or food consumption, hypoactivity, hypothermia and emaciation.

There were no statistically significant differences among the groups in the following parameters: body weights, food consumption, organ weights or relative organ weights.

There were no statistically significant differences in the remaining haematology and serum chemistry parameters.

*Necropsy*: Postmortem findings were minimal in the control group and groups 2 and 3. These findings included abnormalities of the gastrointestinal tract, uterus, lungs, ovaries, pericardium and staining of the fur. Single incidences were also noted of liver and diaphragm abnormalities, a thoracic mass, discolouration of the mesenteric lymph nodes, fluid in the thoracic cavity and a dilated renal pelvis. The majority of the animals in these groups displayed no observable abnormalities at terminal sacrifice.

Abnormalities noted in groups 4 and 5 included infrequently noted abnormalities of the gastrointestinal tract, kidney, uterus, heart, parathyroid, urinary bladder, liver, testes and staining of the fur, which may be considered reversible. The following abnormalities were also noted and appear related to the aforementioned dosing trauma, discoloured oesophagus, torn oesophagus, lung discolouration and tissue consolidation, abnormal contents of the thoracic cavity, discoloured thymus and distension of the pericardium.

Histopathology: No microscopic changes considered related to treatment were observed in any tissues processed for histopathological examination, however, changes noted in those animals suspected of succumbing to dosing trauma appear to confirm that hypothesis.

The results of this study suggest that administration of p-88-1628 to rats at up to 250 mg/kg/day has little effect on the biological parameters measured.

# 9.3 Genotoxicity

# 9.3.1 Salmonella typhimurium Reverse Mutation Assay (6)

This study was performed on a compositionally similar chemical (P-88-1628). A positive response was observed with or without metabolic activation in strains TA 1535 and TA 100 but not with TA 98, TA 1537 and TA 1538.

In the repeat mutagenesis assay, P-88-1682 did induce a dose related increase in revertant colonies including at least one positive dose in tester strains TA100 and TA1535 for saline treated plates. Positive dose points were observed for tester strains TA 100 and TA 1535 both with and without metabolic activation.

Results from both the initial and repeat assays indicate that P-88-1682 is mutagenic for the *Salmonella* tester strains.

# 9.3.2 In Vitro mammalian cytogenetic test in Chinese hamster cells (CHO) (7)

Chinese hamster ovary cells were treated with Troika SS ( in acetone) at 10 or 120  $\mu g/mL$  for 3 hours in the presence of metabolic activation and 5 or 35  $\mu g/mL$  for 13 hours in the absence of metabolic activation. MNNG (0.15  $\mu g/mL$ ) and DMBA (10  $\mu g/mL$ ) were used as positive controls in the presence and absence of metabolic activation. Cells were harvested after 16 hours following treatment. Two hours prior to harvesting, the cells were arrested in metaphase with the addition of colcemid at 0.1  $\mu g/mL$  of medium, and slides were prepared for metaphase analyses. Treatment of cells in the absence or presence of metabolic activation did not result in an increase in chromosomal aberrations. Cytotoxicity was reported at 160  $\mu g/ml$  in the presence and absence of metabolic activation. The positive controls induced the expected increase in the incidence of structural chromosomal aberrations in CHO cells in this study.

# 9.3.3 Micronucleus Assay in the Bone Marrow Cells of the Mouse (8)

The study was performed on P-88-1628, a compositionally similar chemical to Troika SS. No increase in the frequency of micronuclei in either male and female mice were noted at 24, 48 or 72 hours for dose levels of 1, 2.5 and 5.0 g/kg.

P-88-197 did not induce a statistically significant increase in the micronucleus. Therefore, P-88-197 was not clastogenic in mouse bone marrow under the conditions of this test.

# 9.4 Neurotoxicity

### 9.4.1 Cholinesterase Determination Study in the Rat (9)

Testing was also conducted to evaluate the potential of Troika to cause neurotoxicity as a result of the possible formation of some specific phosphate derivatives. Satellite groups of 9 rats per sex were sham dosed or dosed with 2g/kg of the test material. Cholinesterase activity in plasma, brain and red blood cells were assessed at 1, 4, and 24 hours after dosing in 3 rats/sex/group. No biologically significant differences in cholinesterase values between sham and treated rats were observed.

# 9.4.2 Acute Delayed Neurotoxicity Study in Domestic Chicken Hens (10)

Acute delayed neurotoxicity was also tested in twelve domestic hens with P-88-1628 by oral gavage at 5 g/kg body weight. Corresponding groups of hens were dosed as negative to positive controls for comparison. Animals were observed for mortality and other clinical observations daily. Specific observation for evidence of delayed neurotoxicity were made 3 times weekly beginning at 72 hours after treatment. No evidence of neurotoxicity was observed in the hens receiving the test material. Clinical observations in this group included decreased food consumption and body weight initially after dosing. Hens in the positive control group showed evidence of neurotoxicity.

# 9.5 Overall Assessment of Toxicological Data

Based on the toxicity studies provided by the notifier, Troika SS was of low acute dermal toxicity in rats, did not cause chromosomal damage in Chinese hamster ovary cells in *vitro*. No significant differences in cholinesterase levels were observed between sham and treated rats nor any evidence of neurotoxicity was observed in the acute delayed neurotoxicity study in Domestic Chicken Hens. Based on studies done and information provided by the notifier with compositionally similar chemical P-88-1628, Troika SS may be of low acute oral toxicity in rats, a severe irritant and corrosive to the skin and eye, mutagenic in S typhimurium strains TA 1535 and TA 100 in an *in vitro* bacterial reverse mutation assay and not clastogenic *in vivo* mouse bone marrow cells. When rats were treated orally with up to 250 mg/kg/day for 28 days only small changes to any of the parameters were observed.

On the basis of submitted data, the notified chemical would not be classified as hazardous in accordance with Worksafe Australia's *Approved Criteria for Classifying Hazardous Substances* (11) in relation to Acute lethal effects (dermal) or Clastogenic effects. However, the notified chemical cannot be classified in relation to irritant effects (skin, eye), Sensitising effects (skin) or mutagenic effects on the basis that the studies pertaining to these effects were done using analogs.

# 10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

No ecotoxicological studies were provided for the notified chemical because it is not expected that significant amounts of the chemical will be released to the environment. Aga UVCB nature of notified substance precludes estimation of aquatic toxicity by QSAR methods.

# 11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The nature of its use and limited environmental exposure indicates the notified chemical is unlikely to present a hazard to the environment.

All the imported Troika SS will be used in automatic transmission oils, which will remain with the engine for its life or may be changed, almost exclusively at garages, service centres or industrial garages i.e. large car fleets, thus most of the used transmission oil will be collected. Of used oil collected in Australia 96% is disposed of by incineration (12). Large fleet owners, with large volumes of used transmission oils, may recycle the oil. Incineration will produce sulphur dioxide, oxides of carbon and nitrogen and water.

Leaks of transmission oils during its use will be mainly limited to driveways and roadways. Significant amounts of Troika SS are not expected to be released and is

estimated at less than 0.5%, based on a recent European report (13), i.e. 125 kg to 625 kg per annum. This will be spread over a large area at low concentration and is not likely to cause significant environmental effects.

# 12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETYEFFECTS

Troika SS is expected to exibit low dermal toxicity and is not expected to be clastogenic. However, studies carried out with compositionally similar chemical P-88-1628 exhibited low oral toxicity and was found to be corrosive to skin and eye and mutagenic in two *Salmonella typhimurium* strains.

Occupational exposure during transport is expected to be low as the imported product containing the notified chemical at a concentration of 2.5% is handled in sealed drums or bulk containers and stored in "sealed areas with adequate spill containment". During reformulation and packaging, dermal, eye and respiratory exposure is expected to be low due to the fact that blending process is carried out in a fully automated closed system with local exhaust ventilation. In the reformulation plant and during container disposal and drum reconditioning, workers will be required to use personal protective equipment.

The risk from adverse effects to skin and eye during connection and disconnection of transfer hoses from the imported containers to the customer transfer lines is expected to be low, due to the use of local exhaust ventilation and personal protective equipment. There would also appear to be a low risk due to adverse effects to skin and eye from the notified chemical during assembly of transmission components, gearbox manufacture and servicing vehicles due to very low level of the notified chemical and use of personal protective equipment.

Troika SS will be used at extremely low levels (0.375%) in automatic transmission fluid. Although some public exposure to the chemical may occur during replacement of automatic transmission fluid, the concentration of Troika SS in the fluid is extremely low and its potential to cause skin and eye irritation, skin sensitisation or genotoxicity will be significantly reduced. Additionally, exposure will be infrequent.

# 13. **RECOMMENDATIONS**

To minimise occupational exposure to Troika SS the following guidelines and precautions should be observed:

- local exhaust ventilation should be employed, a respirator conforms to Australian/New Zealand AS/NZS 1715 (14) and goggles (AS 1336, AS 1337) (15, 16) during connection and disconnection of transfer hoses. During these operations care should be taken not to generate aerosols;
- during all operations in which contact with the dissolved notified chemical is possible, personal protective equipment which conforms to and is used in accordance with Australian Standard (AS) for eye protection (AS 1336, AS 1337) (15, 16), impermeable gloves (AS 2161) (17), protective clothing (AS 2919) (18) and footwear (AS/NZS 2210) (19) should be worn;
- safe work practices such as keeping lids on containers when not in use and providing means for safe storage should be implemented to avoid spillages and splashing

- good housekeeping and maintenance should be practised. Spillages should be cleaned up promptly with absorbents which should then be put into containers for disposal in accordance with Local or State government regulations;
- . the workplace should be well ventilated;
- good personal hygiene such as prohibiting drinking, eating and smoking in contaminated areas should be observed; and
- . a copy of the Material safety data Sheet (MSDS) should be accessible

### 14. MATERIAL SAFETY DATA SHEET

The MSDS for Parabar 9400 containing the notified chemical was provided in a suitable format.

This MSDS was provided by Exxon Chemical Australia Ltd as part of their notification statement. The accuracy of this information remains the responsibility of Exxon Chemical Australia Ltd.

# 15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the *Industrial Chemicals (Notification and Assessment) Act 1989*, secondary notification of Troika SS shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise. No other specific conditions are prescribed.

### 16. REFERENCES

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- 18. Standards Australia, 1987, *Australian Standard 2919 1987 Industrial Clothing,* Standards Association of Australia Publ., Sydney, Australia.
- 19. Standards Australia, 1994, Australian Standard 2210 1994 Occupational Protective Footwear, Part 1: Guide to Selection, Care and Use. Part 2: Specifications, Standards Association of Australia Publ., Sydney, Australia.