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April 1998

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Perkalink 900

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Director Chemicals Notification and Assessment

FULL PUBLIC REPORT

Perkalink 900

1. APPLICANT

Akzo Nobel Chemicals Limited of 6 Grand Avenue CAMELLIA NSW 2142 has submitted a standard notification statement in support of their application for an assessment certificate for Perkalink 900.

2. IDENTITY OF THE CHEMICAL

Chemical Name: 1H-pyrrole-2,5-dione, 1,1'-[1,3-phenylenebis

(methylene)] bis[3-methyl-

Chemical Abstracts Service

(CAS) Registry No.: 119462-56-5

Other Names: 1,3-bis(citraconimidomethyl) benzene

m-xylylene bis(citraconimide) BCI-MX and BCI-MX DP 900

Trade Name: Perkalink 900

Molecular Formula: C₁₈H₁₆N₂O₄

Structural Formula:

$$H_3C$$
 $N-CH_2$
 CH_2
 CH_3

Molecular Weight: 324

Method of Detection

and Determination: uv/visible, infrared and nuclear magnetic

resonance spectroscopy

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C

and 101.3 kPa: off-white pastilles

Boiling Point: > 280°C

Specific Gravity: 1.269

Vapour Pressure: 5 X 10⁻⁸ kPa at 25°C

Water Solubility: 40.8 mg.L⁻¹ at 20°C

Partition Co-efficient

(n-octanol/water): $\log P_{ow} = 2.22$

Hydrolysis as a Function $T_{1/2} = 76.7$ days at pH 4.0

of pH: $T_{1/2} = 68.5$ hours at pH 7.0 $T_{1/2} < 2.4$ hours at pH 9.0

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Adsorption/Desorption: not determined (see comments below)

Dissociation Constant: not determined (see comments below)

Flash Point: > 360°C (open cup); 257°C (closed cup); 284°C

(fire point)

Flammability Limits: non-flammable

Autoignition Temperature: no self-ignition prior to melting

Explosive Properties: non-explosive

Reactivity/Stability: non-oxidising

Comments on Physico-Chemical Properties

The hydrolysis observed is likely to be due to the amide functional groups present in the chemical. Hydrolysis would be assisted by the slight water solubility of the chemical.

The somewhat low log P_{ow} value suggests a moderate tendency for the chemical to be associated with aqueous phases.

The log P_{ow} value suggests that the chemical can be expected to show only a moderate capacity to be adsorbed to soil and sediment, and hence show some mobility.

The dissociation constant of the chemical has not been determined due to its low

solubility. This is acceptable as there are no groups that would readily gain or lose a proton. When hydrolysed the chemical will acquire carboxylic acid functionalities.

4. PURITY OF THE CHEMICAL

Degree of Purity: 95 - 98%

Toxic or Hazardous

Impurities: an impurity with toxic properties possibly similar to

the notified chemical, viz., a potent skin sensitiser and capable of causing serious eye damage, is

present at 2 - 5%

Non-hazardous Impurities

(> 1% by weight): none

Additives/Adjuvants: none

5. USE, VOLUME AND FORMULATION

The notified chemical is to be used as an anti-reversion agent in the manufacture of natural rubber articles such as the treads of tyres, conveyor belts and solid tyres. Anti-reversion agents help repair the sulfur cross-links that break as a result of exposure of the rubber articles to high temperatures resulting from both friction and the vulcanising process. Such repair of sulfur cross-links provides the rubber items with lower rolling resistance. This is claimed to give less wastage, extended life, and in the case of tyres greater fuel efficiency and increase in mileage.

The chemical will be imported in pure form at a rate of less than 100 tonnes per year for the first 5 years.

6. OCCUPATIONAL EXPOSURE

The notified chemical is stated by the notifier to be in the form of dust-free pastilles. It will be imported in plastic bags within 20 kg cardboard cartons. Transport and storage workers should only be exposed in the event of an accident or damaged packaging.

The notified chemical will be repacked into 1 - 2 kg quantities in plastic-lined cardboard cartons on ten days per year for 8 hours per day. This is accomplished by addition to a hopper. The chemical passes down a chute into a plastic container on a scale. When correct weight is achieved the chemical is transferred manually to a container which is then sealed. The weighing apparatus is fitted with local exhaust ventilation. Some dermal exposure may be expected during these operations.

Raw rubber is mechanically softened and transferred to a mixer. The notified chemical, together with other additives is added manually to the mixer or to a

weighing device similar to that used in repacking and added to a final concentration of 0.5%. If the weighing device is used, the additives are added mechanically to the mixer and limited dermal exposure is possible. Typically the mixing machinery is fitted with local exhaust ventilation which passes any gaseous emissions through a scrubber.

Once mixed, the rubber mixture is transferred mechanically into a calendar for forming into sheets. The sheets are mechanically pressed into moulds for vulcanising. Once cooled, the moulds are emptied and the final product stored on racks.

After transfer to the mixer contact with the notified chemical is expected to be minimal.

7. PUBLIC EXPOSURE

The public may contact the tyres, conveyor belts etc. which contain the notified chemical, or be exposed to rubber released during frictional wear of the tyres etc. However, the majority of the notified chemical is chemically bound to the rubber matrix during the high temperature vulcanisation process, and the residual material will be gradually bound to the matrix during its use.

Minor public exposure may result from disposal of unused chemical, or accidental spillage of the notified chemical during transport and storage, and during formulation.

8. ENVIRONMENTAL EXPOSURE

Release

The notifier states that, except for accidental spills, no chemical is wasted during the formulation into rubber. As the chemical is in pastille form any spillage is easily recovered and re-used. Minor wastes and all packaging are disposed of according to environmentally approved methods, presumably to landfill or by incineration. The notifier states that sites of customers formulating the chemical would be bunded and drainage systems designed in accordance with local government requirements will be in place to prevent the entry of polluted water into the storm water drainage system or the sewerage system.

Fate

The fate of the notified chemical will be tied almost entirely to the fate of rubber articles containing it. In all cases the chemical will remain strongly bound to the rubber matrix. Old tyres are known to be used for diverse purposes. Like used oil, most used tyres are burnt as fuel in kilns etc. A proportion is shredded and used to make various other articles such as rubber bricks. Another proportion may be disposed of directly to landfill. During incineration of waste or used rubber articles,

the chemical will be destroyed by conversion to oxides of carbon and nitrogen and water vapour. With the notifier claiming that no waste is generated during formulation into rubber and spills being easily reused, chances of pure chemical going into landfill or into waste water appears to be very low. Small amounts going into the waste water will be trapped to a considerable degree in the treatment plants at these sites. The notified chemical in rubber articles disposed of to landfill will remain bound to rubber and undergo slow degradation (see below).

Ready biodegradability assessed using the Modified Sturm Test (1) with sodium benzoate as the reference material showed, after 28 days, 31% and 6% biodegradation for test concentrations of 10 and 20 mg.L⁻¹, respectively. The notified chemical therefore does not qualify as readily biodegradable. However, up to 80% and 20% biodegradation was observed for the two test concentrations by 73 days. The low rates of degradation observed at 20 mg.L⁻¹ were interpreted as due to inhibitory effects of the chemical on sewage organisms. More extensive biodegradation may be indicated in inherent biodegradability tests. Hence, although the notified chemical is not readily biodegradable, it should ultimately be degraded at rates that may be influenced by its toxicity and/or other physical factors.

Bioaccumulation testing has not been done for the chemical due to its low solubility. Features such as the moderate Log P_{ow} and addition of ionisable functionalities such as acid groups (in this case through hydrolysis) are thought to reduce the lipophilicity of organic chemicals (2). Hence the bioaccumulation potential of the chemical will be low.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Summary of the acute toxicity of Perkalink 900

Test	Species	Outcome	Reference
acute oral toxicity	rat	LD ₅₀ > 2 000 mg.kg ⁻¹	(3)
acute dermal toxicity	rat	$LD_{50} > 2000 \text{ mg.kg}^{-1}$	(4)
skin irritation	rabbit	non-irritant	(5)
eye irritation	rabbit	irritant	(6)
skin sensitisation	guinea pig	sensitiser	(7)

9.1.1 Oral Toxicity (3)

Species/strain: rat/CD (SD) BR VAF plus

Number/sex of animals: 5/sex

Observation period: 14 days

Method of administration: gavage in corn oil

Clinical observations: piloerection in all animals

Mortality: none

Morphological findings: none

Test method: according to OECD guidelines (8)

 LD_{50} : > 2 000 mg.kg⁻¹

Result: the notified chemical was of low acute oral

toxicity in rats

9.1.2 Dermal Toxicity (4)

Species/strain: rat/CD (remote Sprague-Dawley origin)

Number/sex of animals: 5/sex

Observation period: 14 days

Method of administration: under occlusive patch for 24 hours after

moistening the skin with 0.2 mL distilled water

Clinical observations: none

Mortality: none

Morphological findings: none

Test method: according to OECD guidelines (8)

 LD_{50} : > 2 000 mg.kg⁻¹

Result: the notified chemical was of low acute dermal

toxicity in rats; no dermal irritation was

observed

9.1.3 Inhalation Toxicity

not determined

9.1.4 Skin Irritation (5)

Species/strain: rabbit/NZW

Number/sex of animals: 3/unspecified

Observation period: 4 days

Method of administration: 0.5 g of the notified chemical applied under

occlusive dressing with 0.5 mL distilled water

Test method: according to OECD guidelines (8)

Result: no erythema or oedema observed at any time

point up to 4 days after patch removal; the notified chemical was not a skin irritant in

rabbits

9.1.5 Eye Irritation (6)

Species/strain: rabbit/NZW

Number/sex of animals: 1/unspecified

Observation period: 24 hours

Method of administration: 50 mg into the conjunctival sac of one eye

Test method: according to OECD guidelines (8)

Result: at 1 hour, moderate conjunctival redness and

mild chemosis were observed; at 24 hours, mild corneal opacity covering more than 75% of the eye, moderate conjunctival redness and severe swelling with lids more than half closed but no iridal effects; blanching of the eyelids and copious discharge; the notified chemical

was a severe eye irritant in rabbits

9.1.6 Skin Sensitisation (7)

Species/strain: guinea pig/Dunkin-Hartley

Number of animals: 20 test; 20 control

Induction procedure: 3 pairs of intradermal injections (0.1 mL) in the

scapular region:

Freund's complete adjuvant (FCA)

0.1% w/v Perkalink 900 in propylene glycol

• 0.1% w/v Perkalink 900 in propylene glycol

in FCA

 topical induction on day 8: 0.6 mL of 10% w/v Perkalink 900 in propylene glycol under

occlusive dressing for 48 hours

Challenge procedure: on day 21: 30 µL of 0.3% w/v or 3.0% w/v

Perkalink 900 in propylene glycol under

occlusive dressing for 24 hours

Challenge outcome:

Oh alla sa sa	Test animals		Control animals	
Challenge concentration	24 hours*	48 hours*	24 hours	48 hours
0.3%	3/20**	6/20	0/20	0/20
3.0%	17/20***	18/20***	1/20	0/20

^{*} time after patch removal

Test method: Magnusson and Kligman (9)

Result: the notified chemical was a potent skin

sensitiser in guinea pigs

9.2 Repeated Dose Toxicity (10)

Species/strain: rat/CD

Number/sex of animals: 5/sex/dose group with an additional 5/sex for

the control and high dose groups given a 14 day recovery period; dose groups were 0, 10, 50 or 200 mg.kg⁻¹.dy⁻¹ (control, low, mid and high dose groups, respectively) for 28 days

Method of administration: by gavage in maize oil

Dose/Study duration:: 28 days

Mortality: 4 males and 1 female from the high dose

group were found dead (1) or killed on humane grounds (4) between days 9 and 26

Clinical observations: Signs of reaction to treatment in high dose

animals comprised salivation at dosing from days 5 or 6, ungroomed appearance on occasions from day 6 and loose faeces on

days 10 and 11

signs of reaction to treatment in low dose animals comprised salivation at dosing from day 6 and isolated incidences of piloerection, ungroomed appearance and an isolated

^{**} number of animals exhibiting positive response

^{***} total number of responders: 19/20

incidence of hunched posture, noisy, laboured respiration and vocalisation in one animal

signs of reaction to treatment in mid dose animals were confined to salivation at dosing in three male rats on days 25 and 30.

high dose animals in the recovery group showed no signs during the two week respite from treatment.

Clinical chemistry/Haematology

Haematology: haematology was considered to have been unaffected by treatment; red blood cell numbers of mid dose male rats were slightly higher than those of the controls (p < 0.01), but the difference was numerically small and not considered to be biologically significant

Clinical Chemistry: aspartate aminotransferase activities and plasma urea concentrations of high dose male rats killed after four weeks of treatment were slightly higher than those of the control males (p < 0.05 and p < 0.01 respectively); this difference was not apparent after two weeks cessation of treatment; urea concentrations of low dose male rats were also slightly higher after four weeks of treatment than controls (p < 0.05) but in the absence of a significant difference in mid dose rats is not considered to be of toxicological significance

the blood chemistry of high dose females and of low and mid dose rats was considered to have been unaffected by treatment

other minor differences between treated and control values were higher alanine aminotransferase activities (p < 0.05) and aspartate amino-transferase activities (p < 0.01) of low dose females, in higher β globulin concentrations of mid dose female rats treated (p < 0.05), γ globulin concentrations of low dose females (p < 0.05) and potassium concentrations of low dose males (p < 0.05); a slightly lower phosphorus concentration was also observed in low dose male rats than in controls (p < 0.05); all of these differences

were very small and were not considered to be of toxicological significance

Urinalysis:

urinary protein concentrations of two high dose male rats killed after four weeks of treatment, were noticeably higher than control values; reducing substances and glucose were detected in the urine of a further two male rats treated at this dosage; these differences were not observed after ten days' cessation of treatment; the urine of high dose females and of low and mid dose rats was considered to have been unaffected by treatment

Histopathology:

there were no micropathological changes in the adrenals, heart, kidneys, liver or spleen that were attributed to treatment

findings considered to be related to treatment were seen in the stomach; hyperkeratosis and acanthosis in the keratinised region of the stomach were seen in high dose animals; in addition to the hyperkeratosis and acanthosis at the keratinised region, ulceration of the same region was seen in a male decedent treated at the same dosage; all decedents and most animals receiving this dosage and killed after four weeks of treatment showed these findings; although the findings were still evident in animals after two weeks' cessation of treatment, their frequency was much reduced

there were also increased incidences of acute inflammation at both the glandular and keratinised regions of the stomach of high dose rats compared with control animals

Test method: according to OECD guidelines (8)

Result: the notified chemical caused irritation of the

stomach at a dose level of 200 mg.kg⁻¹.dy⁻¹ but no other organ toxicity was identified

9.3 Genotoxicity

9.3.1 Salmonella typhimurium Reverse Mutation Assay (11)

Strains: TA 1535, TA 1537, TA 98 and TA 100

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Concentration range: 50 - 5 000 μg.plate-1

Test method: according to OECD guidelines (8)

Result: the notified chemical was not mutagenic in

S. typhimurium at doses up to 5 000 μ g.plate⁻¹ either in the presence or absence of metabolic activation provided by rat liver S9 fraction

9.3.2 Micronucleus Assay in the Bone Marrow Cells of the Mouse (12)

Species/strain: mouse/CD-1

Number and sex of animals: 15/sex/dose group

Doses: 750, 1 500, 3 000 and 5 000 mg.kg⁻¹

Method of administration: by gavage in corn oil

Test method: according to OECD guidelines (8)

Result: no evidence of induction of micronuclei in

mouse bone marrow polychromatic erythrocytes at dose levels up to

5 000 mg.kg⁻¹ at 24, 48 or 72 hours after oral

administration

9.3.3 Induction of Chromosomal Aberrations in Cultured Human Lymphocytes (13)

Doses: without metabolic activation provided by rat

liver S9 fraction: 1, 2 or 3 μ g.mL⁻¹ for 24 hours; with S9 fraction, 2.5, 5.0, 10.0 or

15.0 μ g.mL⁻¹ for 3 hours

Procedure: 48-hour cultures established from whole

blood; cells harvested at 21 or 45 hours after

treatment as above

Test method: according to OECD guidelines (8)

Result: dose-related clastogenic activity was observed

in either the presence or absence of metabolic activation provided by rat liver S9 fraction

9.4 Overall Assessment of Toxicological Data

The notified chemical was of low acute toxicity in rats ($LD_{50} > 2~000~mg.kg^{-1}$ by the oral and dermal routes). No evidence of organ toxicity was observed in

an oral repeat dose 28-day study except for stomach irritation. The chemical was not a skin irritant but was a severe eye irritant and a potent skin sensitiser. It was not mutagenic in *S. typhimurium* nor clastogenic in mouse bone marrow cells *in vivo* but was clastogenic in cultured human lymphocytes.

On the basis of the toxicological data submitted, the notified chemical would be classified as hazardous according to the National Commission's *Approved Criteria for Classifying Hazardous Substances* (14) (Approved Criteria) in relation to its potential to cause skin sensitisation and serious eye damage.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The following ecotoxicity studies have been supplied by the notifier. The tests were carried out according to OECD Test Methods (8).

Test	Species	Results	Ref
Acute Toxicity	Rainbow Trout	24 h LC ₅₀ = 0.40 mg.L ⁻¹	(15)
	(Oncorynchus mykiss)	96 h LC ₅₀ = 0.17 mg.L ⁻¹	
		96 h NOEC < 0.07 mg.L ⁻¹	
Acute Immobilisation	Water Flea	24 h EC ₅₀ = 2.69 mg.L^{-1}	(16)
	(Daphnia magna)	48 h EC ₅₀ = 2.06 mg.L^{-1}	
		NOEC < 0.74 mg.L ⁻¹	
Growth Inhibition	Algae	96 h E₀C₅₀ = 20 mg.L ⁻¹	(17)
	(Selenastrum	96 h E_rC_{50} = 67 mg.L ⁻¹	
	capricornutum)	NOEC < 7.9 mg.L ⁻¹	

In the Rainbow Trout and Daphnia tests the results are based on measured concentrations. In the algal test actual solution concentrations were not measured and the results are based on nominal concentrations.

All ecotoxicity tests indicated an instability of the chemical in water. By the end of test periods or at the time of changing solutions, marked decreases in concentrations were observed. In the test with Rainbow Trout the measured concentrations after 24 hours were between 18 and 31% of the nominal concentrations. In the Daphnia test the measured concentrations after 48 hours were between less than 1 and 3% of the nominal concentrations. These decreases were attributed to possible hydrolysis of the chemical rather than adsorption, although this is not reflected in the hydrolysis results (see above). In both fish and Daphnia tests, the pH of test solutions as checked at the beginning and end of test periods remained within the range of 7.14 to 7.78. Hence a pH-influenced increase in hydrolysis does not seem to account for the concentration changes observed. All nominal concentrations selected were within the solubility limit of the chemical and the reports claim the solutions remained clear throughout. Therefore, it appears there were no precipitation problems either. Assuming hydrolysis accounted for the observed decreases in the concentrations of

the chemical, the reports concluded that the test organisms were probably exposed to the parent chemical as well as its hydrolysis products.

The ecotoxicity data indicate that the chemical is highly to very highly toxic to fish, moderately toxic to aquatic invertebrates and slightly toxic to algae.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The environmental hazard from the notified chemical would be low primarily due to low environmental exposure given: (i) no waste is generated during formulating into rubber, (ii) minor spills are easily collected and reused and, (iii) the chemical, after formulation is strongly bound to the rubber matrix.

Although the chemical has some potential to be mobile in the environment and is highly toxic to aquatic organisms, significant aquatic contamination is unlikely.

When used rubber articles such as tyres are combusted as fuel, the chemical will be destroyed.

The small proportion of the chemical that may enter the soil environment through wear and tear of tyres or shredding of used rubber articles for the manufacture of other items will be in a highly dispersed manner and this will undergo slow degradation.

The environmental hazard from the notified chemical can therefore be rated as low.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The notified chemical is capable of causing serious eye damage in humans, is a potent skin sensitiser and would be classified as hazardous according to the Approved Criteria on this basis. In a maximisation test in guinea pigs skin sensitisation in approximately 90% of animals was elicited with an induction dose of 0.1% (injected). The chemical is not likely to be acutely toxic nor to exhibit systemic toxicity on repeated or prolonged exposure but may be genotoxic in humans.

Exposure of workers involved is transport and storage of the notified chemical should be minimal and, therefore, the risk of adverse health effects to these workers should be negligible.

For workers involved in mixing the notified chemical into rubber, the potential for exposure via the inhalational route is expected to be low as the notifier states the chemical will be imported in dust-free pastilles and local exhaust ventilation will be employed during repacking and addition to the mixing vessel. Thus the risk of respiratory sensitisation is expected to be low. As the chemical is imported in relatively small 20 kg packages and repacked into small 1 to 2 kg packages, ocular and dermal exposure may be low. However, gloves and goggles should be worn as described below when carrying out these operations to minimise the risk of skin

sensitisation and eye damage. Once the chemical is mixed into the rubber at a concentration of 0.5%, exposure should be negligible as should the risk of adverse health effects.

The risk of skin sensitisation or serious eye damage to members of the public resulting from transport, storage, use or disposal of the notified chemical is expected to be negligible given the likely low exposure.

13. RECOMMENDATIONS

To minimise occupational exposure to the notified chemical the following guidelines and precautions should be observed:

- During weighing out of the notified chemical and its mixing into rubber, safety goggles should be selected and fitted in accordance with Australian Standard (AS) 1336 (18) to comply with Australian/New Zealand Standard (AS/NZS) 1337 (19), industrial clothing should conform to the specifications detailed in AS 2919 (20), impermeable gloves or mittens should conform to AS 2161 (21) and all occupational footwear should conform to AS/NZS 2210 (22);
- Good general and local exhaust ventilation should be employed during weighing out and mixing the notified chemical into rubber;
- Spillage of the notified chemical should be avoided, spillages should be cleaned up promptly with absorbents which should then be put into containers for disposal;
- Good personal hygiene should be practised to minimise the potential for ingestion;
- A copy of the Material Safety Data Sheet should be easily accessible to employees.

14. MATERIAL SAFETY DATA SHEET

The MSDS for the notified chemical was provided in accordance with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (23).

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 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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