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NATIONAL INDUSTRIAL CHEMICALS
NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

2-PYRROLIDONE, 1-ETHENYL-, POLYMER WITH 1-TRIACONTENE

(ANTARON WP-660)

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

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(ANTARON WP-660)

1. APPLICANT

ISP (Australasia) Pty Ltd, 73-75 Derby Street, Silverwater, NSW 2141.

2. IDENTITY OF THE CHEMICAL

Chemical name: 2-Pyrrolidone, 1-ethenyl-, polymer with 1-triacontene

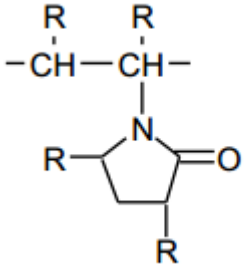
Chemical Abstracts Service (CAS) Registry No.: 136445-69-7

Other names:
AGENT ACP-1009
GANEX WP-660
Poly(vinyl pyrrolidone/1-triacontene)
GANEX V-230
Tricontanyl PVP
Copolymer of N-vinyl-2-pyrrolidone and 1-triacontene

Trade name: Antaron WP-660

Molecular formula: $(C_{30}H_{60}C_6H_9NO)_x$

Structural formula:



R=H or triacontanyl group

Number-average molecular weight: >1000

Maximum percentage of low molecular weight species (molecular weight < 1000): 20 to 30%.

Based on the nature of the chemical and the data provided, Antaron WP-660 is considered to be non-hazardous. Therefore, the number of repeating units, the molecular weight, polydispersity, weight percentage of ingredients and spectral data have been exempted from publication.

Method of detection and determination:

Infrared spectroscopy and Nuclear Magnetic Resonance spectroscopy are used to detect the polymer.

Spectral data:

Infrared spectrum (KBr pellet), NMR spectra (H^1 and C^{13}) were provided.

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	white to off white solid flakes
Melting Point:	56 - 64°C
Density:	947 kg/m^3
Vapour Pressure:	Not applicable as the polymer is not volatile.
Solubility:	Stated to be insoluble in water, acid or base solutions. This is acceptable given that the polymer contains a 30 carbon hydrophobic chain. Antaron WP-660 is used as a water-proofing agent for cosmetics.
Partition Co-efficient:	Not applicable as the polymer is insoluble in water.

Hydrolysis as a function of pH: Stated to be not applicable as the polymer is not soluble in water, acid or base. The polymer contains an amide which would hydrolyse under extreme conditions, which are unlikely to be encountered in the environment.

Adsorption/Desorption: No data were provided on the grounds that the polymer is insoluble

Dissociation Constant: The polymer contains no dissociable groups.

Stability: Antaron WP-660 is stable at room temperature. Incompatible with strong oxidising and reducing agents. Nitrous oxides (NO_X) may be produced when reacted with strong oxidisers.

Flammability Limits: Stated to be non flammable

Flash Point: Not applicable as the polymer is not volatile

Pyrolysis products: Not available

Autoignition Temperature: Not applicable

Explosive Properties: Not available

Particle size distribution: range - 0.25 to 1 cm^2

4. PURITY OF THE CHEMICAL

Degree of purity: >97%

Toxic or hazardous impurities: None known

Non-hazardous impurities: <2% water

Additives/Adjuvants: None

5. INDUSTRIAL USES

Approximately 250 kg per annum of Antaron WP-660 will be imported into Australia for use as a water-proofing and pigment dispersing agent in cosmetics such as lipsticks and eye make-up.

Antaron WP-660 has been manufactured in the USA since June 1990 and is currently marketed in several countries.

6. OCCUPATIONAL EXPOSURE

Antaron WP-660 will be imported and distributed in sealed drums to several manufacturers of cosmetics. Worker exposure during transport and storage of the chemical should be minimal under normal conditions.

Antaron WP-660 will be incorporated in cosmetics at a maximum concentration of 5%. In the case of lipsticks, the polymer will be mixed with waxes, colour pigments, lubricants and emollients, and heated until melted (approximately 80°C). The mix is cooled to about 60°C, perfume is added and the resultant mixture is then poured into moulds to set.

When manufacturing mascaras, Antaron WP-660 is mixed with solvent, waxes, colour pigments and emollients, usually without heating. The mix is then poured into bottles of 25 ml or less.

During use, worker exposure to the raw material may occur when flakes are weighed and added to the mixing tanks and during quality assurance testing. Packers will be exposed to low concentrations of the chemical in cosmetics during the filling and packing operations. However, due to its large particle size, which is well above the respirable size of 7 µm (1), and low volatility, the potential for worker exposure to Antaron WP-660 is low.

7. PUBLIC EXPOSURE

The public will be exposed to the chemical in its use as a water-proofing polymer in cosmetics such as lipsticks and mascaras, generally at concentrations of less than 5% by weight of the final product. Solid wastes produced during manufacturing and after consumer use would be disposed of in landfills.

8. ENVIRONMENTAL EXPOSURE

8.1 Release

The polymer will be compounded into cosmetics by an estimated 10 manufacturing companies in at least 3 major cities and is expected to be sold Australia-wide, providing a wide exposure of the substance to the environment. The total import volume for cosmetic use will be 250 kg per year, therefore the average usage per site of the polymer is expected to be around 25 kg per annum.

The expected total polymer wastage factor will be 2% from unused residues in the polymer containers, equipment washings and batch residues. Batch residues and polymer container residues will be disposed of to landfill while equipment washings will be processed through a treatment system for separation of solids and oils and precipitated into sludge. It is expected that approximately 500 g of polymer per site, some as dried sludge, will be disposed of to landfill, annually.

As Antaron WP-660 will be used for cosmetics, it will be released to the environment via consumer use through washing the residual polymer off the face and into the sewerage system. Due to its insoluble nature Antaron WP-660 is likely to be associated with the sludge/solids compartment of the sewerage system where it is expected to be incinerated or spread onto agricultural land.

8.2 Fate

The notifier states that by nature of the application, the polymer is required to be stable under a wide range of conditions. The polymer will form water vapour and oxides of carbon and nitrogen on combustion.

Antaron WP-660 is unlikely to be mobile in landfill situations given its water insolubility and stated chemical stability.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Test	Species	Outcome	Reference
Oral	rat	LD_{50} >5 g/kg	2
Dermal	rabbit	LD_{50} >2 g/kg	3
Skin irritation	rabbit	slight irritant	4
Eye irritation	rabbit	slight irritant	5
Skin sensitisation	human	non-sensitiser	7
Dermal Phototoxicity	human	negative	8
Dermal Photoallergy	human	negative	9

9.1.1 Oral Toxicity (2)

In a limit test, a single 5 g/kg dose of Antaron WP-660 was fed to 10 Sprague-Dawley rats (5 females and 5 males). The test material was ground into a powder and mixed with peanut butter and honey and consumed within 18 to 24 hours. The animals were observed for 14 days and weighed at days 0, 7 and 14. The average bodyweights of the male and female groups increased during the study and all animals survived. No gross organ changes were noted at necropsy. The acute oral LD_{50} in rats was determined to be greater than 5 g/kg under the conditions of the study.

Note: The protocol used in this acute oral toxicity study is unusual. Administration of a bolus dose by gavage to fasted animals is the preferred method. Administration of the test dose over a 24-hour period via the diet may lessen the acute oral

toxicity observed by changing the absorption and toxico kinetics of the test material.

9.1.2 Dermal Toxicity (3)

A single 2 g/kg dose of Antaron WP-660 was applied to the clipped backs of 10 New Zealand white rabbits. The test material was moistened with water and held in place under an occlusive wrap. The wrap was removed 24 hours after application and excess test material was wiped off. The animals were observed for signs of toxicity at 1, 3, 6 and 24 hours and daily thereafter for 14 days. Bodyweights were measured on days 0, 7 and 14. No abnormal clinical signs were observed and all animals survived. One animal had mucoid diarrhoea on day 7. All animals gained weight during the study. At necropsy one animal had numerous small dark lesions on both kidneys. The acute dermal LD_{50} in rats was greater than 2 g/kg under the conditions of the study.

9.1.3 Skin Irritation (4)

In an acute dermal irritation study, Antaron WP-660 was moistened with saline and applied to the clipped backs of six New Zealand white rabbits. A 0.5 g dose of the test material was applied under an occlusive wrap to one abraded and one intact test site on each rabbit. The wraps were removed 24 hours after application. The sites were washed and examined for signs of oedema and erythema immediately and 72 hours after application. Very slight erythema was observed at 2 intact and 4 abraded sites at 24 hours and one intact and 2 abraded sites at 72 hours. Slight oedema was noted at 1 intact site and 2 abraded sites at 24 hours only. Antaron WP-660 was a slight skin irritant in rabbits at the concentration tested.

9.1.4 Eye Irritation (5)

A 50 mg dose of Antaron WP-660 was instilled into the conjunctival sac of one eye in each of six New Zealand White rabbits. The other eye of each rabbit served as a control. The treated and untreated eyes of 3 rabbits were washed after 30 seconds. The rabbits' eyes were examined at 1 hour and 1, 2, 3, 4 and 7 days post instillation and scored according to the Draize scale (6). Slight erythema, oedema and discharge were noted in all the treated eyes at 1 hour. The conjunctival irritation persisted in one unwashed treated eye for 4 days, and in one washed treated eye for 1 day. The rabbits' eyes were also

examined on day 1 using fluorescein dye and no corneal staining was observed. Antaron WP-660 was considered a slight eye irritant in rabbits at the concentration tested.

9.1.5 Skin Sensitisation (7)

A total of 102 human subjects (21 males and 81 females) completed a repeat insult patch test. A series of 9 induction patches were applied to the subjects over a period of 3 weeks. Approximately 200 mg of Antaron WP-660 was applied to each patch and placed on the left upper back area for 24 hours. The site was observed before each repatching. Two weeks after the removal of the last induction patch the subjects were challenged at a new site. The test material was applied for 24 hours and both the induction and challenge sites were observed immediately, 48 and 72 hours post-patching. During the induction phase 6 subjects exhibited a minimal reaction. Induction sites did not exhibit adverse reactions during the rest period or at the challenge. One subject exhibited a minimal reaction at the challenge site. Under the conditions of the study, Antaron WP-660 did not induce skin sensitisation in humans.

9.1.6 Phototoxicity (8)

Approximately 200 mg of Antaron WP-660 was applied under an occlusive wrap to both forearms of 10 human subjects (1 male and 9 females). The wraps were removed 24 hours after application (day 2) and one forearm of each subject was irradiated (UV-A). Both arms of each subject were scored on days 2, 3 and 4. No reaction was noted in any of the subjects. Antaron WP-660 did not induce a contact dermal phototoxic response in humans under the conditions of this study.

9.1.7 Photoallergy (9)

The photoallergy test involved a 3 week induction phase followed by a 2 week rest period and then a challenge phase. During the induction phase, 200 mg of Antaron WP-660 was applied under an occlusive wrap to both forearms of 30 human subjects (6 males and 24 females). The wraps were removed after 24 hours and one forearm of each subject was irradiated for 15 minutes with 3.3 joules of UV-A and 108 to 144 m joules of UV-B, according to skin type. This induction step was repeated six times in three weeks. Two weeks after the last induction the subjects were challenged with an identical test patch at a new site on their forearm. The

wraps were removed after 24 hours and the designated forearm was irradiated with UV-A only. All forearms were observed immediately and at 48 and 72 hrs post-application. Twenty-eight subjects completed the study. Two subjects did not complete the study due to personal reasons.

At the challenge phase, only one subject exhibited a minimum reaction on the irradiated, test material contact site. No reactions were observed at the non-irradiated, contact sites or at the irradiated, non-contact sites.

Under the conditions of the study, Antaron WP-660 did not induce contact dermal photoallergy in human subjects.

9.2 Genotoxicity (10)

9.2.1 *Salmonella typhimurium* Reverse Mutation Assay

Initially, a dose range finding study was carried out using *Salmonella typhimurium* strain TA100 at ten dose levels of Antaron WP-660 ranging from 2500 to 3.33 µg per plate. No cytotoxicity was observed up to the maximum dose, either in the presence or absence of microsomal activation (S9 liver fraction).

Antaron WP-660 was then tested for its ability to induce reverse mutations in *Salmonella typhimurium* tester strains TA98, TA 100, TA1535, TA1537 and TA1538. The material was tested using three plates per dose level, at concentrations of 2500, 1000, 667, 333, 100 and 66.7 µg per plate. The experiment was repeated twice, both in the presence and absence of S9. The vehicle, ethanol, was used as the negative control. Positive controls included 2-aminoanthracene, 2-nitrofluorene, sodium azide and ICR-191. Incubation with Antaron WP-660 was not associated with an increase in the number of histidine revertants in any of the *Salmonella typhimurium* strains, either in the presence or absence of microsomal activation. In contrast, the positive controls showed marked increases in the number of revertant colonies. Under the conditions of this test Antaron WP-660 was not mutagenic toward *Salmonella typhimurium*.

9.3 Overall Assessment of Toxicological Data

In animal studies, Antaron WP-660 exhibited low acute oral and dermal toxicity and was a slight skin and eye irritant. In human studies, Antaron WP-660 did not induce skin sensitisation,

contact dermal phototoxicity or dermal photoallergy. Antaron WP-660 was not genotoxic in an Ames test.
Approximately 70 to 80% of the notified polymer has a molecular weight >1000 and is therefore unlikely to cross biological membranes such as the skin, gut and the respiratory tract. The remaining 20 to 30% of the material is capable of being absorbed, however, the acute toxicity profile of the notified chemical suggests there is little hazard associated with the polymer as a whole.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

No ecotoxicolgical data were provided, which is acceptable for polymers of NAMW >1000.

Although between 20 and 30% of the substance has a molecular weight of less than 1000 (80% of which has a molecular weight between 500 and 1000), that portion is still likely to be insoluble and, as such, not bioavailable.

11. ASSESSMENT OF ENVIRONMENTAL HAZARDS

The polymer is unlikely to present a hazard to the environment at any stage of its use, whether it be when reformulated into cosmetic products, resulting in an estimated 500 $g.year^{-1}$ per site of reformulation waste disposed of to landfill, or when consumers wash the polymer residue off their faces.

If the polymer remains suspended in sewerage effluent, a predicted environmental concentration for the substance in sewage water throughout Australia can be estimated from the following assumptions, 250 kg maximum annual cosmetic usage, an Australian population of 17 million and daily per capita water usage volume of 150 L. This provides a predicted concentration of well below 1 ppb in sewage which would be swiftly reduced to further insignificant levels by precipitation or dilution in rivers, lakes and oceans which act as receiving waters to nearly all sewage treatment plants in Australia.

The notified substance is not expected to exhibit toxic characteristics because large polymers of this nature are not readily absorbed by biota.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY

Acute toxicity tests indicate that Antaron WP-660 has low acute and dermal toxicity, is a slight eye and skin irritant, is not a skin sensitiser and it is not phototoxic or photoallergic. Antaron WP-660 was not genotoxic in an Ames test.

During use, worker exposure to the raw material may be occur when flakes are weighed and added to the mixing tanks and during quality assurance testing. Due to its large particle size and low volatility, the potential for worker exposure to Antaron WP-660 is low.

The public will be exposed to the chemical in cosmetic products such as lipsticks and mascaras, generally at a concentration of less than 5% by weight. In diluted form in cosmetics, the acute toxicity of the chemical would be very low or negligible. Only very small amounts of the chemical would require disposal, as solid waste, after consumer use.

Therefore, due to its low exposure under normal use conditions, its low acute toxicity and its physico-chemical properties, Antaron WP-660 is unlikely to pose a significant health and safety hazard to the public and workers.

13. RECOMMENDATIONS

The following guidelines and precautions for the use of Antaron WP-660 are recommended:

. the workplace should be well ventilated and engineering controls such as local exhaust ventilation should be employed where the flakes are handled and mixed;

. workers who may come into contact with Antaron WP-660 should:

- wear gloves which comply with Australian Standard AS 2161;

- wear safety glasses or goggles which comply with Australian Standard AS 1337 and chosen and used in accordance with Australian Standard AS 1336;

. good work practices should be observed;

- good housekeeping and maintenance should be practised;

- a copy of the Material Safety Data Sheet should be easily accessible to employees; and

- disposal of Antaron WP-660 should be in accordance with local regulations.

14. MATERIAL SAFETY DATA SHEET

The Material Safety Data Sheet (MSDS) for Antaron WP-660 is provided at Attachment 1. This MSDS was provided by ISP (Australasia) Pty Ltd as part of their notification statement. It is reproduced here as a matter of record. The accuracy of this information remains the responsibility of ISP (Australasia) Pty Ltd.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act), secondary notification of Antaron WP-660 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

1. National Occupational Health and Safety Commission, *Exposure Standards for Atmospheric Contaminants in the Occupational Environment*, AGPS, Canberra, 1990.

2. *Agent ACP-1009 Acute Oral Toxicity, Single Level - Rats*. Biosearch Incorporated, Philadelphia, Pennsylvania. Project No. 89-6734A, 1989.

3. *Acute Dermal Toxicity in Rabbits - Ganex WP-660.* Consumer Product Testing, Experiment Reference No. 90061, 1990.

4. *Agent ACP-1009 Primary Eye Irritation, 3 Unwashed and 3 Washed - Rabbits*. Biosearch Incorporated, Philadelphia, Pennsylvania. Project No. 89-6734A, 1989.

5. *Agent ACP-1009 Primary Skin Irritation - Rabbits*. Biosearch Incorporated, Philadelphia, Pennsylvania. Project No. 89-6734A, 1989.

6. Draize, J.H. et al. *Journal of Pharmacology and Experimental Therapeutics*. 82: 377-390, 1944.

7. *Ganex WP-660, Repeated Insult Patch Test - 100 Human Subject Study*. Harrison Research Laboratories Inc., Maplewood, USA. HRL Panel No. 90-107, 1990.

8. *Ganex WP-660, Phototoxicity Test - 10 Human Subjects*. Harrison Research Laboratories Inc., Maplewood, USA. HRL Panel No. 90-504T, 1990.

9. *Ganex WP-660, Photoallergy Test - 28 Human Subjects*. Harrison Research Laboratories Inc., Maplewood, USA. HRL Panel No. 90-504A (1), 1990.

10. *Mutagenicity Test on Ganex WP-660 in the Salmonella/ Mammalian-Microsome Reverse Mutation Assay*. Hazelton Laboratories America Inc., Maryland, USA. HLA Study No. 12071-0-401R, 1990.