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October 2000

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

MicroLite

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

MicroLite

1. APPLICANT

Grace Australia Pty. Ltd. of 1126-1134 Sydney Road, FAWKNER, VIC 3060 [A.C.N. 080 660 117] has submitted a standard notification statement in support of their application for an assessment certificate for MicroLite. There was no application for exempt information.

2. IDENTITY OF THE CHEMICAL

Chemical Name:	1,2,3-propanetricarboxylic acid, 2-hydroxy-, lithium salts, reaction products with vermiculite.
Chemical Abstracts Service (CAS) Registry No.:	110638-71-6
Other Names:	None
Marketing Name:	MicroLite MicroLite Powder MicroLite HTS-XE MicroLite HTS-XE20 MicroLite HTS-SE MicroLite Speciality Vermiculite MicroLite Vermiculite Dispersions 903, HTS, 923, 963
Molecular Formula:	$(Li,K).\ (Mg,Ca,Fe^{II})_3 \cdot (Si,Al,Fe^{III})_4 \cdot O_{10} \cdot (OH)_2 \cdot 4H_2O$

Structural Formula:

Structural Formula (for unit cell of vermiculite):

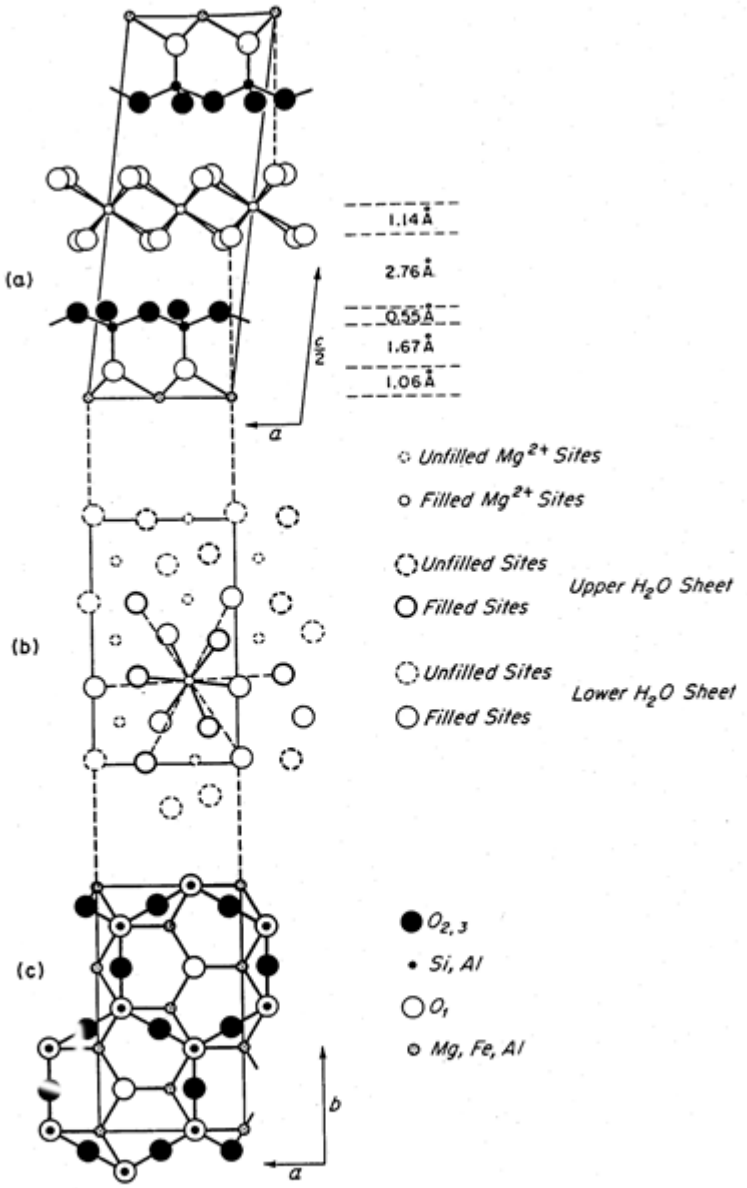

Fig. 4-20. The crystal structure of Mg vermiculite: (*a*) projection normal to the *ac* plane, (*b*) projection normal to the *ab* plane, showing the interlayer region; (*c*) projection normal to the *ab* plane showing one-half of a silicate layer ($z = 0$ to $c/8$). (After Mathieson and Walker.[381])

Molecular Weight: 453 – 2.31 x 10^{16} Daltons.

Method of Detection and Determination: Infra-red absorption and ^{1}H-, ^{13}C-NMR spectroscopy

Spectral Data: Major IR absorbance peaks were observed at 3000, 1800, 1480, 1400, 1200, 1120, 1060, 680, and 575 cm^{-1}

Comments on Identity:
MicroLite is a modified vermiculite in which magnesium and calcium ions have been exchanged for lithium ions. The vermiculite used in this product is a naturally occurring mineral and may have considerably varying chemical composition. The South Carolina vermiculite used to make MicroLite contains both magnesium and calcium (and sometimes small amounts of potassium) in its interlayers. Vermiculite mined from other sources may contain only some of these components.

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C & 101.3 kPa: Brownish green powder with no appreciable odour.

Boiling Point: MicroLite is required to withstand temperatures up to 1000 °C, so melting point/boiling point tests were not conducted.

Specific Gravity: 2.7112. (Directive 84/449/EEC, Annex V, Method A3).

Vapour Pressure: None.

Water Solubility: <10 mg/L by gravimetric limit test.

Particle size:
86.3% >9.8 μm
12.0% 6.0-9.8 μm
1.7% <6 μm

Partition Co-efficient (n-octanol/water): Not determined because of the very low solubility in water and insolubility in octanol.

Hydrolysis as a Function of pH: Not expected under environmentally relevant conditions given the following characteristics:
- Lack of any significant water solubility.
- Commercial stability as an aqueous dispersion; and
- Lack of any structural features, which assert hydrolytic characteristics.

Adsorption/Desorption: Not determined – see notes below.

Dissociation Constant: Not determined – see notes below.

Flash Point: Non-flammable.

Flammability Limits: Non-flammable.

Autoignition Temperature: No auto flammable properties at 400 ºC.

Explosive Properties: Not expected to be Explosive.

Reactivity/Stability: Unreactive.

Comments on Physico-Chemical Properties

The notified chemical is vermiculite mica, and the physico-chemical properties are expected to be the same as for this mineral. Relative density was determined by comparison of the weights of a pycnometer filled with an aqueous suspension (containing a known mass) of vermiculite with that of distilled water. Water solubility was determined gravimetrically, to be <10 mg/L. Analysis for lithium in the saturated solutions indicated a concentration between 0.14 and 0.44 mmol/L (1-3 mg/L), but no conclusions on water solubility of the bulk mineral could be drawn from this result.

Due to the solid nature and very high melting point (>1000 ºC) of the material, vapour pressure is negligible. The water solubility is slight at most and hydrolysis of the essentially ionic silicate and aluminate anions within the solid matrix is unlikely.

Partition coefficient and adsorption/desorption data are not relevant for the notified chemical, which will always remain in the solid form. The crystal structure of vermiculite does not contain exchangeable protons or hydroxy groups, and accordingly dissociation constant data is not relevant. The notifier has indicated in the material safety data sheet (MSDS) for MicroLite Vermiculite Dispersion that the pH of aqueous suspension is between 6.5 and 8.5, which is consistent with the absence of strongly acidic or basic functionalities.

4. PURITY OF THE CHEMICAL

Degree of Purity: >97.0%

Hazardous Impurities: Quartz

Weight percentage: 0-1%

CAS No.: 14808-60-7

Non-hazardous Impurities (>1% by weight):

Chemical name: Biotite

Weight percentage: 0-3%

CAS No.: 1302-27-8

Chemical name: Tremolite.

Weight percentage: Trace amounts.

CAS No.: 14567-73-8

Chemical name: Amphibole (only non-fibrous amphiboles detected).

Weight percentage: 0-2%.

Additives/Adjuvants: None

5. USE, VOLUME AND FORMULATION

MicroLite is used as a fire-resistant coating for fibreglass fabrics. It will be used only by industrial workers who will incorporate the substance into fabric rolls and cut and sew the coated fabrics into customised industrial safety clothing and welding curtains.

MicroLite is not manufactured in Australia. It will be imported into Australia in 208 L closed top plastic drums. Each 208 L drum contains approximately 32.66 kg of the notified chemical. The import of MicroLite is expected to be 12-36 drums in each of the next five years. This equates to about 1200 kg of the notified chemical per year for the next five years.

6. OCCUPATIONAL EXPOSURE

MicroLite is imported into Australia in 208 L closed top plastic drums shrink-wrapped and stored on pallets. All loading, unloading, handling and storage of the product in Australia will be performed by well-trained staff inside a bunded area. Drums will be stored on racks in warehouses. Transport and storage personnel will be exposed to the notified chemical only if packaging is breached.

MicroLite is coated onto fibreglass fabrics to improve temperature resistance. After coating with MicroLite, the fabric is dried and cut into appropriate roll sizes. The coating and drying processes are automated, using pump and conveying systems to move the fabric through a solution of MicroLite contained in a bath trough. Excess MicroLite is squeezed out using a 2-roller pad. The coated fabric is then moved to a drying oven via a conveying system. The coated rolls are sold to downstream customers for cutting and sewing into customized industrial fabrics. The MicroLite is reported to have good affinity for the fibreglass (no supporting data provided), but abrasion from sewing, cutting; handling etc. would result in some amount of dust being generated (less than 2% in harsh conditions). Offcuts are put into waste bins and sent to landfill.

Workers involved in coating the fabrics are plant operators (2), line operators (2), quality control personnel (1) and fabricators (10-15). Plant operators are involved in pouring and the mixing of MicroLite solutions in the bath troughs. The notifier states that mixing is automated using mechanical mixers. Line operators are involved in the coating and drying of fabrics. The maximum duration of exposure for plant and line operators is expected to be 7 hours/day. Engineering controls in place when drying the fabrics are a vented oven with an exhaust system.

Quality control personnel will sample and test the material by cutting the coated fabric with a sample cutter and weighing the sample on a balance. Exposure to the chemical will be 0.5 hour/day. Fabricators are involved in cutting the coated fabric to specified sizes, and perhaps some sewing to provide sealed edges. Maximum duration of exposure is expected to be 7

hours/day. There will be five people per shift (2 shifts per day) involved in the coating process.

Workers handling MicroLite will be equipped with the personal protective equipment recommended in the MSDS for the product, namely rubber or synthetic gloves, dust respirator and goggles.

7. PUBLIC EXPOSURE

The notified chemical will not be sold to the public.

The public is unlikely to come into contact with fabric coated with the notified chemical or industrial-use products made from the fabric. In the event of an accidental spill during transport, instructions on the MSDS indicate that the material will be bunded and collected in sealed labelled drums for disposal.

8. ENVIRONMENTAL EXPOSURE

Release
Very little of the material is likely to be released during application to the glass cloth, since all excess liquid is squeezed from the cloth and replaced in the bath. The notified chemical is a solid, which is maintained and used as a dispersion in water. On prolonged standing the chemical settles as sludge at the bottom of the dipping baths and is periodically collected into a drum and sent to landfill. The notifier indicated that up to 2 kg of MicroLite might be left as residual every production run. Since there may be one production run every month, on an annual basis, this equates to approximately 25 kg, or around 2% of the import quantity. The "supernatant" water is pumped to the sewer, and although this may contain fine suspended material, no indication of the quantity was provided by the notifier. However, the quantity of vermiculite is expected to be small, and it would eventually become associated with sewage sludge.

The residual chemical left in the drums after emptying is likely to be washed out and used in the dipping bath. The emptied drums would probably be sent for reconditioning and recycling where all residual vermiculite would be removed and become associated with waste sludge at the recycling plant. This is likely to be either placed directly into landfill or be incinerated. Since the vermiculite is extremely resistant to heat it would become associated with furnace ash, and would then be placed into a landfill.

The fibreglass cloth coated with the vermiculite will be cut into various shapes prior to being fabricated into protective clothing and other articles. Consequently, some material will be discarded with "off cuts" and other waste, and this would be placed into landfill. The quantity of material discarded with "off cuts" was not indicated, but is likely to be around 10%, which would amount to a maximum of 120 kg of the new chemical being discarded each year.

Although the vermiculite has strong affinity for the glass, the notifier indicated that some would be abraded from the cloth (eg as a result of cutting) during manufacture of articles. This would amount to around 2% of imports, or to a maximum of 24 kg per year. The

abraded material would slowly settle to the floor of the manufacturing premises, and would most probably be vacuumed up and disposed of with cleaning waste to landfill.

The fabricated products would be discarded at the end of their useful lives to landfills.

It is clear that due to the refractory nature of the new chemical, almost all would eventually be deposited into landfill, ie. a maximum of 1,200 kg per annum.

Fate
The new chemical is a mineral, and is not biodegradable. Consequently, all material released into landfill is expected to be persistent, and eventually assimilate into soil. A similar fate is expected for the fibreglass substrate with which the majority of the new chemical is expected to be associated. In such situations, extremely slow decomposition would take place as a result of the usual weathering processes, but such processes will have no significant environmental impact.

If any of the material were to enter the water compartment, eg. as a result of a transport accident, it would become associated with sediments. The inorganic nature of the material would preclude bioaccumulation.

9. EVALUATION OF TOXICOLOGICAL DATA

Toxicological studies were submitted for the notified chemical, 1,2,3-propanetricarboxylic acid, 2-hydroxy-, lithium salts, reaction products with vermiculite (marketing name, MicroLite).

9.1 Acute Toxicity

Summary of the acute toxicity of MicroLite

Test	*Species*	*Outcome*	*Reference*
Acute oral toxicity	Rat	>5000 mg/kg	Huntingdon Research Centre (1990a)
Acute dermal toxicity	Not provided		
Acute inhalation toxicity	Rat	>0.053 mg/L	Huntingdon Research Centre (1991b)
Skin irritation	Rabbit	Not a skin irritant	Huntingdon Research Centre (1990b)
Eye irritation	Rabbit	Slight eye irritant	Huntingdon Research Centre (1990c)
Skin sensitisation	Guinea pig	Not a skin sensitiser	Huntingdon Research Centre (1990d)

9.1.1 Oral Toxicity (Huntingdon Research Centre (1990a))

Species/strain:	Rat/Sprague-Dawley (Crl:CD® (SD) BR VAF PLUS).
Number/sex of animals:	5/sex.
Observation period:	14 days.
Method of administration:	Oral; single dose of 5 g/kg bw of undiluted test substance.
Test method:	OECD TG 401.
Mortality:	None.
Clinical observations:	Pilo-erection was observed in all rats within five minutes of the initial dose and throughout the remainder of Day 1. There were no other clinical signs and recovery was complete by Day 2, as judged by external appearance and behaviour.
Morphological findings:	None.
Comment:	Terminal autopsy revealed small silver particles in the stomach contents of all male rats. There were no macroscopic abnormalities.
LD_{50}:	>5000 mg/kg bw.
Result:	The notified chemical was of very low acute oral toxicity in rats.

9.1.2 Dermal Toxicity

Not provided.

9.1.3 Inhalation Toxicity (Huntingdon Research Centre (1991b))

Species/strain:	Albino rats (Sprague-Dawley).
Number/sex of animals:	5/sex.
Observation period:	14 days.
Method of administration:	Inhalation of a test atmosphere containing dust generated from the test substance for 4 hours (whole body exposure). Due to small proportion of particles of respirable size (<2% less than 6 μm), the highest attainable atmospheric concentration of MicroLite in the experiment was 0.053 mg/L.

Test method:	OECD TG 403.
Mortality:	None.
Clinical observations:	During exposure: Partial closing of the eyes was observed after 1 hour of exposure. During observation period: No significant observations.
Morphological findings:	There were no abnormalities in rats exposed to MicroLite powder. The lung weight to body weight ratio for all rats was within normal limits.
LC_{50}:	>0.053 mg/L (>53 mg/m^3).
Comment:	A single exposure to the low concentration of airborne dust obtained from MicroLite produced no significant effects. MicroLite contains only a small proportion of particles of respirable size.
Result:	The results were inconclusive due to very low concentration of MicroLite in the atmosphere.

9.1.4 Skin Irritation (Huntingdon Research Centre (1990b))

Species/strain:	Rabbit/New Zealand white.
Number/sex of animals:	3 (sex not specified).
Observation period:	4 days.
Method of administration:	0.5 g of MicroLite was applied under a 2.5 cm^2 gauze pad moistened with 0.5 mL of distilled water to one intact skin site on each animal and held under semi-occlusive dressing. After four hours, treatment sites were washed using water to remove any residual test substance.
Test method:	OECD TG 404.
Draize scores:	All Draize scores for erythema and oedema were zero for each animal up to 72 hours.
Comment:	There was no response to treatment with MicroLite in any animal throughout the observation period.
Result:	The notified chemical was not irritating to the skin of rabbits.

9.1.5 Eye Irritation (Huntingdon Research Centre (1990c))

Species/strain: Rabbit/New Zealand white.

Number/sex of animals: 3 (sex not specified).

Observation period: 7 days.

Method of administration: 0.1 mL MicroLite (45 mg) was placed into the lower everted lid of one eye of each animal. The eyelids were then gently held together for one second before releasing. The contralateral eye remained untreated and served as a control.

Test method: OECD TG 405.

Draize scores of unirrigated eyes:

	Time after instillation														
Animal	***1 day***			***2 days***			***3 days***			***4 days***			***7 days***		
Conjunctiva	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***	***r***	***c***	***d***
1	1	1	NR	0	0	NR	0	0	NR	0	0	NR	0	0	
2	0	0	NR	0	0	NR	0	0	NR	0	0	NR	0	0	
3	0	0	NR	0	0	NR	0	0	NR	0	0	NR	0	0	

All Draize scores for cornea and iris were zero up to 72 hours after instillation.

[1] see Attachment 1 for Draize scales. r = redness, c = chemosis, d = discharge, NR = not reported

Comment: Instillation of MicroLite into the rabbit eye elicited transient mild conjunctival inflammation in one animal only.

Result: The notified chemical was slightly irritating to the eyes of rabbits.

9.1.6 Skin Sensitisation (Huntingdon Research Centre (1990d))

Species/strain: Guinea pig/Dunkin Hartley (albino)

Number of animals: 30 female guinea pigs

Induction procedure:

Test group: day 0 — Three pairs of intradermal injections were made on the scapular region:

FCA diluted 1:1 with water
MicroLite, 0.25% w/w in water
MicroLite, 0.25% w/w in a 1:1 mixture of FCA and water

day 7	0.2 mL of 10% sodium lauryl sulphate in petrolatum was gently rubbed on the treated area. Twenty-four hours later a patch of filter paper was saturated with 0.4 mL of MicroLite (20% in distilled water) and placed on the skin and covered by impermeable plastic adhesive tape.
Control group:	During the induction phase the control animals were treated similarly to the test animals with the exception that the test compound was omitted from the intradermal injections and topical applications
Challenge procedure:	The test and control animals were challenged topically two weeks after topical induction using MicroLite, 20% and 10% w/w in distilled water. Patches of filter paper were saturated with 20% and 10% solution of MicroLite and placed on the anterior and posterior sites on the flanks. The patches were sealed to the flank for 24 hours.
Test method:	OECD TG 406, Magnusson and Kligman Maximisation Test.

Challenge outcome:

Number of animals exhibiting positive response

Challenge concentration	***Test animals***		***Control animals***	
	24 hours*	***48 hours****	***24 hours***	***48 hours***
10%	0/20	0/20	0/10	0/10
20%	0/20	0/20	0/10	0/10

*Time after patch removal;

Comment:	In this screening test performed in twenty albino guinea pigs, MicroLite did not produce evidence of delayed contact hypersensitivity. The concentration of MicroLite used for topical induction and challenge (20%) was the maximum achievable concentration.
Result:	The notified chemical was not sensitising to the skin of guinea pigs

9.2 Repeated Dose Toxicity (Huntingdon Research Centre (1991c)).

Species/strain:	Rat/Charles River Crl:CD® SD BR VAF PLUS
Number/sex of animals:	18/sex
Method of administration:	Oral (gavage); dose volume: 10 mL/kg/day

Dose/Study duration: 0, 500 and 1000 mg/kg/day/ 28 days

Test method: OECD TG 407

Clinical observations
There were no mortalities. For rats treated with 500 and 1000 mg/kg/day MicroLite, slight pilo-erection was noted in both sexes during week 4 on a few occasions. There were no significant differences between food consumption and body weight gains of control and treated rats. Intergroup variation in water consumption showed no treatment-related effect.

Haematology
Significantly lower haemoglobin levels were recorded for male rats treated at 500 and 1000 mg/kg/day in comparison with control animals. The change was minor and not dose-dependent.

Significantly higher total white blood cell, neutrophil and lymphocyte counts were recorded for male rats treated with 500 and 1000 mg/kg/day compared to control animals. Again, the changes were minor and not dose-dependent. In all other haematological parameters measured, values were similar for control and treated rats.

Clinical chemistry
Higher glucose and lower globulin and inorganic phosphorous levels were recorded in male rats fed 500 and 1000 mg/kg/day MicroLite. These changes were not dose-related, nor were seen in corresponding female rats.

Pathology
No gross macroscopic changes were observed at necropsy. Statistically significant decreases in absolute adrenal and testes weights were observed in males treated with 1000 mg/kg/day. However, individual weights were reported to be as expected for this strain and age of rat.

Histopathology
Compared to controls, no statistically significant changes were observed in the tissue sections of treated animals.

Comment:
The haematological and blood serum changes noted in male rats receiving MicroLite at 500 and 1000 mg/kg/day were minor and not dose related. No corresponding changes were observed in the macroscopic and microscopic examinations. No statistically significant changes were observed in female rats in the study.

Result:
Based on the minor nature of effects observed in male rats only at 500 and 1000 mg/kg/day, the no observed adverse effect level (NOAEL) of MicroLite was established as 1000 mg/kg/day in this study.

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* Reverse Mutation Assay (Huntingdon Research Centre (1990e)).

Strains: S. typhimurium: TA 1535, TA 1537, TA 1538, TA 98 and TA100.

Metabolic activation: Liver preparation (S9 mix) from Aroclor 1254-induced rats.

Concentration range: Two independent tests were conducted at the following concentrations:
0, 50, 150, 500, 1500 and 5000 μg/plate, with or without S9 mix; triplicate cultures were used for each concentration.

Positive controls:

Without S9 mix
9-aminoacridine at 80 μg/plate with TA 1537.
N-Ethyl-N'-nitro-N-nitrosoguanidine at 3 μg/plate with TA 100.
N-Ethyl-N'-nitro-N-nitrosoguanidine at 5 μg/plate with TA 1535.
2-Nitrofluorene at 1 μg/plate with TA 98.
2-Nitrofluorene at 2 μg/plate with TA 1538.

With S9 mix
2-Aminoanthracene at 0.5 μg/plate, 1 μg/plate and 2 μg/plate with various strains of Salmonella.

Negative control:
Water.

Test method: OECD TG 471

Comment: A preliminary toxicity study revealed that MicroLite was not toxic to any of the strains at concentrations up to 5000 μg/plate with or without metabolic activation. In all assays microbial contamination was observed at the higher concentrations of MicroLite, however this did not interfere with the counting of revertant colonies.

In the main study, no significant increase in the frequency of revertant colonies was observed in any of the bacterial strains, at any concentrations, with or without S9 metabolic activation. All positive controls used in the study confirmed the sensitivity of the various strains and the efficacy of the S9 mix.

Result: The notified chemical was non mutagenic under the conditions of the test.

9.3.2 Chromosomal Aberration Assay in rat peripheral lymphocytes (Huntingdon Research Centre (1991e)

Cells:	Peripheral lymphocytes isolated from rats (Charles River Crl:CD® SD BR VAF PLUS) following 28 days oral exposure to MicroLite.
Methodology:	Approximately 24 hours after the last dose of MicroLite, 0.5 mL of blood was removed from the rats by cardiac puncture and added to the culture medium in a sterile universal plate. The lymphocytes in each blood sample were stimulated to divide by the addition of concanavalin A (10 μg/mL) and mercaptoethanol to each culture. After 45 hours incubation, colchicine was added to arrest cell division. Lymphocytes were separated by centrifugation method and fixed and stained on microscopic slides for examination. Coded slides were examined under the light microscope for any chromosomal aberrations. Incidence of chromosomal aberrations per 50 metaphase spreads per animal/culture were recorded.
Test method:	OECD TG 473
Result:	Animals treated with MicroLite showed no statistically significant increase in the proportion of metaphase figures containing chromosomal aberrations when compared with the control group.
Comment:	The notified chemical was not clastogenic under the conditions of the test.

9.3.3 Micronucleus Assay in the Bone Marrow Cells of the Rat *in vivo* (Huntingdon Research Centre (1991d))

Species/strain:	Rat/Charles River Crl:CD® SD BR VAF PLUS
Number and sex of animals:	30 rats; 5/sex/group
Doses:	500 mg/kg/day and 1000 mg/kg/day
Method of administration:	Oral (gavage)
Test method:	OECD TG 474
Comment:	Rats (Charles River Crl:CD® SD BR VAF PLUS) were treated with 28 daily administrations of the test agent (MicroLite suspended in distilled water) by gavage.

Approximately 24 hours after the last dose, the rats were killed, one femur was removed from each animal and bone marrow smears were prepared.

The smears were stained and examined by light microscopy for the presence of micronuclei in 1000 polychromatic erythrocytes per animal. The ratio of polychromatic to normochromatic erythrocytes was assessed by examining at least 1000 erythrocytes from each animal.

Rats treated with MicroLite did not show any significant increase in the frequency of micronucleated polychromatic erythrocytes. MicroLite did not cause any significant decrease in the ratio of polychromatic to normochromatic erythrocytes.

Result: The notified chemical was not clastogenic under the conditions of the test

9.4 Overall Assessment of Toxicological Data

The notified chemical was of very low acute oral toxicity in rats, with an LD_{50} >2 000 mg/kg bw. Studies on its acute inhalation toxicity were inconclusive due to low atmospheric concentrations of MicroLite. MicroLite contains 1% respirable dust and the maximum achievable atmospheric concentrations are low. However, the MSDS mentions that if spray mist were generated, inhalation of the spray mist could cause slight irritation to nose and respiratory passage. The notified chemical was a slight eye irritant in rabbits, however it was not a skin irritant in rabbits, or sensitising to the skin of guinea pigs.

Oral administration of the notified chemical to rats in a 28-day repeated dose toxicity study did not result in any significant toxicological effects. The biochemical changes, noted in male rats only at 500 and 1000 mg/kg/day MicroLite, were minor and not dose related or supported by pathological changes. Based on these results, the NOAEL of MicroLite was 1000 mg/kg/day.

The notified chemical tested negative in a battery of genotoxicity studies. It was not mutagenic in an Ames test and was not clastogenic *in vitro* in a chromosomal aberration assay in rat peripheral lymphocytes. It was also negative in an *in vivo* rat micronucleus test.

The notified chemical is not classified as a hazardous substance according to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (National Occupational Health and Safety Commission 1999b).

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The notifier provided the following ecotoxicity data on the acute toxicity of the chemical to fish and to *Daphnia magna*. A summary only of the reports was provided, and the notifier also did not include the appropriate references, although these were apparently performed by

a reputable laboratory (Macdonald et al. 1991). However, other reports were also submitted in the notification (see below), and the summary data is acceptable.

TEST/METHOD	SPECIES	RESULTS (nominal concentrations)
Fish acute toxicity OECD 203	Rainbow trout *Oncorhynchus mykiss*	LC_{50} (96 h) >1,000 mg/L
Daphnia acute toxicity OECD 202	*Daphnia magna*	EC50 (48 h) >1,000 mg/L

FISH
The test on rainbow trout was performed over a 96-hour test period using a semi-static methodology in which 20 fish were exposed to an aqueous suspension containing a (nominal) 1,000 mg/L of the test substance. No details of fish mortality or sub-lethal effects were given in the summary, although it was stated that the results lead to the 96 hour LC_{50} of >1,000 mg/L indicating the new chemical to be non toxic to this species up to the limit of its water solubility.

INVERTEBRATES
The test on Daphnia magna was performed by the same laboratory, and 40 daphnia were exposed to a suspension containing (nominally) 1,000 mg/L of the modified vermiculite over a 48 hour test period. Again no further details were given in the summary, and the 48-hour EC50 of >1,000 mg/L indicates the test material to be non-toxic to this species up to the limit of its water solubility.

Due to the absence of acute toxic effects, a chronic (reproduction) study on the *Daphnia magna* was not performed.

The notifier also enclosed a test report, which appears to apply to both acute, and chronic toxicity testing of effluent samples from the plant at which MicroLite is manufactured (South Carolina, USA) against *Ceriodaphnia dubia*. Although toxic effects were apparently noted for some of the waste streams tested, no conclusions can be drawn from the results since the composition of the waste streams were not specified.

ALGAE
No test work was undertaken since it was considered that the material contains a high concentration of cations, and would therefore not sequester these from the water column and deprive algae of these metals which are essential micro-nutrients. This is acceptable since the chemical constitution of the notified chemical is such that other toxic effects to algae are unlikely.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The environmental hazard resulting from use of the new material as a heat resistant coating for fibreglass cloth is considered to be small. The coated fibreglass cloth will be used for fabrication of heat resistant welding curtains and other safety clothing and equipment. Although a very small amount of the material may be released to a metropolitan sewer

systems during coating onto the fibreglass cloth, most is expected to eventually be placed into landfill with off cuts from article manufacture, and when the manufactured articles have reached the end of their service lives. In this situation the notified material would become associated with soil and clay, and is not expected to be mobile in these media.

The new chemical is essentially a modified vermiculite, and since such minerals are not biodegradable the material will be persistent. However, very little is expected to enter the water compartment, and any that does (eg. as a result of transport accident) would become associated with sediments. The mineral does not contain any functionalities or impurities likely to be toxic to aquatic species, and the available test data seem to confirm this with reported 96 hour LC_{50} for rainbow trout and 48 hour EC50 for *Daphnia magna* both >1,000 mg/L.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The notified chemical, MicroLite, will be imported into Australia in 208 L closed plastic drums. Australian workers will use it for coating fabrics and cutting and sewing into customized industrial fabrics.

The notifier provided toxicological studies in support of the application for an assessment certificate. The notified chemical exhibited very low acute oral toxicity (LD_{50}>2 000 mg/kg) in rats. It was a slight eye irritant in rabbits but not a skin irritant in rabbits or a skin sensitiser in guinea pigs.

A single 4-hour exposure to the low concentration of airborne dust obtained from MicroLite produced no significant effects. MicroLite contains a small proportion of particles of respirable size.

Oral administration of the notified chemical to rats in a 28-day repeated dose toxicity study did not result in any significant toxicological effects. The no observed effect level (NOEL) of MicroLite was 1000 mg/kg/day. The notified chemical was considered non-mutagenic to the bacterial strains tested and non-clastogenic *in vitro* in a chromosomal aberration assay.

Based on the toxicological data submitted, the notified chemical would not be classified as a hazardous substance under the NOHSC Approved Criteria for Classifying Hazardous Substances (National Occupational Health and Safety Commission, 1999a).

Occupational Health and Safety
Exposure to the notified chemical is not expected during transport or storage as long as the packaging remains intact. Exposure after a spill would be controlled by use of the recommended practices for spillage clean up given in the MSDS supplied by the notifier. The risk of adverse health effects for transport and storage workers is considered low.

Plant and line operators may be exposed to the notified chemical during coating and drying the fabrics. The main route of exposure will be dermal. Ocular exposure may occur from splashes during dipping the fabric in the chemical solution. However, this is likely to be minimal, as automated systems (conveyors) will be used during these processes. The notified chemical is a slight eye irritant. Workers will therefore be required to wear eye protection

during dipping and drying the fabrics.

Fabricators involved in cutting the coated fabrics will come into contact with dried chemical on the fabrics. MicroLite is stated to have good affinity for the fibreglass, but abrasions from sewing, cutting and handling may result in some amount of dust being generated (less than 2%) in harsh conditions. Inhalation effects of the chemical were inconclusive and reportedly mists may cause respiratory irritation. Workers should therefore take appropriate measures to reduce any inhalation exposure. The area should be well ventilated to avoid any accumulation of dust where the fabrics are being cut, sewn and repacked for selling.

The notifier has recommended that workers wear rubber or synthetic gloves, dust respirators and safety goggles when working with the notified chemical.

Public Health
The notified chemical will not enter the public domain and the risk to public health is assessed as very low. Should the use extend to fabrics within the public domain, additional information would be required to assess the public health risk.

13. RECOMMENDATIONS

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

- Safety goggles should be selected and fitted in accordance with Australian Standard (AS) 1336 (Standards Australia, 1994) to comply with Australian/New Zealand Standard (AS/NZS) 1337 (Standards Australia/Standards anew Zealand, 1992); industrial clothing should conform to the specifications detailed in AS 2919 (Standards Australia, 1987) and AS 3765.1 (Standards Australia, 1990); impermeable gloves should conform to AS/NZS 2161.2 (Standards Australia/Standards anew Zealand, 1998); all occupational footwear should conform to AS/NZS 2210 (Standards Australia/Standards anew Zealand, 1994);

- Spillage of the notified chemical should be avoided. Spillages should be cleaned up promptly with absorbents which should be put into containers for disposal;

- Good personal hygiene should be practised to minimise the potential for ingestion;

- A copy of the MSDS should be easily accessible to employees.

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

14. MATERIAL SAFETY DATA SHEET

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

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

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under subsection 64(1) of the Act, secondary notification will be needed if use as a fire resistant coating extends to fabrics used by the public. Under subsection 64(2) of the Act, secondary notification of the notified chemical may be required if any of the stipulated circumstances arise. No other specific conditions are prescribed.

16. REFERENCES

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Huntingdon Research Centre (1990e) MicroLite Speciality Vermiculite: Bacterial mutation assay. Cambridgeshire UK, Huntingdon Research Centre Ltd.

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

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Standards Australia/Standards New Zealand (1998) AS/NZS 2161.2:1998 Occupational protective gloves, Part 2: General requirements, Standards Australia/Standards New Zealand.

Vermiculite Association (2000) Vermiculite Properties. Lincoln UK, The Vermiculite Association (TVA).

Attachment 1

The Draize Scale (Draize, 1959) for evaluation of skin reactions is as follows:

Erythema Formation	*Rating*	*Oedema Formation*	*Rating*
No erythema	0	No oedema	0
Very slight erythema (barely perceptible)	1	Very slight oedema (barely perceptible)	1
Well-defined erythema	2	Slight oedema (edges of area well-defined by definite raising	2
Moderate to severe erythema	3	Moderate oedema (raised approx. 1 mm)	3
Severe erythema (beet redness)	4	Severe oedema (raised more than 1 mm and extending beyond area of exposure)	4

The Draize scale (Draize *et al*., 1944) for evaluation of eye reactions is as follows:

CORNEA

Opacity	*Rating*	*Area of Cornea involved*	*Rating*
No opacity	0 none	25% or less (not zero)	1
Diffuse area, details of iris clearly visible	1 slight	25% to 50%	2
Easily visible translucent areas, details of iris slightly obscure	2 mild	50% to 75%	3
Opalescent areas, no details of iris visible, size of pupil barely discernible	3 moderate	Greater than 75%	4
Opaque, iris invisible	4 severe		

CONJUNCTIVAE

Redness	*Rating*	*Chemosis*	*Rating*	*Discharge*	*Rating*
Vessels normal	0 none	No swelling	0 none	No discharge	0 none
Vessels definitely injected above normal	1 slight	Any swelling above normal	1 slight	Any amount different from normal	1 slight
More diffuse, deeper crimson red with individual vessels not easily discernible	2 mod.	Obvious swelling with partial eversion of lids	2 mild	Discharge with moistening of lids and adjacent hairs	2 mod.
		Swelling with lids half-closed	3 mod.		
Diffuse beefy red	3 severe	Swelling with lids half-closed to completely closed	4 severe	Discharge with moistening of lids and hairs and considerable area around eye	3 severe

IRIS

Values	*Rating*
Normal	0 none
Folds above normal, congestion, swelling, circumcorneal injection, iris reacts to light	1 slight
No reaction to light, haemorrhage, gross destruction	2 severe