File No: PLC/96

February 1999

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Dehymuls PGPH

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Facsimile:	(61) (02) 9577 9465

Director
Chemicals Notification and Assessment

PLC/96

FULL PUBLIC REPORT

Dehymuls PGPH

1. APPLICANT

Henkel Australia Pty Ltd of 83 Maffra Street BROADMEADOWS VIC 3047 has submitted a notification statement in support of their application for an assessment certificate for a synthetic polymer of low concern, Dehymuls PGPH.

2. IDENTITY OF THE CHEMICAL

The chemical name, CAS number, molecular and structural formulae and spectral data have been exempted from publication in the Full Public Report.

Other Name: SAT 940669

Trade Name: Dehymuls PGPH or Dehymuls KE 3190

Number-Average Molecular Weight (NAMW): 2 400 (visual estimate from mass spectrogram).

It is stated a GPC analysis could not be carried out due to the nature of the notified substance. However the Number Average Molecular Weight and low weight fractions were established from a mass spectrum of the substance.

Maximum Percentage of Low Molecular Weight Species

Molecular Weight < 500: 0.5%

Molecular Weight < 1 000: 1.5%

Weight Percentage of Ingredients:

Chemical Name	*CAS No.*	*Weight %*
polyglycerine	25618-55-7	66.7
poly(12-hydroxystearic acid)	27924-99-8	33.3

Method of Detection and Determination: IR, MS

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	cloudy viscous liquid
Melting Point:	23-32°C
Specific Gravity:	939 kg/m^3 at 25°C
Vapour Pressure:	<0.1 kPa at 25°C
Water Solubility:	< 1 g/L (see comments below)
Partition Co-efficient (n-octanol/water):	not determined
Hydrolysis as a Function of pH:	may hydrolyse under extreme conditions
Adsorption/Desorption:	not determined
Dissociation Constant:	the polymer does not have any group that undergoes dissociation
Flash Point:	292°C
Flammability:	combustible
Autoignition Temperature:	>390°C
Explosive Properties:	no explosive properties
Reactive Functional Groups:	aliphatic hydroxyl (low concern)
Reactivity/Stability:	expected to be stable under normal use conditions (see comments below)

Comments on Physico-Chemical Properties

Tests were performed according to test guidelines at facilities complying with OECD Principles of Good Laboratory Practice.

The water solubility has been determined at less than 1 g/L. A mix at 1 g/L produced a solution that was cloudy. It could not be shown that this was the solubility limit for the polymer. An analysis of the Dissolved Organic Carbon (DOC) in test solutions used for fish ecotoxicity tests was made to confirm the expected "low" solubility. Part of the DOC (of 7.7 mg per gram of product) is probably 0.5% residual 12-hydroxystearic acid.

The substance contains an ester functionality that may undergo hydrolysis under extreme

conditions of temperature and pH.

4. PURITY OF THE CHEMICAL

Degree of Purity: 99.45%

Toxic or Hazardous Impurities: not stated

Non-hazardous Impurities (> 1% by weight): not stated

Maximum Content of Residual Monomers/Other Reactants:

Chemical Name	*CAS No.*	*Weight %*
Polyglycerine	25618-55-7	0.0
12-hydroxystearic acid	106-14-9	0.3-0.5

Additives/Adjuvants: not stated

5. USE, VOLUME AND FORMULATION

The notified polymer is to be used as an emulsifier in skin care lotions at concentrations up to 5%. The notified polymer will not be manufactured in Australia. It will be imported in 200 kg steel drums and reformulated in Australia. The estimated import volumes are:

Year	*1*	*2*	*3*	*4*	*5*
tonnes	6	10	10	10	10

6. OCCUPATIONAL EXPOSURE

The main route for occupational exposure will be dermal contamination as the vapour pressure for the notified polymer is low. Mists are unlikely to be generated as the polymer is viscous.

Transport and Storage
The notified polymer will be imported as a 100% viscous liquid in 200 kg steel drums. It is estimated that 10 workers will be involved in the transport and storage of the polymer, including waterside workers, transport drivers and warehouse operators. They will handle the notified polymer 2-3 hours per day and 10-15 days per year.

Occupational exposure for transport and storage workers is unlikely unless the drums were breached in the event of an accident. The transport and warehouse workers will wear overalls and safety boots.

Formulation-Mixing
At the formulation site, the notified polymer, 50 L per batch, is transferred to 1 000 L sealed mixing tanks by metered dosing pumps. During the process, the oil and water phases will be heated to 80°C, blended together and cooled to approximately 30°C before filling. As the formulation is an enclosed and automatic process, formulators may be contaminated with the notified polymer only during connecting and disconnecting the transfer lines to the mixer.

The formulation will be carried out about 2 batches per day. It is estimated that there will be 8 workers at the formulation site. They will work 8 hours per day and 60-100 days per year. During formulation processes, workers will wear PVC gloves, safety glasses, uniforms and safety shoes. General and local ventilation is used.

Formulation-Filling
The final concentration of the notified polymer in the products is up to 5%. The formulated product is piped directly by metered dosing pumps to the filling machines, which are sealed and automated. The final product is filled into 250 mL moulded plastic bottles ready for distribution to retail outlets. There will be 25 packaging workers handling the products 8 hours per day and 60-100 days per year. They will operate and clean the automated guarded filling equipment. Skin contamination may occur due to overfilling or spills during filling process. Workers also could be exposed to the notified polymer during cleaning up through skin or eye contact.

R&D and Quality Control
There will be 3 R&D workers handling the notified polymer 6 hours per day and 15 days per year. They will disperse the notified polymer with other components by laboratory mixers to prepare trial batches. R&D workers will wear laboratory coats and safety glasses.

In addition, there will be 5 quality control workers who will handle the notified polymer on 4 hours per day and 30 days per year basis. Quality control workers will use laboratory equipment to test the raw material and the final formulations containing the notified polymer. The notifier has not specified the personal protective equipment for quality control workers, however, they would be expected to wear laboratory coats and safety glasses.

Both R&D and quality control workers will handle small amounts of the notified polymer and operate at a small scale in the laboratory.

End use
Beauty salon workers and beauticians will use the products containing the notified polymer. The maximum concentration of the notified polymer in the products will be 5%. Dermal would be the main route of exposure. The duration of handling the products containing the notified polymer among beauty salon workers and beauticians is expected to be short.

7. PUBLIC EXPOSURE

Public exposure from reformulation and disposal is expected to be minimal. Since the notified chemical is to be used as a cosmetic ingredient in body lotions, primary public exposure to the notified polymer will be by dermal contact, and possibly ocular contact.

8. ENVIRONMENTAL EXPOSURE

Release

Although the production activity takes place in a purpose-constructed facility with standard controls for capture of accidental releases, some release to the environment through spillage is possible during product formulation. The notifier estimates that a maximum of 5% (annually 300-500 kg) of the imported volume may be lost in this manner. The material released in the plant as a result of spills and cleaning activities is sent with other waste to an on-site treatment facility consisting of a solids and oil interceptor followed by chemical/biological treatment. The effluent from this treatment is released to sewer. The residual solids and liquids from the interception processes are disposed of by licensed waste contractors.

The notifier indicates that each empty drum is likely to contain 4 kg of the chemical. Drums are cleaned on site and the rinsings treated at the on-site effluent neutralisation plant.

The notifier also estimates that around 2% of the skin care products is likely to remain in the depleted consumer packages. These would be discarded with household garbage and ultimately placed into landfill or incinerated. This would account for 195 kg of the chemical per annum.

The new chemical is a component of cosmetic products, which would consequently be expected to be released into the environment through the sewerage system. The notifier has estimated that the release of the notified substance from an individual application would be 50 mg (10% of that applied), which would be washed off during showering. The usual volume of water used in showering is 60 litres, resulting in an influent concentration of 0.83 mg/L and a predicted environmental concentration (PEC) in metropolitan receiving waters of 0.00083 ppm. Country treatment works could be expected to release a concentration of 0.021 ppm.

Fate

The notifier provided a laboratory report on the assessment of the biodegradation of the notified substance conducted in accordance with the guidelines for the Modified OECD Screening Test [OECD TG 301E]. The results of the test indicated 44% loss of initial chemical oxygen demand (COD) of the notified substance after 7 days, and 88% loss of COD after 28 days. This was interpreted in the report as indicating that the material was readily biodegradable under the conditions of this test. Strictly however, for a compound to be classified as readily biodegradable under TG 301E, > 70 % reduction in DOC should be attained after 28 days and this level of degradation should be achieved within 10 days of attainment of 10% degradation. In this case, it was 14 days. Sodium acetate, used as the standard in this test, had lost 86% of the initial COD after 28 days, but had been 70% degraded after 7 days from start of the test.

Residual chemical disposed of to landfill within empty drums or together with residual solids derived from water treatment at the production facility would be subject to the biological and abiotic processes operative in these situations. The notified chemical is expected to degrade to water, methane and carbon dioxide. Similarly, incineration of the material would produce water vapour and oxides of carbon.

Most of the new chemical is expected to be released into the sewerage system. The hydrophobic and surface active nature of the chemical indicates that it would become associated with the organic component of the particulate matter present in the raw sewage, and eventually become incorporated into sediments where it would be expected to undergo biological degradation.

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Toxicity Studies

Summary of the acute toxicity of Dehymuls PGPH.

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity (analogue)	rat	LD_{50} > 18 500 mg/kg	(FAO/WHO, 1969)
skin irritation	rabbit	a slight skin irritant	(Pels Rijcken, 1994)
eye irritation	rabbit	a slight eye irritant	(Pels Rijcken, 1995)
skin sensitisation	guinea pig	a weak skin sensitiser	(Pittermann, 1994)

9.1.1 Oral Toxicity on Interesterified Ricinoleic Acid (Unilever Research Labs, 1966 cited in FAO/WHO, 1969)

The acute oral LD_{50} in rat for the analogue substance interesterified ricinoleic acid was reported as > 18 500 mg/kg.

9.1.2 Skin Irritation (Pels Rijcken, 1994)

Species/strain:	rabbit/New Zealand White
Number/sex of animals:	3 males
Observation period:	7 days
Method of administration:	the notified chemical (0.5 mL) was applied to the intact skin for 4 hours under a semi-occlusive dressing

Draize scores (Draize, 1959):

Animal	***Time after after treatment***				
	1 hour	***1 day***	***2 days***	***3 days***	***7 days***
Erythema					
1	[a]0	2	2	1	0
2	1	1	1	0	0
3	1	2	1	0	0
Oedema					
1	1	1	0	0	0
2	0	1	0	0	0
3	0	1	0	0	0

[a] see Attachment 1 for Draize scales

Test method:	OECD TG 404 (Organisation for Economic Co-operation and Development, 1995-1996)
Result:	the notified chemical was slightly irritating to the skin of rabbits

9.1.3 Dermatological Evaluation in Humans (Matthies & Molitor, 1995)

A brief report entitled "Dehymuls PGPH, RIS-No: 51Z1200325000, Dermatological Evaluation" from Department of Dermatology, Henkel KgaA was provided.

A 20% ethanolic dilution of the substance was applied to the skin of 20 volunteers over a 24 hour period. The application was performed using Finn Chambers to create conditions for a higher penetration of the test substance. The application site was not described.

Three individuals developed slight to moderate erythema and slight squamation. The authors concluded that "Dehymuls PGPH can be recommended as good skin compatible for the use as emulsifier up to 10% in cosmetic and pharmaceutic products".

9.1.4 Eye Irritation (Pels Rijcken, 1995)

Species/strain:	rabbit/New Zealand White
Number/sex of animals:	3 males
Observation period:	72 hours
Method of administration:	the notified chemical (0.1 mL) was instilled in the conjunctival sac of one eye of each animal

Draize scores (Draize, 1959):

	Time after instillation			
Animal	***1 hour***	***1 day***	***2 days***	***3 days***
Conjunctiva	***r***	***r***	***r***	***r***
1	2	1	0	0
2	2	1	0	0
3	2	1	0	0

[1] see Attachment 1 for Draize scales
r - redness

The Draize scores for cornea (opacity and area), iris and conjunctiva (chemosis and discharge) were zero for all animals up to 72 hours. No corneal epithelial damage was revealed, under fluorescein staining.

Test method: OECD TG 405 (Organisation for Economic Co-operation and Development, 1995-1996)

Result: the notified chemical was a slight irritant to the eyes of rabbits

9.1.5 Skin Sensitisation (Pittermann, 1994)

Species/strain: guinea pig/Dunkin Hartley

Number of animals: 20 females (treatment), 10 females (control)

Induction procedure: 0.5 mL of the notified chemical (12.5% in peanut oil) was applied 3 times (day 1, 8, 15) to the left flank under an occlusive dressing for 6 hours.

Challenge procedure: 14 days after the third induction, 0.5 mL of the notified chemical (10% in peanut oil) was applied to both flanks under an occlusive dressing for 6 hours

Challenge outcome:

Challenge concentration	***Test animals***			***Control animals***		
	24 h*	***48 h***	**72 h**	***24 h***	***48 h***	**72 h**
10% (left flank)	**1/20	5/20	0/20	0/10	1/10	0/10
10% (right flank)	0/20	1/20	0/20	0/10	2/10	0/10

* time after patch removal
** number of animals exhibiting positive response

Test method:	Buehler test, similar to OECD TG 406 (Organisation for Economic Co-operation and Development, 1995-1996)
Result:	the notified chemical was a weak skin sensitiser in guinea pigs

9.1.6 Photo-Irritation-Cytotoxicity in Mouse Fibroblasts *in vitro* (Schroder, 1997)

Cell culture:	mouse fibroblast (Balb/c)
Concentration range:	preliminary test: 3 – 10 000 µg/mL; main test: 1 – 2 000 µg/mL as either an emulsion or as a solution in 1-propanol
Test method:	cell viability was determined after cell cultures incubated with the notified chemical were irradiated with a UV dose of approximately 5 J/cm^2. Chlorpromazine and Texapon ASV were used as the positive and negative controls.
Result:	the notified polymer did not show any phototoxic potential in the *in vitro* test while both positive and negative controls demonstrated the appropriate responses.

9.1.7 *Salmonella typhimurium* Reverse Mutation Assay (Banduhn, 1994)

Strains:	*S. typhimurium* TA 1535, TA 1537, TA 1538, TA 98 and TA 100
Concentration range:	8.0 – 5 000 µg/plate in the absence or presence of metabolic activation by S9-mix
Test method:	OECD TG 471 (Organisation for Economic Co-operation and Development, 1995-1996)
Remarks:	No cytotoxicity or precipitation was observed at the test concentrations. The positive and negative controls tested accordingly.
Result:	Dehymuls Ke 3190 (Dehymuls PGPH) did not induce gene mutations in this bacterial mutagenicity test, with or without S9 metabolic

activation.

9.1.8 Repeated Dose Toxicity (Unilever Research Labs, 1966 cited in FAO/WHO, 1969)

Some short-term and long-term studies for the analogue substance interesterified ricinoleic acid in animals and humans were included in the FAO/WHO report. The treated animals essentially did not show any adverse effects apart from an increase in liver and kidney weights after more than 45 weeks treatment.

9.2 Overall Assessment of Toxicological Data

The notifier provided published FAO/WHO literature on the acute toxicity of polyglycerol esters of interesterified ricinoleic acid, which has a similar structure to the notified polymer. The level of reporting in this paper is basic and it cites an earlier study for the oral LD_{50}. As cited, the acute oral LD_{50} for polyglycerol esters of interesterified ricinoleic acid in rats is >18 500 mg/kg. Thus, the notified polymer is expected to be of very low acute oral toxicity.

The notifier provided a published paper on a validation study of hen's egg chorioallantoic membrane (HET-CAM) test (Spielmann et al., 1993), which is an *in vitro* screening test for eye irritation. Dehymuls PGPH has been tested and found to produce slight reactions in the vascular system of the chorioallantoic membrane. The report is unpublished and was unavailable for assessment. However, based on the slight positive findings, an eye irritation study was conducted in rabbits and this study was provided for assessment. It showed that the notified polymer was a slight eye irritant, but would not warrant a health hazard classification as an eye irritant.

The notified polymer was a slight skin irritant in rabbits and a weak skin sensitiser in guinea pigs. A skin irritation study in humans revealed that the notified polymer was a slight skin irritant in humans (3/20 volunteers). The notified polymer did not show any phototoxic potential in mouse fibroblast cell cultures *in vitro* suggesting that the chemical in skin products does not increase danger from the sun.

Dehymuls PGPH was not mutagenic in bacteria with and without metabolic activation.

Dehymuls PGPH could not be classified as a hazardous substance according to NOHSC *Approved Criteria for Classifying Hazardous Substances* (National Occupational Health and Safety Commission, 1994a) based on the available data.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

Although not required by the Act for new chemicals assessed as Synthetic Polymers of Low Concern, the notifier supplied the following ecotoxicity data - specifically laboratory reports on the acute toxicity of the notified substance to zebra fish and on the inhibition of bacteria.

Test	*Species*	*Results (Nominal)*
Acute Toxicity (semi static)	*Brachydanio rerio*	LC_{50}(96 h) > 10 000 mg/L
[EU TG 92/96 EWG]	(Zebra fish)	LC_0 (96 h) = 10 000 mg/L
Bacterial inhibition	*Pseudomonas putida*	EC_{10} > 10 000 mg/L
[DIN 38412, Part 27]		EC_0 = 10 000 mg/L

The tests results indicate that the notified substance is non toxic to the zebra fish, with a 96 hour LC_0 of 10 000 mg/L. Nominal concentrations were used because of the lack of solubility of the substance even with the aid of a dispersant (ultraturrax). The measured concentrations of dissolved organic carbon (DOC) were around the average of 7.7 mg per gram of product for the duration of the test showing that the substance was present at low levels. Values did not alter over the period of the test. No fish died or were affected at any concentration tested.

The acute bacterial toxicity test assesses the ability of a bacteria to continue normal respiration in the presence of the test substance over a period of 30 minutes. The notified substance is shown to be non toxic to bacteria at the maximum nominal rate tested of 10 000 mg/L.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

Release to the environment from formulation and packaging of the notified substance at the factory site is expected to be captured by the on-site collection and treatment systems. Effluent released after this treatment to the municipal sewage stream will be further fixed to sludge or reduced by micro-organisms in the digesters.

Packaging into individual 250 mL containers and packaging in boxes for distribution to retail point of sale will reduce potential exposure from transport accident.

Domestic use across Australia is expected and low levels of the notified substance in effluent would be quickly diluted in the receiving waters or degraded by micro-organisms. The worst case dilution figures provided by the notifier show limited release at concentrations of 0.021 mg/L, below the level of concern for harm to the most sensitive ecotoxicity test of 10 000 mg/L for fish and bacteria.

Calculations based on 100% discharge of the new chemical into Australian domestic sewers (of 10 000 kg per year, or 27 kg per day), and assuming an average of 150 L of water released to sewer per person per day and a national population of 18 000 000, show the mean nationwide PEC in sewage treatment plant effluent is 0.01 mg/L. This confirms the expected low hazard from the proposed use.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The notified polymer is expected to be of very low acute toxicity, based on acute rat data for a similar chemical, polyglycerol esters of interesterified ricinoleic acid. Slight skin and eye irritation was observed in animals with the notified polymer. A 20% solution in ethanol placed under occlusive dressing for 24 h caused slight to moderate erythema and slight squamation of the skin in 3/24 human volunteers. The polymer was a slight skin sensitiser in

guinea pigs by the Buehler method. No cytotoxicity to mouse fibroblast cells was demonstrated following culture with the polymer under UV irradiation. The polymer was not mutagenic in the Ames test. No repeat dose study was available for the notified polymer, but the high molecular weight would limit absorption through biological membranes. Based on the available data, the notified polymer is not classified as a hazardous substance according to NOHSC *Approved Criteria for Classifying Hazardous Substances* (National Occupational Health and Safety Commission, 1994a).

As the notified polymer is viscous and has a low vapour pressure, dermal contamination is considered to be the main route for occupational exposure rather than inhalation.

Transport and Storage
The health risk for transport and storage workers arising from potential contact with the notified polymer is expected to be low due to the low toxicity of the polymer and the expected nil exposure except in the case of accidental spillage.

Formulation
Formulation is an automatic process and taken place in sealed mixers. Formulators will handle the undiluted polymer and could be contaminated with the notified polymer during connecting and disconnecting the pumps. Both skin and eye contamination is possible. Workers wear PVC gloves, safety glasses, uniform and safety shoes. General and local ventilation will be provided. The potential health risk for mixing workers is considered to be low due to anticipated low exposure.

Filling workers could be exposed to the notified polymer during cleaning up through skin or eye contact. The concentrations of the notified polymer in the final products are low (up to 5%). Workers will wear gloves, safety glasses, overalls and safety shoes. The health risk for filling workers is expected to be low.

R&D and Quality Control
Both R&D and quality control workers will handle small amounts of the notified polymer and operate on a small scale in the laboratory. R&D and quality control workers will wear laboratory coats and safety glasses. The anticipated health risk will be low.

End Use
Beauty salon workers and beauticians may use the products containing the notified polymer in their work. Dermal contact is the primary route in end uses. However, adverse health risk is considered to be low for beauty salon workers and beauticians because of the low toxicity of the notified polymer, low amount of the notified polymer in products and short duration of occupational exposure. The skin sensitisation label warning statement proposed for skin lotions for public health (see below) will serve as a warning for occupational users also.

Public Health
Since the notified chemical will be used as a cosmetic ingredient in body lotions, primary public exposure will be by dermal contact, and possibly ocular contact. The notified polymer was a slight skin and eye irritant in rabbits. At the use level in skin lotions (around 5%), it is unlikely to be a skin or eye irritant. However, 10% of the notified polymer caused slight skin sensitisation in a guinea pig study. Skin sensitisation could occur in some individuals at the intended use level in skin lotions. A warning on the skin sensitisation potential is

recommended.

13. RECOMMENDATIONS

Skin lotions containing the notified polymer should carry the following warning on the labels: "Sensitive persons may experience allergic reactions".

To minimise occupational exposure to Dehymuls PGPH prior to end use 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 New 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 or mittens should conform to AS 2161 (Standards Australia/Standards New Zealand, 1998);
- All occupational footwear should conform to AS/NZS 2210 (Standards Australia/Standards New 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.

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* (National Occupational Health and Safety Commission, 1994b).

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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Matthies W & Molitor C (1995) Dehymuls PGPH, RIS-No: 51Z1200325000, Dermatological Evaluation, Project No. R 9400795, Henkel KGaA.

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Pels Rijcken W (1994) Primary skin irritation/corrosion study with SAT 940669 in the rabbit, Project No. R 9400993, NOTOX B.V., The Netherlands.

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Pittermann W (1994) Dehymuls Ke 3190, Skin sensitization (Buehler Test) on guinea pig, Project No. R 9400843, Henkel KGaA, Germany.

Schroder K (1997) Dehymuls PGPH Ke 3190, In-vitro test: photo-irritation-cytotoxicity in mouse fibroblasts (Balb/c 3T3), Project No. R 9700261, Henkel KGaA, Germany.

Spielmann Hea (1993) Validation study of alternatives to the Draize eye irritation test in Germany: cytotoxicity testing and HET-CAM test with 136 industrial chemicals. Toxic in Vitro, **7**(4): 505-510.

Standards Australia (1987) Australian Standard 2919-1987, Industrial Clothing. Sydney, Standards Association of Australia.

Standards Australia (1990) Australian Standard 3765.1-1990, Clothing for Protection against Hazardous Chemicals Part 1 Protection against General or Specific Chemicals. Sydney, Standards Association of Australia.

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

Standards Australia/Standards New Zealand (1992) Australian/New Zealand Standard 1337-1992, Eye Protectors for Industrial Applications. Sydney/Wellington, Standards Association of Australia/Standards Association of New Zealand.

Standards Australia/Standards New Zealand (1994) Australian/New Zealand Standard 2210-1994, Occupational Protective Footwear. Sydney/Wellington, Standards Association of Australia/Standards Association of New Zealand.

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

Attachment 1

The Draize Scale 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 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.
Diffuse beefy red	3 severe	Swelling with lids half-closed	3 mod.	Discharge with moistening of lids and hairs and considerable area around eye	3 severe
		Swelling with lids half-closed to completely closed	4 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