File No: EX29(NA/621)

July 2001

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Sodium Ascorbyl Phosphate

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Director
Chemicals Notification and Assessment

Sodium Ascorbyl Phosphate

1. APPLICANTS

Original Holder of Assessment Certificate (First Applicant)

An Assessment Certificate for the notified chemical known by the name sodium ascorbyl phosphate was granted to BASF Australia Limited of 500 Princes Highway NOBLE PARK VICTORIA 3174.

The Assessment Report for sodium ascorbyl phosphate is identified by the sequence number NA/621.

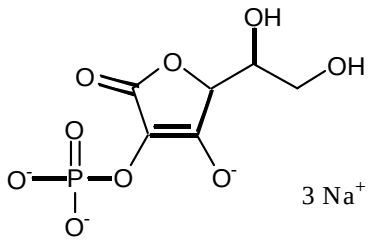
Second Applicant

Since granting of the abovementioned Assessment Certificate, Beiersdorf Australia Limited of 4 Khartoum Road NORTH RYDE NSW 2113 has submitted a notification statement in support of their application for an extension of the original Assessment Certificate for sodium ascorbyl phosphate. BASF Australia Limited has agreed to this extension.

Beiersdorf Australia Limited intends to import less than one tonne per annum over the next five years as a cosmetic ingredient in a skin care formulation. Additional results from ecotoxicity tests were available in this application. The original assessment report (NA/621) has been amended to incorporate both the results and the additional import volume into Australia.

This amended report is identified by the sequence number EX/29 (NA/621).

2. IDENTITY OF THE CHEMICAL

Chemical Name:	L-ascorbic acid, 2-(dihydrogen phosphate), trisodium salt
Chemical Abstracts Service (CAS) Registry No.:	66170-10-3
Other Names:	sodium ascorbyl monophosphate trisodium ascorbate-2-phosphate L-ascorbic acid, 2-monophosphate, trisodium salt
Trade Name:	none
Molecular Formula:	$C_6H_6O_9P.\ 3Na$
Structural Formula:	
Molecular Weight:	322
Method of Detection and Determination:	ultraviolet-visible (UV/Vis), Nuclear Magnetic Resonance (NMR) and infrared (IR) spectroscopy
Spectral Data:	major characteristic IR peaks identified at the following wavelengths: 3 512, 3 397, 3 168, 1 722, 1 597, 1 414, 1 162, 1 149, 1 118, 1 085, 1062, 1 036, 1 024, 991, 844, 790, 712, 666 and 563 cm^{-1} UV/Vis spectrum; absorbance maxima in water 261.3 nm, in 1 molar sodium hydroxide 262.8 nm and in 1 molar hydrochloric acid 236.7 nm

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	white to slightly beige powder, almost odourless
Melting Point:	not determined; the notified chemical turns brown at approximately 245°C and remains solid up to 260°C

	(end point temperature of the measurement)
Relative Density:	1.94 at 20°C
Bulk Density:	290 kg/m^3
Vapour Pressure:	< 10^{-8} KPa at 20°C < 10^{-7} KPa at 130°C
Water Solubility:	789 g/L at 20°C, approximate pH 8.3
Partition Co-efficient (n-octanol/water):	log P_{ow} < -4 at 25°C
Hydrolysis as a Function of pH:	stable at pH 5-8; stability decreases at pH 3 (see comments below)
Adsorption/Desorption:	not determined (see comments below)
Dissociation Constant:	not determined (see comments below)
Flash Point:	not applicable
Flammability Limits:	not determined
Autoignition Temperature:	238°C
Explosive Properties:	not determined (notifier states based on the molecular structure the notified chemical will not be hazardous)
Particle Size:	not determined
Reactivity/Stability:	the notified chemical is stable at ambient temperature and is not considered to be reactive; it is non-flammable and non-explosive; the notified chemical like many other organic powders can cause dust explosions
Surface Tension:	69.5 mN/m at 20°C

Comments on Physico-Chemical Properties

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

The melting point could not be determined. The notified chemical turns brown from approximately 245°C, but remains solid up to 260°C (end point temperature of the measurement). The boiling point cannot be determined as the vapour pressure of the chemical is lower than the detection limit of the test [92/69/EEC test A4, effusion method (by loss of weight)].

No test under OECD guidelines was undertaken for hydrolysis, but data on stability was supplied by the notifier. At low pH the recovery rate of the notified chemical over 185 days decreased with increasing temperature. At higher temperatures, the recovery rate decreased over the pH range 3.05 to 8.08. See below for an extract of the results table. Samples at low pH and high temperature exhibited a distinct discolouration and CO_2 release after 20 and 35 days, respectively. Ascorbic acid was determined (by HPLC) to be partially produced.

Temperature	*pH Range*	*% Recovered (after 185 days)*
5-8°C	3	88
	5-8	104-106
Ambient	3	41
	5-8	95-102
40°C	3	0.3
	5-8	74-87

NB: Varying or excessive values were due to errors in HPLC determination.

The adsorption/desorption coefficient and dissociation constant have not been determined. Given the chemical's high water solubility and low partition coefficient it is anticipated that it will not strongly adsorb. The notified chemical is a highly water soluble salt and is expected to remain ionic in water in the environmental pH range of 4-9.

The notified chemical is not expected to be surface active. By definition, a chemical has surface activity when the surface tension is less than 60 mN/m (European Economic Community (EEC), 1992).

4. PURITY OF THE CHEMICAL

Degree of Purity: 83-90%

Toxic or Hazardous Impurities: none

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

Chemical name: water
Weight percentage: 2-11%
CAS No.: 7732-18-5

Chemical name: ascorbic acid-2, 6-diphosphate pentasodium salt
Weight percentage: 3-5%
CAS No.: -

Additives/Adjuvants: none

5. USE, VOLUME AND FORMULATION

The notified chemical will be manufactured as a powder overseas. Sodium ascorbyl phosphate which is a sodium salt of a stable vitamin C derivative will be used in sunscreen preparations, skin-care products and vitamin creams.

In Australia the notified chemical will be imported by BASF Australia Limited in powder form and reformulated, and predominantly for use in sunscreen preparations, and to a lesser extent in other applications. The final concentration of sodium ascorbyl phosphate in end-use products could be up to 5% depending on the application, but is typically 0.01 to 0.1% in sunscreen preparations. Beiersdorf Australia Limited will import a formulated skin care cream in plastic jars containing the notified chemical at 0.1%.

Import volumes for the notified chemical by BASF Australia Limited are less than 400 kg per year for each of the first five years. Beiersdorf Australia Limited expects to import less than 30 kg per annum of the notified chemical over the next two to three years.

6. OCCUPATIONAL EXPOSURE

The notified chemical is imported by BASF Australia Limited in 5 kg or 30 kg metal drums with antistatic inner lining. The total imported volume (shipping container with drums) will be transported by road to the notifier's warehouse. At the warehouse metal drums containing the notified chemical will be unloaded from the container and transported to a customer site. One to 2 drivers and 2 store persons are expected to be involved in this process. Beirsdorf Australia will import the formulated skin care product in 50 mL plastic retail jars which are sold on to pharmaceutical/cosmetic distributors. No further formulation or repackaging will occur.

Transport and Storage
Transport workers and storemen are unlikely to be exposed to the notified chemical unless the containers are accidently breached.

The following applies to introduction of the notified chemical by BASF Australia Limited only.

Reformulation
At the customer site, one to 2 store personnel will receive the drums containing the notified chemical. Drums will be carried on pallets or individually on forklifts to quarantine and sampling areas, and then to the manufacturing site. The total delivery time could be up to 10 minutes with an expected 2 deliveries per year. One quality control person will open, sample and close each drum containing the notified chemical. Sampling may involve maximum of 5 minutes twice per year. The notifier has not provided details of the sampling procedure or the methodology of testing.

One to 2 plant operators are involved in the reformulation production process for a maximum period of 30 minutes. The number of times per week will depend on the number of batches. Manufacturing of sunscreen is normally carried out over an eight week period.

An operator will open the drum containing the notified chemical and manually (or automatically) weigh and transfer the chemical to the blending vessel with other ingredients. Blending is carried out within an enclosed system. The blended product containing the notified chemical is then pumped within the closed system to containers, which could be 50 gm sticks, 125 gm tubes, 250 gm bottles or 1 L pump packs. The concentration of the notified chemical in the final product could be up to 5%, but will typically be 0.01 to 0.1% for sunscreen preparations. Following batch production, the vessels are cleaned. Spillage could occur during normal operating procedures, and will be contained and covered with sand, soil or a dust binding material. The notifier states the spill will be mixed thoroughly, but not vigorously, to avoid dust generation. It will then be swept and collected for disposal in appropriately labelled containers. It is estimated that less than 0.8 kg of the notified chemical will be disposed of annually. The primary source of exposure to the notified chemical during reformulation will be when opening and closing of drums and when weighing and charging the blending vessel. Inhalation, ocular and dermal exposure may occur during these processes. Local exhaust ventilation will be in place over the weighing, mixing and filling areas to capture any airborne dust particles or vapours. The notifier states that the local exhaust ventilation will be installed in areas where natural ventilation is considered to be inadequate.

The total number of workers that may be potentially exposed to the notified chemical at the formulation facility is normally less than 15.

The notifier states that during reformulation operations, workers will be attired with suitable industrial clothing, safety glasses/goggles, face shields and protective gloves. In areas where there is exposure to dusts approved air purifying (dust) respirators will be used, except where local exhaust ventilation is adequate to prevent exposure.

7. PUBLIC EXPOSURE

The notified chemical will be used as a component of cosmetic formulations for use on most areas of the body. The number of people exposed to the product is not determinable from the information provided and is likely to be limited only by the commercial success of the products containing it.

Transport of finished cosmetic products containing the notified chemical or of the notified chemical itself is unlikely to result in significant public exposure. In the event of a transport accident the products, which are small volume packs, are likely to be widely dispersed and will be readily recoverable through adsorption on sand, vermiculite or similar materials. Spillage of the notified chemical powder could be contained by sweeping or vacuuming. Wind dispersion may lead to wider exposure.

8. ENVIRONMENTAL EXPOSURE

Release

The notified chemical will be reformulated into sunscreen and skin care products. Potential environmental exposure may occur during the weighing of ingredients, although automatic weighing is employed where possible. After mix preparation, mixing occurs in an essentially closed system. Release of the notified chemical to the environment during reformulation is expected to be very low. Batch residues will be retained and sent to a licensed waste disposal facility. Empty product containers will be disposed of according to appropriate guidelines, i.e. either to an approved drum recycler or to approved landfill. The expected total wastage from unused residues, equipment washings and batch residues is estimated by the notifier to be approximately 0.2%, or 0.8 kg per annum at maximum import quantities.

Release of the chemical to the environment through its proposed use as a consumer product is expected to be widespread. For example, the notifier estimates that for each 10-20 g wipe of sunscreen onto the skin, typically 0.005 to 0.1 g of the notified chemical will be released.

The product containers used by consumers of the notified chemical are expected to be disposed of with normal household garbage to landfill.

Fate

The reformulation of products containing the notified chemical is likely to occur at a small number of formulating plants. Spillages will be contained and collected for disposal. Wastes will be retained and sent to an approved waste disposal facility, presumably either to a trade waste sewer or landfill. The notified chemical is not expected to partition to sediment/sludge of the waste water treatment plant, but is likely to undergo degradation (see below).

The notified chemical is intended for use in sunscreens and skin care products and, as such, would be expected to be released to the environment, via consumer use through washing the residual chemical off the skin, into either natural waterways or the sewerage system. It is unclear what proportion will be absorbed into the skin before being washed off, but the notifier has indicated that the chemical is readily absorbed and hydrolysed to ascorbic acid by enzymes in the skin.

Residues in empty consumer packaging sent to landfill are likely to remain within the containers, and will slowly degrade (see below). Incineration of the notified chemical will produce predominantly oxides of carbon and water.

The notified chemical has been determined to be not readily biodegradable according to OECD criteria in the Manometric Respirometry Test (OECD TG 301F), displaying only partial biodegradability after 28 days (20-30% of theoretical oxygen demand ThOD) (Beimborn, 1997). However, these results indicate that the notified chemical can be expected to undergo some degree of degradation in the environment with time.

No bioaccumulation of the chemical is expected because of its very high water solubility and low octanol/water partition coefficient (Connell, 1989).

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Summary of the acute toxicity of Sodium Ascorbyl Phosphate

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD_{50} > 5 000 mg/kg	(Kuehlem, 1997a)
skin irritation	rabbit	slight irritant	(Kuehlem, 1997b)
eye irritation	rabbit	slight to moderate irritant	(Kuehlem, 1997c)
skin sensitisation	guinea pig	mild sensitiser	(Kuehlem, 1997d)

9.1.1 Oral Toxicity (Kuehlem, 1997a)

Species/strain:	rat/Wistar(SPF)
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	oral (gavage), 5 000 mg/kg in water
Clinical observations:	all animals showed impaired general state; dyspnoea, apathy; staggering; piloerection; and diarrhea
Mortality:	none
Morphological findings:	none

Test method:	limit test, OECD TG 401
LD_{50}:	> 5 000 mg/kg
Result:	the notified chemical was of very low acute oral toxicity in rats

9.1.2 Skin Irritation (Kuehlem, 1997b)

Species/strain:	rabbit/New Zealand White
Number/sex of animals:	6 animals; 3/sex
Observation period:	72 hours
Method of administration:	dermal application of 0.5 g of the notified chemical moistened with water to flanks under semi-occlusive dressing for 4 hours
Test method:	OECD TG 404
Result:	two rabbits exhibited well defined erythema at one hour after application, this disappeared by 48 hours in one animal and by 72 hours in the other; the other 4 rabbits exhibited very slight erythema at one hour after application which persisted up to 48 hours in one animal the notified chemical was a slight to moderate irritant to the skin of rabbits

9.1.3 Eye Irritation (Kuehlem, 1997c)

Species/strain:	rabbit/New Zealand White
Number/sex of animals:	6 animals; 3/sex
Observation period:	72 hours
Method of administration:	58 mg (0.1 mL)of the notified chemical was applied into the conjunctival sac of the right eye of each animal
Irrigated eyes (24 hours after application):	slight conjunctival redness (scores 1 and 2) observed in 5 animals persisted up to 48 hours; slight chemosis observed in one animal persisted up to 48 hours; all eyes were normal after 72 hours

Test method:	OECD TG 405 (Organisation for Economic Co-operation and Development, 1987)
Result:	the notified chemical was a slight eye irritant in rabbits

9.1.4 Skin Sensitisation (Kuhlem, 1997d)

Species/strain:	guinea pigs/Pirbright White Strain (Tif:DHP)
Number of animals:	30 females (test), 20 females (10 for each of 2 control groups)
Induction procedure:	day 1: 3 pairs of injections (0.1 mL) were made on shaved shoulder of each animal: • front row: Freund's Complete Adjuvant (FCA) without notified chemical emulsified with 0.9% aqueous NaCl-solution (1:1) (v/v) • middle row: 5% notified chemical in 0.9% aqueous NaCl solution • back row; 5% notified chemical in FCA/0.9% aqueous NaCl-solution (1:1) (w/v) Control groups were treated similarly without the notified chemical day 8-topical induction: occluded application to the shoulder, 50% notified chemical in distilled water for 48 hours; no treatment was carried out on the control groups since the aqueous formulation was not expected to influence the results of the study
Challenge procedure:	day 22-challenge: occluded application of 50% notified chemical in distilled water for 24 hours; control group 1 was treated in a similar way to the test group and control group 2 remained untreated day 28-rechallenge: similar to the first challenge but the treatment was carried out on the test group and both control groups control group 1 was used for challenge and control group 2 for rechallenge

Challenge outcome:

	Test animals		***Control animals***	
Concentration of notified chemical	***24 hours[a]***	***48 hours[a]***	***24 hours***	***48 hours***
Challenge 50%[c]	[b]4/23	4/23	0/10[d] 0/10[e]	0/10[d] 0/10[e]
Re-challenge 50%[c]	0/23	0/23	0/10[d] 0/10[e]	0/10[d] 0/10[e]

a time after patch removal
b number of animals exhibiting positive response
c 50% notified chemical in distilled water
d control group 1
e control group 2

after the first challenge with 50% of the notified chemical 2 test animals developed very slight spotted erythema and 2 other test animals had well defined spotted erythema; at 48 hours 3 animals exhibited very slight spotted erythema (2 of these with scaling) and one animal exhibited well-defined spotted erythema and scaling

Test method:	Magnusson and Kligman Maximisation Test, similar to OECD TG 406
Comments:	rationale in using two control groups is that in the event of borderline results after the first challenge the first control group cannot be re-used; the second control group was used exclusively for the second challenge 7 test group animals died at days 8, 9 or 10; a macroscopic examination revealed the deaths were due to pneumonia and were not related to treatment due to the notified chemical
Result:	the notified chemical was a mild skin sensitiser in guinea pigs

9.2 Genotoxicity

9.2.1 *Salmonella typhimurium* and *Escherichia coli* Reverse Mutation Assay (Engelhardt, 1997)

Strains:	*S. typhimurium* TA 98, TA 100, TA 1535, TA 1537 and *E.coli* WP2*uvr*A
Concentration range:	Standard Plate Test: 0, 24, 120, 600, 3 000 and 6 000 μg/plate in the presence or absence of metabolic activation provided by Aroclor induced rat liver S9 fraction Preincubation Test similar to above dosage and conditions
Test method:	OECD TG 471 and 472
Comment:	no increase in the mutation freguency was observed for the notified chemical in comparison with negative control (water); mutagenicity was observed with the positive control
Result:	the notified chemical did not induce gene mutations in the strains of bacteria tested in the study with or without metabolic activation

9.3 Overall Assessment of Toxicological Data

The notified chemical was of very low acute oral toxicity (LD_{50} > 5 000 mg/kg) in rats. It was a slight to moderate skin irritant and a slight eye irritant in rabbits. It was a mild skin sensitiser in guinea pigs.

The notified chemical was not mutagenic in a reverse mutation assay.

According to the NOHSC *Approved Criteria for Classifying Hazardous Substances* (National Occupational Health and Safety Commission, 1994a), the notified chemical is not determined to be a hazardous substance based on the above studies.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

Although no ecotoxicological data are required for chemicals with import volumes < 1 tonne per annum according to the Act, the notifier has provided an aquatic invertebrate toxicity test result and report.

Results from tests on algal inhibition and acute toxicity to fish are listed on the BASF Australia Limited MSDS submitted for this extension application and are reproduced here.

Test	***Species***	***Results (Actual)***	***References***
Acute Immobilisation Static 48 hour Dir 79/831/EEC C2	Water Flea (*Daphnia magna*)	EC_{50} > 100 mg/L	(Nikolaitschik, 1997)
Algal cell multiplication Inhibition Test	*Scenedesmus subspicatus*	EC_{50} (72 h) > 100 mg/L	BASF Australia Limited MSDS, May 1999
Acute toxicity to fish		EC_{50} (96 h) = 5.3 g/L	BASF Australia Limited MSDS, May 1999

The notified chemical was tested on daphnids in the range of concentrations between 12.5 and 100 mg/L. No statistically significant immobilisation was observed over the 48 hours at any of the test concentrations. In addition, the notified chemical was tested on algae and fish but no reports are available for fish and algal tests.

The data for the notified chemical indicated that it is practically non-toxic to aquatic invertebrates.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The majority of notified chemical will be incorporated into sunscreen and skin care products at concentrations up to 5%. Use of these products is expected to be widespread across Australia with release of a portion of the chemical directly to the aquatic compartments of the environment occurring through use. Release of the chemical from sunscreens is more likely to natural waterways, e.g. oceans, lakes and rivers. However, this release is expected to be very diffuse and at concentrations unlikely to be toxic to aquatic life. The notified chemical was shown to be practically non-toxic to aquatic invertebrates.

Other products, such as skin care creams, may be discharged directly into the sewer through washing. A calculation based on a worst case scenario, predicts an environmental concentration of 0.43×10^{-3} mg/L if all the imported chemical remains dissolved in sewage waters (assuming: 430 kg maximum annual use, an Australian population of 18 million and a daily per capita waste water discharge of 150 L). This is below levels that have been shown to be non-toxic to aquatic invertebrates (by greater than five orders of magnitude).

Wastes generated through product reformulation are estimated to be minimal, and will be disposed of to approved disposal facilities. Small amounts of residues in product containers

will be disposed of with normal household garbage in a very diffuse manner to landfill.

The environmental hazard from the notified chemical is expected to be very low.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The notified chemical exhibited very low acute oral toxicity (LD_{50} > 5 000 mg/kg) in rats. The notified chemical was a slight to moderate skin irritant and a slight eye irritant in rabbits and a mild sensitiser in guinea pigs and may cause these effects in some individuals. The notified chemical was not mutagenic *in vitro*. Based on the data submitted the notified chemical is not determined to be a hazardous substance in accordance with NOHSC *Approved Criteria for Classifying Hazardous Substances* (National Occupational Health and Safety Commission, 1994a).

Occupational Health and Safety

During transportation of the notified chemical, there is unlikely to be any worker exposure, except in the event of an accidental spill. Exposure after a spill may be controlled by use of the recommended practices for cleaning up of spills given in the Material Safety Data Sheet (MSDS) supplied by the notifier.

There is potential for ocular contact and inhalation exposure to the dust form of the notified chemical during opening or closing of drums, weighing and charging the blending vessel. However, exposure to the notified chemical will be minimal due to local exhaust ventilation over weighing, mixing and filling areas and general ventilation in rest of the work area. Exposure may also occur during cleaning of mixer vessels. Should dermal, ocular contact or inhalation exposure occur, it is unlikely that the notified chemical will cause systemic toxicity based on toxicity studies presented. Of particular concern would be respiratory irritation, as the particle size of the notified chemical was not provided, so may be within the respirable range (that is an aerodynamic diameter less than 7 μm). If necessary, respiratory and ocular exposure should be controlled and workers must be attired with safety glasses/goggles, face shields or head covering, protective gloves, respiratory protection and overalls as stipulated under Recommendations.

The notifier states that the workers will receive education and training on safe use of dust products and preventive controls. This, in combination with engineering controls and personal protective equipment, will control exposure to the notified chemical and consequently any adverse health effects.

To avoid adverse health effects of high concentration of dust in the workplace, good hygiene practices should be adopted to minimise airborne dust levels. Exposure to the dust in the workplace should be controlled below the NOHSC exposure standard for Dusts, not otherwise classified, 10 mg/m^3 TWA (measured as inspirable fraction) (National Occupational Health and Safety Commission 1995). Employers are responsible for ensuring the exposure standard is not exceeded. It is recommended that labels for the notified chemical carry the safety phrase – avoid breathing dust.

The potential for dust explosion exists when handling the notified chemical in the powdered

form. The notifiers MSDS provides advice on safe storage and handling.

Public Health

As the notified chemical is to be used in cosmetic formulations intended for application directly to the skin, substantial public exposure is likely. However, given the nature of the compound, its use in this manner is unlikely to result in systemic toxicity and the skin and eye irritancy potential at concentrations below 5% is likely to be low. At concentrations at or below 5% the notified chemical is unlikely to present a skin sensitisation hazard.

13. RECOMMENDATIONS

To minimise occupational exposure to sodium ascorbyl phosphate the following guidelines and precautions should be observed:

- Safety glasses/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 Zraland, 1992);
- Air-purifying (dust) respirators should be selected and fitted in accordance with Australian/New Zealand Standard (AS/NZS) 1715 (Standards Australia/Standards New Zealand, 1994a);
- Industrial clothing should conform to the specifications detailed in AS 2919 (Standards Australia, 1987);
- Impermeable gloves or mittens should conform to AS 2161.2 (Standards Australia/Standards New Zealand, 1998);
- All occupational footwear should conform to AS/NZS 2210 (Standards Australia/Standards New Zealand, 1994b);
- Spillage of the notified chemical should be avoided. Spillage 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;
- NOHSC exposure standard for dust should be observed and MSDS and label should carry the safety phrase – avoid breathing dust; and
- A copy of the MSDS should be easily accessible to employees.

It the conditions of use are varied, and in particular if the notified chemical is to be used at greater than 5% of a cosmetic product formulation, greater exposure of the public to the notified chemical may occur and further information may be required in order to assess the risks to public health.

As sodium ascorbyl phosphate is a pharmacologically active substance its use at concentrations likely to lead to physiological actions such as skin whitening may constitute a therapeutic use, regardless of whether therapeutic claims are made for products containing the compound, for which TGA approval may be required.

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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Engelhardt G (1997) Bacterial Reverse Mutation Test of P-#620, Project No. 40M0170/974073, Department of Toxicology of BASF Aktiengesellschaft D-67056 Ludwigshafen/Rhein, FRG.

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Kuehlem MV (1997b) P-#97/170: Skin Irritation to the Rabbit, Project No. 14H0170/972068, BASF Aktiengesellschaft Department of Toxicology, Rhein, Germany.

Kuehlem MV (1997c) P-#97/170: Eye Irritation to the Rabbit, Project No. 13H0170/972069, BASF Aktiengesellschaft Department of Toxicology, Rhein, Germany.

Kuehlem MV (1997d) P-#97/170: Skin Sensitisation in the Guinea Pig, Project No. 30H0170/972070, BASF Aktiengesellschaft Department of Toxicology, Rhein, Germany.

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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