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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

STEPAN TAB™-2

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

STEPAN TAB™-2

1. APPLICANT

Bronson & Jacobs Pty Limited, Park View Drive, Australia Centre Homebush Bay NSW 2140

2. IDENTITY OF THE CHEMICAL

Based on the nature of the chemical and the data provided, STEPAN TAB™-2 is not considered to be hazardous. Therefore the chemical name, CAS Number, other names, molecular and structural formulae and spectral data have been exempted from publication in the Full Public Report and the Summary Report. Additionally, details of the UVCB composition, use and import data have been exempted.

Molecular weight:	all major constituents of the variable composition reaction product have a molecular weight <1000.
Method of detection and determination:	STEPAN TAB™-2 may be determined by a high performance liquid chromatography technique with a UV or IR detector

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	Ivory coloured waxy solid, may occur in powder form.
Melting Point:	41.4°C,

Boiling Point:	BP range > 250°C
Density:	970 kg/m^3
Vapour Pressure:	0.12 x 10^{-3} kPa at 25°C
Water Solubility:	below detection limit, <1ppm at 20°C
Partition Co-efficient (n-octanol/water)	log $P_{O/W}$: > 6.2 at 50°C
Hydrolysis as a function of pH:	
Adsorption/Desorption:	not determined
Dissociation Constant:	not applicable
Hydrolysis as a function of pH	not applicable
Flash Point:	140°C
Flammability Limits:	non flammable and non pyrophoric
Decomposition Products:	oxides of nitrogen, ammonium vapours, carbon dioxide
Autoignition Temperature:	395°C
Explosive Properties:	not explosive when exposed to thermostress or shock
Reactivity/Stability:	based on the structure oxidising properties appear low. However for safety reasons the notifier assumes incompatibility with combustion agents corrosive agents and alkalis
Particle size distribution:	not applicable as fine particles are not present and grinding will cause melting due to generation of heat.

Comment on physical and chemical properties

Water solubility:

The reaction product contains a low amount (2%) of a compound which has a known solubility of 6.25 $g.L^{-1}$ [1]. Other derivatives are likely to be less soluble.

Hydrolysis as a Function of pH:

Whilst the notified substance has functionalities associated with some of its components indicating a susceptibility to hydrolysis, no results were available. This is acceptable, as due to the low solubility of the notified substance in water (< 1 ppm) hydrolysis is unlikely to occur under environmental conditions.

Adsorption/desorption:

No adsorption/desorption data was provided due to the low solubility of the notified UVCB substance in water. However, the high log P indicates that it is likely to sorb to sediment particulates.

Dissociation constant:

Dissociation tests were not conducted due to the low solubility and relatively high MW of the notified substance. A functionality associated with a number of the components in the mixture suggest solubility in basic media. The literature indicates that one of the components has a pK_a of 2.89. However, this component represents only 2% of the mixture. A number of other components present at > 70% of the mixture would have a slightly higher pK_a. A component comprising 26% of the mixture is basic and would be expected to have a high pK_a around 10. These components are likely to be more soluble in either acidic or basic media.

4. PURITY OF THE CHEMICAL

Degree of purity: STEPAN TAB^{TM}-2 is a reaction product and as such is 100% pure.

Toxic or hazardous impurities: none

Additive(s)/Adjuvant(s): none

5. INDUSTRIAL USE

STEPAN TAB^{TM}-2 is to be used in cosmetics and hair care products. It will be imported into Australia in quantities greater than 1 tonne p.a for the first 5 years.

6. OCCUPATIONAL EXPOSURE

STEPAN TAB^{TM}-2 will be imported as the solid and will be formulated into products containing 2.5% of the notified chemical.

Occupational exposure may take place at the following stages

- transport;
- handling and storage;
- formulation;
- sampling and testing of the formulated product; and
- dispensing, packaging and transport of the formulated product.

The notified chemical will be transported in polythene bags contained in fibre packs and stored in closed containers. The use of non-breakable packs is designed to minimise accidental damage. Exposure will occur only in the event of an accidental spill.

During formulation, it will be handled in the pure solid form either as the wax or the powder (eg during transfer or the loading of equipment). The notifier has recommended protective equipment to minimise exposure to the dusts.

Mixing and dispensing of the formulation will be carried out either in a closed system or in equipment designed to minimise aerosol or dust generation.

7. PUBLIC EXPOSURE

STEPAN TAB^{TM}-2 will be imported to Australia (1-10 tonnes/annum) and transported to commercial users in unbreakable polythene bags contained in fibre packs. It will be stored in closed

containers. There is low potential for public exposure to the notified chemical during shipment and distribution.

During the formulation process, the notified chemical will be transferred in the pure solid form as a wax or powder. Mixing and dispensing of the formulation will be carried out either in a closed system or in equipment designed to minimise aerosol or dust generation. In the event of accidental spills or leakage, material will be recovered (process unspecified) either for reprocessing or disposal to suitable landfill. Quantities to require disposal by this route are likely to be considerably less than 1 tonne/year Australia wide.

The public will be directly exposed to STEPAN TAB^{TM}-2 from its use in cosmetics and toiletries, in which case it will be in a liquid formulation.

8. ENVIRONMENTAL EXPOSURE

. Use

STEPAN TAB^{TM}-2 is to be used in the production of cosmetic products.

It is anticipated that six manufacturers in the cosmetic and toiletry industries are likely to become users of the notified chemical. These manufacturers are located in the suburbs of Melbourne [three], Sydney [two] and Brisbane [one].

The concentration of STEPAN TAB^{TM}-2 in the final product is expected to range between 2.5 - 5 %. The estimated amount of notified substance to be used by a typical reformulator has been estimated by the notifier at 500 - 5000 kg per annum.

The notifier has indicated that end-use products containing the notified polymer will be prepared in bulk batches ranging in size from 1000 -2000 kg. The estimated number of batches prepared annually will vary according to the scale of the reformualtor's operation ranging from 4 - 6 batches every 2 - 3 months to 1 batch a day 40 days per year.

. **Release**

Exposure to the environment from the notified substance will be largely restricted to the aquatic compartment.

The notifier indicates that there are 6 potential sites where the polymer will be compounded into cosmetics. Potential reformulators of the notified substance are based in 3 major cities and the resultant products are expected to be sold Australia-wide, providing a potentially wide environmental exposure of the substance. It is anticipated that usage of STEPAN TAB^{TM}-2 per site will range from 500 - 5000 kg per annum.

The notifier indicates that the total polymer wastage during the manufacturing process will not exceeding 0.05%.

The maximum release of notified substance from a single manufacturing site can be estimated using a worst case scenario, based upon the following parameters:

- the plant uses 5000 kg of notified substance per annum
- the minimum number of batches were produced, namely 16 (i.e. 4 batches every 3 months)
- each batch takes 1 day to process
- plant wastage of 0.05%

Therefore, the expected release of notified substance from one site will be < 160 g.d^{-1} released over 16 days. Further, it follows that a maximum of 2.5 kg of the notified substance will be disposed of annually at a given site. The batch residues and packaging container residues will be disposed of to landfill while equipment washings will be processed through a treatment system for separation of solids and oils and precipitated into sludge. The dried sludge is expected to be disposed of to landfill.

STEPAN TAB^{TM}-2 is intended for use in cosmetic products including roll-on deodorants and shampoos. It is expected that 100% of the notified substance applied to the hair and body will be released to the environment as the consumer washes residues from their hair and body into the sewerage system.

The high log P_{ow} (> 6.2) of the notified UVCB substance indicates that the majority of the components are likely to strongly bind

to the sludge/solids compartment of the sewerage system which is expected to be incinerated, disposed of to landfill or spread onto agricultural land. The notable exception is the soluble component present at less than 5% which is likely to remain in solution where it will undergo biodegradation.

. **Fate**

Stepan Tab^{TM}-2 is a reaction mixture containing products of low water solubility (with the exception of one minor component) and therefore leaching from landfill sites or agricultural land is not expected. Incineration of the notified substance will produce oxides of carbon. Upon release to the environment in sewage effluent, the notified substance would be expected to disperse and partition to sediment.

The biodegradation potential of the notified substance was assessed using a "closed bottle test" with activated sludge bacteria. Testing was over a 28 d period, with the samples incubated in the dark at a temperature of 20 1°C. Analysis for degradation (by oxygen consumption) is indirect and therefore the insolubility of the notified substance in water does not interfere with the analysis.

The notified substance was found to degrade 57.1% after 28 d in a 2 $mg.L^{-1}$ solution, indicating that it is not readily biodegradable. According to the OECD guidelines (No 301D) for the "closed bottle test" the cut-off figure to be considered readily biodegradable is 60%. This result probably reflects the ready biodegradability for some components but not others.

Although no bioaccumulation data was presented, the high fat solubility of the notified substance would suggest that the notified substance has a potential to bioaccumulate. However, the low water solubility of the bulk of the notified substance negate this initial indicator since without an effective transport mechanism bioaccumulation is unlikely.

9.1 EVALUATION OF TOXICOLOGICAL DATA

9.2 Acute Toxicity

Table 1 Summary of the acute toxicity of STEPAN TAB^{TM}-2

Test	Species	Outcome	Reference
Acute oral toxicity	rat	LD_{50} > 5,000 mg/kg	(2)
Acute dermal toxicity	rabbit	LD_{50} > 2,000 mg/kg	(3)
Skin irritation	rabbit	Minimal-Slightly irritating	(4)
Eye irritation	rabbit	Moderately irritating	(5)
Skin sensitisation	guinea-pig	non sensitising	(6)

9.2.1 Oral Toxicity (2)

Five male and five female Sprague-Dawley rats received single doses of the notified chemical (5000 mg/kg) as a 25% w/v solution in corn oil by gavage and were observed for a 14 day post-treatment period.

No deaths occurred during the study and all animals gained weight. The only clinical sign noted during observation were red stains on the muzzle of one female on day 10 and scruffy/oily hair on the coat of all 5 males early in the study. No findings were reported at necropsy.

The LD_{50} of the notified chemical was concluded to be > 5,000 mg/kg.

9.2.2 Dermal Toxicity (3)

STEPAN TAB^{TM}-2 was applied to the shaved ventral area of each of 5 male and 5 female New Zealand White rabbits in doses of 2,000 mg/kg. The material had been moisten with distilled water and was held in position under an occlusive dressing for a 24 hour period. Animals were observed for 14 days and weighed weekly. Gross necropsy was carried out at sacrifice.

During the study some animals had nasal discharges and faecal staining. Inspection of the application site showed mild to moderate erythema which persisted in two animals for 11-12 days. Most animals showed oedema, minimal to mild, persisting for up to 4 days. There were isolated reports of atonia on day 3 or 4 which had cleared following day. Desquamation of the skin was reported in a few animals following application of the material. All males gained weight as did 4 out of 5 females. One female showed a very slight weight loss which was not associated with any clinical symptoms although erythema persisted in this animal for 12 days, oedema for 7 and atonia persisted for 2.

The LD_{50} by dermal application was determined to be > 2,000 mg/kg. The test material when moistened with distilled water and applied for a 24 hour period appeared to be mildly to moderately irritating to the skin.

9.2.3 Skin Irritation (4)

A five hundred milligram quantity of the notified chemical was moistened with distilled water and applied to an (unspecified) shaved area of intact skin of each of 6 New Zealand White rabbits. After 4 hours under an occlusive dressing, the test material was removed and the site inspected at time intervals of 1, 24, 48 and 72 hours after removal of the dressing.

Five animals had minimal to mild erythema at the application site at 1 hour. One animal had minimal oedema at 1 hour. No irritant response was observed in any animal at 24, 48 or 72 hours.

The material was concluded to have slight skin irritation properties.

9.2.4 Eye Irritation (5)

Six New Zealand White rabbits received instillations of 0.063g STEPAN TAB^{TM}-2 into one eye. The other eye served as control. Treated eyes were rinsed 24 hours after application of the test substance. Animals were observed and effects noted at 1, 24, 48 and 72 hours and 4, 7, 10 days after administration.

All animals showed mild to moderate erythema of the treated eye which persisted to day 4 or day 7. All animals were recorded as having some degree of swelling at 1 hour which was still present at 24 hours in 3 animals. Four animals had mild discharges at 1 hour and 2 had moderate discharges. All 6 animals had what was described as "blistered appearance of conjunctiva" one hour after administration of the test substance. This effect had resolved at 24 hours. However, in 4 animals "thickening" was reported at 72 hours which had not resolved in 1 animal by day 10. Corneal opacity was reported in 1 animal at 24 hours. The cornea was reported clear at 48 hours and remained so.

STEPAN TAB^{TM}-2 can be concluded to be moderately irritating to the eye.

9.2.5 Skin Sensitisation (6)

The test method used for this study was an adaptation of the method of Ritz and Buehler (7). Closed patches containing a 25% w/v formulation of the notified chemical were applied to the shaved skin of ten male and ten female guinea pigs for a perod of 6 hours. This procedure was repeated twice at weekly intervals for a total of three exposures. An additional group of five male and five female animals served as untreated controls. No positive control groups were used.

All animals were challenged two weeks after the third application to the treated animals. Challenge was by application of a 5% w/v solution to a previously untreated, depilated site.

Nine of the 20 treated animals showed some degree of slight, patchy oedema 24 hours after challenge compared with 8/10 untreated controls. Forty eight hours after challenge there was no increase in the response in the test group.

Under the conditions of this study, the notified chemical was concluded not to be a skin sensitiser in the guinea pig.

9.3 Repeated Dose Toxicity (8)

A preliminary range finding study was undertaken to determine appropriate dose levels for the 28 day study. Groups of three male and three female SPF Wistar rats received STEPAN TAB^{TM}-2 in corn oil at dose levels of 0, 50, 200, 1,000 mg/kg/day by gavage for a period of 5 days.

No differences in body weight or clinical observations were reported during this 5 day period. Doses chosen for the 28 day study were 50, 200, 1,000 mg/kg/day.

For the 28 day study, animals were divided into groups of 5 males and 5 females. Groups received doses of 50, 200 or 1,000 mg/kg/day STEPAN TAB^{TM}-2 in corn oil for a period of 28 days. A control group received corn oil for the 28 day period. Additional groups of 5 males and 5 females received the corn oil control and the 1,000 mg/kg/day dose for a 28 day period and then went through a 14 day recovery period at the end of the study.

Animals were observed daily during the test and weekly during the recovery period. Body weights were taken weekly. Eye examinations were conducted on all animals at week four and again for recovery animals at week six, at the end of recovery period. Haematological testing and clinical chemistry determinations were carried out at the end of the study. At necropsy, gross examination of the organs was undertaken and organ weights were recorded. Histopathological examination was carried out in the control and high dose group for the adrenals, heart, kidneys, liver, spleen and stomach. All gross abnormalities were also examined by a pathologist.

Clinical signs reported during the study were hair loss in all groups including the control group and excessive salivation in all groups, again including the control group. No spontaneous deaths occurred during the study. One animal died when anesthetised for blood sampling at the conclusion of the study. Eye examinations showed some abnormalities in the high dose

group. At 4 weeks, one female had opacity of the anterior lens. This did not clear during the recovery period and in fact an additional three females developed a similar condition during the recovery period. The five females who were sacrificed at four weeks and did not have a recovery period did not show any eye abnormalities at this time. One control female had also developed anterior lens opacity at the end of the recovery period.

Isolated haematological and clinical chemistry abnormalities which were not considered to be of toxicological significance were reported at the end of the four weeks study or the two week recovery period. Pathological examination after death did not reveal any gross or microscopic abnormalities related to treatment. No treatment related changes in organ weights occurred.

9.4 Genotoxicity

9.4.1 Salmonella typhimurium Reverse Mutation Assay (9)

The potential of STEPAN TAB^{TM}-2 to produce reverse mutations *in vitro* was determined using *Salmonella typhimurium* strains TA-98, TA-100, TA-1535, TA-1537 and TA-1538 and *Escherichia coli* WP2 *uvr* A with and without metabolic activation.

STEPAN TAB^{TM}-2 was delivered as a suspension in acetone at 5 dose levels of up to 10,000 µg/plate. Controls were the delivery vehicle and as positive controls, 2-aminoanthracene, 2-nitrofluorene, sodium azide, ICR 191 and methyl methanesulfonate. There was no increase in revertants in any strain of either *S. typhimurium or E. coli* either with or without metabolic activation after exposure to the test compound.

The notified chemical was not considered to be mutagenic to bacteria *in vitro*.

9.4.2 Chromosome Aberration Assay in Chinese Hamster V-79 Cells in Vitro with STEPAN TAB^{TM}-2. (10)

The potential of STEPAN TAB^{TM}-2 to cause chromosome aberrations was determined in the Chinese hamster V-79 cells.

Cells were incubated for four hours with concentrations of 20, 100 and 200 µg/ml of STEPAN TAM^{TM}-2, with and without metabolic activation by S-9 mix. Negative controls were the culture medium and the solvent (ethanol). Cyclophosphamide served as the positive control with S-9 mix, ethylmethanesulfonate as the positive control without S-9 mix.

Chromosome preparation was carried out 18 hours after the start of treatment for the 20, 100, 200 µg/ml of STEPAN TAB^{TM}-2, culture medium control, solvent control and positive controls. 28 hours after commencement of treatment additional slides were prepared from the solvent control and 200µg/ml test article cultures.

One culture containing 100µg/ml of the test article showed a statistically significant increase in aberrations when compared to the control. However, the negative control was exceptionally low and this increase was concluded not to be biologically significant.

STEPAN TAB^{TM}-2 was found not to cause chromosome aberrations in the Chinese Hamster V-79 cell line *in vitro*.

9.5 Overall Assessment of Toxicological Data

The notified chemical has low acute toxicity by the oral and dermal route. It has minimal skin irritation properties in the rabbit over a period of four hours but on more prolonged application (24 hours) in the dermal toxicity study proved to be mildly to moderately irritating. It is also a moderate eye irritant. It is not a skin sentitiser nor a mutagen when tested against *S typhimurium, E coli* or Chinese hamster V-79 cells *in vitro*. The relationship of lens opacity in females receiving 1000mg/kg/day to the test compound is not certain.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

10.1 Toxicity in Carp

A study to determine the acute toxicity of the notified substance in carp (*Cyprinus carpio*) was reported. Testing was in accordance with OECD guidelines (No. 203: "Fish Acute Toxicity Test") using a semi-static test system. Testing was conducted over 96 h using three sets of 10 carp. The test solutions had a

maximum nominal concentration of 1000 mg.L^{-1} and were replaced daily. The report indicates that the test solutions were a turbid dispersion with undissolved notified substance (particulates). During the 96 h exposure period no mortality or observable effects were noted for the treated carp. The notified substance was found to have an LC_{50} > 1000 mg.L^{-1} nominal concentration. However, measurement of the final test solutions revealed actual concentrations ranging from 130 to 222 mg.L^{-1}.

The high concentration of notified substance (up to 1000 mg.L^{-1}, nominal) in the test solutions, was well above the measured water solubility (< 1 mg.L^{-1}) and was achieved with the aid of an emulsifier (Tween 80) and moderate heating (50°C). The final test solutions (22°C) were observed to be turbid.

10.2 Toxicity in Daphnia magna

The acute toxicity of the notified substance to *Daphnia magna* was determined in accordance with OECD guidelines (No 202). Nominal concentrations studied ranged from 100 to 1000 mg.L-1, and were achieved with the aid of Tween 80 (0.01%) as per the carp test. A total of 10 Daphnia per vessel were exposed to the notified substance for 48 h.

After 48 h only 10% immobilisation was observed at a nominal concentration of 1000 mg.L^{-1}, no affects were noted at any other concentration studied. Therefore the notified substance was found to have an EC50 > 1000 mg.L^{-1} to Daphnia.

10.3 Homogeneity in test solutions

Homogeneity testing conducted in conjunction with the carp tests revealed actual concentrations ranging from 78 mg.L^{-1} in the top layer (90% height) to 337 mg.L^{-1} in the bottom layer (10% height). Further, it was found that after 24 h the dispersions were significantly lower in both the upper and lower layers than was initially determined. At the half height the actual concentration was in the same range as the values determined initially. During the carp toxicity testing it was observed that undissolved particulates of the notified substance were floating on the surface of the water, with other particulates deposited.

The site of deposition was not specified but was presumably to the base of the container. However, some may have been deposited on the sides of the tank.

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

The notified substance is unlikely to present a hazard to the environment at any stage of its use, whether it be during reformulated into cosmetic products (resulting in a maximum estimated release of 2.5 kg.year^{-1} of waste per site, which is disposed to landfill) or when consumers wash product residue from their body/hair.

If the notified substance remains suspended, a predicted environmental concentration (PEC) for the notified substance in sewage water throughout Australia can be estimated from the following assumptions: 10 tonne maximum annual use, an Australian population of 17 million and a daily per capita water usage volume of 150 L (i.e. national usage = 930.8 GL per annum). This provides a PEC of 10 ppb in sewage water which would be reduced to insignificant levels, likely to be in the ppt (parts per trillion) range, by precipitation or dilution in receiving waters.

Acute aquatic toxicity studies have shown the notified substance to be practically non-toxic towards aquatic species, up to the level of its solubility.

The high fat solubility indicates that the notified substance has a potential for bioaccumulation, particularly in the aquatic compartment. However, the low solubility of STEPAN TAB^{TM}-2 (< 1 ppm) in water and high log P_{OW} (> 6.2) clearly indicates that water does not provide an effective transport vehicle for the mobilisation of the notified substance. Therefore, the potential impact of the notified substance on aquatic species is limited.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

The most significant occupational exposure to the notified chemical will occur during any transfer of the chemical in solid wax or powder form. If dusts or aerosols are generated, exposure of the skin, eyes and respiratory tract is possible. Particles are not of respirable size but irritation of the nasal passages and throat may occur. Any concentrates used as intermediates during the formulation of products may also have significant irritant properties if contact with the eye or respiratory tract occurs. Generation of dusts and aerosols should be minimised.

STEPAN TAB^{TM}-2 has only minimal skin irritant potential in powder form. However, long term exposure of the skin should be minimised.

There is low potential for public exposure to STEPAN TAB^{TM}-2 in the industrial setting. However, significant public exposure to the notified chemical is expected as a result of its use in cosmetics and toiletries. Although the chemical has slight irritant potential, the low concentration intended for such formulations should result in minimal acute hazards to the public.

13. RECOMMENDATIONS

To minimise occupational exposure to STEPAN TAB^{TM}-2 the following guidelines and precautions should be observed:

. handling of powders of or waxes of STEPAN TAB^{TM}-2 should be carried out in well ventilated areas or local exhaust ventilation should be used to minimise dusts.

. If engineering measures are insufficient to reduce exposure to STEPAN TAB^{TM}-2 to a safe level, the following personal protective equipment should be worn.

- dust masks conforming with Australian Standard 1716 -1991 (11)

- gloves conforming with AS 2161 - 1978 (12)

- safety glasses confirming with AS 1337 -1984 (13)

. spilled materials should be swept up and disposed to landfill

. spilled solutions should be absorbed and disposed to landfill

. good housekeeping practices should be observed.

14. MATERIAL SAFETY DATA SHEET

The Material Safety Data Sheet (MSDS) for STEPAN TAB^{TM}-2 Attachment 1) was provided in Worksafe Australia format (14). This MSDS was provided by Bronson and Jacobs as part of their notification statement. It is reproduced here as a matter of record. The accuracy of this information is the responsibility of Bronson and Jacobs Pty Limited.

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act), secondary notification of STEPAN TAB^{TM}-2 shall be required if any of the circumstances stipulated under subsection 64(2) of the Act arise. No other specific conditions are prescribed.

16. REFERENCES

(1) The Merck Index 9th Edition, Merck and Co Inc Rahway New Jersey USA.

(2) Acute Oral Toxicity in rats - limit test of; STEPAN TAB™-2. Hill Top Biolabs Project No 90-4030-21 (A). Data on file Stephan Company Northfield, IL 60093 USA.

(3) Acute Dermal Toxicity study in rabbits - limit test of; STEPAN TAB™-2. Hill Top Biolabs Project No 90-4030-21 B. Data on file Stepan Company Northfield, IL 60093 USA.

(4) Primary Skin Irritation study in rabbits of STEPAN TAB™-2. Hill Top Biolabs Project No 90-4030-21 (C) Data on file Stepan Company Northfield, IL 60093 USA.

(5) Primary Eye Irritation study in rabbits of; STEPAN TAB™-2. Hill Top Biolabs Project No 90-430-21 (D). Data on file Stepan Company Northfield, IL 60093 USA.

(6) Delayed contact high persensitivity study in guinea-pigs of; STEPAN TAB™-2. Hill Top Biolabs Project No 90-4030-21 (E). Data on file Stepan Company Northfield, IL 60093 USA.

(7) Ritz, HL and Buehler EV Current Concepts in Cutaneous Toxicity, ed Drill VA and Lazar T Academic Press 1980 pp 25-40.

(8) 28 day oral toxicity with STEPAN TAB™-2 by daily gavage in the rat followed by a fourteen day recovery period. RCC NOTOX Project 058962 Data on file Stepan Company Northfield, IL 60093 USA.

(9) *Salmonella* plate incorporation nutagenicity assay (Ames test) *Escherichia coli* WP2 *uvr* A mutation assay. Test Article STEPAN TAB™-2. Laboratory study number T9784.501038 Microbiological Associates Incorporated. Data on file Stepan Company Northfield, IL 60093 USA.

(10) Chromosome Aberration Assay in Chinese Hamster V79 Cells in Vitro with STEPAN TAB™-2. CCR Project 238206. Data on file Stepan Company Northfield, IL 60093 USA.

(11) Australian Standard 1716-1991 Respiratory Protective Devices, Standards Association of Australia Publ, Sydney 1991.

(12) Australian Standard 2161-1978 Industrial Safety Gloves and Mittens (excluding Electrical and medical Gloves) Respiratory Protective Devices, Standards Association of Australia Publ, Sydney 1991.

(13) Australian Standard 1337-1984 Eye Protectors for Industrial Applications, Standards Association of Australia Publ, Sydney 1984.

(14) Guidance Note for Completion of a Material Safety Data Sheet [NOHSC : 3001 (1991)], 3rd edition October 1991.