File No: NA/611

July 1998

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

FULL PUBLIC REPORT

Santocure TBSI

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Director
Chemicals Notification and Assessment

FULL PUBLIC REPORT

Santocure TBSI

1. APPLICANT

Akzo Nobel Chemicals Limited of 6 Grand Avenue CAMELLIA NSW 2124 has submitted a standard notification statement in support of their application for an assessment certificate for Santocure TBSI

2. IDENTITY OF THE CHEMICAL

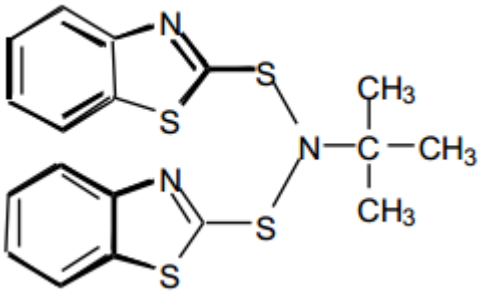
Claims were made and accepted for the identity of Santocure TBSI to be exempt from publication in the Full Public Report. The data items were:

percent concentration of purity and impurities;
spectral data; and
import volume and use.

Santocure TBSI is not considered to be hazardous based on the nature of the chemical and the data provided.

Chemical Name:	N-tert-butyl-di(2-benzothiazolesulfen)imide
Chemical Abstracts Service (CAS) Registry No.:	3741-80-8
Other Names:	2-benzothiazolesulfenamide N-(2-benzothiazolylthio)-N-(1,1-dimethylethyl)- CP-22595
Trade Name:	Santocure TBSI
Molecular Formula:	$C_{18}H_{17}N_3S_4$

Structural Formula:



Molecular Weight:	404
Method of Detection and Determination:	atomic absorption (AAS) and infrared (IR) spectral data were provided

3. PHYSICAL AND CHEMICAL PROPERTIES

Appearance at 20°C and 101.3 kPa:	white powder
Melting Point:	137°C (range 115 - 142°C)
Boiling Point:	not determined
Specific Gravity:	1.35
Vapour Pressure:	5.3×10^{-6} hPa at 25°C
Water Solubility:	0.0029mg/L at 20°C
Partition Co-efficient (n-octanol/water):	log P_{ow} ~ 6.7
Hydrolysis as a Function of pH:	not determined, see comments below
Adsorption/Desorption:	not determined, see comments below
Dissociation Constant:	pK_a ~ 7
Flash Point:	not determined, see comments below
Flammability Limits:	not determined, see comments below

Autoignition Temperature: not determined, see comments below

Explosive Properties: dust explosion potential: minimum explosible concentration:

45 g/m unoiled Santocure TBSI
40 g/m oiled Santocure TBSI

minimum spark ignition energy:

31 mJ unoiled Santocure TBSI
51 mJ unoiled Santocure TBSI

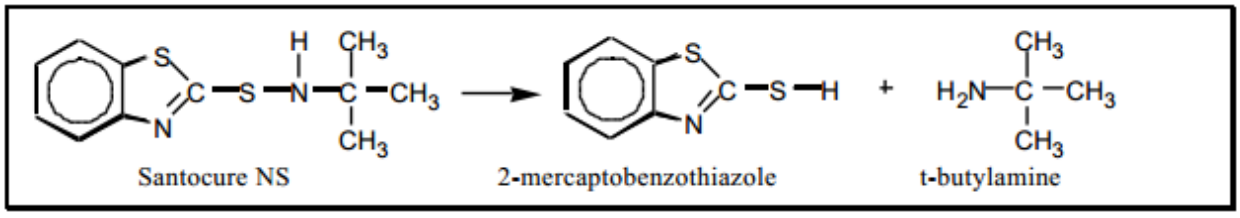
Reactivity/Stability: non oxidising; avoid storing near strong bases and oxidising agents

Comments on Physico-Chemical Properties

Tests were performed at facilities complying with OECD/TSCA Principles of Good Laboratory Practice.

The aqueous water solubility of the notified chemical was determined to be 0.0029 mg/L (2.9 ppb) in water that had been adjusted to pH 7.5 with phosphoric acid after adding 1 g of trisodium phosphate to 2 L of deionised water. A couple column technique was used to detect the concentration of chemical in the saturator column. The low solubility is supported by the partition coefficient test, which claims a water solubility of 1.75 µg/L.

Due to the extremely low solubility of the notified chemical, the notifier claims that it is not feasible to conduct hydrolysis testing. However, data on the starting material/major impurity (Santocure NS[1]) were submitted (Cranor W, 1984). This chemical completely hydrolysed within the 25 hour trial period in pH 7.0 buffered deionised water with light excluded. Santocure NS hydrolysed stoichiometrically to mercaptobenzothiazole and t-butylamine, see below.



While similar mechanisms could apply to the (highly lipophilic) notified chemical, hydrolysis will be hindered due to the additional mercaptobenzothiazole group and by its very low water solubility (2.9 ppb).

According to the OECD TG 106, adsorption/desorption can not be determined for substances, which are not soluble in water to an extent that can be measured analytically. The notifier claims that the water solubility of the notified chemical is lower than the limit of

[1] *N*-t-butyl-2-benzothiazole sulfenamide

detection of this method. Based on the notified chemical's very low water solubility, it is expected to become adsorbed to soil and sediment, and hence show little mobility.

The notified chemical has limited water solubility and no dissociable groups. The dissociation constant was measured using the Conductometric Method and found to be no different from that of deionised water (Anonymous, 1997).

4. PURITY OF THE CHEMICAL

Degree of Purity: > 90 %

Toxic or Hazardous Impurities: <5 %

Chemical name:	N-t-butyl-2-benzothiazole sulfenamide
CAS No.:	95-31-8
Weight percentage:	>1%
Toxic properties:	skin sensitiser; respiratory tract irritant (US National Library of Medicine, 1994-97)

Chemical name:	2-mercaptobenzothiazole disulfide
CAS No.:	120-78-5
Weight percentage:	>1%
Toxic properties:	skin sensitiser (US National Library of Medicine, 1994-97)

Non-hazardous Impurities (> 1% by weight): no single impurity present at greater than 0.2%

Additives/Adjuvants: none

5. USE, VOLUME AND FORMULATION

The notified chemical will be used as a primary accelerator in the vulcanisation of tie gum rubbers during rubber manufacture. The estimated import quantity over the first 5 years will be between 10 to 100 tonnes per annum.

The notified chemical will be re-packed at a company in Victoria, specialising in the preparation of pre-weighed packages of chemicals. Other chemicals used in the rubber manufacturing process, such as fillers and vulcanisers, are also weighed out and added to the

Santocure TBSI to produce a package ready to be added to the rubber mixer when required.

6. OCCUPATIONAL EXPOSURE

The notified chemical will not be manufactured in Australia. It will be imported into Australia in 20 kg cardboard cartons as the product Santocure TBSI, which contains the notified chemical at a concentration greater than 87.5%. The product is treated with mineral oil to suppress dust formation. The product will be transported to one re-packing site. Worker exposure to the notified chemical during this stage of handling and transportation will not occur, unless there is an accidental spill.

At the packaging site, Santocure TBSI will be placed under local exhaust ventilation into a hopper attached to an automatic packaging line. Here, it will be mixed with other chemicals to a concentration of 50% and automatically transferred to 1 to 2 kg plastic-lined cardboard cartons. The estimated potential exposure time of workers is 8 hours per day per year. Transfer of Santocure TBSI to the hopper during re-packing could lead to worker exposure via the dermal, ocular and inhalatory routes, however, local exhaust ventilation should minimise exposure of workers to fugitive dusts of the Santocure product. No worker exposure is anticipated during re-packaging of the re-formulated Santocure product as this is an automated process.

Once re-packaged, the Santocure product containing the notified chemical, will be transported to a manufacturer of rubber products where it is used to aid the vulcanising process. Santocure product, together with various additives, are manually added to an enclosed mixer containing softened rubber. This process may lead to worker exposure predominantly via the dermal route, although ocular and inhalation exposure is possible. The resulting rubber mixture is transferred to a calender where it is formed into rubber sheets. These sheets are mechanically pressed into moulds and vulcanised under high temperature and pressures using hydraulic presses. Once incorporated and reacted in the rubber mass, worker exposure to the notified chemical during subsequent handling is expected to be negligible.

A total of seven workers are involved in the rubber production line for an estimated exposure time of 8 hours per day, 200 days per year.

7. PUBLIC EXPOSURE

There is negligible potential for public exposure to the notified chemical arising from use as a primary accelerator in the vulcanisation of rubbers. There may be some public contact with rubber products containing the notified chemical, but its incorporation into the rubber matrix will preclude its bioavailability.

8. ENVIRONMENTAL EXPOSURE

Release

The notifier does not expect any notified chemical to be released to the environment at the site of repacking. Should disposal be necessary, it will be performed according to the requirements of the Victorian EPA and local government regulations, presumably to landfill or by incineration. Contaminated product packaging should be disposed of as hazardous waste as per the label and Material Safety Data Sheet (MSDS) instructions, i.e. incinerated or disposed of to an approved landfill site.

During rubber product manufacture, the notified chemical becomes chemically reacted and bonded in the rubber compound. Any 'green' offcuts are reclaimed for further use. The site is bunded with a system designed to prevent entry of polluted water into the stormwater drainage system or sewer.

Fate

The fate of the notified chemical will be associated almost entirely with the fate of rubber articles containing it. In all cases the chemical will remain strongly bound to the rubber matrix. The small proportion of rubber that may enter the soil environment through wear and tear of the rubber product will be in a highly dispersed manner, with the notifier claiming that it will undergo slow degradation.

A proportion may be disposed of directly to landfill. The chemical in rubber articles disposed of to landfill will remain bound to the rubber and undergo slow degradation (see below). During incineration of waste or used rubber articles, the chemical will be destroyed by conversion to oxides of carbon, sulfur and nitrogen, and water vapour. However, based on the repacking and manufacture processes, the probability of pure chemical going into landfill or into waste water is very low. Should small amounts be sent to sewer, the chemical will be trapped to a considerable degree in the sludge.

Ultimate biodegradation screening of the notified chemical at mean concentrations of 10 and 20 mg/L was carried out using the shake flask carbon dioxide (CO_2) evolution procedure (Saeger VW O'Reilly JV Gledhill WE, 1990). This test was performed according to an in house test guideline which appears to be patterned on the OECD 301B test Guideline (Modified Sturm Test). The CO_2 evolved was monitored as a function of time providing a measure of the rate and extent of ultimate biodegradation of the test chemical. After a 57 day exposure period using non-acclimated inoculum, mean evolution was 32% of theory at 10 mg/L and 11% at 20 mg/L. Based on these results, the authors claim that the notified chemical shows some evidence for ultimate biodegradation, but at a relatively slow rate. As such, unless acclimation occurred over a period of time, rapid mineralisation of the notified chemical in an aqueous aerobic environment is unlikely.

A bioaccumulation study has not been provided. Given the notified chemical's low molecular weight, high fat solubility and predicted slow degradation, it may have some potential to bioaccumulate. However, due to its very low water solubility, a log P_{OW} of approximately

6.7 and expected low aquatic environment exposure, the bioaccumulation potential is predicted to be low (Connell, 1989).

9. EVALUATION OF TOXICOLOGICAL DATA

9.1 Acute Toxicity

Test	*Species*	*Outcome*	*Reference*
acute oral toxicity	rat	LD_{50} > 5 000 mg/kg	(Rush RE, 1990a)
acute dermal toxicity	rat	LD_{50} > 2 000 mg/kg	(Rush RE, 1990b)
skin irritation	rabbit	not irritating	(Rush RE, 1990c)
eye irritation	rabbit	slightly irritating	(Rush RE, 1990d)
skin sensitisation	guinea pig	not sensitising	(Kreuzmann, 1990)

9.1.1 Oral Toxicity (Rush RE, 1990a)

Species/strain:	rat/Sprague-Dawley
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	the notified chemical at 5 000 mg/kg was mixed with corn oil
Clinical observations:	transient incidences of urine/faecal stains and soft stools and reddish coloured urine were noted
Mortality:	none
Morphological findings:	one animal displayed reddened adrenals
Test method:	similar to OECD guidelines (Organisation for Economic Co-operation and Development, 1995-1996)
LD_{50}:	> 5 000 mg/kg
Result:	the notified chemical was of low acute oral toxicity in rats

9.1.2 Acute Dermal Toxicity (Rush RE, 1990b)

Species/strain:	rabbit/New Zealand White
Number/sex of animals:	5/sex
Observation period:	14 days
Method of administration:	single dose of moistened notified chemical at 2 000 mg/kg was applied to the shaved skin of each animal; the area was sealed with gauze dressing and plastic for 24 hours
Clinical observations:	transient incidences of diarrhea, soft stools, and faecal stains; mild erythema occurred at the test sites
Mortality:	nil
Morphological findings:	2 animals had mottled lungs; this change may have been due to the method of sacrifice (T61 euthanasia solution)
Test method:	similar to OECD guidelines (Organisation for Economic Co-operation and Development, 1995-1996)
LD_{50}:	> 2 000 mg/kg
Result:	the notified chemical was of low acute dermal toxicity in rats

9.1.3 Inhalation Toxicity

not determined

9.1.4 Skin Irritation (Rush RE, 1990c)

Species/strain:	rabbit/New Zealand White
Number/sex of animals:	3/sex
Observation period:	72 hours
Method of administration:	0.5 g of the notified chemical was moistened with 0.5 mL of distilled water and applied to the shaved

skin of each animal; semi-occlusive dressing was used to secure contact for 4 hours

Comments: all dermal irritation scores were zero

Test method: similar to OECD guidelines (Organisation for Economic Co-operation and Development, 1995-1996)

Result: the notified chemical was non irritating to the skin of rabbits

9.1.5 Eye Irritation (Rush RE, 1990d)

Species/strain: rabbit/New Zealand White

Number/sex of animals: 1 male/5 females

Observation period: 72 hours

Method of administration: 0.027 g of the notified chemical (~ 0.1 mL) was instilled into the conjunctival sac of each animal's right eye; the left eye served as a control

Occular Irritation scores of unirrigated eyes:

	Time after instillation											
Animal	***1 hour***			***24 hours***			***48 hours***			***72 hours***		
Conjunctiva	***r[a]***	***c[b]***	***d[c]***	***r[a]***	***c[b]***	***d[c]***	***r[a]***	***c[b]***	***d[c]***	***r[a]***	***c[b]***	***d[c]***
1	1	1	2	1	0	0	0	0	0	0	0	0
2	2	1	1	1	0	0	0	0	0	0	0	0
3	1	1	2	1	0	0	0	0	0	0	0	0
4	1	1	2	1	0	0	0	0	0	0	0	0
5	2	1	2	2	1	2	0	0	0	0	0	0
6	1	0	0	1	0	0	0	0	0	0	0	0

[1] see Attachment 1 for Draize scales
[a] redness [b] chemosis [c] discharge

Comments: no corneal effects; slight transient irritation of the iris at 1 hour after dosing

Test method: similar to OECD guidelines (Organisation for Economic Co-operation and Development, 1995-1996)

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

9.1.6 Skin Sensitisation (Kreuzmann, 1990)

Species/strain: guinea pig/Hartley

Number of animals: 20 control/10 test animals

Induction procedure: day 0 - 50% (w/v) solution of the notified chemical in 80% ethanol/20% distilled water was applied to the shaved skin (back) of each of each animal using a Hill Top Chamber; exposure was for 6 hours

day 7 and day 14 – the above procedure was repeated

Challenge procedure: a 50% (w/v) solution of the notified chemical in acetone was applied to the shaved right flank of each animal, 14 days after the last induction dose. Application was carried out using the Hill Top Chamber.

Challenge outcome:

	Test animals		***Control animals***	
Challenge concentration	***24 hours****	***48 hours****	***24 hours***	***48 hours***
50%	0/20	0/20	0/10	0/10

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

Comments: the notifier noted 4 deviations from protocol:
4 test animals were replaced with 4 vehicle control animals; 2 power failures interrupted the light/dark cycle; it is stated that these deviations did not compromise the study

Test method: similar to OECD guidelines (Organisation for Economic Co-operation and Development, 1995-1996)

Result: the notified chemical was not sensitising to the skin of guinea pigs

9.2 Repeated Dose Toxicity (Bechtel CL, 1990)

Species/strain:	rat/Sprague-Dawley
Number/sex of animals:	20/sex/group
Method of administration:	the notified chemical was mixed with the feedstock; 0 , 2 500, 7 500 and 15 000 ppm to each group respectively
Dose/Study duration::	corresponding average consumption of the notified chemical: males/females 0 control 178/222 mg/kg/day 533/673 mg/kg/day 1093/1334 mg/kg/day half of the animals were treated for seven weeks, the remainder treated for 90 days
Clinical observations:	no treatment-related changes except for statistically significant weight loss in females across all groups; there were two unscheduled deaths, one low dose male and one mid dose female; there were slight increases in absolute kidney weights and liver/body weight ratios in high dose males; there were increases in brain weight in mid and high dose females; the study authors did not consider these effects to be treatment-related
Clinical chemistry/Haematology	no treatment-related changes
Histopathology:	no treatment-related changes
Test method:	similar to OECD guidelines (Organisation for Economic Co-operation and Development, 1995-1996)
Result:	the notified chemical was not toxic to any specific organ; the no observed effect level (NOEL) was considered to be 15 000 ppm for males and 2 500 ppm for females based upon slight, non-significant decreases in body weights

9.3 Genotoxicity

9.3.1 *Salmonella typhimurium* Reverse Mutation Assay (Stegeman SD, 1990)

Strains:	TA 98, TA 100, TA 1535,TA 1537
Concentration range:	0.01, 0.03, 0.1, 0.3, 1.0 mg.plate^{-1} with or without metabolic activation by S9 mix
Test method:	similar to OECD guidelines (Organisation for Economic Co-operation and Development, 1995-1996)
Comments	in the mutagenicity tests, the notified chemical was insoluble at 1 mg/plate and occasionally at 0.3 mg/plate, both with or without metabolic activation; in the toxicity screen using strain TA 100 toxicity was observed at 1.0 mg/plate with or without activation
Result:	the notified chemical was not mutagenic in *Salmonella typhimurium*, with or without metabolic activation, under the conditions of the experiment

9.3.2 Micronucleus Assay in the Bone Marrow Cells of the Mouse (SanSebastian JR, 1990)

strain:	CD-1 mice
Number and sex of animals:	4/sex/group (dose range-finding study) 5/sex/group (micronucleus test)
Doses:	1 000, 2 500, 3 750 and 5 000 mg/kg (dose range-finding test); 5 000 mg/kg in the micronucleus test.
Method of administration:	oral intubation
Test method:	similar to OECD guidelines (Organisation for Economic Co-operation and Development, 1995-1996)
Result:	the notified chemical was not clastogenic at 5 000 mg/kg in bone marrow cells of the mouse

9.4 Overall Assessment of Toxicological Data

The notified chemical has low acute oral toxicity in rats (LD_{50} > 5 000 mg/kg) and low acute dermal toxicity in rabbits (LD_{50} >2 000 mg/kg). It is not a skin irritant in rabbits, but it is a slight eye irritant in this species. It is not a skin sensitiser in guinea pigs.

No inhalation studies were provided by the notifier.

A 90-day repeat oral dose study in rats did not demonstrate specific organ toxicity at doses below 1 000 mg/kg. The NOEL was less than 222 mg/kg based on decreased body weight of female rats.

The genotoxicity studies provided show that the notified chemical is not mutagenic to *Salmonella typhimurium*, or clastogenic *in vivo* in the mouse micronucleus test.

The notified chemical would not be classified as hazardous according to the National Occupational Health and Safety Commission Approved Criteria on the basis of the available toxicological information.

10. ASSESSMENT OF ENVIRONMENTAL EFFECTS

The following ecotoxicity studies have been supplied by the notifier. The tests were carried out to US EPA/OECD Principles of Good Laboratory Practice. Due to the very low aqueous solubility of the notified chemical (i.e. 2.9 µg/L), test solutions were prepared by dissolving it in the solvent dimethylformamide (DMF). All results are based on mean-measured concentrations.

Test	Species	Results (95% confidence limits)	Reference
Acute Toxicity [a] 96 hours Flow-Through US EPA 797.1400	Fathead minnow *Pimephales promelas*	96 hr LC_{50} > 2.7 mg/L 96 hr NOEC = 2.7 mg/L	(Anonymous, 1990)
Acute Immobilisation [b] 48 hours Flow-Through US EPA 797.1300	Water Flea *Daphnia magna*	24 hr EC_{50} > 7.2 µg/L 48 hr EC_{50} = 5.0 µg/L (4.1-6.2 µg/L) 48 hr NOEC = 2.8 µg/L	(Burgess D Blasberg JW, 1990)
Growth Inhibition [c] 96 hours Static ABC 8004-PMN [d]	Algae *Selenastrum capricornutum*	96 hr EC_{50} > 0.87 mg/L 96 hr NOEC = 0.87 mg/L	(Forbis AD Blasberg JW, 1990)

a) Mean-measured test concentrations: control, solvent control (DMF), 0.13, 0.25, 0.50, 1.0 & 2.0 mg/L;
b) Mean-measured test concentrations: control, solvent control (DMF), 0.70, 1.7, 1.9, 2.8 & 7.2 µg/L;
c) Mean-measured test concentrations: control, solvent control (DMF), 0.037, 0.11, 0.29, 0.55 & 0.87 mg/L
d) Test procedure was patterned after methods that were formulated by the US Environmental Protection Agency, Office of Toxic Substances (OTS) and American Society for Testing and Materials (ASTM).

Toxicity testing to the fathead minnow indicated that the LC_{50} was greater than the water solubility limits of the notified chemical. No mortality nor abnormal effects were observed in any test concentration during the 96 hour test.

The abnormal effects of immobility, erratic swimming and daphnids tending to the bottom of the test chamber were observed at the maximum test concentration of 7.2 µg/L, with 15% immobile at 24 hours and 85% at 48 hours. No other abnormal effects were noted, with the single immobile daphnid observed in the 1.9 µg/L test concentration at 24 hours considered to be aberrant.

After 96 hours, the multiple means test indicated that no significant inhibition of algal growth occurred for any of the test concentrations as compared to the controls. However, it should be noted that significant ($p < 0.05$) inhibition occurred at 24, 48 and 72 hours in the 0.87 mg/L test concentration. While cell growth was reduced after 96 hours as compared to the controls in the 0.87 mg/L test concentration, i.e. 170 cell.mL.10^{-4} as compared to the control value of 220 cell.mL.10^{-4}, it was determined not to be significant.

Considering these results, the notified chemical is expected to be non-toxic to fish and algae up to the limits of its solubility. The LC_{50} for fish and the EC_{50} for algae are all well above the water solubility. However, the EC_{50} for daphnia is only slightly above the water solubility. As such, the notified chemical can be classed as very highly toxic to aquatic invertebrates.

The US EPA has found the (potential) hydrolysis product 2-mercaptobenzothiazole (see *Comments on Physical-Chemical Properties*) to be highly toxic to freshwater fish and moderately toxic to aquatic invertebrates (EPA, 1994).

11. ASSESSMENT OF ENVIRONMENTAL HAZARD

Environmental exposure to the notified chemical will be low as no waste is generated during repackaging and rubber product formulation, and the chemical becomes strongly bound to the rubber matrix during rubber formulation.

The chemical has been shown to be non-toxic to fish, daphnia and algae up to its limit of solubility, and is not expected to be mobile in the environment. Should the notified chemical or its rubber products be incinerated, the chemical will be destroyed.

A small proportion of the chemical may enter the soil environment through the 'wear and tear' and disposal of steel cord belts. The chemical should remain strongly bound in the rubber matrix. However, degradation of the rubber may release the notified chemical (and consequently degradation products, e.g. 2-mercaptobenzothiazole disulfide) into the wider environment which, is potentially of concern based on the aquatic toxicity. However, release will generally be disperse in nature, with rubber degradation occurring slowly over time resulting in temporal dilution.

Considering the above, the environmental hazard is expected to be low when used as proposed.

12. ASSESSMENT OF PUBLIC AND OCCUPATIONAL HEALTH AND SAFETY EFFECTS

On the basis of the toxicological information supplied, exposure to the notified chemical would not be expected to result in significant adverse health effects in workers. However, ocular exposure could lead to slight irritation of the conjunctiva of workers.

The notified chemical contains two impurities (2-mercaptobenzothiazole disulfide and N-t-butyl-2-benzothiazole sulfenamide) that are known skin sensitisers present in concentrations exceeding the NOHSC concentration cut-off levels for skin sensitisers. The notifier indicates that no skin allergy was observed in human volunteers following repeated exposure to 2-mercaptobenzothiazole disulfide; and Santocure TBSI did not induce skin sensitisation in guinea pigs. The second impurity, N-t-butyl-2-benzothiazole sulfenamide, is a known respiratory irritant. However, it is present in concentrations well below the concentration cut-off level for respiratory irritants. In the absence of inhalation studies, adverse effects on the respiratory systems of workers upon dust inhalation cannot be precluded. Santocure TBSI is provided in a dust-free form, but the degree of dustiness is not defined by the notifier. The risk of exposure and any consequent respiratory effects is likely to be low as the notifier states that exhaust ventilation is employed and the national exposure standard for nuisance dust, 10 mg/m^3 TWA, measured as inspirable dust (NOHSC, 1995) is observed during re-packaging and formulation. The notifier indicates that workers handling the notified chemical will wear protective goggles, dust masks, PVC or rubber gloves, and industrial standard overalls. Use of this personal protective equipment should ensure minimal exposure to Santocure TBSI, ensuring that the risk to worker health is minimal.

Although some public contact with the rubber products containing the notified chemical may occur, the notified chemical is chemically bound within the rubber matrix at a low concentration and no risks to public health are imminent.

13. RECOMMENDATIONS

To minimise occupational exposure to Santocure TBSI 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, 1992);
- Impermeable gloves or mittens should conform to AS 2161.2 (Standards Australia, 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 then 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.

Engineering controls are required to limit exposure to dusts generated during handling and use. Regular workplace air monitoring should be conducted to ensure adopted control measures are effective. The NOHSC *Exposure Standards for Atmospheric Contaminants in the Occupational Environment* (NOHSC, 1995) for nuisance dust is 10 mg/m^3 TWA, measured as inspirable dust. All employers are responsible for ensuring exposure standards are not exceeded.

14. MATERIAL SAFETY DATA SHEET

The MSDS for Santocure TBSI was provided in a format consistent with the *National Code of Practice for the Preparation of Material Safety Data Sheets* (National Occupational Health and Safety Commission, 1994).

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

15. REQUIREMENTS FOR SECONDARY NOTIFICATION

Under 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

Anonymous (1990) Acute Flow-Through Toxicity of CP 22595 to Fathead Minnow (*pimephales promelas*), Project No. 38575, Analytical Bio-Chemistry Laboratories, Colombia, USA.

Anonymous (1997) Determination of Dissociation Constant in Water: Santocure TBSI, Flexsys America LP, Akron USA. Unpublished.

Bechtel CL (1990) Three Month Study of CP 22595 (Santocure TBSI) Administered in Feed to Sprague-Dawley Rats, Project No. 90016, Environmental Health Laboratory, St Louis, Missouri.

Burgess D Blasberg JW (1990) Acute Flow-Through Toxicity of CP 22595 (Santocure TBSI) to Daphnia Magna, Project No. 38576, Analytical bio-Chemistry, Colombia, USA.

Connell DW (1989) General characteristics of organic compounds which exhibit bioaccumulation. In: D. W. Connell ed. Bioaccumulation of Xenobiotic Compounds. CRC Press, Boca Raton, .

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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