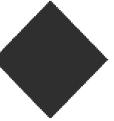


KEEP OUT OF REACH OF CHILDREN READ SAFETY DIRECTIONS BEFORE OPENING OR USING

# STERIGAS 1000<sup>™</sup> Fumigant



ACTIVE CONSTITUENT: 1000 g/kg ETHANEDINITRILE (EDN)





OYIC

For the control of insect pests and fungi infesting timber and logs

For use by licensed fumigators only

**NET CONTENTS: 30 Kg** 

BOC

BOC Limited ABN 95 000 029 729 10 Julius Avenue, North Ryde NSW 2113 Australia Phone: 61 2 8874 4400

Emergency Telephone: 1800 653 572

#### DIRECTIONS FOR USE RESTRAINTS

DO NOT use this product unless trained in the use of required respirator equipment and detection devices, emergency procedures and safe handling of fumigants. Fumigators must hold the relevant State/Territory fumigation license.

DO NOT use without use of a liquid scrubbing system

DO NOT exceed the maximum application rate specified on the label

DO NOT fumigate below 15°C

SITUATION	PEST	APPLICATION RATE	CRITICAL COMMENTS
	Fungi infesting timber	50 g/m <sup>3</sup> for 6 hours exposure	Fumigate using good fumigation practice in accordance with the Australian Fumigation Standard AS 2476 and State regulations.
Timber and logs in sealed fumigation chambers or in shipping containers sealed under tarpaulins or as a stacks sealed under tarpaulins	Insect pests of timber	50 g/m <sup>3</sup> for 10 hours exposure	Fill rate should not exceed 20%.
			Commodity temperature should be greater than 15°C
			Residual gas is to be scrubbed for a minimum of 4 hours using a liquid scrubbing system at the completion of the fumigation period followed by 24 hours of ventilation.
			Disposal of scrubbing solution waste must be handled by an approved waste management company and in compliance with relevant Local, State or Territory government regulations

# NOT TO BE USED FOR ANY PURPOSE OR IN ANY MANNER CONTRARY TO THIS LABEL UNLESS AUTHORISED UNDER APPROPRIATE LEGISLATION

#### GENERAL INSTRUCTIONS

STERIGAS 1000 is a rapid acting, flammable fumigant for fumigation of timber and logs to control pests and pathogen. STERIGAS 1000 penctrates deep into the timber or logs being fumigated. Fumigation for the recommended exposure period is essential to ensure control of target pests and pathogen.

#### Application

Prior to use, ensure that an appropriate liquid scrubbing system is installed (for use post funnigation). Use BOC approved equipment to deliver Sterigas 1000 into the funnigation enclosure. Keep the treated area sealed for a minimum of 6 hours followed by a minimum of 4 hours of liquid scrubbing of EDN and for another 24 hours ventilation. Re-entry to the buffer zone should be restricted for a minimum of 34 hours based on a 6 hour funnigation period.

#### Engineering controls

All funigation workers must carry portable monitoring devises, calibrated to detect EDN levels in air at or below 1 ppm (with upper level of detection above 50 ppm). A buffer zone (risk area) of 50 metres from the fumigation area is required to protect bystanders and unprotected personnel during fumigation.

All entrances to the furnigation area must be clearly palcarded in accordance with local OHS requirements and regulations with the warning: "DANGER, area under furnigation, Do not enter unless wearing appropriate personal protective equipment"

If the area cannot be physically secured, a watchman must be stationed to prevent people entering the risk area. This placard should also carry a skull and crossbones pictogram with date and time of the fumigation commencement, date and time the restrictions expire, fumigant product name and contact details (telephone number) for the funigator.

### PRECAUTIONS

#### Re-entry Period

DO NOT enter the buffer zone during fumigation and for up to 34 hours after completion of ventilation of timber stack or where EDN levels above 1 ppm, unless wearing chemical resistant clothing fastened to the neck, chemical resistant gloves and full face respirator. If EDN levels are above 50 ppm use a supplied air respirator.

Rehandling

DO NOT handle fumigated timber for 24 hours after commencement of ventilation, unless wearing chemical resistant clothing fastened to the neck, chemical resistant gloves and, if levels of EDN in air are at or above 1 ppm, wear a full or half facepiece respirator.

#### WARNING

May cause fire or explosions. Keep away from heat, sparks and naked flames

#### PROTECTION OF WILDLIFE, FISH, CRUSTACEANS AND ENVIRONMENT

The funigation site must not be bounded by areas inhabited by native animals and birds or where significant populations of birds are known to congregate. These include agricultural fields, natural bushlands, forests and urban parks.

Fumigations conducted at port locations must be undertaken only at locations where waterbird colonies are not known to exist. Atmospheric cooditions should be monitored and EDN should not be vented under very low wind speed conditions (less than 5 km/h) or under inversion conditions.

DO NOT contaminate streams, rivers or waterways with the chemical or used containers

#### STORAGE and DISPOSAL

Store cylinders upright in a secure, locked, well-ventilated, cool room or place, away from children, animals, food, feedstuffs, seed and fertilisers and out of direct sunlight. Do not heat cylinder.

Cylinders remain the property of BOC Limited. Empty contents fully into application equipment. When empty, close all valves and return to the point of supply for refill or storage.

#### SAFETY DIRECTIONS

Very dangerous. Can kill if inhaled. Poisonous if absorbed by skin contact and if swallowed. Will irritate the eyes, nose, throat and skin. Avoid contact with eyes and skin. Do not inhale.

When using the product and preparing the product for use and when uncovering the treated area/material, wear protective clothing (chemically resistant) fastened to the neck, elbow length chemical resistant gloves, impervious footwear (non-sparking) and full face piece respirator with canister specified for EDN (or where levels above 50 ppm) a supplied air respirator. Detailed instructions for safe use appear in State/Territory regulations.

Thoroughly ventilate treated areas before reoccupying. After each day's use wash gloves, respirator and contaminated clothes

#### FIRST AID

For advice, contact a Poisons Information Centre (Phone 13 11 26) or doctor at once. If inhaled, remove from contaminated area. Apply artificial respiration if not breathing. To protect rescuer, use air-viva, oxy-viva or one-way mask. Resuscitate in a well-ventilated area.

#### Material Safety Data Sheet

Additional safety information is given in the STERIGAS 1000 MSDS available from BOC Limited.

Batch No.: Date of Manufacture: APVMA Approval Number: 60096/37416

# IN A TRANSPORT EMERGENCY DIAL 000, POLICE OR FIRE BRIGADE

BOC Limited Emergency Contact

# 1800 653 572

(Australia wide, 24 hours)



A Member of The Linde Group BOC Limited ABN 95 000 029 729 10 Julius Avenue, North Ryde NSW 2113 Australia Phone: 61 2 8874 4400





Australian Government

Australian Pesticides and Veterinary Medicines Authority



# PUBLIC RELEASE SUMMARY

on the Evaluation of the New Active Constituent Ethanedinitrile

in the Product Sterigas 1000 Fumigant

APVMA Product Number P60096

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ISSN: 1443-1335 (electronic) ISBN: 978-1-922188-33-5 (electronic)

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# PREFACE

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is the Australian Government regulator with responsibility for assessing and approving agricultural and veterinary chemical products prior to their sale and use in Australia.

In undertaking this task, the APVMA works in close cooperation with advisory agencies, including the Department of Health and Ageing, Office of Chemical Safety (OCS), Department of Sustainability, Environment, Water, Population and Communities (DSEWPaC), and State Departments of Primary Industries.

The APVMA has a policy of encouraging openness and transparency in its activities and of seeking community involvement in decision making. Part of that process is the publication of Public Release Summaries for products containing new active constituents.

The information and technical data required by the APVMA to assess the safety of new chemical products, and the methods of assessment, must be consistent with accepted scientific principles and processes. Details are outlined in the APVMA's publications *Ag MORAG: Manual of Requirements and Guidelines* and *Vet MORAG: Manual of Requirements and Guidelines*.

This Public Release Summary is intended as a brief overview of the assessment that has been conducted by the APVMA and of the specialist advice received from its advisory agencies. It has been deliberately presented in a manner that is likely to be informative to the widest possible audience thereby encouraging public comment.

# About this document

This is a Public Release Summary.

It indicates that the Australian Pesticides and Veterinary Medicines Authority (APVMA) is considering an application for registration of an agricultural or veterinary chemical. It provides a summary of the APVMA's assessment, which may include details of:

- the toxicology of both the active constituent and product
- the residues and trade assessment
- occupational exposure aspects
- environmental fate, toxicity, potential exposure and hazard
- efficacy and target crop or animal safety.

Comment is sought from interested stakeholders on the information contained within this document.

# Making a submission

In accordance with sections 12 and 13 of the Agvet Code, the APVMA invites any person to submit a relevant written submission as to whether the application for registration of **Sterigas 1000 Fumigant** should be granted. Submissions should relate only to matters that the APVMA is required, by legislation, to take into

account in deciding whether to grant the application. These matters include aspects of **public health**, **occupational health and safety**, **chemistry and manufacture**, **environmental safety**, and **efficacy and target crop or animal safety**. Submissions should state the grounds on which they are based. Comments received that address issues outside the relevant matters cannot be considered by the APVMA.

Submissions must be received by the APVMA by close of business on **Wednesday**, **July 3**, **2013** and be directed to the contact listed below. All submissions to the APVMA will be acknowledged in writing via email or by post.

Relevant comments will be taken into account by the APVMA in deciding whether the product should be registered and in determining appropriate conditions of registration and product labelling.

When making a submission please include:

- contact name
- company or group name (if relevant)
- email or postal address (if available)
- the date you made the submission.

All personal information, and confidential information judged by the APVMA to be *confidential commercial information (CCI)*<sup>1</sup> contained in submissions will be treated confidentially.

Written submissions on the APVMA's proposal to grant the application for registration that relate to the **grounds for registration** should be addressed in writing to:

Contact Officer Pesticides Program Australian Pesticides and Veterinary Medicines Authority PO Box 6182 Kingston ACT 2604 Phone: +61 2 6210 4748 Fax: +61 2 6210 4776

Email: pesticides@apvma.gov.au

<sup>&</sup>lt;sup>1</sup> A full definition of "confidential commercial information" is contained in the Agvet Code.

# **Further information**

Further information can be obtained via the contact details provided above.

Copies of full technical evaluation reports covering toxicology, occupational health and safety aspects, residues in food and environmental aspects are available from the APVMA on request.

Further information on public release summaries can be found on the APVMA website: www.apvma.gov.au

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# 1 INTRODUCTION

## Applicant

**BOC** Limited

## **Details of Product**

It is proposed to register Sterigas 1000 fumigant containing 1000 g/kg ethanedinitrile as a compressed gas for use as a fumigant of timber under tarpaulins or in shipping containers under tarpaulins. Sterigas 1000 Fumigant is intended to be applied to create a concentration of 50g/m<sup>3</sup> which is held for 6 hours prior to the residual gas in the enclosure being scrubbed via a liquid scrubbing system followed by a further aeration period.

Ethanedinitrile was developed and patented as a potential replacement for the fumigant methyl bromide. Methyl Bromide has been used in Australia and overseas for the fumigation of a range of plant materials, including timber but has been identified as an ozone depleting substance and its use is being phased out under the Montreal Protocol.

Sterigas Fumigant has been proposed as a methyl bromide replacement for a wide range of commodities including for use as a fumigant of timber and logs, for soil fumigation and for the sterilisation of grain. It has been the subject of many studies which have looked at the control of insect pests, weed seeds and pathogens on a range of commodities and in a range of situations. This summary addresses the assessment for the proposed use as a timber fumigant onlyfor use under tarpaulins, in shipping containers under tarpaulins or purpose built fumigation chambers.

Neither the active (ethane dinitrile) nor the product (Sterigas 1000 fumigant) is registered in any country although Malaysia has included the option of Cyanogen (ethanedinitrile) fumigation as a phytosanitary treatment for logs and sawn timber acceptable to that country.

This publication provides a summary of the data reviewed and an outline of the regulatory considerations for the proposed registration of **Sterigas 1000 Fumigant**, and approval of the new active constituent, **Ethanedinitrile**.

# 2 CHEMISTRY AND MANUFACTURE

## 2.1 Active constituent

Ethanedinitrile is a new active constituent for use as a fumigant. The active constituent is manufactured by United Fluoride (Shenyang) Co., Ltd at its manufacturing site in China.

The chemical active constituent Ethanedinitrile has the following properties:

CHEMICAL NAME (IUPAC):	Ethanedinitrile
CAS NAME:	Cyanogen
CAS REGISTRY NUMBER:	460-19-5
MOLECULAR FORMULA:	C <sub>2</sub> N <sub>2</sub>
MOLECULAR WEIGHT:	52.04
PHYSICAL FORM:	Colourless gas
ODOUR:	Bitter almond (pungent)
MELTING POINT:	-27.9 °C
BOILING POINT:	-21.2 °C
DENSITY:	For liquid at −40 °C, 0.989 g/cm <sup>3</sup> . Relative density 1.8 (air = 1).
PARTITION COEFFICIENT (KOW):	0.07
VAPOUR PRESSURE:	515.7 kPa at 21.1 °C
FLAMMABME LIMITS:	6-32 vol. % in air
STRUCTURAL FORMULA:	N=C-C=N

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APVMA Active Constituent Standard for ETHANEDINITRILE

CONSTITUENT	SPECIFICATION	LEVEL
Ethanedinitrile	Colourless gas	Minimum 860 g/kg
Hydrogen Cyanide	Colourless liquid	Maximum 50 g/kg

A maximum water content of 0.1 g/kg has been determined in the assessment of the active constituent. Water reacts with the active constituent ethanedinitrile to form hydrogen cyanide; the variation in the content of both ethanedinitrile and hydrogen cyanide is water dependant.

## 2.2 Product

The product Sterigas 1000 Fumigant contains the new active constituent Ethanedinitrile at a minimum concentration of 860 g/kg. The product is Gas (GA) formulation.

PHYSICAL FORM:	Gas
COLOUR:	Colourless
ODOUR:	Bitter almond (pungent)
SPECIFIC GRAVITY:	For liquid at $-40^{\circ}$ C, 0.989 g/cm <sup>3</sup> ; Relative density 1.8 (air = 1)
VAPOUR PRESSURE:	515.7 kPa at 21.1 °C
AUTO-IGNITION TEMPERATURE:	>650 °C
CRITICAL TEMPERATURE:	127 °C
FLAMMABILITY:	6-32% (by volume in air)
STORAGE STABILITY:	Stability data provided by the applicant indicates that the product is expected to remain within specification for up to two years when stored under normal conditions in stainless steel container

The product Sterigas 1000 Fumigant has the following properties:

# **3 TOXICOLOGICAL ASSESSMENT**

The toxicological database for ethanedinitrile, which consists primarily of toxicity studies on hydrogen cyanide and cyanide salts conducted in animals, is extensive and considered sufficient to determine the toxicological profile of Sterigas® 1000 Fumigant and to characterise the potential risks to humans from exposure. In interpreting the data, it should be noted that toxicity tests generally use doses that are high compared with likely human exposures. The use of high doses increases the likelihood that potentially significant toxic effects will be identified. Findings of adverse effects in any one species do not necessarily indicate such effects might be elicited in humans. From a conservative risk assessment perspective however, adverse findings in animal species are assumed to represent potential effects in humans, unless convincing evidence of species specificity is available.

Where possible, considerations of the species-specific mechanisms of adverse effects are given strong weight in the extrapolation of animal data to likely human hazard. Equally, consideration of the risks to human health must take into account the likely human exposure levels compared with those, usually many times higher, which produce effects in animal studies. Toxicity tests should also indicate dose levels at which the specific toxic effects are unlikely to occur. Such dose levels as the No-Observable-Effect-Level (NOEL) are used to develop acceptable limits for dietary (ADI and ARfD) or other exposures (occupational and bystander), at which no adverse health effects in humans would be expected.

## 3.1 Toxicokinetics and Metabolism

Ethanedinitrile hydrolyses to yield one molecule of hydrogen cyanide and one of cyanate in the environment and biological systems. The rate of the breakdown depends on pH and is faster in basic media than in acidic media. In the absence of specific studies with ethanedinitrile, it is reasonable to consider the toxicokinetics and metabolism of ethanedinitrile by referring to hydrogen cyanide or cyanide.

Hydrogen cyanide is readily absorbed following inhalation, oral, and dermal exposure. Humans retained around 60% of hydrogen cyanide in the lungs after inhaling the gas. Gastrointestinal absorption of cyanide salts is slower than pulmonary absorption, and the onset of symptoms is delayed and the severity of symptoms diminished compared with inhalation. Essentially all cyanide ingested as cyanide salts will form hydrogen cyanide and will be rapidly absorbed. However, after oral intake, only part of the dose reaches the systemic circulation due to first-pass metabolism by the liver.

Liquid cyanide compounds are readily absorbed through intact skin upon direct contact. Skin absorption of vapours of hydrogen cyanide is also possible when air concentrations are high. In vitro studies with human skin have shown that penetration of sodium cyanide in aqueous solution through skin decreases with increasing pH. The permeability constant measured for the cyanide ion in aqueous solution was  $3.5 \times 10^{-4}$  cm/h, and that calculated for hydrogen cyanide was  $1 \times 10^{-4}$  cm/h.

Inhaled or percutaneously absorbed hydrogen cyanide passes immediately into the systemic circulation. The major portion of cyanide in blood is sequestered in the erythrocytes, and a relatively small proportion is transported via the plasma to target organs. The distribution of cyanide to the various tissues is rapid and fairly uniform. Higher levels are generally found in the liver, lungs, blood, and brain. In rats dosed by gavage,

highest concentrations of cyanide were found in the liver, followed by the lungs and blood, whereas following inhalational exposure, the highest concentrations were found in the lungs, followed by the blood and liver.

The major route of metabolism for hydrogen cyanide and cyanides is detoxification in the liver by the mitochondrial enzyme rhodanase, which converts cyanide to thiocyanate. About 80% of cyanide is detoxified by this route. The rate-limiting step is the availability of thiosulfate. While rhodanase is present in the mitochondria of all tissues, the species and tissue distributions of rhodanase are highly variable. In general, the highest concentrations of rhodanese are found in the liver, kidney, brain, and muscle. Dogs have a lower overall activity of rhodanase than monkeys, rats, and rabbits, and hence are more sensitive to cyanide toxicity.

## 3.2 Acute Toxicity

In an acute inhalation study, male rats were exposed to ethanedinitrile ranging from 540-8540 mg/m<sup>3</sup> (250–4000 ppm) for 7.5-120 min. Mortality was dependent on dose and length of exposure. Exposure to 850 mg/m3 (400 ppm) for 45 min caused no mortality, but the same dose for 60 min caused death of all animals. The calculated 60-min  $LC_{50}$  in rats for ethanedinitrile was 750 mg/m<sup>3</sup> (350 ppm). Exposures to 210 mg/m<sup>3</sup> (100 ppm) for 2-3 hours, or to 840 mg/m<sup>3</sup> (400 ppm) for less than 2 hours, were lethal to cats and rabbits, respectively.

LC<sub>50</sub> values for hydrogen cyanide in rats and rabbits were 158 mg/m<sup>3</sup> (for 60 min) and 188 ppm (for 30 min).

Oral  $LD_{50}$  values of hydrogen cyanide in rats and rabbits were 0.156 and 0.092 mmol/kg bw, respectively. The dermal  $LD_{50}$  of hydrogen cyanide to intact skin of New Zealand rabbits was 0.260 mmol/kg bw. The dermal toxicity of hydrogen cyanide is markedly greater ( $LD_{50}$  of 0.087), following application to abraded rabbit skin.

The following estimations for cyanide lethality were obtained for humans, based on case report studies with different cyanide containing compounds: an  $LC_{50}$  of 524 ppm for a 10 minute inhalation exposure;  $LD_{50}$  of 1.52 mg/kg bw for the oral route;  $LD_{50}$  of 100 mg/kg bw for the dermal route. Human case reports on exposure to hydrogen cyanide report fatalities ranging from 135 to 270 ppm.

Death from cyanide poisoning is believed to result from CNS depression, subsequent to inhibition of brain cytochrome oxidase activity. Typical signs of toxicity after inhalation of hydrogen cyanide in test species include rapid breathing, weak and ataxic movements, convulsions, loss of voluntary movement, coma, and decrease and irregularities in respiratory rate and depth preceding death.

Acute inhalation studies with ethanedinitrile in rabbits also reported irritation to eyes and upper respiratory tract. There are no studies indicating potential skin irritation or sensitising properties for ethanedinitrile or hydrogen cyanide.

# 3.3 Systemic Effects

Two studies on ethanedinitrile per se were available for evaluation. Both were 6-month inhalation studies, carried out in rats and rhesus monkeys. No effects were seen on haematology, clinical chemistry, gross

pathology or histopathology in either species. A NOEL of 11 ppm (54 mg/m3) was established, based on significant body weight decrease in rats and transient behavioural changes in monkeys at 54 mg/m<sup>3</sup> ethanedinitrile.

The main systemic effects seen in repeat-dose animal studies on different cyanide containing compounds comprised effects on CNS, lung, thyroid, liver, kidney and changes in male reproductive organs.

In oral studies carried out with cyanide salts, the most sensitive effect was on male reproductive organs (increased testes weight, reduction in cauda epididymis weight and sperm motility) seen in 90-day rat and mouse studies, with effects seen at 1.4 mg cyanide/kg bw/day in rats. No dermal studies were available for assessment.

In a human epidemiology studies on workers exposed to cyanide salts for up to 10 years, toxicological observations included confusion, hallucination, headache, dizziness, weakness, dyspnoea, irritation of throat, precordial pain, vomiting, increased haemoglobin and lymphocytes and thyroid enlargement (goitre). The thyroid effects observed were associated with increased uptake of iodine probably through competitive inhibition by cyanide. Mean breathing-zone cyanide concentrations ranged from

6.4 to 10.4 ppm (7.1 to 11.5 mg/m<sup>3</sup>), equivalent to 3.5 to 5.7 mg/m<sup>3</sup> ethanedinitrile. A significant positive trend for prevalence of cyanide-related symptoms measured against levels of exposure was demonstrated, supporting a dose-response effect. Some symptoms occurring seven or more months after exposure also exhibited a dose-response trend.

# 3.4 Genotoxicity and Carcinogenicity

Ethanedinitrile was weakly mutagenic to S. typhimurium TA100 and Escherichia coli WP2uvrA, but not to TA1535, TA1537 and TA98, with or without exogenous metabolic activation. It also showed mutagenicity in mouse lymphoma L5178Y cells.

Hydrogen cyanide induced mutations in S. typhimurium TA100 in the absence of exogenous metabolic activation, but was not mutagenic to strain TA98 with or without exogenous metabolic activation. Hydrogen cyanide also induced DNA damage in baby hamster kidney cells (BHK-21) in vitro. Potassium cyanide induced dose-dependent DNA fragmentation in rat thymocytes and double strand breaks in human A549 lung cells. Sodium cyanide was a highly effective inducer of germ-line aneuploidy in Drosophila. Neither sodium nor potassium cyanide were mutagenic in S. typhimurium strains TA97, TA98, TA100 or TA1535, with or without exogenous metabolic activation.

In vivo studies in rats and mice did not demonstrate any statistically significant increases in the frequency of chromosomal aberrations or changes in mitotic index in bone marrow cells (rats dosed with ACH) or testicular DNA synthesis inhibition (mice dosed with potassium cyanide).

Available long-term toxicology studies in animals do not provide adequate information on potential carcinogenicity of cyanides. Also, no epidemiological data were available regarding possible carcinogenic effects in humans.

# 3.5 Reproductive and Developmental Toxicity

No reproductive and developmental toxicity studies are available for ethanedinitrile, however studies on cyanide containing compounds have shown them to be damaging to reproductive organs and function and to be embryotoxic and teratogenic.

Several studies support adverse effects on the male reproductive system. In male rats ingesting sodium cyanide in the drinking water for 13 weeks, decreases were noted in the caudal epididymal weight, epididymis weight, testis weight, spermatid heads, and spermatid counts, whereas in male mice significant decreases in the epididymal and caudal epididymal weights were noted without changes in sperm parameters. Increased gonadal weight was observed in male rats exposed by oral gavage to copper cyanide or potassium silver cyanide for 90 days. A reduction in the spermatogenic cycle, testicular germ cell sloughing and degeneration and abnormal cells were noted in dogs ingesting sodium cyanide in a rice diet or as the equivalent cassava diet. In female rats, increased resorptions were noted following oral exposure of pregnant rats to cyanogenic glycosides in a cassava diet.

Developmental abnormalities (microcephaly with open eyes, limb defects, and growth retardation) were observed in 28% of the foetuses of rats exposed to feed containing 80% cassava powder during gestation. Foetotoxicity (reduced foetal weight and ossification of sacrocaudal vertebrae, metatarsals, and sternebrae) were found in the offspring of hamsters fed a cassava diet providing 1.0 mg/kg/day cyanide during pregnancy. In tropical countries, maternal ingestion of cassava during pregnancy has been associated with congenital hypothyroidism in some of the offspring.

# 3.6 Neurotoxicity

The most significant effects of cyanide exposure occur in the nervous system, especially in the brain (encephalopathy). The CNS is particularly sensitive to the adverse effects of cyanide due to its high metabolic demand for oxygen and its control of respiratory function. Acute inhalation of high concentrations of cyanide provokes a brief CNS stimulation followed by depression, convulsions, coma, and death in humans and animals associated with effects on the neurological centre controlling respiration. Convulsions and coma have also reported in humans and animals following acute dermal exposure to cyanide.

In animal studies, inhalation exposure of rats to hydrogen cyanide at 34 mg/m3 for 3.5 h caused impaired auditory function by producing significant oxidative stress in the cochlea. Repeated intraperitoneal dosing of Wistar rats with sodium cyanide (2 mg/kg bw/d) for 4 weeks resulted in reductions of memory (T-maze test) along with reductions in the levels of dopamine and 5-hydroxytryptamine and increases in norepinephrine and epinephrine levels in the hippocampus. Dogs administered sodium cyanide in capsules up to 4 mg/kg bw daily for 15 months showed severe signs of acute cyanide poisoning. At autopsy, degenerative changes in ganglia cells of the central nervous system were observed (interpreted to be caused by multiple episodes of acute cerebral hypoxia).

# 3.7 PUBLIC HEALTH STANDARDS

## **Poisons Scheduling**

The National Drugs and Poisons Schedule Committee (now ACCS) considered the toxicity of ethanedinitrile and assessed the necessary controls to be implemented under States' poisons regulations to prevent the occurrence of poisoning.

On the basis of its toxicity, ethanedinitrile is included in Schedule 7 of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) with an inclusion in Appendix J (condition 1 – Not to be available except to authorised or licensed persons). There are provisions for appropriate warning statements and first-aid directions on the product label.

## **NOEL/ADI**

The ADI for humans is the level of intake of an agricultural or veterinary chemical that can be ingested daily over an entire lifetime without appreciable risk to health. It is calculated by dividing the overall NOAEL for the most sensitive toxicological endpoint from a suitable study (typically an animal study) by an appropriate safety factor.

As the product is to be used only for treating cut timber, potential exposure to residues in food is not an issue. Therefore no ADI was established for ethanedinitrile or hydrogen cyanide.

JECFA has recently established a provisional maximum tolerated daily intake (PMTDI) of 0.02 mg/kg bw/d for cyanide, in a review of dietary exposure to cyanogen glycosides in food products. This value has been adopted by FSANZ.

## Acute Reference Dose (ARfD)

The ARfD is the estimate of the amount of a substance in food or drinking water, expressed on a milligram per kilogram body weight basis, that can be ingested over a short period of time, usually in one meal or during one day, without appreciable health risk to the consumer on the basis of all known facts at the time of the evaluation.

As the product is to be used only for treating cut timber, potential exposure to residues in food is not an issue. Therefore no ARfD was established for ethanedinitrile or hydrogen cyanide.

JECFA has recently established an ARfD of 0.09 mg/kg bw/d for cyanide, in a review of dietary exposure to cyanogen glycosides in food products. This value has been adopted by FSANZ.

# 4 OCCUPATIONAL HEALTH AND SAFETY ASSESSMENT

Based on an assessment of the toxicology and occupational health and safety, it was considered that there should be no adverse effects on human health (workers and/or bystanders) from the use of Sterigas® 1000 Fumigant for treating timber, when used in accordance with the manufacturers product specific directions, including the product label and Material Safety Data Sheet, together with the procedures outlined in the Australian Standard AS 2476 (2008).

## **Health Hazards**

Ethanedinitrile (CAS: 460-19-5) is currently listed on the Safe Work Australia's Hazardous Substances Information System (HSIS) Database with the following risk phrases:

- R12 Extremely flammable
- R23 Toxic by inhalation

Based on the available toxicology data, the OCS has revised this classification, in accordance with the NOHSC Approved Criteria for Classifying Hazardous Substances as follows:

- R12 Extremely flammable
- R24/25 Toxic in contact with skin and if swallowed
- R26 Very toxic by inhalation
- R36/37 Irritating to eyes and respiratory system
- R48/23/25 Danger of serious damage to health by prolonged exposure via inhalation and ingestion
- R60 (Cat 2) May impair fertility
- R61 (Cat 2) May cause harm to the unborn child
- R68 (Cat 3) Possible risk of irreversible effects

This classification also applies to the product, Sterigas® 1000 Fumigant.

## Formulation, packaging, transport, storage and retailing

Sterigas® 1000 Fumigant will be manufactured overseas and imported into Australia. The product is packaged in 25 kg, 80 kg low-pressure steel gas cylinders complying with AS 2473 fitted with an eductor tube and protected valves to minimize the possibility of damage or leakage. The product will undergo transportation from storage facilities to fumigation sites. It is proposed to be distributed widely and used broadly, mainly at shipping terminals.

As a Schedule 7 Poison (SUSMP Appendix J) Sterigas® 1000 Fumigant is only available to authorised or licensed persons. Workers must hold the relevant State/Territory licence for fumigation.

### Use pattern

Sterigas® 1000 Fumigant is intended for the fumigation of timber and logs in shipping containers (tarped) and/or log stacks under tarpaulin, for the control of pathogens, weeds or insect pests. The product cylinders are placed outside the tarped area, and attached by delivery lines connected to an application tube (inside tarp). The application rate is 50 g product /m3 (~20-30,000 ppm target concentration) air space for 6 hours. Following fumigation, residual gases are vented to a scrubbing system. After a 4–6 hours scrubbing period, the tarp is rolled back to vent remaining ethanedinitrile and hydrogen cyanide to atmosphere, over a 24 hour (venting) period.

## Exposure during use

Workers may be exposed to the product when opening fumigant cylinder valves, removing tarp covers for ventilation, opening and entering shipping containers, leakage from damaged (leaking) fumigant delivery lines, as well as handling fumigated timber. Other workers not involved in fumigation may also be exposed, in particular dock workers, where dockside fumigation of shipping containers is being carried out.

Worker exposure studies were submitted and assessed in the present application. Results from these studies, together with the available toxicological data were considered to justify the label First Aid Instructions, Warning Statements, Safety Directions, Precaution Statements and Re-handling statements established for Sterigas® 1000 Fumigant.

## Exposure during re-entry and re-handling

During fumigation and venting both workers and bystanders may be exposed to ethanedinitrile and hydrogen cyanide, mainly via inhalation. For timber under tarp fumigation (with scrubbing), a conservative buffer zone of 50 m was established to provide adequate protection for bystanders. In addition, entry into the fumigation area should be restricted until ventilation is complete (i.e. 34 hours after commencement of fumigation). In any event, re-entry into the buffer zone should not be undertaken until levels of ethanedinitrile and/or hydrogen cyanide are below 1 ppm, unless wearing appropriate personal protective equipment [protective clothing (chemically resistant) fastened to the neck, elbow length chemical resistant gloves, impervious footwear (non-sparking) and full face piece respirator with canister specified for EDN (or where levels above 50 ppm) a supplied air respirator]. Removing tarpaulins, opening and entry into shipping containers or fumigation chambers should be undertaken only when wearing personal protective equipment and not until levels of ethanedinitrile inside the container are below 200 ppm. At levels above 1 ppm, and less than 50 ppm workers must not enter unless wearing chemical resistant clothing fastened to the neck, chemical resistant gloves and full face respirator fitted with a canister specified for EDN. If EDN levels are above 50 ppm (and below 200 ppm) a supplied air respirator fitted with a canister specified for EDN.

At no time during fumigation and ventilation, should unprotected personnel be allowed to enter the buffer zone. All entrances to the fumigation area (buffer zone) should be marked with warning placards in accordance with local OHS requirements and regulations.

Estimates provided on timber residues and emissions data indicate that re-handling of fumigated timber should be restricted to 24 hours after commencement of ventilation (i.e. 34 hours after commencement of fumigation). Fumigated timber should not be handled prior 24 hours after commencement of ventilation,

unless the workers are wearing chemical resistant clothing fastened to the neck, chemical resistant gloves and, if levels of EDN in air are at or above 1 ppm, they should wear wear a full or half-facepiece respirator fitted with a canister specified for EDN.

## **Air Monitoring**

Fumigation site air monitoring is an important risk management measure during fumigation and should be routinely conducted during the introduction of the fumigant product into storage or the site; during fumigation and ventilation of the fumigated timber and before operators or bystanders enter the risk area.

Operators should be equipped with portable gas detectors for ethanedinitrile and hydrogen cyanide. The registrant provided data on monitors suitable for measuring ethanedinitrile and hydrogen cyanide at the concentrations required (ie LDL below 1 ppm in air; HDL at and above 50 ppm). All equipment used for measuring and monitoring fumigant concentrations should be in good working order and calibrated according to manufacturer's instructions.

## Recommendations for safe use

Users should follow the First Aid Instructions, Warning Statements, Safety Directions, Precaution Statements, Re-entry and Re-handling statements established on the product label, in association with the manufacturer's product specific directions, including the Material Safety Data Sheet.

## Conclusion

The approval of the active ethanedinitrile and registration of Sterigas® 1000 Fumigant containing 1000 g/L ethanedinitrile for use as a fumigant for the control of pathogens, weeds and insects in timber is supported.

Sterigas® 1000 Fumigant can be used safely if handled in accordance with the instructions on the product label and other control measures, including the requirement for under tarp fumigation with scrubbing, described above. Additional information is available on the product Material Safety Data Sheet.

# 5 ENVIRONMENTAL ASSESSMENT

BOC Limited (Ltd) has applied for approval for the new active constituent ethanedinitrile (EDN) and registration of the new product Sterigas 1000 Fumigant containing 1000 g/kg EDN. The product is proposed for use for the fumigation of timber and logs prior to export.

# 5.1 Environment Exposure and Fate

As EDN is an old chemical limited environmental fate data are available, but its fate in the environment will largely be governed by its physical-chemical properties. It is a colourless gas of boiling point of -21°C, and based on its vapour pressure is highly volatile and will readily partition to the atmosphere from dry soil surfaces. EDN is readily soluble in water and based on its calculated Henry's Law Constant is at best moderately volatile from water, and may be retained to some extent in moist soil and water despite its high vapour pressure. However, based on its calculated adsorption coefficient Koc, EDN is expected to be very highly mobile in soil.

Timber fumigations may occur onshore or in the holds of ships. Typically, the fumigations of logs take place inside a tarp which covers an open container. These are intended to be conducted under sealed air-tight conditions.

Some studies were provided in support of the above use pattern.

A timber penetration study in a sealed fumigation chamber with a timber loading of 20% showed that equilibrium concentrations were reached in 6 hours and with 39% of the applied EDN remaining in the headspace at equilibrium. In another study EDN injected into polyethylene tents containing wooden logs with a moisture content >50% and a filling ratio of 50% in a field fumigation trial was significantly reduced (85%) in the headspace over 3 days of fumigation, indicating strong absorption by the logs. This was supported by a further study which show similar rates of headspace decline of EDN over 24 hours of fumigation. Rates of sorption ranged from 61-92%, indicating that up to 39% of EDN is available for release to the environment upon venting.

A commercial scale study investigated releases into the surrounding environment during and after fumigation at 50 g/m3 of a 20 ft (6.1 m) container filled 50% by volume with logs and sealed with a tarpaulin. EDN was detected at a maximum concentration of 4 ppm at up to 25 m downwind of the container during fumigation but after venting increased both in terms of concentration and downwind distance, reaching 11 ppm at 25 m and 21.5 ppm just outside the container (1 hour later) and 2.5 ppm at 210 m. HCN was detected at lower levels than EDN throughout the fumigation and venting periods at up to 8.5 ppm at 10 m just after dosing and was detected (2.5 ppm) at a maximum distance of 100 m (24 hours after dosing).

The extent of desorption from timber is unclear but the applicant indicates that much of the EDN is sorbed by timber commodities and transformed to ammonium compounds with the extent of sorption dependent on moisture content and the amount of timber in the chamber. The applicant argues that only residual EDN is available for release to air and that the trials indicate this to be less than 10% of applied. However, the results of the above commercial scale study where EDN was retained at ~1% of the equilibrium fumigation concentration, and where EDN was measured downwind of the container at up to 30 hours, suggests an

ongoing desorption process and a steady ongoing concentration of EDN to which taxa in the vicinity could be exposed.

# 5.2 Environmental Effects

Very limited quantitative data is available for environmental effects on the organisms likely to be exposed from timber fumigations, such as birds and mammals, and since fumigations may take place near water, aquatic organisms, and therefore this area has relied heavily on published data.

In respect of birds EDN is said to be comparable in toxicity to HCN. Qualitative arguments by the applicant indicate that high concentrations of EDN are lethal, but it is argued that human presence at the site of venting will limit the number of birds, mammals and other vertebrates that may be present within or adjacent to fumigation sites.

Qualitative arguments by the applicant also indicate that high concentrations of EDN are lethal to mammals and other vertebrates. DSEWPaC's data holdings include old data that indicates a lowest endpoint of a 1 hour LC50 of 31.5 mg/m3 (= 15 ppm) for inhalation toxicity to rats. However, as the extent of acute lethal incidence of the available endpoints is unclear, the reliability of this and the other reported endpoints is questionable.

DSEWPaC's data holdings also report and provide more detail on the acute lethal effects of EDN on rats which show an apparent time dependency on mortality as well as dose dependency. For exposures of a few minutes the LC50 in rats would be ~4,000 ppm, but this reduces to between 250-400 ppm for an hour and ~250 ppm for 2 hours. The endpoint for rats therefore appears to be more reliable than those for mice, rabbits or cats.

DSEWPaC's data holdings indicate that the open literature identify the aquatic toxicity of EDN being comparable in toxicity to HCN, with acute doses of 30  $\mu$ g/L of the latter being ultimately fatal to sensitive species and reproductive effects at 5  $\mu$ g/L. The European Union has classified EDN with the risk phrases R50 (very toxic to aquatic organisms) and R53 (may cause long-term adverse effects in the aquatic environment) based on the fact that EDN dissociates to HCN in water. The rainbow trout is said to be most sensitive with an endpoint of 28  $\mu$ g/L of HCN. Several aquatic endpoints for EDN were derived through modelling but DSEWPaC's data holdings indicate that the QSAR used is not appropriate for EDN.

## 5.3 Environmental Risk Assessment

Birds and mammals were grouped together for the assessment of risk as the exposure scenarios are expected to be similar, but as there was no available effects data on birds the most sensitive mammalian endpoints were used to provide an indicative risk to birds.

The primary route of exposure to EDN for birds and mammals is expected to be via inhalation of EDN that enters the atmosphere during the fumigation of timber, from leakage or penetration through the tarpaulin, or following venting through escape of residual EDN in the container, including desorption of EDN from the container material and timber.

A worst case scenario considered a bird or mammal standing at the location nearby to a container fumigation area where the concentration of EDN is the highest. The maximum detected concentrations of EDN at various distances from the fumigation area as measured in the commercial scale study were used as inputs for the risk assessment. Similarly the most reliable rat endpoint obtained where a dose and time dependency on mortality was indicated was used, with the  $LC_{50}$  values ranging from ~250 ppm for long term exposures of 2 hours to ~4,000 ppm for exposures of a few minutes. However, in the absence of other information, DSEWPaC also had to consider the less reliable but more conservative endpoint for mice, to provide an indication of potential risks for birds and very small mammals.

The risk assessment indicated an acceptable risk based on the endpoint for rats. However, the more conservative (indicative) mouse endpoints indicate limited (to <1 hour in duration) unacceptable risk levels at up to 25 m, consistent with long term (>18 hours) mitigable levels to which birds and mammals could be exposed if present within 100 m of the fumigation area after venting, or shorter term (~1 hour) if present at up to 210 m, the greatest distance measured. As this was an indicative risk assessment based on an assumed LC100 value, the real risk may be considerably underestimated, with the possibility that the real levels of unacceptable risk are extended both in duration and distance from the site of fumigation.

Where fumigations are undertaken in quarantine approved premises in industrial locations or at port locations, much of the risk identified above is expected to be mitigated. However, as the intended fumigation locations have not been made clear, and a potential risk to mammals, and, by extension birds, has been identified, DSEWPaC considers that restraints on the proposed fumigation are warranted. These are:

The fumigation site must not be bounded by areas inhabited by native mammals and birds, or where significant populations of birds are known to congregate. These include agricultural fields, natural bushland, forests, and urban parks.

Fumigations conducted at port locations must be undertaken only at locations where waterbird colonies are not known to exist.

Due to the limitations in data quality and realistically predicting water concentrations of EDN from air concentrations, the aquatic risk assessment was only qualitative in nature. Again this used the maximum atmospheric concentrations over the measured distances from the container from the commercial scale study. However, the choice of end point was difficult as the use of the QSAR data were deemed to be unsuitable, and given that HCN appears to be formed in water (albeit at <10%) a more reliable approach was to consider the one supported and lowest endpoint for HCN of 0.028 mg/L for rainbow trout.

The risk assessment showed that measured air concentrations of EDN are higher than the lowest aquatic toxicity endpoint for HCN, and that HCN concentrations formed at up to 10% from the EDN would also be higher. However, this would require that EDN partitions into bodies of water in the vicinity of the treatment zone, and also assumes that EDN partitioning into water will retain the same concentration as in air. There is no reliable way to verify this based on concentration alone, i.e. a mass balance would needed to estimate the concentration of EDN in a water body of a known size.

A more reliable and realistic assessment of the risk is based on exposure grounds, and for this, the lateral movement and partitioning behaviour of EDN needs to be considered. Based on the physical-chemical data air is the favoured compartment in open systems and partitioning to water is unlikely in the field. With respect

to lateral movement, EDN is likely to stay close to the ground under certain atmospheric conditions, with potential movement down slopes, and potentially over water bodies. However, dissipation through mechanical turbulence, such as wind, is expected to prevail over any negative buoyancy effects the further the distance from the site of fumigation.

In summary, the above suggests that the risk to aquatic species is limited on the basis of low potential for exposure, especially under windy conditions that are expected to provide the mechanical turbulence to disperse the fumigant. Therefore, DSEWPaC has recommended the following label restraint:

Atmospheric conditions should be monitored and ethanedinitrile should not be vented under very low wind speed conditions (less than 5 km/h) or under inversion conditions.

DSEWPaC recommends that the APVMA be satisfied that the proposed use of EDN in Sterigas 1000 Fumigant for timber fumigations would not be likely to have an unintended effect that is harmful to animals, plants or things or to the environment provided that the above label restraints are included on the product label.

# 6 EFFICACY AND SAFETY ASSESSMENT

Sterigas 1000 Fumigant contains the active ingredient ethanedinitrile at a concentration of 1000 g/kg, and is proposed to be applied as a fumigant, using approved equipment and procedures, for the control of a range of pathogens and insect pests of timber and logs.

Field and laboratory tests were undertaken in a range of substrates, including logs and soil, to demonstrate control a range of plant pathogens, insects and nematodes. Ethanedinitrile is water soluble and is claimed to penetrate wood faster than methyl bromide. It is also claimed that its toxicity to insects in enhanced at high relative humidity. As with most fumigants, the efficacy of ethanedinitrile is dependent on concentration, time and temperature; a longer fumigation at a lower concentration can result in the same level of mortality as a shorter fumigation with a higher concentration.

The data provided was considered in conjunction with the proposed label to determine whether the use of the product as proposed would control timber pests and pathogens effectively. The proposed label states that the product should be applied at 50 g.m<sup>-3</sup> and held for 6 hours or more, depending on the target pest, prior to airing off and should only be applied at temperatures above 15°C.

## Fungi

Laboratory studies were submitted which tested the impact of fumigation on various fungi including a number which are known to colonise timber. Seven different fungi (*Sclerotium rolfsi, Pythium sulcatum, Rhizoctonia solani, Fusarium acuminatum, Phytophthora cactorum, Phytophthora cryptogea,* and *Bipolaris soroikiniana*) were fumigated at various rates in the presence of wet soil (50% fill rate) at 25°C. The trials showed that all tested fungi could be controlled by exposure to 20 g.m<sup>-3</sup> for 6 hours (120 g.h.m<sup>-3</sup>) and that increasing the fumigation duration to 24 hours reduced the concentration required to control all of the tested fungi to 10 g.m<sup>-3</sup>. Although these fungi are noted as soil-borne fungi, the studies are considered to be relevant, the two Phytophthora species are known to produce soft-rot in timber and the general evidence of controlling all species tested appears to be strong.

Ethanedinitrile was also assessed in a field trial against three wood colonising fungal pathogens; *P. cactorum, S. rolfsi,* and *Rhizoctonia fragariae.* The product was applied directly to soils. Observations following the fumigations included that sclerotia (resistant mycelial masses formed by some fungi and capable of remaining dormant during adverse conditions, seen in wood cells colonised by such sclerotia-forming fungi like the Phytophthora genus) were killed.

These data were considered sufficient to demonstrate efficacy of the proposed product against fungi which may infest timber, on the proviso that a Concentration x Time (CT) product of 120 g.h.m<sup>-3</sup> is achieved in the timber following the proposed application of 50 g.m<sup>-3</sup>.

## Insects

Laboratory trials were undertaken on three species of important termites: *Coptotermes acinaciformis, C. brevis,* and *Mastotermes darwiniensis.* Worker termites were killed by fumigation rates of 1.61 g.m<sup>-3</sup> held for 6 hours at 21-25°C. A common grain pest, *Rhyzopertha dominica* (a member of the Family Bostrichidae

which includes a number of timber pests) was also tested and adults were controlled by fumigation rates of  $1.4 \text{ g.m}^{-3}$  for 6 hours.

European House Borer (*Hylotrupes bajulus*) is an exotic pest in Western Australia. A trial which included both laboratory studies of naked larvae (i.e. larvae removed from timber) and infested timber demonstrated that a concentration x time (CT) product of 15 g.h.m<sup>-3</sup> would control naked borer larvae at 25°C. A single trial of infested timber with (fill rate of 30%) showed that an application of 40 g.m<sup>-3</sup> held for 24 hours (achieving a CT product of approximately 180 g.h.m<sup>-3</sup>) controlled all larvae in the infested timber.

Data from laboratory trials on larvae of the Asian Longhorn beetle undertaken in China were submitted in support of the claim for general insect control. The Asian Long Horn beetle is a significant pest of green and processed timber in China, Japan and Korea and an exotic pest in the USA. It has the potential to devastate Australian hardwood forests, apple and pear plantations and parkland trees.Data presented showed that naked larvae were killed (LC99.5) by exposure to ethanedinitrile at a concentration of 21 g.m<sup>-3</sup> held for 6 hours at approximately 15°C (i.e. 126 g.h.m<sup>-3</sup>) and 10 g.m-3 held for 6 hours at 21°C (i.e. 60 g.h.m<sup>-3</sup>). These trials indicate that if such concentrations can be achieved and maintained for the same length of time within the timber, then the product should be effective at controlling this hidden (in timber) stage of the Asian Longhorn beetle in poplar logs treated at 60-64 g.m<sup>-3</sup> and held for 24 hours. This trial included temperatures as low as 4.4°C.

## Penetration and Sorption

Ethane dinitrile was applied to two 100 x 100 x 300mm blocks of Oregon, at a rate of 48gm<sup>-3</sup> in a 30 L stainless steel chamber (fill rate 20%). The penetration and sorption of ethanedinitrile were measured at intervals during the fumigation both with and across the grain of the timber. Within 1 hour of application, the concentration in the centre of the timber block was approximately 50% of that in the chamber. And after 6 hours the concentration in the centre of the block was equivalent to that in the chamber. This demonstrated that ethanedinitrile readily penetrates into timber and given a scenario of 20% fill rate, the concentration up to 10 cm depth in timber would reflect that of the chamber within 6 hours. The falling concentration noted in the fumigation chamber was assumed to be due to sorption or reaction between the fumigant and the timber (i.e. removing it from the gaseous form). The sorption accounted for a loss of 61% of the applied gas over the 6 hour period with the equilibrium concentration being 39% of that applied (i.e. 18.7 g.m<sup>-3</sup>). The CT product achieved within the timber in this scenario was in excess of 112 g.h.m<sup>-3</sup> (based on the final concentration by time). Based on concentrations measured within the timber, the CT product was calculated to be greater than 500 g.h.m<sup>-3</sup> at 24 hours. Similar rates of sorption were observed in field trials during the fumigation of logs.

Extrapolating from this data, an application at the proposed 50 g.m<sup>-3</sup> at a fill rate of 20% will result in a CT product of approximately 120 g.h.m<sup>-3</sup> over 6 hours, 160 g.h.m<sup>-3</sup> over 8 hours and 195 g.h.m<sup>-3</sup> over 10 hours.

## Conclusions

Based on the limited data assessed, the active ingredient ethanedinitrile in Sterigas 1000 is expected to diffuse into wood and control wood infesting insects, including termites, and wood-colonising fungi.

The submitted data, suggest that ethanedinitrile is an effective fumigant under certain conditions. Its insecticidal and fungicidal properties were influenced by temperature, length of time the material is exposed (i.e. residence times within the substrates fumigated). For example at higher temperatures a shorter exposure time and/or lower concentration could achieve the same level of control. Data indicated that the concentration and time required to achieve control was less reliable at temperatures below 15°C and the proposed label appropriately states that the timber commodity temperature should be above 15°C for fumigation to be effective.

The data were considered to be sufficient to support that fungi infesting timber could be controlled by fumigation in a chamber with approximately 20% fill rate, when applied at 50 g.m<sup>-3</sup> and held for 6 hours. For control of internal stages of insect larvae, the fumigation time would need to be lengthened to a minimum 10 hour fumigation at the same application and fill rates.

# 7 LABELLING REQUIREMENTS

# **DANGEROUS POISON**

KEEP OUT OF REACH OF CHILDREN READ SAFETY DIRECTIONS BEFORE OPENING OR USING

# STERIGAS 1000 FUMIGANT

ACTIVE CONSTITUENT: 1000 g/kg ETHANEDINITRILE

For the control of certain insect pests and fungi infesting timber and logs as per the Directions for Use Table

**NET CONTENTS: 30 Kg** 

**BOC** 

**BOC Limited** ABN 95 000 029 729 10 Julius Avenue, North Ryde NSW 2113 Australia Phone: 61 2 8874 4400

Emergency Telephone: 1800 653 572

# DIRECTIONS FOR USE RESTRAINTS

DO NOT use without use of a liquid scrubbing system DO NOT exceed the maximum application rate specified on the label DO NOT fumigate at temperatures below 15°C

SITUATION	PEST	APPLICATION RATE	CRITICAL COMMENTS
Timber and logs in the following situations:	Timber infecting Fungi	50 g/m <sup>3</sup> for 6 hours exposure	Fumigate using good fumigation practice in accordance with the Australian Fumigation Standard AS 2476 and State regulations.
<ol> <li>In sealed fumigation chambers</li> <li>In shipping containers sealed under gas proof tarpaulins</li> <li>As stacks sealed under gas proof tarpaulins</li> </ol>	Insect pests of timber	50 g/m <sup>3</sup> for 10 hours exposure	Fill rate should not exceed 20%. Commodity temperature should be greater than 15°C Residual gas must be scrubbed for a minimum of 4 hours using a liquid scrubbing system at the completion of the fumigation period, followed by a further 24 hours of ventilation prior to clearance.

# NOT TO BE USED FOR ANY PURPOSE OR IN ANY MANNER CONTRARY TO THIS LABEL UNLESS AUTHORISED UNDER APPROPRIATE LEGISLATION

#### GENERAL INSTRUCTIONS

STERIGAS 1000 is a rapid acting, flammable fumigant for fumigation of timber and logs to control pests and pathogens of timber. STERIGAS 1000 penetrates deep into the timber or logs being fumigated. Fumigation for the recommended exposure period is essential to ensure control of target pests and pathogens.

#### Application

Prior to use, ensure that an appropriate liquid scrubbing system is installed (for use post fumigation). Use BOC approved equipment to deliver Sterigas 1000 into the fumigation enclosure. Keep the treated area sealed for a minimum of 6 hours followed by a minimum of 4 hours of liquid scrubbing of EDN and for another 24 hours ventilation. Re-entry to the buffer zone should be restricted for a minimum of 34 hours based on a 6 hour fumigation period (see Re-entry Period below).

#### **Engineering controls**

All fumigation workers must carry portable monitoring devises, calibrated to detect EDN levels in air at or below 1 ppm (with upper level of detection above 50 ppm). A buffer zone (risk area) of 50 metres from the fumigation area is required to protect bystanders and unprotected personnel during fumigation.

All entrances to the fumigation area must be clearly palcarded in accordance with local OHS requirements and regulations with the warning:

#### "DANGER, area under fumigation, DO NOT enter unless wearing appropriate personal protective equipment"

This placard should also carry a skull and crossbones pictogram with date and time of the fumigation commencement, date and time the restrictions expire, fumigant product name and contact details (telephone number) for the fumigator. If the area cannot be physically secured, a watchman must be stationed to prevent people entering the risk area.

#### PRECAUTIONS

#### **Re-entry Period**

DO NOT enter the buffer zone during fumigation and for up to 34 hours after completion of ventilation of timber stack or where EDN levels above 1 ppm, unless wearing chemical resistant clothing fastened to the neck, chemical resistant gloves and full face respirator. If EDN levels are above 50 ppm use a supplied air respirator.

#### Rehandling

DO NOT handle fumigated timber for 24 hours after commencement of ventilation, unless wearing chemical resistant clothing fastened to the neck, chemical resistant gloves and, if levels of EDN in air are at or above 1 ppm, wear a full or half-facepiece respirator.

#### WARNING

May cause fire or explosions. Keep away from heat, sparks and naked flames.

#### PROTECTION OF WILDLIFE, FISH, CRUSTACEANS AND ENVIRONMENT

The fumigation site must not be bounded by areas inhabited by native animals and birds or where significant populations of birds are known to congregate. These include agricultural fields, natural bushlands, forests and urban parks.

Fumigations conducted at port locations must be undertaken only at locations where waterbird colonies are not known to exist. Atmospheric conditions should be monitored and EDN should not be vented under very low wind speed conditions (less than 5 km/h) or under inversion conditions.

DO NOT contaminate streams, rivers or waterways with the chemical or used containers.

#### STORAGE and DISPOSAL

Store cylinders upright in a secure, locked, well-ventilated, cool room or place, away from children, animals, food, feedstuffs, seed and fertilisers and out of direct sunlight. Do not heat cylinder.

Cylinders remain the property of BOC Limited. Empty contents fully into application equipment. When empty, close all valves and return to the point of supply for refill or storage.

#### SAFETY DIRECTIONS

Very dangerous. Can kill if inhaled. Poisonous if absorbed by skin contact and if swallowed. Will irritate the eyes, nose, throat and skin. Avoid contact with eyes and skin. Do not inhale.

When using the product and preparing the product for use and when uncovering the treated area/material, wear protective clothing (chemically resistant) fastened to the neck, elbow length chemical resistant gloves, impervious footwear (non-sparking) and full face piece respirator with canister specified for EDN (or where levels above 50 ppm) a supplied air respirator. Detailed instructions for safe use appear in State/Territory regulations.

Thoroughly ventilate treated areas before reoccupying. After each day's use wash gloves, respirator and contaminated clothes

#### **FIRST AID**

For advice, contact a Poisons Information Centre (Phone 13 11 26) or doctor at once. If inhaled, remove from contaminated area. Apply artificial respiration if not breathing. To protect rescuer, use air-viva, oxy-viva or one-way mask. Resuscitate in a well-ventilated area.

#### MATERIAL SAFETY DATA SHEET

Additional safety information is given in the STERIGAS 1000 MSDS available from BOC Limited.

Batch No.: Date of Manufacture: APVMA Approval Number: XXXX/XXXX

# **ABBREVIATIONS**

ACCS	Advisory Committee on Chemicals Scheduling
ACH	Acetone cyanohydrin
ADI	Acceptable Daily Intake (for humans)
ARfD	Acute reference dose
bw	bodyweight
°C	Degrees Celsius
cm	centimetre
CNS	Central Nervous System
CT product	Concentration multiplied by Time
d	day
DNA	Deoxyribonucleic acid
DSEWPaC	Department of Sustainability, Environment, Water, Populations and Communities
EDN	Ethanedinitrile
FSANZ	Food Standards Australia New Zealand
g	gram
h	hour
HCN	Hydrogen Cyanide
HDL	Highest Detection Level
HSIS	Hazardous Substances Information System
IUPAC	International Union of Pure and Applied Chemistry
JEFCA	Joint FAO/WHO Expert Committee on Food Additives
kg	kilogram
K <sub>oc</sub>	Organic carbon partitioning coefficient
K <sub>ow</sub>	Octanol-Water partition coefficient
kPa	kiloPascal
L	Litre
LC <sub>50</sub>	concentration that kills 50% of the test population of organisms

LC <sub>100</sub>	concentration that kills 100% of the test population of organisms
LD <sub>50</sub>	dosage of chemical that kills 50% of the test population of organisms
LDL	Lowest Detection Level
LOD	Limit of Detection – level at which residues can be detected
LOQ	Limit of Quantitation – level at which residues can be quantified
m	metre
mg	milligram
min	minutes
mL	millilitre
mmol	Millimole [One thousandth (10 <sup>-3</sup> ) of a mole]
MSDS	Material Safety Data Sheet
ng	nanogram
NOAEL	No Observable Adverse Effect Concentration Level
NOEC/NOEL	No Observable Effect Concentration/ Level
OCS	Office of Chemical Safety [Department of Health and Ageing]
OECD	Organisation for Economic Co-operation and Development
OHS	Occupational Health and Safety
PMTDI	Provisional Maximum Tolerable Daily Intake
ppb	parts per billion
PPE	Personal Protective Equipment
ppm	parts per million
QSAR	Quantitative structure-activity relationship
SCBA	Self-Contained Breathing apparatus
SUSDP	Standard for the Uniform Scheduling of Drugs and Poisons
t	tonne
hð	microgram
у	year

# GLOSSARY

Active constituent	The substance that is primarily responsible for the effect produced by a chemical product
Acute	Having rapid onset and of short duration.
Carcinogenicity	The ability to cause cancer
Chronic	Of long duration
Codex MRL	Internationally published standard maximum residue limit
Desorption	Removal of a material from or through a surface
Efficacy	Production of the desired effect
Formulation	A combination of both active and inactive constituents to form the end use product
Genotoxicity	The ability to damage genetic material
Hydrophobic	repels water
Leaching	Removal of a compound by use of a solvent
Log Pow	Log to base 10 of octanol water partitioning co-efficient, synonym KOW
Metabolism	The chemical processes that maintain living organisms
Photodegradation	Breakdown of chemicals due to the action of light
Photolysis	Breakdown of chemicals due to the action of light
Subcutaneous	Under the skin
Toxicokinetics	The study of the movement of toxins through the body
Toxicology	The study of the nature and effects of poisons

# REFERENCES

Australian Pesticides and Veterinary Medicines Authority 2008, *Ag MORAG: Manual of Requirements and Guidelines*, APVMA, Canberra.