

Rotterdam Convention - Operation of the Prior Informed Consent (PIC) procedure for banned or severely restricted chemicals

Decision Guidance Document

Asbestos

(All forms of asbestos as listed below)

crocidolite

amosite

actinolite

anthophyllite

tremolite

This document incorporates information contained in the previous Decision Guidance Document for *Crocidolite*



**Secretariat for the Rotterdam Convention on the
Prior Informed Consent Procedure for
Certain Hazardous Chemicals and Pesticides in
International Trade**

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Introduction

The objective of the Rotterdam Convention is to promote shared responsibility and cooperative efforts among Parties in the international trade of certain hazardous chemicals in order to protect human health and the environment from potential harm and to contribute to their environmentally sound use, by facilitating information exchange about their characteristics by providing for a national decision-making process on their import and export and by disseminating these decisions to Parties. The interim secretariat of the Convention is provided jointly by the United Nations Environment Programme (UNEP) and the Food and Agriculture Organization of the United Nations (FAO).

Candidate chemicals¹ for the Rotterdam Convention include those that have been banned or severely restricted by national regulatory actions in two or more Parties² in two different regions. Inclusion of a chemical in the Convention is based on regulatory actions taken by Parties that have addressed the risks associated with the chemical by banning or severely restricting it. Other ways might be available to control/reduce such risks. However, inclusion does not imply that all Parties to the Convention have banned or severely restricted this chemical. For each chemical included in the Rotterdam Convention, Parties are requested to make an informed decision whether they consent or not to the future import of the chemical.

At its tenth session, held in Geneva on 17 to 21 November 2003 the Intergovernmental Negotiating Committee adopted the decision guidance document for crocidolite, actinolite, amosite, anthophyllite and tremolite asbestos with the effect that these chemicals became subject to the interim PIC procedure.

At its first meeting, held in Geneva 20 to 24 September 2004, the Conference of the Parties agreed to include actinolite, amosite, anthophyllit and tremolite asbestos in Annex III of the Rotterdam Convention, with the effect that these chemicals became subject to the PIC procedure.

The present decision guidance document was communicated to the Designated National Authorities on 1 February 2005 in accordance with Article 7 and 10 of the Rotterdam Convention.

Purpose of the Decision Guidance Document

For each chemical included in Annex III of the Rotterdam Convention, a decision guidance document has been approved by the Conference of the Parties. Decision guidance documents are sent to all Parties with a request that they provide a decision regarding future import of the chemical.

The decision guidance document is prepared by the Chemical Review Committee (CRC). The CRC is a group of government designated experts established in line with Article 18 of the Convention, that evaluates candidate chemicals for possible inclusion in the Convention. The decision guidance document reflects the information provided by two or more Parties in support of the national regulatory actions to ban or severely restrict the chemical. It is not intended as the only source of information on a chemical nor is it updated or revised following its adoption by the Conference of the Parties.

There may be additional Parties that have taken regulatory actions to ban or severely restrict the chemical as well as others that have not banned or severely restricted it. Such risk evaluations or information on alternative risk mitigation measures submitted by Parties may be found on the Rotterdam Convention web-site (www.pic.int).

¹ “‘Chemical’ means a substance whether by itself or in a mixture or preparation and whether manufactured or obtained from nature, but does not include any living organism. It consists of the following categories: pesticide (including severely hazardous pesticide formulations) and industrial.”

² “‘Party’ means a State or regional economic integration organisation that has consented to be bound by this Convention and for which the Convention is in force.”

Under Article 14 of the Convention, Parties can exchange scientific, technical, economic and legal information concerning the chemicals under the scope of the Convention including toxicological, ecotoxicological and safety information. This information may be provided directly to other Parties or through the Secretariat. Information provided to the Secretariat will be posted on the Rotterdam Convention website.

Information on the chemical may also be available from other sources.

Disclaimer

The use of trade names in this document is primarily intended to facilitate the correct identification of the chemical. It is not intended to imply any approval or disapproval of any particular company. As it is not possible to include all trade names presently in use, only a number of commonly used and published trade names have been included in this document.

While the information provided is believed to be accurate according to data available at the time of preparation of this Decision Guidance Document, the Food and Agriculture Organization of the United Nations (FAO) and the United Nations Environment Programme (UNEP) disclaim any responsibility for omissions or any consequences that may flow there from. Neither FAO nor UNEP shall be liable for any injury, loss, damage or prejudice of any kind that may be suffered as a result of importing or prohibiting the import of this chemical.

The designations employed and the presentation of material in this publication do not imply the expression of any opinion whatsoever on the part of FAO or UNEP concerning the legal status of any country, territory, city or area or of its authorities or concerning the delimitation of its frontiers or boundaries

Background

This decision guidance document includes five amphibole forms of asbestos amosite, anthophyllite, actinolite, crocidolite and tremolite.

Crocidolite asbestos was included in Annex III with the adoption of the text of the Rotterdam Convention in September 1998 by the Conference of Plenipotentiaries. A decision guidance document (dated 1992) has been circulated to all participating countries. Crocidolite was included here in the interest of completeness. This decision guidance document replaces the one for crocidolite circulated previously.

The five forms of asbestos included in this decision guidance document are divided between two chapters. First in the light of the fact that it was already included in Annex III crocidolite forms the first chapter. The four remaining amphibole forms of asbestos (actinolite, amosite, anthophyllite and tremolite) are grouped into a second chapter. While there is some redundancy among the chapters the information has been presented in this way to try to improve the usability of the document.

Separate import decisions must be submitted for each of the five individual forms of asbestos. Where import responses have been provided for crocidolite, they need not be resubmitted.

ABBREVIATIONS WHICH MAY BE USED IN THIS DOCUMENT

(N.B. Chemical elements and pesticides are not included in this list)

| | |
|------------------|--|
| < | less than |
| ≤ | less than or equal to |
| << | much less than |
| > | greater than |
| ≥ | greater than or equal to |
| µg | Microgram |
| µm | Micrometre |
| a.i. | active ingredient |
| ACGIH | American Conference of Governmental Industrial Hygienists |
| ADI | acceptable daily intake |
| ADP | adenosine diphosphate |
| ATP | adenosine triphosphate |
| b.p. | boiling point |
| bw | body weight |
| °C | degree Celsius (centigrade) |
| CA | Chemicals Association |
| CAF | Compressed asbestos fibre |
| cc | Cubic centimetre |
| CCPR | Codex Committee on Pesticide Residues |
| CHO | Chinese hamster ovary |
| cm | centimetre |
| CSTEE | E.C. Scientific Committee on Toxicity, Ecotoxicity and the Environment |
| D | Dust |
| DNA | Deoxyribose Nucleic Acid |
| E.C. | European Community |
| EC ₅₀ | Effect concentration, 50% |
| ED ₅₀ | Effect dose, 50% |
| EEC | European Economic Community |
| EHC | Environmental Health Criteria |
| ERL | Extraneous residue limit |
| FAO | Food and Agriculture Organization of the United Nations |
| g | Gram |
| GL | Guideline level |
| GR | Granules |
| h | Hour |
| ha | Hectare |
| i.m. | Intramuscular |
| i.p. | Intraperitoneal |
| IARC | International Agency for Research on Cancer |
| IC ₅₀ | Inhibition concentration, 50%; |
| ILO | International Labour Organisation |
| IPCS | International Programme on Chemical Safety |
| IRPTC | International Register of Potentially Toxic Chemicals |
| IUPAC | International Union of Pure and Applied Chemistry |
| JMPR | Joint FAO/WHO Meeting on Pesticide Residues (Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and a WHO Expert Group on Pesticide Residues) |
| k | Kilo- (x 1000) |
| kg | Kilogram |
| Koc | Organic carbon-water partition coefficient |
| l | Litre |
| LC ₅₀ | Lethal concentration, 50% |
| LD ₅₀ | Lethal dose, 50% |
| LOAEL | Lowest observed adverse effect level |
| LD _{LO} | Lowest lethal dose |

ABBREVIATIONS WHICH MAY BE USED IN THIS DOCUMENT

(N.B. Chemical elements and pesticides are not included in this list)

| | |
|-------|---|
| LOEL | lowest observed effect level |
| m | Metre |
| m.p. | melting point |
| mg | Milligram |
| ml | Millilitre |
| mPa | MilliPascal |
| MRL | maximum residue limit |
| MTD | maximum tolerated dose |
| NCI | National Cancer Institute (United States) |
| ng | Nanogram |
| NIOSH | National Institute of Occupational Safety and Health (United States) |
| NOAEL | no-observed-adverse-effect level |
| NOEL | no-observed-effect level |
| NOHSC | National Occupational Health and Safety Commission (Australia) |
| NTP | National Toxicology Program |
| OECD | Organisation for Economic Co-operation and Development |
| OP | organophosphorus pesticide |
| PCM | Phase contrast microscopy |
| PHI | pre-harvest interval |
| PIC | Prior Informed Consent |
| Pow | octanol-water partition coefficient |
| POP | persistent organic pollutant |
| ppm | parts per million (used only with reference to the concentration of a pesticide in an experimental diet. In all other contexts the terms mg/kg or mg/l are used). |
| RfD | reference dose for chronic oral exposure (comparable to ADI) |
| SBC | secretariat for the Basel Convention |
| SC | Soluble concentrate |
| SG | water soluble granules |
| SL | soluble concentrate |
| SMR | standardized mortality ratio |
| STEL | short term exposure limit |
| TADI | temporary acceptable daily intake |
| TLV | threshold limit value |
| TMDI | theoretical maximum daily intake |
| TMRL | temporary maximum residue limit |
| TWA | time weighted average |
| UNEP | United Nations Environment Programme |
| USEPA | United States Environmental Protection Agency |
| UV | Ultraviolet |
| VOC | volatile organic compound |
| WHO | World Health Organization |
| WP | wettable powder |
| wt | Weight |

Crocidolite
(amphibole form of asbestos)

ASBESTOS: AMPHIBOLE – CROCIDOLITE

1. Identification and uses (see Annex 1) - Crocidolite

| | |
|---|--|
| Common name | Crocidolite |
| Chemical name | Crocidolite, asbestos, Blue asbestos |
| Other names/ synonyms | |
| CAS-No.(s) | Crocidolite CAS number 12001–28–4 |
| Other CAS numbers that may be used | General CAS number for asbestos: 1332–21–4 |
| Harmonized System Customs Code | 2524.00 (asbestos) |
| Other numbers: | European Community Customs number: CUS-No: 23648 (crocidolite) |
| Category | Industrial |
| Regulated Category | Industrial |
| Use(s) in regulated category | Asbestos cement, insulation material, protective textile products, beverage filters. |
| Trade names | Amorphous crocidolite asbestos, asbestos, blue asbestos, fibrous crocidolite asbestos, krokydolith, NCI C09007, riebeckite asbestos. |
| Formulation types | Natural mineral fibre |
| Uses in other categories | No reported uses as a pesticide chemical. |
| Basic manufacturers | Naturally occurring, mined |

2. Reasons for inclusion in the PIC procedure – Crocidolite

Crocidolite is included in the PIC procedure as an industrial chemical. It is listed on the basis of the final regulatory actions to ban all uses of crocidolite notified by the European Community, Chile, Australia and Sri Lanka.

2.1. Final regulatory action: (see Annex 2 for details)

Australia

Severe restriction on use of all forms of amphibole asbestos (crocidolite, amosite, anthophyllite, actinolite and tremolite) is implemented through State and Territory legislation.

Reason: Human Health

Chile

Asbestos is severely restricted:

Production, importation, distribution, sale and use of crocidolite and any material or product containing it is prohibited.

Reason: Human Health

European Community

Banned - The placing on the market and use of all forms of asbestos (crocidolite, amosite, anthophyllite, actinolite, tremolite and chrysotile), and products containing these fibres added intentionally, is prohibited, with one limited exception in the case of chrysotile.

Reason: Human Health

Previous notifications

Crocidolite is included in Annex III on the basis of notifications from Sri Lanka, European Community countries and Sweden (not a member of the E.C. at that time).

Reason: Human Health

2.2 Risk evaluation

Australia

Decisions (by States and Territories of Australia) to take final regulatory action were taken on the basis of established risk/hazard to human health. Risk evaluations were undertaken to the standards then current.

Chile

A hazard evaluation was carried out based on a compilation of bibliographic sources and verification of adverse chronic effects in exposed workers in the asbestos cement industry. It was concluded that those at greatest risk are workers who handle asbestos fibres for various uses. In Chile, this means in particular those workers who have been exposed to fibres from the manufacture of construction materials.

European Community

An independent risk assessment was undertaken. This confirmed that all forms of asbestos can cause lung cancer, mesothelioma, and asbestosis; that no threshold level of exposure could be identified below which asbestos does not pose carcinogenic risks.

3. Protective measures that have been applied concerning the chemical – Crocidolite

3.1 Regulatory measures to reduce exposure

| | |
|---------------------------|--|
| Australia | Protective measures were taken by prohibiting all uses of all amphibole forms of asbestos except sampling and analysis, maintenance, removal, disposal, encapsulation or enclosure, and uses associated with reducing the risk of human exposure to it. |
| Chile | Protective measures were taken by prohibiting all uses of crocidolite for use as an input to the manufacture of construction materials. All types of asbestos prohibited for use for any item, component or product that does not constitute a construction material unless excepted. |
| European Community | Protective measures were taken by prohibiting the placing on the market and use of crocidolite, amosite, anthophyllite, actinolite, tremolite and chrysotile and of products containing these fibres added intentionally, with one specific exception for chrysotile in respect of diaphragms for existing electrolysis installations (see Annex 2 for further details). |

3.2 Other measures to reduce exposure

Australia

Guidance provided in documents available from NOHSC website at <http://www.nohsc.gov.au/OHSLegalObligations/NationalStandards/asbest.htm> are:

Code of Practice for the Safe Removal of Asbestos [NOHSC: 2002 (1988)]

Guidance Note on the Membrane Filter Method for Estimating Airborne Asbestos Dust [NOHSC: 3003(1988)]

Guide to the Control of Asbestos Hazards in Buildings and Structures [NOHSC: 3002 (1998)]

European Community

Directive on the demolition of buildings, structures and installations containing asbestos and the removal of asbestos or materials containing asbestos therefrom (Council Directive 87/217/EEC (OJ L 85, 28.3.1987, p.40), as amended by Council Directive 91/692/EEC (OJ L 377, 31.12.1991, p.48))

Directive on disposal of construction materials (Council Directive 91/689/EEC (OJ L 377, 31.12.1991, p.20))

General

Dust control by wetting material, use of respirators, use of full protective clothing with attention when further treating any contaminated clothing.

Further guidance is provided in the ILO Convention No. 162 “Safety in the Use of Asbestos”

(<http://www.ilo.org/ilolex/cgi-lex/convde.pl?C162>) which applies to all activities involving exposure of workers to asbestos in the course of work.

The ILO recommendation 172 (<http://www.ilo.org/ilolex/cgi-lex/convde.pl?R172>), contains recommendations on safety in the use of asbestos, including details on protective and preventative measures, surveillance of the working environment and workers’ health, information and education measures.

More specific information on measures to reduce exposures on construction sites is provided in the International Standard Organisation (ISO) 7337 “Asbestos-reinforced cement products – Guidelines for on-site work practices.”

3.3 Alternatives

It is essential that before a country considers substituting alternatives, it ensures that the use is relevant to its national needs, and the anticipated local conditions of use. The hazards of the substitute materials and the controls needed for safe use should also be evaluated.

Chile

It has been proved that it is feasible to replace asbestos with other fibres in manufacturing fibro-cement materials and still obtain products of similar quality. In fact, the company producing the greatest quantity of panels and sheeting for dwellings in Chile has replaced asbestos with other fibres such as cellulose. In the case of brake parts, asbestos-containing and asbestos-free brake pads and linings are in use, until the existing in use asbestos-containing brake pads and linings at the time of publication of the prohibition should be replaced.

European Community

Identified alternatives include cellulose fibres, polyvinyl alcohol (PVA) fibres and P-aramid fibres.

General

Guidance on substituting alternatives to asbestos fibres is provided in IPCS Environmental Health Criteria 151 “Selected Synthetic Organic Fibres” (www.inchem.org).

3.4 Socio-economic effects

Australia

A regulatory impact statement for 1991 regulations in Victoria, a State of Australia, concluded that a process of substituting alternative materials had eliminated the use of asbestos in the majority of its former applications.

Chile

No assessment of socio-economic effects was undertaken.

4. Hazards and risks to human health and/or the environment – Crocidolite

4.1 Hazard Classification

| | |
|---------------------------|--|
| IARC | Carcinogenic to humans (<i>Group 1</i>) IARC (1987) |
| European Community | Carc. Cat. 1 R45 May cause cancer T:R48/23 Toxic: danger of serious damage to health by prolonged exposure through inhalation (E.C., 2001) |
| NTP | Crocidolite is classified as “Known Human Carcinogen” (US, 2001) |

4.2 Exposure limits

No internationally agreed exposure limits available.

4.3 Packaging and labelling

The United Nations Committee of Experts on the Transportation of Dangerous Goods classifies the chemical in:

| | |
|---|--|
| Hazard Class and Packing Group: | UN number: 2212 Class 9 - Miscellaneous dangerous goods and articles Proper shipping name: BLUE ASBESTOS Packaging Group: II Hazchem Code: 2X Special Provision number: 168 Packaging requirements: 3.8.9 General: Mineral fibres of varying length. Non-combustible. Inhalation of the dust of asbestos fibres is dangerous and therefore exposure to the dust should be avoided at all times. Always prevent the generation of asbestos dust. Crocidolite (blue asbestos) should be regarded as the most hazardous type of asbestos. A safe level of airborne concentration of asbestos fibres may be obtained through effective packaging or unitizing. Compartments and vehicles or containers that have contained asbestos should be carefully cleaned before receiving other cargo. Hosing down or vacuum cleaning as appropriate, instead of sweeping, will prevent the atmosphere from becoming dust laden. |
| International Maritime Dangerous Goods (IMDG) Code | UN No: 2212: Class or division: 9 |
| Transport Emergency Card | TEC (R) – 912 |

4.4 First aid

NOTE: The following advice was correct at the time of publication. This advice is provided for information only and is not intended to supersede any national first aid protocols.

Not acutely toxic. In case of exposure, prevent dispersion of dust. Avoid all contact. Avoid exposure of adolescents and children. There is no antidote. Seek medical advice.

4.5 Waste management

Asbestos may be recovered from waste slurries. Otherwise friable waste should be wetted and containerised (sealed, double bagging) to avoid dust formation during transport and disposal. Landfilling is recommended in a supervised landfill and waste should initially be covered with at least 15 cm of soil. For final closure of an area containing asbestos, a cover of at least 1 m of compacted soil should be applied.

Annexes

| | |
|---------|---|
| Annex 1 | Further information on the substance |
| Annex 2 | Details on Final regulatory action |
| Annex 3 | Address of designated national authorities |
| Annex 4 | References |

Introduction to Annex I

The information presented in this Annex reflects the conclusions of the notifying parties: Australia, Chile and the European Community. In a general way, information provided by these parties on these hazards are synthesised and presented together, while the risk assessments, specific to the conditions prevailing in these countries, are presented separately. This information is contained in the documents referenced in the notifications in support of their final regulatory actions banning asbestos, including international reviews. The notification from Australia was first reported in the PIC Circular XI of June 2000, the notification from Chile was first reported in the PIC Circular XV of June 2002 and the notification from the European Community in PIC Circular XIII of June 2001.

Crocidolite was included as one of the subjects of an IPCS Environmental Health Criteria document (Asbestos and other Natural Mineral Fibres, EHC 53) published in 1986.

Annex 1 – Further information on Crocidolite

1. Physico-Chemical properties

| | | |
|-----|--|---|
| 1.1 | Identity | Crocidolite |
| 1.2 | Formula | $\text{Na}_2\text{FeII}_3\text{FeIII}_2(\text{Si}_8\text{O}_{22})(\text{OH})_2$ |
| 1.3 | Colour and Texture | Blue, Flexible to brittle and tough |
| 1.4 | Decomposition temperature | 400–600°C |
| 1.6 | Density (g/cm³) | 3.3–3.4 |
| 1.7 | Resistance to acids | Good |
| 1.8 | Resistance to alkalis | Good |
| 1.9 | Tensile strength (10³ kg/cm²) | 35 |

2. Toxicological properties

| | | |
|-----|---------------------------------|--|
| 2.1 | General | <p>Crocidolite is an amphibole form of asbestos (as are amosite, actinolite, anthophyllite and tremolite).</p> <p>There is general consensus amongst the scientific community that all types of asbestos fibres are carcinogenic (IPCS, 1986, 1998; Royal Society of Canada, 1996 cited by E.C., 1997) and can cause asbestosis, lung cancer and mesothelioma when inhaled.</p> |
| 2.2 | Deposition and Clearance | <p>Depending largely on size and shape, deposition of inhaled asbestos fibres may occur in lung tissue. Some fibres may be removed by mucociliary clearance or macrophages while others may be retained in the lungs for extended periods. Inhalation exposure is, therefore, generally regarded as cumulative, and exposures have been expressed in terms of concentration of fibres over time or phase contrast microscopy (PCM) fibre-years/ml.</p> |
| 2.3 | Mode of Action | <p>The ability of fibres to induce fibrogenic and carcinogenic effects seems to be dependent on their individual characteristics, including fibre dimension and durability (i.e. biopersistence in target tissues), which are determined in part by the physico-chemical properties (IPCS, 1998).</p> <p>It is well documented from experimental studies that fibres shorter than 5µm are less biologically active than fibres longer than 5µm. However, it is still uncertain whether short fibres have any significant biological activity. Furthermore it is still uncertain as to how long a fibre needs to remain in the lung in order to induce preneoplastic effects (IPCS, 1998).</p> <p>The mechanisms by which these fibres cause fibrogenic and carcinogenic effects are not completely understood. Possible mechanisms of fibrogenic effects of fibres include chronic inflammation processes mediated by production of growth factors (e.g., TNF-alpha) and reactive oxygen species. With regard to fibre-induced carcinogenicity, several hypotheses have been proposed. These include: DNA damage by reactive oxygen species induced by fibres; direct DNA damage by physical interactions between fibres and target cells; enhancement of cell proliferation by fibres; fibre-provoked chronic inflammatory reactions leading to prolonged release of lysozymal enzymes, reactive oxygen species, cytokines and growth factors; and action by fibres as co-carcinogens or carriers of chemical carcinogens to the target tissues (IPCS, 1998).</p> |
| 2.4 | Effects on animals | <p>Lowest published lethal dose for rat: 300 mg/kg bw.</p> <p>Results from animal studies reflect the known human health effects of asbestos. IARC (1977) reports that there was sufficient evidence for carcinogenicity to animals. All types of commercial asbestos fibre that have been tested are carcinogenic to mice, rats, hamsters and rabbits, producing mesotheliomas and lung carcinomas after inhalation exposure and after administration intrapleurally, intratracheally, or intraperitoneally (IPCS, 1986).</p> <p>Crocidolite produced mesothelioma and lung carcinomas in rats after inhalation and mesothelioma following intrapleural administration. Crocidolite induced</p> |

mesothelioma in hamsters following intrapleural administration. Intraperitoneal administration of crocidolite induced peritoneal tumours, including mesothelioma, in mice and rats. Given by the same route, crocidolite produced abdominal tumours in hamsters.

There is no convincing evidence that ingested asbestos is carcinogenic in animals (IPCS, 1986).

2.5 Effects on humans

Inhalation of asbestos dust including crocidolite can cause fibrosis of the lung (asbestosis), changes in one or both surfaces of the pleura, bronchial carcinoma (lung cancer), mesothelioma of the pleura and peritoneum, and possibly cancers of other sites (IPCS, 1986).

2.5.1 Asbestosis

Asbestosis was the first asbestos-related lung disease to be recognised. It is defined as diffuse interstitial fibrosis of the lungs resulting from exposure to asbestos dust. Scarring of the lungs reduces their elasticity and function resulting in breathlessness. It can appear and progress many years after the termination of exposure.

Under recent exposure conditions, asbestosis will rarely be detectable, even in its early stages, in less than 20 years from first exposure (IPCS, 1986). There is no substantial evidence that asbestos fibre type influences the frequency or severity of pulmonary fibrosis. However the risk may be higher in the textile industry than in mining or milling, or in the manufacture of friction products (McDonald, 1984 cited by IPCS, 1986).

2.5.2 Lung cancer

The first reports (Gloyne, 1935; Lynch & Smith, 1935, both cited by IPCS, 1986), suggesting that asbestos might be related to lung cancer occurrence were followed by approximately 60 case reports over the next 20 years. The first epidemiological confirmation of this association was published by Doll (1955, cited by IPCS 1986). Since then, over 30 cohort studies (on various forms of asbestos) have been carried out in industrial populations in several countries. The majority, but not all, have shown an excess lung cancer risk (IPCS 1986).

Crocidolite is in IARC Group I: sufficient evidence for carcinogenicity to humans. Inhalation can cause fibrosis of the lung (asbestosis), bronchial carcinoma, mesothelioma of the pleura and peritoneum, and possibly cancers at other sites. Extra risk for mesothelioma: 10^{-4} at life-time exposure to 500 fibres/m³ (0.0005 fibres/ml).

Type of industrial process may affect the incidence of lung cancer. The variations may be related to the state and physical treatment of the asbestos in different situations, the dust clouds thus containing asbestos fibres of different physical dimensions (IPCS, 1986). Combined exposure to asbestos and cigarette smoke synergistically increases the risk of lung cancer.

2.5.3 Mesothelioma

Pulmonary mesothelioma is a primary malignant tumour of the mesothelial surfaces, generally affecting the pleura and less commonly the peritoneum. Mesothelioma has been associated with occupational exposure to various types and mixtures of asbestos (including talc containing asbestos), although occupational exposures have not been identified in all cases. The long latency required for mesothelioma to develop after asbestos exposure has been documented in a number of publications. An increasing proportion of cases have been seen with increasing duration of exposure (IARC, 1987). It has been suggested that increased risk of mesothelioma may be related to the duration and intensity of asbestos exposure, and perhaps also the time from first exposure (IPCS, 1986).

The majority of known cases of mesothelioma arise as a result of occupational or para-occupational exposure to asbestos (IPCS, 1986). No association with smoking has been observed (McDonald, 1984 cited by IPCS 1986).

There is a general consensus that amphiboles, and crocidolite in particular, pose a risk of induction of mesothelioma in exposed workers. (Meldrum, 1996 cited by E.C., 1997). Mesothelioma has appeared frequently in subjects with exposure to amphiboles. Current information does not suggest an important differential of mesothelioma risk according to the industrial process (IPCS, 1986).

Studies suggest that amphibole asbestos may result in the development of mesothelioma at lower levels of cumulative exposure than that required for lung cancer, although no reliable exposure-response curve can be produced for asbestos-induced mesothelioma in animals or humans (Meldrum, 1996 cited by E.C., 1997). Bignon (1997 cited by E.C., 1997) states that mesothelioma can develop at doses of maybe 10 to 1,000 times lower than those required for broncho-pulmonary cancer.

Case-control epidemiological studies, in employees at plants manufacturing asbestos cement products, showed a relationship between duration of employment and risk of mesothelioma especially from crocidolite. A strong correlation between mesothelioma and exposure to asbestos (mostly crocidolite) was found in mine workers (Western Australia) and in gas masks makers. In an asbestos factory (East London 1933-1980) mesotheliomas and lung cancer rates showed a dose response relationship and were related to duration of employment.

In a review of studies, IPCS (1986) has found that some studies suggest that cancer at sites other than the lung, pleura and peritoneum has resulted from occupational exposure to asbestos, while others have shown no excess of cancer at other sites. IARC (1987) reports that gastrointestinal cancers occurred at an increased incidence in groups occupationally exposed to asbestos, although not all studies are consistent in this respect.

2.6 Summary of mammalian toxicity and overall evaluation

Fibrosis in many animal species, and bronchial and pleural carcinomas in the rat, have been observed following inhalation of amphibole asbestos. In these studies there were no consistent increases in tumour incidence at other sites, and there is no convincing evidence that ingested asbestos is carcinogenic in animals (IPCS, 1986). Epidemiological studies, mainly on occupational groups, have established that all types of asbestos fibres are associated with diffuse pulmonary fibrosis (asbestosis), bronchial carcinoma (lung cancer), and primary malignant tumours of the pleura and peritoneum (mesothelioma). That asbestos causes cancers at other sites is less well established. Cigarette smoking increases the asbestosis mortality and the risk of lung cancer in persons exposed to asbestos but not the risk of mesothelioma (IPCS, 1986).

3 Human exposure/Risk evaluation

3.1 Food

In tallow-treated rice concentrations up to 3.7×10^{12} fibres/kg may be found. Crocidolite may occur in beverages up to 12×10^6 fibres per litre (National Drinking Water regulations 1991). Up to 12×10^6 fibres/litre have been found in soft drinks (IPCS, 1986).

3.2 Air

At remote rural locations, fibre levels ($> 5\mu\text{m}$) are generally < 1 fibre/litre (< 0.001 fibre/ml) and in urban air they range from < 1 to 10 fibres/litre (0.001 to 0.01 fibres/ml) or occasionally higher. Airborne levels in residential areas in the vicinity of industrial sources have been found to be within the range of those in urban areas or occasionally slightly higher. Non-occupational indoor levels are generally within the range found in ambient air (IPCS, 1986; 1998).

Concentrations in air: near mills, mines and industrial sites up to 600,000 fibres/m³ (0.6 fibres/ml), at urban locations 10,000 fibres/m³ (0.01 fibres/ml).

3.3 Water

Reported concentrations of asbestos in drinking-water range up to 200×10^6 fibres/litre (all fibre lengths) (IPCS, 1986).

Maximum residue limits: In drinking water: 7×10^6 fibres/l (National drinking water, 1991)

3.4 Occupational exposure

Main exposure sources are handling, processing and disposal of dry asbestos or asbestos containing products, where fibres are released into the air. The highest concentrations measured during mining and industrial handling were 800×10^6 fibres/m³ (800 fibres/ml), but were without any means of dust suppression. During home construction and renovation up to 10×10^6 fibres/m³ (10 fibres/ml) have been recorded. Exposure limits: USA, 200,000 fibres/m³ (0.2 fibres/ml) (TLV, 8-hr TWA); EEC 300,000 fibres/m³ (0.3 fibres/ml) for fibre length $>5\mu\text{m}$.

Among occupational groups, exposure to asbestos poses a health hazard that may result in asbestosis, lung cancer and mesothelioma. The incidence of these diseases is related to fibre type, fibre size, fibre dose and industrial processing (IPCS, 1986).

The European Community notification noted that exposure of workers and other users of asbestos-containing products is in general technically extremely difficult to control in practice and may greatly exceed current limit values on an intermittent basis. It was recognized that a controlled and safe occupational use of asbestos could not be established for several working situations like e.g. building sites, repairs, or waste removal. As asbestos was widely used and no safe concentration threshold could be established it was decided to severely restrict the use of asbestos.

The Chile notification noted that in general the highest exposures to asbestos are amongst the working population whether during manufacture of materials containing asbestos or during installation or demolition. In Chile this means in

particular those workers who have been exposed to fibres from the manufacture of construction materials. In the case of brake linings or parts that contain asbestos, not only the workers who handle asbestos during manufacture are exposed to high risk, so are brake repair workshop mechanics who blow off the dust produced by wear. Health controls over this activity are very difficult to implement because of its very nature. In many cases, the workshops involved are small ones that do not have the occupational health means to control the risks.

3.5 Para-occupational exposure

Members of the families of asbestos workers handling contaminated work clothes and, in some cases, members of the general population may be exposed to elevated concentrations of airborne asbestos fibres. Asbestos has been used widely in building materials for domestic application (e.g. asbestos-cement products and floor tiles) and elevated airborne levels have been measured during the manipulation of these materials (e.g. home construction and renovation by the homeowner) (IPCS, 1986).

In para-occupational groups, which include persons with household contact and neighbourhood exposure, the risk of mesotheliomas and lung cancer is generally much lower than for occupational groups. Risk estimation is not possible because of the lack of exposure data required for dose-response characterization. The risk of asbestosis is very low (IPCS, 1986).

The Chile notification notes that asbestos fibres are not easily released from asbestos in a cement matrix, in sheeting used in construction. However, people who cut or trim such sheeting using high-speed tools (circular saws or sanders) are exposed to risk from the asbestos-fibre dust given off.

3.6 Public exposure

In the general population, the risks of mesothelioma and lung cancer attributable to asbestos cannot be quantified reliably and are probably undetectably low. The risk of asbestosis is virtually zero. (IPCS, 1986).

4 Environmental fate and effects

- | | | |
|------------|----------------|--|
| 4.1 | Fate | Crocidolite fibres are relatively stable and are transported via air and water over great distances. |
| 4.2 | Effects | Not enough data available to draw a conclusion. |

5 Environmental Exposure/Risk Evaluation

Environmental effects are not relevant to the risk evaluation used to support the regulatory decisions.

Annex 2 – Details on final regulatory actions reported – Crocidolite

Country Name: Australia

| | |
|--|---|
| <p>1 Effective date(s) of entry into force of actions Reference to the regulatory document</p> | <p>Most jurisdictions placed severe restrictions on asbestos use during the late 1970's and early 1980s (some of the legislation under which the current restrictions are in force was enacted during the 1990s and incorporated/superseded existing restrictions). <u>Commonwealth</u> – <i>Industrial Safety Health and Welfare (Administrative and General) Regulation 1979.</i> <u>New South Wales</u> – <i>Factories (Health and Safety – Asbestos Process) Regulations 1984 under Factories, Shops and Industries Act 1962; Occupational Health and Safety (Hazardous Substances) Regulation 1996 under Occupational Health and Safety Act 1983.</i> <u>Northern Territory</u> – <i>Work Health (Occupational Health and Safety) Regulations 1996 under Work Health Act 1996.</i> <u>Queensland</u> – <i>Workplace Health and Safety Regulation 1997 under Work Health and Safety Act 1995.</i> <u>South Australia</u> – <i>Occupational Health, Safety and Welfare Regulations 1995 under Occupational Health, Safety and Welfare Act 1986.</i> <u>Tasmania</u> – <i>Industrial Safety Health and Welfare (Administrative and General) Regulation 1979.</i> <u>Victoria</u> – <i>Occupational Health and Safety (Asbestos) Regulations 1992 under Occupational Health and Safety Act 1985.</i> <u>Western Australia</u> – <i>Occupational Health Safety and Welfare Regulation 1988; Health (Asbestos) Regulations 1992 under Health Act 1911.</i></p> |
| <p>2 Succinct details of the final regulatory action(s)</p> | <p>Amphibole forms of asbestos are severely restricted. Legislation is primarily through States and Territories.</p> |
| <p>3 Reasons for action</p> | <p>Carcinogenic when inhaled. Should minimise exposure of people to risk of inhalation of amphibole asbestos.</p> |
| <p>4 Basis for inclusion into Annex III</p> | |
| <p>4.1 Risk evaluation</p> | <p>The basis of the Australian regulatory actions was human health risk assessments, taken at national and state level that focussed on the carcinogenicity of inhaled asbestos and conditions of exposure in that country.</p> |
| <p>4.2 Criteria used Relevance to other States and Region</p> | <p>Unacceptable risk to human health. Regulatory actions for asbestos were taken incrementally, reflecting the building knowledge on its risks. The major health effects identified as a result of inhalation of amphibole asbestos are asbestosis and carcinogenicity (NHMRC 1982). Crocidolite is already included in the Rotterdam Convention.</p> |
| <p>5 Alternatives</p> | <p>No information</p> |
| <p>6 Waste management</p> | <p>No information</p> |
| <p>7 Other</p> | <p>Crocidolite is listed in the Australian National Occupational Health and Safety Commission (NOHSC) <i>Draft</i> List of Designated Hazardous Substances, with the classification: Carcinogen. Cat.1 • R45 – May cause cancer Toxic (T) R48/23 – Toxic: danger of serious damage to health by prolonged exposure through inhalation No exposure standards available. Previously TWA 0.1 fibre per ml of air. Currently being reviewed by Chemicals Framework Team under the NOHSC.</p> |

| |
|----------------------------|
| Country Name: Chile |
|----------------------------|

| | | |
|------------|---|---|
| 1 | Effective date(s) of entry into force of actions | Supreme Decree No. 656 entered into force 180 days after its publication in the Official Journal, on 12 July 2001. |
| | Reference to the regulatory document | Supreme Decree No. 656 of 12 September 2000, Official Journal, 13 January 2001 |
| 2 | Succinct details of the final regulatory action(s) | Production, importation, distribution, sale and use of crocidolite and any material or product containing it are prohibited. Production, importation, distribution, sale and use of construction materials containing any type of asbestos are prohibited. Production, importation, distribution, sale and use of chrysotile, actinolite, amosite, anthophyllite, tremolite and any other type of asbestos, or mixture thereof, for any item, component or product that does not constitute a construction material are prohibited, with certain specific exceptions. |
| 3 | Reasons for action | Human Health To reduce exposure to asbestos amongst the working population during manufacture of material containing asbestos or during installation or demolition. |
| 4 | Basis for inclusion into Annex III | |
| 4.1 | Risk evaluation | The foreign literature and analysis of domestic cases of asbestosis and mesothelioma indicate that those at greatest risk are workers who handle asbestos fibres for various uses. In Chile, this means in particular those workers who have been exposed to fibres from the manufacture of construction materials. No epidemiological precedents are known that show that there is a risk to the population from asbestos, which is already included within a cement matrix in sheeting used in construction, given that the asbestos fibres are not easily released from the matrix. Nor is there any significant known risk from consuming water piped through asbestos cement piping. Nevertheless, people who cut or trim such sheeting using high-speed tools (circular saws or sanders) are exposed to risk from asbestos-fibre containing dust given off. In the case of brake lining or parts that contain asbestos, not only the workers who handle asbestos during manufacture are exposed to high risk, so are brake repair workshop mechanics who blow off the dust produced by wear. It should be noted that health controls over this activity are very difficult to implement because of its very nature. In many cases, the workshops involved are small ones that do not have the occupational health means to control the risks. |
| 4.2 | Criteria used | Unacceptable risk to workers. All types of asbestos are hazardous to health to varying degrees depending on the form of exposure (it has been shown that the risk is from inhalation), the class of asbestos (blue asbestos is the most toxic), the size of the fibres, fibre concentration and interaction with other factors (tobacco smoking potentiates the effects). Generally speaking, the highest exposures are amongst the working population whether during manufacture of the materials containing asbestos or during installation or demolition. |
| | Relevance to other States and Region | The regulatory action prohibits imports of asbestos in general, whatever the country of origin. Therefore no country may export asbestos to Chile except in specific cases, which exclude material and inputs for construction material and must be expressly authorized by Health Authority. |
| 5 | Alternatives | It has been proved that it is feasible to replace asbestos with other fibres in manufacturing fibre-cement materials and still obtain products of similar quality. In fact, the company producing the greatest quantity of panels and sheeting for dwellings in Chile has replaced asbestos with other fibres such as cellulose. In case of brake parts, asbestos-containing and asbestos-free brake pads and linings are in use until the existing in-use asbestos-containing brake pads and linings at the time of publication of the prohibition should be replaced. |
| 6 | Waste management | No information |
| 7 | Other | Crocidolite is listed in the Chilean Regulations on Basic Sanitary and Environmental Conditions in Workplaces (Supreme Decree No. 594), with the classification: A.1 |

Proved Human Carcinogen

In accordance with the Chilean Regulations on Basic Sanitary and Environmental Conditions in Workplaces (Supreme Decree No. 594), crocidolite fibres exposure limit value for workers is 0.16 fibres/cc determined by means of a contrast microscope with magnifying potency of 400–450, in a sample from a membrane filter, counting fibres greater than 5_μ length and a ratio length to diameter equal to or greater than 3:1.

| |
|---|
| Country Name: European Community |
|---|

- | | | |
|------------|---|--|
| 1 | Effective date(s) of entry into force of actions | Regulatory action was first taken in 1983, in relation to crocidolite. Subsequently, such action has progressively been extended to all forms of asbestos. The latest regulatory action entered in force on 26.8.1999 (OJ L 207 of 6.8.1999, p. 18). Member States of the E.C. were obliged to implement the necessary national legislation at the latest by 1 st January 2005. |
| | Reference to the regulatory document | Directive 1999/77/ E.C. of 26.7.1999 (Official Journal of the European Communities (OJ) L207 of 6.8.99, p.18) adapting to technical progress for the sixth time Annex 1 to Directive 76/769/EEC of 27.7.1976 (OJ L 262 of 27.9.1976, p.24). Other relevant Regulatory Actions: Directives 83/478/EEC of 19.9.1983 (OJ L 263 of 24.9.1983, p.33), 85/610/EEC of 20.12.1985 (OJ L 375 of 31.12.1985, p.1), 91/659/EEC of 3.12.1991 (OJ L 363 of 31.12.91, p.36) |
| 2 | Succinct details of the final regulatory action(s) | The placing on the market and use of crocidolite fibres and products containing these fibres added intentionally are prohibited. The use of products containing asbestos fibres that were already installed and/or in service before the implementation date of Directive 1999/77/ E.C. by the Member State concerned could continue to be authorised until they are disposed of, or reach the end of their service life. However, Member States could, for reasons of protection of health, prohibit within their territory the use of such products before they are disposed of or reach the end of their service life. |
| 3 | Reasons for action | Prevent health effects (asbestosis, lung cancer, mesothelioma) for workers and general public. |
| 4 | Basis for inclusion into Annex III | |
| 4.1 | Risk evaluation | A comparison of asbestos with possible substitutes by the Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) concluded that all forms of asbestos are carcinogenic to humans and are likely to present a greater risk than substitutes (CSTEE 1998). |
| 4.2 | Criteria used | Standard E.C. criteria used for evaluation of exposure. |
| | Relevance to other States and Region | Health problems similar to the ones experienced in the E.C. may occur in states where the substance is used in industrial plants and/or as building material, especially in developing countries, where the use of asbestos is still growing. A ban protects health of workers and of the general public. |
| 5 | Alternatives | The risk assessment under taken by the CSTEE on chrysotile asbestos and candidate substitutes would be relevant for other variants of asbestos also. It concludes that, both for the induction of lung and pleural cancer and lung fibrosis and for other effects, it is unlikely that the alternatives cellulose fibres, PVA fibres or P-aramid fibres pose an equal or greater risk than chrysotile asbestos. With regard to carcinogenesis and induction of lung fibrosis the risk is regarded to be lower. (CSTEE, 1998) |
| 6 | Waste management | In accordance with Council Directive 87/217/EEC (OJ L 85, 28.3.1987, p.40), as amended by Council Directive 91/692/EEC (OJ L 377, 31.12.1991, p.48) on the demolition of buildings, structures and installations containing asbestos and the removal of asbestos or materials containing asbestos therefrom or materials containing asbestos involving the release of asbestos fibres or dust must not cause significant environmental pollution. Construction materials have been classified as hazardous waste and will thus, as from 1 January 2002, have to be disposed of in line with the obligations laid down in Council Directive 91/689/EEC (OJ L 377, 31.12.1991, p.20). In addition, the Commission is considering measures to promote the practice of selective demolition in order to segregate the hazardous waste present in construction materials and ensure their safe disposal. |
| 7 | Other | In accordance with Council Directive 83/477/EEC (OJ L 263, 24.9.1983, p.25), as amended by Council Directive 91/382/EEC (OJ L 206, 29.7.1991, p.16) the European Community exposure limit values for workers are currently 0.3 fibres/ml for forms of asbestos other than chrysotile. Exposure limit values for workers: Proposal still under consideration before the Council and the European Parliament: in 2001 the European Commission proposed (OJ C 304 E 30/10/2001, p.175) that these limits be replaced by a reduced, single limit value of 0.1 fibres/ml for all forms of asbestos. |

Previous notifications

Crocidolite is already listed on Annex III of the Rotterdam Convention on the basis of: regulatory actions in Sri Lanka in 1986, European Community in 1988 and Sweden in 1988. In Sri Lanka, import and sale were banned. In E.C. countries, crocidolite asbestos fibre or products containing it were prohibited for use. In Sweden, the substance was severely restricted and could not be used without the permission of the Labour Inspectorate.

Reason for the control action: The link between exposure to crocidolite and asbestos-type diseases such as mesothelioma (lung cancer) is well documented from occupational data and scientific evidence. The substance is carcinogenic in both humans and test animals, and is considered to be a more potent carcinogen than white or brown asbestos (DGD for crocidolite, 1992).

Annex 3 – Addresses of designated national authorities

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P

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EUROPEAN COMMUNITY

CP

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C Industrial chemicals

CP Pesticides, industrial chemicals

P Pesticides

Annex 4 – References – Crocidolite

Regulatory actions

Australia

Commonwealth of Australia – *Industrial Safety Health and Welfare (Administrative and General) Regulation 1979*.

New South Wales – *Factories (Health and Safety – Asbestos Process) Regulations 1984 under Factories, Shops and Industries Act 1962; Occupational Health and Safety (Hazardous Substances) Regulation 1996 under Occupational Health and Safety Act 1983*.

Northern Territory – *Work Health (Occupational Health and Safety) Regulations 1996 under Work Health Act 1996*.

Queensland – *Workplace Health and Safety Regulation 1997 under Work Health and Safety Act 1995*.

South Australia – *Occupational Health, Safety and Welfare Regulations 1995 under Occupational Health, Safety and Welfare Act 1986*.

Tasmania – *Industrial Safety Health and Welfare (Administrative and General) Regulation 1979*.

Victoria – *Occupational Health and Safety (Asbestos) Regulations 1992 under Occupational Health and Safety Act 1985*.

Western Australia – *Occupational Health Safety and Welfare Regulation 1988; Health (Asbestos) Regulations 1992 under Health Act 1911*.

Chile

Supreme Decree No. 656 of 12 September 2000, Official Journal, 13 January 2001

European Community

Directive 1999/77/ E.C. of 26.7.1999 (Official Journal of the European Communities (OJ) L207 of 6.8.99, p.18) adapting to technical progress for the sixth time Annex 1 to Directive 76/769/EEC of 27.7.1976 (OJ L 262 of 27.9.1976, p.24). Other relevant Regulatory Actions: Directives 83/478/EEC of 19.9.1983 (OJ L 263 of 24.9.1983, p.33), 85/610/EEC of 20.12.1985 (OJ L 375 of 31.12.1985, p.1), 91/659/EEC of 3.12.1991 (OJ L 363 of 31.12.91, p.36)

Other Documents

Bignon J (1997) Asbestos, the true risks and the false problems, In: Recherche et Santé No. 69

CSTEE (1998) Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) – Opinion on Chrysotile asbestos and candidate substitutes expressed at the 5th CSTEE plenary meeting, Brussels, 15 September 1998 http://europa.eu.int/comm/food/fs/sc/sct/out17_en.html

Directive 1999/77/ E.C. of 26.7.1999 (Official Journal of the European Communities (OJ) L207 of 6.8.99, p.18) adapting to technical progress for the sixth time Annex I to Directive 76/769/EEC of 27.7.1976 (OJ L 262 of 27.9.1976, p. 24).

Directive 2001/59/ E.C. of 6.8.2001 (Official Journal of the European Communities (OJ)) L225/1.

Doll R (1955) Mortality from lung cancer in asbestos workers. British Journal of Industrial Medicine 12: 81-86

E.C. (1997) European Commission DGIII, Environmental Resources Management. Recent assessments of the hazards and risks posed by asbestos and substitute fibres, and recent regulation of fibres worldwide. Oxford.

E.C. (2001) Commission Directive 2001/59/ E.C. August 2001

Gloyne S R (1935) Two cases of squamous carcinoma of the lung occurring in asbestosis. Tuberculosis 17:5

IARC (1987) IARC monographs on the evaluation of carcinogenic risks to humans: overall evaluations of carcinogenicity: updating of IARC monographs volumes 1 to 42 (supplement 7), International Agency for Research on Cancer, Lyon.

International Labour Organisation (1986) Convention No. 162 and Recommendation 172 concerning safety in the use of asbestos [ILO]. International Labour Office, 1986.

International Standards Organisation (1984) Asbestos reinforced cement products – Guidelines for on-site work practices. ISO 7337. First edition 1984-07-01

IPCS (1986) Environmental Health Criteria 53: Asbestos and other Natural Mineral Fibres. World Health Organisation, Geneva.

IPCS (1998) Environmental Health Criteria 203: Chrysotile asbestos. World Health Organisation, Geneva.

Lynch K M and Smith W A (1935) Pulmonary asbestosis. III. Carcinoma of lung in asbestos-silicosis. American Journal of Cancer 24:56

McDonald J C (1984) Mineral fibres and cancer. Ann. Acad Med Singapore 13:345-352

Meldrum M (1996) Review of fibre toxicology. Health and Safety Executive, UK.

National primary drinking water regulations—synthetic organic chemicals and inorganic chemicals, final rule, 56 Federal Register 3526 (January 30, 1991)

NHMRC (1982) National Health and Medical Research Council (NHMRC) Report on the Health Hazards of Asbestos (*Adopted by the NHMRC in June 1981 and published in 1982*)

Royal Society of Canada: (1996). A review of the INSERM Report on the health effects of exposure to asbestos: Report of the Expert Panel on Asbestos Risk.

US (2001) U.S National Toxicology Program ‘9th Report on Carcinogens’, revised Jan 2001

**Amosite, Anthophyllite, Actinolite, Tremolite
(amphibole forms of asbestos)**

ASBESTOS: AMPHIBOLE – OTHER FORMS

1. Identification and uses (see Annex 1) - Other amphibole forms

| Common names | AMOSITE | ANTHOPHYLLITE | ACTINOLITE | TREMOLITE |
|---|---|--|---------------------|--------------------|
| Chemical name | Varieties of asbestiform hydrated silicates, with complex crystal structures | | | |
| Other names/synonyms | Brown asbestos Mysorite | Anthophyllite asbestos Azbolen asbestos | Actinolite asbestos | Tremolite asbestos |
| CAS-No.(s) | 12172-73-5 | 77536-67-5 | 77536-66-4 | 77536-68-6 |
| Other CAS numbers that may be used | 1332-21-4 (general CAS number for asbestos) | | | |
| E.C. number | E.C.-No: 310-127-6 Naturally occurring substances (Asbestos fibres fall under this E.C.-number) | | | |
| Harmonized System Customs Code | 2524.00: amphibole asbestos concentrates, amphibole asbestos crude ore, asbestos, asbestos flakes, asbestos powder, asbestos, crude, asbestos, raw, chrysotile asbestos concentrates, chrysotile asbestos crude ore, waste and scrap of asbestos) | | | |
| Other numbers: | E.C. Customs numbers: CUS-No: 23743 (amosite), 23672 (anthophyllite), 23696 (actinolite), 23706 (tremolite), | | | |
| Category | Industrial | | | |
| Regulated Category | Industrial | | | |
| Use(s) in regulated category | <p>Australia – (Information on amphibole forms) Fireproof fabrics, yarn and thread; gaskets and compressed asbestos fibre jointing; reinforcing agent in rubber, plastics, cement, sheets and panels; paper, millboard and felt; tubes and pipes; chemical filters and diaphragms.</p> <p>Chile – (Information on all forms) Manufacture of construction materials, in particular asbestos-cement panelling, asbestos pipes, roof tiles, and preformed products such as tanks. Manufacture of brake lining and clutches.</p> <p>European Community – (Information on all forms) Used mainly in seals, gaskets, joints, diaphragms, and armaments. Former usage (before restriction/ban in E.C.) in heat-resistant insulators, cements, furnace and hot pipe coverings, inert filler medium (laboratory & commercial), fireproof gloves, clothing, brake lining. NaOH treated asbestos, AscariteBaker, has been used to absorb CO₂ in combustion analysis.</p> | | | |
| Trade names | - | | | |
| Formulation types | Asbestos has been used in the manufacture of a wide range of articles and products. | | | |
| Uses in other categories | No reported uses as a pesticide chemical. | | | |
| Basic manufacturers | Naturally occurring, mined | | | |

2. Reasons for inclusion in the PIC procedure – Other amphibole forms

Amosite, anthophyllite, actinolite and tremolite (amphibole forms of asbestos) are included in the PIC procedure as industrial chemicals. They are listed on the basis of the final regulatory actions to ban or severely restrict their uses as notified by Australia, Chile and the European Community.

2.1 Final regulatory action: (see Annex 2 for details)

Australia

Severe restriction on use of all forms of amphibole asbestos (crocidolite, amosite, anthophyllite, actinolite and tremolite) is implemented through State and Territory legislation.

Reason: Human Health

Chile

Severely restricted:

Production, importation, distribution, sale and use of construction materials containing any type of asbestos is prohibited.

Production, importation, distribution, sale and use of actinolite, amosite, anthophyllite, tremolite and any other type of asbestos, or mixture thereof, for any item, component or product that does not constitute a construction material is prohibited, with certain specific exceptions.

Reason: Human Health

European Community

Banned – The placing on the market and use of, amosite, anthophyllite, actinolite and tremolite, and products containing these fibres added intentionally, is prohibited.

Reason: Human Health

2.2 Risk evaluation

Australia

Decisions (by States and Territories of Australia) to take final regulatory action were taken on the basis of established risk/hazard to human health. Risk evaluations were undertaken to the standards then current.

Chile

A hazard evaluation was carried out based on a compilation of bibliographic sources and verification of adverse chronic effects in exposed workers in the asbestos cement industry. It was concluded that those at greatest risk are workers who handle asbestos fibres for various uses. In Chile, this means in particular those workers who have been exposed to fibres from the manufacture of construction materials.

European Community

An independent risk assessment was undertaken. This confirmed that all forms of asbestos can cause lung cancer, mesothelioma, and asbestosis; that no threshold level of exposure could be identified below which asbestos does not pose carcinogenic risks.

3. Protective measures that have been applied concerning the chemical – Other amphibole forms

3.1 Regulatory measures to reduce exposure

| | |
|---------------------------|--|
| Australia | Protective measures were taken by prohibiting all uses of all amphibole forms of asbestos except sampling and analysis, maintenance, removal, disposal, encapsulation or enclosure, and uses associated with reducing the risk of human exposure to it. |
| Chile | Protective measures were taken by prohibiting all uses of all types of asbestos for use as an input to the manufacture of construction materials. All types of asbestos prohibited for use for any item, component or product that does not constitute a construction material unless excepted. Any type of asbestos (except crocidolite): the use of asbestos may be authorized in the manufacture of products or components that are not construction materials so long as the interested parties can prove that there is no technically or economically feasible substitute for it. |
| European Community | Protective measures were taken by prohibiting the placing on the market and use of, amosite, anthophyllite, actinolite, tremolite and of products containing these fibres added intentionally, (see Annex 2 for further details). |

3.2 Other measures to reduce exposure

Australia

Guidance documents available from NOHSC website at <http://www.nohsc.gov.au/OHSLegalObligations/NationalStandards/asbest.htm> are:

Code of Practice for the Safe Removal of Asbestos [NOHSC:2002 (1988)]

Guidance Note on the Membrane Filter Method for Estimating Airborne Asbestos Dust [NOHSC:3003(1988)]

Guide to the Control of Asbestos Hazards in Buildings and Structures [NOHSC:3002 (1998)]

European Community

Directive on the demolition of buildings, structures and installations containing asbestos and the removal of asbestos or materials containing asbestos therefrom (Council Directive 87/217/EEC (OJ L 85, 28.3.1987, p.40), as amended by Council Directive 91/692/EEC (OJ L 377, 31.12.1991, p.48))

Directive on disposal of construction materials (Council Directive 91/689/EEC (OJ L 377, 31.12.1991, p.20))

General

Dust control by wetting material, use of respirators, use of full protective clothing with attention when further treating any contaminated clothing.

Further guidance is provided in the ILO Convention No. 162 “Safety in the Use of Asbestos”

(<http://www.ilo.org/ilolex/cgi-lex/convde.pl?C162>) which applies to all activities involving exposure of workers to asbestos in the course of work.

The ILO recommendation 172 (<http://www.ilo.org/ilolex/cgi-lex/convde.pl?R172>), contains recommendations on safety in the use of asbestos, including details on protective and preventative measures, surveillance of the working environment and workers’ health, information and education measures.

More specific information on measures to reduce exposures on construction sites is provided in the International Standard Organisation (ISO) 7337 “Asbestos-reinforced cement products – Guidelines for on-site work practices.”

3.3 Alternatives

It is essential that before a country considers substituting alternatives, it ensures that the use is relevant to its national needs, and the anticipated local conditions of use. The hazards of the substitute materials and the controls needed for safe use should also be evaluated.

Chile

It has been proved that it is feasible to replace asbestos with other fibres in manufacturing fibro-cement materials and still obtain products of similar quality. In fact, the company producing the greatest quantity of panels and sheeting for dwellings in Chile has replaced asbestos with other fibres such as cellulose. In the case of brake parts, asbestos-containing and asbestos-free brake pads and linings are in use, until the existing in use asbestos-containing brake pads and linings at the time of publication of the prohibition should be replaced.

European Community

Identified alternatives include cellulose fibres, polyvinyl alcohol (PVA) fibres and P-aramid fibres.

General

Guidance on substituting alternatives to asbestos fibres is provided in IPCS Environmental Health Criteria 151 "Selected Synthetic Organic Fibres".

3.4 Socio-economic effects

Australia

A regulatory impact statement for 1991 regulations in Victoria, a State of Australia, concluded that a process of substituting alternative materials had eliminated the use of asbestos in the majority of its former applications.

Chile

No assessment of socio-economic effects was undertaken.

4 Hazards and risks to human health and/or the environment – Other amphibole forms

4.1 Hazard Classification

| | |
|---------------------------|--|
| IARC | <i>Carcinogenic to humans</i> (Group 1) IARC (1987) |
| European Community | Carc. Cat. 1 R45 May cause cancer T:R48/23 Toxic: danger of serious damage to health by prolonged exposure through inhalation (E.C., 2001) |
| NTP | Amphibole asbestos is classified as "Known Human Carcinogen" (US, 2001) |

4.2 Exposure limits

No internationally agreed exposure limits available.

4.3 Packaging and labelling

The United Nations Committee of Experts on the Transportation of Dangerous Goods classifies the chemical in:

| | |
|---|---|
| Hazard Class and Packing group for amosite: | UN number: 2212 Class 9 – Miscellaneous dangerous goods and articles Proper shipping name: BROWN ASBESTOS Packing Group: II Hazchem Code: 2X Special Provision number: 168 Packaging requirements: 3.8.9 General: Mineral fibres of varying length. Non-combustible. Inhalation of the dust of asbestos fibres is dangerous and therefore exposure to the dust should be avoided at all times. Always prevent the generation of asbestos dust. Crocidolite (blue asbestos) should be regarded as the most hazardous type of asbestos. A safe level of airborne concentration of asbestos fibres may be obtained through effective packaging or unitizing. Compartments and vehicles or containers that have contained asbestos should be carefully cleaned before receiving other cargo. Hosing down or vacuum cleaning as appropriate, instead of sweeping, will prevent the atmosphere from becoming dust laden. |
| Hazard Class and Packing group for actinolite, anthophyllite and tremolite | UN number: 2590 Class 9 – Miscellaneous dangerous goods and articles Proper shipping name: WHITE ASBESTOS Packing Group: III Hazchem Code: 2X Emergency Procedure Guide: <i>This item of information not yet available</i> Special Provision number: 168 Packaging requirements: 3.8.9 General: Mineral fibres of varying length. Non-combustible. Inhalation of the dust of asbestos fibres is dangerous and therefore exposure to the dust should be avoided at all times. Always prevent the generation of asbestos dust. A safe level of airborne concentration of asbestos fibres may be obtained through effective packaging or unitizing. Compartments and vehicles or containers that have contained asbestos should be carefully cleaned before receiving other cargo. Hosing down or vacuum cleaning as appropriate, instead of sweeping will prevent the atmosphere from becoming dust laden. This entry may also include talc containing tremolite and/or actinolite. |
| International Maritime Dangerous Goods (IMDG) Code | Amosite: UN No: 2212: Class or division: 9 Actinolite, anthophyllite and tremolite: UN No:2590 Class or division: 9 |
| Transport Emergency Card | Information not available on these forms. (Note: numbers have been assigned for crocidolite and chrysotile.) |

4.4 First aid

NOTE: The following advice was correct at the time of publication. This advice is provided for information only and is not intended to supersede any national first aid protocols.

Not acutely toxic. In case of exposure, prevent dispersion of dust. Avoid all contact. Avoid exposure of adolescents and children. There is no antidote. Seek medical advice.

4.5 Waste management

Asbestos may be recovered from waste slurries. Otherwise friable waste should be wetted and containerised (sealed, double bagging) to avoid dust formation during transport and disposal. Landfilling is recommended in a supervised landfill and, waste should initially be covered with at least 15 cm of soil. For final closure of an area containing asbestos a cover of at least 1 m of compacted soil should be applied.

Annexes

- Annex 1 **Further information on the substance**
- Annex 2 **Details on Final regulatory action**
- Annex 3 **Address of designated national authorities**
- Annex 4 **References**

Introduction to Annex I

The information presented in this Annex reflects the conclusions of the notifying parties: Australia, Chile, and European Community. In a general way, information provided by these parties on these hazards are synthesised and presented together, while the risk assessments, specific to the conditions prevailing in these countries, are presented separately. This information is contained in the documents referenced in the notifications in support of their final regulatory actions banning asbestos, including international reviews. The notification from Australia was first reported in the PIC Circular XI of June 2000, the notification from Chile was first reported in the PIC Circular XV of June 2002 and the notification from the European Community in PIC Circular XIII of June 2001.

The amphibole forms of asbestos were included as subjects of an IPCS Environmental Health Criteria document (Asbestos and other Natural Mineral Fibres, EHC 53) published in 1986.

Annex 1 – Further information – Other amphibole forms

1. Physico-Chemical properties

| | AMOSITE | ANTHOPHYLLITE | TREMOLITE | ACTINOLITE |
|--|--|--|---|--|
| 1.1 Identity | | | | |
| 1.2 Formula | (Fe,Mg) ₇ (Si ₈ O ₂₂)(OH) ₂ | (Mg,Fe) ₇ Si ₈ O ₂₂ (OH) ₂ | Ca ₂ Mg ₅ (Si ₈ O ₂₂)(OH) ₂ | Ca ₂ (Mg,Fe) ₅ (Si ₈ O ₂₂)(OH) ₂ |
| 1.3 Colour and Texture | Light grey to pale brown Usually brittle | White to grey pale brown Usually brittle | White to grey Usually Brittle | Pale to dark green |
| 1.4 Decomposition Temperature (°C) | 600–800 | 600–850 | 950–1040 | 620-960 |
| 1.5 Fusion temperature of Residual material (°C) | 1400 | 1450 | 1315 | 1400 |
| 1.6 Density (g/cm³) | 3.4 – 3.5 | 2.85 – 3.1 | 2.9 – 3.1 | 3.0 – 3.2 |
| 1.7 Resistance to acids | Attacked slowly | Very good | Very good | Attacked slowly |
| 1.8 Resistance to alkalis | Good | Very good | Good | Good |
| 1.9 Tensile strength (10³ kg/cm²) | 17 | (<7) | 5 | 5 |

2 Toxicological properties

| | |
|-------------------------------------|---|
| 2.1 General | Amosite, actinolite, anthophyllite and tremolite are amphibole forms of asbestos (as is crocidolite). There is general consensus amongst the scientific community that all types of asbestos fibres are carcinogenic (IPCS, 1986, 1998; Royal Society of Canada, 1996 cited by E.C., 1997) and can cause asbestosis, lung cancer and mesothelioma when inhaled. Mesothelioma has appeared more frequently in subjects with exposure to amphiboles than in those exposed to chrysotile. As commercial chrysotile may contain low levels of tremolite, it has been suggested that tremolite may be the cause of mesothelioma in populations exposed primarily to chrysotile because the association of chrysotile with mesothelioma did not seem clear (IPCS, 1986). |
| 2.2 Deposition and Clearance | Depending largely on size and shape, deposition of inhaled asbestos fibres may occur in lung tissue. Some fibres may be removed by mucociliary clearance or macrophages while others may be retained in the lungs for extended periods. Inhalation exposure is, therefore, generally regarded as cumulative, and exposures have been expressed in terms of concentration of fibres over time or PCM fibre-years/ml. |
| 2.3 Mode of action | The ability of fibres to induce fibrogenic and carcinogenic effects seems to be dependent on their individual characteristics, including fibre dimension and durability (i.e. biopersistence in target tissues), which are determined in part by the physico-chemical properties (IPCS, 1998). |

It is well documented from experimental studies that fibres shorter than 5µm are less biologically active than fibres longer than 5µm. However, it is still uncertain whether short fibres have any significant biological activity. Furthermore it is still uncertain as to how long a fibre needs to remain in the lung in order to induce preneoplastic effects (IPCS, 1998).

The mechanisms by which asbestos fibres cause fibrogenic and carcinogenic effects are not completely understood. Possible mechanisms of fibrogenic effects of fibres include chronic inflammation process mediated by production of growth factors (e.g., TNF-alpha) and reactive oxygen species. With regard to fibre-induced carcinogenicity, several hypotheses have been proposed. These include: DNA damage by reactive oxygen species induced by fibres; direct DNA damage by physical interactions between fibres and target cells; enhancement of cell proliferation by fibres; fibre-provoked chronic inflammatory reactions leading to prolonged release of lysozymal enzymes, reactive oxygen species, cytokines and growth factors; and action by fibres as co-carcinogens or carriers of

- chemical carcinogens to the target tissues (IPCS, 1998).
- 2.4 Effects on animals** Results from animal studies reflect the known human health effects of asbestos. IARC (1987) reports that asbestos has been tested for carcinogenicity by inhalation in rats, by intrapleural administration in rats and hamsters, by intraperitoneal injection in mice, rats and hamsters and by oral administration in rats and hamsters. Amosite, anthophyllite and tremolite produced mesothelioma and lung carcinomas in rats after inhalation and mesothelioma following intrapleural administration. Amosite and anthophyllite induced mesothelioma in hamsters following intrapleural administration. Intraperitoneal administration of amosite induced peritoneal tumours, including mesothelioma, in mice and rats. Given by the same route, tremolite and actinolite produced abdominal tumours in rats. .
- There is no convincing evidence that ingested asbestos is carcinogenic in animals (IPCS, 1986).
- 2.5 Effects on humans** Inhalation of asbestos dust can cause fibrosis of the lung (asbestosis), changes in one or both surfaces of the pleura, bronchial carcinoma (lung cancer), mesothelioma of the pleura and peritoneum, and possibly cancers of other sites (IPCS, 1986). .
- 2.5.1 Asbestosis** Asbestosis was the first asbestos-related lung disease to be recognised. It is defined as diffuse interstitial fibrosis of the lungs resulting from exposure to asbestos dust. Scarring of the lungs reduces their elasticity and function resulting in breathlessness. It can appear and progress many years after the termination of exposure.
- Under recent exposure conditions, asbestosis will rarely be detectable, even in its early stages, in less than 20 years from first exposure (IPCS, 1986). There is no substantial evidence that asbestos fibre type influences the frequency or severity of pulmonary fibrosis. However the risk may be higher in the textile industry than in mining or milling, or in the manufacture of friction products (McDonald, 1984 cited by IPCS, 1986).
- 2.5.2 Lung cancer** The first reports (Gloyne, 1935; Lynch & Smith, 1935, both cited by IPCS, 1986), suggesting that asbestos might be related to lung cancer occurrence were followed by approximately 60 case reports over the next 20 years. The first epidemiological confirmation of this association was published by Doll (1955, cited by IPCS 1986). Since then, over 30 cohort studies (on various forms of asbestos) have been carried out in industrial populations in several countries. The majority, but not all, have shown an excess lung cancer risk (IPCS 1986).
- Type of industrial process may affect the incidence of lung cancer. The variations may be related to the state and physical treatment of the asbestos in different situations, the dust clouds thus containing asbestos fibres of different physical dimensions (IPCS, 1986). Combined exposure to asbestos and cigarette smoke synergistically increases the risk of lung cancer (IPCS, 1986).
- 2.5.3 Mesothelioma** Pulmonary mesothelioma is a primary malignant tumour of the mesothelial surfaces, generally affecting the pleura and less commonly the peritoneum. Mesothelioma has been associated with occupational exposure to various types and mixtures of asbestos (including talc containing asbestos), although occupational exposures have not been identified in all cases. The long latency required for mesothelioma to develop after asbestos exposure has been documented in a number of publications. An increasing proportion of cases have been seen with increasing duration of exposure (IARC, 1987). It has been suggested that increased risk of mesothelioma may be related to the duration and intensity of asbestos exposure, and perhaps also the time from first exposure (IPCS, 1986). Current information does not suggest an important differential of mesothelioma risk according to the industrial process (IPCS, 1986).
- The majority of known cases of mesothelioma arise as a result of occupational or para-occupational exposure to asbestos (IPCS, 1986). No association with smoking has been observed (McDonald, 1984 cited by IPCS 1986).
- Studies suggest that amphibole asbestos may result in the development of mesothelioma at lower levels of cumulative exposure than that required for lung cancer, although no reliable exposure-response curve can be produced for asbestos-induced mesothelioma in animals or humans (Meldrum, 1996 cited by E.C., 1997). Bignon (1997 cited by E.C., 1997) states that mesothelioma can develop at doses of maybe 10 to 1,000 times lower

than those required for broncho-pulmonary cancer.

2.5.4 Other malignant effects In a review of studies, IPCS (1986) has found that some studies suggest that cancer at sites other than the lung, pleura and peritoneum has resulted from occupational exposure to asbestos, while others have shown no excess of cancer at other sites. IARC (1987) reports that gastrointestinal cancers occurred at an increased incidence in groups occupationally exposed to asbestos, although not all studies are consistent in this respect.

2.6 Summary of mammalian toxicity and overall evaluation Fibrosis in many animal species, and bronchial and pleural carcinomas in the rat, have been observed following inhalation of amphibole asbestos. In these studies there were no consistent increases in tumour incidence at other sites, and there is no convincing evidence that ingested asbestos is carcinogenic in animals (IPCS, 1986). Epidemiological studies, mainly on occupational groups, have established that all types of asbestos fibres are associated with diffuse pulmonary fibrosis (asbestosis), bronchial carcinoma (lung cancer), and primary malignant tumours of the pleura and peritoneum (mesothelioma). That asbestos causes cancers at other sites is less well established. Cigarette smoking increases the asbestosis mortality and the risk of lung cancer in persons exposed to asbestos but not the risk of mesothelioma (IPCS, 1986).

3 Human exposure/Risk evaluation

- 3.1 Food** The extent of asbestos contamination of solid foodstuffs has not been well studied. Asbestos fibres have been detected in beverages. Up to 12×10^6 fibres/litre have been found in soft drinks (IPCS, 1986).
- 3.2 Air** At remote rural locations, fibre levels ($> 5\mu\text{m}$) are generally < 1 fibre/litre (< 0.001 fibre/ml) and in urban air they range from < 1 to 10 fibres/litre (0.001 to 0.01 fibres/ml) or occasionally higher. Airborne levels in residential areas in the vicinity of industrial sources have been found to be within the range of those in urban areas or occasionally slightly higher. Non-occupational indoor levels are generally within the range found in ambient air (IPCS, 1986; 1998).
- 3.3 Water** Reported concentrations of asbestos in drinking-water range up to 200×10^6 fibres/litre (all fibre lengths) (IPCS, 1986).
- 3.4 Occupational exposure** Occupational exposure levels vary depending on the effectiveness of dust-control measures; they may be up to several hundred fibres/ml in industry or mines without or with poor dust control, but are generally well below 2 fibres/ml in modern industry (IPCS, 1986).

Among occupational groups, exposure to asbestos poses a health hazard that may result in asbestosis, lung cancer and mesothelioma. The incidence of these diseases is related to fibre type, fibre size, fibre dose and industrial processing (IPCS, 1986).

The European Community notification noted that exposure of workers and other users of asbestos containing products is in general technically extremely difficult to control in practice, and may greatly exceed current limit values on an intermittent basis. It was recognized that a controlled and safe occupational use of asbestos could not be established for several working situations like e.g. building sites, repairs, or waste removal. As asbestos was widely used and no safe concentration threshold could be established it was decided to severely restrict the use of asbestos.

The Chile notification noted that in general the highest exposures to asbestos are amongst the working population whether during manufacture of materials containing asbestos or during installation or demolition. In Chile this means in particular those workers who have been exposed to fibres from the manufacture of construction materials. In the case of brake linings or parts that contain asbestos, not only the workers who handle asbestos during manufacture are exposed to high risk, so are brake repair workshop mechanics who blow off the dust produced by wear. Health controls over this activity are very difficult to implement because of its very nature. In many cases, the workshops involved are small ones that do not have the occupational health means to control the risks.

3.5 Para-occupational exposure Members of the families of asbestos workers handling contaminated work clothes and, in some cases, members of the general population may be exposed to elevated concentrations of airborne asbestos fibres. Asbestos has been used widely in building materials for domestic application (e.g. asbestos-cement products and floor tiles) and elevated airborne levels have been measured during the manipulation of these materials (e.g. home construction and renovation by the homeowner) (IPCS, 1986).

In para-occupational groups, which include persons with household contact and neighbourhood exposure, the risk of mesotheliomas and lung cancer is generally much lower than for occupational groups. Risk estimation is not possible because of the lack of exposure data required for dose-response characterization. The risk of asbestosis is very low (IPCS, 1986).

The Chile notification notes that asbestos fibres are not easily released from asbestos in a cement matrix, in sheeting used in construction. However, people who cut or trim such sheeting using high-speed tools (circular saws or sanders) are exposed to risk from the asbestos-fibre dust given off.

3.6 Public exposure

In the general population, the risks of mesothelioma and lung cancer attributable to asbestos cannot be quantified reliably and are probably undetectably low. The risk of asbestosis is virtually zero. (IPCS, 1986). See also sections on occupational and para-occupational exposure above.

4 Environmental fate and effects

5 Environmental Exposure/Risk Evaluation

Environmental effects are not relevant to the risk evaluation used to support the regulatory decisions.

Annex 2 – Details on final regulatory actions reported – Other amphibole forms

Country Name: Australia

- | | | |
|-----|--|---|
| 1 | Effective date(s) of entry into force of actions Reference to the regulatory document | <p>Most jurisdictions placed severe restrictions on asbestos use during the late 1970's and early 1980s (some of the legislation under which the current restrictions are in force was enacted during the 1990s and incorporated/superseded existing restrictions).</p> <p><u>Commonwealth</u> – <i>Industrial Safety Health and Welfare (Administrative and General) Regulation 1979.</i></p> <p><u>New South Wales</u> – <i>Factories (Health and Safety – Asbestos Process) Regulations 1984 under Factories, Shops and Industries Act 1962; Occupational Health and Safety (Hazardous Substances) Regulation 1996 under Occupational Health and Safety Act 1983.</i></p> <p><u>Northern Territory</u> – <i>Work Health (Occupational Health and Safety) Regulations 1996 under Work Health Act 1996.</i></p> <p><u>Queensland</u> – <i>Workplace Health and Safety Regulation 1997 under Work Health and Safety Act 1995.</i></p> <p><u>South Australia</u> – <i>Occupational Health, Safety and Welfare Regulations 1995 under Occupational Health, Safety and Welfare Act 1986.</i></p> <p><u>Tasmania</u> – <i>Industrial Safety Health and Welfare (Administrative and General) Regulation 1979.</i></p> <p><u>Victoria</u> – <i>Occupational Health and Safety (Asbestos) Regulations 1992 under Occupational Health and Safety Act 1985.</i></p> <p><u>Western Australia</u> – <i>Occupational Health Safety and Welfare Regulation 1988; Health (Asbestos) Regulations 1992 under Health Act 1911.</i></p> |
| 2 | Succinct details of the final regulatory action(s) | Amphibole forms of asbestos severely restricted. Legislation is primarily through States and Territories. |
| 3 | Reasons for action | Carcinogenic when inhaled. Should minimise exposure of people to risk of inhalation of amphibole asbestos. |
| 4 | Basis for inclusion into Annex III | |
| 4.1 | Risk evaluation | The basis of the Australian regulatory actions was human health risk assessments, taken at national and state level that focussed on the carcinogenicity of inhaled asbestos and conditions of exposure in that country. |
| 4.2 | Criteria used | Unacceptable risk to human health. Regulatory actions for asbestos were taken incrementally, reflecting the building knowledge on its risks. The major health effects identified as a result of inhalation of amphibole asbestos are asbestosis and carcinogenicity (NHMRC, 1982). |
| | Relevance to other States and Region | |
| 5 | Alternatives | No information available |
| 6 | Waste management | No information available |
| 7 | Other | <p>Actinolite, amosite, anthophyllite, tremolite are listed in the Australian National Occupational Health and Safety Commission (NOHSC) <i>Draft</i> List of Designated Hazardous Substances, with the classification:</p> <p>Carcinogen. Cat.1</p> <ul style="list-style-type: none"> • R45 – May cause cancer <p>Toxic (T) R48/23 – Toxic: danger of serious damage to health by prolonged exposure through inhalation</p> <p>No exposure standards available Previously TWA was 0.1 fibre/ml. <i>NOHSC: 10005(1999)</i>. Currently being reviewed by Chemicals Framework Team under the National Occupational Health & Safety Commission.</p> |

Country Name: Chile

| | | |
|------------|---|---|
| 1 | Effective date(s) of entry into force of actions | Supreme Decree No. 656 entered into force 180 days after its publication in the Official Journal, on 12 July 2001. |
| | Reference to the regulatory document | Supreme Decree No. 656 of 12 September 2000, Official Journal, 13 January 2001 |
| 2 | Succinct details of the final regulatory action(s) | <p>Production, importation, distribution, sale and use of crocidolite and any material or product containing it are prohibited.</p> <p>Production, importation, distribution, sale and use of construction materials containing any type of asbestos are prohibited.</p> <p>Production, importation, distribution, sale and use of chrysotile, actinolite, amosite, anthophyllite, tremolite and any other type of asbestos, or mixture thereof, for any item, component or product that does not constitute a construction material are prohibited, with certain specific exceptions.</p> |
| 3 | Reasons for action | <p>Human Health</p> <p>To reduce exposure to asbestos amongst the working population during manufacture of material containing asbestos or during installation or demolition.</p> |
| 4 | Basis for inclusion into Annex III | - |
| 4.1 | Risk evaluation | <p>The foreign literature and analysis of domestic cases of asbestosis and mesothelioma indicate that those at greatest risk are workers who handle asbestos fibres for various uses.</p> <p>In Chile, this means in particular those workers who have been exposed to fibres from the manufacture of construction materials.</p> <p>No epidemiological precedents are known that show that there is a risk to the population from asbestos which is already included within a cement matrix in sheeting used in construction, given that the asbestos fibres are not easily released from the matrix. Nor is there any significant known risk from consuming water piped through asbestos cement piping.</p> <p>Nevertheless, people who cut or trim such sheeting using high-speed tools (circular saws or sanders) are exposed to risk from asbestos-fibre containing dust given off.</p> <p>In the case of brake lining or parts that contain asbestos, not only the workers who handle asbestos during manufacture are exposed to high risk, so are brake repair workshop mechanics who blow off the dust produced by wear. It should be noted that health controls over this activity are very difficult to implement because of its very nature. In many cases, the workshops involved are small ones that do not have the occupational health means to control the risks.</p> |
| 4.2 | Criteria used | <p>Unacceptable risk to workers.</p> <p>All types of asbestos are hazardous to health to varying degrees depending on the form of exposure (it has been shown that the risk is from inhalation), the class of asbestos, the size of the fibres, fibre concentration and interaction with other factors (tobacco smoking potentiates the effects). Generally speaking, the highest exposures are amongst the working population whether during manufacture of the materials containing asbestos or during installation or demolition.</p> |
| | Relevance to other States and Region | The regulatory action prohibits imports of asbestos in general, whatever the country of origin. Therefore no country may export asbestos to Chile except in specific cases, which exclude material and inputs for construction material and must be expressly authorized by Health Authority. |
| 5 | Alternatives | <p>It has been proved that it is feasible to replace asbestos with other fibres in manufacturing fibre-cement materials and still obtain products of similar quality. In fact, the company producing the greatest quantity of panels and sheeting for dwellings in Chile has replaced asbestos with other fibres such as cellulose.</p> <p>In case of brake parts, asbestos-containing and asbestos-free brake pads and linings are in use until the existing in use asbestos-containing brake pads and linings at the time of publication of the prohibition should be replaced.</p> |
| 6 | Waste management | No information available. |

7 Other

Amosite and others forms of asbestos are listed in the Chilean Regulations on Basic Sanitary and Environmental Conditions in Workplaces (Supreme Decree No. 594), with the classification: A.1 Proved Human Carcinogen.

In accordance with the Chilean Regulations on Basic Sanitary and Environmental Conditions in Workplaces (Supreme Decree No. 594), Amosite fibres exposure limit value for workers is 0.4 fibres/cc determined by means of a contrast microscope with magnifying potency of 400–450, in a sample from a membrane filter, counting fibres greater than 5_μm length and a ratio length to diameter equal to or greater than 3:1. For other types of asbestos, except crocidolite and amosite, fibres exposure limit value for workers is 1.6 fibres/cc determined by means of a contrast microscope with magnifying potency of 400–450, in a sample from a membrane filter, counting fibres greater than 5_μm length and a ratio length to diameter equal to or greater than 3:1.

| |
|---|
| Country Name: European Community |
|---|

- | | | |
|------------|---|--|
| 1 | Effective date(s) of entry into force of actions | Regulatory action was first taken in 1983, in relation to crocidolite. Subsequently, such action has progressively been extended to all forms of asbestos. The latest regulatory action entered in force on 26.8.1999 (OJ L 207 of 6.8.1999, p. 18). Member States of the E.C. were obliged to implement the necessary national legislation at the latest by 1 st January 2005. |
| | Reference to the regulatory document | Directive 1999/77/ E.C. of 26.7.1999 (Official Journal of the European Communities (OJ) L207 of 6.8.99, p.18) adapting to technical progress for the sixth time Annex 1 to Directive 76/769/EEC of 27.7.1976 (OJ L 262 of 27.9.1976, p.24). Other relevant Regulatory Actions: Directives 83/478/EEC of 19.9.1983 (OJ L 263 of 24.9.1983, p.33), 85/610/EEC of 20.12.1985 (OJ L 375 of 31.12.1985, p.1), 91/659/EEC of 3.12.1991 (OJ L 363 of 31.12.91, p.36) |
| 2 | Succinct details of the final regulatory action(s) | The placing on the market and use of amosite, anthophyllite, actinolite or tremolite fibres and products containing these fibres added intentionally are prohibited. The use of products containing asbestos fibres that were already installed and/or in service before the implementation date of Directive 1999/77/ E.C. by the Member State concerned could continue to be authorised until they are disposed of, or reach the end of their service life. However, Member States could, for reasons of protection of health, prohibit within their territory the use of such products before they are disposed of or reach the end of their service life. |
| 3 | Reasons for action | Prevent health effects (asbestosis, lung cancer, mesothelioma) for workers and general public. |
| 4 | Basis for inclusion into Annex III | |
| 4.1 | Risk evaluation | A comparison of asbestos with possible substitutes by the Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) concluded that all forms of asbestos are carcinogenic to humans and are likely to present a greater risk than substitutes (CSTEE, 1998). |
| 4.2 | Criteria used | Standard E.C. criteria used for evaluation of exposure. |
| | Relevance to other States and Region | Health problems similar to the ones experienced in the E.C. may occur in states where the substance is used in industrial plants and/or as building material, especially in developing countries, where the use of asbestos is still growing. A ban protects health of workers and of the general public. |
| 5 | Alternatives | The risk assessment under taken by the CSTEE on chrysotile asbestos and candidate substitutes would be relevant for other variants of asbestos also. It concludes that, both for the induction of lung and pleural cancer and lung fibrosis and for other effects, it is unlikely that the alternatives cellulose fibres, PVA fibres or P-aramid fibres pose an equal or greater risk than chrysotile asbestos. With regard to carcinogenesis and induction of lung fibrosis the risk is regarded to be lower (CSTEE, 1998). |
| 6 | Waste management | In accordance with Council Directive 87/217/EEC (OJ L 85, 28.3.1987, p.40), as amended by Council Directive 91/692/EEC (OJ L 377, 31.12.1991, p.48) on the demolition of buildings, structures and installations containing asbestos and the removal of asbestos or materials containing asbestos therefrom or materials containing asbestos involving the release of asbestos fibres or dust must not cause significant environmental pollution. Construction materials have been classified as hazardous waste and will thus, as from 1 January 2002, have to be disposed of in line with the obligations laid down in Council Directive 91/689/EEC (OJ L 377, 31.12.1991, p.20). In addition, the Commission is considering measures to promote the practice of selective demolition in order to segregate the hazardous waste present in construction materials and ensure their safe disposal. |
| 7 | Other | In accordance with Council Directive 83/477/EEC (OJ L 263, 24.9.1983, p.25), as amended by Council Directive 91/382/EEC (OJ L 206, 29.7.1991, p.16) the European Community exposure limit values for workers are currently 0.3 fibres/ml for forms of asbestos other than chrysotile. Exposure limit values for workers: Proposal still under consideration before the Council and the European Parliament: in 2001 the European Commission proposed (OJ C 304 E 30/10/2001, p.175) that these limits be replaced by a reduced, single limit value of 0.1 fibres/ml for all forms of asbestos. |

Annex 3 – Addresses of designated national authorities

AUSTRALIA

P

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EUROPEAN COMMUNITY

CP

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C Industrial chemicals

CP Pesticides, industrial chemicals

P Pesticides

Annex 4 – References – Other amphibole forms

Regulatory action

Australia

Commonwealth of Australia – *Industrial Safety Health and Welfare (Administrative and General) Regulation 1979*.

New South Wales – *Factories (Health and Safety – Asbestos Process) Regulations 1984 under Factories, Shops and Industries Act 1962; Occupational Health and Safety (Hazardous Substances) Regulation 1996 under Occupational Health and Safety Act 1983*.

Northern Territory – *Work Health (Occupational Health and Safety) Regulations 1996 under Work Health Act 1996*.

Queensland – *Workplace Health and Safety Regulation 1997 under Work Health and Safety Act 1995*.

South Australia – *Occupational Health, Safety and Welfare Regulations 1995 under Occupational Health, Safety and Welfare Act 1986*.

Tasmania – *Industrial Safety Health and Welfare (Administrative and General) Regulation 1979*.

Victoria – *Occupational Health and Safety (Asbestos) Regulations 1992 under Occupational Health and Safety Act 1985*.

Western Australia – *Occupational Health Safety and Welfare Regulation 1988; Health (Asbestos) Regulations 1992 under Health Act 1911*

Chile

Supreme Decree No. 656 of 12 September 2000, Official Journal, 13 January 2001

European Community

Directive 1999/77/ E.C. of 26.7.1999 (Official Journal of the European Communities (OJ) L207 of 6.8.99, p.18) adapting to technical progress for the sixth time Annex 1 to Directive 76/769/EEC of 27.7.1976 (OJ L 262 of 27.9.1976, p.24). Other relevant Regulatory Actions: Directives 83/478/EEC of 19.9.1983 (OJ L 263 of 24.9.1983, p.33), 85/610/EEC of 20.12.1985 (OJ L 375 of 31.12.1985, p.1), 91/659/EEC of 3.12.1991 (OJ L 363 of 31.12.91, p.36)

Other Documents

NHMRC (1982) National Health and Medical Research Council (NHMRC) Report on the Health Hazards of Asbestos (*Adopted by the in June 1981 and published in 1982*)

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