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**HEALTH & ENVIRONMENTAL RISK ASSESSMENT REPORT**  
**FOR**  
**“TOPRO 94”**

**(DALRRD Reg. No: L4824 Act No: 36 of 1947)**

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**CONTENTS**

	<b>Page</b>
<b>SHORT SUMMARY OF RISK ASSESSMENT REPORT OUTCOME .....</b>	<b>2</b>
<b>1. BACKGROUND .....</b>	<b>2</b>
<b>2. PRODUCT DETAILS .....</b>	<b>3</b>
<b>3. RISK ASSESSMENT .....</b>	<b>4</b>
<b>4. RISK MANAGEMENT .....</b>	<b>6</b>
<b>5. EXCEPTIONAL CIRCUMSTANCE .....</b>	<b>8</b>
<b>6. ECONOMIC IMPORTANCE .....</b>	<b>9</b>
<b>7. DISCUSSION .....</b>	<b>9</b>
<b>8. CONCLUSIONS .....</b>	<b>10</b>
<b>9. RECOMMENDATION .....</b>	<b>10</b>
<b>10. REFERENCES .....</b>	<b>11</b>

## SHORT SUMMARY OF RISK ASSESSMENT REPORT OUTCOME

Because **Topro 94** is an industrial wood preservative restricted to “For industrial use only”, it is not sold to the public and therefore poses no direct threat or risk to the general public. Exposure to inorganic borates is restricted to personnel involved in (i) the manufacturing of, and (ii) the application of these wood preservatives at industrial timber treatment plants that are approved by the NRCS (National Regulator for Compulsory Specifications) and certified by SANAS (South African National Accreditation System) accredited certification bodies in accordance with the provisions and requirements of SANS 10005 and SANS 1288. Potential risk of direct exposure to inorganic borates during the manufacture and application of the borate wood preservatives is manageable through the correct handling and use by properly trained people wearing the appropriate PPE. Apart from this, there is also no clear evidence that occupational exposure to inorganic borates in practice poses a reproduction risk to humans. Therefore, when manufactured and used in a controlled manner for the purpose it is meant for, there is no need for **Topro 94** to be phased out. It is also important to note that **Topro 94** qualifies as “an exceptional circumstance where there is no other agricultural remedy available for its intended use”. The continued registration and availability of **Topro 94** as a diffusible wood preservative for treatment of timber is of definite economic importance, especially when considering that application can also be done by a simple dip diffusion treatment process that not only requires low capital investment, but is also a much less complicated treatment process when compared to conventional vacuum/pressure impregnation. Lastly, when used under normal conditions of good building practice, no long-term health effects have been reported as far as the potential release of boron from boron-treated timber is concerned.

### 1. BACKGROUND

The new Regulations relating to Agricultural Remedies (No. 3812) under the Fertilizer, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act No. 36 of 1947), were promulgated on 25 August 2023 [1].

In a notification addressed to “All Regulatory Holders” that was circulated on 14 April 2022, the Registrar (Act No.36 of 1947) of the Department of Agriculture, Land Reform and Rural Development has stated his intention that, when renewal of registrations become due during 2024, he will pay special attention to pesticides that pose an unmanageable risk with an understanding that the use of those pesticides should be prohibited and phased-out, including active ingredients and their formulations that meet the criteria of carcinogenicity, mutagenicity and reproductive toxicity (CMR) categories 1A or 1B when classified according to the Globally Harmonized System of Classification and Labelling of Chemicals (“the GHS”).

However, regulatory decisions taken about the permissible use of a particular pesticide should be taken after carefully weighing up the benefits that they confer against any possible adverse effects. Regulatory decisions will involve risk assessment that will be evaluated by focusing on whether the health and environmental risks posed by the pesticide, when used as directed, are acceptable or not [1].

The Registrar may grant registration of an implicated agricultural remedy when the following conditions are met:

- The risk to humans, animals or the environment from exposure to the active substance in the agricultural remedy, under realistic worst-case conditions of use, is negligible.

- Not approving the active substance would have a disproportionate negative impact on society when compared with the risk to human health, animal health or the environment arising from the use of the substance [1].

The Registrar has indicated that the use of GHS Category 1A and 1B classified products may be exempt from prohibition in exceptional circumstances where the risk(s) presented by the product are manageable if used according to the label instructions and where there is no other agricultural remedy for the intended use[1].

A specific prerequisite under regulation 8.(7) of the new Regulations relating to Agricultural Remedy (No. 3812), is that a risk assessment report explaining why the use of a GHS Category 1A and/or 1B classified pesticide should not be prohibited in South Africa, must be published by the registration holder for public comment before applying for registration renewal of such a product. If successful, approval of such an agricultural remedy may be granted for a specified period and for restricted uses [1].

It is important to keep in mind that public exposure to chemicals that meet any of the criteria of CMR categories under the GHS requires careful assessment. Although the argument is about hazards in the CMR category according to the GHS, the deciding factor should be the likelihood of the risk of exposure to such chemicals. Therefore, risk assessments must be evaluated by focusing on whether the health and environmental risks posed by the pesticide, when used as directed, are manageable and acceptable.

Inorganic borates have been classified as a CMR Health hazard: Reproductive toxicity, GHS Category 1B (H360FD: May damage fertility or the unborn child) [2]. This report therefore deals with health and environmental risks and management of risks associated with inorganic borates, from manufacturing up to its end use as a wood preserving chemical product, in this case **Topro 94** that is a wood preservative comprising a mixture of boric acid and borax pentahydrate. The report also considers whether there are exceptional circumstances that would permit the use of **Topro 94** and that, when used in accordance with the label instructions, its risk to human health and the environment is trivial and manageable, thereby meeting the necessary requirements for approval of the application for renewal of its current registration.

## 2. PRODUCT DETAILS

This risk assessment report is applicable to the following agricultural remedy/product:

### 2.1 Product trade name

“Topro 94”

### 2.2 Product type

Boron-based wood preservative granular powder

### 2.3 Product description and use

**Topro 94** is a water-soluble borate wood preservative granular powder for treatment of all timbers used indoors (Hazard Class H2) as well as timber used outdoors, above ground (Hazard Class H3). It provides permanent protection against wood decay fungi, wood boring insects and drywood termites when applied in accordance with SANS 10005 [3] and SANS 1288 [4].

## 2.4 Registration status

DALRRD Reg. No: L4824 (Act No: 36 of 1947)

## 2.5 Active ingredients

A mixture of inorganic borates in the form of boric acid and borax pentahydrate, conforming to a SANS 871, Type II boron timber preservative [5].

## 2.6 Unique product feature

Wood preservatives such as **Topro 94**, consisting of inorganic borates, have the unique feature of being able to penetrate timbers that are regarded as impermeable to treatment with other wood preservatives by conventional vacuum/pressure impregnation processes. Inorganic borates can penetrate any moist timber, whether permeable or impermeable, by the process of diffusion via the moisture in the wood.

It is the only recognized wood preservative that can rapidly spread throughout moist wood by the process of diffusion and can therefore be applied by either conventional vacuum/pressure impregnation or by means of a relatively simple dip diffusion process. In the latter case, moist or green timber is submersed in a concentrated borate solution for a redetermined time and then close stacked and wrapped to contain the moisture in the wood until the required depth of preservative penetration through the process of diffusion has been obtained, generally after a holding period of about 2 to 3 weeks, depending on the timber dimensions.

## 2.7 Registration holder

CMC Chemicals (Pty) Ltd t/a TimberLife  
31 Axle Street, Silverton Ext. 52, Pretoria

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**NOTE: Topro 94 and Thatchpro** are identical products as far as their active ingredients and formulation compositions are concerned. **Topro 94** is a wood preservative for the treatment and protection of timber against wood boring insects, termites and decay fungi. **Thatchpro** on the other hand, is marketed and supplied in combination with **Thatchcon** as a dual-purpose preservative and fire-retardant treatment, known as **Thatchbor FR**, for the protection of thatching grass and reed against insect attack, decay fungi as well as fire.

## 3. RISK ASSESSMENT

### 3.1 CMR Health hazard classification

A full scientific rationale for the GHS classification of **Topro 94** (DALRRD Reg. No. L4824), Report No 078-2022, Rev 4.0 was prepared by INFOTOX (Pty) Ltd [2]. This rationale not only forms the basis for the GHS classification of **Topro 94** but also for its revised Safety Data Sheet as amended.

Inorganic borates have been classified as a CMR Health hazard: Reproductive toxicity, GHS Category 1B (H360FD: May damage fertility or the unborn child) [2].

It is important to note that, although the GHS classification denotes inorganic borates as substances of concern, they are not banned substances, globally nor in South Africa.

### 3.2 Health risk assessment

Apart from being non-flammable, non-combustible and non-explosive, inorganic borates are of low acute oral and dermal toxicity and do not have any carcinogenic or mutagenic potential. The fact that they have been classified as GHS Category 1B substances with regards to reproductive toxicity, it is the only CMR health risk of concern. In this case the toxicological endpoints of concern arise from feeding studies in laboratory animals and relate to effects on fertility as well as developmental effects at high doses [2, 6, 7].

Animal ingestion studies in several species, at high doses, indicate that borates cause reproductive and developmental effects [8]. A human study of occupational exposure to borate dust showed no adverse effect on reproduction. A recent epidemiological study and a peer reviewing report of the past epidemiological studies conducted in China didn't show any negative effect of boron on human fertility [9]. A study conducted in Turkey with boron exposed mine workers showed that mean blood concentrations of the high exposure group is ~6 times and ~9 times lower than those of the highest no effect level of boron in blood with regard to developmental and reprotoxic effects (respectively) in rats. With those findings, no unfavourable effects of boron exposure on reproductive indicators are observed in humans [10, 11].

Therefore, although prolonged over-exposure in the occupational setting may impact on fertility and the developing foetus, it should be noted that the GHS Category 1B classification is based on animal tests where animals were exposed to high doses of boric acid over long periods of time. These doses are multiple times higher than what humans are exposed to under conditions of normal handling and use [2, 12].

Developmental or fertility effects have never been demonstrated in human beings even among population groups with high exposure to borates. Borates do not accumulate in the body and are rapidly excreted with a half-life less than 24 hours [12].

Another point of interest is the fact that inorganic borates have been safely used in household cleaning products such as detergents for nearly a century with no reported negative effects [12].

Because **Topro 94** is manufactured and supplied as a solid granular product and not as a fine powder, during application there is:

- (i) a low risk of exposure to borate dust through inhalation,
- (ii) a relatively low risk of exposure through skin absorption,
- (iii) a low risk of eye irritation that may be caused by exposure to borate dust.

In their latest publication (updated: 07 March 2023), BRANZ reports that "Under normal conditions with good building practice, boron from boron-treated timber has no reported long-term health effects" [13].

### 3.3 Environmental risk assessment

Inorganic borates are naturally occurring in the ground and are widely distributed in the environment. Borates are essential micronutrients for the healthy development of all higher plants. In the case of borate poor or deficient soils, boron containing fertilizers are administered in small quantities to ensure healthier plant growth [12].

However, large amounts of inorganic borates can be harmful to plants and other species. Therefore, the product should only be used as part of a balanced plant nutrition program, preferably after soil and/or tissue analysis. Accidental releases to the environment should be avoided or at least minimized [6].

The water solubility of borates also means that they are widely dispersed and do not bio-accumulate in the environment. In the case of a spill, the rate at which inorganic borates will be dispersed in soil will depend on the soil type, the soil moisture content and the amount and concentration of the spill [12].

In the rationale for the GHS classification of **Topro 94** that was done by Fourie [2], a classification of hazardous to the aquatic environment, over acute or chronic periods of exposure, is not proposed for **Topro 94**. It is further noted that none of the boric acid or borax pentahydrate active ingredients used in the manufacture of **Topro 94**, are classified as acute chronic hazards to the aquatic environment [2].

## 4. RISK MANAGEMENT

### 4.1 Manufacturing process

**Topro 94** is manufactured inside the Timberlife factory building. The predetermined quantities of boric acid and borax pentahydrate (supplied in 25 kg bags) are added to a slow speed tumble blender in 800 kg batch sizes. The tumble blender is then closed and sealed off before the mixing process starts. After one hour of blending, the tumble blender is stopped, and the contents drained into open top steel containers before being packed and sealed in 25 kg HDPE bags.

A Production Control Sheet detailing the required mixing instructions and procedures as well as a list of essential personal protective equipment to be worn is issued and signed off for each batch of product manufactured.

Only fully trained staff are allowed to take part in the manufacturing process. Full protective clothing, rubber gloves and dust masks are worn during the tumble blender loading and emptying as well as during the packing phase of the manufacturing process.

**Topro 94** is manufactured in accordance with the South African National Standard SANS 871:2017, Edition 2.1 that specifies the minimum requirements for the manufacturing and quality control procedures for boron timber preservatives [5].

Section 8 of the Occupational Health and Safety Act, Act No. 85 of 1993 stipulates that employers in South Africa shall provide and maintain, as far as is reasonably practicable, a working environment that is safe and without risk to employee's health. In this regard, CMC Chemicals (Pty) Ltd t/a TimberLife has appointed an accredited company, specializing in occupational health and safety requirements, to draw up and manage a formal occupational health risk management plan for the company that outlines occupational hazards and risks, exposure monitoring, and medical surveillance, in accordance with the Regulations outlined in Section 4 [14].

### 4.2 Packaging and transport

Inorganic borates are not classified as acutely toxic by inhalation, oral or dermal exposure. Therefore, these substances are not dangerous for transport and no special precautionary transport measures are necessary.

No specific packaging group has been assigned under UN transport regulations.

### 4.3 Handling and use of Topro 94

**Topro 94** is registered “For industrial use only”. It is therefore used in restricted industrial applications and is not available for purchase and use by the general public.

Certified wood preservative treatment plants are designed, constructed and operated in accordance with relevant SANS standards or equivalent codes of practice to minimize exposure of people involved in the treatment process to the product and treatment solution as well as preventing the potential release of these chemicals into the environment.

Various South African National Standards have been published by the South African Bureau of Standards, some of which are listed below:

- South African National Standard SANS 10005:2020, Edition 9 provides specific guidance on the preservative treatment of timber. The purpose of this standard is “to give guidance on required timber treatment processes and preservatives and to establish a common basis of methods and criteria for the timber industry”. The standard also gives recommendations to the handling and safety of preservative treated timber [3].
- South African National Standard SANS 1288:2020, Edition 4 specifies the penetration and retention requirements for preservative-treated timber. The standard also outlines the importance of treatment of timber in the economy of South Africa and states that “All timber, when exposed under certain conditions, is subject to attack by wood-destroying organisms, the more common destructive organisms being fungi, wood-destroying insects, marine borers and bacteria” [4].
- South African National Standard SANS 10255: 2015, Edition 3 is a comprehensive guidance document for the safe design, construction, operation and management of timber treatment plants and facilities. The standard also lists a range of other SANS documents as normative references [15].

It is also important to note that the South African National Standards are aligned with best practices applied by industry organizations and bodies regulating the operation of state-of-the-art wood treatment facilities in the European Union.

In addition to the SANS specification and guidance standards, occupational exposure to hazardous substances is controlled in South Africa under the Regulations for Hazardous Chemical Agents of the Occupational Health and Safety Act, 1993 (Act No. 85 of 1993) [14]. All timber treatment facilities have to comply with these regulations and implement occupational health risk management plans.

Both the Safety Data Sheet and the product label for **Topro 94** have been revised in accordance with the guideline on the implementation of the Globally Harmonized System of the classification and labelling of chemicals, issued by the Department in March 2022 [16]. The Safety Data Sheet and product label information serve to ensure that management of the product in all its applications will be safe and in accordance with the relevant health and environmental requirements.

As already mentioned, **Topro 94** is marketed and supplied certified treaters as a wood preservative for the treatment and protection of timber against wood boring insects, termites and decay fungi.

The packaging label clearly stipulates the following:

- FOR INDUSTRIAL USE ONLY
- READ THE LABEL BEFORE USE
- KEEP OUT OF REACH OF CHILDREN, UNINFORMED PERSONS AND ANIMALS

The label also provides clear “DIRECTIONS FOR USE” for (i) “PRESSURE IMPREGNATION” and (ii) “DIFFUSION TREATMENT” to ensure that the treatments are done strictly in accordance with the chemical manufacturer’s prescribed directions for use and that the required borate average net retention of 5 kg boric acid equivalent per m<sup>3</sup> is achieved as specified in South African National Standard SANS 1288:2020, Edition 4 [4].

Apart from all the necessary “WARNINGS”, the following are some of the more important “PRECAUTIONS” that are prescribed on the label:

- Obtain, read and follow all safety instructions before use. (Under “Directions for Use”).
- Wear suitable protective clothing, rubber gloves and eye protection when handling the powder.
- Avoid breathing dust and wear a dust mask when handling the powder.
- Wash hands and exposed skin thoroughly after handling and use.

The above demonstrates that the risk of direct exposure to the raw materials used in the manufacturing process as well as during the handling and use of **Topro 94** itself, is and can be safely and well managed.

#### 4.4 Handling and use of borate-treated timber

After treatment, the borates are deeply penetrated and distributed inside the wood structure, leaving relatively low concentrations of the physically accessible chemicals on the wood surface. Therefore, once dry, normal handling and use of the treated timber is unlikely to cause health problems because of the very small potential exposure to inorganic borates from contact with **Topro 94**-treated wood. As a result, risks due to exposure to inorganic borates in treated wooden structures are low, if not insignificant.

It would also appear that scientific evidence of an increase in public health risks associated with the use of borate-treated timber is lacking and that a decrease in public exposure to inorganic borates as a result of prohibiting the use of **Topro 94** in timber treatment will be impossible to demonstrate.

Although BRANZ [13] reports that boron from boron treated timber has no reported long-term health effects under normal conditions of good building practice, any fine wood dust is hazardous and all the necessary PPE such as eye protection, dusk masks, overalls and rubber gloves must be worn when the timber is machined.

## 5. EXCEPTIONAL CIRCUMSTANCE

Under regulation 8. (6), the Registrar has indicated that the use of GHS Category 1A and 1B classified products may be exempt from prohibition “... *in exceptional circumstances, where there is no other agricultural remedy for the intended use* ...” [1].

Inorganic borates are one of only two known chemical substances that can diffuse and move through timbers that are impermeable to treatment with other wood preservatives applied by conventional vacuum/pressure impregnation processes. The only other diffusible alternative



active ingredient is sodium fluoride. However, apart from being much more toxic and with a lower fungicidal efficacy than sodium borate, sodium fluoride has never been registered as a standalone wood preservative anywhere in the world.

Wood preservatives such as **Topro 94**, comprising of inorganic borates, can penetrate any moist timber, whether permeable or impermeable, by the process of diffusion via the moisture in the wood. It is therefore the only recognized wood preservative that can rapidly spread throughout moist wood by the process of diffusion and can therefore be applied by either conventional vacuum/pressure impregnation or by means of a relatively simple dip diffusion process.

As far as the availability of alternative products for the same intended end use is concerned, there are no other diffusible wood preservatives available, both locally and internationally. In the formulation of diffusible wood preservatives such as **Topro 94**, sodium borate is therefore a unique active ingredient that cannot be replaced with an alternative, which certainly makes this case an exceptional circumstance.

## 6. ECONOMIC IMPORTANCE

Inorganic borates are well known for its low mammalian toxicity with little to no impact on the environment if used correctly. They have been used as wood preservatives for well over 70 years with great success, primarily for treatment of timber used in interior structural applications. Together with other wood preservatives such as CCA and creosote, the use of inorganic borate formulations such as **Topro 94** are important to prevent or at least reduce the risk of economic losses that may result due to the adverse impacts of biodegradation on timber structures that have not been treated with an approved wood preservative.

Extending the service life of timber, especially when used in structural applications, by proper wood preservation not only prevent unwanted and unexpected early failures but also help to conserve and greatly reduce the pressure on our rather limited forest resources.

The fact that **Topro 94** can also be applied to timber by means of a simple dip diffusion process means that, instead of a rather complicated and highly expensive vacuum/pressure plant, a simple and relatively inexpensive dip tank with heating and mixing facilities can be used as a wood treatment facility. Apart from huge capital cost savings on plant and infrastructure requirements, the timber to be treated by dip diffusion does not to be dried before treatment and, as described under **2.6** above, requires a much less complicated treatment process when compared to conventional vacuum/pressure impregnation.

## 7. DISCUSSION

The potential risks of exposure during manufacture and application of wood preservatives to timber in general, are manageable through the correct handling and use by properly trained personnel and wearing of the required PPE. Incidental exposure of members of the general public to boron-based wood preservatives such as **Topro 94** in the outdoor environment, is also extremely unlikely and may be disregarded.

Exposure to inorganic borates is therefore limited to personnel involved in the manufacture of the boron-based wood preservatives and those involved in the application of these chemicals at certified commercial timber treatment plants.

Also, as reviewed in in this report, there are no viable alternatives to replace the borates in the applications where it is currently used.

In summary, health as well as environmental risks associated with the manufacture, handling and use of **Topro 94** are effectively managed through safe work procedures, engineering controls, personal protective equipment, worker training, good housekeeping, and occupational health risk management. It is also important to note that the use of **Topro 94** is restricted to industrial applications, i.e. “For industrial use only” and it is therefore not available for purchase and use by the general public.

As far as the potential release of boron from boron-treated timber is concerned, no long-term health effects have been reported when used under normal conditions of good building practice.

## 8. CONCLUSIONS

The risk assessments done show that **Topro 94**, classified as GHS Category 1B hazardous boron-based chemical product, poses no direct threat to the general public. It is also important to note is that the use of **Topro 94** is restricted to industrial applications, i.e. “For industrial use only”. Exposure to inorganic borates is restricted to personnel involved in (i) the manufacturing of, and (ii) the application of these wood preservatives at certified and well-regulated industrial treatment plants. The potential risk of direct exposure to inorganic borates during the manufacture and application of boron-based preservatives is manageable through the correct handling and use by properly trained people wearing appropriate PPE. Furthermore, there is no clear evidence that occupational exposure to inorganic borates in practice poses a reproduction risk to humans. Therefore, when manufactured and used in a controlled manner for the purpose it is meant for, there is no need for **Topro** to be phased out.

Although inorganic borates are substances of concern (Reproductive toxicity – GHS Category 1B), the risk of exposure to these substances when handled and used in accordance with the label instructions, is minimal. The risks associated with using **Topro** are therefore considered manageable provided that its use is restricted to “**For industrial use**” as indicated on the currently approved label.

**Topro 94** clearly qualifies as “an exceptional circumstance where there is no other alternative agricultural remedy available for the intended use” and its use should therefore not be prohibited.

Furthermore, the continued registration and availability of **Topro 94** as a diffusible wood preservative for treatment of timber is of definite economic importance, especially when considering that application can also be done by a simple dip diffusion treatment process that requires (i) low capital investment and (ii) a much less complicated treatment process when compared to conventional vacuum/pressure impregnation.

Lastly, when used under normal conditions of good building practice, no long-term health effects have been reported as far as the potential release of boron from boron-treated timber is concerned.

## 9. RECOMMENDATION

In the light of the above risk assessment and motivation for its continued use, it is recommended that the application for renewal of the **Topro 94** registration (DALRRD Reg.

No: L4824) be considered favourably for approval of its continued use in accordance with the label conditions and directions for use.

## 10. REFERENCES

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