
HEALTH & ENVIRONMENTAL RISK ASSESSMENT REPORT
FOR
“VIKA GEL”

(DALRRD Reg. No: L5823, Act No: 36 of 1947)

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SHORT SUMMARY OF RISK ASSESSMENT REPORT OUTCOME

Should **Vika Gel**, be restricted to “For industrial use” only as recommended in this Risk Assessment Report, it would then not be available for sale to the public. As a result of that, it should then also not pose any direct threat or risk to the general public. Exposure to the inorganic borates contained in **Vika Gel** would then be restricted to personnel involved in (i) the manufacturing of, and (ii) the contractors involved in the application of the **Vika Gel** chemical paste to wooden poles in service. The potential risk of direct exposure to inorganic borates during the manufacture and application of wood preserving pastes is manageable through the correct handling and use by properly trained people wearing appropriate PPE. Also noteworthy is the fact that, after treatment, the chemical paste is completely covered up by the plastic wrap applicator and is therefore inaccessible to any further physical contact. Therefore, when manufactured and used in a controlled manner for the purpose it is meant for, there is no need for **Vika Gel** to be phased out. It is also important to note that (i) **Vika Gel** qualifies as “an exceptional circumstance where (except for **Rempro** that is aimed at the broader wooden pole user market, excluding the power transmission and distribution pole users) there is no other agricultural remedy available for its intended use”, and (ii) the continued registration and availability of **Vika Gel** for remedial and supplementary treatment of wooden poles is of high strategic importance, especially to prevent unexpected failures of utility poles and ensure the uninterrupted supply of electricity via Eskom’s power transmission and distribution lines.

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 **Vika Gel** that, amongst other active ingredients, also contains a mixture of inorganic borates. The report also considers whether there are exceptional circumstances that would permit the use of **Vika Gel** 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

“Vika Gel”

2.2 Product type

Multi component fungicidal and termiticidal wood preserving paste

2.3 Product description and use

Vika Gel is a ready-for-use, thixotropic wood preserving paste, packed in a wrap applicator, for remedial and supplementary treatment of the external groundline portion of wooden poles in service to protect it against fungal decay and external attack by subterranean termites, thereby extending its service life.

2.4 Registration status

DALRRD Reg. No: L5823 (Act No: 36 of 1947)

2.5 Active ingredients

A mixture of copper naphthenate, 2-(thiocyanomethylthio) benzothiazole (TCMTB), cypermethrin and inorganic borates in the form of boric acid and borax pentahydrate.

2.6 Unique product feature

The inorganic borate active ingredient in **Vika Gel** has the unique feature of being able to penetrate any moist cellulosic material such as timber, whether permeable or impermeable, by the process of diffusion via the moisture in the material.

2.7 Registration holder

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

NOTE: Vika Gel and **Rempro** are similar products. **Vika Gel**, however, contains an additional insecticidal additive (cypermethrin) for added termite protection and is exclusively marketed and supplied to the power transmission and distribution pole user markets that are represented by Eskom and the larger Metros. **Vika Gel** is also the only wood preserving paste that has been approved in the Eskom Distribution Technical Bulletin: 08TB-020 for external remedial and supplementary treatment of their wooden power transmission and distribution poles [3]. Marketing and supply of **Rempro** on the other hand, is aimed at the rest of the wooden pole user markets.

3. RISK ASSESSMENT

3.1 CMR Health hazard classification

A full scientific rationale for the GHS classification of **Vika Gel** (DALRRD Reg. No. L5823), Report No 187-2022, Rev 1.0 was prepared by INFOTOX (Pty) Ltd [2]. This rationale not only forms the basis for the GHS classification of **Vika Gel** 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]. Therefore, in the case of **Vika Gel**, it is the mixture of inorganic borates that it contains in the form of boric acid and borax pentahydrate as part of its composition that is regarded as a “substance of concern”. This risk assessment is therefore mainly focused on the inorganic borate component of the **Vika Gel** formulation.

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, 4].

Animal ingestion studies in several species, at high doses, indicate that borates cause reproductive and developmental effects [5]. 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 [6]. 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 [7, 8].

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, 9].

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 [9].

A 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 [9].

Because **Vika Gel** is manufactured and supplied as a ready-for-use, thixotropic wood preserving paste, packed in a wrap applicator, during application there is:

- (i) no risk of exposure to borate dust through inhalation,
- (ii) a very low risk of exposure through skin absorption,
- (iii) no risk of eye irritation that may be caused by exposure to borate dust,
- (iv) a very low risk of exposure through oral intake.

Also, of importance is the fact that, after the wrap applicator filled with the chemical paste has been fitted around the pole, stapled into place and sealed off, the **Vika Gel** is completely covered up by the outside surface of the plastic wrap applicator and therefore inaccessible to any further physical contact.

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 [9].

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 [4].

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 [9].

The environmental hazard classification for **Vika Gel**, as a whole, has been reported as (i) Aquatic Acute Toxicity Category 1 (H400) and (ii) Aquatic Chronic Toxicity Category 1 (H410) [2].

4. RISK MANAGEMENT

4.1 Manufacturing process

Vika Gel is manufactured inside the Timberlife factory building. The raw materials are added to a steel mixing tank and subjected to high shear mixing for approximately 90 minutes. The mixture is then packed into the plastic wrap applicator at a rate of ± 11 kg per 10 m length and covered with a removal foilene plastic backing layer. Each 10 m length of wrap applicator filled with **Vika Gel** is rolled up and packed and sealed in a cardboard box.

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, dust masks and face shields are worn during the loading and emptying of the mixing tank as well as during the packing phase of the manufacturing process.

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 [10].

4.2 Packaging and transport

In the Safety Data Sheet for **Vika Gel**, under "14. Transport information", the UN proper shipping name for **Vika Gel** is stated as "Environmentally hazardous substance, solid, n.o.s.". The **Vika Gel** product is also regarded as a potential marine pollutant.

A packaging group III has been assigned under UN transport regulations for **Vika Gel**.

4.3 Handling and use of Vika Gel

Currently **Vika Gel** is registered "For DIY and industrial use". It is recommended that this be changed to "For industrial use" only in order to restrict its use to industrial applications and to ensure that **Vika Gel** is not available for purchase and use by the general public.

Both the Safety Data Sheet and the product label for **Vika Gel** 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 [11]. 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, **Vika Gel** is exclusively supplied to the power transmission and distribution pole users such as Eskom and the larger Metros. Only fully trained and accredited contractors are appointed and used by these companies to do the pole inspections and external chemical paste treatments. It is a prerequisite that all accredited inspectors are certified by a qualified inspection body as competent to perform inspections and supplemental treatments. The inspections are done in accordance with Eskom's and the Metros' own inhouse specifications while adhering to strict inhouse health and safety protocols as well as the warnings and precautions prescribed by the chemical paste manufacturer. The external wood preserving paste treatments are done strictly in accordance with the manufacturer's directions for use.

The label for **Vika Gel** clearly stipulates the following:

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

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

- Wear suitable protective gloves and clothing.
- Use only outdoors or in a well-ventilated area. Do not breath vapours.
- Thoroughly wash hands and contaminated skin with soap and water after use.
- Collect and re-use all waste as far as possible. Avoid release to the environment.

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 **Vika Gel** itself, is and can be safely and well managed.

4.4 Exposure to Vika Gel chemicals after application

After the wrap applicator filled with the chemical paste has been fitted around the pole, stapled into place and sealed off, the **Vika Gel** is completely covered up by the outside surface of the plastic wrap applicator and therefore inaccessible to any further physical contact.

NOTE: A revised South African National Standard on the inspection and supplemental treatment of treated wooden poles in ground contact, SANS 10324, Ed 2 is to be published before the end of 2024. This standard covers the in situ remedial and supplementary treatment of all treated wooden poles to protect it against internal and external fungal decay, including poles used in power transmission and distribution lines, street lighting as well as for other purposes such piling, structural and agricultural uses, shade netting, fencing, building and foundations [12].

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].

Wood preserving pastes are used specifically for remedial and supplementary treatment of the external portion of wooden poles in service to (i) eradicate any existing fungal decay and/or termite activity at or near the pole surface and (ii) prevent any further development of fungal decay and/or potential termite attack. **Vika Gel** is surface applied treatment and although all the other active ingredients in the formulation have limited penetration into the wood and therefore only provide relatively superficial protection against fungal decay, the inorganic borate component has the ability to diffuse and move through moist wood by the process of diffusion to arrest and kill wood rotting fungi at a much deeper depth inside the pole.

Sodium borate is one of only two known chemical substances that is able to diffuse and move through moist wood by the process of diffusion; the other diffusible alternative being sodium fluoride. However, apart from being much more toxic and with a lower fungicidal efficacy than inorganic borates, sodium fluoride has not been registered as a standalone diffusible wood preserving compound anywhere in the world.

As far as the availability of alternative products for the same intended end use is concerned, there are no other diffusible wood preserving pastes registered, both locally and internationally that do not contain sodium borate as the active ingredient or having sodium borate or sodium fluoride as part of the active ingredients, which certainly makes this case an exceptional circumstance.

6. STRATEGIC AND ECONOMIC IMPORTANCE

Vika Gel is used extensively in Eskom's and in some of South African Metro's power transmission and distribution lines as an external remedial and supplementary maintenance treatment to extend the service life of their wooden poles. Together with the **Rempro**, it is one of only two locally manufactured and DALRRD registered products available and approved in South Africa for this purpose and use.

Vika Gel is also the only locally manufactured wood preserving paste that is registered with DALRRD and that has been tested and approved for use as an external remedial and supplementary treatment for Eskom's power transmission and distribution poles [3].

Without regular supplementary maintenance treatment of wooden poles used in transmission and distribution lines, unexpected and in some cases relatively early failures of wooden poles may be experienced, resulting in extended power outages due to interruptions in electricity supply, potential costly claims as well as expensive and time-consuming pole replacements.

Remedial and supplementary maintenance treatment of Eskom's and some South African Metro's wooden poles with chemical pastes has now been done for nearly 30 years with great success in maintaining uninterrupted electricity supply and with huge economical savings in pole replacement costs.

In short, regular remedial and supplementary maintenance treatment of wooden poles, especially in the case of Eskom's power transmission and distribution network, is of critical importance to ensure the uninterrupted supply of electricity, especially in rural areas of South Africa.

7. DISCUSSION

The potential risks of exposure during manufacture and application of wood preserving pastes to wooden poles 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 containing wood preserving pastes such as **Vika Gel** in the outdoor environment, is also extremely unlikely and may be disregarded.

Exposure to inorganic borates contained in the **Vika Gel** product is therefore restricted mainly to personnel involved in the manufacture of the wood preserving paste and those involved in the application of these chemical pastes to wooden poles in service.

Also, as reviewed in in this report, there are no viable alternatives to replace borates in the **Vika Gel** formulation and in the applications where it is currently used for.

In summary, health as well as environmental risks associated with the manufacture, handling and use of **Vika Gel** are effectively managed through safe work procedures, engineering controls, personal protective equipment, worker training, good housekeeping, and occupational health risk management. It is also recommended that the use of the **Vika Gel** be changed from “For DIY and industrial use” to “For industrial use” only in order to restrict its use to industrial applications and to ensure that **Vika Gel** is not available for purchase and use by the general public.

8. CONCLUSIONS

If restricted to “For industrial use” only as recommended under **4.3 Handling and use of Vika Rod**, the risk assessments that have been done show that **Vika Gel**, classified as GHS Category 1B hazardous boron-based chemical product, should pose no direct threat to the general public. Exposure to inorganic borates should then be restricted to personnel involved in the manufacturing and contractors involved in the application of the **Vika Gel** chemical paste to wooden poles in service.

The potential risk of direct exposure to inorganic borates during the manufacture and application of wood preserving pastes 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 **Vika Gel** to be phased out.

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

It is also important to note that, after treatment, the chemical pastes are completely covered up by the outside surface of the plastic wrap applicator and therefore inaccessible to any further physical contact.

Vika Rod also 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 **Vika Gel** for remedial and supplementary treatment of wooden poles is of high strategic importance, especially to ensure the uninterrupted supply of electricity via Eskom's power transmission and distribution lines.

9. RECOMMENDATIONS

In the light of the above risk assessment and motivation for its continued use, it is recommended that the application for renewal of the **Vika Gel** registration (DALRRD Reg. No: L5823) be considered favourably for approved of its continued use in accordance with the label conditions and directions for use, and its use be restricted to "FOR INDUSTRIAL USE" only, if so required.

10. REFERENCES

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