

OTHER NOTICES

Suspension of quintozone active constituent approvals, products containing quintozone and label approvals of products containing quintozone

The APVMA has suspended the active constituent approvals for quintozone listed in Table 1 and the product registrations and label approvals of products containing quintozone listed in Table 2.

Table 1: Active constituent approvals for quintozone

Approval Number	Approval Holder
46112	Barmac Industries Pty Ltd
53706	Amvac Chemicals Corporation

Table 2: Registered products containing quintozone

Product Number	Product Name	Label Approval Numbers	Registrant
41110	Barmac Turf Renovation Mixture	41110/0203	Barmac Industries Pty Ltd
45883	Uniroyal Chemical Terraclor Super-X E.C. Soil Fungicide	45883/0903	Barmac Industries Pty Ltd
47211	Barmac Chloroturf Dg Fungicide	47211/1102 47211/3427	Barmac Industries Pty Ltd
48308	Barmac Rhysol Dg Turf Fungicide	48308/01 48308/0400	Barmac Industries Pty Ltd
50787	Uniroyal Chemical Cotton Planter Box Protectant	50787/0498 50787/0603	Barmac Industries Pty Ltd
50788	Uniroyal Chemical Peanut Seed Protectant Fungicide	50788/0898 50788/0903	Barmac Industries Pty Ltd
50789	Uniroyal Chemical Terraclor Cotton Seed Protectant	50789/0300 50789/0498	Barmac Industries Pty Ltd
51382	Optimerge Peanut Seed Dressing	51382/0106 51382/1298	Peanut Company Of Australia Limited
53533	Terraclor Soil Fungicide	53533/0702 53533/0201 53533/0403	Barmac Industries Pty Ltd
55743	Terraclor Seed Treatment	55743/0105 55743/1106	Barmac Industries Pty Ltd

The active constituent approval suspensions are in effect from 9 April 2010 until 12 April 2011.

The product and label suspensions apply as a consequence of the suspension of quintozone active constituent approvals and are in effect from 12 April 2010 until 12 April 2011.

BASIS FOR SUSPENSION

The APVMA has become aware of new information indicating the presence of undeclared dioxins as impurities in products that contain quintozone as the active constituent.

Dioxins are listed as toxicologically significant impurities in the *Definition of Standards for Active Constituents* (see http://www.apvma.gov.au/products/constituents/standards/actives_definition.php). The presence of any impurity that is listed as toxicologically significant is a matter that the APVMA considers to be a relevant particular to the approval of an active constituent.

As stated in the *Agricultural Manual of Requirements and Guidelines* (AgMORAG) (http://www.apvma.gov.au/products/constituents/standards/actives_definition.php), an active constituent approval is not supportable unless any known impurities of toxicological significance have been adequately evaluated. AgMORAG specifies that an impurity that is present at levels above 0.1 mg/kg should be declared and evaluated, and also emphasises that toxicologically significant impurities in the active constituent should be declared when present, regardless of the level present.

The APVMA conducted its own testing of quintozone products and found dioxins with significant variability between the samples tested. The APVMA has also been provided with further information that indicates that dioxins may be present as impurities in quintozone active constituents from approved sources. These dioxin impurities were not declared or evaluated at the time that quintozone sources were approved.

The presence of undeclared dioxins in an active constituent is a concern to the APVMA. Polychlorinated dibenzodioxins (PCDDs) and polychlorinated dibenzofurans (PCDFs), or 'dioxins', are a group of similar molecules that are toxic, persistent and accumulate in the fat of animals and humans. Dioxins are associated with cancer and non-cancer health effects at low levels of exposure. Dioxins are not deliberately produced but are released into the environment mainly as by-products of combustion or certain chemical processes.

The APVMA considers that the active constituent quintozone may be an undue hazard to the safety of people exposed to it during its handling and may have an effect that is harmful to human beings. A full assessment of the dioxin impurities has not been conducted in accordance with section 14 of the Agvet Code Act. On this basis the APVMA has concluded that it cannot allow the active constituent to be supplied and used in chemical products when it contains undeclared dioxins. Consequently, the APVMA has suspended the approvals of quintozone active constituents.

The Agvet Code provides that if the APVMA suspends the only approval, or all the approvals, of an active constituent for an existing chemical product, it must also suspend any registration of that product. In addition, if the APVMA suspends the registration of a chemical product, it may also suspend any approval relating to a label for containers for the product.

IMPACT ON PRODUCT REGISTRANTS

Suspension action is based on the concern that undeclared dioxins may be present in quintozone active constituents and formulated products. The APVMA considers that it may be possible to allow some use of existing stocks of quintozone products during the period of suspension. Continued uses will only be permitted on the basis of test results for total dioxins in each batch of product proposed for use, and following evaluation by the Office of Chemical Safety and Environmental Health, to ensure that any continued use does not pose a risk to users.

INSTRUCTIONS FOR DEALING WITH SUSPENDED ACTIVE CONSTITUENTS AND PRODUCTS

Pending any further testing of quintozone products for the presence of dioxins, the following instructions apply for persons having possession or custody of stocks, and are considering using or otherwise dealing with suspended active constituent and product during the period of suspension.

INSTRUCTIONS FOR POSSESSING, HAVING CUSTODY OF, USING OR DEALING WITH SUSPENDED ACTIVE CONSTITUENTS AND PRODUCTS

Possession and custody

Possession and custody of existing stocks of quintozone active constituent and/or products is permitted.

Supply

No supply of the active constituent quintozone and/or any product that contains it as an active constituent is permitted.

Use

No use of suspended product containing quintozone is permitted.

Any person who possesses or has custody of, or otherwise deals with the active constituents or products listed in Tables 1 and 2 (above) in accordance with the instructions in this notice is taken to have been issued with a permit to possess, have custody of, or deal with the active constituents or products during the period of suspension or until further notice.

WARNING

A person must not possess with the intent to supply, or deal with any materials containing quintozone during this period, except in accordance with the instructions contained in this notice. A failure to comply with these instructions will result in an offence against the Agvet Codes and the APVMA will take appropriate compliance action. It is an offence for any person to possess with the intent to supply, use or deal with the active constituent after 9 April 2010 unless authorised to do so by the APVMA. Similarly, it is an offence for any person to possess with the intent to supply, use or deal with quintozone products after 12 April 2010, unless authorised to do so by the APVMA.

APVMA CONTACT

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