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Agrotech Chlorthalonil (M13176)

Information Update: 11/2010

Issued: 3 June 2010

Following the revocation of Agrotech Chlorthalonil 500SC (MAPP 13176) on 19 May 2010 ([Regulatory Update 13/2010](#)), the Chemicals Regulation Directorate (CRD) has been made aware that there is conflicting information circulating in the industry. This information update provides background to why the decision was taken to revoke Agrotech Chlorthalonil 500SC's approval.

CRD have not received information to suggest that the issues identified with Agrotech Chlorthalonil 500SC are present in other chlorothalonil products. Formulation analysis carried out by CRD on a limited number of chlorothalonil products in 2008 (which did not include Agrotech Chlorthalonil 500SC) found all tested products to be consistent with their approved formulations. None of the tested formulations contained hexachlorobenzene in excess of permitted levels.

CRD does not currently have plans to carry out further monitoring of other chlorothalonil products although we will continue to investigate specific cases brought to our attention or which otherwise come to light.

Background

What is Agrotech Chlorthalonil?

Agrotech Chlorthalonil was approved for use in the UK as an agricultural and horticultural fungicide for use on a wide range of crops including cereals, potatoes, a range of field and salad vegetables, soft fruits and tomatoes.

Why has this product been revoked?

This product has been revoked because of concerns that the formulation of the product being placed on the market is not consistent with the approved formulation.

What were the concerns about the product?

Samples from different batches of the product, obtained from various suppliers, were tested. Some samples showed high levels of hexachlorobenzene (HCB), whilst others had levels lower than required by the approval of the active ingredient chlorothalonil. Both these variations are inconsistent with the approval for this product.

Why were there concerns about the formulation of the product?

HCB is listed as a persistent organic pollutant (POP) under the Stockholm Convention and under the EU legislation that enacts the Convention ([Regulation 850/2004](#)). HCB is classified as a possible human carcinogen (Class 2B) and there are strict limits about the

amount of HCB that may be present in an approved pesticide. The levels found in this product were higher than those permitted under the approval conditions for this product.

The active ingredient chlorothalonil was found to be at a lower concentration than that approved. In some samples the level of chlorothalonil was almost half the approved level in the product.

How was Agrotech Chlorthalonil approved?

Agrotech Trading GmbH was granted a Permit for sale and supply of Agrotech Chlorthalonil in the UK under the EU's parallel import arrangements. These arrangements allow pesticide products to be traded across borders provided that the products traded have full authorisation for sale and supply in their country of origin and are identical to a product already on the market in the country of import.

In this case Agrotech Chlorthalonil was given a permit on the basis that the original product, sourced from a named EU country, was identical to a product already authorised for sale in the UK.

Who is the approval holder?

The approval holder is Agrotech Trading GmbH, Kirchenberg 13, A-4310 Mauthausen, Osterreich.

How will it be disposed of – what about part used product?

It is recommended that unopened supplies of the product are returned to your supplier and that unused amounts (in opened containers) are disposed of by a waste contractor qualified for disposing of hazardous materials.

Why wasn't the product withdrawn earlier?

CRD were first alerted to a potential problem on the 15 March 2010. Whilst we sought to confirm this claim we alerted (on 19 March 2010) the approval holder to the issue. CRD received the results of independent analysis of a sample of product on the 30 March 2010; these were copied to the approval holder and supplier who agreed to voluntarily recall remaining stocks of product from distributors.

So far as revoking the approval was concerned, this is a very serious step and HSE has to be satisfied that the analysis of the samples it has tested warrants this action. For example, CRD has not just tested one batch, but has tested a number of batches that were supplied to different suppliers. CRD has taken action to revoke the product as soon as practicable following confirmation of the test results.

Are users at risk from the hexachlorobenzene?

Although the level of HCB present in the product were higher than the levels permitted, it is not thought that these levels would put users at risk.

Would the product work with reduced levels of chlorothalonil?

It is not possible to make a generalisation on the possible impact of using a product that has a lower level of active ingredient than approved. This will depend on a number of

different factors, including the dosage used and whether the product was used to tackle a problem that had already arisen or if it was used prophylactically. In the first instance it is recommended that you contact your supplier for further advice.

How did CRD discover this problem?

CRD received a complaint that the product formulation contained high levels of HCB on the 15 March 2010. In order to independently confirm this allegation CRD obtained samples of the product for independent testing. These tests were undertaken at FERA over recent weeks and the analyses done have shown the various problems referred to above.

Will Agrotech be prosecuted?

The investigation of this case is continuing and at this stage it is not possible to say whether further enforcement action will be taken.

If you have any concerns or questions about this issue please contact CRD as below.

Agrotech Chlorthalonil 500SC - Expiry Dates and Revocation Notice:

- Approval for the advertisement, sale, supply and use of the product by anyone was revoked from 19 May 2010.
- Approval has been given until 31 July 2010 for storage pending disposal.

Contact Information

Enquiries concerning this update should be addressed to the Communications Branch:

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