BASF

The Chemical Company

Quinclorac Summary Document
Registration Review: Initial Docket
December 2007

Case # 7222

Docket ID Number EPA-HQ-OPP-2007-1135
Federal Register Notice Volume 72, Number 243, Dec 19, 2007

BASF hereby submits to the EPA initial docket for quinclorac the following materials on March 14, 2008:

1. Comments to Summary Document – 6 pages
2. An Acute Daphnia Study (Doc ID 2001/1015083) – 28 pages
3. A Skin Sensitization Study (Doc ID 2005/1011566) – 35 pages
4. Email Dated November 29, 2007 Regarding the Reanalysis of Soil Samples from 1988/89 Field Dissipation Trials – 3 pages

Contact Information:
Rebecca Johnston
BASF Corporation
Phone: 919-547-2609
Email: mail to: rebecca.johnston@basf.com

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Comments to Summary Document

| Page | Comments |
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| | |
| 5 | Request for acute and chronic aquatic vertebrate toxicity tests will be discussed later on pages 36-38 of the summary document. |
| 5 | Request for the 90-day inhalation study is presented in the HED section on pages 60 and 62 as a 28-day inhalation study and it is recommended not required. |
| 5, 10 | Request for drinking water assessment is inconsistent with HED's determinations on pages 58 and 61 that state that the existing assessment is adequate and no new assessment is needed. |
| 5, 11 | Request for aggregate risk assessment is inconsistent with HED's determinations on pages 58 and 61 that state that the existing assessment is adequate and no new assessment is needed. |
| 9 | Quinclorac is not registered for use in ornamentals. |
| 9 | BASF is the basic technical registrant of quinclorac. |
| 9 | Quinclorac is not registered for use in corn. |
| 20 | Request for acute and chronic aquatic vertebrate toxicity tests will be discussed later on pages 36-38 of the summary document. |
| 23 | Data on the reanalysis of soil samples from 1988/1989 terrestrial field dissipation studies was submitted to EPA per Jim Tompkins request on November 29, 2007. |
| 36 - 38 | MRID 41063556 acute daphnia toxicity study used 96% TGAI test substance with surfactant. The request for a new acute daphnia can be satisfied with a 2001 study not previously submitted to EPA using 98.6% TGAI. The results of this study ($EC_{50}$ > 100 mg/L) are consistent with the chronic daphnia study (MRID 44129202) with NOAEC = 110 mg/L. The submission of the 2001 study should remove the uncertainty expressed by EFED and serve as a toxicity endpoint to estimate the risks to estuarine animals. With the submission of this study, the requirements for new acute and chronic daphnia studies should also be considered fulfilled. |

Rebecca Johnston
BASF Corporation
(919)-547-2609
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| 58 | Drinking water and aggregate risk assessments are adequate; in direct conflict with information in the overview section on pages 5, 10 and 11. |
| 59 | Quinclorac is not registered for use in ornamentals. |
| 59 | An updated dermal sensitization is available for submission which demonstrates that quinclorac technical is non-sensitizing. |
| 60 | A 28-day rat inhalation study is recommended; in direct conflict with information in the overview section on page 5. |
| 61 | Drinking water and aggregate risk assessments are adequate; in direct conflict with information in the overview section on pages 5, 10 and 11. |
| 62 | A 28-day rat inhalation study is recommended; in direct conflict with information in the overview section on page 5. |

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**Request for Inhalation Study:** A NOAEL of 70 mg/kg/day is identified for residential and occupational exposure. With a NOAEL this high the MOEs are likely to be high (i.e., >> 100) for dermal / systemic exposure. Since inhalation is generally only a very small percentage of the exposure component an inhalation study will not add value to the risk assessment. On pages 60 and 62 of HEDs section of the summary document, a 28-day study is recommended. On page 5 of the overview section it is stated that a 90-day study is required. BASF would like clarification on this inconsistency but still contend that conducting an inhalation study is not necessary for determining exposure assessments.

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BASF Corporation
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**Request for a Prospective Ground Water Study: Dietary Assessment**

Based on the existing environmental fate lab data submitted to the Agency, it has been determined that under certain conditions quinclorac can exhibit mobility in soil toward ground water. Detailed terrestrial field dissipation studies conducted by BASF also indicate that the molecule can exhibit this same mobility. Based on the existing data for the molecule, it is clear that mobility in the field is a possibility, therefore conducting an additional environmental fate (PGW) study that will indicate the same results does not provide any additional value.

Given that prospective ground water studies are not predictive of possible residues in drinking water supplies, the studies have dubious value for a human health assessment. The registrant has conducted a dietary assessment for the molecule and determined that if drinking water sources contained 1,000 ug/L, the MOE for infants (the most susceptible population subgroup) is still acceptable at a calculated MOE value of ~505 (food and water). Using the SciGrow model, the Agency has calculated a maximum expected ground water concentration of ~ 29 ug/L. The 1,000 ug/L value used by the registrant in their dietary assessment is 30 times higher than the highest expected ground water exposure value calculated by the Agency. Even at this exaggerated level, the molecule still has acceptable MOEs based on its low toxicological profile.

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**Request for a Prospective Ground Water Study: Non-Target Plant Assessment**

Based on the maximum seasonal use rate for quinclorac (1.5 lb ai/ac) an estimate of exposure in ground water was made using SciGrow. From the SciGrow estimate of exposure, the resulting concentration in water (ug/L) was calculated up to the mass of quinclorac in an acre foot of water ( 325,851 gallons). Once the mass was figured, it was estimated that 0.009 lb ai/ac of quinclorac would be applied to a field in an acre with a foot of water. The University of Florida has estimated that a vegetable crop would require a maximum of 8.52 inches of water during the most demanding thirty day growing period. From the non-target plant study, we selected a sensitive species NOEC of 0.005 lb ai based on a single application for comparison. If we take the estimated mass in the foot of water (0.009 lb ai/ac) and adjust it for the peak 30 day water requirement (8.52"/12" = 0.71), the load per acre in 30 days is 0.006 lb/ac ai (0.009 lb ai/ac x 0.71 ~ 0.006 lb ai/ac). Since the time required to deliver this amount of ai is 30 days, the dose is far below the single application rate NOEC of 0.005 lb/ac ai. Therefore based on these calculations, it is not possible that any non-target plant injury could occur via contaminated ground water even using worst case assumptions.

Rebecca Johnston
BASF Corporation
(919)-547-2609
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