

Section 12 Notice Additional Information Required to Fulfill the Terms and Conditions for Conditional Registration

Product Name: CLEAROUT GLYPHOSATE TECHNICAL GRADE

Registration Number: 28321

Application Number: 2006-6800

PMRA #: 1427952

During the conditional registration period which has been granted to December 31, 2009, the following information is to be generated and must be provided to the Pest Management Regulatory Agency by **December 1, 2009**, and must indicate the DACO numbers specified. A partial response to the outlined Terms and Conditions will not be accepted.

REQUIRED DATA:

During the conditional registration period, the applicant is required to generate data to address the following list of data. The list of studies proposed by CPT to meet the point count value of the glyphosate database has been reviewed by PMRA. Please find below a revised list of studies the applicant is required to submit, followed by notes detailing/qualifying some of the study requirements:

<u>REQUIRED STUDIES</u>	<u>DACO</u>
Oral 90-day dog	4.3.8
Inhalation 90-day rat	4.3.6
Inhalation 21-day rat	4.3.7
Lifetime oncogenicity rat	4.4.2
Lifetime oncogenicity mouse	4.4.3
Multi-generation repro rat/rabbit	4.5.1
Teratogenicity rabbit	4.5.2
Teratology rat	4.5.2
Delayed Neurotoxicity chicken	4.5.11
Exposure Studies –specified study: <i>In Vivo</i> dermal Absorption on Rodents	4.8
Metabolism (labelled) rat	4.5.9
Metabolism (labelled) goat	6.2
Metabolism (labelled) chicken	6.2
Metabolism (labelled) plants –three specific studies are requested, see notes	6.3
Mobility: absorption/desorption – two studies are requested, see notes	8.2.4.2
Leaching - lab study (cold) –see notes	8.2.4.3

REQUIRED STUDIES	DACO
Soil metabolism aerobic –see notes	8.2.3.4.3
Soil metabolism anaerobic	8.2.3.4.4
Biotransformation in aquatic systems anaerobic sediment/water	8.2.3.5.6
Non-target terrestrial invertebrates: predators and parasites –two studies, see notes	9.2.5 and 9.2.6
Non-target marine invertebrates: mollusk embryo larvae	9.4.3
Non-target marine invertebrates: mollusk shell deposition	9.4.4
Acute studies with fish: Marine estuarine fish	9.5.2.4
Sublethal and chronic studies : fish early life cycle toxicity test	9.5.3.1
Sublethal and chronic studies : fish life cycle toxicity test –see notes	9.5.3.2
Chronic studies with birds: avian reproduction -see notes	9.6.3.3
Non-target plants: marine algae	9.8.3
Non-target plants: aquatic vascular plants -conducted with duckweed, see notes	9.8.5
Non-target plants: aquatic vascular plants –conducted with northern watermilfoil, see notes	9.8.5
Non-target plants: terrestrial vascular plants - see notes	9.8.4

Notes on Studies Required

EXPOSURE STUDIES

In Vivo Dermal Absorption on Rodents:

- Refer to the *EPA's OPPTS Test Guidelines Series 870 - Health Effects Test Guidelines* (formerly Subdivision F) for guidance on conducting *in vivo* dermal absorption studies on rodents.

METABOLISM STUDIES

GLP Compliant Ruminant Metabolism (labelled) - Goat

GLP Compliant Poultry Metabolism (labelled) - Chicken

GLP Compliant Plant Metabolism (labelled) - Pre-emergent to oilseed or cereal:

GLP Compliant Plant Metabolism (labelled) - Pre-harvest to soybean:

GLP Compliant Plant Metabolism (labelled) - Pre-harvest to wheat:

ENVIRONMENTAL CHEMISTRY STUDIES

In this list, the term "ideally" means strongly preferred; however, a study conducted with a soil/sediment/species other than the one(s) specified would still be accepted.

- Mobility: adsorption/desorption soil:

- ideally conducted with soils other than clay loam, sand or loamy sand
- guideline recommended: OPPTS 835.1220 by US EPA

- Mobility: adsorption/desorption sediment:
 - conducted with any kind of sediments as long as they are well characterized
 - guideline recommended: OPPTS 835.1220 by US EPA

- Leaching (lab study):
 - ideally conducted with soils other than sandy loam, silt loam or clay loam
 - guideline recommended: Test No. 312 by OECD

- Soil metabolism aerobic:
 - ideally conducted with soils other than sandy loam or silt loam
 - guidelines recommended: OPPTS 835.3300 by US EPA and Test No. 307 by OECD

- Soil metabolism anaerobic:
 - conducted with any kind of soils as long as they are well characterized
 - guideline recommended: Test No. 307 by OECD

- Biotransformation in aquatic systems anaerobic sediment/water:
 - conducted with any kind of sediments as long as they are well characterized
 - guideline recommended: Test No. 308 by OECD