

**Status Report
The Birth Defect
Prevention Act of 1984**

A Report to the Legislature



**California Environmental Protection Agency
DEPARTMENT OF PESTICIDE REGULATION**

February 1999

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DEPARTMENT OF PESTICIDE REGULATION**

Gray Davis, Governor

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**This report's executive summary is available on the DPR internet Web site
at <<http://www.cdpr.ca.gov>>.**

EXECUTIVE SUMMARY

of the February 1999 Report to the Legislature

PURPOSE:

This report presents the status of the chronic health effects studies required by the Birth Defect Prevention Act (the Act) for the priority 200 active ingredients. The Department of Pesticide Regulation (DPR) identified these active ingredients in 1985 as having the most significant data gaps, widespread use, and which were suspected of being hazardous to people. For the priority 200 active ingredients, the chronic health effects studies were due to DPR by March 30, 1996. If pesticide registrants failed to submit the required studies, data gaps exist. A "data gap" means that DPR lacks adequate health effects studies in any of the following areas: chronic toxicity, mutagenicity, neurotoxicity, oncogenicity, reproductive effects, and teratology. Pesticide registrants are in compliance with the Act when DPR receives final reports for all required studies, unless later evaluation determines that any study is not adequate.

This is DPR's annual report to the Legislature on the data gaps that remain for the priority 200 active ingredients, as required by 1991 legislation (SB 550), amending the Act.

BACKGROUND:

The Act required DPR to acquire certain toxicological data for registered pesticide active ingredients in order to make a scientific determination that their continued uses will not cause significant adverse health effects. If the use of an active ingredient presents potential significant adverse effects, the Act requires DPR to suspend or cancel the registration of pesticide products containing those active ingredients.

In January 1986, DPR notified each registrant of pesticide products containing any of the priority 200 active ingredients of the data required to fill the data gaps. DPR found that much of the data submitted in response to this data call-in notice were from studies that did not meet the U.S. Environmental Protection Agency (U.S. EPA) guidelines for conducting such studies. Because these studies had been conducted some years ago, many registrants were unable to obtain additional data from the laboratories which conducted the original studies;

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thus, the studies could not be upgraded. Then, registrants contracted with laboratories to begin new studies; however, most registrants failed to complete and submit new chronic health effects studies within the time frames in the law.

AMENDMENTS:

The Act was significantly amended in 1991 and 1996. In 1991, amendments strengthened the Director's authority to suspend product registrations. They required the Director to initiate a suspension process for products containing active ingredients for which data gaps existed after December 31, 1991. These amendments provided that under certain conditions, registrants and others could petition for additional time to submit the data. However, the law clearly states that no pesticide product shall remain registered if it contains any of the priority 200 active ingredients for which data gaps exist after March 30, 1996.

In March 1996, another amendment to the Act allowed continued registration of products containing two active ingredients while studies were being completed. For methyl bromide and pentachlorophenol, the final reports were submitted to DPR before December 31, 1997.

REPORT SUMMARY:

Of the priority 200 active ingredients, 145 remain subject to the data call-in. Of the 55 active ingredients that are no longer subject to the data call-in, DPR suspended registrations for eight active ingredients. Product registrations are suspended if data for any active ingredient cannot be upgraded with the submission of additional information or if data was not submitted. Of the 145 active ingredients still subject to the data call-in, this report identifies nine active ingredients (1) with data at DPR pending evaluation, (2) with data that may be upgraded with the submission of additional information, or (3) exempted from the data requirements.

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Data gaps exist for four active ingredients. DPR suspended registrations of products containing two of these active ingredients (bendiocarb and petroleum distillates, aromatic) and granted a three-year exemption from the data requirements for one active ingredient (diclofop-methyl). A decision is pending on a three-year exemption request for the fourth active ingredient (chloroneb). Label amendment approval by U.S. EPA is required before DPR can approve the exemption request.

The table summarizing the February 1999 annual report follows.

**BIRTH DEFECT PREVENTION ACT OF 1984
REPORT SUMMARY
FEBRUARY 1999**

Status summary of the priority 200 pesticide active ingredients identified according to Food and Agricultural Code section 13127(a).

- I. 55 active ingredients are no longer registered or are suspended**
- | | |
|------------------------------------|----|
| Products no longer registered | 53 |
| Products registered, but suspended | 2 |
-
- II. 145 active ingredients are subject to the data call-in**
- | | |
|--|-----|
| a. A set of adequate data is on file | 127 |
| b. Adequate data exist in public literature to assess potential adverse health effects | 9 |
| c. All data submitted to DPR; one or more studies are pending review and/or studies are upgradable | 7 |
| d. Active ingredient exemptions | 2 |
- Chloroneb: one product registration suspended; one product granted FAC section 13127(e) exemption; one product pending review for FAC section 13127(e) exemption.
- Diclofop-methyl: one product exempted from data requirements for three years under FAC section 13127(e)(2); exemption expires 7/9/99.

200 active ingredients

The Birth Defect Prevention Act of 1984
Status of Priority Active Ingredients With Data Pending Review,
Upgradable Studies, and Data Requirement Exemptions

Bentazon, Sodium Salt

Chronic Feeding, Rat	Adequate data on file
Chronic Feeding, Dog	Data submitted, under review
Oncogenicity, Rat	Adequate data on file
Oncogenicity, Mouse	Adequate data on file
Reproduction, Rodent	Adequate data on file
Teratology, Rat	Adequate data on file
Teratology, Rabbit	Adequate data on file
Gene Mutation	Adequate data on file
Chromosome Aberration	Adequate data on file
DNA Damage/Repair	Adequate data on file
Neurotoxicity, Hen	Data not required

Chloroneb

Chronic Feeding, Rat	Data not adequate
Chronic Feeding, Dog	Data not adequate
Oncogenicity, Rat	No data on file
Oncogenicity, Mouse	No data on file
Reproduction, Rodent	Data not adequate
Teratology, Rat	Data not adequate
Teratology, Rabbit	Data not adequate
Gene Mutation	Adequate data on file
Chromosome Aberration	Data not adequate
DNA Damage/Repair	Data not adequate
Neurotoxicity, Hen	Data not required

Registration of one product suspended. An FAC section 13127(e) exemption was granted for one product and is under consideration for the remaining product. U.S. EPA approval of a label amendment is needed before DPR can approve the exemption.

Diclofop Methyl

Chronic Feeding, Rat	Data submitted, under review
Chronic Feeding, Dog	Data not adequate
Oncogenicity, Rat	Data submitted, under review
Oncogenicity, Mouse	Data not adequate
Reproduction, Rodent	Data not adequate
Teratology, Rat	Adequate data on file
Teratology, Rabbit	Data not adequate
Gene Mutation	Adequate data on file
Chromosome Aberration	Adequate data on file
DNA Damage/Repair	Adequate data on file
Neurotoxicity, Hen	Data not required

An FAC section 13127(e) exemption from data requirements expires 07/09/99 for the only registered product.

06/30/98

The Birth Defect Prevention Act of 1984
Status of Priority Active Ingredients With Data Pending Review,
Upgradable Studies, and Data Requirement Exemptions

Metaldehyde

Chronic Feeding, Rat . . .	Adequate data on file
Chronic Feeding, Dog . . .	Adequate data on file
Oncogenicity, Rat . . .	Adequate data on file
Oncogenicity, Mouse . . .	Upgradable study
Reproduction, Rodent . . .	Adequate data on file
Teratology, Rat . . .	Adequate data on file
Teratology, Rabbit . . .	Adequate data on file
Gene Mutation . . .	Adequate data on file
Chromosome Aberration . . .	Adequate data on file
DNA Damage/Repair . . .	Adequate data on file
Neurotoxicity, Hen . . .	Data not required

Methyl Bromide

Chronic Feeding, Rat . . .	Data submitted, under review
Chronic Feeding, Dog . . .	Data submitted, under review
Oncogenicity, Rat . . .	Adequate data on file
Oncogenicity, Mouse . . .	Adequate data on file
Reproduction, Rodent . . .	Adequate data on file
Teratology, Rat . . .	Adequate data on file
Teratology, Rabbit . . .	Adequate data on file
Gene Mutation . . .	Adequate data on file
Chromosome Aberration . . .	Adequate data on file
DNA Damage/Repair . . .	Adequate data on file
Neurotoxicity, Hen . . .	Data not required

Methylenebis (Thiocyanate)

Chronic Feeding, Rat . . .	Adequate data on file
Chronic Feeding, Dog . . .	Adequate data on file
Oncogenicity, Rat . . .	Adequate data on file
Oncogenicity, Mouse . . .	Adequate data on file
Reproduction, Rodent . . .	Data submitted, under review
Teratology, Rat . . .	Adequate data on file
Teratology, Rabbit . . .	Adequate data on file
Gene Mutation . . .	Adequate data on file
Chromosome Aberration . . .	Adequate data on file
DNA Damage/Repair . . .	Adequate data on file
Neurotoxicity, Hen . . .	Data not required

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Status of Priority Active Ingredients With Data Pending Review,
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Ortho-Phenyiphenol

Chronic Feeding, Rat . . .	Upgradable study
Chronic Feeding, Dog . . .	Adequate data on file
Oncogenicity, Rat . . .	Adequate data on file
Oncogenicity, Mouse . . .	Adequate data on file
Reproduction, Rodent. . .	Upgradable study
Teratology, Rat. . .	Adequate data on file
Teratology, Rabbit . . .	Adequate data on file
Gene Mutation. . .	Adequate data on file
Chromosome Aberration . . .	Adequate data on file
DNA Damage/Repair . . .	Adequate data on file
Neurotoxicity, Hen . . .	Data not required

Resmethrin

Chronic Feeding, Rat . . .	Adequate data on file
Chronic Feeding, Dog . . .	Adequate data on file
Oncogenicity, Rat . . .	Adequate data on file
Oncogenicity, Mouse . . .	Data submitted, under review
Reproduction, Rodent. . .	Adequate data on file
Teratology, Rat. . .	Adequate data on file
Teratology, Rabbit . . .	Adequate data on file
Gene Mutation. . .	Adequate data on file
Chromosome Aberration . . .	Adequate data on file
DNA Damage/Repair . . .	Adequate data on file
Neurotoxicity, Hen . . .	Data not required

Tetramethrin

Chronic Feeding, Rat . . .	Adequate data on file
Chronic Feeding, Dog . . .	Data submitted, under review
Oncogenicity, Rat . . .	Adequate data on file
Oncogenicity, Mouse . . .	Data submitted, under review
Reproduction, Rodent. . .	Adequate data on file
Teratology, Rat. . .	Adequate data on file
Teratology, Rabbit . . .	Adequate data on file
Gene Mutation. . .	Adequate data on file
Chromosome Aberration . . .	Adequate data on file
DNA Damage/Repair . . .	Adequate data on file
Neurotoxicity, Hen . . .	Data not required