SUPERIOR COURT OF THE STATE OF CALIFORNIA
FOR THE COUNTY OF SAN FRANCISCO

DEWAYNE JOHNSON, Plaintiff,

v.

MONSANTO COMPANY
Defendants.

Case No. CGC-16-550128

DECLARATION OF CURTIS G. HOKE IN SUPPORT OF PLAINTIFF’S REPLY IN SUPPORT OF PLAINTIFF’S MOTION IN LIMINE NO. 7 TO EXCLUDE ANY ARGUMENT AND TESTIMONY REGARDING WHAT THE EPA WOULD HAVE DONE HAD MONSANTO ATTEMPTED TO ADD A WARNING OF NON-HODGKIN’S LYMPHOMA TO ITS LABELING

Trial Date: June 18, 2018
Time: 9:30 AM
Department: TBD
DECLARATION OF CURTIS G. HOKE

I, Curtis Hoke, declare and state:

1. I am an attorney at law admitted to practice before all of the courts in the state of California. I am an attorney at The Miller Firm, LLC, attorneys of record for Plaintiff Dewayne Johnson. I am over eighteen years of age and am fully competent to make this Declaration in support of Plaintiff’s Motion in Limine No. 7. Except as otherwise expressly stated below, I have personal knowledge of the facts stated in this declaration, and if called to testify, I could and would competently testify to the matters stated herein.

2. Attached hereto as Exhibit A is a true and correct copy of excerpts of MONGLY03737014, a document produced by Monsanto in discovery.

3. Attached hereto as Exhibit B is a true and correct copy of excerpts of MONGLY04272196, produced by Monsanto in discovery.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

Executed on June 12, 2018 in Orange, Virginia.

By  

Curtis G. Hoke,
Declarant
EXHIBIT A
Donna

We dropped the programme for glyphosate because a further study was not likely to help us meet the project objective:
> we initiated the studies from a regulatory angle to help meet the requirements for operator exposure, given that the Annex I end point for dermal absorption for glyphosate was set at 3%, which we believed was a high value based on a weight of evidence approach.
> the results of the rat skin studies show levels of absorption for glyphosate of a similar order to the Annex I end point; also confirm our expectation that surfactant concentration affects the dermal absorption
> therefore, from the regulatory angle, there is no point in pursuing the studies further (even though it would be interesting to show that the unusual results on a few skin samples were an artifact of the experimental work)
> given that we need to do additional studies on triallate it seems a sensible use of budget and of TNO's time to replace the glyphosate studies with additional work on triallate

For clarification - a decision was made to not repeat the rat skin study and to stop any further dermal penetration studies with MON 35012 with and without surfactant - correct? Are any other glyphosate-based formulations going to be tested? Or has the whole program been dropped?

Donna

Dear all,

Thanks for the good discussion we had on dermal penetration issues. Please find below the main actions which have been decided:

**Glyphosate:**
Although we agreed to repeat the *in vitro* dermal penetration study with rat skin as proposed by TNO, we came to the conclusion that the penetration of glyphosate would have been [probably] greater than the 3% already imposed by the German authorities. We decided thus to STOP the study (effective today morning).
EXHIBIT B
The accompanying report has been reviewed and accepted. A quality assurance review was performed by International Research and Development Corporation. A summary of the methods and results and an evaluation of the conclusions presented in this report are summarized below.

METHODS

CP 76100 was administered by gavage as an aqueous solution of the sodium salt to Charles River CD-1 mice daily for 104 weeks. Dosing was at a constant volume of 10 ml/kg at dosage levels of 50, 150, and 500 mg/kg/day. Seventy male and 70 female mice were dosed at each level. A control group of 70 mice of each sex received a solution of NaCl (5.0 mg Na+/ml) at the same dosing volume. The concentration of sodium in the control dosing solution was selected to equal that received by the high dose group.

The mice were observed daily for mortality and overt signs of toxicity. A detailed physical examination of each animal was performed weekly. Individual body weights and food consumption measurements were recorded weekly for the first 14 weeks and biweekly thereafter. The following hematological parameters were measured for 10 mice/sex/group at 12 and 24 months: hematocrit, hemoglobin concentration, erythrocyte count, total and differential leukocyte counts, platelet count, and reticulocyte count.

Complete postmortem examinations were performed on all animals dying spontaneously, sacrificed in extremis, or sacrificed at the twelve month interim and 24-month terminal sacrifice periods. The following tissues were examined microscopically: adrenals, brain, eyes and Harderian glands, gall bladder, heart, esophagus, stomach, duodenum, jejunum, ileum, large intestine, kidneys, urinary

*received report
bladder, prostate, testes with epididymides, ovaries, cervix uteri, liver, lung and mainstem bronchi, lymph nodes, mammary gland, salivary glands, sciatic nerve, pancreas, pituitary, skin, spinal cord, spleen, thymus, trachea, thyroid/parathyroid, sternum (bone marrow), and other tissues with lesions. In addition, 10 animals/sex/group were examined microscopically as follows: 3 coronal sections through the head which included the nasal cavity, paranasal sinuses, tongue, oral cavity, nasopharynx, and middle ear.

Tumor incidences were statistically analyzed by the testing laboratory employing life table methods and Chi-square analysis to assess differences between control and treated groups. Analysis for the presence of a linear trend was performed both with and without adjustment for time of death (life table method). In addition, Monsanto analyzed the data for differences between group incidences by the Fisher Exact test and for the presence of a linear trend by the Cochran-Armitage test.

RESULTS

During the first twelve months of the study, mortality was higher in treated male mice as compared to controls (See Table 1). Percent mortality was 4.3, 7.1, 14.3, and 11.4% for the control, low, mid, and high dose level males respectively. For the remainder of the study, mortality was similar for control and treated males. At study termination, survival for mid- and high-dose males was 6 and 10 percent less than control, respectively. For female mice, survival was similar for all groups throughout the study. At study termination, survival in high dose females was 5% lower than controls. Body weight and food consumption were similar for control and treated mice throughout the study. Although occasional differences were statistically significant, no consistent differences were observed. No treatment-related changes were observed in appearance or behavior.

There were no test material related effects observed in the hematological data for either sex at either of the sampling periods. Occasional differences were observed between control and treated groups. However, due to large variability, lack of dose-response, and the absence of appropriate similar findings in both sexes, none of these differences were considered to be treatment related. There were no compound-related macroscopic or microscopic changes observed during necropsy or during
microscopic examination. All changes observed were considered to be spontaneous or incidental in nature and commonly encountered lesions for mice of this age, sex, and strain.

There were several statistically significant differences for adjusted trend of life table data for some tumors among males. This included percent animals with tumors, hardenerian gland adenoma, liver hemangioma and malignant lymphocytic lymphoma. These differences were considered to have resulted from and reflected the pattern of earlier deaths in the high dose animals. This resulted in earlier discovery of clinically silent tumors or the recording of non life-threatening tumors when death occurred early for other reasons. The only statistically significant differences in unadjusted trend in any group of tumors or individual tumors among males were for malignant lymphocytic lymphoma and liver hemangioma. When analyzed by the Cochran-Armitage test (Table 2), no linear trend was observed for lymphocytic lymphoma. Also, the combined incidence for histiocytic plus lymphocytic lymphomas observed for high dose males in this study (7%) falls within the historical control range of this laboratory (0-15%) for malignant lymphomas. In addition, the incidence of lymphocytic lymphomas in treated female mice was significantly less than in control females (Table 2). There was a statistically significant trend (Cochran-Armitage) for liver hemangioma. However, since both benign and malignant tumors of blood vessels are not unusual tumors in mice, the low incidence observed in this study (2/70 males) was not considered to be indicative of a treatment-related effect. The testing laboratory's historical control range for this tumor in male CD-1 mice is 0-2.0%.

Similarly, for female mice there were several significant differences for adjusted trend of life table data. These included alveolar bronchiolar carcinoma, malignant lymphocytic lymphoma, malignant histiocytic lymphoma and ovarian adenoma. For alveolar bronchiolar carcinoma there was no statistically significant trend for unadjusted data or when analyzed by the Cochran-Armitage test (Table 2). In addition, the high dose incidence (6%) was lower than the mean historical control incidence (7.2%) for the testing laboratory. The unadjusted trend was statistically significant for histiocytic and for lymphocytic lymphomas. However, the trend for lymphocytic lymphomas was negative and was, therefore, not an adverse treatment effect. The trend for histiocytic lymphoma was not statistically
significant however for male mice when analyzed by the Cochran-Armitage test (Table 2). Also, in high-dose males the incidence of histiocytic lymphomas was less than in the concurrent control group. The combined incidences of these two tumors in female mice at the high dose level (17%) was less than that for concurrent controls (23%) and was within the testing laboratory's historical control range (3.3-27.0%) for malignant lymphomas. The incidence of ovarian adenomas in the high dose group (4%) was well within the laboratory's historical control range (0-18%). Additionally, no statistically significant trend was observed for unadjusted data or when analyzed by the Cochran-Armitage test (Table 2). Finally, none of the tumor incidences observed in female mice were elevated when compared to control incidences by the Fisher Exact test.

In summary, none of the tumors observed in this study were considered to be the result of treatment with CP 76100.

CONCLUSIONS

Treatment of male and female mice with CP 76100 by gavage at dosages of 50, 150, and 500 mg/kg/day elicited no treatment-related changes in appearance, behavior, body weight, food consumption, hematological parameters, or macroscopic and microscopic pathology. Mortality was increased in treated male mice during the first twelve months of treatment. For the remainder of the study, mortality was similar for control and treated males. Mortality for control and treated female mice was similar throughout the study.

Under the conditions of this study, CP 76100 was not considered to be carcinogenic in mice at dosages up to and including 500 mg/kg/day.

Timothy J. Long, PhD
Senior Product Toxicologist
Monsanto Company
Department of Medicine and Environmental Health

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