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Attention: (8e) Coordinator
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
401 M Street, SW
Washington, DC 20460

Ladies and Gentlemen:

Subject: Notice in Accordance to TSCA Section 8(e) - Preliminary results of an avian reproduction study with Sulfonamide.

BASF Corporation is submitting the preliminary results of an avian feeding reproduction study in Mallard ducks administered 1, 100, 300 or 1,000 mg/kg of the developmental herbicide Sulfonamide in the diet. The study was conducted by BASF Aktiengesellschaft, Ludwigshafen, Germany. Approximately 5 kg have been shipped to the US.

The NOEC was found to be 300 mg/kg in the diet. No compound related effects were noted at any dose in the parent generation. A summary of the preliminary findings is attached.

Although the findings are not considered to present a substantial risk to the health or the environment, BASF Corporation understands that the reporting of these results is in accordance with EPA's policy. Any reports or additional information that we receive will be forwarded to the Agency and Material Safety Data Sheets will be updated with this preliminary information.

If you have any questions, please feel free to call me at (734) 324-6207.

Very Truly Yours,

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BASF Corporation

Edward Kerfoot /dr

Edward J. Kerfoot, Ph.D.
Director, Toxicology and Product Regulations

Company Sanitized

/Attachment

1609 Biddle Avenue, Wyandotte, Michigan 48192 (313) 246-6100

## 1. SUMMARY

The study was designed to determine the effect of oral administration of on the reproduction in the mallard duck. After an acclimation period, the birds were offered the test substance, incorporated in their feed, for a period of 22 weeks (9 weeks pre-egg production, 13 weeks egg production period).

Dates of testing:

- Start of acclimation period (allocation to the test cages): Dec. 01, 1997
- Start of substance feeding: Dec. 16, 1997
- Start of egg-laying period: Feb. 17, 1998
- End of egg-laying period: May 18, 1998
- Sacrifice of the parent generation: May 20, 1998
- Experimental termination date (sacrifice of last hatchlings): June 30, 1998

Protocol

The method followed the (U.S.) EPA-FIFRA Protocol PB 83-153908 of October 1982, § 71-4 and the Standard Evaluation Procedure (= SEP), Avian Reproduction Test. EPA 540/9-86-139, July 1986.

| Group | Treatment (mg/kg diet) | No. of replicates | Birds / replicate | | Birds / treatment | |
|---|---|---|---|---|---|---|
| | | | ♂♂ | ♀♀ | ♂♂ | ♀♀ |
| 0 (control) | 0 | 16 | 1 | 1 | 16 | 16 |
| 1 | 100 | 16 | 1 | 1 | 16 | 16 |
| 2 | 300 | 16 | 1 | 1 | 16 | 16 |
| 3 | 1,000 | 16 | 1 | 1 | 16 | 16 |

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# RESULTS

## PARENT GENERATION

No compound-related effects in the parent generation on mortality, birds' health, palatability, feed consumption and body weight could be detected.

## EGG AND CHICK DATA (cf. Summary Tables)

- 100 mg/kg diet:
  No biologically significant compound-related effects could be detected.

- 300 mg/kg diet
  No biologically significant compound-related effects could be detected.

- 1,000 mg/kg diet:
  For the corrected proportions (see foot notes pp. 13 and 14) of 14-day old surviving chicks of hatched live chicks there was a statistically significant decrease between the control group and the highest dose group ($p \leq 0.01$) for the time periods weeks 5 – 8, 9 – 12 and for the whole egg-laying period (weeks minus 1 to 12). It cannot be ruled out that this may be a biologically significant test compound-related effect.

Thus, under the conditions of this study, the "no observed adverse effect level (= NOAEL)" is 300 mg/kg diet.

## ANALYTICAL CONCENTRATION CONTROLS

The results of the analytical concentration controls of the test compound in the diet generally confirm a good compliance of the analytically detected concentrations with the nominal concentrations.

## Summary of egg production and chick data

| Group | 0 | 1 | 2 | 3 |
|---|---|---|---|---|
| Treatment (mg/kg feed) | 0 (control) | 100 | 300 | 1,000 |
| No. of eggs laid | 768 | 1,027 | 984 | 909 |
| No. of eggs laid/female bird | 48.0 | 64.2 | 61.5 | 56.8 |
| No. of cracked and broken eggs | 22 | 20 | 16 | 12 |
| Mean egg weight (g) | 60.9 | 60.6 | 58.9 | 60.4 |
| Mean egg shell thickness (mm) | 0.37 | 0.36 | 0.37 | 0.36 |
| No. of eggs set* | 686 | 936 | 896 | 831 |
| No. of fertile eggs | 633 | 913 | 838 | 769 |
| No. of infertile eggs | 53 | 23 | 58 | 62 |
| No. of early embryonic mortalities | 17 | 40 | 36 | 27 |
| No. of viable 14-day old embryos | 616 | 873 | 802 | 742 |
| No. of late embryonic mortalities | 6 | 13 | 7 | 9 |
| No. of viable 21-day old embryos | 610 | 860 | 795 | 733 |
| No. of total embryonic deaths | 23 | 53 | 43 | 36 |
| No. of "dead-in-shell" | 123 | 259 | 239 | 157 |
| No. of chicks hatched** | 487 (474) | 601 (586) | 556 (526) | 577 (547) |
| No. of 14-day surviving chicks** | 453 | 552 | 485 | 479 |
| No. of chicks hatched/female bird** | 30.4 | 37.6 | 34.8 | 36.1 |
| No. of 14-day surviving chicks/female bird** | 28.3 | 34.5 | 30.3 | 29.9 |
| Mean body weight of chicks at hatching (g)** | 32.9 | 32.7 | 30.9 | 31.2 |
| Mean body weight of chicks 14 days after hatching (g) | 254.0 | 259.6 | 259.4 | 262.6 |



* = incubated
** = During weeks 3 through 8, due to a technical and organizational failure, hatched chicks died in the hatcher before being removed from the hatcher. Thus, they have to be counted and are included in the figures.
() = Chicks minus chicks accidently died in the hatcher before being removed.

## Summary of egg production and chick data expressed as percentages

| Group | 0 | 1 | 2 | 3 |
|---|---|---|---|---|
| Treatment (mg/kg feed) | 0 (control) | 100 | 300 | 1,000 |
| % cracked and broken eggs of total laid | 2.9 | 2.0 | 1.6 | 1.3 |
| % fertile eggs of total set* | 92.3 | 97.5 | 93.5 | 92.5 |
| % infertile eggs of total set* | 7.7 | 2.5 | 6.5 | 7.5 |
| % early embryonic mortalities of fertile eggs | 2.7 | 4.4 | 4.3 | 3.5 |
| % viable 14-day old embryos of eggs set | 89.8 | 93.3 | 89.5 | 89.3 |
| % late embryonic mortalities of fertile eggs | 0.9 | 1.4 | 0.8 | 1.2 |
| % viable 21-day old embryos of eggs set | 88.9 | 91.9 | 88.7 | 88.2 |
| % viable eggs at day 21 of eggs set at day 14 | 99.0 | 98.5 | 99.1 | 98.8 |
| % total embryonic deaths of fertile eggs | 3.6 | 5.8 | 5.1 | 4.7 |
| % "dead-in-shell" of fertile eggs | 19.4 | 28.4 | 28.5 | 20.4 |
| Hatchability (% chicks hatched of total eggs set)** | 71.0 | 64.2 | 62.1 | 69.4 |
| Hatchability (% chicks hatched of fertile eggs)** | 76.9 | 65.8 | 66.4 | 75.0 |
| % 14-day survivors of chicks hatched | 93.0 (95.6) | 91.9 (94.2) | 87.2 (92.2) | 83.0 (87.6) |

* = incubated
** = During weeks 3 through 8, due to a technical and organizational failure, hatched chicks died in the hatcher before being removed from the hatcher. Thus, they have to be counted and are included in the figures.
() = Chicks minus chicks accidently died in the hatcher before being removed; corrected proportions.

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