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RANKING MEMBER

ONE HUNDRED THIRTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115
Majority (202) 225–2927
Minority (202) 225–3641

August 1, 2013

Dr. Len Sauers
Vice President of Global Sustainability
Procter and Gamble
701 Pennsylvania Avenue, N.W.
Suite 520
Washington, D.C. 20004

Dear Dr. Sauers:

Thank you for providing testimony to the Subcommittee on Environment and the Economy on Friday, July 11, 2013, hearing entitled "Regulation of New Chemicals, Protection of Confidential Business Information, and Innovation."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions by the close of business on Thursday, August 15, 2013. Your responses should be e-mailed to the Legislative Clerk in Word format at Nick.Abraham@mail.house.gov and mailed to Nick Abraham, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

John Shimkus
Chairman
Subcommittee on Environment and the Economy

cc: The Honorable Paul Tonko, Ranking Member,
Subcommittee on Environment and the Economy

Attachments

The Honorable John Shimkus

1. The following two (2) questions relate to testimony provided to the Committee by Heather White, on behalf of EWG.

   a. Ms. White suggested there was no incentive for companies to test chemicals under TSCA Section 5's new chemicals program. How does this statement compare with your companies' experiences under TSCA Section 5?

   b. Ms. White cited two EWG studies that "detected nearly 300 industrial chemicals in the umbilical cord blood of newborn babies". Based on these studies, she raised alarms about "pre-polluted" infants.

      i. Can you please explain to the Committee P&G's position on biomonitoring information?

      ii. What does P&G think of the EWG's suggestion that cord blood testing be required as part of any chemical assessment process?

      iii. Please discuss the CDC's National Exposure Reports on measurement of chemicals in the blood and urine of Americans and the CDC's interpretation of that information?

2. Please discuss your companies' experiences under REACH with respect to its requirements for minimum data sets for new chemicals.

   a. What's been the impact of this requirement on innovation in new chemistries in the EU?

   b. How does that compare to the innovation in the U.S. under TSCA's new chemicals program?

3. Please explain a bit more the challenges of introducing new chemicals into commerce.

   a. Why do only 50 percent of them get notices of commencement?

   b. How easy it is to have a chemical's production stopped or curtailed in the early going?

4. When P&G does testing on their chemicals prior to submitting a Pre-Manufacturing Notice:

   a. Are there use and exposure patterns that drive chemical testing?

   b. Do volumetric changes in a chemical change the focus of testing?

5. What is the major criticism of the Pre-Manufacturing Notice program under TSCA?

6. Can EPA obtain enough data (without a minimum data set requirement) on which to make a science based decision on whether a new chemical should be introduced into commerce?

7. Does EPA approve new chemicals quickly enough to meet marketplace needs? When does it work well and when does it not work as well?

8. What is a trade secret and what does TSCA section 14 protect?

9. Can health and safety information be claimed CBI and kept from the public under TSCA?

10. What happens when a company submits a health and safety study to EPA under TSCA and the company claims confidential chemical identity?

11. How critical to your business is protection of CBI?

12. What other types of confidential commercial information, other than confidential chemical identities, is protected?

13. Is confidential information always disclosed to EPA?

14. What is the purpose of the generic name?

15. What suggestions would you have to improve the Confidential Business Information provisions in a modernized TSCA?

16. Hasn't there been disagreement among some stakeholders, as well as EPA, about whether chemical identity can be claimed CBI?

    a. Don't they maintain that section 14 requires disclosure of chemical identity in health and safety studies except in two limited circumstances?

    b. If so, what are those?

17. What accounts for this disagreement in interpretation?

18. Do Canada and Europe provide CBI protections under their chemical management programs?

19. Does the TSCA new chemicals program contribute to technological and sustainable innovation?

The Honorable Henry A. Waxman

At the July 11, 2013, hearing, you testified that current disclosures, including structurally descriptive, generic chemical names are sufficient for consumers. Generally, consumers would want to use chemical names to determine whether a product on the shelf has as an ingredient a chemical substance that they wish to avoid.

1. Please provide an example of a generic chemical name used for a specific chemical in the products of your company that is sufficient to allow consumers to determine which products on the shelf include that specific chemical and which do not.

Much of what is known about chemical risk under the existing TSCA scheme is submitted to EPA and published online in the form of TSCA §8(e) notices. Several examples of such notices are attached. These examples, from the most recent batch posted for the public by EPA, have been redacted to protect information claimed by the submitter as confidential business information (CBI). The redactions include information that a consumer might use to identify the chemical implicated.

Almost the only thing left unredacted is the description of the harms found through chemical testing - "erosions and ulcerations in the forestomach," "severely dysfunctional pathological changes," and "spontaneous death." Clearly, these are chemicals that consumers could reasonably choose to avoid.

2. In your view, do these redacted notices provide enough information for consumers to make informed choices and avoid these chemicals if they so desire?

One of these notices also provides an example of what a manufacturer views as substantiation of a CBI claim. The manufacturer writes, "Disclosure of this information would harm [REDACTED]'s efforts to commercialize this compound." Given the serious risks identified in the notice, including atrophy of reproductive organs, it seems quite likely that disclosure of this risk information could harm efforts to commercialize this compound.

3. Do you support requirements for up front substantiation of CBI claims?

4. In your view is this example substantiation sufficient?

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2013 APR 11 AM 6:00

8EHQ-13-19061

April 3, 2013

This Report CONTAINS Confidential Business Information

DELIVERY BY CERTIFIED MAIL
CONFIRMATION OF RECEIPT REQUESTED

Document Control Office (7407M)
U.S. Environmental Protection Agency
Attn: TSCA Section 8(e) Coordinator
Office of Pollution Prevention and Toxics
1200 Pennsylvania Avenue, NW
Washington, DC 20460-0001

8813000021975

SUBJECT: TSCA 8(e) SUBMISSION

Dear Sir or Madam:

( ) (formerly .) is submitting certain data which we believe to be reportable under TSCA 8(e). The information concerns , an experimental aryl hydrazide insecticide. is identified by IUPAC as:

The CAS number assigned for this compound is .

recently learned of new toxicological effects in a one month oral toxicity study of in rats. An outline of the study follows:

One month oral toxicity study of in rats

was administered daily in feed to male and female rats at dose levels of 10, 100, 300, and 1000 ppm for one month. The No Observed Adverse Effect Level (NOAEL) was 10 ppm for both sexes (male rats: 1.1 mg/kg/day, female rats: 1.0 mg/kg/day). In addition, severely dysfunctional pathological changes, such as atrophy of prostate, seminal vesicle, vagina (epithelium), uterus, and thymus were observed.

believes that the NOAEL of <200 mg/kg/day in an oral study of ≤ 4 weeks, and the pathological changes are reportable under TSCA 8(e).

Company Sanitized

Performing Laboratory:

Study methods:
Test substance:
Animals: BrlHan:WIST@Jcl(GALAS) rats, males and females, 6 animals/sex/group
Animal age at initiation of treatment: 5 weeks old
Body weight range at initiation of treatment: males: 107 to 118 g; females; 90 to 107 g
Administration route: Oral via diet
Dose levels: 10, 100, 300, and 1000 ppm
Treatment period: one month
Observation items: Clinical signs, body weight, food consumption, ophthalmology, urinalysis, motor activity, FOB, hematology, blood biochemistry, gross pathology, organ weight, histopathology, electron microscopic examination

RESULTS:
Low body weight and/or suppressed food consumption were observed in both male and female rats at 300 and 1000 ppm. As a result of hematology, blood biochemistry, gross pathology, organ weight or histopathology, some changes indicating hemolytic anemia were observed in both sexes at 100 ppm and above, and the effects on liver were observed in both sexes at 300 and 1000 ppm.

Substantiation of CBI Claims

We wish to substantiate 's claims that certain information in this letter be treated as Confidential Business Information ('CBI'). All information which has been deleted from the sanitized version of this letter (copy attached) should be treated as CBI. In substantiation of this CBI claim, wishes to protect its confidential business plan for the commercial development of this compound. Disclosure of this information would harm 's efforts to commercialize this compound. Please refer to the attached letter regarding substantiation of CBI claims.

If there are any questions on this submission please feel free to contact me at ( ).

Sincerely,

me# 342508

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2012 MAR -9 AM 10: 40

Sanitized Copy

March 8, 2012

Via Federal Express

United States Environmental Protection Agency - East
Attn: TSCA Section 8(e)
Room 6428
1201 Constitution Avenue, NW
Washington, DC 20004

Subject: 8EHQ-12-18571 [Supplemental Information]
Notice in Accordance with Section 8(e): Results of OECD 422 Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test in Wistar Rats with [ ] CAS No. [ ]

Dear Sir/Madam:

We are submitting supplemental information related to our initial submission dated February 21, 2012 [8EHQ-12-18571] . This information was inadvertently omitted due to a clerical error; therefore, we are submitting a corrected version of the Confidential Letter and the Sanitized Letter.

[ ] is submitting results of OECD 422 Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test in Wistar Rats [Crl:WI(HAN)] with [ ] CAS No. [ ], conducted by [ ].

The aim of this study was to obtain initial information on the possible effects of the substance on the integrity and performance of the male and female reproductive systems including gonadal function, mating behavior, conception, gestation and parturition. Furthermore, information about the general toxicological profile including target organs and no-observed-adverse-effect-level (NOAEL) should be elucidated.

The study was carried out with reference to the requirements of the following guidelines:

- OECD Guidelines for Testing of Chemicals; No. 422, Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test (22 Mar 1996)
- EPA, Health Effects Test Guidelines; OPPTS 870.3650: Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test (Jul 2000)

Company Sanitized

The test substance was administered by gavage at dose levels of 0; 100, 300 and 1000 mg/kg bw/d. Because premature deaths in animals of test group 3 (high dose), the dose level for this group was reduced from 1000 to 600 mg/kg bw/d during the mating period (study day 19).

All animals were observed daily for any clinical signs during the study period.

After a 14-day premating period, the male and female parental animals were mated overnight in a 1:1 ratio until evidence of copulation (vaginal smear). The day on which sperm was detected was referred to as gestation day (GD) 0 and the following day as GD 1. All parental males were sacrificed and examined after the end of the administration period (at least 28 days). The parental females were allowed to deliver and rear their pups until postnatal day (PND) 4. On PND 4, all pups were sacrificed and examined.

The following is a summary of the most relevant results:

Test group 3 (1000 and 600 mg/kg bw/d):

Males:

- One male animal was found dead on study day 35.
- Salivation after treatment in all animals over the entire study period.
- Erosions and ulcerations in the forestomach of all male animals

Dams:

- One female animal was found dead on study day 16 (mating day 3) and another one was sacrificed moribund on study day 18 (gestation day 2).
- Salivation after treatment in 9 of 10 animals over the entire study period.
- Piloerection after treatment was observed in 3 female animals during gestation and lactation periods.
- Hunched posture was observed in 1 female during gestation.
- Semiclosed eyelids after treatment were observed in both eyes of 2 animals during gestation.
- Respiratory sounds were observed in 3 females during gestation.
- Two animals were gasping during gestation.
- One animal showed vaginal discharge during gestation.
- Poor general condition in 2 animals during gestation.
- Erosions and ulcerations in the forestomach of 9 of 10 female animals
- Postimplantation loss of 19%

Test group 2 (300 mg/kg bw/d):

Males:
- Salivation after treatment in 9 of 10 animals over the entire study period.
- Piloerection after treatment was observed in 1 male animal on study day 23.
- Erosions and ulcerations in the forestomach of 3 of 10 male animals.

Dams:
- Salivation after treatment in 5 of 10 animals over the entire study period.
- Erosions and ulcerations in the forestomach of 5 of 10 female animals

Test group 1 (100 mg/kg bw/d):

Males:
- Salivation after treatment in 2 of 10 animals over towards the end of the treatment period.

Dams:
- One animal, with only one implantation site, delivered one dead pup

The latter effect is assessed as being incidental, as such findings are occasionally noted in control animals, and were not observed at 300 mg/kg bw/d.

[[redacted]] understands that reporting of results from this study under TSCA 8(e) is in accordance with EPA's policy.

Please note that a confidential version of this letter is enclosed, treating the chemical identity and company identity as Confidential Business Information.

Sincerely,

Enclosures

MR# 350894

Sanitized Copy

January 3, 2013

Via Federal Express

United States Environmental Protection Agency - East
Attn: TSCA Section 8(e) / Room 6428
1201 Constitution Avenue, NW
Washington, DC 20004

Subject: Notice in Accordance with TSCA Section 8(e): Results of a combined repeat dose reproduction toxicity screening test with [redacted]

Dear Section 8(e) Coordinator:

[redacted] is submitting results of a combined repeat dose reproduction toxicity screening test (OECD422) in Wistar Rats with [redacted] conducted by [redacted]. The test substance a hardener for coatings.

The study has been performed with the dose levels of 0, 75, 250, or 750 mg/kg bw/day via gavage with 11 male and 11 female rats per dose group.

The following findings were seen:

One female at 750 mg/kg bw/day died towards the end of the gestation period. It showed hunched posture and ruffled fur starting 14 days prior to the spontaneous death, accompanied by weakened condition and visible body weight loss. Severe ulcerations of the forestomach were observed at histopathological examination.

An increase in incidence and severity of ulceration/erosion of the glandular and forestomach, squamous hyperplasia and/or inflammatory cell infiltration in the submucosa of the stomach was observed in animals at 250 and 750 mg/kg bw/day. The lesions were considered to represent a localized stomach reaction to a repeatedly gavaged irritant test material.

No compound-related effects were observed at 75 mg/kg bw/day.

Company Sanitized

Sanitized Copy

[redacted] understands that reporting of results from this study under TSCA 8(e) is in accordance with EPA's policy.

Please note that a confidential version of this letter is enclosed, treating the chemical identity and company identity as Confidential Business Information.

A Confidentiality Substantiation Questionnaire is being submitted.

Sincerely,

Enclosures