

ORIGINAL

TSCA NON-CONFIDENTIAL BUSINESS INFORMATION

DOCUMENT DESCRIPTION	DOCUMENT CONTROL NUMBER	DATE RECEIVED
8FHQ-09-17466	89100000207	5/7/10

COMMENTS:

DOES NOT CONTAIN CBI

MR# 32640



RECEIVED
OPPT EDIL

10 MAY -7 AM 10:20

Peter T. Grass
President

May 6, 2010

Document Processing Center (7407M)
EPA East - Room 6428 Attn: Section 8(e)
U.S. Environmental Protection Agency
1201 Constitution Avenue, NW
Washington, DC 20004



8EHQ-0510-17466B
DCN: 89100000207

ATTN: TSCA Section 8(e) Coordinator

RE: 8EHQ-0409-17466A, Submitted April 6, 2009



Sir:

The Asphalt Institute is writing on behalf of its member companies to report supplemental information relevant to the TSCA 8(e) Substantial Risk Notice referenced above, which reported on findings from a mouse skin carcinogenicity evaluation of asphalt fume condensate samples. We reported in the original notice that a field-generated Type III oxidized built up roofing asphalt (BURA) (CASRN: 64742-93-4) fume condensate sample (hereinafter referred to as "TRA") caused a weak tumorigenic response in the assay. It was noted that significant skin irritation was also observed and it is known from past studies that significant repeated and prolonged skin irritation can influence the development of skin tumors, e.g., via a mechanism known as tumor promotion. Therefore, in a follow-up to the initial skin painting study, the Asphalt Institute commissioned a mouse skin tumor initiation-promotion (IP) study of the sample (TRA) to investigate the possible mechanism of tumor development.

The follow-up IP study was conducted by MPI Research Inc. Mattawan, MI, under the direction of the Asphalt Institute, and in accordance with Good Laboratory Practice standards. The design followed a typical IP protocol using groups of 30 CD-1 mice (Ref.). TRA was the test substance. Control substances included dimethylbenzanthracene (DMBA, CASRN 57-97-6) as an initiator and the commonly used phorbol ester 12-O-tetradecanoylphorbol-13-acetate (TPA, CASRN 16561-29-8) as a tumor promoter. The TRA test material was tested for both initiation and promotion activity. In the initiation phase, TRA was applied twice in the first two weeks of the study and then followed with twice weekly treatments with TPA for 6 months. In the promotion phase, DMBA was applied once on the first day of the study, and then followed by twice weekly applications of TRA starting at week 2 and continuing for 6 months.

Although a draft laboratory report, audited by the laboratory's Quality Assurance Unit, is not scheduled to be completed until July 2010, tumor data have been audited. Preliminary results of this study indicate a low, but statistically significant number of tumor bearing animals (8) in the

EXECUTIVE OFFICES & RESEARCH CENTER
2696 RESEARCH PARK DRIVE
LEXINGTON, KENTUCKY 40511-8480
(859) 288-4960 • FAX (859) 288-4999
pgrass@asphaltinstitute.org

CONTAINS NO CBI

RE: 8EHQ-0409-17466A, Submitted April 6, 2009

May 6, 2010

TRA initiation phase of the study. No statistical increase in tumors was observed in the TRA promotion phase of the study. The negative control group (no tumors, treated with mineral oil) and positive control group (29 tumor bearing animals, initiated with DMBA and promoted with TPA) both responded consistently with past studies. These results suggest that TRA was a tumor initiator in the IP assay. These findings also suggest that the weak tumorigenic activity observed in the original mouse skin bioassay (8EHQ-0409-17466A) involved a genotoxic mechanism.

If you need additional technical information, please contact Dr. Earl W. Arp at the Asphalt Institute, 2696 Research Park Drive, Lexington, KY 40511-8480.

This report contains no Confidential Business Information.

Sincerely,



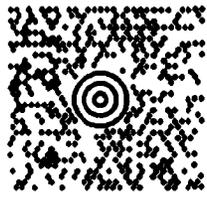
Peter T. Grass

Reference: C.S. Nessel, JJ Freeman, RC Forgash, RH McKee 1999. Tox Sci 49, 48-55: The role of dermal irritation in the skin tumor promoting activity of petroleum middle distillates.

MAILROOM
859-288-4960
ASPHALT INSTITUTE
2696 RESEARCH PARK DRIVE
LEXINGTON KY 40511

1 LBS 1 OF 1

SHIP ATTN: SECTION 8(E)
859-288-4970
TO: US ENVIRONMENTAL PROTECTION AGENCY
1201 CONSTITUTION AVENUE NW
EPA EAST ROOM 6428
TSCA CONFIDENTIAL BUS INFO CTR 7407M
WASHINGTON DC 20004-3302



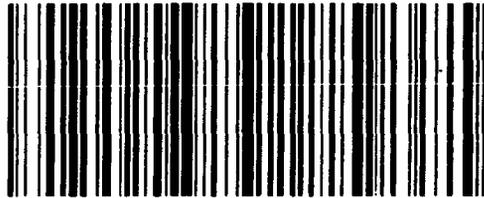
MD 201 9-80



UPS NEXT DAY AIR

TRACKING #: 1Z X40 394 01 0006 7772

1



BILLING: P/P

SHIP: 05/06/10

REF: .