

ORIGINAL

TSCA NON-CONFIDENTIAL BUSINESS INFORMATION

DOCUMENT DESCRIPTION	DOCUMENT CONTROL NUMBER	DATE RECEIVED
8EHQ-12- 18894	8813000052	11 27 12

COMMENTS:

DOES NOT CONTAIN CBI



The Chemical Company

November 26, 2012

Via Federal Express

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

350099

RECEIVED
OPPT CBIC

2012 NOV 27 AM 10:41



Subject: Notice in Accordance with TSCA Section 8(e): Results of a skin sensitization study (LLNA) with Pigment Blue 15:2 (147-14-8) preparation containing CAS No. 28654-73-1 (Copper, [N,N,N',N',N'',N''-hexaethyl-29H,31H-phthalocyanine-C,C,C-trimethanaminato(2-)-N29,N30,N31,N32])

Dear Section 8(e) Coordinator:

BASF Corporation is submitting the results of a skin sensitization study (LLNA) with Pigment Blue 15:2 (147-14-8) preparation containing CAS 28654-73-1 (Copper, [N,N,N',N',N'',N''-hexaethyl-29H,31H-phthalocyanine-C,C,C-trimethanaminato(2-)-N29,N30,N31,N32]) conducted by Bioassay, Labor für biologische Analytik GmbH, Heidelberg Germany for BASF SE, Ludwigshafen, Germany. The substance is a colorant.

In this study the test item, Pigment Blue 15:2 (147-14-8) preparation containing CAS 28654-73-1 (Copper, [N,N,N',N',N'',N''-hexaethyl-29H,31H-phthalocyanine-C,C,C-trimethanaminato(2-)-N29,N30,N31,N32]) was assessed for its skin sensitizing potential using the Local Lymph Node Assay (LLNA) in mice. Test item suspension at different concentrations was prepared in the vehicle N,N-dimethylformamide (DMF)

For this purpose a local lymph node assay was performed using test item concentrations of 0.25, 0.5 and 1% (w/w). Doses based on previously performed three pretests in the same animal strain. Radioactive labeling as well as cell-counting were used to measure cell proliferation in the lymph nodes.

The animals did not show any relevant signs of systemic toxicity during the course of the main study and no cases of mortality were observed. In dose group 0.25, 0.5 and 1% incrustations, scaling and blue test item residues could be observed on day 5. On day 3 test item residues were detected for the first time in the high dose group 1% only. According to OECD guideline 442B, an increase in ear weight exceeding the threshold value of 25% was considered to be indicative for excessive local skin irritation. This threshold was not exceeded in any test item treated group.

BASF Corporation
100 Park Avenue
Florham Park, NJ, 07932
Tel: (800) 526-1072
www.basf.com/usa



CONTAINS NO CBI



The Chemical Company

United States Environmental Protection Agency – East

November 26, 2012

Page 2

A test item is regarded as a sensitizer in the LLNA if exposure to one or more test item concentration results in a 1.6-fold or greater increase in incorporation of BrdU compared with concurrent controls, as indicated by the Stimulation Index (S.I.). The estimated test item concentration required to produce a S.I. of 1.6 is referred to as the EC1.6 value.

In this study Stimulation Indices (S.I.) of 1.3, 1.9 and 2.0 were determined with the test item at concentrations of 0.25, 0.5 and 1% (w/w) in N,N-dimethylformamide, respectively. Based on the S.I.s obtained with 0.25 and 0.5% test item concentration, an EC1.6 value of 0.4% was calculated. A clear dose response was observed.

A biologically relevant increase in BrdU labeling was observed in the 0.5 and 1% dose group. In the 1% dose group the increase in BrdU labeling reached also statistical significance. For dose group 1% this was also observed in lymph node weights and lymph node cell count. The cut-off-value for a positive response regarding the lymph node cell count index of 1.55 reported for BALB/c mice (see Ref. 8) was not exceeded in any test item dose group.

The test item Pigment Blue 15:2 (147-14-8) preparation containing CAS 28654-73-1 (Copper,[N,N,N',N',N'',N''-hexaethyl-29H,31H-phthalocyanine-C,C,C-trimethanaminato(2-)-N29,N30,N31,N32]) was thus a skin sensitizer under the test conditions of this study.

BASF Corporation understands that reporting of the results from this study under TSCA 8(e) is in accordance with EPA's policy.

Please note the technical contact and address below and direct all correspondence regarding this submission accordingly. If you have any questions, please call (248) 948-2051.

Sincerely,

Technical Contact: Alisa Boucher

BASF Corporation
Product Regulatory Center of Expertise – North America
26701 Telegraph Road, Southfield, MI 48033

Enclosures/

1415th_Letter.doc

BASF Corporation
100 Park Avenue
Florham Park, NJ, 07932
Tel (800) 526-1072
www.basf.com/usa

CONFIDENTIAL

From: (248) 948-2051
Alisa Boucher
BASF
1609 Biddle Avenue

Origin ID: NFBA

FedEx
Express



J12201209200325

WYANDOTTE, MI 48192

Ship Date: 26NOV12
ActWgt: 1.0 LB
CAD: 4487533/INET3300

Delivery Address Bar Code



SHIP TO: (202) 564-8930

BILL SENDER

ATTN: TSCA Section 8(e)
USEPA East Room 6428
1201 Constitution Ave., NW

WASHINGTON, DC 20004

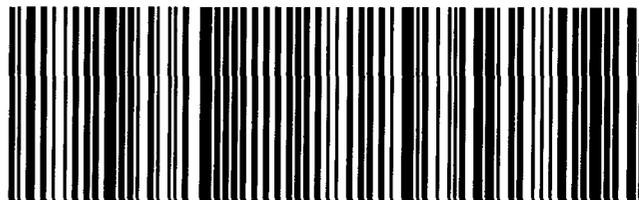
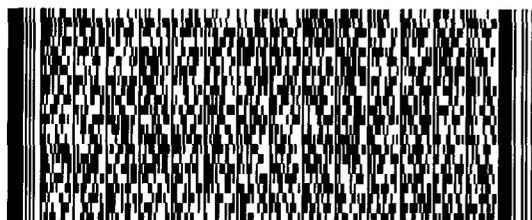
Ref # US635018
Invoice #
PO #
Dept #

TUE - 27 NOV A1
STANDARD OVERNIGHT

TRK# 7941 4355 1117

0201

20004
DC-US
DCA

ZD RDVA

515G3/EE3B/AA44

After printing this label:

1. Use the 'Print' button on this page to print your label to your laser or inkjet printer.
2. Fold the printed page along the horizontal line.
3. Place label in shipping pouch and affix it to your shipment so that the barcode portion of the label can be read and scanned.

Warning: Use only the printed original label for shipping. Using a photocopy of this label for shipping purposes is fraudulent and could result in additional billing charges, along with the cancellation of your FedEx account number.

Use of this system constitutes your agreement to the service conditions in the current FedEx Service Guide, available on fedex.com. FedEx will not be responsible for any claim in excess of \$100 per package, whether the result of loss, damage, delay, non-delivery, misdelivery, or misinformation, unless you declare a higher value, pay an additional charge, document your actual loss and file a timely claim. Limitations found in the current FedEx Service Guide apply. Your right to recover from FedEx for any loss, including intrinsic value of the package, loss of sales, income interest, profit, attorney's fees, costs, and other forms of damage whether direct, incidental, consequential, or special is limited to the greater of \$100 or the authorized declared value. Recovery cannot exceed actual documented loss. Maximum for items of extraordinary value is \$1,000, e.g. jewelry, precious metals, negotiable instruments and other items listed in our Service Guide. Written claims must be filed within strict time limits, see current FedEx Service Guide.