

ORIGINAL

TSCA NON-CONFIDENTIAL BUSINESS INFORMATION

DOCUMENT DESCRIPTION	DOCUMENT CONTROL NUMBER	DATE RECEIVED
8EHQ-10-17947	88100000276	5/19/10

COMMENTS:

DOES NOT CONTAIN CBI



The Chemical Company

326995

Helping Make
Products Better™

RECEIVED
OPPT CBIC

May 17, 2010

10 MAY 19 AM 6:01



Via Federal Express

8EHQ-0510-17947A

DCN: 88100000276

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 Section 8(e): Results of a Skin Sensitization Study
(Maximization Test in Guinea Pigs) with Alkenyl Succinic Anhydride
(CAS No. 68784-12-3)

Dear Sir/Madam:

BASF Corporation is submitting, on behalf of Consortium members¹, results of a Skin Sensitization Study (Maximization Test in Guinea pigs) with Alkenyl Succinic Anhydride (CAS No. 68784-12-3), conducted by BASF SE, Ludwigshafen, Germany. The substance is used as a sizing agent for paper.

The test substance was investigated for possible sensitization to the skin by means of the Maximization Test developed by Magnusson and Kligman in guinea pigs.

Due to the intradermal administration of test substance and Freund's complete adjuvant, the Maximization Test is regarded as a very sensitive method for assessment of a sensitizing potential of test substances.

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

- OECD Guideline for Testing of Chemicals No. 406, July 17, 1992 ("Skin Sensitization")
- Commission Regulation (EC) No 440/2008 of 30 May 2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), *Part B: Methods for the determination of toxicity and other health effects: Skin Sensitization; Official Journal of the European Union, No. L 142*
- U. S. EPA Health Effects Test Guidelines OPPTS 870.2600, March 2003 ("Skin Sensitization")
- Japan MAFF Testing Guideline of 12 Nousan No. 8147, November 24, 2000 as this is in line with OECD 406.

¹ Consortium members include: Hercules BV, an Ashland Affiliate, Pentagon Chemical Specialties Limited, Eka Chemicals AB, Bercen, Inc., Dixie Chemical Company, Inc., Kemira Chemie GmbH, Mare S.p.A.

United States Environmental Protection Agency – East

May 17, 2010

Page 2

The test-item concentrations for the main test were selected based on the results of the pretests. The intradermal induction was performed with a 5% test-item preparation in corn oil (ÖAB9) or 5% test-item preparation in Freund's complete adjuvant / 0.9% aqueous NaCl-solution (1:1) and the epicutaneous induction with a 25% test-item preparation in corn oil. For the challenge, a 5% test-item preparation in acetone was chosen.

The study was performed using 1 control group and 1 test group.

The intradermal induction was performed on day 0 and the epicutaneous induction on day 7. One challenge was carried out 14 days after the epicutaneous induction.

The **intradermal induction** caused slight to intense erythema and swelling at the injection sites of the test-item preparations in all test group animals.

After the **epicutaneous induction**, incrustation, partially open (caused by the intradermal induction) could be observed in addition to slight to intense erythema and swelling in all test group animals.

5 animals with skin findings were observed after the 1st **challenge**, as summarized in the following table:

	1 st challenge					
	Test item 5 % in acetone (w/w)			Vehicle control (acetone only)		
	24 h	48 h	Total	24 h	48 h	Total
Control group	0/5	0/5	0/5	0/5	0/5	0/5
Test group	5/10	4/10	5/10	0/10	0/10	0/10

x/y: number of positive reactions/number of animals tested (**reading at 24 h and/or 48 h after the removal of the patch**)

Based on the results of this study and applying the evaluation criteria cited in Chapter 3.8, it was concluded that Alkenyl Succinic Anhydride **has a sensitizing effect** on the skin of the Guinea pig in the Maximization Test under the test conditions chosen.



The Chemical Company

United States Environmental Protection Agency – East
May 17, 2010
Page 3

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

If you have any questions, please call Janet Cerra at (973) 245-6693.

Sincerely,

Janet Cerra

Janet Cerra
Product Regulatory Center of Expertise
North America

/jc

1063rd Letter.doc

From: Origin ID: LKKA (973) 245-6693
Janet Cerra
BASF
100 Campus Drive

Florham Park, NJ 07932



Ship Date: 17MAY10
Act/Wgt: 1.0 LB
CAD: 4487533/INET3010

Delivery Address Bar Code

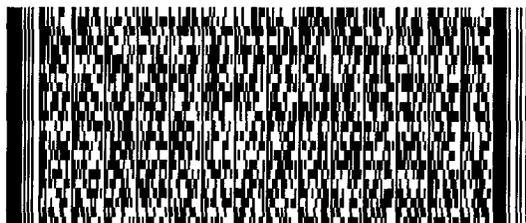


Ref # US635018
Invoice #
PO #
Dept #

SHIP TO: (202) 564-8930 BILL SENDER
Attn: TSCA Section 8(e)
USEPA East
Room 6428
1201 Constitution Avenue, NW
Washington, DC 20004

TRK# 7986 6875 4331
0201

TUE - 18 MAY A1
STANDARD OVERNIG

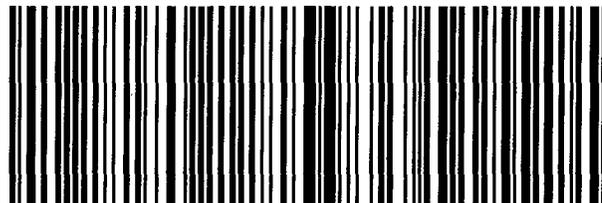


20004

DC-US

DCA

ZD RDVA



605C18169/5FE8

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 can 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 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 \$500, 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.

Global Home | Small Business Center | Service Info | About FedEx | Investor Relations | Careers | fedex.com Terms of Use | Security & Privacy | Site
This site is protected by copyright and trademark laws under US and International law. All rights reserved. © 1995-2010 FedEx