



**RHÔNE-POULENC**

8EHQ-0893-12005

**RHÔNE-POULENC INC.**  
SPECIALTY CHEMICALS DIVISION  
CN 7500, CRANBURY, NJ 08512-7500  
TELEPHONE (609) 980-4000

August 19, 1993

**Contains No CBI**

(A)

Ref. No. 93-93-160L.EPA  
CERT # P 378 286 325  
RETURN RECEIPT REQUESTED

93 AUG 24 AM 8:05  
OTS CBIC

TSCA Document Processing Center (TS-790)  
Room 201 East Tower  
Attn: Section 8(e) Coordinator  
Office of Toxic Substances  
Environmental Protection Agency  
401 M Street, SW  
Washington, DC 20460

RE: TSCA §8(e) Notification of Substantial Risk:  
Cocamidopropyl Betaine (CAS Registry Number 70851-07-9)  
REF: 8EHQ-0492-3312 INIT

Dear Sir or Madam:

In accordance with the provisions of Section 8(e) of the Toxic Substances Control Act (TSCA) as interpreted in the TSCA Section 8(e) - Reportability of Toxicologic Case Studies (Draft Final, June 13, 1991), Rhône-Poulenc, Inc. respectfully submits to the Agency the following documents:

- "Primary Eye Irritation Study of Mirataine BD-J in Rabbits"
- "Primary Eye Irritation Study of Mirataine CBC in Rabbits"

The Agency was notified as to the preliminary findings (irreversible ocular irritation) attributable to the above products in a letter dated April 23, 1992 (included herein as Attachment 1).



8EHQ-93-12005  
INIT 88/24/93



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77 PS

August 19, 1993  
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Rhone-Poulenc, Inc. asserts that none of the information included in this submission is Confidential Business Information.

If you have any questions, or require any further information, please call (609) 860-3589. Thank you.

Very truly yours,  
RHONE-POULENC, INC.

A handwritten signature in cursive script, appearing to read 'Charles E. Moyer, Jr.', written in dark ink.

Charles E. Moyer, Jr.  
Director, Product Safety

CEMJr/rc  
Attachments

Contains No CBI

ATTACHMENT 1



RHÔNE-POULENC INC.

CN 7500, CHARENTON, NJ 08812-7500  
TELEPHONE: (609) 384-6300

April 23, 1992

Ref: 92-0411.EPA  
FEDERAL EXPRESS #3682671252

TSCA Document Processing Center (TS-790)  
Room 201 East Tower  
Attn: Section 8(e) Coordinator  
Office of Toxic Substances  
US Environmental Protection Agency  
401 M Street, SW  
Washington, DC 20460

RE: TSCA §8(e) Notification of Substantial Risk :  
Cocamidopropyl Betaine (CAS Registry number 70851-07-9) <sup>AS</sup>

Dear Sir or Madam:

In accordance with the provisions of Section 8(e) of the Toxic Substances Control Act (TSCA) as interpreted in the TSCA Section 8(e) - Reportability of Toxicologic Case Studies (Draft Final, June 13, 1991), Rhône-Poulenc, Inc. is hereby submitting the following notification of Substantial Risk:

Chemical Substance:

Cocamidopropyl Betaine  
CAS Registry Number: 70851-07-9

Manufacturer:

Rhone-Poulenc, Inc.  
CN 5266  
Princeton, NJ 08543-5266

Study Results:

Primary Eye Irritation Study in Rabbits : Material caused ocular irritation through Day 21 (study termination) in the unwashed eyes of rabbits. (pH is

93 AUG 24 AM 8:05  
OTS CBIC

reported to be 8-9).

Rhone-Poulenc, Inc. has requested the full study from the testing laboratory, and will forward it to the Agency upon receipt.

Rhone-Poulenc, Inc asserts that none of the information contained herein is confidential business information.

Should you have any questions, or require any further information, please call (609-860-3589). Thank you.

Very truly yours,  
RHONE-POULENC, INC.

*Charles E. Moyer, Jr.*

Charles E. Moyer, Jr.  
Director, Product Safety

**CORRECTED PAGE**

**SUMMARY**

The primary eye irritation potential of Mirataine BD-J was evaluated when instilled into the eyes of six rabbits. The test material produced corneal and iridal involvement and moderate to severe conjunctival irritation. Ocular irritation was still present in three animals at Day 21 after treatment.

**OBJECTIVE**

The objective of this study was to assess the relative level of irritation produced, following a single exposure of a test material to one eye of albino rabbits. All procedures used in this study are in compliance with the Animal Welfare Act Regulations, effective October 30, 1989. In the opinion of the Sponsor and study director, the study did not unnecessarily duplicate any previous work.

**TEST MATERIAL**

Identification

The test material was identified as Mirataine BD-J; DA2A014290 and described as a clear, light-yellow liquid.

Purity and Stability

The Sponsor assumes responsibility for purity and stability determinations (including under test conditions). The Sponsor-supplied certificate of analysis is on Page 36 of this report.

Storage and Retention

The test material was stored at room temperature. Any unused test material will be discarded after issuance of the final report according to Hazelton Wisconsin (HWI) Standard Operating Procedure's (SOP).

Safety Precautions

The test material handling procedures were according to HWI SOPs and policies.

TRIAGE of 8(e) Submissions

Date sent to triage: \_\_\_\_\_

NON-CAP

CAP

Submission number: 12005A

TSCA Inventory  Y N D

STUDY TYPE (circle appropriate):

Cheng-Chun Lee (E609C)  
 ATOX      SBTX      SEN      W/NEUR

Larry Newsome (E425)  
ECO      AQUATO

Katherine Anitole (E611G)  
RTOX/DTOX

Daljit Sawhney (E611A)  
CTOX      STOX

Deborah Norris (E602)  
NEUR

Jeff Beaubier (E608)  
EPI

Ron Ward (E611F)  
IMMUNO/ALLERG

Davis Lai (E611B)  
CARC

Michael Cimino (E611D)  
GTOX

Leonard Keifer (E611C)  
META/PHARM

NOTES:

CECA INTRIGAGE TRACKING DBASE ENTRY FORM

CLIENTS DATA: Submission # BEHQ 0813-12005 SEQ A

TYPE: INT-SUPP FLWP

SUBMITTER NAME: Rhone-Poulenc Inc.

INFORMATION REQUESTED: FLWP DATE:  
 0501 NO INFO REQUESTED  
 0502 INFO REQUESTED (TECH)  
 0503 INFO REQUESTED (VOL ACTIONS)  
 0504 INFO REQUESTED (REPORTING RATIONALE)  
 DISPOSITION:  
0639 REFER TO CHEMICAL SCREENING  
 0678 CAP NOTICE

VOLUNTARY ACTIONS:  
0401 NO ACTION REPORTED  
 0402 STUDIES PLANNED/UNDERWAY  
 0403 NOTIFICATION OF WORKER/THIRDS  
 0404 LABEL/MSDS CHANGES  
 0405 PROCESS/HANDLING CHANGES  
 0406 APP/USE DISCONTINUED  
 0407 PRODUCTION DISCONTINUED  
 0408 CONFIDENTIAL

SUB DATE: 08/19/93 OTS DATE: 08/24/93 CSRAD DATE: 10/07/93

CHEMICAL NAME:

Mirtazapine BD-J CAS# 70851-07-9

INFORMATION TYPE:	P F C	INFORMATION TYPE:	P F C	INFORMATION TYPE:	P F C
0201 ONCO (HUMAN)	01 02 04	0216 EPI/CLIN	01 02 04	0241 IMMUNO (ANIMAL)	01 02 04
0202 ONCO (ANIMAL)	01 02 04	0217 HUMAN EXPOS (PROD CONTAM)	01 02 04	0242 IMMUNO (HUMAN)	01 02 04
0203 CELL TRANS (IN VITRO)	01 02 04	0218 HUMAN EXPOS (ACCIDENTAL)	01 02 04	0243 CHEM/PHYS PROP	01 02 04
0204 MUTA (IN VITRO)	01 02 04	0219 HUMAN EXPOS (MONITORING)	01 02 04	0244 CLASTO (I VITRO)	01 02 04
0205 MUTA (IN VIVO)	01 02 04	0220 ECO/AQUA TOX	01 02 04	0245 CLASTO (ANIMAL)	01 02 04
0206 REPRO/TERATO (HUMAN)	01 02 04	0221 ENV. OCCUR/REL/FATE	01 02 04	0246 CLASTO (HUMAN)	01 02 04
0207 REPRO/TERATO (ANIMAL)	01 02 04	0222 EMER INCI OF ENV CONTAM	01 02 04	0247 DNA DAM/REPAIR	01 02 04
0208 NEURO (HUMAN)	01 02 04	0223 RESPONSE REQEST DELAY	01 02 04	0248 PROD/USE/PROC	01 02 04
0209 NEURO (ANIMAL)	01 02 04	0224 PRODCOMP/CHEM ID	01 02 04	0251 MSDS	01 02 04
0210 ACUTE TOX. (HUMAN)	01 02 04	0225 REPORTING RATIONALE	01 02 04	OTHER	01 02 04
0211 CHR. TOX. (HUMAN)	01 02 04	0226 CONFIDENTIAL	01 02 04		
<u>0212</u> ACUTE TOX. (ANIMAL)	<u>01 02 04</u>	0227 ALLERG (HUMAN)	01 02 04		
0213 SUB ACUTE TOX (ANIMAL)	01 02 04	0228 ALLERG (ANIMAL)	01 02 04		
0214 SUB CHRONIC TOX (ANIMAL)	01 02 04	0239 METAB/PHARMACO (ANIMAL)	01 02 04		
0215 CHRONIC TOX (ANIMAL)	01 02 04	0240 METAB/PHARMACO (HUMAN)	01 02 04		

TRIGAGE DATA: NON-CBI INVENTORY ONGOING REVIEW: YES (DROPP/REPR) SPECIES: RST TOXICOLOGICAL CONCERN: LOW USE: PRODUCTION:

YES (CONTINUE) YES (DROPP/REPR) NO (CONTINUE) MED HIGH

DETERMINE REFER: HIGH

COMMENTS: Non-Cop

“12005A”<sup>N</sup> = “COCCAMIDOPROPYL BETAINE (CAS NO. 70851-07-9): THE FOLLOWING ABSTRACT WAS WRITTEN FROM A SUMMARY PROVIDED BY THE SUBMITTER. EYE IRRITATION IN THE RABBIT IS OF MODERATE CONCERN. AN UNSPECIFIED CONCENTRATION OF THE TEST SUBSTANCE WAS INSTILLED INTO THE EYES OF SIX RABBITS. THE TEST MATERIAL PRODUCED CORNEAL AND IRIDAL INVOLVEMENT AND MODERATE TO SEVERE CONJUNCTIVAL IRRITATION. OCULAR IRRITATION WAS STILL PRESENT IN THREE ANIMALS AT DAY 21 AFTER TREATMENT.”