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ATO

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8e Original (1)
Contains No CBI

8EHQ-0993-12432

September 13, 1993

**FEDERAL EXPRESS
RETURN RECEIPT REQUESTED**



8EHQ-93-12432
INIT 09/17/93

Document Processing Center (TS-790)
Office of Toxic Substances
Environmental Protection Agency
401 M St. S.W.
Washington, D.C. 20460
Attn: Section 8(e) Coordinator



88930000449



09 SEP 17 11:55

Subject: TSCA Section 8(e) Submission

Dear Sir/Madam:

Elf Atochem North America Inc. is submitting the attached study to the Environmental Protection Agency (EPA) pursuant to Toxic Substances Control Act (TSCA) Section 8(e). This study does not involve effects in humans.

The enclosed study summary recently came into our possession via our parent company in France and provides information on ADAMQUAT BZ 80. ADAMQUAT BZ 80 is N,N-Dimethyl-N-[2-[(1-oxo-2-propenyl)oxy]ethyl], benzenemethanaminium chloride (CAS No. 46830-22-2). This product is manufactured for research and development purposes by Elf Atochem for use as a monomer in polymer synthesis.

Nothing in this letter or the enclosed study report is considered confidential business information of Elf Atochem.

The title of the enclosed study summary report is ADAMQUAT BZ 80 Skin Sensitization Test in Guinea Pigs. The following is a summary of the adverse effects observed in the skin sensitization test.

ADAMQUAT BZ 80 was tested for potential to produce allergic skin reaction by intradermal injection and skin application to guinea pigs using a modified Magnusson and Klingman method. The test material produced a 70% (14/20) sensitization rate and was classified as a strong sensitizer.

10-1-93

(2)

TSCA 8(e) Submission
ADAMQUAT BZ 80
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Page 2

Elf Atochem has not previously filed any 8(e) notices on the subject material. A premanufacture notification was previously submitted by Elf Atochem and assigned case number P93-1395.

Results from the study summary report are being included in the current Elf Atochem Material Safety Data Sheet for ADAMQUAT BZ 80.

A copy of the full study will be submitted to the Agency as soon as it becomes available. Further questions regarding this submission may be directed to me at (215) 337-6892.

Sincerely,



C.H. Farr, PhD, DABT
Manager, Product Safety
and Toxicology

Enclosure

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CIT

CN 14587

M-1181

ADAMOUAT BZ 80

SKIN SENSITIZATION TEST

IN GUINEA-PIGS

CENTRE INTERNATIONAL DE TOXICOLOGIE

SEREY / BP. 563 / 27005 EVREUX CEDEX FRANCE TEL. 33 27 67 87 05 FAX 33 27 67 87 05

SUMMARY

At the request of Atochem S.A., Paris-la-Défense, France, the sensitization potential of the test substance ADAMQUAT BZ 80 was evaluated in guinea-pigs by intradermal injection and cutaneous application, according to the maximization method of Magnusson and Kligman (1), the O.E.C.D. Guideline No. 406 and the Principles of Good Laboratory Practice (O.E.C.D., 12th May 1981).

Methods

Thirty guinea-pigs (15 males and 15 females) were allocated to 2 groups: a control group (5 males and 5 females) and a treated group (10 males and 10 females).

The sensitization potential of the test substance was evaluated after a 10-day induction period during which the animals were treated with the vehicle (control group) or the test substance (treated group). On day 1, 0.1 ml of the test substance was administered by intradermal route at a concentration of 10%. On day 8, 0.5 ml of the test substance in its original form was applied by cutaneous route. After a period of 12 days without treatment, a challenge cutaneous application of 0.5 ml of the vehicle (left flank) and 0.5 ml of the test substance in its original form (right flank) were then performed on all animals. The substances were held in place for 24 hours by means of an occlusive dressing. The cutaneous reactions were then evaluated at the challenge application site, 24 and 48 hours after removal of the dressing.

After the final scoring period, the animals were sacrificed and cutaneous samples were taken from the challenge application sites in all animals. No histological examination was performed on the cutaneous samples.

Reference

- (1) Magnusson, B.; Kligman, A.M.: The identification of contact allergens by animal assay. The guinea pig maximization test. J. Invest. Derm. 52: 268-276 (1969).

Results

No clinical signs were observed and no deaths occurred throughout the study.

After the challenge cutaneous application of the test substance, no cutaneous reactions in the control group and positive cutaneous reactions in the treated group were observed. The positive reactions consisted of a well-defined or moderate to severe erythema after 24 hours in 7/10 males and 7/10 females. The positive reactions had reversed after 48 hours slight cutaneous reactions in 7/10 males and 6/10 females or remained positive (erythema, score of 2) in 1/10 females. The slight cutaneous reactions noted in 2/10 males and 1/10 females were inconclusive of a sensitization process.

A dryness of the skin in 9/10 males and 10/10 females was noted after 48 hours.

Conclusion

The test substance ADAMQUAT BZ 80 induced cutaneous reactions as a result of a sensitization process in 5% (1 out of 20) guinea-pigs or as due to a slight sensitization process in 65% (13 out of 20). The allergenicity level of the test substance ADAMQUAT BZ 80 was IV "Strong" in guinea-pigs.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

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OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

JAN 18 1994

This letter formally acknowledges EPA's receipt of information submitted by your organization under Section 8(e), the "substantial risk" information reporting provision of the Toxic Substances Control Act (TSCA). For your reference, copies of the first page(s) of your submission(s) are enclosed and display the TSCA Section 8(e) Document Control Number (i.e., 8EHQ-0000-0000 Init.) assigned by EPA to your submission(s). Please refer to this cited number when submitting follow-up or supplemental information.

Please note that all submitted correspondence will be placed in the public files unless confidentiality is claimed according to the procedures outlined in Part X of EPA's TSCA Section 8(e) policy statement (43 FR 11110, March 16, 1978).

Confidential submissions submitted pursuant to the TSCA Section 8(e) Compliance Audit Program (CAP) should already contain information supporting confidentiality claims, because substantiation of CBI claims is required at the same time the 8(e) CAP is submitted to EPA. (If not done so already, please ensure that this information is provided to the Agency). When substantiating any/all claims, answer the questions detailed in the following attachment.

For NON-CAP submissions, any confidentiality claims should be supported by submission of information as described in the attachment(s).

12432 A



CHECATS DATA:
Submission # BEHQ- 0993-12432 SEQ B

TYPE: INT. SUP FLWP ELF
SUBMITTER NAME: Alachem North
America, Inc.

SUB. DATE: 09/27/93 OTS DATE: 09/29/93 CSRAD DATE: 10/25/93

CHEMICAL NAME:
Benzene methanaminum, chloro-
N,N-Dimethyl-N-[2-[(1-oxo-2-propenyl)
oxy]ethyl], chloride

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
067R CAP NOTICE

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

CAS# 46830-22-2 | Adamquat BZ 80 → 46830-22

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 CELI. TRANS (IN VITRO)	01 02 04	0218 HUMAN EXPOS (ACCIDENTAL)	01 02 04	<input checked="" type="radio"/> 0243 CHEM/PHYS PR. P	01 02 04
0204 MUTA (IN VITRO)	01 02 04	0219 HUMAN EXPOS (MONITORING)	01 02 04	0244 CLASTO (IN 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 REQUEST DELAY	01 02 04	0248 PROD/USE/PROC	01 02 04
0209 NEURO (ANIMAL)	01 02 04	<input checked="" type="radio"/> 0224 PROD/COMP/CHEM ID	01 02 04	0251 MSDS	01 02 04
0210 ACUTE TOX. (HUMAN)	01 02 04	0225 REPORTING RATIONALE	01 02 04	0299 OTHER	01 02 04
0211 CHR. TOX. (HUMAN)	01 02 04	0226 CONFIDENTIAL	01 02 04		
0212 ACUTE TOX. (ANIMAL)	01 02 04	0227 ALLERG (HUMAN)	01 02 04		
0213 SUB ACUTE TOX (ANIMAL)	01 02 04	<input checked="" type="radio"/> 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		

TRIALGE DATA: NON-CBI INVENTORY ONGOING REVIEW SPECIES TOXICOLOGICAL CONCERN: USE: PRODUCTION:

YES (CONTINUE) YES (DROP/REFER) GP LOW

NO (DROP) NO (CONTINUE) (MED) Dermal Sensitization

DETERMINE REFER HIGH

COMMENTS: on use: Dermal Sensitization. No clinical signs of toxicity or deaths were observed during the guinea pig maximization test (Magnusson & Kligman). After challenge, positive reactions (well-defined or moderate-to-severe erythema) were seen after 24 hours in 7/10 males and 7/10 females. Positive signs had reversed after 48 hours in all animals, except for 1/10 females. Cutaneous reactions from sensitization occurred in 5% (1/20) animals. Slight sensitization occurred over

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in $13/20$ animals (65%)

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