Contains No CBI

RHÔNE-POULENC

RHÔNE-POULENC INC.
CN 7500, CRANBURY, NJ 08512-7500
TELEPHONE: (609) 395-8300

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October 27, 1992

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CERTIFIED MAIL
RETURN RECEIPT REQUESTED
P 416 555 411

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

RE: Report Submitted Pursuant to the TSCA Section 8(e) Compliance Audit Program

CAP ID NO.: 8ECAP - 0004

RP CAP REPORT NO.: RPS - 0348

Dear Sir/Madam:

On behalf of Rhône-Poulenc Inc. (RPI, CN5266, Princeton, NJ 08543-5266) and its subsidiaries, the attached report is being submitted to the Environmental Protection Agency (EPA) pursuant to the Toxic Substances Control Act (TSCA) Section 8(e) Compliance Audit Program (CAP Agreement) executed by RPI and EPA (8ECAP - 0004).

The enclosed report provides information on the following chemical substance:

Product Name:	Celynol MSPO-11
CAS Registry No:	100403-39-2
CAS Registry Name:	Glycerides, palm-oil, reaction products with sucrose

The title of the enclosed report is:

Study Regarding the Effect of MSPO-11 on Reproduction in the Rat

The following is a summary of the adverse effects in this report.

Dietary administration of 20,000 ppm MSPO-11 to female rats during mating, gestation, and lactation resulted in an increase in pup weight. Control pups had an average weight of 48.5 g while pups from the MSPO-11 group weighed an average of 59.4 g.

RPI does not claim any portion of the information in this submission to be TSCA confidential business information (TSCA CBI).

9/7/95

RPI has not previously submitted any TSCA Section 8(e) notices or premanufacture notification on the subject chemical substance. In total, we are submitting three copies of the enclosed report and this cover letter: an original and two copies.

Further questions regarding this submission may be directed to Dr. Glenn S. Simon, Director of Toxicology at (919)549-2222 (Rhône-Poulenc, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709).

Sincerely,

Charles E. Moyer, Jr., Ph.D.
Director, Product Safety
(609)860-3589

Enclosure 12

SOCIETE DE PRODUITS CHIMIQUES ET DE SYNTHESE

Corporate Offices: 29, rue Emile-Zola, BEZONS

STUDY REGARDING THE EFFECT OF MSPO-11 ON REPRODUCTION IN THE RAT

Work carried out under the direction of Dr. Raymond Ferrando, Veterinary Surgeon at the Veterinary School of ALFORT (Seine)

STUDY REGARDING THE EFFECT OF M.S.P.O.11 ON REPRODUCTION IN THE RAT

The purpose of the tests was to determine whether M.S.P.O.11 palm-oil sucroglyceride could exercise an effect on the reproduction function of the rat when distributed in the diet at the concentration of two per cent.

EXPERIMENTAL SCHEME

The experiments took place from October 15, 1963 to January 31, 1964. Twenty female rats selected at random were divided after a preparatory period of ten days, into two lots of ten subjects each.

The basic diet was as follows:

Wholemeal flour	78 per cent
Lactic casein	10 " "
Germalyne	5 " "
Brewer's yeast	3 " "
Fish meal	1 " "
Mineral mixture	3 " "
Vitamins A, E and D according to classic procedure + 1 to 2 drops of iodine-iodized solution in each drinking bottle	

Ten subjects were given this diet, whereas the other ten received the same diet to which 2 per cent M.S.P.O 11 palm-oil sucroglyceride had been added. Mating was carried out according to normal breeding methods and, of course, under identical conditions in the two lots.

RESULTS OBTAINED

The results obtained were as follows:

continued

Table I - Effect of M.S.P.O. 11 on the reproductive faculties of the weight rat

	Control group	M.S.P.O.11 Group
Number of litters	19	19
" " weaned	9	12
" of dead litters at birth	8	6
Litters that did not live to be weaned	2	1
Total number of subjects born	145	178
Number of subjects born alive	131	165
Number of subjects born dead	14	13
Number of subjects that died before weaning	61	77
Number of subjects weaned	64	92
Number of subjects weaned per litter	7.1	7.6

Lastly, if we consider the weight of the subjects at the moment of their separation from the mother *), it can be noted that the weight was much higher in the subjects receiving M.S.P.O. 11. In order to effect this control, males and females were selected when the last litter of rats making up the two experimental groups were weaned. The subjects were weighed and then divided according to sex. In the control group, 6 males and 15 females were selected. In the group receiving M.S.P.O. 11, 22 males and 21 females were selected in the same way.

*) when the young rats already consumed a little of the nourishment distributed to the mother.

continued

The average weight was as follows:

	Control group	M.S.P.O.11 group
	(weight in gm)	
Males	52.13	62.09
Females	44.80	56.61

DISCUSSION AND CONCLUSIONS

The use of M.S.P.O 11 in the diet of the adult female rat during a period of three and a half months shows that when the product is adopted in the region of two per cent in the diet, it has no harmful effect on the reproduction function. Similarly, compared with the control animals, it appears that reproduction, weaning and the commencement of growth are carried out in optimum conditions. This confirms what had been observed in other Laboratories, according to the documentation made available to us.

The number of litters weaned represented 47 per cent among the controls, compared with 63 per cent among the females receiving 2 per cent M.S.P.O. 11. Mortality of litters at birth was respectively 42 per cent and 31 per cent. The number of subjects at birth was on average 7.6 among the controls and 9.3 among the animals receiving the product.

We did not observe any anomalies at any time or in any group during the external morphological examination of the newly-born rats. We therefore believe that, when used at 2 per cent, the M.S.P.O. 11 product does not present any disadvantage in respect of the reproduction function or in respect of lactation. Similarly, it appears that the general nutrition of the animals receiving the product is slightly better.

ALFORT, February 17, 1964

(sgd) Professor R.FERRANDO

517

Enclosure 12

SOCIÉTÉ DE PRODUITS CHIMIQUES ET DE SYNTHÈS

SIÈGE SOCIAL : 29, RUE ÉMILE-ZOLA, BEZONS (S.-&-O.)
PARIS-CHArlebourg 37.07 et PARIS 968 70-75
: CHIMIQUES-BEZONS - TELEX N° 22655

Bezons, le

Vos réf.
Nos réf.

ETUDE de L'ACTION du MSPO - 11

SUR LA REPRODUCTION CHEZ LA RATE

::

Travail effectué sous l'autorité de
Monsieur le Docteur Raymond Ferrando
Vétérinaire - Docteur es-Sciences
Professeur à l' Ecole Vétérinaire
d'ALFORT (Seine)

SB

ETUDE DE L'ACTION DU M.S.P.O.11 SUR LA REPRODUCTION CHEZ LA RATE

Cette expérience a pour but de déterminer si le sucroglycéride de l'huile de palme M.S.P.O.11, pouvait avoir une action sur la fonction de reproduction du rat quand il est distribué dans la ration à raison de deux pour cent.

PROTOCOLE EXPERIMENTAL.-

L'expérience s'est déroulée du 15 Octobre 1963 au 31 Janvier 1964. Vingt rates prélevées au hasard dans l'élevage furent, après une période préparatoire de dix jours, réparties en deux lots de dix sujets chacun.

Le régime de base était le suivant :

Farine de blé complète ..	78 p.100
Caséine lactique	10 "
Germalyne	5 "
Levure de distillerie ...	3 "
Farine de poisson	1 "
Mélange minéral	3 "

Vitamine A, E et D selon les normes classiques + 1 à 2 gouttes de solution iodo-iodurée dans chaque biberon.

Dix sujets recevaient ce régime, dix autres recevaient le même régime supplémenté avec 2 p.100 de sucroglycéride de l'huil de palme M.S.P.O.11. Les accouplements furent effectués selon la méthode habituelle de l'élevage et, bien entendu, dans des conditions identiques dans les deux lots.

.../...

RESULTATS OBTENUS.-

La répartition des résultats est la suivante : (tableau

TABLEAU I - INFLUENCE DU M.S.P.O.11 SUR LES FACULTES REPRODUCTRICE DU RAT BLANC

	Groupe témoins	Groupe M.S.P.O.11
Nombre de portées	19	19
" " " sevrées	9	12
" " " mortes à la naissance	8	6
Portées non parvenues au sevrage	2	1
Nombre total de sujets nés	145	178
Nombre de sujets nés vivants	131	165
Nombre de sujets morts nés	14	13
" " " " avant sevrage	61	77
Nombre de sujets sevrés .	64	92
Nombre de sujets sevrés par portées	7,1	7,6

Si nous considérons enfin le poids des sujets au moment où ils sont séparés de leur mère*, on note que ce poids est largement supérieur chez les sujets recevant le M.S.P.O.11. Afin d'effectuer ce contrôle, des mâles et des femelles ont été prélevés dès le sevrage de la dernière portée des rates constituant les deux groupes expérimentaux. Les sujets ont été pesés puis répartis selon le sexe. Dans le groupe témoin on a ainsi prélevé 6 mâles et 15 femelles. Dans le groupe recevant le M.S.P.O.11 on a prélevé de la même façon 22 mâles et 21 femelles.

* A ce moment là les jeunes consomment déjà un peu de la nourriture distribuée à leurs mères.

La moyenne des poids est la suivante :

	Groupe Témoin (poids en g)	Groupe M.S.P.O.11 (poids en g)
Mâles	52,13	62,09
Femelles	44,80	56,61

DISCUSSION ET CONCLUSIONS.-

L'utilisation du M.S.P.O.11 chez la femelle adulte du ra pendant une période de trois mois et demi, montre que le produit utilisé à raison de deux pour cent dans le régime, n'a aucune infl ence néfaste sur la fonction de reproduction. Il semble même que, par rapport aux animaux témoins, la reproduction, le sevrage et le début de la croissance s'effectuent dans de meilleures conditions. Ceci confirme d'ailleurs ce qui, d'après la documentation qui nous fut communiquée, a été observé dans d'autres Laboratoires.

Le nombre de portées sevrées fut de 47 p.100 chez les témoins contre 63 p.100 chez les femelles recevant 2 p.100 de M.S.P.O.11. La mortalité des portées à la naissance a été respecti ment de 42 p.100 contre 31 p.100. Le nombre de sujets était en moy ne à la naissance de 7,6 chez les témoins et de 9,3 chez les anima recevant le produit.

A aucun moment et dans aucun groupe nous n'avons observé d'anomalies lors de l'examen de la morphologie externe des nouvea nés. Nous croyons donc, qu'utilisé à 2 p.100, le produit M.S.P.O. ne présente aucun inconvénient vis-à-vis de la fonction de reprod tion comme vis-à-vis de la lactation. Il semblerait même que la nutrition générale des animaux recevant le produit soit légèremen améliorée.

ALFORT le 17 Février 1964

Professeur R. FERRANDO

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

Charles E. Moyer, Jr., Ph.D.
Director, Product Safety
Rhône-Poulenc Inc.
CN 7500
Cranberry, New Jersey 08512-7500

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MAR 30 1995

EPA acknowledges the receipt of information submitted by your organization under Section 8(e) 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 §8(e) Document Control Number (e.g., 8EHQ-00-0000) assigned by EPA to your submission(s). Please cite the assigned 8(e) number when submitting follow-up or supplemental information and refer to the reverse side of this page for "EPA Information Requests".

All TSCA 8(e) submissions are placed in the public files unless confidentiality is claimed according to the procedures outlined in Part X of EPA's TSCA §8(e) policy statement (43 FR 11110, March 16, 1978). Confidential submissions received pursuant to the TSCA §8(e) Compliance Audit Program (CAP) should already contain information supporting confidentiality claims. This information is required and should be submitted if not done so previously. To substantiate claims, submit responses to the questions in the enclosure "Support Information for Confidentiality Claims". This same enclosure is used to support confidentiality claims for non-CAP submissions.

Please address any further correspondence with the Agency related to this TSCA 8(e) submission to:

Document Processing Center (7407)
Attn: TSCA Section 8(e) Coordinator
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
Washington, D.C. 20460-0001

EPA looks forward to continued cooperation with your organization in its ongoing efforts to evaluate and manage potential risks posed by chemicals to health and the environment.

Sincerely,

Terry R. O'Bryan

Terry R. O'Bryan
Risk Analysis Branch

Enclosure 12073A

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Printed with Soy/Canola Ink on paper that contains at least 50% recycled fiber

Triage of 8(e) Submissions

Date sent to triage: MAY 10 1995

NON-CAP (CAP)

Submission number: 12073A

TSCA Inventory: Y N (D)

Study type (circle appropriate):

Group 1 - Dick Clements (1 copy total)

ECO AQUATO

Group 2 - Ernie Falke (1 copy total)

ATOX SBTOX SEN w/NEUR

Group 3 - Elizabeth Margosches (1 copy each)

STOX CTOX EPI (RTOX) GTOX

STOX/ONCO CTOX/ONCO IMMUNO CYTO NEUR

Other (FATE, EXPO, MET, etc.):

Notes:

THIS IS THE ORIGINAL 8(e) SUBMISSION; PLEASE REFILE AFTER TRIAGE DATABASE ENTRY

For Contractor Use Only

entire document: 0 (1) 2 **pages** 1,2 **pages** 1,2,TAB

Notes:

Contractor reviewer : PAL **Date:** 2/22/95

CECATS\TRIAGE TRACKING DBASE ENTRY FORM

CECATS DATA:
Submission # 8EHQ- 1192 - 12073 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 WORKERS/OTHERS
0404 LABEL/MSDS CHANGES
0405 PROCESS/HANDLING CHANGES
0406 APP./USE DISCONTINUED
0407 PRODUCTION DISCONTINUED
0408 CONFIDENTIAL

SUB. DATE: 10/27/92 OTS DATE: 11/02/92 CSRAD DATE: 02/07/95

CHEMICAL NAME:
Glycerides, palm-oil, reaction products with sucrose
Celynol MSPO-11

CAS#
100403-39-2
"

INFORMATION TYPE:		P F C
0201	ONCO (HUMAN)	01 02 04
0202	ONCO (ANIMAL)	01 02 04
0203	CELL TRANS (IN VITRO)	01 02 04
0204	MUTA (IN VITRO)	01 02 04
0205	MUTA (IN VIVO)	01 02 04
0206	REPRO/TERATO (HUMAN)	01 02 04
(0207)	REPRO/TERATO (ANIMAL)	01 02 04
0208	NEURO (HUMAN)	01 02 04
0209	NEURO (ANIMAL)	01 02 04
0210	ACUTE TOX. (HUMAN)	01 02 04
0211	CHR. TOX. (HUMAN)	01 02 04
0212	ACUTE TOX. (ANIMAL)	01 02 04
0213	SUB ACUTE TOX (ANIMAL)	01 02 04
0214	SUB CHRONIC TOX (ANIMAL)	01 02 04
0215	CHRONIC TOX (ANIMAL)	01 02 04

INFORMATION TYPE:		P F C
0216	EPI/CLIN	01 02 04
0217	HUMAN EXPOS (PROD CONTAM)	01 02 04
0218	HUMAN EXPOS (ACCIDENTAL)	01 02 04
0219	HUMAN EXPOS (MONITORING)	01 02 04
0220	ECO/AQUA TOX	01 02 04
0221	ENV. OCCC/REL/FATE	01 02 04
0222	EMER INCI OF ENV CONTAM	01 02 04
0223	RESPONSE REQEST DELAY	01 02 04
0224	PROD/COMP/CHEM ID	01 02 04
0225	REPORTING RATIONALE	01 02 04
0226	CONFIDENTIAL	01 02 04
0227	ALLERG (HUMAN)	01 02 04
0228	ALLERG (ANIMAL)	01 02 04
0239	METAB/PHARMACO (ANIMAL)	01 02 04
0240	METAB/PHARMACO (HUMAN)	01 02 04

INFORMATION TYPE:		P F C
0241	IMMUNO (ANIMAL)	01 02 04
0242	IMMUNO (HUMAN)	01 02 04
0243	CHEM/PHYS PROP	01 02 04
0244	CLASTO (IN VITRO)	01 02 04
0245	CLASTO (ANIMAL)	01 02 04
0246	CLASTO (HUMAN)	01 02 04
0247	DNA DAM/REPAIR	01 02 04
0248	PROD/USE/PROC	01 02 04
0251	MSDS	01 02 04
0299	OTHER	01 02 04

TRIAGE DATA:	NON-CBI INVENTORY	ONGOING REVIEW	SPECIES	TOXICOLOGICAL CONCERN:	USE:	PRODUCTION:
	YES	YES (DROP/REFER)	RAT	(LOW)		
CAS SR	NO	NO (CONTINUE)		MED		
	(IN TERMINI)	REFER		HIGH		

COMMENTS: fact

20,000 ppm - increased prep wt