MR 2755
8EHQ-1297-14082

High Point Chemical

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December 9, 1997

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(Attn: Section 8(e) Coordinator) Mail Code 7407
Office of Pollution Prevention and Toxic Substances
U.S. Environmental Protection Agency
401 "M" St., S.W.
Washington, D.C. 20460

88980000051

Dear Section 8(e) Coordinator:

This letter is to notify the Agency that I have recently received and reviewed summaries of toxicity testing reports from Kao Corporation, which suggest that moderate adverse effects may result from exposure to a fragrance substance. This product (AMBER CORE) was introduced to the U.S. in PMN P-93-344 through High Point Chemical Corporation, which is the U.S. Chemical Division of Kao Corporation, headquartered in Japan.

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The summaries were reviewed on December 9,1997.

Chemical Description:

CASRN: 139504-68-0

CBI status: NON-CONFIDENTIAL

Usage pattern:

This substance is not intended for large volume use. It is used as a minor ingredient of a finished fragrance which is used in personal care products such as detergents and softeners.

As an example of the usage:

1. The finished fragrances can readily contain 20 or more components, one of which would be this substance.
   (The fragrance formulation is specific to the user involved , and is

Contains No CBI

not determined by Kao Corporation, when this substance is sold to others).

Example of finished fragrance: (Attachment 1)
18 components
This substance is about 20% of the fragrance formulation.

2. The example fragrance would be used at about 30% of the formulation of the household detergent (or other household products) .

   The amount of this substance in the example detergent formulation would be about 6% .

3. Very little of this substance is expected to be released into the aquatic environment at the time of usage because :
   a. The detergent is diluted by a factor greater than 100 times in usage.
   b. The substance is insoluble in water, hence will tend to adsorb to the fabrics being washed. As an aroma, the fragrance material will slowly vaporize into the atmosphere.

Adverse Effects being reported:

Study results of concern are presented in Tables A.

The results of subacute toxicity testing indicate possible neurotoxic effects because salivation and increased urine production were observed among test animals. However, salivation was observed just before or after administration and disappeared within 40 minutes. Salivation was not observed in the recovery period. Increase of urine volume was also not seen during the recovery period. The summary is attached (Attachment 2).

The results of ecotoxicity tests are of moderate concern, according to criteria provided earlier by the Agency, and by our evaluation, the potential for damage to the aquatic environment is minor. However, these results of ecological tests are being reported in order make the information available to the Agency for an official interpretation.

Complete reports, translated into English if necessary, will be made available to the Agency upon request.

The submission of the attached information is part of Kao Corporation's good faith effort to comply with requirements under TSCA Section 8(e).

Sincerely,

Hester Kobayashi

Hester Kobayashi, Dr.PH
Manager, Kao Product Safety, North America

KAO

FLAVOURS, FRAGRANCES AND AROMA CHEMICALS

AMBER CORE

DEMONSTRATION FORMULA

◇NAME : MODEL-10404

◇ODOUR : Fruity floral

		A	B
LEMON TERPENES		100	100
ETHYL LINALOOL		20	20
ALLYL AMYL GLYCOLATE		5	5
HELIONAL		20	20
PHENYL ACETALD. G.A		20	20
cis-3-HEXENYL SALICYLATE		10	10
POIRENATE	(KAO)	20	20
FRUITATE	(KAO)	10	10
PATCHOSPIROL	(KAO)	10	10
SAGETONE V	(KAO)	10	10
EUGENOL		20	20
HEDIONE		40	40
PHENOXANOL		20	20
LILIAL		100	100
HEXYL CINNAMIC ALDEHYDE	(KAO)	200	200
BENZYL SALICYLATE		50	50
AMBER CORE	(KAO)	200	–
D.E.P		145	345
		1000	1000

◇In the version B, AMBER CORE is replaced with D.E.P.

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95-01

Attachment 1

1 Summary

Amber Core: Subacute toxicity

(1) P-#620 was administered to SD strain rats of both sexes for 28 days. A recovery period of 14 days was set for rats of the control and high-dose groups.

(2) The test substance was suspended in 0.5% Tween 80 in 0.5% CMC-Na aqueous solution and administered orally via a stomach tube. The dosage levels used were 20, 140, and 1,000 mg/kg. Control rats were given the vehicle alone. The dose volume was set at 1.0 ml per 100 g of body weight in all dose groups.

(3) No deaths occurred throughout the observation period.

(4) Salivation was noted in all male and female rats of the high-dose group and in one male and one female rats of the medium-dose group. This was observed just before or after administration and disappeared within 40 minutes after administration. Salivation was not observed in the recovery period.

(5) The body weight and food consumption of all test groups were the same as those of the control group.

(6) An increase in water consumption was observed in the high-dose group of both sexes in the treatment period, but was not observed in the recovery period.

(7) There was no adverse effect related to the test substance in hematological examinations.

(8) In blood chemical examination, increases in γ-GTP and total cholesterol were found in the high-dose group of both sexes, but recovery was noted after withdrawal.

(9) An increases of urine volume and a decrease of specific gravity were found in the high-dose group of both sexes, but were not observed in the recovery period.

(10) Autopsies at the end of the treatment showed increases of both absolute and relative liver weight and brownish change of the liver in the high-dose group of both sexes. Microscopical examinations revealed hypertrophy of hepatocyte which were considered to be cellular adaptation phenomena. There was a tendency to recover of these findings after withdrawal.

(11) At the end of treatment, bile pigments in hepatocyte and connective tissue, bile plugs in interlobular bile duct, and cholangitis were found microscopically in the high-dose group of male. At the end of recovery period, bile pigments in connective tissue, bile plugs in interlobular bile duct, and colangitis were found, but there was a tendency to recover.

(12) Autopsies at the end of the treatment showed discoloration of the kidneys in the high-dose group of male. Hyaline droplets in the tubular epithelium and basophilic change of the tubular epithelium were found microscopically in the medium-dose and high-dose group of male. Basophilic change of the tubular epithelium and increases in both absolute and relative kidney weights were found at the end of the recovery period, and these were considered to be regenerative changes.

(13) These results indicate that the no-effect level of P-#620 is 20 mg/kg in rats.

Table A
Results of Tests on AMBER CORE Suggestive of Potential for Adverse Effects

Test Performed	Notes on Method	Results Summarized	Laboratory
Sub acute toxicity (rats)	28 day rat test performed in Japan	salivation and increase urination in high dosage groups after administration of substance, but not during the recovery period. Complete summary attached.	Mitsubishi Kasei Institute of Toxicological and Environmental Sciences
Daphnia magna, acute toxicity	OECD No. 202 Part 1, and EEC Method in EEC Directive 67/548.	EC50 = 5.9 mg/L (48 hr, Static test).	Huntingdon Research Centre
Daphnia magna, prolonged effect testing	OECD No. 202, Part 2.	EC50 14 days: 2.6 mg/L 21 days: 2.4 mg/L NOEC 21 days: 1.4 mg/L	Huntingdon Research Centre
Algal growth inhibition	OECD 201	NOEC 1.5 mg/L	Huntingdon Research Centre
Fish toxicity	OECD No. 203 on Rainbow trout	LC50= 4.1 mg/L (48 hr)	Huntingdon Research Centre

ENTRY FORM

CAPNUM	LTR	DATE	CBI	CASNO	CONCERN	AI	SOLUBILITY
14082	a	1297		139504680	MODERA	NS	NS

CHEMNAME

Amber Core, static

PHYSTATE

NS

ORGANISM	DURATION	ENDPOINT	CODE	TOXVALUE	UNITS	MELTINGPT
Water flea, Daphnia magna	48h	EC50		5.9	mg/l	NS

COMMENTS

ENTRY FORM

CAPNUM	LTR	DATE	CBI	CASNO	CONCERN	AI	SOLUBILITY
14082	a	1297		139504680	MODERA	NS	NS

CHEMNAME

Amber Core

PHYSTATE

NS

ORGANISM	DURATION	ENDPOINT	CODE	TOXVALUE	UNITS	MELTINGPT
Water flea, Daphnia magna	21d	EC50		2.4	mg/l	NS

COMMENTS

14dEC50=2.6mg/L
21dNOEC=1.4mg/L

ENTRY FORM

CAPNUM	LTR	DATE	CBI	CASNO	CONCERN	AI	SOLUBILITY
14082	a	1297		139504680	MODERA	NS	NS

CHEMNAME

Amber Core

PHYSTATE

NS

ORGANISM	DURATION	ENDPOINT	CODE	TOXVALUE	UNITS
Algae	NS	NOEC		1.5	mg/l

MELTINGPT

NS

COMMENTS

Growth inhibition

ENTRY FORM

CAPNUM	LTR	DATE	CBI	CASNO	CONCERN	AI	SOLUBILITY
14082	a	1297		139504680	MODERA	NS	NS

CHEMNAME	PHYSTATE
Amber Core	NS

ORGANISM	DURATION	ENDPOINT	CODE	TOXVALUE	UNITS	MELTINGPT
Rainbow trout, O. mykiss	48h	LC50		4.1	mg/l	NS

COMMENTS