

8EHQ-1297-14086

MR 278

High Point Chemical

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Office of Pollution Prevention and Toxic Substances
U.S. Environmental Protection Agency
401 "M" St., S.W.
Washington, D.C. 20460



8EHQ-97-14086

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 (Poirenate) was introduced to the U.S. in PMN P-92-526 through High Point Chemical Corporation, which is the U.S. Chemical Division of Kao Corporation, headquartered in Japan.

The summaries were reviewed on December 9, 1997.

Chemical Description:

CASRN: 2511-00-4

CBI status: NON-CONFIDENTIAL



8898000055

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

Example of finished fragrance: (Attachment 1)

15 components

This substance is about 71% of the formulation

2. The example fragrance 5% of the household detergent (or other household products) formulation.

The amount of this substance in the example detergent would be about 3.6% of the formulation.

3. Very little would get 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 Table A.

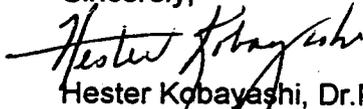
The results of acute (4 hour) inhalation toxicity testing indicate that the substance is moderately toxic, or possibly even of low concern. This is because the testing did not extend beyond 5.4 mg/L. Also, observations at 5.4 mg/L were not indicative of harmful effects. The testing was performed for use in the E.U., and according to criteria used there, the product is not classifiable as a respiratory hazard. 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.

A complete copy of the studies will be obtained and 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, Dr.PH
Manager, Kao Product Safety, North America

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

Tests Performed	Notes on Method	Results Summarized	Laboratory
Daphnia magna, acute toxicity	OECD No. 202 Part 1	EC50 = 1.1 mg/L (48 hr, Static test).	Huntingdon Research Centre
Inhalation Toxicity Study	Acute toxicity (Rat, 4-hour exposure). Highest concentration tested: 5.4 mg/L	LC 50 >5.4 mg/L	Huntingdon Research Centre



FLAVOURS, FRAGRANCES AND AROMA CHEMICALS

POIRENATE

DEMONSTRATION FORMULA

◇ NAME : MODEL - 10301

◇ ODOUR : fruity (tropical fruits)

	A	B
b-PINENE	30	30
cis-3-HEXENOL	10	10
ALCOHOL C-12	20	20
ETHYL NONANOATE	20	20
HERBAROSE (KAO)	50	50
METHYL CINNAMATE	2	2
MALTOL 1%DEP	20	20
ALLYL IONONE	10	10
p-MENTHAN-8-THIOL-3-ONE 1%DPG 10%DEP	3	3
BUCCOXIME	2	2
DAMASCENONE 10%DEP	3	3
ALDEHYDE C-14 PEACH	40	40
METHYL ANTHRANILATE	30	30
VANILLIN(L)	10	10
POIRENATE (KAO)	600	-
D. E. P	-	600
	850	850

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



SUMMARY

Introduction

The objective of this study was to establish the acute inhalation toxicity (LC_{50}) of Poirenate to rats according to OECD and EEC testing guidelines.

Methods

One group of 5 male and 5 female Sprague-Dawley CD rats was exposed to an atmosphere containing a chemically analysed concentration of Poirenate of 5.40 mg/l, which was the highest concentration required by the test guidelines. The corresponding nominal concentration was 21.5 mg/l. Exposure was continuous for 4 hours using a snout-only exposure system. An additional group of 5 male and 5 female rats acted as controls and was exposed to clean air only for 4 hours.

The rats were observed during the exposure period and for 14 days post exposure. Group food and water consumption were measured daily throughout. Each rat was subjected to post mortem examination.

Results

There were no deaths following exposure at 5.40 mg/l of air.

During exposure there were no clinical signs attributable to exposure to Poirenate. Soiling of the fur by excreta, as a consequence of the method of restraint was seen in the control and test groups. During the observation period the only clinical sign observed in test rats was exaggerated respiratory movements on Day 0. All rats exposed to Poirenate were normal in appearance and behaviour by Day 1 of the observation period.

The rate of bodyweight gain for rats exposed to Poirenate was reduced for 1 day following exposure.

Food consumption for male test rats was slightly reduced for 1 day following exposure to Poirenate. Water consumption for all test rats and food consumption for female test rats were unaffected following exposure to Poirenate.

Lung weight to bodyweight ratios for rats were within normal limits. There were no macroscopic abnormalities in any of the rats exposed to Poirenate.

Conclusions

The acute inhalation LC_{50} (4-hour) of Poirenate to rats was in excess of 5.40 mg/l of air. The exposure concentration was the highest required by the test guidelines.

EEC classification: Not indicated

Risk phase: Not indicated