

ORIGINAL

TSCA NON-CONFIDENTIAL BUSINESS INFORMATION

DOCUMENT DESCRIPTION	DOCUMENT CONTROL NUMBER	DATE RECEIVED
8EHQ-10-18108	88100000433	9/20/10

COMMENTS:

DOES NOT CONTAIN CBI

330084



VIA HAND DELIVERY

RECEIVED
SEP 20 2010

September 17, 2010

10 SEP 20 AM 6:06

TSCA Confidential Business Information Center (7407M)
EPA East - Room 6428 Attn: Section 8(e)
U.S. Environmental Protection Agency
1201 Constitution Avenue, NW
Washington, DC 20004-3302
Phone: (202) 564-8940

Nalco Company
1601 West Diehl Road
Naperville, IL 60563-1198
phone 630.305.1000
www.nalco.com

8EHQ-0810-18108A



Dear TSCA Section 8(e) Coordinator:

Pursuant to TSCA Section 8(e), 15 U.S.C. Section 2607(e), and EPA's associated guidance, Nalco Company is submitting results of acute toxicity testing on two mixtures.

A. First Mixture

The components of the mixture are: aliphatic hydrocarbon (CASRN 64742-47-8); propylene glycol (CASRN 57-55-6); 2-propanol, 1-(2-butoxy-1-methylethoxy)- (CASRN 29911-28-2); di(2-ethylhexyl) sodium sulfosuccinate (CASRN 577-11-7); ethoxylated sorbitan trioleate (CASRN 9005-70-3); ethoxylated sorbitan monooleate (CASRN 9005-65-6); sorbitan monooleate (CASRN 1338-43-8); and water (CASRN 7732-18-5).

Acute Oral Toxicity (Up and Down Procedure)

In accordance with EPA Health Effects Test Guidelines OPPTS 870.1100 (December 2002) and OECD 425 (October 2008), Sprague Dawley rats (3 females) were dosed orally with 5000 mg/kg of the mixture and then observed for 14 days post-dosing. All animals survived the single dose. The LD50 was determined by the testing laboratory to be greater than 5000 mg/kg.

Acute Dermal Toxicity

In accordance with OECD 402 (February 1987), New Zealand White rabbits (5 male/5 female) were dosed once dermally with 5000 mg/kg of the mixture, which was kept in contact with the skin for 24 hours, and observed for 14 days post-dosing. All animals survived. From this test, the dermal LD50 was determined by the testing laboratory to be greater than 5000 mg/kg.

Acute Inhalation Toxicity

In accordance with OECD 403 (May 12, 1981), Sprague Dawley rats (5 males/5 females) were exposed to a laboratory-generated respirable aerosol of the mixture at a concentration of 5.35 mg/L for 4 hours and then observed for up to 14 days post-exposure. Three females died by day 3. The LC50 was determined by the testing laboratory to be approximately 5.35 mg/L.

DCN:8810000433

CONTAINS NO CBI



Primary Dermal Irritation/Corrosion

In accordance with OECD 404 (April 24, 2002), New Zealand White rabbits (3 females) were dosed once dermally with 0.5 ml of the mixture which was kept in contact with the skin for 4 hours, followed by evaluation for up to 10 days. Very slight to well defined erythema was observed in two of three rabbits at 1, 24, 48, and 72 hours, but there was no erythema in these animals at day 10. There was no other erythema or edema during the observation period. The mixture was determined by the testing laboratory to be a dermal irritant.

Bovine Corneal Opacity and Permeability Test (BCOP)

In accordance with methodology described in *Bovine Corneal Opacity and Permeability Test: An In-Vitro Assay of Ocular Irritancy*, (1992); Gautheron, P. et al – *Fundamental and Applied Toxicology 18: 442 -449 and OECD 437 (September 7, 2009)*, bovine corneas were dosed once with 0.75 ml of the mixture and measured for opacity and sodium fluorescein permeability. The In Vitro score was determined by the testing laboratory to be 3.45, by which the mixture would be classified a mild eye irritant.

Acute Eye Irritation/Corrosion

In accordance with OECD 405 (April 24, 2002), New Zealand White rabbits (3 males) each had one eye treated by placing 0.1 ml of the mixture directly into the conjunctival sac (created by pulling the lower eyelid away from the eye) and then holding the eye closed for about one second afterward to ensure distribution of the material. The animals then were observed for 21 days. Corneal opacity was observed in 3 of 3 (3/3) eyes and cleared by day 7 in 1/3 eyes. Iritis observed in 2/3 eyes cleared by day 21. Conjunctival irritation was observed in 3/3 eyes and cleared in 1/3 by day 14. The mixture was determined under this test by the testing laboratory to be corrosive. We note that this result is inconsistent with the results of the bovine corneal opacity/permeability testing, which indicated that the mixture is a mild irritant. The result is also inconsistent with acute eye irritation testing on the similar mixture discussed below, as well as with testing on individual components of the mixture. These other tests determined the mixtures or components to be moderate eye irritants. As a result, additional work on these issues may be completed by the Company.

B. Second Mixture

The mixture consisted of: 2-butoxyethyl alcohol (CASRN 111-76-2); propylene glycol (CASRN 57-55-6); di(2-ethylhexyl) sodium sulfosuccinate (CASRN 577-11-7); ethoxylated sorbitan trioleate (9005-70-3); ethoxylated sorbitan monooleate (CASRN 9005-65-6); sorbitan monooleate (CASRN 1338-43-8); and water (CASRN 7732-18-5).

Acute Oral Toxicity

The laboratory has provided the following preliminary information: 8 female rats were orally dosed once with 550 mg/kg (1 animal), 1750 mg/kg (3 animals), 2000 mg/kg (1 animal), or 5000

mg/kg (3 animals). The one animal receiving 2000 mg/kg and the three animals receiving 5000 mg/kg died within 6 days of dosing; the others survived through the test period. The LD50 estimated by the testing laboratory is 3110 mg/kg.

Acute Dermal Toxicity -- Rabbits

In accordance with OECD 402 (February 24, 1987), New Zealand White rabbits were dosed once dermally with 400 mg/kg (1 male) or 1000 mg/kg (5 males/5 females) of the mixture, which was kept in continuous contact with the skin for 24 hours. The rabbits were then observed for 14 days. All animals survived. Erythema was well defined to severe and edema slight to moderate at 24 hours post-dosing. By Day 7 there was no erythema or edema. The testing laboratory determined that the LD50 of the mixture is greater than 1000 mg/kg.

Acute Dermal Toxicity -- Rats

In accordance with OECD 402 (February 24, 1987), Sprague Dawley rats (5 males/5 females) were dosed once dermally with 2000 mg/kg of the mixture, which was kept in continuous contact with the skin for 24 hours. The rats were then observed for 14 days. All animals survived. All males and 4 females had very slight erythema at 24 hours; 1 male and 1 female had very slight edema at 24 hours. There were not other observations of erythema or edema. The testing laboratory determined that the LD50 of the mixture is greater than 2000 mg/kg.

Acute Inhalation Toxicity

The laboratory has provided the following preliminary information: Rats were exposed for four hours in an inhalation chamber to a laboratory-generated respirable aerosol of 2.08 mg/L of the mixture, in accordance with OECD 403. Six of ten animals died; the remainder survived through day 14, indicating that the acute inhalation LC50 is less than 2.08 mg/L according to the testing laboratory. The testing laboratory then repeated the test using an aerosol concentration estimated to be 1.16 mg/L. All animals survived.

Acute Eye Irritation/Corrosion

In accordance with OECD 405 (April 24, 2002), New Zealand White rabbits (4 females) each had one eye treated by placing 0.1 ml of the mixture directly into the conjunctival sac (created by pulling the lower eyelid away from the eye) and then holding the eye closed for about one second afterward to ensure distribution of the material. The animals then were observed for 14 days. Corneal opacity was noted in 1 of 4 (1/4) eyes and cleared by day 14. Iritis was observed in 1/4 eyes and cleared by day 7. Conjunctival irritation was observed in 4/4 eyes and cleared by day 14. The testing laboratory determined that the mixture is an ocular irritant.

Primary Dermal Irritation/Corrosion

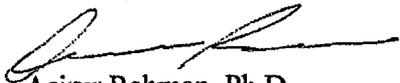
In accordance with OECD 404 (April 24, 2002), New Zealand White rabbits (3 females) were dosed once dermally with 0.5 ml of the mixture, which was kept in continuous contact with the skin for 4 hours. Animals were observed for 10 days. In one animal, there was well-defined

erythema at 1 hour post-dosing and edema was very slight in another animal. At 24 hours post-dosing erythema was still well defined in the first animal while no edema was observed in the second animal. At 48 and 72 hours, one animal was noted with very slight erythema with no edema or erythema being observed in other animals. There were no other observations of erythema or edema. The testing laboratory determined that the mixture is a dermal irritant.

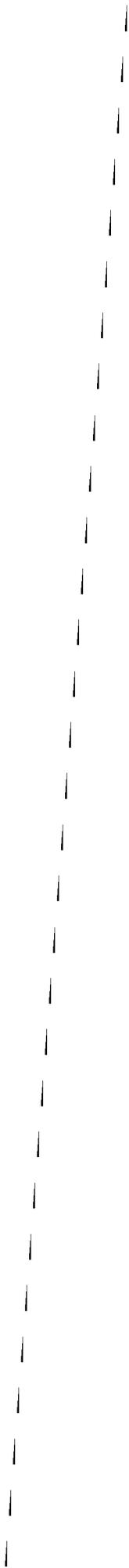
* * *

Nalco believes that these mixtures do not pose a substantial risk of injury to human health or the environment when manufactured and used as intended. Moreover, many of the results are preliminary and inconclusive. However, we submit this information in accordance with EPA's current guidance on its interpretation of Section 8(e), exercising an abundance of caution, and because it is information in which EPA may have an interest.

Sincerely,



Asirur Rahman, Ph.D
Director
Product Regulatory Affairs
Nalco Company
1601 W. Diehl Road
Naperville, IL 60563-1198
(630) 305-1000
arahman@nalco.com



Contains No CBI

