

Interoffice
Communication

TO: Distribution

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FROM: T. G. Grumbles

DATE: July 27, 1990

SUBJ: ALUMINA TOXICITY TESTING RESULTS

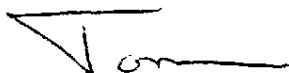
VISTA

The initial toxicity testing done on our alumina to investigate employee allegations of multiple health effects has been completed. The results of that testing are summarized in the attached report.

In summary, the results of the studies indicate that there is little probability that the signs and symptoms reported to us by employees were actually caused by exposure to alumina. Acute oral toxicity, dermal, eye and lung irritation, and sensitization studies were conducted.

Based on these results, we will update our MSDS with this data and communicate with our alumina customers as we told them we would do in our mailing last year. I'll draft a letter for distributing the revised MSDS and work with J. A. Hall to distribute.

We need to decide how to communicate the testing results to the LCCP employees. With this memo, I am asking John Friend and Keith Fogg to review the enclosed and let me know how they would like to proceed. If desirable, we could make presentations to the employees signing the original 8(c) allegation.



T. G. Grumbles

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Attachment

Distribution: Keith Fogg, John Friend-LCCP, W. L. McClain, J. A. Hall, G. Hoenes, D. Andersen-Houston

cc: w/o attachment
D. Penney

VVV 000013395

TOXICOLOGY RESOURCES

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TGG

Evaluation of the Irritation Potential
of
VISTA CATAPAL ALUMINA
(CAS No. 1318-23-6)

Lawrence J. Jenkins

9 July 1990

VVV 000013396

EXECUTIVE SUMMARY

Signs and symptoms of toxicity such as drying of the skin and mucousal tissues, tightness in the chest, sinus irritation and nose bleeds have been alleged to result from exposure to Vista Catapal Alumina (CAS No. 1318-23-6). Because (a) most of the toxicity information which has been published is based on studies of alumina (CAS No. 1344-28-1) and (b) previous testing with alumina (CAS No. 1318-23-16) was done with a slurry (Scientific Associates, 1970) which could have masked irritant responses, it was recommended (Toxicology Resources, 1989) that a tiered testing program for any irritation potential of alumina (CAS No. 1318-23-16).

The first tier of the proposed program has been completed (Stillmeadow, 1990a; 1990b; 1990c; 1990d and 1990e). The results indicate that, as a result of these studies in animal models, Vista Catapal Alumina (CAS No. 1318-23-16):

- (1) has a low order of acute oral toxicity;
- (2) has a low dermal irritation potential;
- (3) is minimally irritating to the eyes
(which may be a mechanical phenomenon);
- (4) did not show pathologic evidence of irritation to the lungs or nasal turbinates of rats, and;

(5) is negative when tested for sensitizing potential.

It is therefore concluded that the signs and symptoms referred to above are probably not the result of exposure to Vista Catapal Alumina (CAS No. 1318-23-16). It is also concluded, based on these studies, that there is no requirement at the present time to proceed to the second (more sensitive) tier.

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INTRODUCTION

There is a significant literature on the toxicology of aluminum compounds, including the oxides (Toxicology Resources, 1989). The oxides of aluminum, collectively referred to as alumina, are generally considered to be "nuisance dusts" and industrial hygiene guidelines are applied accordingly. Because most of the toxicologic information on alumina is based on studies of alumina (CAS No. 1344-28-1 and because previous studies of Vista Catapal Alumina (CAS No. 1318-23-6) had been done with a slurry (Scientific Associates, 1970) which may have masked irritation potential in studies with experimental animals, it was recommended that a tiered animal study be undertaken.

EXPERIMENTAL

The studies which comprise the first tier have been completed.

Acute Oral Toxicity. There was no reason to suppose that acute oral toxicity of Vista Catapal Alumina (CAS No. 1318-23-6) would be altered in the previous studies because they had been done with a slurry (Scientific Associates, 1970). Determination of the acute toxicity of Vista Catapal Alumina (CAS No. 1318-23-6) was done primarily for completeness and for comparison with other studies in the

first tier, if sufficient toxicity was observed. The results of the acute oral toxicity study which was done in rats (Stillmeadow, 1990a) indicate that alumina, as anticipated, has a low order of acute toxicity when administered to rats by the oral route.

Primary Dermal Irritation. Dermal irritation potential is one of the studies that could have been influenced by the use of a slurry of the test material in previous studies (Scientific Associates, 1970). Also, a material with sufficient dermal irritation potential could be anticipated to provoke some of the respiratory signs and symptoms alleged to result from exposure to Vista Catapal Alumina (CAS No. 1318-23-6) at the nuisance dust level. Results of the most recent study (Stillmeadow, 1990b) do not indicate that Vista Catapal Alumina (CAS No. 1318-23-6) caused any dermal irritation when applied directly to the shaved backs of rabbits.

Primary Ocular Irritation. The use of a slurry of test material could have influenced the outcome of previous eye irritation studies (Scientific Associates, 1970). The results of the most recent eye irritation studies with Vista Catipal Alumina (CAS No. 1318-23-6) where the dry particulate matter was instilled directly into the conjunctival sac of rabbits indicate some irritation. However, because the irritation encountered was accompanied by the presence of particles of alumina in the eye, this

finding is most likely caused by mechanical effects related to the shape and configuration of the particles. Ocular tissue is very sensitive to irritants and, had Vista Catapal Alumina (CAS No. 1318-23-6) been a frank irritant, a much more severe response would have been anticipated.

Pulmonary Irritation. Most of the signs and symptoms alleged to occur from exposure to Vista Catapal Alumina (CAS No. 1318-23-6) (Toxicology Resources, 1989) involve respiratory tissue or tissues that are contiguous with respiratory tissue. Previous study design (Scientific Associates, 1970) could have masked irritant responses. Short of doing pulmonary function studies to determine alterations of sensory irritation potential, it was elected to design a study which would maximize the probability of identifying a pulmonary irritation potential should one exist (Stillmeadow, 1990d). No significant alterations of respiratory patterns were evident during the exposure and there were no indications of irritation of the nasal turbinates, major airways or lung parenchyma from gross examinations at necropsy or subsequent histopathologic microscopy.

Sensitization. There is some literature evidence of the presence of an asthma or asthma-like condition in pot room workers (Chan-Yeung et al., 1983). Because signs and symptoms from exposure to Vista Catapal Alumina (CAS No. 1318-23-6) were alleged in individuals who had histories of

previous exposure, the possibility of an enhanced response caused by development of sensitization was considered. A standard guinea-pig sensitization test (Stillmeadow, 1990e) was negative, indicating that development of an enhanced response to Vista Catapal Alumina (CAS No. 1318-23-6) is unlikely.

CONCLUSIONS

The results of the studies referred to above indicate that there is little probability that the signs and symptoms which were previously alleged are actually caused by exposure to Vista Catapal Alumina (CAS No. 1318-23-6). These studies which were done were done at high doses to maximize the probability of identifying effects; for example the inhalation study was done at a concentration of 5090 mg/m³. This exposure concentration is far higher than is likely to be encountered in an occupational environment. There have been reports (Lindenschmidt *et al.*, 1990) that there is variability within and among the "nuisance" dusts, but such differences are unlikely to cause signs and symptoms such as those which have been alleged. It is possible to extend to another tier of studies which are more sensitive, such as pulmonary function testing, but the lack of evidence of irritation found following the high doses and

exposure concentrations in these studies does not support such a venture.

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