THE SHERWIN-WILLIAMS CO.

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December 27, 1971.

Hearing Clerk
Department of Health, Education
and Welfare
Room 6-88 — 5600 Fishers Lane
Rockville, Maryland 20852

Subject: 21 CFR Part 191
Hazardous Substances
Federal Register, Vol. 36, No. 211

Gentlemen:

As a responsible corporate citizen, Sherwin-Williams is vitally concerned about our environment. We are completely sympathetic with existing regulations and concur with the obvious intent of many of the proposed regulations, however, we do feel that some of the proposed regulations are not based on facts and the best scientific evidence available.

Our posture has always been to take corrective action where evidence becomes available that certain products unduly affect the environment.

We support the general objectives of the FDA proposal as published in the November 2, 1971 Federal Register. While we know of no incidents of lead poisoning in humans from ingestion of modern paints containing up to 1% lead, we accept the .5% restriction as affording a reasonable safety factor. We encourage the adoption of this portion of the regulation (191.8 (2) (i)). However, we feel that that portion of the regulation pertaining to other heavy metals (191.8 (2) (ii)) should be qualified.

As now proposed in 21 CFR Part 191, which appears to follow the American National Standards Institute (ANSI) voluntary standard Z66.1, there is an implication that the heavy metals listed are toxic in all their forms. We suggest respectfully that this is not wholly valid. Just as barium sulfate is commonly ingested for radiography purposes, without harm to the patient, we believe heavy metals other than barium may also be ingested without harm if they are not solubilized in the digestive tract.

Further, the current, April 29, 1964, revision of ANSI Z66.1 only lists methods for analysis for total lead and mercury in whole paint. It wholly lacks specific methods for antimony, arsenic, cadmium and selenium. It could add a reference to ASTM D2642-68 method for arsenic.

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More importantly, ANSI Z66.1, to become fully operable in both intent and detail, needs a detailed analytical procedure for preparing a sample of dried paint for analysis for each of the metals listed. This procedure should distinguish between soluble and insoluble forms for all metals, not just for barium. A group of analytical chemists in the American Society for Testing and Materials (ASTM), in its Committee D01 on Paint and Paint Materials, is preparing such a method and experts to validate the analytical precision of said method through interlaboratory testing of practical samples. Working drafts of these methods, after one round of cooperative testing, may be offered by this group for ASTM adoption as an Emergency Standards, hopefully in mid-1972, and would comprise one general method for determination of all soluble heavy metals as a group, supplemented by specific methods for each metal. Each method would have its own D_ _ _ _ designation for reference in Federal Regulations.

We are specifically concerned with a yellow pigment commonly referred to as nickel titanate (Ex: Sherwin-Williams Solfast Titan Yellow) but containing antimony, nickel and titanium, when used in paint, would require labeling as hazardous substances. All evidence available to us indicates that antimony in this form is not absorbed when ingested. Feeding tests on experimental animals of both massive single doses and prolonged smaller doses have not shown any toxic effects. (Note Attachments 1 and 2).

The high insolubility (Attachment 3) and the lack of evidence that these pigments are toxic on animal feeding tests, leads us to suggest that further testing is required before the compounds are classified as hazardous. While we are quite ready to do further "in vivo" testing, we suggest the need for discussion between FDA technical representatives and ours to establish acceptable test parameters. The proposal we have from the Huntington Research Center (Attachment No. 4) could be a basis for such discussions.

It should be emphasized that the amount of metal is not important but rather the form it is in which determines whether it is absorbed in the body when ingested. As stated previously, barium, when in the form of barium sulphate, is taken internally in large amounts for use as an X-ray contrast medium. But the same metal in another form, i.e., barium chloride, is so toxic that 0.8 to 0.9 gr. is reported to be a fatal dose for humans.

Metals, in the form of pigments, when used in paints are coated or encapsulated with resins which slow or prevent the absorption into the body when ingested.

We know of no replacement which has adequate durability for exterior exposure. ANSI Z66.1, as originally promulgated, was directed to children's toys, furniture, and interior surfaces. For these uses, organic yellow pigments are available. They do not, however, have the lightfastness required for exterior surfaces.

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We submit that the proposal in Paragraph 191.8 is unnecessarily restrictive. We find no evidence that ingestion of modern paints containing no more than 1% lead have been responsible for "lead poisoning" in humans.

We urge a more direct participation by toxicologists specializing in lead poisoning in establishing hazard levels corresponding to lead contents of 0.5% and less. Recognized toxicology authorities should have opportunities to testify whether quotations of their publications are sufficiently within context or have been misinterpreted. Their liabilities and prerogatives may extend beyond mere publication for quotation.

Cost increases necessary to achieve essentially zero lead are not justifiable by proven reduction in hazard.

Thank you for the opportunity to express our position. Your consideration is appreciated.

Very truly yours,

THE SHERWIN-WILLIAMS CO.

H. E. Spitzer
Technical Director, Coatings

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Attachments (4)

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