

201-15372

June 21, 2004

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Michael O. Leavitt, Administrator  
U.S. Environmental Protection Agency  
Ariel Rios Bldg. (1101A)  
1200 Pennsylvania Ave. NW  
Washington, DC 20460



**Comments on the HPV test plan for the fatty-nitrogen-derived nitriles category**

Dear Administrator Leavitt:

The following comments on the American Chemistry Council's test plan for fatty-nitrogen-derived (FND) nitriles are submitted on behalf of People for the Ethical Treatment of Animals, the Physicians Committee for Responsible Medicine, the Humane Society of the United States, the Doris Day Animal League, and Earth Island Institute. These animal, health, and environmental protection organizations have a combined membership of more than ten million Americans.

The ACC is proposing to conduct a reproductive/developmental toxicity test (OECD no. 421) on one member of the FND nitriles category, dodecanenitrile (CAS no. 2437-25-4). This test will kill at least 675 animals.

We do not understand why the ACC has not combined the FND nitriles with other FND compounds to make a single category, especially considering the fact that the ACC itself makes the following statement:

The available data shows that, over this range, the FND Nitrile Category chemicals as well as the other FND chemicals (amines, cationics, amides) are not expected to, or exhibit, significant differences in the HPV/SIDS endpoints. Therefore, for the purposes of this screening program, these chemicals are considered essentially equivalent. (test plan, p. 6)

Other FND compounds include amides, cationics, amines, and ether nitriles, and the ACC's HPV test plans for these categories were posted online on January 11, 2002, January 25, 2002, January 23, 2003, and February 23, 2004, respectively. None of these test plans proposed animal testing, and it is unclear why the ACC has now decided to carry out an animal test on dodecanenitrile.

It is also worth pointing out that at least one animal study that has been carried out on dodecanenitrile was not mentioned in the test plan (DuPont 1992). We attempted to obtain a copy of this document from the EPA, but did not receive it in a timely fashion prior to the submission of these comments.

In addition to the above points, we must stress that the FND nitriles are of low toxicity (p. 12) and are closed-system intermediates. The compounds are handled at only seven sites in the U.S. (and three in the rest of the world), and the ACC ought therefore to have provided more

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information about the numbers of employees at those sites and the consequent potential for human exposure. If, for example, all personnel who have the potential to be exposed are male, it could be argued that there is no need for developmental toxicity studies.

Finally, the ACC states that it intends to carry out an *in vitro* chromosomal aberration study (OECD no. 473) on dodecanenitrile. The cells used in this study should either be human lymphocytes or mammalian cells obtained from established cultures, so as to avoid killing additional animals in order to supply the cells.

I can be reached at 757-622-7382, ext. 8001, or via e-mail at [JessicaS@peta.org](mailto:JessicaS@peta.org).

Sincerely,

Jessica Sandler  
Federal Agency Liaison

### **References**

DuPont Chemical Co., "Morphologic investigations on the organotoxic action of adiponitrile, sebaconitrile and laurylnitrile," EPA/OTS, document no. 88-920010964, 1992.