ACTIVITY REPORT

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Japan Technical Information Center, Inc.

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PC-1864

November 16, 1992

Ms. Carol Hetfield
Prenotice Coordinator
Premanufacture Notice Management Branch (TS-794)
U.S. Environmental Protection Agency
401 M St. SW
Washington, DC 20460

Dear Ms. Hetfield:

This matter concerns EPA's interpretation of TSCA's regulations.

My client plans to import a "new" chemical from Japan which fills high performance liquid chromatography columns as a separation medium and will be used in U.S. pharmaceutical companies' laboratories to separate optical isomers for R & D purposes. Should he submit a PMN for this chemical even though it will be used exclusively for pharmaceutical R & D? What about if it is used for industrial R & D uses?

If you have any questions, please feel free to call me at 543-3040.

I would very much appreciate your prompt response to our inquiries. Many thanks.

Sincerely yours,

Hiroshi Uyama

TELEFAX COVER SHEET

NEW CHEMICALS BRANCH
OFFICE OF TOXIC SUBSTANCES (TS-794)
U.S. ENVIRONMENTAL PROTECTION AGENCY

Washington D.C 20460

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SUBJECT: PC-1864

To: Hiroshi Uyama

FROM: Carol Hetfield

FAX:#

Phone # (To Confirm):

Comments:

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JAN 04 1993

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Mr. Hiroshi Uyama
Japan Technical Information
Center Incorporated
1002 Pennsylvania Avenue, S.E.
Washington D.C. 20003

Subject: Prenotice Communication # 1864

Dear Mr. Uyama:

This is in response to your letter of November 16, 1992 on whether a new chemical substance your client intends to import as a separation medium to be used in high performance liquid chromatography (HPLC) columns is exempt from Premanufacture notification (PMN) requirements because the columns will be used for Research and Development (R&D) purposes at pharmaceutical and other industrial laboratories.

In a June 15, 1992 letter (Prenotice Communication #1733), you requested information on whether imported HPLC columns are excluded from PMN requirements because they are "articles". The Agency responded that:

1) Pursuant to the definition of an article at 40 CFR 720.3(c) the stainless steel column by itself is considered an article. Of concern to your client, though, is whether the silica gel coated with adsorbents is considered "part of an article" thereby also excluded from PMN. It is the Agency's position that the coated silica gel would be considered part of an article when contained in the packed column in which it is used. That is, the coated gel is meant to be permanently contained and used within the column; the removal or loss of any of the gel during the use of the column is considered to occur incidentally; **and 2)** You may inform your client that the importation of a silica gel packed column is not considered subject to PMN or for that matter, § 13 import certification requirements. However, if the coated silica gel is manufactured in or imported into the U.S. for purposes of packing the columns domestically, the chemical substance or substances comprising the packing material would be subject to PMN unless already listed on the TSCA Inventory.

Based on your November 16, 1992 letter, it appears that it is now your client's intention to import the separation medium into the United States to fill extant high performance liquid

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chromatography columns for R&D purposes. R&D includes synthesis of new chemical substances and analysis, experimentation or research on new or existing chemical substances (note: general distribution of chemical substances to consumers does not constitute R&D). A chemical substance may be considered a R&D substance if either the substance is the focus of R&D itself, or be used in an R&D activity focussing on another chemical substance. The latter category encompasses reagents, chemicals to be used as standards for chemical analysis in laboratories, and intermediates used solely to produce R&D substances.

Based on the above information, the use of the separation medium to separate optical isomers for R&D purposes would be exempt from PMN provided all procedural and recordkeeping requirements of the R&D exemption at 40 CFR § 720.36 and .78 are observed.

Furthermore, you will need to contact the Food and Drug Administration (FDA) if you want further clarification as to whether the use of chromatography columns at pharmaceutical laboratories would be otherwise regulated under the Federal Food, Drug, and Cosmetic Act (FFDCA) and thereby excluded from the Toxic Substance Control Act's (TSCA's) jurisdiction. However, it is doubtful that a chromatography column containing the separation medium would be considered a medical device per se.

Should you have any additional questions pertaining to this issue, please contact either Carol Hetfield or Miriam Wiggins-Lewis, the Prenotice Coordinators, at (202) 260-1745 and 260-3937 respectively.

Sincerely,

Mary Cushmac

Mary Cushmac, Chief
Policy and Administrative Section
New Chemicals Branch (TS-794)