VELSICOL CHEMICAL CORPORATION

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May 24, 1985

U.S. Nuclear Regulatory Commission, Region III
Materials Licensing Section
799 Roosevelt Road
Glen Ellyn, Illinois 60137

Dear Sirs:

Attached is our application for an amendment to our Materials License (Number 12-08920-01, dated May 15, 1984) which would allow us to use small quantities of Carbon-14 and Hydrogen-3 in a small field plot at our Research Farm. We have addressed the points listed in your checklist received by us May 10, 1985 and have numbered our responses according to the checklist.

We did not address the last point on the checklist, but rather will let you decide if the Illinois N.R.C. needs to act on the amendment or merely be informed of the action taken by your office.

We look forward to your reply. Please contact us if any additional information is needed.

Sincerely,

C. C. Yu

C. C. Yu, Ph.D.
Radiation Protection Officer

Applicant June 3 III
Check No. 191912 $120
Amount
Type 3 M amd
Date Check Rec'd 7/11/85
Received By

CCY:rm
Attachment

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REG3 LIC30 PDR
12-08920-01

CONTROL NO. 7 9 0 5 7

1. Type and amount of Material to be Used, Location, Training and Experience of Individuals

Radioisotopes that will be used at the field plot are limited to Carbon-14 (^{14}C) and Hydrogen-3 (^{3}H). Generally radiolabeled compounds are organic compounds with molecular weights of 200 to 700, vapor pressures of 10^{-5} to 10^{-9} mm Hg and water solubilities of 1.0 ppb to 10,000 ppm. Total radioactivity (^{14}C + ^{3}H) on the field plot will be limited to 500 microcuries. Generally individual experiments require 100 to 300 microcuries each and only one or two experiments will be conducted each year. Typically, 1.0 to 10 microcuries of radioactivity are applied per plant.

The field plot is located on the property of Velsicol Chemical Corporation known as the Velsicol Agricultural Research Center (VARC) at 2414 Deepcut Rd., P. O. Box 507, Woodstock, IL 60098. VARC is a research facility equipped with laboratories, greenhouses and farm facilities. VARC greenhouses and laboratories are included as a location at which Velsicol is licensed to use radioactive materials (NRC license number 12-08920-01, May 15, 1984). The field plot will be fenced with a 5 foot high welded wire fence fitted with a gate which will be kept locked at all times. The fence will be posted with signs reading "caution radioactive materials".

Two personnel at VARC, Dr. J. F. Kunkel and Dr. A. A. Goloff are trained and experienced in handling of radioactive materials and are authorized for use of material under the above mentioned license. In addition, Dr. R. G. Butz will be responsible for experiments conducted at the field plot at VARC. Dr. C. C. Yu, the Radiation Protection Officer will review all protocols of studies to be conducted at the field plot. The resumes of the above individuals are part of the NRC license application of September 26, 1983. No radioactive use at the field plot will be allowed without a study protocol. Preliminary and range finding experiments will be conducted in the laboratory or greenhouse unless specifically authorized by the study protocol.

2. Experimental Protocol

See Appendix A

3. Amount of Release and Procedures for Minimization

Individual releases of radioactive in the field will be made exclusively onto soil or growing plant material (such as corn, soybeans, grapes, etc.) within the fenced site. In the case of plants, individual leaves and/or fruiting bodies will be treated with a microsyringe (0.05 to 0.50 milliters per leaf) or a small paint brush. The amount applied will be quantitated to the nearest 0.01 microcurie. Treated plant parts will be physically attached to a stationary post by means of water resistant tape and monofilament fishing line. This is to prevent the escape of ^{14}C- or ^{3}H-treated plant material from the field plot.

In the case of soil applied radiochemicals, the treated soil will be contained in an appropriate casing or container, normally a partially buried 55-gallon oil drum painted with epoxy paint.

In both cases the soil around the radiochemical treatment area will be monitored for total radioactivty. Soil and/or plant material with total radioactivity greater than 0.05 microcuries per gram, that is not removed from the field plot as a sample, will be removed and disposed of as radioactive waste in accordance with Velsicol Safety Standard Operating Procedure 5.5, Handling of Radioactive Chemicals (see appendix B).

4. Expected Radiation Dose to Humans

The radionuclides to be handled (^{14}C and ^{3}H) are weak beta emitters. Control will be exercised in the use of these materials so that no significant exposure or hazard is expected. Any exposure should be confined to the individual applying the radioactivity to the field plot and lower probability of much smaller doses to the person(s) maintaining and sampling the field plot.

The maximum dose to the person applying the ^{14}C- or ^{3}H-radiochemicals is estimated at 0.1 microcuries per application with a maximum of 3 applications per year. The maximum dose to those persons maintaining and sampling the field plot is estimated at 1/10 to 1/100 of the above or 0.001 to 0.01 microcuries per application.

5. Property Ownership

The property at VARC, Woodstock, IL is owned by Velsicol Chemical Corporation, 341 E. Ohio St., Chicago, IL, 60611.

Appendix A

PROTOCOL

METABOLISM AND TRANSLOCATION OF RADIOLABELED PESTICIDES AND PLANT GROWTH REGULATORS IN THE FIELD

OBJECTIVE

To determine the metabolic fate of developmental pesticides and plant growth regulators (PGRs) in the field. Emphasis will be placed on defining the nature of radiocarbon residues produced in crops after application simulating expected commercial use and on determining components of terminal residues in this crop at maturity. Specific objectives are to:

a) Identify terminal residues of pesticides or PGRs in crops for which analytical methods will need to be developed.

b) Evaluate absorption and distribution of residues in crops, particularly in the portions of the plant that comprise human food and possibly animal feed.

c) Determine efficacy of extraction procedure(s) for application to routine residue analysis techniques where unlabeled residue is quantitated.

INTRODUCTION

Generally, no information relevant to metabolism of these compounds is available. Metabolism studies in plants are required by EPA to establish the "nature of residues" and the "total toxic residue" which must be included in the tolerance expression. The protocol for the current study is designed to meet test requirements for plant metabolism studies as outlined by EPA (Pesticide Assessment Guidelines, Sub-Division O, Residue Chemistry, October 1982: Section 171-4).

RADIOLOGICAL SAFETY

All unnecessary exposure to radioactive material will be avoided. Only qualified personnel (listed on NRC licence number 12-08920-01) will be involved in the use of radioactive materials at the field plot. Velsicol Safety Standard Operating Procedure No. 5.5, "Handling of Radioactive Materials," will be strictly followed. In addition, all applicable regulations of the U.S. Nuclear Regulatory Commission will be followed.

Personnel will wear disposable gloves, suits, and shoe covers when working within the field plots and will remove these at exit. When radiochemicals with a vapor pressure greater than

10^{-7} mmHg at 25°C are employed, the person making the application of ^{14}C- or ^{3}H-radiochemicals will wear a respirator equipped with an activated charcoal cartridge to minimize inhalation of radioactivity. A portable monitoring device will be available to monitor total radioactivity on personnel and articles being removed from the site.

MATERIALS AND METHODS

These studies are to be conducted according to Good Laboratory Practices. This protocol and relevant standard operating procedures must be followed. Deviations from the above procedures are not permitted without prior authorization from the Study Director. The Director of Environmental Sciences will appoint the Study Director.

CHEMICALS

Analytical reference standard chemicals (unlabeled) with a purity of 98 to 100% will be utilized to reduce the specific activity of radiolabeled chemicals. Radiolabeled chemical with specific activity of 10 to 50 millicuries per millimole and radiochemical purity of 98 to 100% will be the sole sources of radioactivity in these studies. Radioisotopes used in the field will be limited to radiocarbon (^{14}C) and tritium (^{3}H). Analytical reference standards (unlabeled) of model metabolites will also be available to aid in identification of probable metabolites. Other chemicals used in the experiment including solvents will be reagent grade or better.

DOSE PREPARATION

Radiolabeled chemicals will be diluted with unlabeled analytical reference standards to the appropriate specific activity (about 10 millicuries/millimole) to achieve a limit of detection of approximately 0.01 ppm. The dose will be premixed with appropriate carriers (water and solvent or surfactant) for application to plants.

TREATMENT AND SAMPLING OF PLANTS

Plants which are healthy will be selected for use in these studies. As shown in Table 1, at least two treatment rates will normally be involved. The first will be equal to the commercial rate. The second treatment will involve application of an exaggerated rate (to make identification of metabolites easier).

Application to foliage or soil will be made by either microsyringe, painting or dipping of selected plant parts such as fruiting bodies, flowers or leaves.

The standard commercial rate of application will be used and put on at rates equal to approximately 0.05 to 5.0 pounds per acre. The actual volume of radiolabeled solution applied per plant is generally 0.1 to 2.0 milliliters. The amount of radioisotope to be applied will normally be from 1.0 to 10 microcuries per plant. In general it is unnecessary to treat more than 24 plants at one time. The maximum radioactivity in the field plot at any time will be limited to 500 microcuries.

Immediately after application, 0 time foliar and/or soil samples will be collected and frozen for subsequent analysis. Subsequent samples will be taken according to a prearranged design (e.g. Table 1). Pre-treatment and control samples will be taken at each interval.

Sampling intervals may be modified to derive maximum benefit from the analysis time-course point of view. Most studies will last 4 to 52 weeks.

ANALYSIS

Samples collected at preselected dates will be homogenized prior to analysis. As mentioned, focus will be on edible parts with sampling also of leaves, petioles, root and stem tissue. Analyses will include combustion of samples to $^{14}CO_2$ and $^{3}H_2O$ to determine total radioactivity and to identify samples with sufficient radiocarbon will be subjected to extraction and analysis by TLC, GC and/or HPLC (and other suitable methods for analysis to achieve the objectives). Mass spectroscopy or other analytical techniques will be applied as required to identify major organo-soluble metabolites. Use of model metabolites will be necessary.

Bound and water-soluble residues will be further studied as needed on an "best effort" basis to determine if acid or enzymatic treatment will release bound or conjugated residues. It may also be necessary to distinguish between surface and internal residues for leaves and edible parts.

REPORT

The metabolism distribution and translocation profile of the radioactivity and parent compound in these tissues (in ug/g of equivalents per gram of tissue) and the nature of radiocarbon discovered will be presented. A flow sheet showing the metabolic pathway as interpreted from data derived from the experiment will be included. A material balance of the applied radiocarbon will be shown.

5/22/85
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