

PACKAGE: ML113330774 / 030-38510



101 ARC Drive
Saint Louis, MO 63146 USA
Phone: 314-991-4545 or 800-331-6661
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Monday, November 21, 2011

Division of Industrial and Medical Nuclear Safety
Office of Nuclear Materials Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, DC 20555-001

Gentlemen:

American Radiolabeled Chemicals, Inc (ARC) requests an Exempt Distribution License for the distribution of radioactive material in quantities not exceeding those found in 10CFR30.71 Schedule B. NRC Form 313 with attachments is enclosed.

ARC employs less than 35 people and therefore is a "small entity" as described in 10CFR170.16(c).

At the present time, ARC is the only supplier of Tritium labeled saxitoxin and brevetoxin. These items were developed at the request of FDA researchers to support FDA and IAEA programs for protecting consumer safety. Under our existing manufacturing license (24-21362-01) these products may only be distributed to holders of a specific US NRC license. For reasons outlined below, it is our desire to broaden the distribution, specifically by the exempt distribution of 50 microcurie kits of the labeled toxin and additional C-14 and Tritium labeled biomedical research compounds.

Clams, mussels, oysters, and other kinds of seafood can accumulate potent natural toxins. Seafood that is normally wholesome can become lethal in a couple of days, with no outward signs of toxicity. In an incident in Guatemala (26 dead, 160 sick in three days), the vectors were small clams harvested from the beach that had been being consumed without incident for weeks prior, up to the day when they started killing people.

There are several different families of toxins. Those of concern along US coasts are paralytic shellfish poisoning (PSP), which also caused the tragedy in Guatemala, and neurotoxic shellfish poisoning (NSP). PSP occurs in all the Pacific Coast states, Florida, and New England. NSP occurs along the Gulf Coast.

The main strategy for protecting consumers from PSP and NSP is monitoring, taking samples and checking them for toxicity. Unfortunately, the main tool for detecting the toxins is mouse bioassay. The FDA is committed to finding alternatives to the use of animals for such routine assays.

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The monitoring is mainly done by the states. It would be better if industry and others could get involved, but difficulties associated with the mouse assay have tended to prevent this.

There are options to mouse bioassay. The best so far is the receptor binding assay (rba), which uses tritiated toxin. For PSP, the rba uses tritiated saxitoxin; for NSP, the rba uses tritiated brevetoxin. The amounts used are very small; most labs would likely use only one 50 microcurie vial in a season.

In addition to avoiding the use of live animals, the rba is far more sensitive than the mouse bioassay and provides a very high throughput. The greater sensitivity and throughput mean much better protection for consumers, particularly the ability to detect toxicity long before it increases to levels of concern.

Implementation of the rba in the US is currently limited by the perceived complexity of complying with NRC licensing requirements.

Globally, the IAEA is supporting the implementation of the rba in less developed nations through its Technical Assistance program.

The total number of labs using the rba, and the number of 50 microcurie vials used, will likely remain small. The FDA researcher has informed us that perhaps a dozen labs in the US would set up to use the rba.

It is because of this that we began to explore the possibility of exempt distribution. It is our hope that, if the 50 microcurie vials of tritiated saxitoxin or brevetoxin for the rba can be considered exempt, many labs in the US will use the rba instead of the mouse bioassay.

If you need any additional information, please contact Regis A Greenwood, CHP, our Radiation Safety Officer directly

Sincerely,

A handwritten signature in dark ink, appearing to read "Surendra Gupta", is written over a light blue horizontal line.

Surendra K. Gupta, PhD
President,
American Radiolabeled Chemicals

NRC FORM 313 (3-2009) 10 CFR 30, 32, 33, 34, 35, 36, 39, and 40	U.S. NUCLEAR REGULATORY COMMISSION APPROVED BY OMB: NO. 3150-0120 EXPIRES: 3/31/2012 Estimated burden per response to comply with this mandatory collection request: 4.3 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Send comments regarding burden estimate to the Records and FOIA/Privacy Services Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by internet e-mail to infocollects.resource@nrc.gov , and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0120), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.
APPLICATION FOR MATERIALS LICENSE	
INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.	
APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH: OFFICE OF FEDERAL & STATE MATERIALS AND ENVIRONMENTAL MANAGEMENT PROGRAMS DIVISION OF MATERIALS SAFETY AND STATE AGREEMENTS U.S. NUCLEAR REGULATORY COMMISSION WASHINGTON, DC 20555-0001	IF YOU ARE LOCATED IN: ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO: MATERIALS LICENSING BRANCH U.S. NUCLEAR REGULATORY COMMISSION, REGION III 2443 WARRENVILLE ROAD, SUITE 210 LISLE, IL 60532-4352
ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS: IF YOU ARE LOCATED IN: ALABAMA, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, KENTUCKY, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, NORTH CAROLINA, PENNSYLVANIA, PUERTO RICO, RHODE ISLAND, SOUTH CAROLINA, TENNESSEE, VERMONT, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO: LICENSING ASSISTANCE TEAM DIVISION OF NUCLEAR MATERIALS SAFETY U.S. NUCLEAR REGULATORY COMMISSION, REGION I 475 ALLENDALE ROAD KING OF PRUSSIA, PA 19406-1415	ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MISSISSIPPI, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON, OR WYOMING, SEND APPLICATIONS TO: NUCLEAR MATERIALS LICENSING BRANCH U.S. NUCLEAR REGULATORY COMMISSION, REGION IV 612 E. LAMAR BOULEVARD, SUITE 400 ARLINGTON, TX 76011-4125
PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTIONS.	
1. THIS IS AN APPLICATION FOR (Check appropriate item) <input checked="checked" type="checkbox"/> A. NEW LICENSE <input type="checkbox"/> B. AMENDMENT TO LICENSE NUMBER _____ <input type="checkbox"/> C. RENEWAL OF LICENSE NUMBER _____	2. NAME AND MAILING ADDRESS OF APPLICANT (Include ZIP code) American Radiolabeled Chemicals, Inc. 101 ARC Drive St. Louis, MO 63146
3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED American Radiolabeled Chemicals, Inc. 100 ARC Drive and 104 ARC Drive St. Louis, MO 63146	4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION Regis A. Greenwood, CHP TELEPHONE NUMBER <div style="text-align: right;">(314) 991-4545</div>
SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.	
5. RADIOACTIVE MATERIAL a. Element and mass number; b. chemical and/or physical form; and c. maximum amount which will be possessed at any one time.	6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.
7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE.	8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.
9. FACILITIES AND EQUIPMENT.	10. RADIATION SAFETY PROGRAM.
11. WASTE MANAGEMENT.	12. LICENSE FEES (See 10 CFR 170 and Section 170.31) FEE CATEGORY _____ AMOUNT ENCLOSED \$ 11,400
13. CERTIFICATION. (Must be completed by applicant) THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT. THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 39, AND 40, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF. WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.	
CERTIFYING OFFICER – TYPED/PRINTED NAME AND TITLE Surendra K. Gupta, PhD, President	SIGNATURE DATE 11/21/11
FOR NRC USE ONLY	
TYPE OF FEE APPROVED BY _____	FEE LOG DATE _____
FEE CATEGORY \$ _____	CHECK NUMBER COMMENTS

AMERICAN RADIOLABELED CHEMICALS, INC.
NRC APPLICATION FOR NEW EXEMPT DISTRIBUTION LICENSE

ITEM 5 – RADIOACTIVE MATERIALS

Pursuant to Materials License 24-21362-01; American Radiolabeled Chemicals, Inc. may possess the following radioactive materials

a. Element and mass number	b. Chemical and/or physical form	c. Amount which will be possessed at any one time
A. Carbon-14	A. Any	A. 400 curies
B. Calcium-45	B. Any	B. 1 curie
C. Chlorine-36	C. Any	C. 300 millicuries
D. Chromium-51	D. Any	D. 100 millicuries
E. Hydrogen-3	E. Any	E. 12,000 curies
F. Iodine-125	F. Any	F. 1.5 curies
G. Phosphorous-32	G. Any	G. 1 curie
H. Phosphorous-33	H. Any	H. 1 curie
I. Sulfur-35	I. Any	I. 10 curies
J. Iron-59	J. Prepackaged units	J. 100 millicuries
K. Strontium-85	K. Prepackaged units	K. 100 millicuries
L. Cobalt-60	L. Prepackaged units	L. 100 millicuries
M. Iron-55	M. Prepackaged units	M. 100 millicuries

AMERICAN RADIOLABELED CHEMICALS, INC.
NRC APPLICATION FOR NEW EXEMPT DISTRIBUTION LICENSE

ITEM 6 – PURPOSES FOR WHICH LICENSED MATERIAL WILL BE USED

A. Use – As described in the transmittal letter.

B. Packaging; see attached pictures

1. Five (5) mL Vial – labeled as attached; contains compound.
2. Absorbent Material – sufficient to absorb 3x the liquid volume of the compound and serve as shock absorber.
3. Outer Container – approximately 120 mL; containing items 1 and 2 above. Labeled identically to inner container.

C. Pictures of Typical Containers

1


2

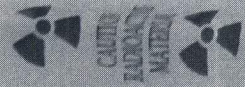


Saxitoxin
Radioisotope-Tritium
Activity- 50 uCi



Saxitoxin
Radioisotope
Activity


Brevetoxin
Radioisotope-Tritium
Activity- 50 uCi


CAUTION
RADIOACTIVE
MATERIAL
Brevetoxin
Radioisotope-Tritium
Activity-



Tetrodotoxin
Radioisotope-Tritium
Activity- 50 uCi



Tetrodotoxin
Radioisotope
Activity



Labeled Biomedical Compounds
Radioisotope-Tritium
Activity- xxx uCi



Labeled
Radioisotope
Activity



Labeled Biomedical Compounds
Radioisotope-Carbon 14
Activity- xxx uCi



Labeled Biomedical Compounds
Radioisotope-Carbon 14
Activity- xxx uCi

D. Labels

Where XXX is a value less than the 10CFR30.71 Schedule B value



Saxitoxin
Radioisotope-Tritium
Activity- 50 uCi



Brevetoxin
Radioisotope-Tritium
Activity- 50 uCi



Tetrodotoxin
Radioisotope-Tritium
Activity- 50 uCi



Labeled Biomedical Compound
Radioisotope-Tritium
Activity- xxx uCi



Labeled Biomedical Compound
Radioisotope-Carbon 14
Activity- xxx uCi

E. Handling Instructions



American
Radiolabeled
Chemicals, Inc.

101 ARC Dr.
St. Louis, MO 63146 U.S.A.
Ph. (314) 991-4545 or (800) 331-6661
Fax (314) 991-4692 or (800) 999-9925
Web: <http://www.arc-inc.com>
E-mail: arcinc@arc-inc.com

INSTRUCTIONS RELATING TO THE HANDLING, USAGE, STORAGE, AND DISPOSAL OF EXEMPT RADIOACTIVE MATERIAL

Materials that are labeled as exempt in this package are exempt from NRC or Agreement State licensing requirements.

CAUTION: RADIOACTIVE MATERIAL – NOT FOR HUMAN USE

Introduction into foods, beverages, cosmetics, drugs, medicine, or manufactured products for commercial distribution is prohibited. Exempt quantities should not be combined.

A. For any source

1. All radioactive materials should be stored in specifically designated areas.
2. All work with these materials should be carried out only in authorized areas.

B. For unsealed sources

1. No pipetting should be done by mouth.
2. There should be no smoking, eating, or drinking within the work area.
3. Hands should be washed after handling radioactive materials.
4. Any spilled material should be wiped up quickly and thoroughly and the contaminated materials transferred to a suitable waste receptacle. The surfaces involved should be washed thoroughly with a suitable detergent.
5. Exempt radioactive material can be discarded into a sanitary sewerage system. The radioactive materials labels should be removed or defaced prior to disposal of the empty container and packaging. While there are no NRC requirements, the proper disposal of exempt product should be in accordance with other local, state, and federal guidelines where applicable.

AMERICAN RADIOLABELED CHEMICALS, INC.
NRC APPLICATION FOR NEW EXEMPT DISTRIBUTION LICENSE

**ITEM 7 – INDIVIDUALS RESPONSIBLE FOR RADIATION SAFETY PROGRAM
AND THEIR TRAINING EXPERIENCE**

INFORMATION CAN BE FOUND BY REFERENCING

MATERIALS LICENSE 24-21362-01

AMERICAN RADIOLABELED CHEMICALS, INC.
NRC APPLICATION FOR NEW EXEMPT DISTRIBUTION LICENSE

ITEM 8 – TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING
RESTRICTED AREAS

INFORMATION CAN BE FOUND BY REFERENCING

MATERIALS LICENSE 24-21362-01

AMERICAN RADIOLABELED CHEMICALS, INC.
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ITEM 9 – FACILITIES AND EQUIPMENT

INFORMATION CAN BE FOUND BY REFERENCING
MATERIALS LICENSE 24-21362-01

AMERICAN RADIOLABELED CHEMICALS, INC.
NRC APPLICATION FOR NEW EXEMPT DISTRIBUTION LICENSE

ITEM 10 – RADIATION SAFETY PROGRAM

INFORMATION CAN BE FOUND BY REFERENCING
MATERIALS LICENSE 24-21362-01

AMERICAN RADIOLABELED CHEMICALS, INC.
NRC APPLICATION FOR NEW EXEMPT DISTRIBUTION LICENSE

ITEM 11 – WASTE MANAGEMENT

INFORMATION CAN BE FOUND BY REFERENCING

MATERIALS LICENSE 24-21362-01

ORIGIN ID: ZSVA (314) 991-4545
OFFICE
AMERICAN RADIOLABELED CHEMICALS
101 ARC DRIVE

ST. LOUIS, MO 63146
UNITED STATES US

SHIP DATE: 22NOV11
ACTWGT: 0.1 LB MAN
CAD: 0747982/CAFE2509

BILL SENDER

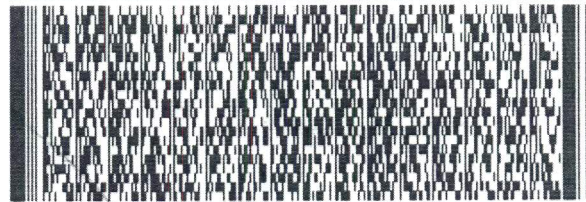
TO

DIV. OF INDST. & MED. NUCLEAR SFTY
OFF. OF NUCLEAR MATERIALS SAFETY
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON DC 20555

(314) 991-4545

DEPT: NRC LETTER 11/22/11

*T8E24
Tracy Kline*



FedEx
Express



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STANDARD OVERNIGHT

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DC-US IAD

Part # 156148-434 RIT2 07/11

