POLICY ISSUE

(Notation Vote)

August 2, 2001 SECY-01-0145

FOR: The Commissioners

FROM: Janice Dunn Lee, Director

Office of International Programs /RA/

SUBJECT: PROPOSED LICENSE TO EXPORT HEAVY WATER TO JAPAN FOR NON-NUCLEAR

END USE (XMAT0401)

PURPOSE:

To request Commission review of the proposed issuance of a license to Sigma-Aldrich Corporation involving the export of heavy water. The application is being referred to the Commission in accordance with 10 CFR 110.40(b)(3).

DISCUSSION:

On April 24, 2001, Sigma-Aldrich Corporation applied for a license (Attachment 1) to export 2,500 kilograms of heavy water, deuterium gas, and deuterium compounds to Japan over a three-year period for non-nuclear end use. The applicant plans to sell the various deuterium compounds to Sigma-Aldrich Japan and Nippon Sanso Corporation in Japan for further distribution into the Japanese medical, pharmaceutical, chemical, and industrial markets. Typically, the Sigma-Aldrich customers in Japan use these materials in relatively small quantities (i.e., less than 1 kg) for scientific research which may include identification of chemicals in reaction pathways, metabolic studies, or environmental analysis.

The applicant also noted that most of the products are sold to Japan in prepackaged units; however, some heavy water is sold to Nippon Sanso in bulk form for further labeling of compounds for distribution throughout Japan.

In response to NRC's request for views on the proposed export, the Executive Branch, in a letter dated July 9, 2001 (Attachment 2), recommends that the license be issued to Sigma-Aldrich. It is the Executive Branch judgment that the proposed export will not be inimical to the common defense and security of the United States, and is consistent with the provisions of the Atomic Energy Act of 1954, as amended by the Nuclear Non-Proliferation Act of 1978.

CONTACT: B.L. Wright, OIP

415-2342

The Executive Branch letter notes that, as a party to the NPT, Japan has committed itself to maintain IAEA safeguards on all its peaceful nuclear activities and has pledged not to produce or otherwise acquire any nuclear explosive device, therefore satisfying criteria (1) and (2) of section 109b of the Atomic Energy Act, as amended, for exports of nuclear components, substances and items. The remaining criterion, agreement not to retransfer any of the U.S.-supplied heavy water or deuterium gas without prior U.S. consent, has been satisfied by the receipt of generic assurance letters dated October 5, 1978, and February 28, 1979, from the Embassy of Japan, the subject of previous correspondence on exports of nuclear moderator material to Japan.

CONCLUSION:

The staff concurs with the Executive Branch judgment that the proposed export would not be inimical to the common defense and security of the United States and also meets the three specific export licensing criteria of Section 109b of the Atomic Energy Act of 1954, as amended. There are no applicable international safeguards or foreign physical protection requirements for the proposed export.

RECOMMENDATION:

That the Commission authorize the issuance of the requested license to Sigma-Aldrich Corporation.

/RA/

Janice Dunn Lee, Director Office of International Programs

Attachments: 1. 4/24/01 Sigma-Aldrich Corp. Export License Application

2. 7/09/01 DOS Letter R.J.K. Stratford to JDLee

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Saint Louis, Missouri 63103 USA
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email: sig-ald@sial.com
visit us at www.sigma-aldrich.com

NRC Form 7 (4-2000) Attachment Applicants Reference: SIAL-Japan

Below are explanations of attachment references made on the Sigma-Aldrich application to export deuterium oxide, deuterium (gas) and other deuterium compounds to Japan for <u>non-nuclear end-use</u>.

Box 10a. Ultimate Foreign Consignee

Sigma-Aldrich intends to use the two Ultimate Foreign Consignees identified below.

Distributors:

1) Sigma-Aldrich Japan 368 Oomachi Chiba-ken 272 Ichikawa, Japan

2) Nippon Sanso Corporation
4-320-1 Tsukagoshi
Saiwai-Ku
Kawasaki 210-8509, Japan

Box 11. Ultimate End Use

Sigma-Aldrich plans to sell the various deuterium compounds to the ultimate consignees above for further distribution into the Japanese medical, pharmaceutical, chemical and industrial markets. Their customers in Japan typically use these materials in relatively small quantities (i.e., less than 1 Kg) for scientific research. This type of research may include identification of chemicals in reaction pathways, metabolic studies or environmental analysis.

Most of the products are sold in the prepackaged units, however some heavy water is sold to Nippon Sanso listed above for further labeling of compounds for distribution throughout Japan. No material will be used in any activity related to isotope separation, heavy water production or in the fabrication of nuclear fuel.

Box 25. Additional information on consignees, end uses, and product descriptions

The deuterium oxide is of Canadian origin.

Both consignees have warehouses where final product will be stored. The facilities are secured and monitored

KIND ON



Chlorobenzene-d₅

[3114-55-4]

FW 117.60 bp 130° nB 1.5220 d 1.157 Fp 75°F (23°C) FT-IR 1(2), 1087C Safety 2, 738B R&S 1(2), 2935A FLAMMABLE UQUID IRRITANT

Cat. No.	Isotopic Purity %	Name	Size	Pkg Type	Each
17,660-5	99	Chlorobenzene-d₅	1g 5g	ampule ampule	\$29.65 98.80
CDCl ₃	Beil. 1(3), 63	m-d p-64" bp 60.9" nB 1.4445 d 1.500 FT-NMR 1(3), 620A FT-IR 1(2), 1074D Sa CANCER SUSPECT AGENT	nfety 2 , 7868		[865-49-6]

	Cat. No.	Isotopic Purity %	Name	Size	Pkg Type	Each
	15,185-8	100.0 (99.96 min)	Chloroform-d	10g	ampule	\$20.50
				50g	ampule	68.80
	23,691-8	100.0 (99.96 min)	Chloroform-d	10 x 0.5mL	ampule	24.90
	44,473-1	100.0 (99.96 min)	Chloroform-d	10 x 0.75mL	ampule	30.20
	42,309-2	100.0 (99.96 min)	Chloroform-d	10 x 1.0mL	ampule	34.45
	49,427-5	100.0 (99.96 min)	Chloroform-d	10g	ampule	19.10
	•		contains 0.03% v/v TMS	50g	ampule	64.25
	49,428-3	100.0 (99.96 min)	Chloroform-d contains 0.03% v/v TMS	10 x 0.75mL	ampule	30.10
	43,191-5	100.0 (99.96 min)	Chloroform-d	10mL	ampule	31.95
	.,	•	stabilized with 0.5 wt. % silver w		ampule	106.95
	15,182-3	99.8	Chloroform-d	50g	screw-cap bottle	14.50
				100g	screw-cap bottle	24.30
				$10 \times 100g$	screw-cap bottle	183.80
		•		1 <i>5</i> 0g	Sure/Seal™ bottle	32.70
				250g	screw-cap bottle	53.40
	30,873-0	99.8	Chloroform-d	$5 \times 0.5 mL$	ampule	7.00
(NEW)	52,201-5	99.8	Chloroform-d	10 x 0.6ml	ampule	7.10
	44,133-3	99.8	Chloroform-d	10 x 0.75mL	ampule	8.30
	23,689-6	99.8	Chloroform-d	10 x 1.0mL	ampule	11.55
	22,578-9	99.8	Chloroform-d	100g	screw-cap bottle	25.30
			contains 0.03% v/v TMS	10 x 100g	screw-cap bottle	197.00
				1 <i>5</i> 0g	Sure/Seal™ bottle	[::`33.70
				500g	screw-cap bottle	107.95
	42,366-1	99.8	Chloroform-d	10 x 1.0mL	ampule	₹11.55
			contains 0.03% v/v TMS			支
	43,487-6	99.8	Chloroform-d	100g	screw-cap bottle	25.10
			contains 0.1% v/v TMS	10 x 100g	screw-cap bottle	194.90
				1 <i>5</i> 0g	Sure/Seal™ bottle	33.40
				500g	screw-cap bottle	106.90
	15,183-1	99.8	Chloroform-d	50g	screw-cap bottle	15.50
			contains 1% v/v TMS	100g	screw-cap bottle	√ 26.10
				10 x 100g	screw-cap bottle	203.00
				150g	Sure/Seal™ bottle	34.75
				250g	screw-cap bottle	57.30
	41,675-4	99.8	Chloroform-d	100g	screw-cap bottle	31.75
			stabilized with 0.5 wt. % silver foi		screw-cap bottle	285.50 67.95
			·	250g	screw-cap bottle	07.73

[1735-17-7]

[28788-42-3]

[80997-90-6]

Applicant Ref# SIAL-Japan

Example #1, Box 17 Description, Deuterium Compounds

Cyclohexane- d_{12}

FW 96.26 bp 78° no 1.421 d 0.893 Fp -1°F (-18°C)
Beil. 5(3), 36 FT-NMR 1(3), 619A FT-IR 1(2), 1073B Safety 2, 959D

FLAMMABLE LIQUID IRRITANT

Cat. No.	Isotopic Purity %	Name	Size	Pkg Type	Each
15,186-6	99.6	Cyclohexane-d ₁₂	1g	ampule	\$22.15
			5g	ampule	81.95
			10g	ampule	131.50
26,973-5	99.6	Cyclohexane-d ₁₂	10 x 1.0mL	ampule	162.15



Decahydronaphthalene- d_{18}

FW 156.40 bp 70-71*/13mm nb 1.4750 d 1.014 Fp 135*F (57*C)

FT-IR 1(2), 1073C Safety 2, 1011D

HYGROSCOPIC IRRITANT

Cat. No.	Isotopic Purity %	Name	Size	Pkg Type	Each
21,713-1	99	Decahydronaphthalene-d ₁₈ mixture of cis and trans	1g	ampule	\$85.80



cis-Decahydronaphthalene-d₁₈

FW 156.40 bp 94-96'/30mm nB 1.4761 d 1.015 Fp 137'F (58'C)

FT-IR 1(2), 1073D Safety 2, 1011C

HYGROSCOPIC IRRITANT

Cat. No.	Isotopic Purity %	Name	Size	Pkg Type	Each
22,679-3	98+	Decahydronaphthalene-d ₁₈	1g	ampule	\$195.25

Deuterium bromide, see Reagents, Acids, Bases and Buffers, page 24 Deuterium chloride, see Reagents, Acids, Bases and Buffers, page 24

Deuterium oxide

[7789-20-0]

FW 20.03 mp 3.8° bp 101.4° nb 1.3280 d 1.107 D_2O Merck Index 12, 2984 **HYGROSCOPIC**

Cat. No.	Isotopic Purity %	Name	Size	Pkg Type	Each
19,170-1	100.00 (99.990 min)	Deuterium oxide	10g <i>5</i> 0g	ampule ampule	\$60.45 152.00
45,335-8	100.00 (99.990 min)	Deuterium oxide	10 x 0.25mL	ampule	#2.80
45,336-6	100.00 (99.990 min)	Deuterium oxide	10 x 0.5mL	ampule	51:40
19,234-1	100.0 (99.96 min)	Deuterium oxide low in paramagnetic impurities	10g 30g	septum bottle septum bottle	125,85
15,189-0	100.0 (99.96 min)	Deuterium oxide	10g 30 x 10g 50g 125g 250g 1kg	screw-cap bottle screw-cap bottle screw-cap bottle Sure/Seal TM bottle screw-cap bottle screw-cap bottle	28.50 354.00 85.30 184,85 227,65 682,05
45,333-1	100.0 (99.96 min)	Deuterium oxide	10 x 0.25mL	ampule	17.10
26,978-6	100.0 (99.96 min)	Deuterium oxide	10 x 0.5mL	ampule	20.60
44,136-8	100.0 (99.96 min)	Deuterium oxide	10 x 0.75mL	ampule	29.00

Sure/Seal is a trademark of Sigma-Aldrich Co.



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XMATO401 11005266

Deputy Director Office of International Programs U.S. Nuclear Regulatory Commission 2120 L. Street, NW Washington, DC 20037

Dear Deputy Director:

Enclosed is NRC Form 7, Application for License to Export Nuclear Material. The license application is to export deuterium oxide, deuterium gas and various deuterium compounds to Japan for Non-nuclear end uses.

Should you have any questions regarding this license application please contact me at 1-800-521-8956 ext. 2710 or (314) 286-8337.

Sincerely,

Timothy A. Klages Director of Compliance Sigma-Aldrich Corporation

7 - MAY - 1 3 - 29

United States Department of State

Washington, D.C. 20520

July 9, 2001

Ms. Janice Dunn Lee Director, International Programs United States Nuclear Regulatory Commission Rockville, Maryland Docket # 11005266

Dear Ms. Lee:

I refer to the letter from your office dated May 11, 2001, requesting the views of the Executive Branch as to whether issuance of an export license in accordance with the application hereinafter described meets the applicable criteria of the Atomic Energy Act of 1954, as amended:

NRC No. XMAT0401 -- Sigma-Aldrich Corp. has applied for authorization to export to Japan 2,500 kilograms of heavy water, deuterium gas and deuterium compounds over a three year period for non-nuclear end-use. The materials will be exported to Sigma-Aldrich Japan and Nippon Sanso Corporation for distribution to the Japanese medical, pharmaceutical, chemical and industrial markets. Sigma-Aldrich customers in Japan typically use these materials in relatively small quantities (i.e., less than 1 kg) for scientific research. Most of the products will be sold to Japan in prepackaged units; however, some heavy water will be sold to Nippon Sanso in bulk form for further labeling of compounds for distribution throughout Japan.

It is the judgment of the Executive Branch that the proposed export will not be inimical to the common defense and security of the United States, and is consistent with the provisions of the Atomic Energy Act of 1954, as amended by the Nuclear Non-Proliferation Act of 1978.

As a party to the NPT, Japan has committed itself to maintain IAEA safeguards on all of its peaceful nuclear activities and has pledged not to produce or otherwise acquire any nuclear explosive device, therefore satisfying criteria (1) and (2) of Section 109b of the Atomic Energy Act, as amended, for exports of nuclear components, substances and items. The remaining criterion, agreement not to retransfer any of the U.S.-supplied heavy water or deuterium gas without prior U.S. consent, has been satisfied by the receipt of generic assurance letters dated October 5, 1978 and February 28, 1979 from the Embassy of Japan, the subject of previous correspondence on exports of nuclear moderator material to Japan.

On the basis of the foregoing, the Executive Branch recommends that the license be issued.

Sincerely,

Richard J.K. Stratford

Director

Nuclear Energy Affairs

100 MII: 28

SECENTED OIL