



File Number 90/15764

SI

PERMIT TO IMPORT

THERAPEUTIC SUBSTANCE(S) UNDER REGULATION 5A
OF THE CUSTOMS (PROHIBITED IMPORTS) REGULATIONS

Number
19399
LT

This permit is to be presented to the Collector of Customs at the port of entry

Importer's
Name and
Address

E. Merck Pty Ltd	[Redacted]
207 Colchester Rd	Offices Commanding
KILSYTH VIC 313	Randwick Supply Company
	Brook St RANDWICK NSW 2031

Permission is granted to the above named to import into Australia the following therapeutic substance(s) under the above stated Regulations (where applicable, the application to import has been subjected to quarantine scrutiny)

Fourteen (14) kilos Oxidoxime chloride (Toxogon) raw material
manufactured by E. Merck, Frankfurt Strassen 250,
Postfach 4119, 6100 Darmstadt 1, Federal Republic of
Germany.

THIS PERMISSION IS SUBJECT TO THE FOLLOWING REQUIREMENTS OR PROHIBITIONS:

1. This permit is a LIMITED AUTHORITY for the importation of the above stated quantity (ies) ONLY.
2. The importer is required to keep records with respect to the custody, use, disposal or distribution of the above therapeutic substance(s) for a period of three years from the date of importation.

3. For use in the local manufacture of oxidoxime chloride ampoules for use in Warat zone only. Not for use/distribution in Australia. As this Dept has not evaluated any data for this product, no guarantees of quality, safety or efficacy are given or implied

THIS PERMISSION IS ALSO SUBJECT TO THE PROHIBITIONS OR REQUIREMENTS SPECIFIED WITH AN 'X' BELOW:

- | | |
|--|--|
| <input type="checkbox"/> for invitro (diagnostic) use ONLY. | <input type="checkbox"/> for delivery into store ONLY - distribution may NOT take place without permission of the Secretary. |
| <input type="checkbox"/> to be labelled 'CAUTION MAY BE INFECTIOUS'. | <input type="checkbox"/> for supply to approved users ONLY. |
| <input type="checkbox"/> Australian Radiation Laboratory approval to import also required. | <input type="checkbox"/> for laboratory animal use ONLY. |
| <input type="checkbox"/> for personal use ONLY - NOT to be distributed for use by other persons or in animals. | <input type="checkbox"/> for veterinary use ONLY. |
| | <input type="checkbox"/> NOT to be used in animals. |

Signature of Authorised Officer for the Secretary

[Redacted Signature]

Date

17.9.90

Further applications to import this/these or any other Therapeutic substance(s) should be made in writing to:
The Drug Evaluation Branch, Therapeutic Goods Administration, P.O. Box 100, WODEN ACT 2606, AUSTRALIA



Therapeutic
Goods
Administration

PO Box 100, Woden, ACT 2606, Australia
 Woden Telephone: (06) 289 1555. Fax: (06) 289 8709
 Mawson Telephone: (06) 286 0222. Fax: (06) 286 1386



DEPARTMENT OF
COMMUNITY SERVICES
AND HEALTH

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Surgeon General Australian Defence Force
 Headquarters Australian Defence Force
 Department of Defence
 Russell Offices
 CANBERRA ACT 2600

Attention: [REDACTED]

Dear Sir

I refer to your facsimile letter of 9 January 1991, about a request for approval in principle for the Australian manufacture of nerve gas antidote, obidoxime chloride injections.

A permit from this Administration has already been issued to enable importation of 14 kilos of obidoxime chloride raw material to be effected (copy attached). The proposed use, ie. making into a pharmaceutical for use outside Australia, falls within the terms of the permit for this material. This Branch, therefore, has no jurisdiction in this matter.

The Good Manufacturing Practice Audit and Licensing Section of this Administration have advised that all the manufacturers named in your facsimile letter follow good manufacturing practice.

You should contact this office again if it is proposed to use the finished product within Australia.

Yours sincerely

[REDACTED]

[REDACTED] has
 advised that [REDACTED]

Director
 Evaluation Unit 1
 Drug Evaluation Branch
 9 January 1991

is analysing ~~data~~ obtained
 for herk. D o D will
 eventually use as standard
 [REDACTED]