

6-4/FF/42/2010-DC

GOVERNMENT OF INDIA  
Central Drugs Standard Control Organisation  
Ministry of Health & Family Welfare  
FDA BHAWAN, NEW DELHI (INDIA)

Form 41

(See Rule 27-A)

**REGISTRATION CERTIFICATE**

Registration Certificate issued for import of drugs into India  
Under Drugs and Cosmetics Rules, 1945

Registration Certificate No. FF-424

Dated 29 AUG 2012

1. M/S. Microgen, Inc. 33, Clinton Road, Suite 102, West Caldwell, NJ 07006 USA having factory premises at M/s. Misco Products Corporation, 1048 Stinson Drive, Reading PA, 19605 has been registered under Rule 27-A as a manufacturer and is hereby issued this Registration Certificate.
2. Name(s) of drug(s), which may be imported under this Registration Certificate (Please refer the enclosed list of drugs).
3. This Registration Certificate shall be in force from 01/08/2012 to 31/07/2015 unless it is sooner suspended or cancelled under the rules.
4. This Registration Certificate is issued through the office of the manufacturer or his authorised agent in India M/S Microgen Hygienic Pvt. Ltd. 9/1 K.C Inds Estate, 1st Flr Subhash Road Jogeshwari (East) Mumbai-400 060 who will be responsible for the business activities of the manufacturer in India in all respects.
5. This Registration Certificate is subject to the conditions stated overleaf and to such other conditions as may be specified in the Act and the Rules, from time to time.

Place: New Delhi

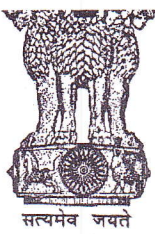
Date: \_\_\_\_\_

29 AUG 2012



  
LICENSING AUTHORITY  
Seal/Stamp

Dr. S. N. Mishra  
Deputy Controller General (India)  
General of Health Services  
Ministry of Health & Family Welfare  
New Delhi, India



6-4/FF/42/2010-DC

GOVERNMENT OF INDIA

Central Drugs Standard Control Organisation  
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FDA BHAWAN, NEW DELHI (INDIA)

NAME (S) OF DRUGS, WHICH MAY BE IMPORTED  
UNDER REGISTRATION CERTIFICATE NO. FF-424  
DATED

29 AUG 2012

D-125 Disinfectant Cleaner

Each Bottle Contains:-

N-Alkyl Dimethyl Benzyl Ammonium Chloride.....2.37%

and

N-Alkyl Dimethyl Ethyl Benzyl Ammonium Chloride.....2.37%

Inert-Ingredients.....95.26%



ITEMS (One) ONLY

Place: New Delhi

Date:

29 AUG 2012



LICENSING AUTHORITY

Seal/Stamp

(Dr. S. N. SENGA)  
Deputy Controller General (India)  
Ministry of Health Services  
New Delhi, India



**From:**  
The Drugs Controller General (India)  
Directorate General of Health Services

FDA Bhawan, New Delhi

Dated

To,

29 AUG 2012

M/S. Microgen Hygenie Pvt. Ltd.  
9/1 K.C Inds Estate, 1st Flr Subhash Road Jogeshwari (East)  
Mumbai-400 060

**Sub: -Registration of M/S. Misco Products Corporation, 1048 Stinson Drive, Reading PA, 19605 under the Provisions of Drug & Cosmetics Rules for the purpose of import of drugs in India**

FF-424

Dear Sir,

Please refer to your application no. Nil dated 23/06/2012, received by this Office vide diary no. 25682 dated 26/06/2012 on the above subject. Registration Certificate in Form 41 under the Rules is issued for the manufacturing site along with the name (s) of drug (s) imported under the said Certificate subject to the condition:

1. The drugs shall confirm to the standards / specifications mentioned in the Second Schedule of the Act, or such other standards / specifications forwarded by you and approved by this Directorate.
2. The drugs shall have the composition, strengths, standards and packing as approved by this Directorate.
3. Dispute, if any, in respect of the payment of fees and submission of TR6 challan, shall have to be settled between the bank and the applicant.
4. The drugs will be required to be withdrawn from sale from the market in case any undesirable reactions due to its medication are brought to light at any stage. This Directorate should be informed of adverse reports on the drug, if any.
5. The drugs shall be marketed for indications for which they have been approved.
6. If any claim is made for these drugs in future other than those approved, prior permissions from this Directorate will be necessary before such claim is made.
7. The drugs shall be supplied and marketed as per the provisions of the existing Drugs & Cosmetics Act and Rules thereunder.

- o. This registration in no way relieves you of the responsibility of complying with all other provisions of the Drugs & Cosmetics Act and Rules there under, and any other provisions of any other Act and Rules applicable in the matter concerned.
9. Each consignment of the drugs to be imported by you shall be accompanied by a test / analysis reports.
10. Based on this registration, import applications for the drug (s) endorsed in the enclosed Registration Certificate shall be considered for the issue of Form 10 Licence under the Rules.
11. This Registration Certificate is being issued under the condition that during the pendency of Registration, the applicant may be required to deposit inspection fee as stipulated under Clause (5) of Rule 24-A and enable inspection of manufacturing site by the officials authorised for this purpose. Non-compliance to this condition as and when so directed would result in cancellation of Registration Certification.

Please note that Registration Certificate issued is liable to be suspended / cancelled, if any of the condition stipulated above is not complied with, apart from any other condition that may be taken under the provisions of the Drugs & Cosmetics Act, 1940 and the Rules there under.

Please acknowledge the receipt.

Yours faithfully,



Drugs Controller General (India)

**Copy forwarded to:**

1. The Assistant Drug Controller (I), New Custom House, Annexe, Ballard Estate, Fort, Mumbai-400038.
2. The Assistant Drug Controller (I), 15/1, Strand Road, Custom House, Kolkata-700001.
3. The Assistant Drug Controller (I), Room No. 66, 2<sup>nd</sup> Floor, Custom House, Chennai-600001.
4. The Assistant Drug Controller (I), Jawaharlal Nehru Port, Trust Nhava Seva Port, Raigard, Maharashtra.
5. The Assistant Drug Controller (I), International Air Cargo Complex, Indira Gandhi International Air Port, New Delhi-110037.