

F. No. J-11011/456/06/2006-IA-II (I)
Government of India
Ministry of Environment & Forests
(IA Division)

Paryavaran Bhawan
CGO Complex, Lodhi Road
New Delhi - 110 003

E-mail : pb.rastogi@nic.in
Telefax : 011-24367668
Dated 15th June, 2007

To, ✓
Shri P.S.R.K. Prasad
Vice President (Corporate Engineering Services)
M/s NATCO Organics Ltd.
NATCO House, Road No. 2, Banjara Hills
Hyderabad - 500 033, A.P.

E-mail : mkengg@natcopharma.co.in ; Fax No. : 040-23548243 / 24993449

Subject : Bulk Drug Unit at Valkkadu, Ambattur, Thiruvallur, Tamilnadu by M/s NATCO Organics Ltd. - reg.

Sir,

This has reference to your letter no. nil dated 16th November, 2006 on the above subject seeking environmental clearance alongwith a copy of Questionnaire and EIA /EMP report and subsequent communication dated 29th January, 2007 and 27th February, 2007 seeking environmental clearance for the above project under the EIA Notification, 1994.

2.0 The Ministry of Environment and Forests has examined your application. It is noted that M/s NATCO Organics Ltd. have proposed to set up a Bulk drug unit at Vaikkadu, Manali Industrial Area, Ambattur, Thiruvallur, Tamil Nadu. Total land acquired in the notified industrial area is 10.57 ha. Following drugs will be manufactured :

S.N.	Name of the product	Production (Kg per Annum)
1	Allylestrenol	4
2	Drospirenone	50
3	Daunomycin Hydrochloride	12
4	Altretamine	5
5	Epirubicin Hydrochloride	2
6	Idarubicin Hydrochloride	0.5
7	Nandrolone Decanoate	2
8	Chlorambucil	1
9	Doxorubicin Hydrochloride	2
10	Fulvestrant	1
11	Testosterone Decanoate	2
12	Geftinib	500
13	Imatinib Methane Sulfonate	1000
14	GB-5 Intermediate	3670
15	Temozolomide	15
16	Sumatriptan	36000
17	Setraline Hydrochloride	5000
18	Melphalan	1
Total		40,267.5

2.0 Scrubbers will be provided to the furnace oil fired boiler and incinerator to control air emissions. Reactor vents will be provided with vent condensers after the chillers or brine to condense all the evaporated solvents. Solvents will be handled in closed circuit system. No odour problem is envisaged. SO_2 will be absorbed by caustic lye scrubber, HCl , Cl_2 and Br_2 gas by Alkali scrubber. Total water requirement from Chennai Metropolitan Water Supply & Sewage Board will be $216.5 \text{ m}^3/\text{day}$. Low TDS x Low COD will be treated in ETP. High TDS x High COD effluent will be incinerated in the incinerator. No wastewater will be discharged on land and 'zero' discharge will be adopted. The high TDS effluent will be sent to MEE and salts from MEE and thin film drier will be sent to CHWTSD (TWML). Solid waste in the form of organic residue, inorganic residue, spent carbon, sludge from the ETP, incinerator ash and forced evaporator salts will be sent to T.N. Common TSD (TWML) for final disposal.

3.0 Public hearing meeting was held on 14th September 2006. Total cost of the project is Rs. 20.00 Crores.

4.0 The Ministry of Environment and Forests hereby accords environmental clearance to the above project under EIA Notification dated 14th September, 2006 subject to strict compliance of the following conditions:

A SPECIFIC CONDITIONS :

- i) The gaseous emissions (SO_2 , NO_x & HCl) and particulate matter from various process units shall conform to the standards prescribed by the concerned authorities from time to time. At no time, the emission levels shall go beyond the stipulated standards. In the event of failure of pollution control system(s) adopted by the unit, the respective unit shall not be restarted until the control measures are rectified to achieve the desired efficiency.
- ii) Ambient air quality monitoring stations shall be set up in the downwind direction as well as where maximum ground level concentration are anticipated in consultation with the TNPCB.
- iii) Efficient scrubber for control of Chlorine, Bromine and Methyl amine shall be installed. SO_2 shall be absorbed by caustic lye scrubber and HCl , Cl_2 and Br_2 gas by Alkali scrubber. Scrubbers shall also be provided to the furnace oil fired boiler and incinerator to control air emissions. The scrubbed water after neutralization shall be sent to ETP for further treatment.
- iv) Solvent recovery system shall be installed. Spent solvents shall be recovered as far as possible & recovery shall not be less than 95 percent. During purification process, solvent vapours are emitted from purification tanks as fugitive emissions. Action shall be taken to reduce the emissions as far as possible. Reactor vents shall be provided with vent condensers after the chillers or brine to condense all the evaporated solvents. Chemicals/solvents shall be handled in closed circuit system. Closed centrifuges shall be provided to minimize the solvent emission.
- v) Use of toxic solvents like Methylene Chloride (M.C.) etc. shall be minimum and Benzene shall be replaced with alternate solvents. All venting equipment shall have vapour recovery system. Methylene Chloride shall be phased out in a time bound manner. A report shall be submitted to the Ministry after 2 year on the status of replacement of Methylene Chloride and Chloroform solvent.
- vi) Necessary arrangement shall be made for monitoring of vent exhaust from solvent recovery system and in the work environment for specific solvents like Methylene Chloride, Toluene, Chloroform, VOCs.

- vii) Industry shall switch over to aqueous based coating film in place of use of *Methylene Chloride* in coating operation and to non-halogenated solvents in place of halogenated solvents in a phased manner.
- viii) Hazardous and toxic waste generated during the process like distillation residue, spent carbon, spent mixture solvents, process organic residue shall be incinerated in a properly designed incinerator with energy recovery facility. The incinerator shall meet the CPCB standards and guidelines.
- ix) The company shall undertake following Waste Minimization measures :-
- > Metering and control of quantities of active ingredients to minimize waste.
 - > Reuse of by-products from the process as raw materials or as raw material substitutes in other processes.
 - > Use of automated filling to minimize spillage.
 - > Use of "Close Feed" system into batch reactors.
 - > Venting equipment through vapour recovery system.
 - > Use of high pressure hoses for equipment clearing to reduce wastewater generation.
- x) Fugitive emissions in the work zone environment, product, raw materials storage area shall be regularly monitored. The emissions shall conform to the limits imposed by APPCB.
- xi) Total water requirement from Chennai Metropolitan Water Supply & Sewage Board shall not exceed 216.5 m³/day and prior permission shall be obtained. The effluent generation shall not exceed 113.7 m³/day. Low TDS x Low COD effluent shall be treated in ETP for primary, secondary and tertiary treatment. Reverse Osmosis plant shall be installed for the recovery of fresh water and totally recycled back into the plant process. High TDS x High COD effluent shall be incinerated in the incinerator. No wastewater shall be discharged on land and 'zero' discharge shall be adopted. The high TDS effluent shall be sent to MEE and then agitated in thin film drier. The salts from MEE and thin film drier shall be sent to CHWTSDF (TWML). The domestic wastewater shall be treated in the septic tank followed by the soak pit.
- xii) The solid waste generated in the form of organic residue, inorganic residue, spent carbon, sludge from the ETP and forced evaporator salts shall temporarily be stored at site and sent to T.N. Common TSDF (TWML) for final disposal whenever comes into operation. The solvents from the mother liquor shall be recovered and reused in the plant operation wherever possible. The incinerator ash shall also be disposed off in common CHWTSDF (TWML). All the solid /Hazardous waste shall be disposed off as per the Hazardous Waste (Management & Handling) Rules.
- xiii) The company shall adopt surface as well as roof top rain water harvesting measures to harvest the run off water for recharge of ground water. Methods shall also be adopted for the conservation of water through and recycling and reusing the treated wastewater.
- xiv) Green belt shall be raised in 4.961 ha. (47 %) out of total 10.57 ha. land to mitigate the effects of fugitive emissions as per the Central Pollution Control Board guidelines.
- xv) Occupational health surveillance of the workers shall be done on a regular basis and records maintained as per the Factories Act.

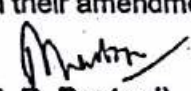
B. GENERAL CONDITIONS :

- i. The project authorities must strictly adhere to the stipulations made by the Tamil Nadu Pollution Control Board (TNPCB) and the State Government.
- ii. No further expansion or modifications in the plant shall be carried out without prior approval of the Ministry of Environment and Forests.
- iii. Adequate number of influent and effluent quality monitoring stations shall be set up in consultation with the TNPCB. Regular monitoring shall be carried out for relevant parameters.
- iv. The project proponent shall also comply with all the environmental protection measures and safeguards recommended in the EIA report.
- v. As proposed in EIA/EMP, Rs. 5.00 Crores and Rs. 3.50 Crores earmarked towards capital and recurring cost/annum for environmental protection measures shall be exclusively used to implement the conditions stipulated by the Ministry of Environment and Forests and State Government. A time bound action plan alongwith the implementation schedule to comply with all the conditions stipulated herein shall be submitted to the Ministry's Regional Office at Bangalore. The funds so provided shall not be diverted for any other purpose.
- vi. The implementation of the project vis-à-vis environmental action plans will be monitored by Ministry's Regional Office at Bangalore / TNPCB / CPCB. A six monthly compliance status report shall be submitted to the monitoring agencies.
- vii. The Project Proponent shall advertise in at least two local newspapers widely circulated in the region around the project, one of which shall be in the vernacular language of the locality concerned informing that the project has been accorded environmental clearance by the Ministry and copies of the clearance letter are available with the TNPCB / Committee and may also be seen at Website of the Ministry and Forests at <http://envfor.nic.in>. The advertisement shall be made within 7 days from the date of issue of the clearance letter and a copy of the same should be forwarded to the Ministry's Regional Office at Bangalore.
- viii. The Project Authorities shall inform the Regional Office as well as the Ministry the date of financial closure and final approval of the project by the concerned authorities and the date of start of land development work.

5.0. The Ministry may revoke or suspend the clearance, if implementation of any of the above conditions is not satisfactory.

6.0. The Ministry reserves the right to stipulate additional conditions if found necessary. The company will implement these conditions in a time bound manner.

7.0. The above conditions will be enforced, inter-alia under the provisions of the Water (Prevention & Control of Pollution) Act, 1974, the Air (Prevention & Control of Pollution) Act, 1981, the Environment (Protection) Act, 1986, Hazardous Waste (Management & Handling) Rules, 2003 and the Public Liability Insurance Act, 1991 along with their amendments and rules.


(Dr. P. B. Rastogi)
Additional Director

Copy to :

1. The Secretary (Environment) Govt. of Tamil Nadu, Fort St. George, Chennai -560 560, Tamil Nadu.
2. The Chairman, Central Pollution Control Board, Parivesh Bhavan, CBD-cum-Office Complex, East Arjun Nagar, Delhi-110 032.
3. The Chairman, Tamil Nadu Pollution Control Board, 100, Anna Salai, Guindy, Chennai-600 032, Tamil Nadu.
4. The Chief Conservator of Forests (Central), Regional Office (SZ), Kendriya Sadan, 4th Floor, E&F Wings, 7th Main Road, 2nd Block, Koramangala, Bangalore - 560034, Kanmataka.
5. JS (CCI), Ministry of Environment and Forests, Paryavaran Bhavan, CGO Complex, New Delhi.
6. Monitoring Cell, Ministry of Environment and Forests, Paryavaran Bhawan, CGO Complex, New Delhi.
7. Guard file
8. Monitoring file
9. Record file


(Dr. P. B. Rastogi)
Additional Director