Evaluating unlicensed DynamicPDF feature. Click here for details. [4:0:eval]

By speed post

भारत सरकार
पर्यावरण एवं वन मंत्रालय
Government of India
Ministry of Environment & Forests
(IA Division)

Paryavaran Bhawan
CGO Complex, Lodhi Road
New Delhi – 110 003
E-mail: hsmalviya@gmail.com
Telephone: 011: 24367076

F. No. J-11011/484/2008-IA-II (I)
Dated : October 30, 2008

To

M/s Endoc Pharma
Plot no. 4 to 7, Survey No. 53
B/H. Surashtra Paper Board Mill
Shapar-Veraval Ind. Area,
Shapar,Taluka: Kotda Sangani
Distt. Rajkot, Gujarat
endoc@endocpharma.com

Sub : Expansion of bulk drug manufacturing unit at Plot No. 4-7, Survey no. 53, behind Saurashtra Paper Board Mill, Shapar Verabal Industrial area, Shapar, Taluk Kotdasangani, District Rajkot, Gujarat by M/s Endoc Pharma – Environmental Clearance reg.

Sir,

This has reference to your letter no. nil dated May, 2008 received in the Ministry on 14th May 2008 along with application in Form – 1 and feasibility cum detailed report seeking environmental clearance for the above project under the Environment Impact Assessment Notification 2006.

2.0 The Ministry of Environment and Forests has examined the proposal and it is noted that the proposal is for environmental clearance for expansion of bulk drug manufacturing unit at Plot No. 4-7, Survey no. 53, behind Saurashtra Paper Board Mill, Shapar Verabal Industrial area, Shapar, Taluk Kotdasangani, District Rajkot, Gujarat by M/s Endoc Pharma. The total cost of the expansion project will be Rs. 314.0 Lakhs. The total land required for the project will be 5046.9 m^2. The details of the existing and proposed products and production capacity are as given below:

Sr. No.	Name of Products	Capacity, MT/Month		
		Existing	Proposed	Total
1.	N-Methyl – 3(4-Trifluoromethyl Phenoxy) – 3- Phenyl Propanamine base	0.5	Nil	0.5

Evaluating unlicensed DynamicPDF feature. Click here for details. [4:0:eval]

2.	1-[2-(2,4 difluorophenyl)-Oxiranyl Methyl – 1H-[1,2,4]- Triazole Methane Sulphonate	0.1	Nil	0.1
3.	1-(Oxiranyl Methyl)-2 Methyl-5 Nitro Imidozole	0.5	Nil	0.5
4.	Ornidazole	NIL	50.0	50.0
Total		**1.1**	**50.0**	**51.1**

3.0 No process gas emission is envisaged. There will be fugitive emission due to use of solvents and material handling & transportation. Presently unit has installed one steam boiler and one D.G. set having capacity of 0.4 TPH and 10 KVA respectively. The total water requirement (37.145 KLD including 15 KLD for gardening) will be met through ground water. The area does not fall under critical zone of ground water. The fresh industrial water requirement will increase from 0.745 KLD to 19.895 KLD. The domestic water requirement will be 2.25 KLD. The wastewater generation will be 13.335 KLD. The plant will install ETP with primary, secondary and tertiary treatment system for treatment of the wastewater as per the GPCB norms and present practice of evaporation will be discontinued. Treated wastewater will be used for plantation/greenbelt.

3. The project activity "manufacturing of synthetic organic chemicals" is listed at S.N. 5(f) under Category 'A'. The proposal was considered and appraised at central level in 85th meeting of the Expert Appraisal Committee (Industry) held during 23rd – 25th September 2008. The proposal was exempted from public hearing and EIA/EMP as per para 7(ii) of the EIA notification 2006.

4. Based on the information submitted by the Project Authorities, the Ministry of Environment and Forests hereby accords the environmental clearance to the above project under the provisions of EIA Notification dated 14th September, 2006 subject to compliance of the following specific and general conditions:

A SPECIFIC CONDITIONS:

i) The project authorities shall install the effluent treatment plant to treat the wastewater up to the norms laid down by the Gujarat Pollution Control Board. The company shall submit a copy of the ETP installation scheme to the Ministry's Regional Office at Bhopal.

ii) The water requirement and waste water generation shall not exceed 37.145 KLD and 13.335 KLD respectively. The company shall utilize the treated effluent for green belt development and maintain zero discharge status.

iii) The project authorities shall provide the chilled brine solution in secondary condenser for condensation of the VOCs and ensure that the solvent recovery shall not be less than 95%.

Evaluating unlicensed DynamicPDF feature. Click here for details. [4:0:eval]

iv) The company shall provide the monitoring arrangement with vents and regular monitoring shall be carried out and reports submitted to the SPCB, CPCB and Ministry's Regional Office at Bhopal.

v) To prevent solvent loss, following measures shall be taken :

A. Reactor shall be connected to chilled brine condenser system.
B. The condensers shall be provided with sufficient HTA and residence time so as to achieve more than 95% recovery
C. Solvents shall be stored in a separate space specified with all safety measures.
D. Proper earthing shall be provided in all the electrical equipment wherever solvent handling is done.
E. Entire plant shall be flame proof. The solvent storage tanks shall be provided with breather valve to prevent losses.

vi) The process emissions VOCs and particulate matter from various 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 unit shall be immediately put out of operation and shall not be restarted until the desired efficiency has been achieved.

vii) Fugitive emissions in the work zone environment, product and raw materials storage area shall be regularly monitored. The emissions shall conform to the limits imposed by GPCB.

viii) For control of fugitive emission and VOCs following steps shall be followed :

A. Closed handling system shall be provided for chemicals.
B. Reflux condenser shall be provided over reactor.
C. Solvent handling pump shall be provided with mechanical seals to prevent leakages.
D. System of leak detection and repair of pump/pipeline based on preventive maintenance.
E. Solvent shall be taken from underground storage tanks to reactors through closed pipeline. Storage tanks shall be vented through trap receiver and condenser operated on chilled water.

ix) The hazardous waste generated from the plant shall be disposed of as per the provisions of Hazardous Waste (Management and Handling) Rules 1989. The company shall submit the copy of membership to TSDF to the Ministry's Regional Office at Bhopal.

x) The company shall obtain prior permission from the SPCB for disposal of hazardous waste to the TSDF and concurrence from the TSDF Company regarding their accepting capacity of the waste.

Evaluating unlicensed DynamicPDF feature. Click here for details. [4:0:eval]

xi) During transfer of materials, spillages shall be avoided and garland drains be constructed to avoid mixing of accidental spillages with domestic waste and storm drains.

xii) The project authorities shall develop greenbelt in 1261 m^2 of project area as per the guidelines of CPCB to mitigate the effect of fugitive emission.

xiii) Adequate financial provision shall be made in the budget of the project for implementation of the above suggested environmental safeguards. Fund so earmarked shall not be diverted for any other purposes.

xiv) Occupational health surveillance of the workers shall be done on a regular basis and records maintained as per the Factories Act.

xv) The company shall make the arrangement for protection of possible fire hazards during manufacturing process in material handling.

xvi) Usage of personnel protective equipments (PPEs) by all employees/ workers shall be ensured.

xvii) Provision shall be made for the housing of construction labour within the site with all necessary infrastructure and facilities such as fuel for cooking, mobile toilets, mobile STP, Safe drinking water, medical health care, crèche etc. The housing may be in the form of temporary structures to be removed after the completion of the project

GENERAL CONDITIONS

i. The project authorities shall strictly adhere to the stipulations of the SPCB/state government or any statutory body.

ii. No further expansion or modifications in the plant shall be carried out without prior approval of the Ministry of Environment and Forests. In case of deviations or alterations in the project proposal from those submitted to this Ministry for clearance, a fresh reference shall be made to the Ministry to assess the adequacy of conditions imposed and to add additional environmental protection measures required, if any.

iii. The project authorities shall strictly comply with the rules and regulations under Manufacture, Storage and Import of Hazardous Chemicals Rules, 1989 as amended. Authorization from the SPCB shall be obtained for collection, treatment, storage, and disposal of hazardous wastes.

Evaluating unlicensed DynamicPDF feature. Click here for details. [4:0:eval]

iv. 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 State Pollution Control Board.

v. For control of process emissions, stacks of appropriate height as per the Central Pollution Control Board guidelines shall be provided. The scrubbed water shall be sent to ETP for further treatment.

vi. The company shall undertake following Waste Minimization measures :-

- Metering 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.
- Maximizing recoveries
- Use of automated material transfer system to minimize spillage.
- Use of "Closed Feed" system into batch reactors.

vii) The project authorities must strictly comply with the rules and regulations with regard to handling and disposal of hazardous wastes in accordance with the Hazardous Wastes (Management and Handling) Rules, 2003. Authorization from the SPCB shall be obtained for collections/treatment/ storage/disposal of hazardous wastes.

viii. The overall noise levels in and around the plant area shall be kept well within the standards (85 dBA) by providing noise control measures including acoustic hoods, silencers, enclosures etc. on all sources of noise generation. The ambient noise levels shall conform to the standards prescribed under Environment (Protection) Act, 1986 Rules, 1989 viz. 75 dBA (day time) and 70 dBA (night time).

ix. A separate Environmental Management Cell equipped with full fledged laboratory facilities shall be set up to carry out the environmental management and monitoring functions.

x. The project authorities shall provide rainwater harvesting system and ground water recharge.

xi. The implementation of the project vis-à-vis environmental action plans shall be monitored by Ministry's Regional Office /SPCB / CPCB. A six monthly compliance status report shall be submitted to monitoring agencies.

xii. The project proponent shall inform the public that the project has been accorded environmental clearance by the Ministry and copies of the clearance letter are available with the SPCB and may also be seen at Website of the Ministry at http://envfor.nic.in. This shall be advertised within seven days from the date of issue of the clearance letter, at least in two local newspapers that are widely circulated in the region of which one shall be in the vernacular language of the

Evaluating unlicensed DynamicPDF feature. Click here for details. [4:0:eval]

locality concerned and a copy of the same shall be forwarded to the Ministry's Regional Office.

xiii. 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 the project.

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

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

8. Any appeal against this environmental clearance shall lie with the National Environment Appellate Authority, if preferred within a period of 30 days as prescribed under Section 11 of the National Environment Appellate Authority Act, 1997.

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

(H.S. Malviya)
Joint Director

Copy to : -

1. The Secretary, Department of Environment and Forests, Govt. of Gujarat, Secretariat Gandhinagar-382010
2. The Chairman, Central Pollution Control Board, Parivesh Bhavan, CBD-cum-Office Complex, East Arjun Nagar, New Delhi – 110032.
3. The Chairman, Gujarat State Pollution Control Board, Paryavaran Bhavan, Sector-10A, Gandhinagar-382010.
4. The Chief Conservator of Forests (Central), Ministry of Environment & Forests, Regional Office (WZ), Ravishankar Nagar, Link Road-3 , Bhopal- 462016, M.P.
5. Monitoring Cell, Ministry of Environment and Forests, Paryavaran Bhavan, CGO Complex, New Delhi-110003.
6. Guard file.
7. Record file

(H.S. Malviya)
Joint Director