

F. No.J-11011/484/2008-IA-II (I)
Government of India
Ministry of Environment, Forest and Climate Change
IA Division

Indira Paryavaran Bhawan
Jor Bagh Road, N Delhi - 3
Dated: 19th July, 2019

To,

M/s Endoc Lifecare Private Limited
Plot No. 4-7, S.No. 52 & 53,
B/h Saurashtra Paper Board Mill,
Shapar (Veraval), Taluka Kotda Sanghani,
District **Rajkot** (Gujarat)

Sub: Expansion of Bulk Drugs manufacturing unit by M/s Endoc Lifecare Private Limited at Plot No. 4-7, S.No. 52 & 53, Taluka Kotda Sanghani, District Rajkot (Gujarat) - Environmental Clearance - reg.

Sir,

This has reference to your online proposal No.IA/GJ/IND2/28061/2008 dated 13th March, 2019 for environmental clearance to the above project.

2. The Ministry of Environment, Forest and Climate Change has considered the proposal for environmental clearance to the project for expansion of bulk drugs manufacturing unit from 51 TPM to 122 TPM by M/s Endoc Lifecare Private Limited in an area of 25390.68 sqm located at Plot No.4-7, Sy.No. 52 & 53, B/h Saurashtra Paper Board Mill, Shapar (Veraval), Taluka Kotda Sanghani, District Rajkot (Gujarat).

3. The details of existing and proposed products are as under:-

S. No.	Product	Quantity (MTPM)		
		Existing	Proposed	Total
1	Ornidazole	46	54	100
2	Fluconazole	05	5	10
3	Tizanidine Hydrochloride	00	5	05
4	Fluoxetine Hydrochloride	00	5	05
5	R & D Product	00	2	02
Total		51	71	122

4. Existing land area of 5053.68 sqm is proposed to be increased by 20337 sqm and thus after expansion, total land area will be 25390.68 sqm. Greenbelt will be developed in an area of 33% i.e. 8400 sqm out of total area of the project. The estimated project cost is Rs.8.33 crore including existing investment of Rs.3.83 crore. Total capital cost earmarked towards environmental pollution control measures will be Rs.35Lakhs and the Recurring cost (O&M) will be about Rs.30 Lakhs per annum. Total employment including direct and indirect after expansion will be 70 persons.

5. There are No National Parks, Wildlife Sanctuaries, Biosphere Reserves, Tiger/Elephant Reserves, Wildlife Corridors etc within 10 km distance.



6. Total water requirement is estimated to be 87.17 cum/day, which includes fresh water requirement of 59.72 cum/day proposed to be met from bore well.

Total effluent generation will be 31.95 cum/day. Domestic effluent of 4.5 cum/day will be disposed to soak pit. Industrial effluent of 19.75 cum/day will be send to MEE. MEE condensate of 18.7 m³/day will be further treated in ETP along with effluent from washing and utilities (boiler and cooling) 8.75 m³/day. Treated effluent will be utilized in greenbelt. There shall be no discharge of treated/untreated waste water from the unit, and thus ensuring Zero Liquid Discharge.

Power requirement will be increased from 300 kVA to 700 kVA proposed to be met from Paschim Gujarat Vij Company Ltd (PGVCL). Existing unit has one DG set of 400 kVA capacity.

Existing unit has one CNG fired boiler (1 TPH). Additionally one CNG fired boiler (2 TPH) and one Agro Briquettes/Coal fired Boiler (2 TPH) will be installed along with cyclone & bag filter and stack of height of 21 m to control the particulate emissions within the statutory limit of 150 mg/Nm³.

7. The project/activity is covered under category A of item 5(f) 'Synthetic organic chemicals industry' of the Schedule to the Environment Impact Assessment Notification, 2006, and requires appraisal/approval at central level in the Ministry.

8. The terms of reference (ToR) for the project was granted on 13th October, 2015. Public hearing was conducted by the State Pollution Control Board on 22nd August, 2017.

9. The proposal was considered by the Expert Appraisal Committee (Industry-2) in its meeting held on 6-8 May, 2019 wherein the project proponent and their accredited consultant presented the EIA/EMP Report. The Committee found the EIA/EMP report to be satisfactory, complying with the ToR, and recommended the project for grant of environmental clearance.

10. Based on the proposal submitted by the project proponent and recommendations of the EAC (Industry-2), Ministry of Environment, Forest and Climate change hereby accords environmental clearance to the project for **expansion of bulk drugs manufacturing unit from 51 TPM to 122 TPM by M/s Endoc Lifecare Private Limited** located at Plot No.4-7, Sy.No. 52 & 53, Shapar (Veraval), Taluka Kotda Sanghani, District Rajkot (Gujarat), under the provisions of the EIA Notification, 2006, subject to the compliance of terms and conditions as below:-

(a) Necessary permission as mandated under the Water (Prevention and Control of Pollution) Act, 1974 and the Air (Prevention and Control of Pollution) Act, 1981, as applicable from time to time, shall be obtained from the State Pollution Control Board.

(b) As already committed by the project proponent, Zero Liquid Discharge shall be ensured and no waste/treated water shall be discharged outside the premises.

(c) Necessary authorization required under the Hazardous and Other Wastes (Management and Trans-Boundary Movement) Rules, 2016, Solid Waste Management Rules, 2016 shall be obtained and the provisions contained in the Rules shall be strictly adhered to.



- (d) National Emission Standards for Organic Chemicals Manufacturing Industry issued by the Ministry vide G.S.R.608(E) dated 21st July, 2010 and amended from time to time shall be followed. Fugitive emissions shall be controlled at 99.98% with effective chillers.
- (e) No raw material/solvent prohibited by the concerned regulatory authorities from time to time, shall be used.
- (f) To control source and the fugitive emissions, suitable pollution control devices shall be installed to meet the prescribed norms and/or the NAAQS. The gaseous emissions shall be dispersed through stack of adequate height as per CPCB/SPCB guidelines.
- (g) Solvent management shall be carried out as follows:-
- (i) Reactor shall be connected to chilled brine condenser system.
 - (ii) Reactor and solvent handling pump shall have mechanical seals to prevent leakages.
 - (iii) The condensers shall be provided with sufficient HTA and residence time so as to achieve more than 95% recovery.
 - (iv) Solvents shall be stored in a separate space specified with all safety measures.
 - (v) Proper earthing shall be provided in all the electrical equipment wherever solvent handling is done.
 - (vi) Entire plant shall be flame proof. The solvent storage tanks shall be provided with breather valve to prevent losses.
 - (vii) All the solvent storage tanks shall be connected with vent condensers with chilled brine circulation.
- (h) Total fresh water requirement shall not exceed 59.72 cum/day to be met from Bore well. Prior permission in this regard shall be obtained from the concerned regulatory authority.
- (i) Process effluent/any wastewater shall not be allowed to mix with storm water. The storm water from the premises shall be collected and discharged through a separate conveyance system.
- (j) Hazardous chemicals shall be stored in tanks, tank farms, drums, carboys etc. Flame arresters shall be provided on tank farm, and solvent transfer through pumps.
- (k) Process organic residue and spent carbon, if any, shall be sent to cement industries. ETP sludge, process inorganic & evaporation salt shall be disposed off to the TSDF.
- (l) The Company shall strictly comply with the rules and guidelines under Manufacture, Storage and Import of Hazardous Chemicals (MSIHC) Rules, 1989 as amended time to time. All transportation of Hazardous Chemicals shall be as per the Motor Vehicle Act (MVA), 1989.
- (m) Fly ash should be stored separately as per CPCB guidelines so that it may not adversely affect the air quality. Direct exposure of workers to fly ash and dust should be avoided.
- (n) The company shall undertake waste minimization measures as below:-
- (i) Metering and control of quantities of active ingredients to minimize waste.
 - (ii) Reuse of by-products from the process as raw materials or as raw material substitutes in other processes.
 - (iii) Use of automated filling to minimize spillage.
 - (iv) Use of Close Feed system into batch reactors.
 - (v) Venting equipment through vapour recovery system.

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- (vi) Use of high pressure hoses for equipment clearing to reduce wastewater generation.
- (o) The green belt of at least 5-10 m width shall be developed in nearly 33% of the total project area, mainly along the plant periphery, in downward wind direction, and along road sides etc. Selection of plant species shall be as per the CPCB guidelines in consultation with the State Forest Department.
- (p) At least 1% of the total project cost shall be allocated for Corporate Environment Responsibility (CER) and item-wise details along with time bound action plan shall be prepared and submitted to the Ministry's Regional Office.
- (q) All the commitments made regarding issues raised during the public hearing/consultation meeting shall be satisfactorily implemented.
- (r) For the DG sets, emission limits and the stack height shall be in conformity with the extant regulations and the CPCB guidelines. Acoustic enclosure shall be provided to DG set for controlling the noise pollution.
- (s) The unit shall make the arrangement for protection of possible fire hazards during manufacturing process in material handling. Fire-fighting system shall be as per the norms.
- (t) Occupational health surveillance of the workers shall be done on a regular basis and records maintained as per the Factories Act.
- (u) Continuous online (24x7) monitoring system for stack emissions shall be installed for measurement of flue gas discharge and the pollutants concentration, and the data to be transmitted to the CPCB and SPCB server. For online continuous monitoring of effluent, the unit shall install web camera with night vision capability and flow meters in the channel/drain carrying effluent within the premises.

10.1 The grant of Environmental Clearance is further subject to compliance of other generic conditions as under:-

- (i) The project authorities must strictly adhere to the stipulations made by the state Pollution Control Board (SPCB), State Government and/ or any other statutory authority.
- (ii) No further expansion or modifications in the plant shall be carried out without prior approval of the Ministry of Environment, Forest and Climate Change. 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 locations of ambient air quality monitoring stations shall be decided in consultation with the State Pollution Control Board (SPCB) and it shall be ensured that at least one stations each is installed in the upwind and downwind direction as well as where maximum ground level concentrations are anticipated.
- (iv) The National Ambient Air Quality Emission Standards issued by the Ministry vide G.S.R. No. 826(E) dated 16th November, 2009 shall be complied with.
- (v) The overall noise levels in and around the plant area shall be kept well within the standards 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).

(vi) The Company shall harvest rainwater from the roof tops of the buildings to recharge ground water, and to utilize the same for different industrial operations within the plant.

(vii) Training shall be imparted to all employees on safety and health aspects of chemicals handling. Pre-employment and routine periodical medical examinations for all employees shall be undertaken on regular basis. Training to all employees on handling of chemicals shall be imparted.

(viii) The company shall comply with all the environmental protection measures and safeguards proposed in the documents submitted to the Ministry. All the recommendations made in the EIA/EMP in respect of environmental management, risk mitigation measures and public hearing shall be implemented.

(ix) The company shall undertake all measures for improving socio-economic conditions of the surrounding area. CSR activities shall be undertaken by involving local villagers, administration and other stake holders. Also eco-developmental measures shall be undertaken for overall improvement of the environment.

(x) A separate Environmental Management Cell equipped with full-fledged laboratory facilities shall be set up to carry out the Environmental Management and Monitoring functions.

(xi) The company shall earmark sufficient funds towards capital cost and recurring cost per annum to implement the conditions stipulated by the Ministry of Environment, Forest and Climate Change as well as the State Government along with the implementation schedule for all the conditions stipulated herein. The funds so earmarked for environment management/ pollution control measures shall not be diverted for any other purpose.

(xii) A copy of the clearance letter shall be sent by the project proponent to concerned Panchayat, Zila Parishad/ Municipal Corporation, Urban local Body and the local NGO, if any, from whom suggestions/ representations, if any, were received while processing the proposal.

(xiii) The project proponent shall also submit six monthly reports on the status of compliance of the stipulated Environmental Clearance conditions including results of monitored data (both in hard copies as well as by e-mail) to the respective Regional Office of MoEF&CC, the respective Zonal office of CPCB and SPCB. A copy of Environmental Clearance and six monthly compliance status report shall be posted on the website of the company.

(xiv) The environmental statement for each financial year ending 31st March in Form-V as is mandated shall be submitted to the concerned State Pollution Control Board as prescribed under the Environment (Protection) Rules, 1986, as amended subsequently, shall also be put on the website of the company along with the status of compliance of environmental clearance conditions and shall also be sent to the respective Regional offices of MoEF&CC by e-mail.

(xv) 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/Committee and may also be seen at Website of the Ministry at <http://moef.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 locality concerned and a copy of the same shall be forwarded to the concerned Regional office of the Ministry.

11. The Ministry reserves the right to stipulate additional conditions, if found necessary at subsequent stages and the project proponent shall implement all the said conditions in a time bound manner. The Ministry may revoke or suspend the environmental clearance, if implementation of any of the above conditions is not found satisfactory.

12. 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 Water Pollution) Act, 1981, the Environment (Protection) Act, 1986, the Hazardous Waste (Management, Handling and Trans-boundary Movement) Rules, 2016 and the Public Liability Insurance Act, 1991, read with subsequent amendments therein.

S.K.
19/7/2019

(S. K. Srivastava)
Scientist E

Copy to:-

1. The Principal Secretary, Forests & Environment Department, Government of Gujarat, Sachivalaya, 8th Floor, **Gandhi Nagar** - 382 010 (Gujarat)
2. The Chief Conservator of Forests (Western Zone), Ministry of Environment & Forests, Regional Office, E-5, Arera Colony, Link Road -3, **Bhopal** - 462 016 (M P)
3. The Chairman, Central Pollution Control Board Parivesh Bhawan, CBD-cum-Office Complex, East Arjun Nagar, **Delhi** -32
4. The Member Secretary, Gujarat State Pollution Control Board, Paryavaran Bhawan, Sector 10 A, **Gandhi Nagar**-382 043 (Gujarat)
5. Monitoring Cell, MoEF&CC, Indira Paryavaran Bhawan, Jor bagh road, **New Delhi**
6. Guard File/Monitoring File/Record File

S.K.
19/7/2019

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