

Government of Maharashtra

No. EC (Lupin) -2009/153/CR.167/TC.1
Environment department
Room No. 217, 2nd floor,
Mantralaya Annexe,
Mumbai- 400 032.
Dated: 16th November, 2010

To,
M/s. Lupin Limited
Plot No. A-142,
MIDC Tarapur,
Taluka: Palghar
Dist - Thane
Maharashtra

Sub: Expansion of bulk drug unit at Plot No. A-142, MIDC Tarapur, Dist - Thane by
M/s. Lupin Limited - Environmental clearance regarding.

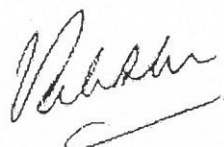
Sir,

This has reference to your communication dated nil on the above mentioned subject. The proposal was considered as per the EIA Notification - 2006, by the State Level Expert Appraisal Committee, Maharashtra in its 21st meeting and decided to recommend the project for prior environmental clearance to SEIAA. Information submitted by you has been considered by State Level Environment Impact Assessment Authority in its 26th and 30th meetings. Authority noted office memorandum of MOEF J-11013/5/2010-IA-II(I) dated 26th October, 2010 regarding lifting the moratorium on consideration of projects for environmental clearance.

2. It is noted that the proposal is for grant of Environmental Clearance for Expansion of bulk drug unit at Plot No. A-142, MIDC Tarapur, Dist - Thane by M/s. Lupin Limited. The project considered by SEAC under screening category 5 (f) of EIA Notification 2006.

Project information from submitted & considered documents is summarized as below-

Name of the Project	:	Expansion of bulk drug unit
Type of Project	:	Bulk drugs and intermediates category (SF)
Project Proponent	:	M/s. Lupin Limited
Location of the project	:	Survey No. 30/10, 30/11, 30/12, 30/13 & 64/7 Plot No. A-142, MIDC Tarapur, Taluka: Palghar, Dist - Thane
Land	:	Existing : 1, 52,500 sq. m Additional : 39,430 sq. m.
Total built-up area	:	Existing: 30,800 sq. m. Additional : 7,200 sq. m
Estimated cost of the project	:	₹ 128.75 Crores



Production capacity:

Change in Product Mix of existing consented products:

Sr. No.	Name of the product	Consented products(TPY)	Proposed products (TPY)
		360.00	404.00
1	Rifa- S, Rifa- O & Rifampicin		
	Rifampicin		264.00
	Rifa-S		115.00
	Rifa- O		25.00
2	Lovastatin	72.00	150.00
3	Rifabutin	4.08	3.00
4	Simvastatin	18.00	72.00
5	Lasnosoprazole	18.00	7.00
6	Zolpidem Tartrate	6.00	1.00
7	Venlafaxin	18.00	18.00
8	Setralin	21.60	36.00
9	Rifaximin	6.00	5.00
10	Pentaprazole	25.20	6.00
11	Pyrazinamide	240.00	225.00
12	Levitracitam	19.20	60.00
13	Carvediol & Carvediol phosphate	6.00	3.00
14	Ethambutol	60.00	10.00
15	Risperidone	1.20	0.25
16	Risperidone	6.00	4.00
17	Amlodipine Besilate	12.00	20.00
18	Azythromycin	4.20	0.00
19	Quina	1.50	0.00
20	Rami 8	12.00	0.00
21	Levomopromazine Maleate	35.00	15.00
22	Topiramate	35.00	10.00
23	Lamotrigine	2.40	5.00
	R & D batches		
	Total	983.46	1054.25

Change in Product mix - New Products:

Sr. No.	Name of the product	Proposed Capacity (TPY)
1.	Imipramin HCl	3.00
2.	Imipramin Palmoate	1.00
3.	Nabumatone	60.00
4.	Desloratidine	0.50
5.	Diacerein	3.00
6.	Fenofibrate	15.00
7.	Omeprazole mg.	15.00
8.	Sevelamer Hcl	45.00
9.	Losartan potassium	10.00
10.	Atorvastatin	15.00

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11.	Levofloxacin	30.00
12.	Memantine	1.00
13.	Lamivudine	3.00
14.	Clinadamyacin	2.00
15.	Esomeprazole	20.00
16.	Sevelmar carbonate	45.00
17.	Pregramblin	20.00
18.	Mesalamine	30.00
19.	Eszopiclone	0.50
20.	Doloxetone	8.00
21.	Ziprasidone	3.00
22.	Tioterodine	0.50
23.	Lisinopril	65.00
Total		395.50
Grand Total (Change + New)		1449.75

Water Requirement: Source: MIDC

Process: 200 m³/day;

Cooling water: 175 m³/day;

Drinking: 60 m³/day;

Green belt: 75 m³/day;

Recycled water: 510 m³/day.

Effluent generated: existing unit: 745 KLD; additional effluent: 400 m³/day.

Capacity of ETP : 1145 m³/day (To treat existing 745 m³/day and treat and recycle additional 400 m³/day). The effluent shall be treated in a full fledged in-house effluent treatment plant and shall be discharged to the CETP; In case CETP is not in a position to accept this additional effluent, a zero discharge unit consisting of reverse osmosis unit, multi effect evaporator and drier is proposed to treat the additional effluent. Thus by virtue of this zero discharge scheme 410 m³/day effluent will be recycled after treatment and used for utility replenishment. In this case the fresh water demand shall be 100 cu.m/day extra.

Fuel requirement :

Furnace oil: boiler: 5000 kg/Day; D.G. Set No. 3: 390 Kg/Hr and for D.G. Set No. 4: 390 kg/Hr

Solid Waste Management:

1. The process (mycelium) solid waste 18.1 MT/D
2. Bio Sludge 5.82 MT/D from ETP Disposal: use as rich manure for Agriculture/ Horticulture purpose

Combined Hazardous Waste Generation due to new proposal

Sr. No.	Item No. of process generating H.W. As per Schedule-I	Types of Wastes	Quantity MT/day	Disposal
1.	20.3 / 36.4	Distillation Residue	2.40	CHW-TSDF (MWML) or to Authorised party
2.	28.2 / 35.3	Spent Carbon	0.510	CHW-TSDF (MWML) or to Authorised party
3.	5.1	Used Oil	0.025	Sale to registered recycler

4.	5.2	Waste Oil	0.02	or to CHW-TSDF Sale to registered recycler or to CHW-TSDF (MWML)
5.	28.1	Process Waste	3.70	to CHW-TSDF (MWML)
6.	28.2	Spent Catalyst	0.367	to manufacturer for recycling or to CHW- TSDF (MWML) or to registered recycler
7.	28.2 / 28.3	Date Expired, discarded and off specification Products	As and when generated	Onsite recycling and reuse, onsite recycling and off site reuse/ Collection, storage, transportation, disposal to manufacturer for recycling or to CHW-TSDF (MWML)
8.	20.2 / 28.5	Spent Solvent / Spent ML	374.42	Onsite Recovery and reuse onsite or sale off site/ Offsite recovery or sale to authorized Recyclers, Dispose to CHW- TSDF(MWML).
9.	33.3	Discarded containers/ Barrels/ Bags/ Liners	As and when generated	Collection, storage, decontamination & sale or return to supplier
10.	33.1	Chemical containing residue from decontamination and disposal	As and when generated	Collection, storage, transportation, disposal to CHW-TSDF (MWML)
11.	28.1	Dried solids for dryer (dry basis)	4.0	Collection, storage, transportation, disposal to CHW-TSDF (MWML)

Air pollution control measures:

1. The fuel in all the industrial is combustible Furnace oil and HSD for the emergency power DG sets. So, in order to have minimum emissions of pollutants, advanced combustion devices have been installed in various units. Combustion air supply is being related to the requirement and the furnace temperature is also controlled.
2. The flue gases emitted from the existing stacks being monitored regularly as per the directives of Maharashtra Pollution Control Board.
3. Collection of meteorological data viz., wind speed, wind direction, temp & cloud cover to be carried out along with ambient air quality monitoring studies within the study area.
4. Ambient Air Quality monitoring within the study area for the air pollutant parameters and assessment of existing status of ambient air quality.
5. Comparison of Baseline Environment with prediction of Impacts on air environment due to the activities in various plants & utilities.
6. Evaluation of the adequacy of the proposed pollution control devices to meet gaseous emission and ambient air quality standards.

7. Vent gas caustic scrubbers provided with well-designed stacks of required height so that the gas would be discharged at a proper height to disperse the gases pollutants which are well within limits specified by MPCB.
8. Adequate stack height would be provided to boiler, DG sets, thermo pack as Air pollution Equipment.
 1. Stack height attached to boiler : 45 m with Diameter : 1.3 m
 2. Stack height attached to DG set no.3 : 48 m; Diameter : 1.0 m
 3. Stack height attached to DG set no.4 : 48 m; Diameter : 1.0 m

Green Belt Development: Green belt: 40,161 sq. m (existing) and 10,640 sq. m (additional).
Existing no. of trees: 2183 nos. and proposed no. of trees: 600 nos.

Environmental Management Plan: Capital cost: ₹ 1605 Lakhs and recurring cost will be ₹ 716 Lakhs

3. The proposal has been considered by SEIAA in its 26th and 30th meetings & decided to accord environmental clearance to the said project under the provisions of Environment Impact Assessment Notification, 2006 subject to implementation of the following terms and conditions:
 - (i) This clearance is subject to conditions stipulated in MoEF office memorandum J-11013/5/2010-IA-II(I) dated 26th October, 2010.
 - (ii) "Consent for Establishment" shall be obtained from Maharashtra Pollution Control Board under Air and Water Act and a copy shall be submitted to the Environment department before start of any construction work at the site.
 - (iii) No land development / construction work preliminary or otherwise relating to the project shall be taken up without obtaining due clearance from respective authorities.
 - (iv) No additional land shall be used / acquired for any activity of the project without obtaining proper permission.
 - (v) For controlling fugitive natural dust, regular sprinkling of water & wind shields at appropriate distances in vulnerable areas of the plant shall be ensured.
 - (vi) Regular monitoring of the air quality, including SPM & SO₂ levels both in work zone and ambient air shall be carried out in and around the power plant and records shall be maintained. The location of monitoring stations and frequency of monitoring shall be decided in consultation with Maharashtra Pollution Control Board (MPCB) & submit report accordingly to MPCB.
 - (vii) A detailed scheme for rainwater harvesting shall be prepared and implemented to recharge ground water.
 - (viii) Arrangement shall be made that waste water and storm water do not get mixed.
 - (ix) Periodic monitoring of ground water shall be undertaken and results analyzed to ascertain any change in the quality of water. Results shall be regularly submitted to the Maharashtra Pollution Control Board.
 - (x) Leq of Noise level shall be maintained as per standards. For people working in the high noise area, requisite personal protective equipment like earplugs etc. shall be provided.
 - (xi) 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.
 - (xii) Green belt shall be developed & maintained around the plant periphery. Green Belt Development shall be carried out considering CPCB guidelines including selection of plant species and in consultation with the local DFO/ Agriculture Dept.



- (xiii) Adequate safety measures shall be provided to limit the risk zone within the plant boundary, in case of an accident. Leak detection devices shall also be installed at strategic places for early detection and warning.
- (xiv) Occupational health surveillance of the workers shall be done on a regular basis and record maintained as per Factories Act.
- (xv) The company shall make the arrangement for protection of possible fire hazards during manufacturing process in material handling.
- (xvi) 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 Waste (Management and Handling) Rules, 2003 (amended). Authorization from the MPCB shall be obtained for collection/treatment/storage/disposal of hazardous wastes.
- (xvii) 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 process.
 - Maximizing Recoveries.
 - Use of automated material transfer system to minimize spillage.
 - Use of "Closed Feed" system into batch reactors.
- (xviii) Regular mock drills for the on-site emergency management plan shall be carried out. Implementation of changes / improvements required, if any, in the on-site management plan shall be ensured.
- (xix) A separate environment management cell with qualified staff shall be set up for implementation of the stipulated environmental safeguards.
- (xx) Transportation of ash will be through closed containers and all measures should be taken to prevent spilling of the ash.
- (xxi) Separate silos will be provided for collecting and storing bottom ash and fly ash.
- (xxii) Separate funds shall be allocated for implementation of environmental protection measures/EMP along with item-wise break-up. These cost shall be included as part of the project cost. The funds earmarked for the environment protection measures shall not be diverted for other purposes and year-wise expenditure should reported to the MPCB & this department
- (xxiii) The project management shall advertise at least in two local newspapers widely circulated in the region around the project, one of which shall be in the marathi language of the local concerned within seven days of issue of this letter, informing that the project has been accorded environmental clearance and copies of clearance letter are available with the Maharashtra Pollution Control Board and may also be seen at Website at <http://envis.maharashtra.gov.in>
- (xxiv) Project management should submit half yearly compliance reports in respect of the stipulated prior environment clearance terms and conditions in hard & soft copies to the MPCB & this department, on 1st June & 1st December of each calendar year.
- (xxv) A copy of the clearance letter shall be sent by proponent to the concerned Municipal Corporation and the local NGO, if any, from whom suggestions/representations, if any, were received while processing the proposal. The clearance letter shall also be put on the website of the Company by the proponent.
- (xxvi) The proponent shall upload the status of compliance of the stipulated EC conditions, including results of monitored data on their website and shall update the same periodically. It shall simultaneously be sent to the Regional Office of MoEF, the respective Zonal Office of CPCB and the SPCB. The criteria pollutant levels namely; SPM, RSPM, SO₂, NO_x (ambient levels as well as stack emissions) or critical sectoral parameters, indicated for the project shall be monitored and displayed at a convenient location near the main gate of the company in the public domain.

(xxvii) The project proponent shall also submit six monthly reports on the status of compliance of the stipulated EC conditions including results of monitored data (both in hard copies as well as by e-mail) to the respective Regional Office of MoEF, the respective Zonal Office of CPCB and the SPCB.

(xxviii) The environmental statement for each financial year ending 31st March in Form-V as is mandated to be submitted by the project proponent 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 EC conditions and shall also be sent to the respective Regional Offices of MoEF by e-mail.

(xxix) The environmental clearance is being issued without prejudice to the court case pending in the court of law and it does not mean that project proponent has not violated any environmental laws in the past and whatever decision of the Hon'ble court will be binding on the project proponent. Hence this clearance does not give immunity to the project proponent in the case filed against him.

4. The Environment department reserves the right to revoke the clearance if conditions stipulated are not implemented to the satisfaction of the department or for that matter, for any other administrative reason.
5. **Validity of Environment Clearance:** The environmental clearance accorded shall be valid for a period of 5 years to start of production operations by the power plant.
6. In case of any deviation or alteration in the project proposed from those submitted to this department for clearance, a fresh reference should be made to the department to assess the adequacy of the condition(s) imposed and to incorporate additional environmental protection measures required, if any.
4. The above stipulations would be enforced among others under the Water (Prevention and Control of Pollution) Act, 1974, the Air (Prevention and Control of Pollution) Act, 1981, the Environment (Protection) Act, 1986 and rules there under, Hazardous Wastes (Management and Handling) Rules, 1989 and its amendments, the public Liability Insurance Act, 1991 and its amendments.
5. Any appeal against this environmental clearance shall lie with the National Environmental Appellate Authority, if preferred, within 30 days as prescribed under Section 11 of the National Environmental Appellate Act, 1997.



(Valsa R Nair Singh)
Secretary, Environment
department & MS, SEIAA

Copy to:

1. Shri. Ashok Basak, IAS (Retd.), Chairman, SEIAA, 502, Charleville, 'A' Road, Churchgate, Mumbai- 400 020, Maharashtra.
2. Shri. P.M.A Hakeem, IAS (Retd.), Chairman, SEAC, 'Jugnu' Kottaram Road, Calicut- 673 006 Kerala.

3. The Secretary, Energy department, Govt. of Maharashtra, Mantralaya, Mumbai - 400032., Maharashtra
4. Member Secretary, Maharashtra Pollution Control Board, with request to display a copy of the clearance.
5. The CCF, Regional Office, Ministry of Environment and Forest (Regional Office, Western Region, Kendriya Paryavaran Bhavan, Link Road No- 3, E-5, Ravi-Shankar Nagar, Bhopal- 462 016). (MP).
6. Regional Office, MPCB, Thane.
7. Collector, Thane.
8. IA- Division, Monitoring Cell, MoEF, Paryavaran Bhavan, CGO Complex, Lodhi Road, New Delhi-110003.
9. Director(TC-1), Dy. Secretary(TC-2), Scientist-1, Environment department
10. Select file (TC-3).

Government of Maharashtra

EC (Lupin) -2009/153/CR.167/TC.1
Environment department,
Room No. 217, 2nd floor,
Mantralaya Annex,
Mumbai 400 032
Date: 4th January, 2011.

To,
M/s. Lupin Limited,
Plot No. T-142, MIDC Tarapur,
Tal—Palghar, Dist – Thane

Subject: Expansion of bulk drug unit at MIDC Tarapur, Dist – Thane by M/s. Lupin Limited - Environmental clearance regarding.

Reference- Even number environment clearance letter dated 16th November, 2010.

Sir,

This has reference to your communication letter on the above mentioned subject

2. Project information from documents submitted by you & considered by SEAC & SEIAA was summarized in even number environment clearance letter dated 16th November, 2010.

Information on following points is modified as-

Point No. 1: Plot No. T-142

Point No. 2: Total Water requirement :2270 m³/day;
Existing: 1760 m³/day; Proposed: 510 m³/day; Source: MIDC

Point No. 3: Fuel used:

Fuel use MT/Month	Existing	Proposed	Total
HSD	12	145	157
Furnace oil	1388	37	1351
Agro waste	-	1903	1903

Point No. 4: Air pollution control measures:

a) Atmospheric emission:

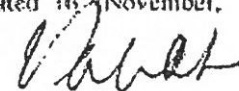
SO ₂ emission due to existing operations	4095 kg/day
Total SO ₂ emission due to existing and proposed operations	4088 kg/day
Increase of SO ₂ emission over existing levels after proposed expansion	Negative(-7) kg/day

b) Stack Height:

Plant section & units	Stack No.	Height from ground level (m)
2 x 10 TPH	1 & 2	Two combined stacks 45.00 & 57.00
1 x 12 TPH existing boilers		
2 x 2.5 MW power generator (run by FO)	3 & 4	48.0 Each
2 x 2.5 MW power generator emergency power only (run by HSD)	5 & 6	30.0 Each
4 x 1.2 MW emergency power generator	7 to 10	6.9 each above roof
3 x 1.6 MW emergency power generator	10 to 13	8.0 each above roof
Stand by/ additional agro waste	14	30.0

c) Scrubbers (12 nos.) of adequate capacity should be provided to limit process emissions as per the standards specified by MPCB

3. Project information of all other points is as per minutes of SEIAA. Terms and conditions stipulated in even number environment clearance letter dated 16th November, 2010, remains the same.


(Vatsa R Nair Singh)
Secretary, Environment
department & MS, SEIAA

Copy to:

1. Shri. Ashok Basak, IAS (Retd.), Chairman, SEIAA, 502, Charleville, 'A' Road, Church gate, Mumbai- 400 020, Maharashtra.
2. Shri. P.M.A Hakeem, IAS (Retd.), Chairman, SEAC, 'Jugnu' Kottaram Road, Calicut- 673 006 Kerala.
3. Additional Secretary, MOEF, 'Paryavaran Bhawan' CGO Complex, Lodhi Road, New Delhi - 110519
4. Member Secretary, Maharashtra Pollution Control Board, with request to display a copy of the clearance.
5. The CCF, Regional Office, Ministry of Environment and Forest (Regional Office, Western Region, Kendriya Paryavaran Bhavan, Link Road No. 3, E-5, Ravi-Shankar Nagar, Bhopal- 462 016), (MP).
6. Regional Office, MPCB, Thane.
7. Collector, Thane.
8. IA- Division, Monitoring Cell, MoEF, Paryavaran Bhavan, CGO Complex, Lodhi Road, New Delhi-110003.
9. Director(TC-1), Dy Secretary(TC-2), Scientist-1, Environment department
10. Select file (TC-3).