



# State Level Environment Impact Assessment Authority-Karnataka

(Constituted by MoEF, Government of India, under section 3(3) of E(P) Act, 1986)

No. SEIAA 1 IND 2016

Date: 28-04-2017

To,

M/s. Shreegen Pharma Limited  
Plot No. 135-F, KIADB Kolhar industrial Area,  
Nazampur hobli, Bidar Taluk & District

Sir,

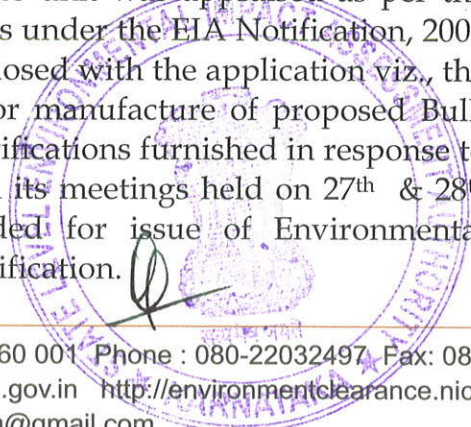
Sub: Expansion & Modification of manufacturing of Bulk drugs & Intermediates unit at Plot No. 135-F, KIADB Kolhar industrial Area, Nazampur hobli, Bidar Taluk & District of M/s. Shreegen Pharma Limited - Issue of Environmental Clearance - Reg.

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This has reference to your online application dated 20<sup>th</sup> January 2016 bearing proposal No. SIA/KA/IND2/9394/2016 addressed to SEIAA, Karnataka and subsequent letters addressed to SEIAA/SEAC Karnataka furnishing further information/seeking prior Environmental Clearance for the above project under the EIA Notification, 2006.

2. It is inter-alia noted that Environmental Clearance has been issued by MoEF, Govt. of India to this project vide letter No. J-11011/379/2005-IA II (I) dated 7<sup>th</sup> December 2005 under EIA Notification, 1994 for manufacturing Bulk Drugs such as Nifedipine of 36 MTPA, Ethambutol Hcl of 60 MTPA, Citalopram HBr of 12 MTPA, Sildenafil citrate of 24 MTPA and Gatifloxacin of 18 MTPA.

3. Your application for the Environmental Clearance to the proposed manufacturing of Bulk drugs & Intermediates unit was appraised as per the prescribed procedure in light of the provisions under the EIA Notification, 2006 on the basis of the mandatory documents enclosed with the application viz., the Form 1, Pre feasibility report, EIA Report for manufacture of proposed Bulk drugs & Intermediates and the additional clarifications furnished in response to the observations of the SEAC, Karnataka, in its meetings held on 27<sup>th</sup> & 28<sup>th</sup> February 2017 and SEAC has recommended for issue of Environmental Clearance for the proposed Expansion & Modification.



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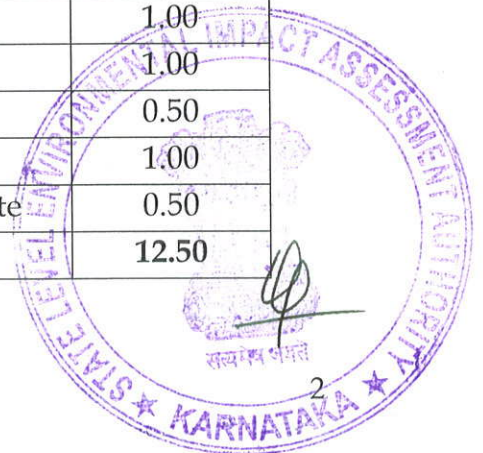
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by M/s. Shreegen Pharma Limited

The proposal is for manufacturing the following Bulk drug and Intermediate

<b>Group-1</b>		
Sl. No	Name of the product	TPM
1.	Capecitabine	0.30
2.	Lamivudine	9.00
3.	Levetiracetam	1.00
4.	Pazopanib HCl	0.10
5.	Ribavirin	2.00
	<b>Total</b>	<b>12.50</b>
<b>Group-2</b>		
Sl. No	Name of the product	TPM
1.	Amlodipine Besilate	1.00
2.	Atorvastatin Calcium	2.0
3.	Esomeprazole Magnesium dihydrate	1.00
4.	Ezetimibe	1.00
5.	Losartan Potassium	1.50
6.	Ondansetron	0.50
7.	Pantoprazole Sodium	1.00
8.	Pregabalin	1.00
9.	Rabeprazole Sodium	1.00
10.	Rosuvastatin Calcium	1.00
11.	Telmisartan	1.00
	<b>Total</b>	<b>12.50</b>
<b>Group-3</b>		
Sl.No	Name of the product	TPM
1.	Chloramphenicol	2.00
2.	Citalopram HBr	1.00
3.	ClopedogrelBisulphate	1.50
4.	Dapoxetine HCl	0.50
5.	Donepezil HCl	1.00
6.	Etodolac	2.50
7.	Fluconazole	1.00
8.	KeterolacTromethamine	1.00
9.	Montelukast Sodium	0.50
10.	Sildenafil Citrate	1.00
11.	SitagliptinPhosphate.Mono Hydrate	0.50
	<b>Total</b>	<b>12.50</b>



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Group-4		
Sl.No	Name of the product	TPM
1.	Zidovudine	12.50

4. It is, inter-alia, noted that M/s. Shreegen Pharma Limited have proposed for manufacture of Bulk drugs & Intermediates. The total plot area is 7,480.31Sqm, out of which built up area is 2,553.55 Sqm, 2,000 Sqm area is for roads, 2,618.10 Sqm area is for green belt and 308.66 Sqm is unused area. Total water consumption is 44 KLD will be met from KIADB supply, out of which 6 KLD for domestic purpose, 11.2 KLD for process, 0.5 KLD for washing, 6 KLD for boiler make ups, 4.5 KLD for cooling tower make up and 15.8 KLD for green belt. Power requirement is 250 KVA sourced from GESCOM. DG set of 1 No X 380 KVA will be installed for emergency power back-up. It is proposed to install 1 No X 2 TPH & 1 No X 0.5 TPH capacity of Coal Fired Boiler and Coal fired hot oil unit of 100000 Kcal. The total cost of the project is Rs.20 Crores.

5. The wastewater generation will be 14.7 KLD, out of which 4.8 KLD will be the domestic sewage, 9.9 KLD will be the industrial effluent. The industrial effluent shall be treated in MEE of capacity 25 KLD and domestic sewage shall be treated in the proposed STP. The Hazardous waste generated are Inorganic salt of 748 Kg/day & spent carbon of 30Kg/day shall be sent to TSDF, organic waste of 139 Kg/day shall be sent to cement industry, Polythene bags of 70/day, used fiber drums of 10 no/day & used oil of 0.05 lts/day shall be sent to KSPCB Authorized agency for reprocessing/recycling and coal ash of 2 Tons/day shall be sold to brick manufactures.

6. The project proposal has been considered by SEAC during the meeting held on 22<sup>nd</sup> & 23<sup>rd</sup> February 2016 and ToR was issued on 22<sup>nd</sup> April 2016 for conducting Environment Impact Assessment (EIA) Study. The project is located within the notified industrial area and hence exempted from public consultation process. The EIA has been conducted and report submitted by Sri. Mahadevaswamy P S/o Sri Pashupathi, No.66/15, 1<sup>st</sup> Floor, 1<sup>st</sup> Cross, 1<sup>st</sup> Main, Ganganagar, R T Nagar Post, Bengaluru- 560 032, Applicability of the Notification No. S. O 648 (E) dated 3<sup>rd</sup> March 2016 issued by the MoEF, GoI, regarding mandatory accreditation of Environmental consultants from NABET/QCI stands deferred in this case in view of the interim order granted by High Court of Karnataka in W. P. No. 15026-15038/2016 (GM-RES): (Sri. Mahadevaswamy Vs. Union of India represented by MoEF &CC, GoI & Dept Ecology & Environment, GoK) dated 21.03.2016. The proponent has submitted the EIA report on 6<sup>th</sup> December 2016.

7. Based on the information submitted by you, presentation made by you and your consultant Sri. Mahadevaswamy P S/o. Sri Pashupathi, No.66/15, 1<sup>st</sup> Floor, 1<sup>st</sup> Cross, 1<sup>st</sup> Main, Ganganagar R T Nagar Post, Bengaluru- 560 032. The State Level Expert Appraisal Committee (SEAC) examined the proposal in the



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meeting held on 18<sup>th</sup> & 19<sup>th</sup> January 2017 and 27<sup>th</sup> & 28<sup>th</sup> February 2017 and has recommended for issue of Environmental Clearance.

8. The SEIAA Karnataka has considered the project in its meeting held on 26<sup>th</sup> & 27<sup>th</sup> April 2017 and after due consideration of the relevant documents submitted by the project proponent and additional clarifications furnished in response to its observations and the appraisal and recommendation of the SEAC and decided to accord Environmental Clearance in accordance with the provisions of Environmental Impact Assessment Notification-2006 and its subsequent amendments, subject to strict compliance of the following terms and conditions: -

## Part A- SPECIFIC CONDITIONS

1. National Emission Standards for Organic Chemicals Manufacturing Industry issued by the Ministry vide G.S.R. 608(E) dated 21st July, 2010 and amended time to time shall be followed by the unit.
2. The total effluent generation shall not exceed 14.7 KLD. The industrial effluent shall be treated in MEE of capacity 25 KLD and domestic sewage shall be treated in the proposed STP.
3. Effluent Treatment Plant shall ensure to prevent ground water contamination due to leakage from unlined tanks.
4. Total water requirement from KIADB water supply shall not exceed 44 KLD and prior permission shall be obtained from the concerned Authority. No ground water shall be used.
5. The process emissions from the boiler shall be dispersed through stack of adequate height as per CPCB/KSPCB standards. The gaseous emissions from the DG set shall be dispersed through stack height as per CPCB standards shall be provided. Acoustic enclosure shall be provided to the DG sets to mitigate the noise pollution.
6. Ambient air quality data shall be collected as per NAAQS standards notified by the Ministry vide G.S.R. No. 826(E) dated 16<sup>th</sup> September, 2009. The levels of PM<sub>10</sub>, PM<sub>2.5</sub>, SO<sub>2</sub>, NO<sub>x</sub>, CO, VOC and HCl shall be monitored in the ambient air and emissions from the stacks and displayed at a convenient location near the main gate of the company and at important public places. The company shall upload the results of monitored data on its website and shall update the same periodically. It shall simultaneously be sent to the Regional office of MoEF - Bangalore, SEIAA - Karnataka, the respective zonal office of CPCB and the KSPCB.
7. The company shall upload the status of compliance of the stipulated environmental clearance conditions, including results of monitored data on its website and shall update the same periodically. It shall simultaneously be sent to the Regional office of MoEF - Bangalore, SEIAA - Karnataka, the respective zonal office of CPCB and the KSPCB. The levels of PM<sub>10</sub>, PM<sub>2.5</sub>, SO<sub>2</sub>, NO<sub>x</sub>, CO and VOC (ambient levels) and emissions from the stacks shall be monitored and displayed at a

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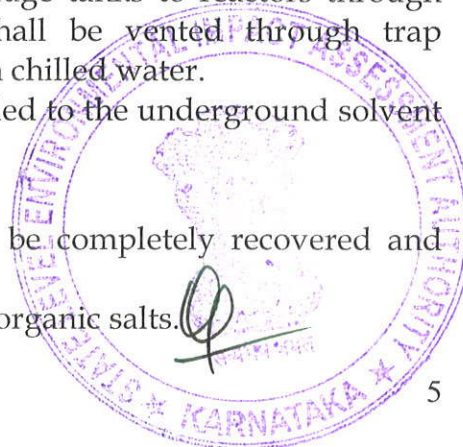
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convenient location near the main gate of the company and at important public places.

8. The Company shall obtain Authorization for collection, storage and disposal of hazardous waste under the Hazardous and other Wastes (Management and Transboundary Movement) Rules, 2016 for management of hazardous wastes and prior permission from KSPCB shall be obtained for disposal of solid / hazardous waste to the TSDF. The concerned company shall undertake measures for firefighting facilities in case of emergency.
9. In plant control measures for checking fugitive emissions from all the vulnerable sources shall be provided. Fugitive emissions shall be controlled by providing closed storage, closed handling & conveyance of chemicals/materials, multi cyclone separator and water sprinkling system. Dust suppression system including water sprinkling system shall be provided at loading and unloading areas to control dust emissions. Fugitive emissions in the work zone environment, product, raw materials storage area etc. shall be regularly monitored. The emissions shall conform to the limits stipulated by the KSPCB.
10. Hazardous chemicals shall be stored in tanks in tank farms, drums, carboys etc. Flame arresters shall be provided on tank farm. Solvent transfer shall be by pumps.
11. The company shall undertake following Waste Minimization measures :-
  - a. Metering and control of quantities of active ingredients to minimize waste.
  - b. Reuse of by-products from the process as raw materials or as raw material substitutes in other processes.
  - c. Use of automated filling to minimize spillage.
  - d. Use of Close Feed system into batch reactors.
  - e. Venting equipment through vapour recovery system.
  - f. Use of high pressure hoses for equipment clearing to reduce wastewater generation.
12. For control of fugitive emission following steps shall be followed:
  - a. Closed handling system shall be provided for chemicals.
  - b. Reflux condenser shall provide over reactor.
  - c. System of leak detection and repair of pump/pipeline based on preventive maintenance.
  - d. The acids shall be taken from storage tanks to reactors through closed pipeline. Storage tanks shall be vented through trap receiver and condenser operated on chilled water.
  - e. Cathodic protection shall be provided to the underground solvent storage tanks.
13. Solvent management shall be as follows:
  - a. Solvent used in the process shall be completely recovered and reused.
  - b. Efforts are to be made to recover inorganic salts.



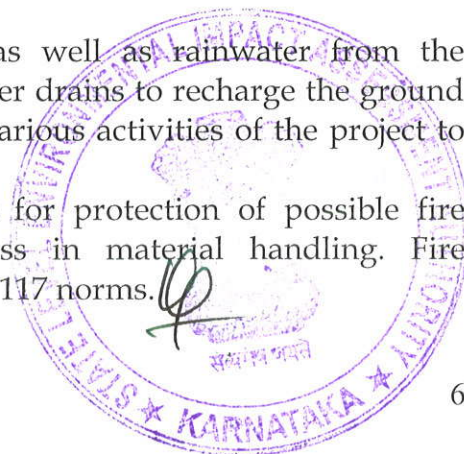
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- c. Reactor shall be connected to chilled brine condenser system.
  - d. Reactor and solvent handling pump shall have mechanical seals to prevent leakages.
  - e. The condensers shall be provided with sufficient HTA and residence time so as to achieve more than 95% recovery
  - f. Solvents shall be stored in a separate space specified with all safety measures.
  - g. Proper earthing shall be provided in all the electrical equipment wherever solvent handling is done.
  - h. Entire plant shall be flame proof. The solvent storage tanks shall be provided with breather valve to prevent losses.
  - i. Fugitive emissions in the work zone environment, product, raw materials storage area etc. shall be regularly monitored. The emissions shall conform to the limits imposed by KSPCB.
14. No effluent shall be discharged outside the factory premises and "Zero" discharge concept shall be adopted.
  15. Multi-cyclone followed by bag filter shall be provided to the boilers to control particulate emissions within 100 mg/Nm<sup>3</sup>. The gaseous emissions shall be dispersed through stack of adequate height as per CPCB/KSPCB guidelines.
  16. Two stage chilled water/caustic scrubber shall be provided to process vents to control HCl. Two stage scrubbers with caustic lye media solution shall be provided to process vents to control SO<sub>2</sub>. The scrubbing media shall be sent to effluent treatment plant (ETP) for treatment. Efficiency of scrubber shall be monitored regularly and maintained properly. At no time, the emission levels shall go beyond the prescribed standards.
  17. As proposed Inorganic salt & spent carbon o shall be sent to TSDF, organic waste shall be sent to cement industry, Polythene bags of, used fiber drums & used oil shall be sent to KSPCB Authorized agency for reprocessing/recycling and coal ash shall be sold to brick manufactures..
  18. Boiler ash shall be stored separately as per CPCB guidelines so that it shall not adversely affect the air quality, becoming air borne by wind or water regime during rainy season by flowing along with the storm water. Direct exposure of workers to fly ash & dust shall be avoided.
  19. 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.
  20. The Company shall harvest surface as well as rainwater from the rooftops of the buildings and storm water drains to recharge the ground water and use the same water for the various activities of the project to conserve fresh water.
  21. 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 OISD 117 norms.



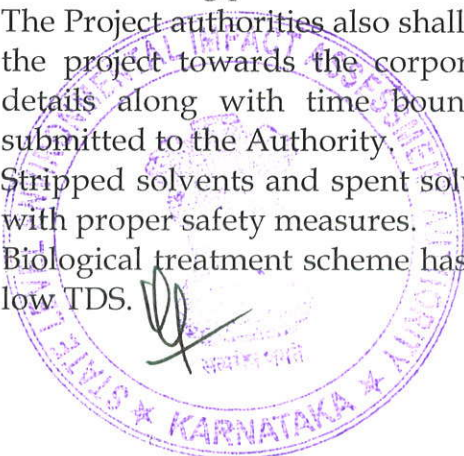
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22. Training shall be imparted to all employees on safety and health aspects of chemicals handling. Pre-employment and routine periodical medical examinations for all employees shall be undertaken on regular basis. Training to all employees on handling of chemicals shall be imparted.
23. Usage of PPEs by all employees/ workers shall be ensured.
24. Occupational health surveillance of the workers shall be done on a regular basis and records maintained as per the Factories Act.
25. Green belt shall be developed in at least 33% of area with suitable species of the plants as per the CPCB guidelines to mitigate the effects of fugitive emissions. Selection of plant species shall be as per the CPCB guidelines.
26. The adequate financial provisions 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.
27. The company shall comply with the recommendations made in the EIA/EMP/Risk assessment report. Risk assessment shall be included in the safety Manual.
28. Provision shall be made for the housing for the construction labour within the site with all necessary infrastructure and facilities such as fuel for cooking, mobile toilets, mobile sewage treatment plant, safe drinking water, medical health care, crèche etc. The housing may be in the form of temporary structure to be removed after the completion of the project. All the construction wastes shall be managed so that there is no impact on the surrounding environment.
29. The coal to be stored in coal stockyard on impervious layer in a covered shed and along the boundary garland canal to be provided leading to a exit pond/tank to arrest coal dust run-off and to allow settling of coal fines. The coal fines to be removed periodically.
30. Avoids bromination processes (wherever followed)
31. Recovers Lithium salts from the effluents wherever Lithium compounds are used in the reactions.
32. Treatment of recalcitrant's to be documented and kept at all times.
33. Adopts Good Management Practices (GMP) & Green Chemistry.
34. Storage facilities for the fuel shall be made in the plant area in consultation with Department of Explosives, Nagpur. Disaster Management Plan shall be prepared to meet any eventuality in case of an accident taking place due to storage of Fuel.
35. The Project authorities also shall earmark at least 2.5 % of the total cost of the project towards the corporate social responsibility and item-wise details along with time bound action plan shall be prepared and submitted to the Authority.
36. Stripped solvents and spent solvents are to be utilized in house scientifically with proper safety measures.
37. Biological treatment scheme has to be provided to treat the MEE condensate, low TDS.



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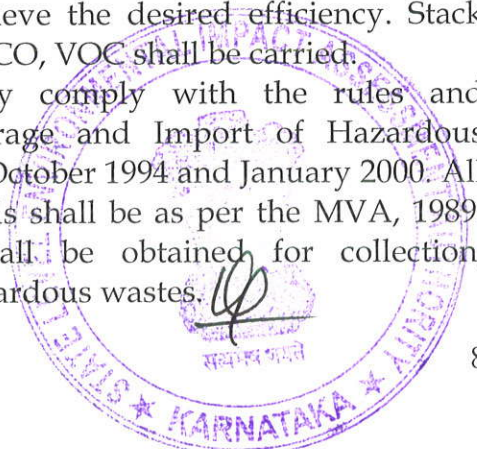
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38. The proponent shall share the cost of mitigative measures that would be undertaken by the Karnataka State Pollution Control Board to rectify the environmental damage caused on pro-rata basis in lieu of the direction of the Government of Karnataka issued under section 18 (i) (b) of the Water (Prevention and Control of Pollution) Act, 1974 to get an assessment of the extent of environmental damage caused by the industries operating in the Kolhar Industrial Area and to undertake relevant remedial measures at the cost of industries in Kolhar Industrial Area.
39. The project proponent shall abide by the Outcome of the report of the Hon'ble House Committee with regard to the complaint regarding the pollution of Kolhar Industrial Area.
40. The project proponent shall extend all cooperation for the establishment of CETP by the KIADB in the Kolhar Industrial area.
41. The industry shall not operate without a functional effluent treatment plant as per the order of the Hon'ble Supreme Court dated February 22, 2017 in W.P. No. 375 of 2012.

## **B. GENERAL CONDITIONS:**

1. The project authorities shall strictly adhere to the stipulations made by the Karnataka State Pollution Control Board (KSPCB).
2. At no time, the emissions shall exceed the prescribed limits. In the event of failure of any pollution control system 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.
3. No further expansion or modifications in the plant shall be carried out without prior approval of the SEIAA/Ministry of Environment and Forests as the case may be. In case of deviations or alterations in the project proposal from those submitted to this Authority for clearance, a fresh reference shall be made to the Authority to assess the adequacy of conditions imposed and to add additional environmental protection measures required, if any.
4. The gaseous emissions (PM<sub>10</sub>, PM<sub>2.5</sub>, SO<sub>2</sub>, NO<sub>x</sub>, CO, VOC) and Particulate Matter along with RSPM levels 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. Stack monitoring for PM<sub>10</sub>, PM<sub>2.5</sub>, SO<sub>2</sub>, NO<sub>x</sub>, CO, VOC shall be carried.
5. The project authorities shall strictly comply with the rules and regulations under Manufacture, Storage and Import of Hazardous Chemicals Rules, 1989 as amended in October 1994 and January 2000. All transportation of Hazardous Chemicals shall be as per the MVA, 1989. Authorization from the KSPCB shall be obtained for collection, treatment, storage, and disposal of hazardous wastes.





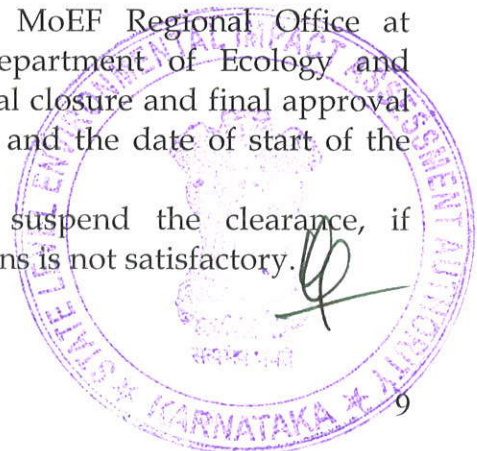
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6. The project authorities must strictly comply with the rules and regulations with regard to handling and disposal of hazardous wastes in accordance with the Hazardous and other Wastes (Management and Transboundary Movement) Rules, 2016. Authorization from the KSPCB must be obtained for collection/treatment/ storage/disposal of hazardous wastes.
7. Application of solar energy should be incorporated for illumination of common areas, lighting for gardens and street lighting in addition to provision for solar water heating. A hybrid system or fully solar system for lighting and heating should be provided. Details in this regard should be submitted to the SEIAA.
8. 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, Rules, 1989 viz. DBA (day time) and 70 dBA (night time).
9. The project proponent shall also comply with all the environmental protection measures and safeguards as per the information provided.
10. The implementation of the project vis-à-vis environmental action plans shall be monitored by MoEF, Regional Office at Bangalore / KSPCB/ CPCB and the Regional Director (Environment), Department of Environment and Ecology, Government of Karnataka, Kalaburgi, the Department of Environment & Ecology, Bangalore. A six monthly compliance status report shall be submitted to monitoring agencies.
11. The project proponent shall inform the public that the project has been accorded environmental clearance by the SEIAA and copies of the clearance letter are available with the KSPCB and may also be seen at Website of the Authority at <http://www.seiaa.karnataka.gov.in>, <http://environmentclearance.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 MoEF Regional Office at Bangalore / KSPCB/ CPCB and the Regional Director (Environment), Department of Environment and Ecology, Government of Karnataka, Kalaburgi.
12. The project authorities shall inform the MoEF Regional Office at Bangalore / KSPCB/ CPCB and the Department of Ecology and Environment, Bangalore, the date of financial closure and final approval of the project by the concerned authorities and the date of start of the project.
13. The SEIAA, Karnataka may revoke or suspend the clearance, if implementation of any of the above conditions is not satisfactory.



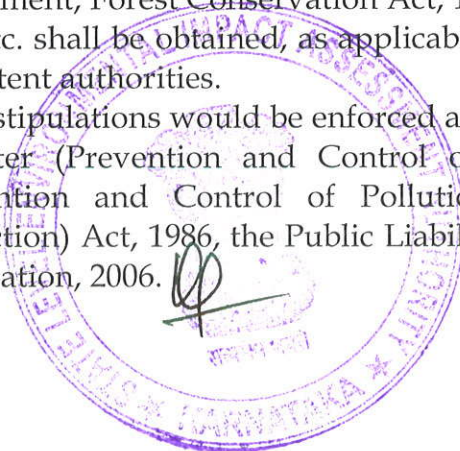
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14. The SEIAA, Karnataka reserves the right to stipulate additional conditions, if found necessary. The company in a time bound manner will implement these conditions.
15. The above conditions will be enforced, inter-alia under the provisions of the Water (Prevention & Control of Pollution) Act, 1981, the Environment (Protection) Act, 1986 Hazardous and other Wastes (Management and Transboundary Movement) Rules, 2016 and the Public Liability Insurance Act, 1991 along with their amendments and rules.
16. The issue of Environment Clearance doesn't confer any right to the project proponent to operate / run the project without obtaining statutory clearances / sanctions from all other concerned Authorities.
17. Concealing factual data or submission of false/fabricated data and failure to comply with any of the conditions mentioned above may result in withdrawal of this clearance and attract action under the provisions of Environmental (Protection) Act, 1986.
18. Any appeal against this environmental clearance shall lie with the National Green Tribunal, if preferred, within a period of 30 days as prescribed under Section 16 of the National Green Tribunal Act, 2010.
19. Officials from the Department of Environment and Ecology, Bangalore/ Regional Office of MoEF, Bangalore who would be monitoring the implementation of Environmental safeguards should be given full cooperation, facilities and documents/ data by the project proponents during their inspection. A complete set of all the documents submitted to MoEF / SEIAA should be forwarded to the APCCF, Regional Office of MoEF, Bangalore/ the Regional Director (Environment), Department of Environment and Ecology, Government of Karnataka, Kalaburgi/ Regional Officer, KSPCB.
20. In the case of any change(s) in the scope of the project, the project would require a fresh appraisal by this Authority.
21. The Authority reserves the right to add additional safeguard measures subsequently, if found necessary, and to take action including revoking of the environment clearance under the provisions of the Environment (Protection) Act, 1986, to ensure effective implementation of the suggested safeguard measures in a time bound and satisfactory manner.
22. All other statutory clearances such as the approvals for storage of diesel from Chief Controller of Explosives, Fire Department, Civil Aviation Department, Forest Conservation Act, 1980 and Wildlife (Protection) Act, 1972 etc. shall be obtained, as applicable by project proponents from the competent authorities.
23. These stipulations would be enforced among others under the provisions of water (Prevention and Control of Pollution) Act, 1974, the Air (Prevention and Control of Pollution) act 1981, the Environment (Protection) Act, 1986, the Public Liability (Insurance) Act, 1991 and EIA Notification, 2006.



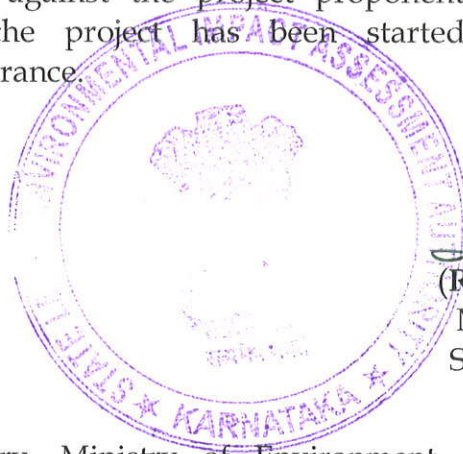
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24. Under the provisions of Environment (Protection) Act, 1986, legal action shall be initiated against the project proponent if it is found that construction of the project has been started without obtaining environmental clearance.



Yours faithfully,

  
(RAMACHANDRA) 28/4/17  
Member Secretary,  
SEIAA - Karnataka.

Copy to:

- 1) The Secretary, Ministry of Environment, Forests and Climate Change, Indira Paryavaran Bhavan, Jor Bagh Road, Aliganj, New Delhi- 110 003.
- 2) The Member Secretary, Karnataka State Pollution Control Board, Bangalore.
- 3) The APCCF, Regional Office, Ministry of Environment & Forests (SZ), Kendriya Sadan, IV Floor, E & F wings, 17<sup>th</sup> Main Road, Koramangala II Block, Bangalore - 560 034.
- 4) Regional Director (Environment), Ecology and Environment Department, Government of Karnataka, Timmapuri Chowk, Vallabhai Patel Circle, Temple Road Near Court, Kalaburgi.
- 5) Guard File.

