



THIRU A.V. VENKATACHALAM, I.F.S
MEMBER SECRETARY

STATE LEVEL ENVIRONMENT
IMPACT ASSESSMENT AUTHORITY -
TAMIL NADU

3rd Floor, Panagal Maaligai,
No.1 Jeenis Road, Saidapet,
Chennai-15.
Phone No.044-24359973
Fax No. 044-24359975

ENVIRONMENTAL CLEARANCE (EC)

Letter No. SEIAA/TN/F. 6493/5(f)/EC -58/2018 dt:16.02.2018

To

The Managing Director,
M/s. Anjan Drug Pvt. Ltd.,
5th Floor, Nelson Towers II Wing ,
11 7, Nelson Manickam Road, Aminjikai,
Chennai - 600 029

Sir,

Sub: SEIAA -TN –Environmental Clearance-Proposed Expansion of Production of Bulk Drug Unit at plot no. 85 to 88, 105 to 109, 112 to 116, SIPCOT Export Promotion, Industrial Park (EPIP), Gummidipoondi, Tiruvallur District, TamilNadu, - Category - "B1" and Schedule :5(f) Synthetic Organic Chemical Industry (Dyes and Dye Intermediate) by M/s.Anjan Drug Pvt. Ltd-Issued - Regarding.

- Ref: 1. Your application to MoEF&CC dated: 22.06.2017.
2. Submission of EIA report and other documents to SEIAA dated:

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23.01.2018

2. Minutes of the 102nd SEAC Meeting held on 01.02.2018 & 02.02.2018
3. Letter No. SEIAA/TN/F.No.6493/2017 dt. 02.02.2018.
5. Letter No. SEIAA/TN/F.No. 6493/2018 dt-05.02.2018.
6. Minutes of 271st SEIAA Meeting held on 13.02.2018.
7. Minutes of 273rd SEIAA Meeting held on 15.02.2018.
8. Minutes of 274th SEIAA Meeting held on 16.02.2018.

This has reference to your application dated 23.01.2018 and subsequent communication on the above mentioned subject by M/s. Anjan Drug Private Limited for Expansion of Production Bulk Drug Unit in Form-1, Prefeasibility Report to MoEF&CC for obtaining Environmental Clearance for the Proposed expansion of production capacity from 205 TPM to 380 TPM with new infrastructure of the existing bulk drug unit in plot no. 85 to 88, 105 to 109, 112 to 116, SIPCOT Export Promotion, Industrial Park (EPIP), Gummidipoondi, Tiruvallur District, TamilNadu under Item No. 5(f)– 'Synthetic Organic chemicals Industry (dyes & dyes intermediate; bulk drugs and intermediates excluding drug formulation; Synthetic rubbers; basic Organic Chemicals, other synthetic organic chemicals and chemical intermediates (located in a notified industrial area/estate) & Category 'B1' of the Schedule to the EIA Notification, 2006.



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Based on the application made in Form-1, Prefeasibility report, Proposed ToR, Annexure, furnished by the proponent and MoEF&CC issued General Vide ToR No.IA-J-11011/157/2017-IA-II(I) dated, 17th August 2017 and EIA report was prepared and submitted the Final EIA report to MoEF&CC on 29.12.2017, subsequently, MoEF&CC has raised the EDS for "The project/activity is covered under category B of item 5(f) of the schedule to the EIA Notification, 2006, which is the jurisdiction of the SEAC/SEIAA. Based on that, the EIA report was resubmitted to SEIAA on 23.01.2018. The proposal (EIA report) was placed in 102nd meeting of the SEAC held on 01.02.2018 & 02.02.2018. The SEAC have requested the proponent to furnish the additional clarifications. Accordingly, the proponent has submitted the additional clarification to SEAC. Based on the recommendations of the SEAC, the SEAC decided to recommend the proposal for the grant of Environmental Clearance to SEIAA – TN subject to condition.

The subject was placed before 271st SEIAA Meeting held on 13.02.2018. The Authority called for certain additional details and the proponent has submitted the additional particulars/proposals to the SEIAA on 15.02.2018 and SEIAA after careful consideration decided to issue Environment Clearance in its 274th meeting held on



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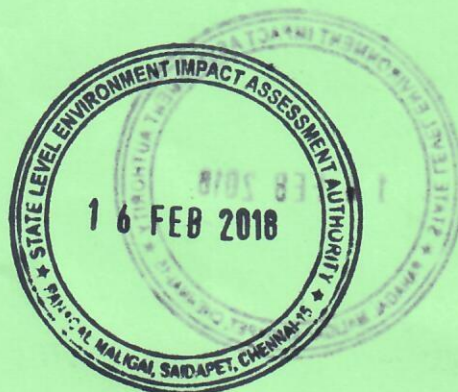
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State Level Environmental Impact Assessment Authority, TN

2018

16.02.2018 vide item no. 274-05 subject to terms and conditions stipulated under the provisions of Environment Impact Assessment Notification, 2006 as amended based on the Information submitted by you which are extracted below:

| | | |
|----|--|--|
| 1 | (i) Name of the Project: (ii) Date of Application: | i) Proposed Expansion of Production of Bulk Drug Unit at Plot no. 85 to 88, 105 to 109, 112 to 116, SIPCOT Export Promotion Industrial Park (EPIP), Gummidipoondi, Tiruvallur District By M/S. Anjan Drug Pvt Ltd. ii) EIA report- 23.01.2018 |
| 2. | Name of Sector: Schedule No(in the EIA Notification,2006) | Schedule S.No. 5(f) of Category "B1" – ' Synthetic Organic chemicals Industry (dyes & dyes intermediate; bulk drugs and intermediates excluding drug formulation; Synthetic rubbers; basic Organic Chemicals, other synthetic organic chemicals and chemical intermediates (located in a notified industrial area/estate). |
| 3. | New Project/ Expansion | Expansion |
| 4 | Name of the Applicant/Project Proponent | M/s. Anjan Drug Private Ltd |
| 5. | Name of the Consultancy Company | M/s. Cholamandalam MS Risk Services |



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|--------|---|---|--------------------------------|---|---------------------------------------|
| 6(i) | Project Location & Coordinates | Plot no. 85 to 88, 105 to 109, 112 to 116, SIPCOT Export Promotion, Industrial Park (EPIP), Gummidipoondi, and Tiruvallur District | | | |
| 6(ii) | Whether any GO attracted | No. | | | |
| 7. | Area of the Site(Sq.ft) | 522720 Sq.ft (12 acres) | | | |
| 8. | Land use Classification as per Record | Industrial area - SIPCOT Industrial Estate. | | | |
| 9. | TOR given by SEAC? (If yes then specify the meeting) | No. ToR has been obtained from MoEF&CC File no.IA-J-11011/157/2017-IA-II(I), dated 17th Aug 2017 | | | |
| 10(i) | Project Cost | Rs. 32 Crores | | | |
| 10(ii) | EMP Cost(O&M) | Rs. 7 Crores | | | |
| 11. | Distance from Protected areas/Critically Polluted areas/Eco-Sensitive areas/Inter-State Boundaries. | <ul style="list-style-type: none">Eco sensitive Zone of Pulicat wildlife and bird sanctuary at located at 9.2 Km from the existing project site andAndhra Pradesh, Tamil Nadu Interstate Boundary at 7.12 Km from the existing project site. | | | |
| 12. | Production Details | Products manufactured | Existing production TPM | Additional Quantities (proposed) | Production after expansion TPM |



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| | | | | |
|--|-------------------------------------|------------|------------|------------|
| | n-Propyl Bromide* | 100 | - | 100 |
| | Di-Ethyl Di-Propyl Malonate (DEDPM) | 100 | - | 100 |
| | Gabapentin | 5 | 45 | 50 |
| | Valproic Acid | - | 100 | 100 |
| | Di-Propyl Malonate Acid (DPMA)** | - | 100** | 100** |
| | Pregabalin | - | 20 | 20 |
| | Ito Pride HCl | - | 10 | 10 |
| | Total Capacity | 205 | 175 | 380 |

*n-propyl Bromide is not manufactured till date due to market conditions although EC is obtained in 2008.

**Based on the market demand the DPMA will be sold separately after completion of stage-2 process of valproic acid. There will not be any increase in overall production quantity

By-Products:-

| S No. | Products manufactured | Existing production | Production after expansion |
|-------|-----------------------|---------------------|----------------------------|
| | | | |



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|-----|---|---|-------------------------------|-----------------------|-----|
| | | | | TPM | TPM |
| | | 1 | Sodium Bromide | 92 | 234 |
| | | 2 | Sodium Formate | - | 40 |
| | | 3 | Sodium Chloride | 4 | 140 |
| | | 4 | Ethanol | - | 65 |
| 13. | Manufacturing Process | Reactor, reflux, Cooling, Distillation, Neutralization, Decarboxylation, Purification | | | |
| 14. | No. of Employees | 150 Nos | | | |
| 15. | Total Water Requirement - 200 KLD (after expansion) | S. No | Activity | Quantity (KLD) | |
| | | 1. | Process & Washing Requirement | 60 | |
| | | 2. | Boiler feed | 15 | |
| | | 3. | Cooling make up | 90 | |
| | | 4. | Domestic | 20 | |
| | | 5. | Greenbelt | 15 | |
| | | 6. | Total | 200 | |
| | Source | SIPCOT | | | |
| 16. | Plant Machinery | Reactor, Distillation Column. | | | |



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|-----|--|--|---------------------------|--|
| 17. | Sewage generation and treatment | Sewage Generation – 15 KLD, Disposed to STP. | | |
| 18. | ETP Details | ETP Capacity 140 KLD. Source of Generation: Total Effluent generation – 90 KLD. 76 KLD of recycled water will be reused. 400 TPA of recovered salt from MEE will be sent to TSDF. | | |
| 19. | Solid waste Management (after Enhancement) | Name of process | Post Project (TPA) | Activities for which Authorization is issued |
| | | Production/ formulation of drugs/pharmaceuticals & health care product (Schedule I) | 160 | Disposal to M/s Tamil Nadu Waste Management Limited, Gummidipoondi |
| | | Purification and treatment of exhaust water and wastewater from the processes in this schedule and CETPs (Schedule I) | 400 | Disposal to M/s Tamil Nadu Waste Management Limited, Gummidipoondi |
| | | Flue Gas cleaning residue (Boiler Ash waste) | 5 | Disposal to M/s Tamil Nadu Waste Management |



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| | | | | Limited, Gummidipoondi | |
| | | Used oil | 5 | Disposed to authorized recycler | |
| | | Food waste | 1000 Kg/month | Piggery yard | |
| | | Plastic waste | 500 kg/month | Sold to the authorized dealers | |
| 20. | Stack emission Details: (All the stacks attached to process units, Boilers, captive power plant, D.G. Sets, (kg/hr) | S. No | Source of Emission | Control Measures | Height |
| | | 1 | Furnace oil (Fired Boiler)(3T x 3nos , 6T x 1no) | Stack | 30 |
| | | 2 | DG Sets- (2 x 320 KVA, 1x325 KVA, 1 x 500KVA) | Stack | 5 |
| 21. | Details of Fuel to be used: | Boiler / DG set | Fuel consumption | Fuel type | |
| | | Furnace oil (Fired Boiler) | 350 KI/Month | HSD | |
| | | DG Sets | 30-40 lit/hr | HSD | |
| 22. | Power Requirement | | | | |



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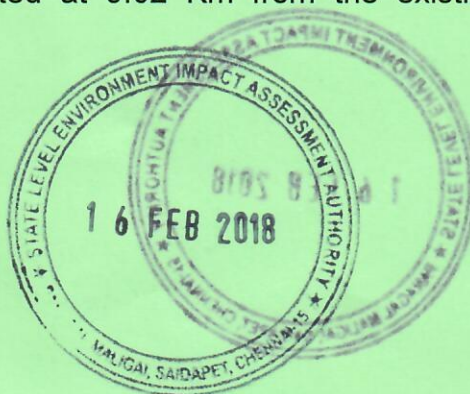



| | | | |
|-----|------------------------|---|---------------------------------------|
| | | TNEB | 1000 kVA |
| | | DG set(Back-up)- | D.G Set of 2x320, 1x325 and 1x500 KVA |
| 23. | Documents Enclosed | EIA Report With related documents in Annexure. | |
| 24. | Storm Water Management | Collected through existing storm water drains and excess storm water will be connected to the SIPCOT main storm water drain | |
| 25. | Rain Water Harvesting | 200 cu.m of storage sump | |
| 26. | Green Belt Development | 4 acres | |
| 27. | CSR details | 80 Lakhs | |

❖ Content of the Affidavit submitted by the Project Proponent:

We hereby declare the following undertaking to the Authority:

1. There is no critically polluted area as listed by CPCB from time to time, within 10 KM radius of the site.
2. As per the Topo Sheet, Eco sensitive zone of Pulicat Wildlife and Bird Sanctuary located at 9.02 Km from the existing project site and Andhra




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Pradesh, Tamil Nadu interstate boundary at 7.12 Km from the existing project site. There is no eco sensitive zone, wildlife protected area, interstate boundary within 5 Km radius of the site.

3. No forest land is involved.

Validity:

The SEIAA hereby accords Environmental Clearance to the above project under the provisions of EIA Notification dated 14th September, 2006 as amended, with validity for Seven years from the date of issue of EC, subject to the compliance of the terms and conditions stipulated below:

(A) Specific Conditions

- (i) It is mandatory for the project proponent to furnish to the SEIAA, Half yearly compliance report in hard and soft copies on 1st June and 1st December of each calendar year in respect of the conditions stipulated in the prior Environmental clearance issued.

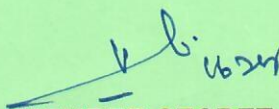


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- (ii) "Consent for Establishment" shall be obtained from Tamil Nadu Pollution Control Board and a copy of the same shall be furnished to the SEIAA, Tamil Nadu before start of project construction activity at the site.
- (iii) The implementation of Environmental Management Plan in regard to treatment and disposal of sewage & Effluent, Solid waste Management, Hazardous - Waste Management, and CSR Activities should be carried out, as proposed and committed. Regular monitoring should be carried out during operation phases.
- (iv) The residue collected from the evaporator shall be documented by maintaining proper register and it should be made available at the time of inspection.
- (v) Adequate dust extraction system such as Ducting with dust extracting arrangement wherever required shall be established to achieve Occupational – health standards and ambient air quality standards.
- (vi) The proponent shall carryout best housekeeping practices as spillage management for handling and maintenance of raw materials and products inside the unit premises.
- (vii) Nature of chemicals Handled, the Do and Don'ts shall be displayed at all vital locations as laided down in MSDS.




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- (viii) The proponent shall ensure that the quantity of Hazardous Waste handed over to the TSDF shall match with the quantity generated.
- (ix) The proponent shall provide a separate closed area earmarked for storing solid waste including Hazardous Waste as proposed.
- (x) The proponent shall dispose Hazardous Waste generated as per the Hazardous and Other Wastes (Management and Transboundary Movement) Rules, 2016. Spent oil from D.G sets should be stored in HDPE drums in an isolated covered facility and disposed off through TNPCB registered recyclers.
- (xi) The Plastic wastes shall be segregated and disposed as per the provisions of Plastic Waste (Management & Handling) Rules 2016.
- (xii) The e - waste generated should be collected and disposed to a nearby authorized e-waste centre as per e waste (Management & Handling), Rules 2016.
- (xiii) The Municipal solid waste generated shall be collected, segregated and disposed as per Solid Waste Management Rules, 2016.



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- (xiv) The industry shall conduct air sampling at least once in six months for the general core parameters (PM₁₀, PM_{2.5}, SO_x, NO_x) through TNPCB/NABL Accredited Laboratory and maintain records of the same and it should be made available at the time of inspection.
- (xv) Regular monitoring on the air quality, water quality and noise on the selected locations in and around the project site as mentioned in the EMP report for creating base line data shall be continued and records shall be maintained.
- (xvi) A separate environment and safety management cell with qualified staff shall be set up before establishment of the facility and shall be retained throughout the lifetime of the industry, for implementation of the stipulated environmental safeguards.
- (xvii) The land area of 3 acres of green belt area already developed within the project area shall be properly maintained.
- (xviii) The industry shall promote tree plantation to neutralize their carbon foot print. The industry shall engage regularly in afforestation programme.



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- (xix) The proponent shall ensure effective risk management strategy regarding confined space management to avoid risk while handling raw materials, products in the process area and storage.
- (xx) Risk cum disaster management plan should be in place at the time of commissioning.
- (xxi) Water conservation scheme including rain water harvesting measures to augment ground water resources shall be implemented so as to collect and reuse the entire rainwater harvested as a supplement to fresh water drawl.
- (xxii) The natural drainage pattern in the project area shall be maintained and storm water drain along the boundary and appropriate places shall be provided considering the Catchment area and maximum intensity of rainfall to collect runoff water/rain water for proper disposal to avoid flooding around the premises.
- (xxiii) The Environmental Clearance is issued without prejudice to any order that may be passed by the Hon'ble NGT/ Honb'le High Court of Madras.
- (xxiv) The salt recovered from the Effluent treatment system shall not be disposed into the secured landfill, in order to prevent ground water pollution problems, being a highly soluble substance.



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- (xxv) The Project Proponent has to provide rain water harvesting collection tank to the capacity of 300 cu.m in order to recover and reuse the rain water during normal rains.
- (xxvi) The project proponent shall earmark adequate funds to develop R&D for the recovery and reuse of salt and/or finding alternative technology.
- (xxvii) As assured, proper health assessment for staff working against pollutants and follow up shall be ensured by periodic health checks.
- (xxviii) All safety standards shall be strictly adopted at site.
- (xxix) No exposures or no toxic emissions shall be released to the atmosphere at any point of time.
- (xxx) Disaster management plan should be in place to meet contingency.
- (xxxi) Extra care shall be taken in order to avoid any seepages into soil, ground , etc.,

(B) GENERAL CONDITIONS:-

- i. This Environmental Clearance shall not be cited to relax any other rules applicable to this project.
- ii. The Project Proponent should advertise at least in two local newspapers widely circulated, one of which shall be in the vernacular language of the locality




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concerned, within 7 days of the issue of the Environmental Clearance informing that the project has been accorded environmental clearance and a copy of the clearance letter is available with TNPCCB and also at the Website of the SEIAA, TN at <http://www.seiaa.tn.gov.in>.

- iii. A copy of the Environmental Clearance shall be sent by the project proponent to concerned local body and local NGO, if any from whom suggestions/representatives, if any were received while processing the proposal.
- iv. The Environmental Clearance shall also be put on the website of the company.
- v. No expansion or modernization in the project shall be carried out without prior approval of the SEIAA-TN. In case of any deviations or alterations in the project proposal from those submitted to this Authority for clearance, a fresh reference shall be made to the SEIAA-TN to assess the adequacy of conditions imposed and to add additional environmental protection measures required, if any.
- vi. All the environmental protection measures and safeguards as recommended in the EIA report shall be complied with.
- vii. The implementation of the project vis-à-vis environmental action plans shall be monitored by the Regional office of MoEF& CC at Chennai, TNPCCB and CPCB.

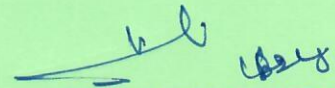


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- A six monthly compliance status report shall be submitted to monitoring agencies regularly.
- viii. Data on ambient air, stack and fugitive emissions shall be regularly submitted online to the Regional office of MoEF&CC,GOI, at Chennai, TNPCB and Central Pollution Control Board as well as hard copy once in six months and display data on RSPM, SO₂ and NO_x outside the premises at the appropriate place for the general public.
- ix. Occupational health surveillance of the workers shall be done on a regular basis and records maintained as per the Factories Act.
- x. Proper house-keeping and cleanliness must be maintained within and outside the plant.
- xi. Occupational health surveillance programme shall be undertaken as regular exercise for all the employees, especially for those engaged in handling hazardous substances. The first aid facilities in the occupational health centre shall be strengthened and the medical records of each employee should be maintained separately.
- xii. The overall noise levels in and around the plant area shall be kept well within the standards prescribed for by providing noise control measures including acoustic

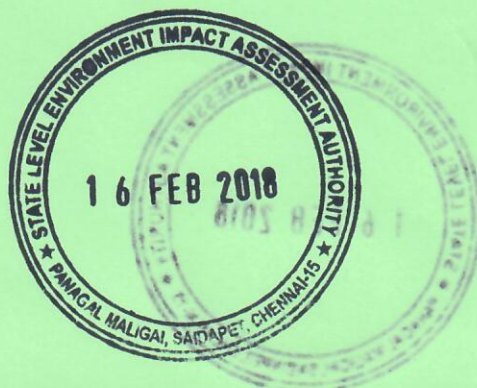




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- hoods, silencers, enclosures etc. on all sources of noise generation. The ambient noise levels should conform to the standards prescribed under EPA Rules, 1989 viz. 75dBA (day time) and 70dBA (night time).
- xiii. CSR activity shall be implemented as committed by drawing a scheme for social upliftment in the surrounding villages with reference to contribution in establishment of health infrastructure, Educational infrastructure, sports infrastructure facilities to schools etc., around the project site. Funds earmarked for CSR activity shall be used for that purpose only and separate account shall be maintained and report on implementation shall be furnished regularly.
- xiv. The requisite amount earmarked towards capital cost and recurring cost/annum for implementing pollution control measures shall be used judiciously to implement the Environment Management Plan as furnished in the EIA report. The funds so provided shall not be diverted for any other purposes.
- xv. The project proponent shall upload the status of compliance of the stipulated environmental clearance 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 the MOEF&CC,GOI at Chennai, the respective Zonal Office of CPCB and the SPCB. The criteria pollutant levels namely; RSPM, SO₂,

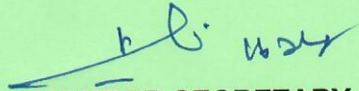



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- NOx (ambient levels as well as stack emissions) or critical sector parameters, indicated for the projects shall be monitored and displayed at a convenient location near the main gate of the company in the public domain.
- xvi. The environmental statement 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 environmental conditions and shall also be sent to the respective Regional Offices of the MoEF&CC by e-mail.
- xvii. The Environmental Clearance is valid for 7 years from the date of issue.
- xviii. Environmental Clearance is being issued without prejudice to the action initiated under Environment (Protection) Act, 1986 or any court case pending or any other court order shall prevail.
- xix. The SEIAA, TN may alter/modify the above conditions or stipulate any further condition in the interest of environment protection.
- xx. The SEIAA/SEAC or any Competent Authority may suitably add any further condition(s) on receiving reports from the project authority. The above condition shall be monitored by the Regional Office of MoEF&CC located at Chennai.



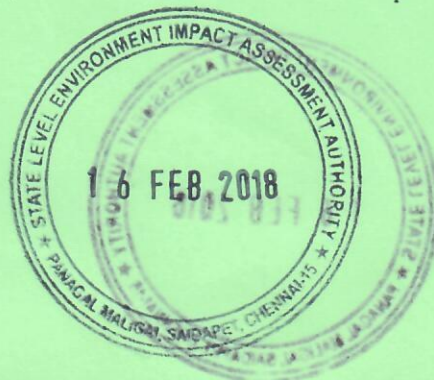

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- xxi. The SEIAA, TN may revoke or suspend the Environmental clearance, if implementation of any of the above conditions is not satisfactory.
- xxii. The SEIAA, TN may cancel the environmental clearance granted to this project under the provisions of EIA Notification, 2006, if, at any stage of the validity of this environmental clearance, if it is found or if it comes to the knowledge of this SEIAA, TN that the project proponent has deliberately concealed and/or submitted false or misleading information or inadequate data for obtaining the environmental clearance.
- xxiii. Failure to comply with any of the conditions mentioned above may result in withdrawal of this clearance and attract action under the provisions of the Environment (Protection) Act, 1986.
- xxiv. The SEIAA-TN reserves the right to stipulate additional conditions if found necessary. The industry in a time bound manner shall implement these conditions.
- xxv. 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, the Public Liability Insurance Act, 1991, along with their amendments ,draft Minor Mineral




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Conservation & Development Rules , 2010 framed under MMDR Act 1957, National Commission for protection of Child Right Rules ,2006 and rules made there under and also any other orders passed by the Hon'ble Supreme Court of India/Hon'ble High Court of Madras and any other Courts of Law relating to the subject matter.

- xxvi. Any appeal against this environmental clearance shall lie with the Hon'ble National Green Tribunal, if preferred, within a period of 30 days as prescribed under Section 16 of the National Green Tribunal Act, 2010.

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SEIAATN

Copy to:-

1. The Principal Secretary to Government,
Environment & Forests Department,
Govt. of Tamil Nadu, Fort St. George,
Chennai – 600 009.
2. The Chairman,
Central Pollution Control Board, Parivesh Bhavan,
CBD Cum-Office Complex, East Arjun Nagar,
New Delhi 110032.
3. The Member Secretary,
Tamil Nadu Pollution Control Board,



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76, Mount Salai, Guindy,
Chennai - 600 032.

4. The ACCF(C), Regional Office of MoEF,
34, hepc Building, 1 & 2 nd Floors,
Cathedral Garden Road, Nungampakkam,
Chennai - 600 034.
5. Monitoring Cell, I A Division,
Ministry of Environment & Forests,
ParyavaranBhavan, CGO Complex,
New Delhi 110003.
6. The District Collector, Thiruvallur District.
7. Stock File.

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