

F. No. J-11011/241/2012- IA II (I)  
Government of India  
Ministry of Environment, Forest & Climate Change  
(I.A. Division)

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Telefax: 011-24695313  
Dated 10<sup>th</sup> December, 2015

To,

Shri Arun Malhotra, Director  
M/s Otsuka Chemicals (India) Pvt. Ltd.  
416, JMD Pacific Square, Sec-15, part-2  
NH-8, Gurgaon Haryana – 122001

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**Subject:** Expansion of Bulk Drug Manufacturing Unit at Village KeshwanaRajpoot, Tehsil Kotputli, District Jaipur, Rajasthan by M/s Otsuka Chemicals (India) Pvt. Ltd.– Environmental Clearance reg.

**Ref. :** Your letter no. nil dated 29<sup>th</sup> August, 2014.

Sir,

This has reference to your letter dated 29<sup>th</sup> August, 2014 alongwith project documents including Form I, Terms of References, Pre-feasibility Report, EIA/EEMP Report alongwith Public Hearing Report regarding above mentioned project and subsequent submission of additional information vide letter dated 8<sup>th</sup> April, 2015 and 6<sup>th</sup> July, 2015.

2.0 The Ministry of Environment, Forest and Climate Change has examined the application. It is noted that proposal is for Expansion of Bulk Drug Manufacturing Unit at Village Keshwana Rajpoot, Tehsil Kotputli, District Jaipur, Rajasthan. Existing plot area is 88000 m<sup>2</sup> and proposed expansion will be carried out in the existing premises. It is reported that there are no eco-sensitive areas or forest or wildlife sanctuaries within the 10 Km distance. Cost of project is Rs.100 Crore (25 Crore for GCLE + 75 Crore for lohexol). Expansion will be done in following two phases.

Item	Detail	
	Existing	Proposed
Production Capacity	GCLE - 200 MTPA Cefditoren – 30 MTPA	<i>Phase 1 (by the year 2017):</i> GCLE (4-Parametho benyle-3- chlormethyl-7-phenyl acetameto-3-cephem-4-carboxilate)- from 200 to 450 MTPA; Production increase from existing 200 MTPA to 450 MTPA through (R&D based) yield improvement, reducing losses etc. <i>Phase 2 (by the year 2019):</i> GCLE – from 350 to 700 MTPA; Production increased from 450 MTPA to 700 MTPA through installation of new equipment like reactors, centrifuges, dryers, distillation system and also reducing batch time cycle etc. lohexol - 250 MTPA

3.0 Bag filter will be provided to the coal/pet coke fired boiler to control particulate emissions within permissible limit. To control the SO<sub>2</sub> emission, limestone powder shall be feed alongwith pet coke in furnace bed as a sulfur capturing agent. Scrubber will be provided to process vents to control process emissions viz. HCl. Fresh water requirement from ground water source will be increased from 280 m<sup>3</sup>/day to 800 m<sup>3</sup>/day after expansion. Industrial effluent generation will be

increased from 66 m<sup>3</sup>/day to 128 m<sup>3</sup>/day after expansion. Trade effluent should be segregated into High COD/TDS and Low COD/TDS effluent streams. High TDS/COD should be passed through steam stripper followed by MEE and ATFD (agitated thin film drier). Low TDS effluent stream should be treated in ETP and then passed through RO system. Condensate and recover water will be recycled/ reused within factory premises. Clear mother liquor of stripper containing dissolved residual solids and high boiling organic solvents will be sent to incinerator. 'Zero' effluent discharge should be adopted and no effluent will be discharged outside the premises. ETP sludge and MEE salt will be sent to TSD. Spent oil will be sent to the authorized recycler/re-processors. DG set (1x 1500 KVA) will be installed.

4.0 Public hearing as per Section 7 (i), III Stage (3), Para (i) (b) of EIA Notification 2006 as project is located in the notified industrial area.

5.0 All the synthetic organic chemicals industry (Bulk Drugs Manufacturing Unit) located inside the notified industrial area are listed at S.N. 5(f) under Category 'B'. However, due to applicability of general condition i.e. interstate boundary within 5 km (i.e. 4 Km Rajasthan-Haryana), project is treated as Category 'A' project and appraised at the Central level.

6.0 The proposal was considered by the Expert Appraisal Committee (Industry-2) in its 3<sup>rd</sup>, 34<sup>th</sup>, 40<sup>th</sup> and 46<sup>th</sup> meetings held during 3<sup>rd</sup> - 5<sup>th</sup> December, 2012, 17<sup>th</sup> -19<sup>th</sup> February, 2015, 18<sup>th</sup> -19<sup>th</sup> May, 2015 and 20<sup>th</sup> - 21<sup>st</sup> August, 2015 respectively. Project Proponent and the EIA Consultant namely (M/s Asian Consulting Engineers Pvt. Ltd.) have presented EIA / EMP report as per the TOR. EAC has found the EIA Study / EMP Report to be adequate and in full consonance with the presented TORs. The Committee recommended the proposal for environmental clearance.

7.0 Based on the information submitted by the project proponent, the Ministry of Environment and Forests hereby accords environmental clearance to above project under the provisions of EIA Notification dated 14<sup>th</sup> September 2006, subject to the compliance of the following Specific and General Conditions:

#### A. SPECIFIC CONDITIONS

- i) National Emission Standards for Organic Chemicals Manufacturing Industry issued by the Ministry vide G.S.R. 608(E) dated 21<sup>st</sup> July, 2010 and amended time to time shall be followed by the unit.
- ii) State Pollution Control Board shall grant consent to operate after ensuring that Company has started sending their evaporated salts to TSD instead of mixing into fly ash and disposing through open landfill.
- iii) Bag filter shall be provided to the coal/pet coke fired boiler to control particulate emissions within permissible limit. The gaseous emissions shall be dispersed through stack of adequate height as per CPCB/SPCB guidelines. To control the SO<sub>2</sub> emission, limestone powder shall be feed alongwith pet coke in furnace bed as a sulphur capturing agent.
- iv) Scrubber should be provided to process vents to control process emissions viz. HCl. The scrubbing media should be sent to effluent treatment plant (ETP) for treatment. Efficiency of scrubber should be monitored regularly and maintained properly. At no time, the emission levels should go beyond the prescribed standards.
- v) Ambient air quality data shall be collected as per NAAEQS standards notified by the Ministry vide G.S.R. No. 826(E) dated 16<sup>th</sup> September, 2009. The levels of PM2.5, PM10, SO<sub>2</sub>, NO<sub>x</sub>, VOC, CO 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, the respective Zonal office of CPCB and the Rajasthan State Pollution Control Board (RSPCB).

- vi) 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. Odour management plan shall be implemented. The emissions shall conform to the limits stipulated by the RSPCB.
- vii) For further control of fugitive emissions, following steps shall be followed :
1. Closed handling system shall be provided for chemicals.
  2. Reflux condenser shall be provided over reactor.
  3. System of leak detection and repair of pump/pipeline based on preventive maintenance.
  4. 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.
  5. Cathodic protection shall be provided to the underground solvent storage tanks.
- viii) The gaseous emissions from DG-set shall be dispersed through adequate stack height as per CPCB standards. Acoustic enclosure shall be provided to the DG sets to mitigate the noise pollution.
- ix) 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.
- x) Total fresh water requirement from ground water source shall not exceed 800 m<sup>3</sup>/day and prior permission shall be obtained from the CGWA/SGWA.
- xi) Trade effluent should be segregated into High COD/TDS and Low COD/TDS effluent streams. High TDS/COD should be passed through steam stripper followed by MEE and ATFD (agitated thin film drier). Low TDS effluent stream should be treated in ETP and then passed through RO system. Condensate and recover water will be recycled/ reused within factory premises. Clear mother liquor of stripper containing dissolved residual solids and high boiling organic solvents will be sent to incinerator.
- xii) 'Zero' effluent discharge should be adopted and no effluent will be discharged outside the premises.
- xiii) Automatic /online monitoring system (24x7 monitoring devices) for flow measurement and relevant pollutants in the treatment system in waste water and air quality monitoring to be installed. The data to be made available to the respective SPCB and in the Company's website.

- xiv) Hazardous chemicals shall be stored in tanks, tank farms, drums, carboys etc. Flame arresters shall be provided on tank farm. Solvent transfer shall be by pumps.
- xv) As proposed, process organic residue and spent carbon shall be sent to cement industries. ETP sludge, process inorganic & evaporation salt shall be disposed off to the TSDF. The ash from boiler shall be sold to brick manufacturers/cement industry.
- xvi) The company shall obtain Authorization for collection, storage and disposal of hazardous waste under the Hazardous Waste (Management, Handling and Trans-Boundary Movement) Rules, 2008 and amended as on date for management of Hazardous wastes and prior permission from RSPCB shall be obtained for disposal of solid / hazardous waste in the TSDF. Measures shall be taken for fire fighting facilities in case of emergency.
- xvii) 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.
- xviii) 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.
- xix) Occupational health surveillance of the workers shall be done on a regular basis and records maintained as per the Factories Act.
- xx) Fly 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.
- xxi) Sufficient funds (2.5 % of project cost) shall be earmarked towards the Enterprise Social Commitment (ESC) based on local needs specially arrangement for supplying potable water to the fluoride affected nearby villages and action plan with financial and physical breakup/details shall be prepared and submitted to the Ministry's Regional Office at Lucknow. Implementation of such program shall be ensured accordingly in a time bound manner.
- xxii) As proposed, green belt over 29040 m<sup>2</sup> area shall be developed within plant premises with at least 10 meter wide green belt on all sides along the periphery of the project area, in downward direction, and along road sides etc. Selection of plant species shall be as per the CPCB guidelines in consultation with the DFO.
- xxiii) 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, 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.

**B. GENERAL CONDITIONS:**

- i. The project authorities shall strictly adhere to the stipulations made by the State Government and Rajasthan State Pollution Control Board (RSPCB).
- ii. No further expansion or modifications in the plant shall be carried out without prior approval of the Ministry of Environment and Forests. In case of deviations or alterations in the project proposal from those submitted to this Ministry for clearance, a fresh reference shall be made to the Ministry to assess the adequacy of conditions imposed and to add additional environmental protection measures required, if any.
- iii. The locations of ambient air quality monitoring stations shall be decided in consultation with the RSPCB and it shall be ensured that at least one station is installed in the

upwind and downwind direction as well as, where maximum ground level concentrations are anticipated.

- iv. 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).
- v. The Company shall harvest rainwater from the roof-tops of the buildings and storm water drains to recharge the ground water and use the same water for the process activities of the project to conserve fresh water.
- vi. During transfer of materials, spillages shall be avoided and gullies drains be constructed to avoid mixing of accidental spillages with domestic wastewater and storm water drains.
- vii. Usage of Personnel Protection Equipments by all employees/ workers shall be ensured.
- viii. 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.
- ix. The company shall also comply with all the environmental protection measures and safeguards proposed in the project report submitted to the Ministry. All the recommendations made in the EIA/EMP in respect of environmental management, risk mitigation measures and public hearing relating to the project shall be implemented.
- x. The company shall undertake CSR activities and all relevant measures for improving the socio-economic conditions of the surrounding area.
- xi. The company shall undertake eco-developmental measures including community welfare measures in the project area for the overall improvement of the environment.
- xii. A separate Environmental Management Cell equipped with full fledged laboratory facilities shall be set up to carry out the Environmental Management and Monitoring functions.
- xiii. The company shall earmark sufficient funds for 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.
- xiv. 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 who suggestions/ representations, if any, were received while processing the proposal.
- xv. 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 the Rajasthan State Pollution Control Board. A copy of Environmental Clearance and six monthly compliance status report shall be posted on the website of the company.

- xvi. The environmental statement for each financial year ending 31<sup>st</sup> March in Form-V as is mandated shall be submitted to the Rajasthan 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 Lucknow Regional Offices of MoEF&CC by e-mail.
- xvii. 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 www.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.
- xviii. The project authorities shall inform the Regional Office as well as the Ministry, the date of financial closure and final approval of the project by the concerned authorities and the date of start of the project.

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

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

10.0 The above conditions will be enforced, inter-alia under the provisions of the Water (Prevention & Control of Pollution) Act, 1974, Air (Prevention & Control of Water Pollution) Act, 1981, the Environment (Protection) Act, 1986 Hazardous Waste (Management, Handling and Trans-boundary Movement) Rules, 2008 and the Public Liability Insurance Act, 1991 along with their amendments and rules.

  
(Lalit Bokolia)  
Additional Director

**Copy to:-**

1. Secretary, Department of Environment and Forests, Government of Rajasthan, Jaipur, Rajasthan.
2. Chairman, Central Pollution Control Board, Parivesh Bhavan, CBD-cum-Office Complex, East Arjun Nagar, Delhi-110032.
3. Chairman, Rajasthan State Pollution Control Board, 4, Institutional area, Jhalana, Doongri, Jaipur, Rajasthan.
4. Chief Conservator of Forests (Central), Ministry of Environment and Forests, Region Office (Central), Kendriya Bhawan, 5<sup>th</sup> Floor, Sector-H, Aliganj, Lucknow – 226 024, U.P.
5. Monitoring Cell, Ministry of Environment, Forest and Climate Change, Indira Paryavaran Bhavan, Jorbagh Road, New Delhi.
6. Guard File/Monitoring File/Record File.

  
(Lalit Bokolia)  
Additional Director