

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

Indira Paryavaran Bhawan
Jorbagh Road, New Delhi - 3

Dated: 19th July, 2019

To

M/s Otsuka Chemical India Pvt Ltd
SP-3, 10 & 11, RIICO Industrial Area
Village Keshwana Rajpoot, Kotputli
District **Jaipur** (Rajasthan)

Sub: Setting up APIs and bulk drugs manufacturing unit at SP-3, 10 & 11, RIICO Industrial Area, Village Keshwana Rajpoot, Kotputli, District Jaipur (Rajasthan) by M/s Otsuka Chemical India Pvt - Environmental Clearance - reg.

Sir,

This has reference to your proposal No. IA/RJ/IND2/89107/2015 dated 12th March 2019, on the subject matter.

2. The Ministry of Environment, Forest and Climate Change has examined the proposal for environmental clearance to the project for setting up active pharmaceutical ingredients (APIs) and bulk drugs manufacturing unit of capacity 25 TPM by M/s Otsuka Chemical India Pvt Ltd in an area of 26800 sqm (out of total plot area of 88000 sqm) located at SP-3, 10 & 11, RIICO Industrial Area, Village Keshwana Rajpoot, Kotputli, District Jaipur (Rajasthan). The unit is presently engaged in manufacturing bulk drugs @ 58.3 TPM, for which environmental clearance was granted by the Ministry on 10th December, 2015.

3. The details of products are as under:

S. No	Product & Intermediates	Existing (TPM)	Proposed (TPM)	Total (TPM)
1	GCLE	58.3	-	58.3
2	Cefexime	---	22.5	22.5
3	CefditorenPivoxil			
4	Cefdinir			
5	Cefprozil			
6	ACLE			
7	Ceftaroline			
8	Ceftibuten			
9	CefpodoximeProxetil			
10	CefcapenePivoxil			
11	Cefuroxime Axetil			
12	Tazobactum Sodium			
13	Sulbactum sodium			
14	SulbactumPivoxil			
15	R & D product			



4. Industry has developed greenbelt in an area of 28776 sqm covering 33% of the total project area. The estimated project cost is Rs.150 crore. Total capital cost earmarked towards environmental pollution control measures is Rs.200 lakhs and the recurring cost (O&M) will be about Rs.145 lakhs per annum. The project will provide employment for 100 persons directly and 54 persons indirectly after expansion.

5. There are no National Parks, Wildlife Sanctuaries, Biosphere Reserves, Tiger/Elephant Reserves, Wildlife Corridors, etc. within 10 km from the project site. Sota Nala (0.7 km in the NW) and Sahibi river (4.8-km in SE direction) exist within 10 km of the project site.

6. Total water requirement is estimated to be 106.3 cum/day, which includes fresh water requirement of 75 cum/day, proposed to be met from bore well. Permission in this regard has been obtained from the CGWA vide letter dated 31st January, 2019 for a total capacity of 800 cum/day which meets water demand of both the units.

Effluent of 18.5 cum/day will be treated through existing ETP. High TDS/ high COD effluent will be treated in MEE & ATFD. Treated effluent will be reused in the process/cooling tower. There will be no discharge of treated/untreated waste water from the unit, and thus ensuring Zero Liquid Discharge.

Power requirement after expansion will be 10 MVA, which will be met from Jaipur Vidyut Vitran Nigam Limited (JVNL). Existing unit has 4 DG sets of 1500 KVA capacity, additionally 1 DG set of 2000 KVA will be used as standby during power failure. Stack (height 30m) will be provided as per CPCB norms to the proposed DG sets.

Existing unit has 18 TPH steam coal based boiler. Additional, two steam coal based boilers of 10 TPH each (1 standby) will be installed with Multi-cyclone separator/bag filter and stack of height 50 m to control the particulate emissions within the statutory limits.

7. The project/activity is covered under category B of item 5(f) 'Synthetic organic chemicals industry' of the Schedule to the Environment Impact Assessment Notification, 2006. Due to applicability of general condition (Interstate boundary of Haryana at 2.38 km), the project requires appraisal/approval at central level in the Ministry.

8. Terms of reference (ToR) for the project was granted on 30th May 2017. Public hearing is exempted as the project is located in the notified Industrial area/estate.

9. The proposal for environmental clearance was considered by the Expert Appraisal Committee (Industry-2) in the Ministry in its meetings held on 22-24 January, 2018 & 6-8 May, 2019, wherein the project proponent and their consultant presented the EIA/EMP report as per the ToR. The Committee found the EIA/EMP report complying with the ToR and recommended the project for grant of environmental clearance.

10. Based on the proposal submitted by the project proponent and recommendations of the EAC (Industry-2), Ministry of Environment, Forest and Climate change hereby accords environmental clearance to the project for **setting up APIs and bulk drugs manufacturing unit of capacity 25 TPM by M/s Otsuka Chemical India Pvt Ltd** at SP-3, 10 & 11, RIICO Industrial Area, Village Keshwana Rajpoot, Kotputli, District Jaipur (Rajasthan), under the provisions of the EIA Notification, 2006, subject to the compliance of terms and conditions as under:-

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



- (ii) As already committed by the project proponent, Zero Liquid Discharge shall be ensured and no waste/treated water shall be discharged outside the premises.
- (iii) Necessary authorization required under the Hazardous and Other Wastes (Management and Trans-Boundary Movement) Rules, 2016, Solid Waste Management Rules, 2016 shall be obtained and the provisions contained in the Rules shall be strictly adhered to.
- (iv) National Emission Standards for Organic Chemicals Manufacturing Industry issued by the Ministry vide G.S.R.608(E) dated 21st July, 2010 and amended from time to time shall be followed.
- (v) Coal with Sulphur content less than 0.5% shall be used as fuel in the boiler, and/or, lignite/bio-fuel/briquettes/bagasse/agro waste.
- (vi) No raw material/solvents prohibited by the concerned regulatory authorities from time to time, shall be used.
- (vii) To control source and the fugitive emissions, suitable pollution control devices shall be installed to meet the prescribed norms and/or the NAAQS. The gaseous emissions shall be dispersed through stack of adequate height as per CPCB/SPCB guidelines. Fugitive emissions shall be controlled at 99.5% with effective chillers.
- (viii) Solvent management shall be carried out as follows:
 - (a) Reactor shall be connected to chilled brine condenser system.
 - (b) Reactor and solvent handling pump shall have mechanical seals to prevent leakages.
 - (c) The condensers shall be provided with sufficient HTA and residence time so as to achieve more than 95% recovery.
 - (d) Solvents shall be stored in a separate space specified with all safety measures.
 - (e) Proper earthing shall be provided in all the electrical equipment wherever solvent handling is done.
 - (f) Entire plant shall be flame proof. The solvent storage tanks shall be provided with breather valve to prevent losses.
 - (g) All the solvent storage tanks shall be connected with vent condensers with chilled brine circulation.
- (ix) Total fresh water requirement shall not exceed 75 cum/day, proposed to be met from ground water. Prior permission in this regard shall be obtained from the concerned regulatory authority/CGWA.
- (x) Industrial/trade effluent shall be segregated into High COD/TDS and Low COD/TDS effluent streams. High TDS/COD shall be passed through stripper followed by MEE. Low TDS effluent stream shall be treated in ETP/RO to meet the prescribed standards.
- (xi) Process effluent/any wastewater shall not be allowed to mix with storm water. The storm water from the premises shall be collected and discharged through a separate conveyance system.
- (xii) Hazardous chemicals shall be stored in tanks, tank farms, drums, carboys etc. Flame arresters shall be provided on tank farm, and solvent transfer through pumps.
- (xiii) Process organic residue and spent carbon, if any, shall be sent to cement industries. ETP sludge, process inorganic & evaporation salt shall be disposed off to the TSDF.

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- (xiv) 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, 1989.
- (xv) Fly ash should be stored separately as per CPCB guidelines so that it may not adversely affect the air quality. Direct exposure of workers to fly ash & dust should be avoided.
- (xvi) The company shall undertake waste minimization measures as below:-
 - (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.
- (xvii) The green belt of at least 5-10 m width shall be developed in nearly 33% of the total project area, mainly along the plant periphery, in downward wind direction, and along road sides etc. Selection of plant species shall be as per the CPCB guidelines in consultation with the State Forest Department.
- (xviii) As committed, funds allocation for the Corporate Environment Responsibility (CER) shall be 2% of the total project cost. Item-wise details along with time bound action plan shall be prepared and submitted to the Ministry's Regional Office.
- (xix) Safety and visual reality training shall be provided to employees.
- (xx) For the DG sets, emission limits and the stack height shall be in conformity with the extant regulations and the CPCB guidelines. Acoustic enclosure shall be provided to DG set for controlling the noise pollution.
- (xxi) 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.
- (xxii) Occupational health surveillance of the workers shall be done on a regular basis and records maintained as per the Factories Act.
- (xxiii) Continuous online (24x7) monitoring system for stack emissions shall be installed for measurement of flue gas discharge and the pollutants concentration, and the data to be transmitted to the CPCB and SPCB server. For online continuous monitoring of effluent, the unit shall install web camera with night vision capability and flow meters in the channel/drain carrying effluent within the premises.

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

- (i) The project authorities must strictly adhere to the stipulations made by the State Pollution Control Board (SPCB), State Government and/ or any other statutory authority.
- (ii) No further expansion or modifications in the plant shall be carried out without prior approval of the Ministry of Environment, Forest and Climate Change. In case of deviations or alterations in the project proposal from those submitted to this Ministry for clearance, a fresh reference shall be made to the Ministry to assess the

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- adequacy of conditions imposed and to add additional environmental protection measures required, if any.
- (iii) The locations of ambient air quality monitoring stations shall be decided in consultation with the State Pollution Control Board (SPCB) and it shall be ensured that at least one stations each is installed in the upwind and downwind direction as well as where maximum ground level concentrations are anticipated.
 - (iv) The National Ambient Air Quality Emission Standards issued by the Ministry vide G.S.R. No. 826(E) dated 16th November, 2009 shall be complied with.
 - (v) The overall noise levels in and around the plant area shall be kept well within the standards by providing noise control measures including acoustic hoods, silencers, enclosures etc. on all sources of noise generation. The ambient noise levels shall conform to the standards prescribed under the Environment (Protection) Act, 1986 and the Rules made thereunder.
 - (vi) The Company shall harvest rainwater from the roof tops of the buildings and storm water drains to recharge the ground water and utilize the same for different industrial operations within the plant.
 - (vii) Training shall be imparted to all employees on safety and health aspects of chemicals handling. Pre-employment and routine periodical medical examinations for all employees shall be undertaken on regular basis. Training to all employees on handling of chemicals shall be imparted.
 - (viii) The company shall comply with all the environmental protection measures and safeguards proposed in the documents submitted to the Ministry. All the recommendations made in the EIA/EMP in respect of environmental management, risk mitigation measures and public hearing shall be implemented.
 - (ix) The company shall undertake all measures for improving socio-economic conditions of the surrounding area. CER activities shall be undertaken by involving local villagers, administration and other stake holders. Also eco-developmental measures shall be undertaken for overall improvement of the environment.
 - (x) A separate Environmental Management Cell equipped with full-fledged laboratory facilities shall be set up to carry out the Environmental Management and Monitoring functions.
 - (xi) The company shall earmark sufficient funds towards capital cost and recurring cost per annum to implement the conditions stipulated by the Ministry of Environment, Forest and Climate Change as well as the State Government along with the implementation schedule for all the conditions stipulated herein. The funds so earmarked for environment management/ pollution control measures shall not be diverted for any other purpose.
 - (xii) A copy of the clearance letter shall be sent by the project proponent to concerned Panchayat, Zila Parisad/ Municipal Corporation, Urban local Body and the local NGO, if any, from whom suggestions/ representations, if any, were received while processing the proposal.
 - (xiii) The project proponent shall also submit six monthly reports on the status of compliance of the stipulated Environmental Clearance conditions including results of monitored data (both in hard copies as well as by e-mail) to the respective Regional Office of MoEF&CC, the respective Zonal office of CPCB and SPCB. A copy of Environmental Clearance and six monthly compliance status report shall be posted on the website of the company.

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- (xiv) The environmental statement for each financial year ending 31st March in Form-V as is mandated shall be submitted to the concerned State Pollution Control Board as prescribed under the Environment (Protection) Rules, 1986, as amended subsequently, shall also be put on the website of the company along with the status of compliance of environmental clearance conditions and shall also be sent to the respective Regional offices of MoEF&CC by e-mail.
- (xv) The project proponent shall inform the public that the project has been accorded environmental clearance by the Ministry and copies of the clearance letter are available with the SPCB/Committee and may also be seen at Website of the Ministry at <http://moef.nic.in>. This shall be advertised within seven days from the date of issue of the clearance letter, at least in two local newspapers that are widely circulated in the region of which one shall be in the vernacular language of the locality concerned and a copy of the same shall be forwarded to the concerned Regional office of the Ministry.


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

12. The above conditions will be enforced, *inter alia* under the provisions of the Water (Prevention & Control of Pollution) Act, 1974, Air (Prevention & Control of Water 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.


19/7/2019
(S. K. Srivastava)
Scientist E

Copy to: -

1. The Deputy DGF (C), MoEF&CC Regional Office (CZ), Kendriya Bhawan, 5th Floor, Sector H, Aliganj, Lucknow - 20
2. The Secretary, Environment Department, Government of Rajasthan, Jaipur
3. The Member Secretary, Central Pollution Control Board, Parivesh Bhawan, CBD-cum-Office Complex, East Arjun Nagar, Delhi - 32
4. The Member Secretary, Rajasthan Pollution Control Board, 4, Jhalana Institutional Area, Jhalana Doongri, Jaipur (Rajasthan) - 302 004
5. Guard File/Monitoring File/Website/Record File.


19/7/2019
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