

**Manufacture and commercialisation of polylactic acid based indigenous bioabsorbable implants.**

**OrthoCrafts Innovations Pvt. Ltd.**

**Environmental and Health Risk Management Plan**

**1. Environmental Impact and risk mitigation**

<b>Risks</b>	<b>Project Specific Risk</b>	<b>Potential Impact</b>	<b>Mitigation Steps</b>
Air Pollution	<ul style="list-style-type: none"> <li>▪ Emissions from air handling unit</li> <li>▪ Solvent vapours</li> </ul>	<ul style="list-style-type: none"> <li>▪ Exposure of AHU emissions to local environment</li> <li>▪ Exposure of solvent vapours to workers</li> </ul>	<ul style="list-style-type: none"> <li>▪ Anticipated emissions will be well below CPCB standards</li> <li>▪ Limited use of air conditioning as per requirement basis</li> <li>▪ Use of appropriate equipment while handling solvent to control evaporation rate</li> <li>▪ Use of safety masks during the handling of solvents</li> </ul>
Water Pollution and Waste water treatment	<ul style="list-style-type: none"> <li>▪ Effluent coming through washing of glassware</li> </ul>	<ul style="list-style-type: none"> <li>▪ Mixing of water containing soap solution into surface water stream, sewage line</li> </ul>	<ul style="list-style-type: none"> <li>▪ Anticipated effluents will be well below CPCB standards</li> </ul>
Chemical waste	<ul style="list-style-type: none"> <li>▪ Halogenated waste</li> <li>▪ Non halogenated waste</li> </ul>	<ul style="list-style-type: none"> <li>▪ Over-exposure leading to headache, sleepiness</li> <li>▪ Spillage leading to soil and water contamination</li> </ul>	<ul style="list-style-type: none"> <li>▪ Storage in separate containers as per internal guidelines within well ventilated area</li> <li>▪ Association with laboratory chemical waste management service providers for disposal of solvents</li> <li>▪ Waste minimisation plan</li> </ul>
Biological Waste	<ul style="list-style-type: none"> <li>▪ No biological waste will be produced during the project</li> </ul>	Not applicable	Not applicable
Heavy metals	<ul style="list-style-type: none"> <li>▪ Proposed solvents, raw materials may be</li> </ul>	<ul style="list-style-type: none"> <li>▪ Mixing of samples containing heavy</li> </ul>	<ul style="list-style-type: none"> <li>▪ Solvents, raw materials contain negligible to none amount of heavy</li> </ul>

	the source of heavy metals	metal with soil and water	metals as compared with permissible standards <ul style="list-style-type: none"> <li>Further mitigation plan will not be required</li> </ul>
Radiation Waste	<ul style="list-style-type: none"> <li>No radioactive waste will be generated during the project</li> </ul>	Not applicable	Not applicable
Destruction/alteration of surrounding ecosystem	<ul style="list-style-type: none"> <li>There will be no destruction/alteration of surrounding ecosystem</li> </ul>	Not applicable	Not applicable

## 2. Occupational Health and Safety and risk mitigation

Risks	Project Specific Risk	Potential Impact	Mitigation Steps
Heat Hazards	<ul style="list-style-type: none"> <li>Reactions at higher temperature</li> <li>Solvent distillation processes</li> </ul>	<ul style="list-style-type: none"> <li>Reactor overheating</li> </ul>	<ul style="list-style-type: none"> <li>Continuous temperature monitoring</li> <li>Standard operating protocols</li> <li>Safety protocols</li> <li>Training to employees</li> <li>Emergency response plan</li> </ul>
Chemical hazards, including fire and explosions	<ul style="list-style-type: none"> <li>Large quantity of solvents</li> </ul>	<ul style="list-style-type: none"> <li>Exposure to chemicals</li> <li>Accidental spills of chemical</li> </ul>	<ul style="list-style-type: none"> <li>Prevention via in-built safety measures, operational safety measures, standard operating procedures</li> <li>Fire safety protection to handle chemical hazards</li> <li>Training to employees</li> <li>Emergency response plan</li> <li>Minimal inventory plan</li> </ul>
Pathogenic and biological hazards	<ul style="list-style-type: none"> <li>No pathogenic or biological samples will be handled during the project</li> </ul>	Not applicable	Not applicable
Radiological hazards	<ul style="list-style-type: none"> <li>No radiological substances are involved in the project</li> </ul>	Not applicable	Not applicable
Noise	<ul style="list-style-type: none"> <li>Noise generated through chemical process</li> </ul>	<ul style="list-style-type: none"> <li>Increased noise levels in the surroundings</li> </ul>	Chemical process equipment, reactors does not involve heavy machinery. No significant noise

	equipment, reactors		problem is expected due to proposed activity
Process safety	<ul style="list-style-type: none"> <li>▪ Solvent spillage</li> <li>▪ Glassware breakage</li> </ul>	<ul style="list-style-type: none"> <li>▪ Prolonged downtime</li> <li>▪ Damage to the facility</li> </ul>	<ul style="list-style-type: none"> <li>▪ Regular maintenance and inspection of equipment</li> <li>▪ Standard operating procedures for each process step</li> <li>▪ Solvent spill control mechanisms</li> <li>▪ Glassware waste collection</li> </ul>

### 3. Community Health and Safety and risk mitigation

Risks	Project Specific Risk	Potential Impact	Mitigation Steps
Safety Transportation Management System (for transport of hazardous material)	<ul style="list-style-type: none"> <li>▪ Transportation of solvents</li> </ul>	<ul style="list-style-type: none"> <li>▪ Solvent spillage on road</li> <li>▪ solvent vapour exposure to transportation agents</li> </ul>	<ul style="list-style-type: none"> <li>▪ Local procurement of materials to minimise transport distance</li> <li>▪ Appropriate labelling of containers</li> <li>▪ Ensuring that the volume, nature, integrity and protection of packaging and containers used for transport are appropriate</li> <li>▪ Providing the necessary means for emergency response</li> </ul>
Emergency preparedness and participation of local authorities and potentially affected communities	<ul style="list-style-type: none"> <li>▪ Electric, chemical fire</li> <li>▪ Reactor explosion</li> <li>▪ Chemical spills</li> <li>▪ Floods</li> <li>▪ Civil disturbance</li> </ul>	<ul style="list-style-type: none"> <li>▪ Human health, property and environment</li> </ul>	<ul style="list-style-type: none"> <li>▪ Guidance document for emergency preparedness and response plan</li> <li>▪ Distinctive and recognisable alarm systems to indicate emergency</li> <li>▪ List of contacts in case of emergency</li> </ul>

In case your organization already has **EHS guideline**, please summarise the same.  
If not, please describe the impact because of hazardous material, release of chemicals, biologicals, management of catastrophic events like fire/explosion.

**Notwithstanding the above other risk (relevant to the project activities) that will be identified in the course shall be addressed as per standard mitigation monitoring parameters and manner of records keeping shall be in accordance to the recommendations of the project monitoring committee on subject experts engaged by BIRAC**

