

Permitting decisions

Low Risk Surrender

We have decided to accept the surrender of the permit for Organomercury Pharmaceutical Manufacturer, Swindon operated by Patheon UK Limited.

The permit number is EPR/NP3436LM.

We are satisfied that the necessary measures have been taken to avoid any pollution risk and to return the site to a satisfactory state. We consider in reaching that decision we have taken into account all relevant considerations and legal requirements.

Purpose of this document

This decision document provides a record of the decision making process. It:

- highlights [key issues](#) in the determination
- summarises the decision making process in the [decision checklist](#) to show how all relevant factors have been taken into account

Unless the decision document specifies otherwise we have accepted the applicant's proposals.

Read the permitting decisions in conjunction with the environmental permit and the surrender notice. The introductory note summarises what the notice covers.

Key issues of the decision

1. Reason for surrender application

The installation was operated as a facility to manufacture eye drops for medicinal purposes involving mercury. The process was manually operated by highly skilled operatives. The potentially polluting material organo-mercury compound was used in very low quantities, and was stored and used in controlled and contained areas.

The site has now been fully decommissioned and the permitted activity ceased in 2016. Any spent materials or process liquids were disposed of directly via onsite licenced waste contractors.

2. Low Risk Surrender

We have agreed with the operator that the criteria for a Low Risk Surrender, as outlined in Regulator Guidance Note (RGN) 9, has been satisfied. RGN 9 states that *'where activities could in principle pollute land or groundwater but the operator can show through....pollution control measures, that the legal test [for surrender] has been met'*.

This has been demonstrated by the fact that installation operated under a Part A Low Risk Installation permit and as such, the activities were inherently seen as low risk. All manufacturing processes ceased in 2016 and the site was fully decommissioned. Any spent materials or process liquids were disposed of directly via onsite licenced waste contractors.

The site was not deemed to have to rely on significant management effort to control its environmental risks. The process was manually operated by highly skilled operatives. The potentially polluting material organo-mercury compound was used in very low quantities and was stored and used in controlled and contained areas. Permit conditions were complied with at all times.

The only waste water produced from the installation was deionised water used for Cleaning In Place (CIP) at maximum capacity 0.3m³/day. There were no direct or indirect discharges to ground during normal or abnormal/emergency operating conditions.

There were no major spills or incidents during the lifetime of the permit.

The process produced on average 0.072 tonnes of waste per week. None of the waste produced was classified as hazardous due to the very low concentrations of dangerous substances contained within the product and the very low levels of product residues contained within the ancillary components.

Environment Agency inspection visits found no major issue during the lifetime of the permit with no compliance/enforcement issues identified.

Decision checklist

Aspect considered	Decision
Receipt of application	
Confidential information	A claim for commercial or industrial confidentiality has not been made.
Identifying confidential information	<p>We have not identified information provided as part of the application that we consider to be confidential.</p> <p>The decision was taken in accordance with our guidance on confidentiality.</p>
The site	
Pollution risk	We are satisfied that the necessary measures have been taken to avoid a pollution risk resulting from the operation of the regulated facility.
Satisfactory state	<p>We are satisfied that the necessary measures have been taken to return the site of the regulated facility to a satisfactory state.</p> <p>In coming to this decision we have had regard to the state of the site before the facility was put into operation.</p>