

Roche Diagnostics REACH SVHC Disclosure

REACH (Registration, Evaluation, Authorization and Restriction of Chemicals Regulation EC No 1907/2006) is a European regulation on chemicals adopted to improve the safety of chemicals to human health and the environment. REACH requires Roche Diagnostics to provide customers with sufficient information in Substances of Very High Concern (SVHC) contained in products in concentration above 0.1% weight by weight to allow safe use and waste management of the product (cf. Art.33 (1) REACH)*.

Based on the current version of the candidate list of SVHC for Authorization, Roche Diagnostic products contain the listed SVHCs above the disclosure threshold:

SVHC	CAS	Application	Products
Lead	7439-92-1	Alloying elements (internal mechanical parts), solders (electrical components, PCBAs)	cobas® p 612 pre-analytical system cobas® p 512 pre-analytical system cobas® p 312 pre-analytical system cobas® p 471 centrifuge unit cobas® p 671 centrifuge unit cobas® p 701 post-analytical unit cobas® p 501 post-analytical unit cobas® connection module (CCM) cobas® 8100 cobas® Bulk Loader Input Module (BLIM)
Lead / Diboron Trioxide	7439-92-1 / 1303-86-2	Sensor Optical Fiber	cobas® p 612 pre-analytical system cobas® p 512 pre-analytical system
Lead titanium zirconium oxide	12626-81-2	Display (PCBA)	cobas® p 312 pre-analytical system

The SVHCs listed above do not pose a risk for the customer under normal use conditions of the instruments.

This document will be updated when new SVHCs are added to the ECHA candidate list and are found to be contained in Roche Diagnostics products.

<https://echa.europa.eu/candidate-list-table>