

Request for Approval under the “Generic Clearance for TSCA Section 4 Test Rules, Test Orders, Enforceable Consent Agreements (ECAs), Voluntary Data Submissions, and Exemptions from Testing Requirement” (OMB Control Number: 2070-0033)

TITLE OF INFORMATION COLLECTION:

Study Plan, Test Rules

DESCRIPTION OF INFORMATION COLLECTION:

For more information about this Information Collection, including description of respondents, need for this collection, and more details of respondent activities, please refer to the Supporting Statement for this generic Information Collection Request (ICR). After the initial response has occurred, test sponsor respondents must provide a study plan to EPA. The study plan includes documents detailing the different types of tests, protocols to be followed, health effects, and endpoints to be covered in each chemical report. One study plan for each chemical is required at the beginning of the testing period. CBI substantiation to support confidentiality claims for relevant data elements for the overall submission throughout the testing period must be provided in conjunction with the study plan transmittal. The CBI substantiations address chemical identity (chemID) and other data elements.

TOTAL ANNUAL BURDEN:

Activity	Adjusted Unit Burden (hours)	Number of Respondents (Sponsors) ¹	Number of Responses (Chemicals Tested within an Action)	Overlap Factor	Total Burden (hours)	Total Labor Cost	Total Non-Labor Cost	Total Cost
Study Plan	12.987	3.50	3.50	2.80	127.27	\$9,713.47	\$0.00	\$9,713.47
CBI Substantiation	1.215	3.50	3.50	2.80	11.91	\$923.36	\$0.00	\$923.36
Total, Reporting	14.202	3.50	3.50	2.80	139.18	\$10,636.83	\$0.00	\$10,636.83
Total, Recordkeeping	0.000	0.00	0.00		0.00	\$0.00	\$0.00	\$0.00
Total, Study Plan, Test Rules	14.202	3.50	3.50	2.80	139.18	\$10,636.83	\$0.00	\$10,636.83
Footnotes:								
¹ Assumes one sponsor per chemical.								

TOTAL 3-YEAR BURDEN: 417.54 hours.