

http://www.epa.gov/chemrtk/pubs/general/srbstsum.htm Last updated on Wednesday, November 28th, 2007. High Production Volume (HPV) Challenge

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Directions for Submitting Robust Summaries

Companies and consortia which sponsor chemicals in the HPV Challenge Program begin by identifying and assessing all existing data to determine whether there are any missing data on SIDS <u>endpoints</u> which will need to be filled by new testing. Existing data should be submitted in the form of robust summaries which contain enough information and data to permit an assessment of study quality. The robust summaries support the test plans submitted by sponsoring organizations, which identify any needed SIDS data and present a strategy for fulfilling the test data requirements. Guidance documents on conducting effective <u>literature searches</u> to locate existing information; on the content and preparation of <u>robust summaries</u>; and on <u>assessing data adequacy</u> are available on this website. <u>Additional guidance</u> specifically addressing test plans and animal welfare concerns is also on the website.

To encourage electronic submission of information in a consistent database format which will enhance the ability of all interested groups to view, study, and analyze submitted data, EPA has developed a database structure for robust summary submissions. This structure will allow the user to enter information about test results and submit them to EPA in electronic format. We are providing this format as a service; we do not require that it be used. EPA will accept robust summary information which already exists in other database formats (for example, the International Uniform Chemical Information Database (IUCLID) system used by the HPV SIDS program of the Organization for Economic Cooperation and Development), other electronic formats (e.g., word processing), or in hard copy.

EPA's databases are being designed to be fully compatible with the anticipated international robust summary changes in IUCLID, so that a single data submission would be acceptable in both the domestic and international programs. A Web query module will also be developed to support public access to the EPA database over the Internet.

Please note that only the input module for this database structure is currently available. Until the web query module is available, robust summaries submitted using the input module will be posted as flat files which users will be able to download and view using their own personal database software.

In order to use the EPA robust summary database input module to make your submissions, you can either <u>download</u> the database software directly from this website, or request a copy on CD-ROM. Instructions for using the input module can be found in the <u>User's Guide</u>.

Because the download is 14 MB in size, you may prefer to request the CD-ROM if your Internet connection is slow. You can make your request by <u>email</u>, or by contacting:

TSCA Non-Confidential Information Center EPA East Building, Room 6428 1201 Constitution Ave., NW Washington, DC. 20460 Telephone: 202-260-7099

The Center is open Monday through Friday from 12:00 noon to 4:0+0 PM Eastern time, except for

national holidays. Ask for the EPA HPV Tracker, Version 1.0. You do not need to have any other database programs or software already on your computer in order to use the EPA robust summary database.

Complete instructions on how to download, install, and use this EPA robust summary database input module software are available on this website in both <u>PDF</u> and <u>HTML</u> formats.

You will need the Adobe Acrobat Reader to view the PDF version. If you do not already have the Reader on your computer, your can download it for free at <u>www.adobe.com</u>.

SUBMITTING COMPLETED SUMMARIES

Electronic Robust Summary submissions to the Agency may be sent via <u>email</u>. Alternatively, they may be submitted on 1.44 MB, high density, double-sided floppy disks mailed to:

Administrator U.S. Environmental Protection Agency Ben Franklin Post Office P.O. Box 862 Washington, DC 20044 Attention: Chemical Right-to-Know Program

Please indicate in the email message or cover letter accompanying the submission that the information is a Robust Summary being submitted for the HPV Challenge Program, AR-201, and identify the program or format in which the files have been saved (for example, EPA HPV Database format; IUCLID; a named word processing format; .PDF; or some other program). Companies and consortia submitting data should also reference the unique seven-digit registration number which they were assigned when the Agency verified the information presented in their original commitment letters. Companies and consortia which need to reconfirm their registration numbers should call 202-566-0278.

If electronic versions are unavailable, hard copy Robust Summaries can be mailed to the Post Office box identified above.

For TSCA Confidential Business Information (CBI):

Enclose the material in a double envelope; the inside envelope should be marked "TSCA CBI, to be opened by addressee only." The outside envelope should have no such distinguishing markings besides this address:

US EPA Document Control Officer (7407M) 1200 Pennsylvania Ave., NW Washington, DC 20460 Attn: HPV Challenge Program.

If delivery is in person, by courier, or overnight/express mail, use this address on the outside envelope: Document Control Office (DCO), EPA East Building, Room 6428, 1201 Constitution Ave., NW, Washington, DC. The DCO is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the DCO is (202) 564-8930.

The second copy should be sanitized to remove the CBI information and included in the same envelope with the CBI version that is sent to the Document Control Office.