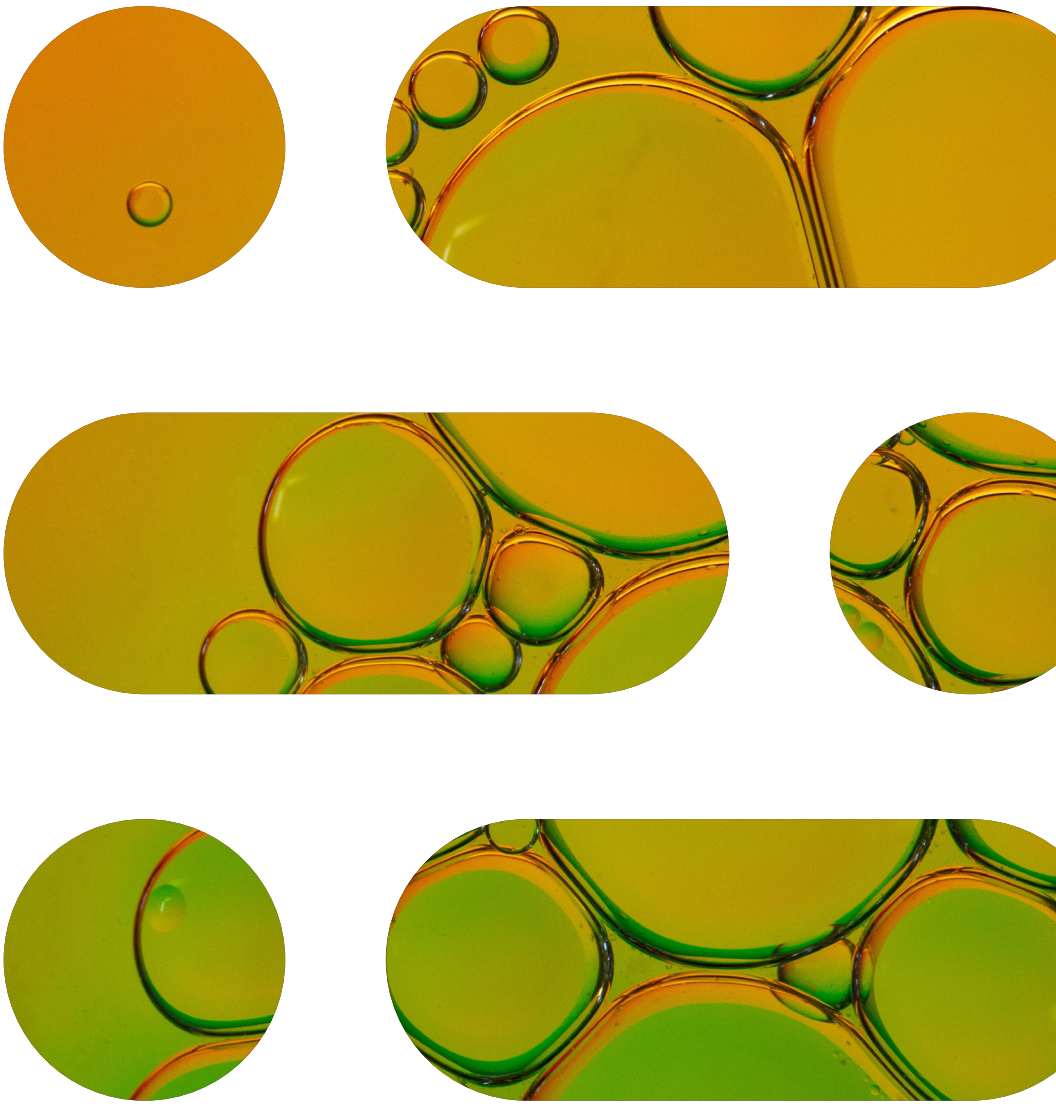
EVALUESERVE

Whitepaper

Chemical Risk Assessment

Strategic and Comprehensive Toxicological Literature Search



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Toxicological Literature Search: Overcoming the Challenges

Chemical risk assessment is a highly focused research activity that has the potential to eliminate the need for frequent chemical testing and the use of animals in toxicological testing, as well as accelerate the use of chemicals in manufacturing and commercial processes. It involves qualitative and quantitative evaluation of complex chemical properties and chemicals' responses to interaction with humans and the environment. Reliable chemical risk assessment requires a thorough and systematic search through high-quality data gathered from publicly available scientific databases, followed by evaluation and summarization.

Toxicological literature search can be a challenging task for researchers due to the presence of a vast number of public and commercial databases, the constantly expanding amounts of data in such databases, the complexity of available data, and the need to adhere to data-sharing policies. As new studies, methods, and regulatory changes are introduced, it becomes increasingly difficult for researchers to keep track of information. Literature search must be properly organized and curated to achieve transparent and robust conclusions during chemical risk assessment.

Therefore, toxicologists need to implement a rigorous and impartial methodology to ensure a comprehensive search of public literature. Poorly defined strategies and inadequately executed searches can result in inaccurate data and knowledge gaps regarding the properties of a chemical. The two major consequences of inefficient searches are additional and unnecessary testing and / or wrong or incomplete chemical risk assessment, which can have serious consequences on human health and the environment.

Evalueserve's Literature Search Guide

Evalueserve's Chemical Safety and Regulatory Affairs (CSRA) team has created a guide to help conduct thorough literature searches for toxicological data for effective assessment of the hazards and risks associated with chemicals, materials, ingredients, and natural substances. The guide focuses on organic and inorganic substances and refers to them as 'chemicals' for ease of use. While the methods espoused by the guide can be adjusted for other substances, such as polymers and biological materials, it does not specifically cover such substances.

THE GUIDE COVERS

- Recommended sources of toxicological data
- A tailored literature search strategy
- Key takeaways and insights

Sources for Chemical Toxicology Screening

Physicochemical, toxicological, and ecotoxicological data on chemicals is available across a diverse array of information sources / databases, which can be typically classified into three categories – primary, secondary, and tertiary – based on the origin of their data. Primary sources include reports, conference papers, journal articles, news, and theses. Secondary sources index or abstract primary literature from across sources and usually present summarized content. These include reviews, dossiers, hazard assessments, and toxicity profiles. Tertiary sources include summaries and assessments presented as reference sourcebooks and textbooks.

The volume and quality of data may differ across databases or there may be a significant data overlap between them. For example, it is common for individual scientific references to be present in multiple databases. Therefore, researchers must be knowledgeable about the subject coverage of each database and the associated information retrieval / capture method. They must also be able to decide which data is relevant for chemical hazard and risk assessment and avoid data duplication.

A comprehensive literature search cannot depend on a single source of information. Multiple sources help avoid information bias. A carefully constructed multi-source search strategy is also essential to minimize the chances of missing critical data.

Some researchers tend to mainly focus on secondary literature during a review. However, it is critical that they perform a thorough literature search across available databases. For example, toxicological information can be extracted from global regulatory databases, meta databases, commercial databases, and bibliographical databases. They must also apply specific curated search terms to each database to specify the retrieval of relevant information.

Additionally, hazard and regulatory information are available as study reports, summary dossiers, hazard profile / assessment reports, regulatory listings, and regulatory limit tables. An abundance of data from one database is sometimes unfavorable since contradictory results may be found in multiple databases. Therefore, examining the reliability and relevance of the retrieved data is a must.

Indicative List of Toxicology Data Sources

Indicative list of key toxicology data sources is provided below. It is important to note that this not an exhaustive list of all the relevant databases. Depending on a specific research need, there may be additional databases should be considered.

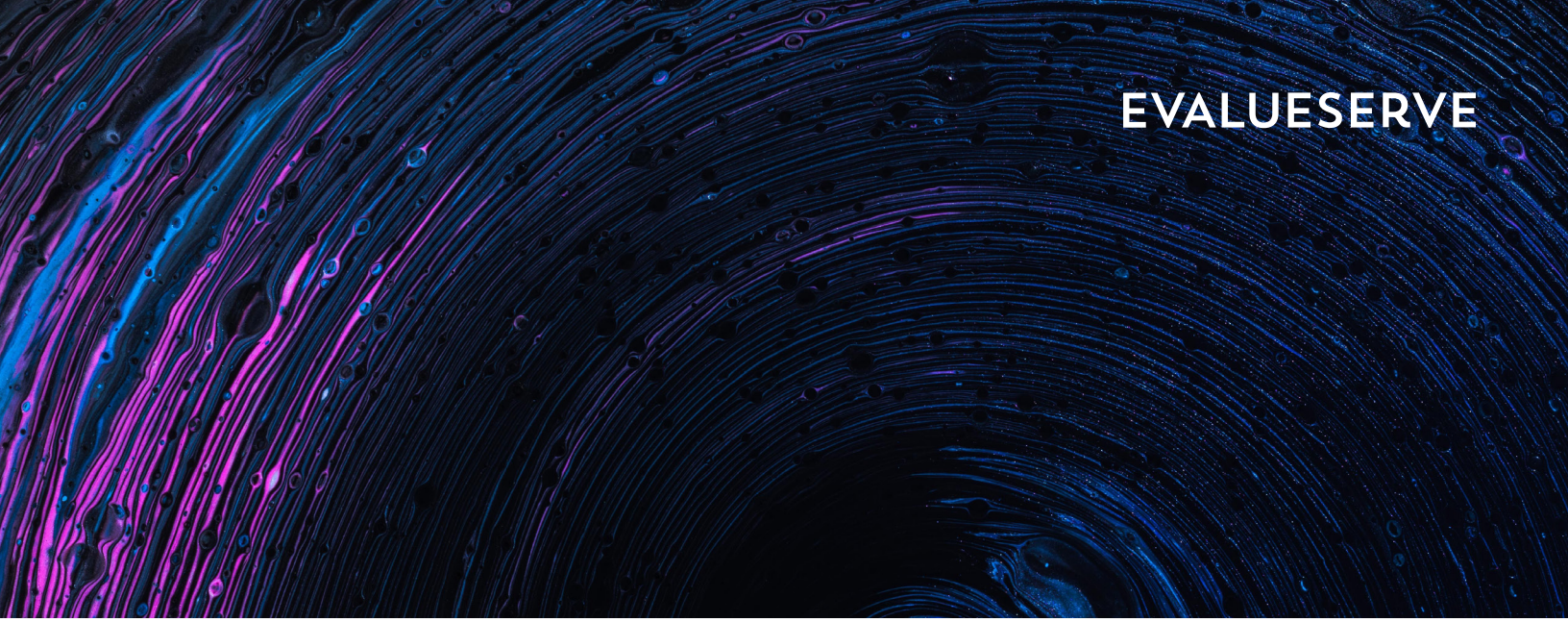
Global Chemical Regulatory Databases	*Publicly available databases developed by government agencies, academia, and professional organizations.*
European Chemicals Agency (ECHA) Database Visit Website	Maintains a comprehensive database on chemicals called the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) database. This database contains information on the properties and uses of thousands of chemicals that are manufactured, imported, or used in the European Union (EU)
ChemView Visit Website	A publicly available online database maintained by the U.S. Environmental Protection Agency (EPA) that provides information on thousands of chemicals regulated under the Toxic Substances Control Act (TSCA). The database includes detailed information on the chemical properties, uses, and potential health and environmental effects of TSCA-regulated chemicals.
National Toxicology Program (NTP) Database Visit Website	Maintains a database that provides information on the potential toxicity of chemicals and other agents. The database, known as the NTP's Chemical Effects in Biological Systems (CEBS) database, contains information on the results of NTP studies on the toxicity of chemicals, as well as information from other sources. The CEBS database includes information on the physical and chemical properties of chemicals, as well as their potential health effects. The database also includes information on the results of animal and cell-based studies on the toxicity of chemicals, as well as epidemiological studies on the potential health effects of exposure to these chemicals.
International Agency for Research on Cancer (IARC) Database Visit Website	Maintains a database called the IARC Monographs Programme, which evaluates the carcinogenicity of chemicals, agents, and mixtures. The IARC Monographs Programme is a global reference source for identifying and classifying carcinogens and assessing their risks to human health.

Global Chemical Regulatory Databases	*Publicly available databases developed by government agencies, academia, and professional organizations.*
Cosmetic Ingredient Review (CIR) Visit Website	Maintains a database that provides safety assessments of cosmetic ingredients. The CIR Expert Panel is an independent group of scientific and medical experts that review and assess the safety of cosmetic ingredients. The CIR database contains safety assessments of over 2,500 cosmetic ingredients, including information on the potential health effects of these ingredients and the recommended safe levels of use. The database also includes information on the types of products in which these ingredients are used and the levels of exposure to consumers.
Australian Industrial Chemicals Introduction Scheme (AICIS) Visit Website	Maintains a database of industrial chemicals that are used in Australia. The database includes information on the potential hazards and risks associated with these chemicals, as well as information on their uses and the types of products in which they are used.
Japan Existing Chemical Database (JECDB) Visit Website	Includes toxicity testing reports for existing chemicals and is maintained by the National Institute of Health Sciences (NIHS). The JECDB contains reports on Japan's existing chemicals safety program and the OECD HPV (high production volume) chemicals program.
JECFA FAO/WHO (Food and Agriculture Organization/World Health Organization) Database Visit Website	The Joint FAO-WHO Expert Committee Report on Food Additives (JECFA) maintains a database that evaluates the safety of food additives, contaminants, and veterinary drugs. JECFA is a scientific expert committee that provides independent advice to the Food and Agriculture Organization (FAO) and the World Health Organization (WHO) on food safety issues.
Human and Environmental Risk Assessments (HERA) Database Visit Website	A comprehensive database that focuses on the environmental and human health risks associated with the use of household and personal care products. The database is maintained by the International Association for Soaps, Detergents and Maintenance Products (AISE) and the European Chemical Industry Council.

Global Chemical Regulatory Databases	*Publicly available databases developed by government agencies, academia, and professional organizations.*
Organization for Economic Cooperation and Development (OECD) Existing Chemicals Database Visit Website	Maintains a database called the Screening Information Dataset for Endocrine Disrupters (SIDS). This database provides information on the potential endocrine-disrupting effects of chemicals, which are substances that can interfere with the hormonal system in humans and animals. The SIDS database includes information on the physical and chemical properties of chemicals, as well as their toxicological profiles, and is used by regulatory agencies and researchers to evaluate the potential risks associated with chemical exposure. The database is regularly updated and includes information on thousands of chemicals.
Agency for Toxic Substances and Disease Registry (ATSDR) Database Visit Website	A comprehensive database that provides information on the toxicological profiles of hazardous substances. The database is maintained by the Centers for Disease Control and Prevention (CDC) in the United States. The ATSDR database contains information on the toxicological effects of hazardous substances, including their potential to cause acute and chronic health effects, as well as information on exposure pathways and routes of exposure. The database also provides information on the health effects of hazardous substances in specific populations, such as children, pregnant women, and workers.
Metadatabases	*Metadatabases (or clustered databases) allow simultaneous searching of chemical data in multiple data sources.*
eChemPortal Visit Website	Managed by the Organisation for Economic Co-operation and Development (OECD). The database provides information on the physical and chemical properties of chemicals, as well as their environmental fate and toxicity. Echemportal contains information from a range of sources, including regulatory agencies, industry, and the scientific community.

Metadatabases	*Metadatabases (or clustered databases) allow simultaneous searching of chemical data in multiple data sources.*
International Program on Chemical Safety (IPCS) Chemical Safety Information from Intergovernmental Organizations (INCHEM) Database Visit Website	Offers quick and easy electronic access to thousands of searchable full-text documents on chemical risks maintained by intergovernmental organizations (ICSC, WHO, FAO, ILO, UNEP, and OECD)
EPA CompTox Chemicals Dashboard Visit Website	A database that contains information on chemicals, including data on chemical structures, toxicity, exposure, and regulatory information. The dashboard provides access to a variety of tools and resources, including toxicity data from EPA programs such as ToxCast and Tox21, as well as links to other databases such as PubChem and ChemIDplus.
Commercial Toxicology Information Databases	*Commercial databases offer a single search box access to hundreds of toxicology and regulatory databases.*
ToxPlanet Visit Website	Offers a single search box access to hundreds of toxicology and regulatory databases through a commercial search interface.
3E Insight Visit Website	A toxicology database that provides information on regulatory compliance and hazardous materials management. It includes information on chemical substances, their properties, and their potential hazards. The database also provides information on global regulations and compliance requirements related to the use, handling, and transport of hazardous materials.

Bibliographical Databases	*Databases for accessing scientific and scholarly journal articles and books.*
PubMed Visit Website	A bibliographic database maintained by the National Library of Medicine (NLM) and provides access to over 30 million citations in the biomedical field, including toxicology. PubMed includes articles from MEDLINE, life science journals, and online books.
EBSCO Visit Website	A commercial interface that provides access online research databases, e-journals, e-books, and other digital content for academic, medical, corporate, and public libraries worldwide.
Google Scholar Visit Website	A web search engine that indexes scholarly literature in all fields, including toxicology. It provides a platform for users to search for academic articles, conference papers, preprints, theses, books, and other scholarly literature from a variety of sources.
DeepDyve Visit Website	A web-based platform that provides access to a large collection of scholarly research articles from various publishers, including those related to toxicology. DeepDyve offers a subscription-based service that allows users to search and read full-text articles from a wide range of scientific, technical, and medical disciplines. The platform also provides tools for researchers to manage and organize their literature searches and citations.
Scopus Visit Website	A large abstract and index database of research literature and quality web sources covering science, technology, medicine, and social sciences.



Tailored Literature Search Strategy

High-quality and comprehensive toxicology data search requires systematic and well-organized examination of published data on chemicals of interest (COI). We have broken down tailored literature search into four steps:

Literature Search Key Steps

STEP 1

Check chemical identity based on parameters such as CAS, synonyms, trade names, structure, etc.

STEP 2

Develop inclusion and exclusion criteria for hazard data, regulatory data, mechanistic data, exposure data, etc.

STEP 3

Start organized database search, which requires knowledge of database content, method of information retrievals, and development of record format.

STEP 4

Manage and report search results by strategically organizing the identified data, based on source information, hazard endpoints, quality, and relevancy.

STEP 1

The first step involves gathering information on a COI, including its various names, properties, category (e.g., cosmetic, pharmaceutical, food, etc.), and usages, as well as ascertaining if it falls within Chemical Substances of Unknown or Variable Composition, Complex Reaction Products and Biological Materials (UVCB substances). Databases such as SciFinder, PubChem, and USEPA Comptox help understand a chemical's identity and properties. It is vital to analyze the data in conjunction with one's knowledge of chemistry to accurately conclude the identity of the test material.

For example, literature search and accurate chemical identification of UVCB substances require additional chemical information, such as feedstock, average molecular weight, chemical structure, carbon chain length, unsaturation, number of repeating units (if polymer), INCI name (if any), etc. In our report Best Practices for Measuring Toxicology Test Material Accuracy in Scientific Data Mining, we have outlined effective techniques for measuring toxicology test materials and focused on a systematic review of toxicology test material information in data sources. **Learn More →**

STEP 2

In the subsequent step, the researcher should identify inclusion and exclusion criteria for chemical-specific toxicological hazard data, regulatory data, mechanistic data, exposure data, etc., based on assessment requirements. Identified databases should be screened to exclude content that is not pertinent to objective assessment. Weight-of-evidence judgments require the inclusion of data reflecting low purity, chemical mixtures, and irrelevant route of exposure (e.g., intravenous); data related to multiple species; as well as less reliable studies (abstract only).

One must be mindful of the fact that some toxicological research questions are challenging and require a unique systematic approach (e.g., when searching for novel mechanistic data on the toxicological endpoint). Such cases require a timely formulation of research questions and search parameters (such as data sources, timeline, relevant keywords, and multi-lingual translation options). Sometimes, looking into cross-references and citations may help build more search keywords to extend the coverage of a topic.

STEP 3

Once a well-defined inclusion and exclusion criteria has been established, it is important to identify literature sources and methods of information retrieval. One should aim to search across as many sources as possible. The following factors should be considered while searching across databases:

- Chemical identity input parameters
- Relevant keywords
- Search optimization with filters and limitations of databases
- Reliability of database content
- Output format

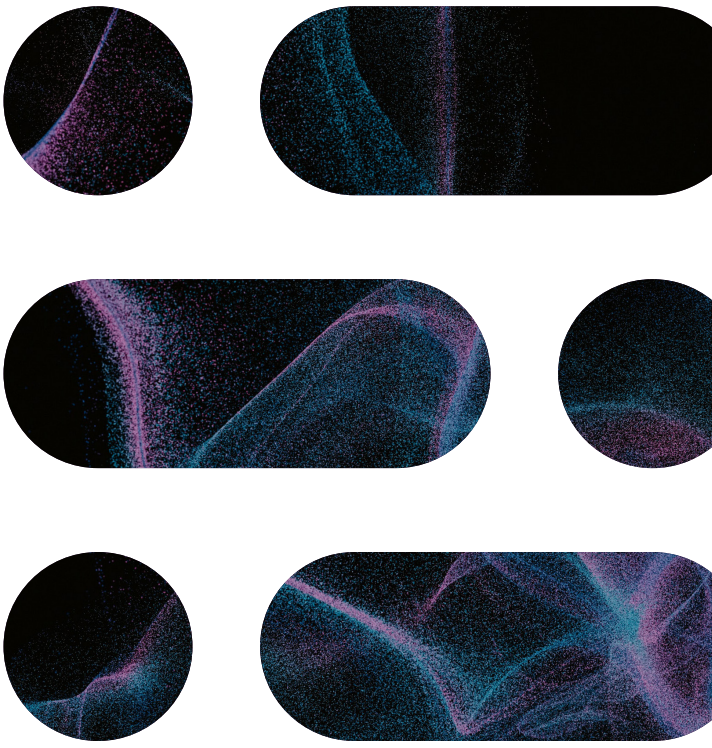
Most publicly available databases are secondary or tertiary sources of information in which the data are either recompiled or reorganized with an additional layer of analysis and dissemination. Therefore, researchers must also include a primary source of information to check the quality and reliability of the data.

Most primary information is retrieved via bibliographical databases in which searches are conducted using chemical synonyms, combined with search terms for a specific endpoint of interest and / or topic. Consultation with information specialists to develop relevant search terms and knowledge of Boolean operators is another critical step. One should focus on retrieving quality data from scientific publications rather than regulatory databases.

Let's take the example of a well-conducted OECD 422 compliant combined repeated dose and reproductive / developmental toxicity screening test for tert-Butylhydrazine monohydrochloride, which is only available in a scientific publication located in a Japanese academic journals database (Kobayashi, T. et al. 2013; The Journal of Toxicological Sciences, 38(2), 177-192). A knowledge gap in publication searching may lead to an endpoint data gap and increase the time and effort needed for chemical toxicity assessment.

STEP 4

The final stage is a systemic compilation of the retrieved information. The gathered data should be constructed in a standardized tabular format. It should be arranged by source, study quality, summary, and source link. Furthermore, it is necessary to define when the last complete literature assessment was conducted in order to ensure that significant information has not been published after the literature search was conducted.



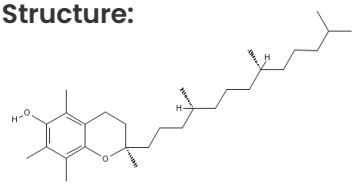
Health Effects of D-α-Tocopherol (CAS 59-02-9)

The literature search and screening strategy aimed at identifying the health effects of D-α-Tocopherol (CAS 59-02-9) is described below. Although this example focuses on the search for human toxicity data, a similar strategy can be used to search for physicochemical and / or ecotoxicological data.

Literature Search Strategy for Health Effect of D-α-Tocopherol (CAS 59-02-9)

Chemical Identity Data Search

Sources: PubChem, EPA CompTox
Synonyms: alpha-Tocopherol, (+)-alpha-Tocopherol, Vitamin E
SMILES: CC(C)CCC[C@@H](C)CCC[C@@H](C)CCC[C@]1(C)CCc2c(C)c(O)c(C)c(C)c2O1
Molecular Formula: C29-H50-O2
Structure:



Defining Inclusion and Exclusion Criteria

Inclusion Criteria

- Chemical-specific information (check isomeric composition)
- Human safety studies
- Standard mammalian animal models, including rat, mouse, rabbit, guinea pig, monkey, and dog
- Exposure via oral, inhalation, or dermal routes
- Studies that include a measure of one or more health effect endpoints
- Mechanistic studies
- Regulatory health limits and hazard statements

Exclusion Criteria

- Studies that do not involve testing of the D-α isomer of tocopherol
- Clinical efficacy studies
- Data on ecological species or non-mammalian species
- Exposure via irrelevant routes (e.g., intravenous)
- Analytical studies
- Chemical inventory and tonnage data

Literature Search Strategy for Health Effect of D-α-Tocopherol (CAS 59-02-9)

Organized Database Search	• Search through regulatory databases (e.g., US FDA, ECHA, EPA, EFSA, EU Opinions, JECFA, NTIS, etc.) • Meta database / clustered database search (eChemPortal, EPA ChemView, DrugBank, etc.) • Publication search using PubMed, Google Scholar, and other relevant search engines • Summary of relevant database hits obtained for the health effect of D-α-tocopherol • Chemical-specific quality health effect data with animal studies located in 12 public regulatory databases • Human safety literature located via US FDA and PubMed/Google Scholar search • Mechanistic toxicology data located via PubMed search • Other supporting health effect data (human case reports, low-quality studies, abstract data) is in two databases (RTECS and HSDB)
Managing and Reporting Search Results	Data arranged in standardized tables based on source, study quality, summary, and source link

About Evalueserve

Evalueserve has a global team of certified toxicologists, with two decades of experience, who offer a literature search service and develop customized chemical risk assessment reports for multiple global clients. The team has developed an in-house platform to identify and deliver chemical-specific hazard and toxicology content from over 100+ toxicological databases. The platform allows the team to complete chemical searches more efficiently and with greater accuracy.

The team develops chemical-specific and product formulation literature reports for global clients across multiple domains. It also helps them to identify data gaps and alternative approaches for risk assessment.

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