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An overview of hazard and risk assessment of the OECD high production volume chemical category—Long chain alcohols [C_6–C_{22}] (LCOH)☆, ☆☆

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ABSTRACT

This review summarizes the findings of the assessment report for the category, long chain alcohols (LCOH) with a carbon chain length range of C_6–C_{22} covering 30 substances, and >1.5 million tonnes/year consumed globally. The category was evaluated under the Organization for Economic Co-operation and Development (OECD) high production volume chemicals program in 2006. The main findings of the assessment include: (1) no unacceptable human or environmental risks were identified; (2) these materials are rapidly and readily biodegradable; (3) a parabolic relationship was demonstrated between carbon chain length and acute and chronic aquatic toxicity; (4) category-specific (quantitative) structure-activity relationships were developed enabling prediction of properties across the entire category; (5) LCOH occur naturally in the environment in an equilibrium between synthesis and degradation; (6) industry coming together and sharing resources results in minimizing the need for additional animal tests, produces cost savings, and increases scientific quality of the assessment.

1. Introduction

The aim of this paper is to summarize and introduce the assessment of the long chained alcohols (LCOH) category, and also to give a brief review of ongoing national and international assessment frameworks addressing non-assessed or high production volume (HPV) chemicals. Most HPV chemicals have been on the market for decades but rarely have comprehensive data sets on their physicochemical and toxicological properties been publicly available. Therefore HPV chemicals are under increasing regulatory scrutiny globally. In 1990, member countries of the Organisation for Economic Co-operation and Development (OECD) decided to undertake the investigation of HPV chemicals in a co-operative way. These HPV chemicals include all chemicals reported to be produced or imported at levels greater than 1000 tonnes/year in at least one member country or in the European Union region. The most recent OECD HPV Chemicals List compiled in 2004 contains 4843 substances based on submissions of nine national inventories and that of the European Union. The OECD HPV program proceeds by the agreement that member countries will co-operatively select the chemicals to be investigated, collect and characterize effects and exposure information from government and public sources and encourage industry to provide information from their files, complete the agreed dossier for the Screening Information Data Set (SIDS), and make an initial assessment of the potential hazard of each chemical investigated. When a full SIDS dossier on a chemical is available, an initial assessment of the information is undertaken and conclusions are

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☆☆ Any studies referred to in this overview article were conducted in accordance to national and/or international guidelines for protection of human subjects and animal welfare. For further details see papers in this issue by: Fisk et al. (2008); Schäfers et al. (2008); Veenstra et al. (2008); and Belanger et al. (2008).

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drawn on the potential hazard(s) and exposure information to put the hazard information into context (e.g., based on use in the Sponsor country). Since 1999, the work in OECD has concentrated on data gathering, testing, and initial hazard assessment. Detailed exposure information gathering and assessment of risk is no longer required as part of the SIDS initial assessment, but can be carried out in follow-up at the national (or regional) level, as appropriate, following national (or regional) priority setting as post-SIDS work. Detailed international assessment of risks to human health and/or the environment is also no longer carried out under the SIDS initial assessments. In the policy bodies of OECD, member countries discuss and agree on any follow-up actions on chemicals for which further work is recommended. Finalized SIDS dossiers and initial assessment reports are made available worldwide through UNEP Chemicals website (http://www.chem.unep.ch/). Protocols were established for close co-operation with the industry in the various stages of the Programme, which is undertaken in co-ordination with national, regional and other international existing chemicals programmes (OECD, 2004).

The global chemical industry, through the International Council of Chemical Associations (ICCA), launched a global initiative on HPV chemicals in 1998 to expedite the OECD HPV program. Through this commitment, the chemical industry has undertaken to provide, as a first step, harmonized data sets on the intrinsic hazards of and initial hazard assessments for approximately 1000 HPV substances by the end of 2004. The information consisting of a SIDS Dossier, a SIDS Initial Assessment Report (SIAR); and the SIDS Initial Assessment Profile (SIAP) are submitted to the OECD for international agreement as part of its refocused HPV Chemicals Programme. The cost of generating data and the work to draft the assessments will be borne by industry—and shared, whenever possible, by companies in international consortia. The main features of the ICCA HPV chemicals initiative are for voluntary action by the world chemical industry to speed up the process under existing regional and/or global programmes with a clear target date, provide globally harmonized, internationally agreed data sets and initial hazard assessments under the refocused HPV Chemicals Programme of the OECD, and the elimination of duplication of testing and assessment efforts. The main expected benefits of these actions are to restore public confidence in chemicals and to foster a positive reputation of the chemical industry on a global basis, to establishment of a sound scientific basis for any subsequent regional, national, or global risk assessment need, to minimize the cost for the industry and to reduction in the number of animals needed for testing (CEFIC, 2007).

There are, of course, other ongoing or planed national and international HPV initiatives with different regulatory objectives, but a common feature among them is the desire for increased transparency regarding the properties of chemicals. The OECD data sets complement these other initiatives, some of which are described in the following paragraphs.

The United States Environment Protection Agency (US EPA) initiated their HPV Challenge program in 1999, challenging industry to provide data on some 2860 HPVs. This was done under the chemical rights-to-know program (http://www.epa.gov/chemrtk/). Of these substances, US EPA found that 43% have no publicly available data on basic toxicity, and only 7% have a full set of basic test data publicly available. EPA also found that only 55% of the chemicals reported in the Toxics Release Inventory had full basic toxicity testing data publicly available. Only about one quarter of chemicals in consumer products had basic testing information publicly available. This lack of publicly available toxicity data compromised, in the Administration's view, the public's right to know about chemicals in their homes, their workplaces, and the products they buy (Goldman, 1998). Hence the US EPA HPV Challenge Program. The results are made publicly available via the US EPA HPV Information System (HPVIS) (http://www.epa.gov/hpvis/).

The Canadian Environment Protection Act (CEPA) was revised in 1999 and required that all existing chemicals on the market and identified the Domestic Substances List (DSL) would need review based on their properties and likelihood of exposure to humans or the environment. The compounds would then be categorized based on their persistence (P), bioaccumulation (B), and toxic (T) (PBT) properties and likelihood of exposure. The DSL includes ~23,000 substances that were in Canadian commerce, used for manufacturing purposes, or manufactured in or imported into Canada in a quantity of 100 kg or more in any calendar year between January 1, 1984 and December 31, 1986. The aim here is to prioritize which chemicals to categorize for and risk assessment (CEPA, 1999).

The European Union (EU) Existing Chemicals Program, initiated in the mid-1990s mandated industry to provide all available data for EU priority chemicals in two priority phases. The first phase included compounds on the EU market >1000 tonnes/year with known hazardous properties, and the second phase included all other compounds >1000 tonnes/year. Subsequently the authorities were to prioritise the substances according to their environmental relevance (exposure) and hazard properties. Starting with the substances of highest concern, comprehensive risk assessments were to be conducted. If relevant data gaps were identified, industry had to conduct and provide data from additional studies. However, the progress of the program was rather slow so that after 10 years only for a minor fraction of the substances at >1000 tonnes/year final risk were assessment available. As a consequence of this the EU issued a white-paper on the future chemicals policy (EU, 2001a, b), and initiated the European Registration Evaluation Authorization of Chemicals (REACH) process in 2001 (EU, 2001b). This policy will address registration of compounds marketed before 1981 in volumes greater than 1 tonne (~30,000 compounds). Priority is given to HPV chemicals under REACH (>1000 tonnes/year). The deadline for registration of chemicals used at these tonnages is 3 years after full implementation of REACH (~2011). For feasibility purposes (minimizing animal tests, time, costs), assessment of chemical categories as well as use of read-across and quantitative structure-activity relationships ((Q)SARs) play important roles in the implementation of REACH. The bottom-line of REACH has been summarized as: No data–No market.

In 2005, the Japanese government started its voluntary HPV program for substances produced or imported in Japan in volumes greater than 1000 tonnes/year. The program focuses on HPV chemicals on the Japanese market which are not evaluated by any other HPV program, such as the OECD and US challenge programs. A total of 652 HPV chemicals appear on the Japanese market today, 140 of which are not covered by any of the other international HPV programs and have no data specific for Japan. Hence, these substances need assessment under the Japanese HPV challenge program. Roughly half of these have voluntarily been sponsored by the Japanese industry and are currently being assessed. The required endpoints are the OECD SIDS data package. The initial assessment phase of the program will be completed by March of 2009 (Japan MOE, 2005).

In concert with these national and international chemical management programs the United Nations Economic and Social Council adopted the Globally Harmonized System (GHS) for Chemicals Classification and Labeling in 2003 (UN, 2003), which will allow the intrinsic hazard properties to be translated into hazard classes that are readily interpretable worldwide for hazard communication. Thus, HPV data sets support national and regional efforts to improve the safe handling and use of chemicals.