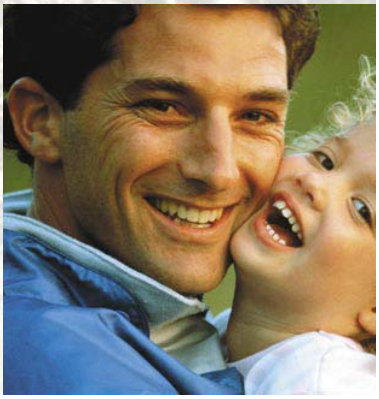
MEETING THE CHALLENGE:

Progress Report on The Soap and Detergent Association (SDA) Commitments under Voluntary High Production Volume (HPV) Chemical Programs



The Soap and Detergent Association

EXECUTIVE SUMMARY

The Soap and Detergent Association (SDA) is a U.S. national trade association representing the formulators of household, institutional and industrial cleaning products and the manufacturers of the ingredients and finished packaging used to bring these products to the marketplace. SDA is a the leading manager of chemical consortia fulfilling commitments to the voluntary global International Council of Chemical Associations (ICCA) and U.S. Environmental Protection Agency (EPA) high production volume (HPV) chemical programs.

SDA manages 62 companies within ten U.S. and global HPV chemical consortia and their commitment to compile and make publicly available a baseline set of health and environmental effects data covering 291 chemicals. Through the global collaboration of producers and users of cleaning product chemicals, data submissions under these programs demonstrate that a wealth of environmental and human safety information has been in existence for cleaning product ingredients, virtually eliminating any need for new testing and dispelling the perception that fundamental safety data were lacking on these materials. In fact, over 6,100 study summaries were prepared by SDA from existing hazard data. The HPV Chemical Challenge provided an opportunity for SDA's members to make chemical safety information publicly available for the first time. Often, publishing studies with negative results is not feasible through peer-reviewed scientific journals and related media.

Although the efforts to compile hazard data on a global basis required additional time and resources, there has been only a very limited need for new testing in this work. Only eight of the more than 6,100 study summaries were based on new testing (about 0.13% of the total number of studies).

SDA's participation extended beyond the basic commitments of these programs; SDA developed and applied tools to facilitate the assessment of human and environmental exposures to HPV chemicals used in cleaning products, which greatly improves the capabilities and understanding of risk-based decision-making on safe uses. SDA's commitment to address HPV chemicals has extended beyond chemicals identified as HPV in 1990 to include some "new" HPV chemicals identified as U.S. HPVs for the first time in the 2002 update of the TSCA Inventory and the addition of some moderate volume chemicals related to categories for which work was underway. SDA developed and published processes and tools for handling use and exposure information in exposure assessments and risk assessments.

SDA and its managed consortia continue to progress towards completion of the commitments to compile and make publicly available a baseline set of health and environmental effects data for the 291 chemicals sponsored. As of June 2008, commitments for 141 chemicals have been completed. SDA is working to complete its commitment to these programs (291 total chemicals) by early 2009.

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1 INTRODUCTION

The Soap and Detergent Association (SDA) is a U.S. national trade association representing the formulators of household, institutional and industrial cleaning products and the manufacturers of the ingredients and finished packaging used to bring these products to the marketplace. SDA is a leading manager of chemical consortia fulfilling commitments to the voluntary International Council of Chemical Associations (ICCA) and U.S. Environmental Protection Agency (EPA) high production volume (HPV) chemical programs.

1.1 Overview of Chemical Challenge Programs

US EPA HPV Challenge Program

The US EPA's Chemical Right-to-Know (RTK) Program is a comprehensive initiative designed to assure that adequate information is publicly available to assess risks for chemicals that are present in the local environments. The RTK Program was created in response to initial reports that many commercial chemicals have very little toxicity information publicly available or adequate for chemical risk assessment purposes (US EPA, 2000). One of the key components of the Chemical Right-to-Know Initiative is the EPA HPV Challenge Program (EPA HPV Program). The goal of this program is to ensure that a baseline set of health and environmental effects data on approximately 2,800 HPV chemicals is made available to EPA and the public (US EPA, 2000). HPV chemicals defined as those that are manufactured in, or imported into, the United States in amounts equal to or greater than one million pounds per year as reported in the year 1990.

The EPA HPV Program is a collaborative partnership whose goal is to ensure that the American public have access to the type of information that will allow it to actively participate in environmental decision making at all levels-federal, state, and local. U.S. manufacturers and importers of HPV chemicals were invited to voluntarily sponsor chemicals in the EPA HPV Program. Sponsorship entails the identification and initial assessment of the adequacy of existing information, the conduct of new testing only if adequate information does not exist, and making the new and existing test results available to the public. Any needed testing on the HPV chemicals in the EPA HPV Program was to be completed by 2004 with all data being made available by EPA to the public by 2005.

Companies can meet the requirements of the EPA HPV Program either directly through that program or indirectly through the OECD HPV SIDS Program and/or the International Council of Chemical Associations (ICCA) HPV Initiative, which is described in the next section.

ICCA HPV Chemical Initiative

The ICCA is the world-wide voice of chemical manufacturers and producers. In October of 1998, the ICCA started the global initiative on the hazard assessment of HPV chemicals and called on ICCA Member Federations and their companies to join. The goal of the ICCA HPV Chemical Initiative (ICCA HPV Program) was to complete hazard assessments on 1,000 HPV chemicals by the end of the year 2004 (ICCA, no date). HPV chemicals under the ICCA HPV Program are defined as those that are manufactured or imported in amounts equal to or greater

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than one million pounds per year globally. The chemical industry, in a partnership with the Organisation for Economic Co-operation and Development (OECD) and its member countries, was to provide harmonised, internationally agreed data on the intrinsic hazards of and initial hazard assessments for approximately 1,000 HPV substances by the end of 2004 as part of the OECD's refocused HPV Chemicals Program (ICCA, 2002). In the policy bodies of OECD, member countries discuss these assessments (at a Screening Information Data Set (SIDS) Initial Assessment Meeting (SIAM)) and agree on any follow-up actions on chemicals for which further work is recommended, and indeed, discuss and confirm all conclusions and recommendations made on all chemicals which have undergone SIDS initial assessments. When full SIDS dossiers and initial assessment reports are finalised, the results are made available worldwide through the United Nations Environment Programme (UNEP) Chemicals (OECD, no date).

Extended HPV (EHPV) Program

The EHPV program, announced in 2005, is a voluntary initiative developed by SDA, the American Chemistry Council (ACC) and the Synthetic Organic Chemical Manufacturers Association (SOCMA), intended to bring additional HPV chemicals into the process. The program identified chemicals produced in high volumes according to the 2002 TSCA Inventory Update but that were not HPVs in earlier inventory updates. As of May 12, 2006, industry sponsors have made commitments on 231 "new" HPV chemicals (ACC, 2005).

Baseline Data for HPV programs

The baseline set of health and environmental effects data encompassed by these programs are provided in Table 1.

Table 1 Baseline data for HPV programs

	Endpoint
Physical chemical	Melting point
	Boiling point
	Water solubility
	Partition coefficient
	Vapor pressure
Environmental fate	Photodegradation
	Fugacity
	Biodegradation
	Hydrolysis
Environmental effects	Acute toxicity to fish
	Acute toxicity to aquatic invertebrates
	Acute toxicity to aquatic plants
Mammalian toxicity	Acute toxicity
	Repeated dose toxicity
	Reproductive toxicity
	Developmental effects
	Bacterial mutagenicity
	Mammalian mutagenicity

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The SDA HPV Chemical Program submissions extended to data endpoints beyond those listed in Table 1 (see Table 2).

Table 2 Additional non-SIDS endpoints in SDA submissions to HPV programs

Endpoint	
Physical chemical	Density
	Surface tension
	Flash point
	Flammability/Auto-flammability
	Explosive/Oxidizing properties
	Dissociation constant
	Viscosity
Environmental fate	Stability in soil
	Monitoring data
	Field studies
	Distribution
	BOD5, COD or BOD5/COD ratio
	Bioaccumulation
Environmental effects	Toxicity to microorganisms
	Chronic toxicity to fish
	Chronic toxicity to aquatic invertebrates
	Toxicity to sediment dwelling organisms
	Toxicity to terrestrial plants
	Toxicity to soil dwelling organisms
	Toxicity to non-mammalian terrestrial species
Mammalian toxicity	Toxicokinetics, metabolism and distribution
	Skin irritation
	Eye irritation
	Sensitization
	Carcinogenicity
	Exposure experience

2 BACKGROUND ON SDA PARTICIPATION

US EPA HPV Challenge Program

SDA provided their commitments to the EPA HPV Program in March and November 1999. In the original commitments, nine SDA managed consortia were formed representing 126 chemicals and 12 companies. Currently, three of the SDA-managed chemical consortia (Alkoxides, LAS/ABS and Triclocarban) have been sponsored under the EPA HPV Program. It was (and is) SDA's intent to participate fully in this program using to the greatest extent possible the extensive existing data, the formation of scientifically defensible chemical categories and the minimization of animal testing. In addition to the EPA HPV Program requested hazard data,

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SDA also committed to developing exposure and risk data relevant to the use of these substances in consumer products, as appropriate, and to make this information available to the public in order to improve the public's understanding of chemical risks.

ICCA HPV Chemical Initiative

Seven of the SDA-managed chemical consortia (aliphatic acids, aliphatic alcohols, alkyl sulfates, amine oxides, glycerides, hydrotropes and methyl esters) have achieved "global consortium" status and sponsored their respective chemicals through the ICCA HPV Program to the OECD chemical screening program by bringing in chemicals that are HPVs in other regions (i.e., Japan, Europe) and companies from those regions. The result of formation of global consortia was that the commitment for sponsorship for these groups was switched from the EPA HPV Program to the ICCA HPV Initiative, and, was largely responsible for the originally committed 126 chemicals expanded to 291 sponsored chemicals and 62 companies between the two programs, requiring the integration of industry organizations and companies from Europe and Japan into the SDA consortia.

SDA also added to the commitments by considering chemicals that were produced in high volumes according to the 2002 TSCA Inventory Update but were not HPVs in earlier inventory updates. As a result, two "new" HPV substances were added to the aliphatic alcohols category commitment; nine were added to the aliphatic acids category; and three were added to the alkyl sulfates category.

2.1 SDA Approach for Fulfilling Commitments

The sponsorship of chemicals under the HPV Programs entailed assembling and reviewing available public and private data (physical-chemical, environmental fate, ecological effects and mammalian toxicity), developing and providing assessment plans for the sponsored chemicals, and, where necessary, conducting additional research, including testing.

SDA's extended commitment to compile and make publicly available a baseline set of health and environmental effects data covers 291 chemicals sponsored by ten U.S. and global HPV chemical consortia that SDA manages.

In order to handle the volume of data expected to be associated with the 291 chemicals, SDA entered into contracts with consulting organizations in order to more quickly achieve the goals of the HPV Programs. These consultants provided expert assistance in the collation, summarization and review of reports, and production of assessment plans based on the available data.

The impact of expanding EPA HPV Program commitments to global consortia, as well as the switch to ICCA HPV Program commitments, was significant, and was a much more time consuming process than envisioned when commitments were originally made to the Challenge Program:

- SDA expanded these consortia to include interested companies and their industry organizations in Europe and Japan in the consortia that were interested in supporting work on the committed chemicals. An outreach was undertaken to identify companies in these regions that might produce the substances that fit into the chemical categories.

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- Chemicals that were HPV chemicals in those OECD regions were nominated by companies in these regions, requiring an assessment as to whether or not they fit structurally and toxicologically into the sponsored chemical categories.
- All added chemicals required data call-ins and literature searches to identify available information. Several of the consortia had multiple data call-ins as the categories were opened up to take in chemicals from Europe and Japan.
- While work on all the chemicals started in nearly the same timeframe, many companies were tied to multiple commitments requiring the pace of the work to be managed very deliberately. Work was targeted to progress more quickly for those consortia where there was direct consumer exposure to sponsored chemicals.
- Under the OECD program, negotiations needed to be held with OECD member countries to gain the support of a member country to sponsor the chemicals through the OECD review process. In addition, the sponsor country needed to review all aspects of the work.
- Under the OECD program, OECD members review the work and adopt recommendations in a formal meeting, requiring six or more months from the time that sponsor countries agree to submit the documents for review to the time that their review is completed.

In addition, SDA added commitments for 14 chemicals that were produced in high volumes according to the 2002 TSCA Inventory Update but were not HPVs in earlier inventory updates.

2.2 Exposure and risk screening methods development

As part of its expanded commitment, SDA developed processes and tools for handling use and exposure information in exposure assessments and risk assessments. The consumer products industry has exposure information and screening methods that can be of value in putting HPV chemical hazard data into an exposure perspective and thereby facilitate prioritization of chemicals for further evaluation if appropriate.

In 2005, SDA published a document entitled "Exposure and Risk Screening Methods for Consumer Product Ingredients".[1] The main purpose of this document is to present methodologies and specific consumer exposure information that can be used for screening-level risk assessments of environmental and repeated human exposures to HPV chemicals through the manufacturing and use of consumer products, mainly laundry, cleaning, and personal care products. However, the approach can be applied to other consumer products when information on how consumers use the products is available. These methodologies allow hazard information to be put into context by using exposure information to characterize risk. Screening-level risk assessments are useful for prioritizing the need for further work. The screening exposure and risk characterization outputs from the application of this methodology can help focus resources to develop more refined risk assessments where such refinement is needed, and assist in deciding where exposures/risks are of minimal concern and refined assessment is not warranted.

[1] http://www.cleaning101.com/files/Exposure_and_Risk_Screening_Methods_for_Consumer_Product_Ingredients.pdf

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2.3 Sponsorship of HPV Challenge chemicals in all programs

The number of chemicals and companies comprising the categories under the original commitments and currently in place are summarized in Table 3. Details of the progression of each category/chemical are provided in Sections 2.3.1 through 2.3.10. The number of chemicals and companies participating in the U.S. HPV Challenge program has remained stable over time. However, the seven consortia under the ICCA program have increased their commitments and levels of company participation dramatically.

Table 3 Summary of sponsored categories/chemicals

Category	Original Number of Chemicals	Current Number of Chemicals	Original Number of Companies	Current Number of Companies	Program
Aliphatic acids	55	86	8	25	ICCA
Aliphatic alcohols	19	30	5	19	ICCA
Alkoxides	15	17	3	3	US EPA
Alkyl sulfates	7	61	6	15	ICCA
Amine oxides	3	15	4	15	ICCA
Glycerides	16	30	6	20	ICCA
Hydrotropes	6	10	6	9	ICCA
LAS/ABS	9	9	7	4	US EPA
Methyl esters	19	32	6	15	ICCA
Triclocarban (TCC)	1	1	2	2	US EPA
Totals	150	291			

2.3.1 Aliphatic Acids

In March 1999, the Aliphatic Acids category was sponsored under the EPA HPV Program and included 55 chemicals and 8 companies. It became apparent that the interest in this chemistry was global, and the category over time expanded to include 86 chemicals, 25 companies in three world regions (USA, Europe and Japan), and two major industry organizations (SDA and the European Oleochemicals and Allied Products Group (APAG)). In all, 877 robust summaries have been prepared from existing data, and entered into the International Uniform Chemical Information Database (IUCLID), allowing for global review and sharing of data. No testing was needed for this group of chemicals; public and private data are readily available and sufficient to complete the hazard assessment and meet the needs of the HPV Program. Once the majority of the data was reviewed and summarized, SDA approached the Italian Competent Authorities (CA) and they agreed to serve as sponsor country in the OECD Program in June 2005. SDA is working with the Italian CA to present the Aliphatic Acids category at the spring 2009 SIAM.

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2.3.2 Aliphatic Alcohols (Long Chain Alcohols)

In March 1999, the Aliphatic Alcohols category was sponsored under the EPA HPV Program and included 19 chemicals and 5 companies. It became apparent that the interest in this chemistry was global, and the category ultimately expanded to include 30 chemicals, 19 companies, in three world regions (USA, Europe and Japan), and two major industry associations (SDA and APAG). In all, approximately 1400 robust summaries have been prepared from existing data, allowing for global review and sharing of data. Only very limited testing was needed for this group of chemicals (i.e., two acute aquatic toxicity tests and four chronic daphnia reproduction tests. Note: The chronic daphnia studies go beyond the requirements of the HPV Challenge Program); public and private data were readily available and sufficient to complete the hazard assessment and meet the needs of the HPV Program. The aliphatic alcohols also were assessed in the SDA screening-level methodologies development to assist in priority setting by integrating exposure information along with the HPV hazard data to characterize risks posed by exposures (SDA, 2005). The United Kingdom CA served as sponsor country in the OECD Program and the category was presented, discussed and agreed to at the April 2006 SIAM (http://www.oecd.org/document/63/0,2340,en_2649_34379_1897983_1_1_1_37465,00.html). In addition to completing the HPV commitment for this group of chemicals, SDA and APAG also have prepared five manuscripts on long chain aliphatic alcohols that will be published by the journal *Ecotoxicology and Environmental Safety* and will cover: a review of the OECD submission, physical/chemical properties, aquatic chronic toxicity, human health risk assessment, and environmental risk assessment. This latter activity is intended to increase global awareness of the availability of the data for this category and gain additional peer review.

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2.3.3 Alkoxides

The Alkoxides category was formed as an offshoot from the Aliphatic Alcohols category, and is sponsored under the EPA HPV Program. The Alkoxides category includes 17 chemicals and three companies. In all, 1,195 robust summaries have been prepared or compiled from existing data, allowing for global review and sharing of data. No testing is needed for this group of chemicals; public and private data are readily available and sufficient to complete the hazard assessment and meet the needs of the HPV Program. SDA submitted the initial assessment plan to EPA in April 2008 (http://www.epa.gov/hpv/pubs/summaries/almalkct/c16706tc.htm).

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2.3.4 Alkyl Sulfates, Alkane Sulfonates, Alpha Olephin Sulfonates (Anionic Surfactants)

In March 1999, the Anionic Surfactants category was sponsored under the EPA HPV Program and included 7 chemicals and 6 companies. It became apparent that the interest in this chemistry

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was global, and the category ultimately expanded as the Alkyl Sulfates category and included 21 chemicals, 15 companies in three world regions (USA, Europe and Japan), and two major industry organizations (SDA and Comite Europeen Des Agents de Surface et de Leurs Intermediaries Organiques (CESIO)). In all, greater than 1,300 robust summaries have been prepared from existing data, allowing for global review and sharing of data. No testing is needed for this group of chemicals; public and private data are readily available and sufficient to complete the hazard assessment and meet the needs of the HPV Program. Alkyl sulfates also were assessed in the SDA screening-level methodologies development to assist in priority setting by integrating exposure information along with the HPV hazard data to characterize risks posed by exposures (SDA, 2005). The German CA served as sponsor country in the OECD Chemicals Program and the category was presented during the October 2007 SIAM where a number of supporting chemicals were included in the final dossier bringing the total to 61 chemicals.

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2.3.5 Amine Oxides

In March 1999, the Amine Oxides category was sponsored under the EPA HPV Program and included 3 chemicals and 4 companies. It became apparent that the interest in this chemistry was global, and the category ultimately expanded to include 15 chemicals, 15 companies in three world regions (USA, Europe and Japan), and two major industry organizations (SDA and CESIO). In all, 180 robust summaries have been prepared from existing data, allowing for global review and sharing of data. No testing was needed for this group of chemicals; public and private data were readily available and sufficient to complete the hazard assessment and meet the needs of the HPV Program. The amine oxides were also assessed in the SDA screening-level methodologies development to assist in priority setting by integrating exposure information along with the HPV hazard data to characterize risks posed by exposures (SDA, 2005). The US agreed to serve as sponsor country in the OECD Chemicals Program and the Amine Oxides category was presented, discussed and agreed to at the April 2006 SIAM (http://www.oecd.org/document/63/0,2340,en_2649_34379_1897983_1_1_1_37465,00.html). In addition to completing the commitment for this group of chemicals, SDA published a manuscript on the human safety of amine oxides (Sanderson et al., 2005). The goal of this publication was to raise awareness of the public availability the exposure scenarios, exposure equations and appropriate parameters regarding habits and practices data relevant to this category of chemicals. SDA is currently preparing a manuscript on the environmental risk assessment of amine oxides.

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2.3.6 Glycerides

In March 1999, the Glycerides category was sponsored under the EPA HPV Program and includes 16 chemicals and 6 companies. It became apparent that the interest in this chemistry

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was global, and the category ultimately expanded to include 30 chemicals, 20 companies in three world regions (USA, Europe and Japan), and four major industry groups (SDA, APAG, CESIO and the Japan Chemical Industry Association (JCIA)). When completed, 275 robust summaries will have been prepared from existing data, allowing for global review and sharing of data. No testing was needed for this group of chemicals; public and private data are readily available and sufficient to complete the hazard assessment and meet the needs of the HPV Program. A sponsor country has not yet been established. SDA is working closely with the consultants preparing the documents and has targeted a schedule to present the category at the fall 2009 SIAM.

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2.3.7 Hydrotropes

In March 1999, the Hydrotropes category was sponsored under the EPA HPV Program and included six chemicals and six companies. Interest in this chemistry was global, and the category ultimately expanded to include ten chemicals and nine companies in two world regions (USA and Europe), and two major industry groups (SDA and CESIO). In all, 125 robust summaries were prepared from existing data, allowing for global review and sharing of data. No animal testing was needed for this group of chemicals; a vapor pressure study was conducted on a single category member. Public and private data were readily available and sufficient to complete the hazard assessment and meet the needs of the HPV Program. Hydrotropes also were assessed in the SDA screening-level methodologies development to assist in priority setting by integrating exposure information along with the HPV hazard data to characterize risks posed by exposures (SDA, 2005). Australia agreed to serve as sponsor country in the OECD Chemicals Program and the Hydrotropes category was presented, discussed and agreed to at the October 2005 SIAM (http://www.chem.unep.ch/irptc/sids/OECDSIDS/Hydrotropes.pdf). Also, SDA has prepared a manuscript for publication entitled "Assessment of the Environmental Risk of Hydrotropes via Industrial and Consumer Use Modeling in the United States, Europe and Australia" in order to raise awareness of the public availability the exposure scenarios, exposure equations and appropriate parameters regarding habits and practices data relevant to this category of chemicals.

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2.3.8 Linear and Branched Alkylbenzene Sulfonic Acids and Derivatives (LAS/ABS)

In November, 1999, the Linear and Branched Alkylbenzene Sulfonic Acids and Derivatives (LAS/ABS) category was sponsored under the EPA HPV Program and included 9 chemicals and 7 companies (http://www.epa.gov/chemrtk/pubs/summaries/alkybenz/c14187tc.htm). In all, 192 robust summaries were prepared from existing data, allowing for global review and sharing of data. No testing was needed for this group of chemicals; public and private data were readily available and sufficient to complete the hazard assessment and meet the needs of the HPV Program. Key to avoiding testing for this category of chemicals was a decision in the initial test

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plan to defer completion of the assessment until work on a category of similar substances (Linear Alkylbenzene Sulfonate under the OECD Program) had been reviewed by OECD. The initial test plan and set of robust summaries was submitted to EPA in December 2002. SDA submitted a revised final test plan and robust study summaries to EPA in April 2008 which addressed the comments of EPA and two environmental organizations.

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2.3.9 Methyl Esters

In March, 1999, the Methyl Esters category was sponsored under the EPA HPV Program and included 19 chemicals and 6 companies. It became apparent that the interest in this chemistry was global, and the category ultimately expanded to include 32 chemicals, 15 companies in three world regions (USA, Europe and Japan), and two major industry groups (SDA and APAG). When completed, more than 500 robust summaries will have been prepared from existing data, allowing for global review and sharing of data. No testing was needed for this group of chemicals; public and private data are readily available and sufficient to complete the hazard assessment and meet the needs of the HPV Program. A sponsor country has not yet been established. SDA is working closely with the consultants preparing the documents and has targeted a schedule to present the Methyl Esters category at the fall 2009 SIAM.

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2.3.10 Triclocarban

In November, 1999, Triclocarban (TCC) was sponsored under the EPA HPV Program, involving two companies (http://www.epa.gov/chemrtk/pubs/summaries/tricloca/c14186tc.htm). In all, 102 robust summaries were prepared from existing data, allowing for global review and sharing of data. The only testing needed for this chemical was a single vapour pressure study; public and private data were readily available and sufficient to complete the hazard assessment and meet the needs of the HPV Program. The EPA review of the assessment plan is complete, and SDA submitted the final assessment plan in May 2006. In March 2008, EPA posted its hazard characterization of Triclocarban.
(http://www.epa.gov/hpvis/hazchar/101202_Triclocarban_HC_INTERIM_March%202008.pdf)

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2.3.11 Conclusion

SDA's extended commitment to compile and make publicly available a baseline set of health and environmental effects data covers 291 chemicals. Submission began in 2005, and will continue in 2008 (see Table 4).

Table 4 Cumulative progression of SDA completed commitments by year

Year	Cumulative No. of completed chemical commitments
2005	10
2006	56
2007	117
2008	143
2009	291 (projected)

3 FUTURE WORK

SDA will continue to progress towards completion the extended commitment to compile and make publicly available a baseline set of health and environmental effects data for the 291 chemicals sponsored by ten U.S. and global HPV chemical consortia that SDA manages. Table 5 provides an overview of the status of each of the ten consortia in the respective HPV programs.

Table 5 Status of sponsored categories/chemicals

Category (No. of chemicals)	Program	No. of robust study summaries	Number of new studies conducted	Completion Status
Aliphatic acids (86)	ICCA	877	0	Spring 2009 SIAM (Projected)
Aliphatic alcohols (30)	ICCA	<1400	6 acute and chronic aquatic toxicity tests	Finished/SIAM April 2006
Alkoxides (17)	US EPA	1195	0	Draft to EPA April 2008
Alkyl sulfates (61)	ICCA	>1300	0	Finished/SIAM October 2007
Amine oxides (15)	ICCA	180	0	Finished/SIAM April 2006
Glycerides (30)	ICCA	275	0	Fall 2009 SIAM (Projected)
Hydrotropes (10)	ICCA	125	1 vapor pressure test	Finished/SIAM October 2005
LAS/ABS (9)	US EPA	192	0	Final to EPA April 2008
Methyl esters (32)	ICCA	>500	0	Fall 2009 SIAM (Projected)
Triclocarban (TCC) (1)	US EPA	102	1 vapor pressure test	Finished/May 2006

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The number of robust study summaries compiled across the SDA consortia commitments total over 6,100, with it being necessary to conduct only 8 new tests (about 0.13% of the total number of summaries).

SDA endorses future work on HPV chemicals proceeding on a volunteer basis, with sufficient flexibility to allow various approaches for improving the availability of information on HPV chemicals to be implemented. As SDA and the consortia managed by SDA consider future work, it is recognized that each individual company would make its own decision, reflecting the circumstances of each company.

4 CONCLUSIONS

From the outset, SDA extended its commitment to the US EPA Challenge Program and the ICCA HPV Chemical Initiative beyond the basic industry voluntary commitments by volunteering to not only compile hazard data on sponsored HPV chemicals, but also compile and utilize use and exposure information. As a result of the cleaning products industry's decades of stewardship, SDA was convinced that the inclusion of exposure information in HPV chemical datasets would allow for a much more informed decision on whether or not further work is needed on a chemical. Hazard information viewed in the context of exposure information allows that decision to be made in a risk context so that hazard data can be placed in a risk context.

SDA's extended commitment to compile and make publicly available a baseline set of health and environmental effects data and use and exposure information covers 291 chemicals sponsored by 62 companies within ten U.S. and ICCA HPV chemical consortia that SDA manages.

SDA gained peer review of information sets and those going through ICCA initiative gained multi-country/regional review leading to the availability of globally recognized data sets, thus promoting global harmonization.

In the process of meeting the commitments, SDA and its consortia committed to resources to share experiences in dosing this type of work so that it could inform the global knowledge base that has grown over this time frame. Specifically, SDA participated with the OECD during a meeting on developing guidance for the use of chemical categories under the ICCA HPV Challenge program. SDA presented the methodology proposed for the environmental hazard assessment for the aliphatic alcohols. Participation in their meeting ensured that SDA's approach to category development as well as the approach adopted by the OECD was done in combination with OECD and the public.

Data submissions under the US EPA Challenge Program and the ICCA HPV Chemical Initiative demonstrate that a wealth of environmental and human safety information had already been developed for cleaning product ingredients, virtually eliminating any need for new testing and dispelling the perception that fundamental safety data were lacking on these materials.

At the outset of the US EPA Challenge Program and the ICCA HPV Chemical Initiative there was a widely held presumption that because hazard and exposure information was not readily available to the public, such data did not exist. This called into question industry stewardship of the chemicals it produced and formulated into cleaning products. Consistent with this

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presumption was another widely held belief that many tests would have to be performed to develop basic hazard information on HPV chemicals.

However, through the global collaboration of producers and users of cleaning product chemicals, a wealth of existing in-house hazard data is being made available through the HPV datasets being compiled and placed into the public domain by SDA and its consortia. In fact, over 6,100 study summaries were prepared based on existing hazard data. The HPV Chemical Challenge provided an opportunity for SDA's members to make chemical safety information publicly available for the first time; often, publishing studies with negative results is not feasible through peer-reviewed scientific journals and related media.

Although the compilation of hazard data on a global basis required additional time, there has been only a very limited need for new testing. This is consistent with US EPA's December 1, 2004 report on its HPV Challenge Program. Less than 10% of endpoints for chemicals in the program required new studies. This demonstrates that the needed hazard data have been in the hands of ingredient producer and formulator companies. Furthermore, through the use of SAR analysis, QSAR models and "read-across" data from similar supporting chemicals made additional animal testing unnecessary.

SDA developed and applied tools to facilitate the assessment of human and environmental exposures to HPV chemicals used in cleaning products, which greatly improves decision-making. Specifically, SDA developed a "tool kit" of screening level exposure methods to compliment the hazard information that is compiled under the US HPV Challenge program and the ICCA HPV Chemical Initiative. These tools allow a screening level exposure assessment and risk characterization to be performed for a wide variety of consumer uses of these chemicals to assist in making a much more informed decision on whether or not further work is needed on a chemical. These tools are available to all stakeholders and interested parties.

SDA's commitment to address HPV chemicals has extended beyond chemicals identified as HPV in 1990 to include 14 "new" HPV chemicals. SDA identified chemicals used in cleaning products that reached HPV thresholds for the first time in the 2002 EPA IUR update. Through the work of the ten consortia SDA manages, 14 of these "new" chemicals have been taken up as sponsored chemicals. As with SDA's original commitment, both hazard and exposure information will also be compiled for these chemicals.

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