Supporting Documents for Initial Risk-Based Prioritization of High Production Volume Chemicals

4-Methyl-2-pentanol (CAS No. 108-11-2) (Methyl isobutyl carbinol, MIBC)

Contents:

- Page 2: Background
- Page 4: Screening-Level Risk Characterization: July 2008
- Not Attached: Screening-Level Hazard Characterization: OECD SIDS Initial Assessment Report, 10/18-21/2005

http://www.chem.unep.ch/irptc/sids/OECDSIDS/108112.pdf

<u>Note</u>: OECD SIDS Initial Assessment Profiles (SIAP) and SIDS Initial Assessment Reports (SIAR) are publicly available through the United Nations Environmental Programme website. These documents are presented in an international forum that involves review and endorsement by governmental authorities around the world. The U.S. EPA is an active participant in these meetings and accepts these documents as reliable screening-level hazard assessments for the purpose of the U.S. HPV Challenge qualitative risk characterization process.

• Page 9: Screening-Level Exposure Characterization: July 2008

BACKGROUND

Screening-level hazard, exposure and risk characterizations for high production volume chemicals (HPV) are important contributions to the chemicals cooperation work being done in North America¹ through the EPA Chemical Assessment and Management Program (ChAMP)². These screening-level characterizations are developed by EPA for individual chemicals or chemical categories to support initial Risk-Based Prioritizations (RBPs) for HPV chemicals. These screening-level characterizations are technical documents intended primarily to inform the Agency's internal decision-making process. Accordingly, they are written for assessment professionals and assume a degree of technical understanding. Each of the support documents is described below.

The Risk-Based Prioritizations are found in an accompanying document and are written for a general audience. They present EPA's initial thinking regarding the potential risks presented by these chemicals and future possible actions that may be needed.

Hazard Characterizations for HPV Chemicals

EPA's screening-level hazard characterizations are based primarily on the review of the summaries of studies and other information submitted by the chemical sponsor(s) under the HPV Challenge Program³. These studies included in the scope of the HPV Challenge comprise the Screening Information Data Set (SIDS) of the Organization for Economic Cooperation and Development (OECD)⁴, an internationally recognized battery of tests that provides the basic data necessary to make an initial evaluation of a chemical's hazards and fate. In preparing the initial hazard characterizations, EPA also consulted a variety of reliable sources⁵ for additional relevant information and considered its own comments and public comments on the original submission as well as the sponsor's responses to comments and revisions made to the submission. In order to determine whether any new hazard information was developed since the time of an HPV submission, EPA also searched publicly available databases⁶ for information entered from one year prior to the HPV submission through May 2008. The screening-level hazard characterization is performed according to established EPA guidance⁷. A more detailed description of the hazard characterization process is available on the EPA website⁸.

With respect to chemicals for which internationally-accepted OECD SIDS Initial Assessment Profiles (SIAP) and Initial Assessment Reports (SIAR) were available, EPA did not generate its own screening-level hazard characterization, but did check for and incorporate updated information in the risk characterization.

Exposure Characterizations for HPV Chemicals

EPA recently received exposure-related data on chemicals submitted in accordance with the requirements of Inventory Update Reporting (IUR)⁹. The 2006 IUR submissions pertain to chemicals manufactured in

¹ U.S. EPA – U.S. Commitments to North American Chemicals Cooperation: http://www.epa.gov/hpv/pubs/general/sppframework.htm.

² U.S. EPA – ChAMP information: http://www.epa.gov/champ/.

³ U.S. EPA – HPV Challenge Program information: http://www.epa.gov/hpv.

⁴ U.S. EPA – Technical Guidance Document, OECD SIDS Manual Sections 3.4 and 3.5: http://www.epa.gov/chemrtk/pubs/general/sidsappb.htm.

⁵ U.S. EPA – Public Database Hazard Information: http://www.epa.gov/hpvis/hazardinfo.htm.

⁶ U.S. EPA – Public Database Update Information: http://www.epa.gov/chemrtk/hpvis/updateinfo.htm.

⁷ U.S. EPA – Risk Assessment Guidelines: http://cfpub.epa.gov/ncea/raf/rafguid.cfm.

⁸ U.S. EPA – About HPV Chemical Hazard Characterizations: http://www.epa.gov/hpvis/abouthc.htm.

⁹ U.S. EPA – Basic IUR Information: http://www.epa.gov/opptintr/iur/pubs/guidance/basic-information.htm.

(including imported into) the U.S. during calendar year 2005 in quantities of 25,000 pounds or more at a single site. The reports include the identity, the quantity, and the physical form of the chemical manufactured or imported, and the number of workers reasonably likely to be exposed during manufacture of the chemical. For chemicals manufactured or imported in quantities of 300,000 pounds or more at a single site, additional reported information includes: the industrial processing and uses of the chemical; the number of industrial processing sites and workers reasonably likely to be exposed to the chemical at those sites; the consumer and commercial uses of the chemical; and an indication whether the chemical was used in products intended for use by children under 14 years of age.

EPA's screening-level exposure characterizations are based largely on the information submitted under the IUR reporting, although other exposure information submitted to the Agency (for example, in HPV submissions) or readily available through a limited set of publicly accessible databases¹⁰ was also considered. The screening-level Exposure Characterizations identify a potential (high, medium, or low) that each of five populations – the environment, the general population, workers, consumers, and children – might be exposed to the chemical. In most cases, this potential doesn't address the quantity, frequency, or duration of exposure, but refers only to the likelihood that an exposure could occur.

In many instances EPA is not able to fully disclose to the public all the IUR exposure-related data reviewed or relied upon in the development of the screening-level documents because some of the material was claimed as confidential business information (CBI) when it was submitted to the Agency. These CBI claims do limit the Agency's ability to be completely transparent in presenting some underlying exposure and use data for chemicals in public documents. EPA does consider all data, including data considered to be CBI, in the screening-level exposure and risk characterization process, and endeavors whenever possible to broadly characterize supporting materials claimed as confidential in ways that do not disclose actual CBI.

Risk Characterizations for HPV Chemicals

EPA combines the information from the screening-level exposure characterization with the screening-level hazard characterization to develop a qualitative screening-level risk characterization, as described in the Agency's guidance on drafting risk characterizations¹¹. These screening-level risk characterizations are technical documents intended to support subsequent priority-setting decisions and actions by OPPT. The purpose of the qualitative screening-level risk characterization is two-fold: to support initial risk-based decisions to prioritize chemicals, identify potential concerns, and inform risk management options; and to identify data needs for individual chemicals or chemical categories.

These initial characterization and prioritization documents do not constitute a final Agency determination as to risk, nor do they determine whether sufficient data are available to characterize risk. Recommended actions reflect EPA's relative judgment regarding this chemical or chemical category in comparison with others evaluated under this program, as well as the uncertainties presented by gaps that may exist in the available data.

¹⁰ U.S. EPA – Summary of Public Databases Routinely Searched: http://www.epa.gov/chemrtk/hpvis/pubdtsum.htm.

¹¹ U.S. EPA – Risk Characterization Program: http://www.epa.gov/osa/spc/2riskchr.htm.

QUALITATIVE SCREENING-LEVEL RISK CHARACTERIZATION OF HIGH PRODUCTION VOLUME CHEMICALS

SPONSORED CHEMICAL

4-Methyl-2-pentanol (CAS No. 108-11-2) (Methyl isobutyl carbinol, MIBC)

July 2008

Prepared by

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QUALITATIVE SCREENING-LEVEL RISK CHARACTERIZATION FOR 4-Methyl-2-pentanol (CAS No. 108-11-2) (Methyl isobutyl carbinol, MIBC)

1. Physical-Chemical Properties and Environmental Fate

4-Methyl-2-pentanol (MIBC) is a liquid at room temperature. It has moderate water solubility and high volatility. It is highly mobile in soil and water systems. It is expected to photolyze slowly and biodegrade rapidly but not to hydrolyze. It is not persistent or bioaccumulative, and is rated P1 and B1 for persistence and bioaccumulation, respectively.

2. Hazard Characterization

This summary is based primarily on information compiled from the OECD SIDS Initial Assessment Profile (SIAP) and SIDS Initial Assessment Report (SIAR) on MIBC which are available publicly at the following URL operated by the United Nations Environment Programme: http://www.chem.unep.ch/irptc/sids/OECDSIDS/108112.pdf . These documents are presented in an international forum that involves review and endorsement by governmental authorities around the world. The U.S. EPA is an active participant in these meetings and accepts these documents as reliable screening-level hazard assessments for the purpose of the U.S. HPV Challenge qualitative risk characterization process. Thus, when such documents exist there is no need to generate a separate Hazard Characterization document. However, two other documents were consulted and used to compile this summary: (1) a recent (2003) Integrated Risk Information System (IRIS) review by EPA on methyl isobutyl ketone (MIBK, available at http://www.epa.gov/ncea/iris/subst/0173.htm) – a major mammalian metabolite of MIBC as noted below – and (2) a 2007 National Toxicology Program (NTP) cancer bioassay on MIBK which has become available since completion of the SIDS case (http://ntpapps.niehs.nih.gov/ntp_tox/index.cfm?fuseaction=ntpsearch.searchresults&searchterm=108-10-1).

Evaluation of the available aquatic toxicity data indicates the acute hazard to fish, aquatic invertebrates and aquatic plants is low.

Studies with experimental animals indicate that MIBC is of low acute toxicity by the oral and dermal routes of exposure. Acute exposures to high vapor concentrations cause general anaesthetic effects in animals. MIBC is slightly irritating to skin and moderately to severely irritating to the eye. A skin sensitization study in animals was negative.

MIBC has been shown to be metabolized first to methyl isobutyl ketone (MIBK) and then ultimately to 4-hydroxy-4-methyl-2-pentanone (HMP) in experiments with rats. Thus, both MIBK and HMP were used to assess the mammalian toxicity of MIBC. Repeated dose studies conducted with the parent compound and the two metabolites indicate that systemic toxicity is minimal with no organ-specific effects observed for either MIBC or MIBK and some limited organ toxicity following HMP exposure. In the HMP studies, rats (males only) showed kidney toxicity which is considered not relevant to humans. MIBC and HMP were not mutagenic to bacterial cells or in a mammalian cell cytogenetic assay. HMP was negative in an *in vitro*

chromosomal assay. As noted in IRIS, a range of genotoxicity tests with MIBK yielded mostly negative results.

MIBC did not show any effects on reproductive organs following repeated inhalation exposures. A two-generation inhalation study with MIBK showed no effects on reproduction or systemic toxicity at any concentration tested. There were no statistically significant effects in developmental/reproductive endpoints observed following high oral exposure to HMP in a combined repeated-dose/developmental/reproductive screening study. Developmental effects in mice and rats were observed following exposure to high doses of MIBK via inhalation; and this study was used to develop a chronic inhalation reference concentration (RfC) in the 2003 IRIS assessment.

The 2007 NTP report on MIBK showed some evidence (in the kidney of male rats and the liver of male and female mice) of carcinogenic activity in mice and rats following two years of exposure via inhalation. However, the pre-cancerous kidney lesions in male rats are "... characteristic of alpha2u-globulin accumulation in male rats..." [as noted by NTP]. A recent study reported findings supporting the hypothesis that MIBK induces alpha2u-globulin in male rats (Hard et al., Society of Toxicology Annual Meeting, 2008, Abstract 465). Hard et al., showed that MIBK-exposed male Fischer 344 rats had increases in the following kidney parameters: protein droplets, accumulation of alpha2u-globulin, and proliferation of kidney cells. These increases were seen in positive control male rats, but not in female rats. Thus, it is likely that the kidney tumors in the male rats observed in the MIBK cancer study are alpha2u-globulin mediated and so, in accordance with current EPA policy (http://cfpub.epa.gov/ncea/raf/recordisplay.cfm?deid=47531), are probably not relevant to humans. Finally, OPPT has reviewed the NTP study for the EPA Office of Air and Radiation and further explains these moderating factors (available at http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=EPA-HQ-OAR-2003-0028. In addition, the tumors of concern [liver tumors in mice] were seen at the highest tested dose (1800 ppm; or 7.5 mg/L) and are likely not a result of genotoxicity because most of the genotixicity assays yielded negative results.

Thus, using the 2005 US EPA Cancer Guidelines (http://www.epa.gov/ord/researchaccomplishments/cancer.html), these data show suggestive evidence for potential carcinogenicity.

Given the lack of specific target organ effects of concern from repeated exposures to MIBC or HMP (the ultimate metabolite formed following exposure to MIBC) the overall potential health hazard concern for MIBC is considered low. EPA considers the developmental effects and liver tumors in mice - both observed following exposure to extremely high doses of MIBK, a metabolite of MIBC – important but not enough to elevate the human health hazard concern level. This is because the doses that caused developmental effects in mice (3000 ppm) and liver tumors in mice (1800 ppm) are much higher than levels of MIBC that are possibly irritating to humans (50 ppm).

3. Exposure Characterization

MIBC has an aggregated production and/or import volume in the United States of 100 to 500 million pounds. Non-confidential IUR information indicates that the chemical is used as intermediate in manufacturing of other chemicals, solvent, flotation agent and lubricant.

Potential Exposures to the General Population and the Environment. It is likely that there would be some releases to water or air during manufacturing, processing and use. A search of additional relevant databases provided further information on releases of this chemical. This chemical was reported in an Organization for Economic Cooperation and Development (OECD) Screening Information Data Set (SIDS) report as being used in the production of lube oil additives, as flotation frother for treating copper ores and coal, and as solvent in surface coatings. Other reported uses from the Hazardous Substances Data Bank include the manufacture of lubricant additives, solvent for dyestuffs, oils, gums, resins, waxes, nitrocellulose, and in brake fluids. Based on the information considered -known uses and the Agency's expert judgment - EPA identifies a medium potential that the general population and the environment might be exposed to MIBC.

Potential Exposures to Workers. Based on the information considered including IUR data and selected data sources including the OECD Screening Information Data Set (SIDS) dossier, and in combination with the Agency's professional judgment, EPA identifies a high relative ranking for potential worker exposure to MIBC. This relative ranking is based primarily on the relatively high production volume, the potential for significant dermal exposure and inhalation exposures to vapor and mist by a large number of workers in commercial settings including auto repair shops and spray coating facilities, and the uncertainty regarding the commercial use information reported in the IUR submissions and the extent of use of personal protective equipment (PPE) at the commercial facilities. MIBC has an OSHA Permissible Exposure Limit (PEL) of 25 ppm as an eight hour time weighted average (TWA).

Potential Exposures to Consumers. Depending on the consumer product, there may be dermal and/or inhalation exposures to consumers from vapors, mists, or particulates. EPA identifies a high potential that consumers might be exposed through the use of products containing MIBC based on IUR data and information from public data sources that indicate this chemical is found in household products.

Potential Exposures to Children. No uses in products specifically intended to be used by children were reported in the IUR, nor were any found in other data sources. Exposures to children, however, may be expected to occur through the household use of some consumer products. EPA identifies a medium potential that children might be exposed to MIBC.

4. Risk Characterization

The statements and rationale provided below are intended solely for the purpose of this qualitative screening-level risk characterization and will be used for prioritizing substances for future work in the Chemical Assessment and Management Program (ChAMP).

Risk Statement and Rationale

Potential Risk to Aquatic Organisms from Environmental Releases (LOW CONCERN). EPA identifies a medium potential for exposure to aquatic organisms from environmental releases. MIBC has low persistence and low bioaccumulation. These characteristics in combination with the low acute toxicity for fish, invertebrates and aquatic plants suggest a low concern for potential risk to these organisms.

Potential Risk to the General Population from Environmental Releases (LOW CONCERN). EPA identifies a medium potential for exposure to the general population from environmental releases. The potential human health hazard is expected to be low. The low hazard and the environmental fate characteristics of low persistence and low bioaccumulation suggest a low concern for potential risk to the general population from environmental releases.

Potential Risk to Workers (LOW CONCERN). EPA identifies a high potential for worker exposure. The potential human health hazard is expected to be low. However, there is potential for skin and eye irritation and for narcosis at high concentrations. Adherence to the OSHA PEL will limit the exposure of workers. Therefore, taken together, the available information suggests a low concern for potential risk to workers.

Potential Risk to Consumers from Known Uses (LOW CONCERN). EPA identifies a high potential that consumers may be exposed. The potential human health hazard is expected to be low. There is potential for skin and eye irritation and for narcosis at high concentrations. To the extent that this chemical might be used as a solvent in consumer products, the hazard profile suggests reversible effects (irritation and possibly narcosis) that could occur if concentrations in such products were high. Taken together, however, the available information suggests a low concern for potential risk to consumers.

Potential Risk to Children (LOW CONCERN). EPA identifies a medium potential that children may be exposed. No uses in products specifically intended to be used by children were reported in the IUR, nor were any found in other data sources. Exposures to children, however, may be expected to occur through the household use of some consumer products. The available animal hazard data suggest a low hazard due to the lack of any specific toxicity in postnatally exposed animals following exposures to high doses. Taken together, the available information suggests a low concern for potential risk to children.

Screening Level Exposure Characterization for HPV Challenge Chemical

4-Methyl-2-Pentanol

CAS # 108-11-2

July 2008

Prepared by

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Screening Level Exposure Characterization 4-Methyl-2-Pentanol (CAS #108-11-2)

Non-CBI Executive Summary

This draft exposure characterization was completed using both public, non-confidential sources, and one or more IUR submissions that were available as of this writing. 4-Methyl-2-Pentanol (CAS #108-11-2) has an aggregated production and/or import volume in the United States of 100 to 500 million pounds¹². Non-confidential IUR information indicates that the chemical is used as intermediate in manufacturing of other chemicals, solvent, flotation agent and lubricant.

Potential Exposures to the General Population and the Environment. It is likely that there would be some releases to water or air during manufacturing, processing and use. A search of additional relevant databases provided further information on releases of this chemical. This chemical was reported in an Organization for Economic Cooperation and Development (OECD) Screening Information Data Set (SIDS) report as being used in the production of lube oil additives, as flotation frother for treating copper ores and coal, and as solvent in surface coatings. Persistence and bioaccumulation ratings for this chemical are Pland B1. These ratings suggest that this chemical is not very persistent in the environment; and is not very bioaccumulative. Other reported uses from the Hazardous Substances Data Bank include the manufacture of lubricant additives, solvent for dyestuffs, oils, gums, resins, waxes, nitrocellulose, and in brake fluids. Based on the information considered – known uses and the Agency's expert judgment – EPA identifies a medium potential that the general population and the environment might be exposed to 4-Methyl-2-Pentanol.

Potential Exposures to Workers. Based on the information considered including IUR data and selected data sources including the OECD Screening Information Data Set (SIDS) dossier, and in combination with Agency's professional judgment, EPA identifies a high relative ranking for potential worker exposure. This relative ranking is based primarily on the relatively high production volume, the potential for significant dermal exposure and inhalation exposures to vapor and mist by a large number of workers in commercial settings including auto repair shops and spray coating facilities, and the uncertainty regarding the commercial use information reported in the IUR submissions and the extent of use of personal protective equipment (PPE) at the commercial facilities. 4-Methyl-2-Pentanol has an OSHA Permissible Exposure Limit (PEL) of 25 ppm time weighted average (TWA).¹⁵

¹² USEPA, 2006. Confidential Inventory Update Reporting Database.

¹³ OECD, 2007. Organization for Economic Cooperation and Development. http://www.chem.unep.ch/irptc/sids/OECDSIDS/108112.pdf. Accessed, 4/4/08.

¹⁴ HSDB, 2008. Hazardous Substances Data Bank. Accessed, 4/4/08. 4-Methyl-2-Pentanol. http://toxnet.nlm.nih.gov/.

¹⁵ OSHA, 2008. Table Z-1 LIMITS FOR AIR CONTAMINANTS http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=9992.

Potential Exposures to Consumers. Depending on the consumer product, there may be dermal and/or inhalation exposures to consumers from vapors, mists, or particulates. EPA identifies a high potential that consumers might be exposed to 4-Methyl-2-Pentanol based on IUR data and information from public data sources that indicate this chemical is found in household products.

Potential Exposures to Children. No uses in products specifically intended to be used by children were reported in the IUR, nor were any found in other data sources. Exposures to children, however, may be expected to occur through the household use of some consumer products. EPA identifies a medium potential that children might be exposed to 4-Methyl-2-Pentanol.

Volume and Use Information

4-Methyl-2-Pentanol (CAS #108-11-2) has an aggregated production and/or import volume in the United States of 100 to 500 million pounds. Non-confidential information in the Inventory Update Rule (IUR) indicates that this chemical was manufactured and/or imported at the following companies and sites: Shell Chemical LP, Deer Park, TX; Petrochem Americas LLC, Plano, TX; Celanese, Dallas, TX; and Union Carbide Corporation, Institute, WV. There may be other companies and sites that are claimed confidential. Persons submitting IUR information for 2005 asserted that some or all of the information was confidential. Only non-confidential information reported in IUR is included in this summary.

The IUR submissions include a variety of industrial processing and uses. The non-confidential industrial processing and uses are listed in Table 1 at the end of this summary. The IUR submissions also include several commercial and consumer uses. These uses are listed in detail in Table 2 at the end of this summary.

An Organization for Economic Cooperation and Development (OECD) Screening Information Data Set (SIDS) dossier has been prepared for this chemical.¹⁷ SIDS report states that the chemical is used in the production of lube oil additives, as flotation frother for treating copper ores and coal, and as solvent in surface coatings.

The Hazardous Substances Data Bank indicates that major uses of 4-Methyl-2-Pentanol include the manufacture of lubricant additives, solvent for dyestuffs, oils, gums, resins, waxes, nitrocellulose, and in brake fluids.¹⁸

Exposures to Workers

Based on the totality of the information considered including IUR data and information from HSDB, SIDS report, and in combination with Agency's professional judgment, EPA identifies, for the purpose of risk-based prioritization, a high relative ranking for the potential worker

¹⁶ USEPA, 2006. Confidential Inventory Update Reporting Database.

¹⁷ OECD, 2007. Organization for Economic Cooperation and Development. http://www.chem.unep.ch/irptc/sids/OECDSIDS/108112.pdf. Accessed, 4/4/08.

¹⁸ HSDB, 2008. Hazardous Substances Data Bank. Accessed, 4/4/08. 4-Methyl-2-Pentanol. http://toxnet.nlm.nih.gov/.

exposure. This relative ranking is based primarily on the relatively high production volume, the potential for significant dermal exposure and inhalation exposures to vapor and mist by a large number of workers in commercial settings including auto repair shops and spray coating facilities, the uncertainty regarding the commercial use information reported in the IUR submissions, and the extent of use of personal protective equipment (PPE) at the commercial facilities. The ranking takes into consideration the likelihood that workers in most manufacturing and industrial processing and use activities would wear adequate personal protective equipment due to the corrosive and irritant nature of the chemical, the possibility that the chemical, due to its flammable characteristics, would be handled under well-controlled systems (e.g. nitrogen blanket), and the assumption that manufacturing, industrial processing and use facilities would adhere to the OSHA PEL.

Summary of Parameters affecting Worker Exposure

Parameter		
Volume *	100-500 million lbs	
Physical Form(s) *	Claimed to be confidential	
Vapor Pressure	5.3 torr	
Concentration *	up to 100 percent	
Number of Industrial Workers *	more than 1,000	
Uses *	Intermediate, solvent in coatings and other	
	formulation, flotation frother, brake fluid	
MSDS Info	Flammable, corrosive	
Other hazard characteristics	e.g. reactivity	

^{*} Only non-confidential IUR data are included

Based on IUR data, the maximum total number of workers reasonably likely to be exposed to this chemical during manufacturing and industrial processing and use may be 1,000 or greater. There may be additional potentially exposed industrial workers that are not included in this estimate since not all submitters were required to report on industrial processing and use and/or there is at least one use that contains a "Not Readily Obtainable" (NRO) response among the submissions. This estimate does not include the number of potentially exposed commercial workers which is generally assumed to be high. The National Occupational Exposure Survey (NOES), conducted from 1981 to 1983, estimated a total of 26,405 workers potentially exposed to this chemical. Differences between numbers of workers estimated by IUR submitters and by the NOES are attributable to many factors, including time, scope, and method of the estimates. For example, NOES estimates are for all workplaces while IUR are for industrial workplaces only, and NOES used a survey and extrapolation method while IUR submitters simply provide their best estimates based on available information for the specific reporting year.

Based on IUR data, the physical state of manufactured chemical is confidential. Also, the non-confidential maximum concentration is up to 100%. This chemical has a vapor pressure of 5.3

¹⁹ NIOSH, 1983. National Occupational Exposure Survey (NOES, 1981-1983). Accessed, 4/4/08. http://www.cdc.gov/noes/srch-noes.html.

torr. This chemical's vapor pressure could result in significant worker exposures to vapors. In addition to the potential inhalation exposure to vapor, there may be potential exposure to mist during the spray coating operations. Additional information on worker exposure is available in the HSDB²⁰ and the SIDS dossier²¹.

This chemical has an OSHA Permissible Exposure Limit (PEL) of 25 ppm time weighted average (TWA). ²²

Environmental Releases

Environmental releases may impact general population and environmental exposures. Factors affecting releases include volumes produced, processed and used; numbers of sites; and, processes of manufacture, processing, and use.

The following release statements are made based on inferences regarding the non-confidential use information reported in IUR and summarized in Tables 1 and 2.

Many chemicals processed as a reactant have industrial releases that are a relatively low percentage of the volume associated with this use. Lower percentage releases occur when a high percentage of the chemical reacts without excess loss during its use as a reactant. The actual percentage and quantity of release of the reported chemical associated with this processing or use are not known.

Many chemicals processed as a product component have industrial releases that are a relatively low percentage of the volume associated with this use. Lower percentage releases occur when a high percentage of the volume is incorporated without significant process losses during its incorporation into formulation, mixture, or product. The actual percentage and quantity of release of the reported chemical associated with this processing or use are not known.

Many chemicals repackaged in industrial processing have industrial releases that are a relatively low percentage of the volume associated with this use. Lower percentage releases occur when a high percentage of the chemical is repackaged without significant process losses during its repackaging. The actual percentage and quantity of release of the reported chemical associated with this processing or use are not known.

Many chemicals designated by IUR to have industrial use as chemical intermediates have industrial releases that are a relatively low percentage of the volume associated with this use. Lower percentage releases occur when a high percentage of the chemical reacts without excess loss during its use as an intermediate. The actual percentage and quantity of release of the reported chemical associated with this category is not known.

²⁰ HSDB, 2008. Hazardous Substances Data Bank. Accessed, 4/4/08. 4-Methyl-2-Pentanol. http://toxnet.nlm.nih.gov/.

²¹ OECD, 2007. Organization for Economic Cooperation and Development. http://www.chem.unep.ch/irptc/sids/OECDSIDS/108112.pdf. Accessed, 4/4/08.

http://www.chem.unep.ch/irptc/sids/OECDSIDS/108112.pdf. Accessed, 4/4/08.

22 OSHA, 2008. Table Z-1 LIMITS FOR AIR CONTAMINANTS

http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=9992.

Many chemicals designated by IUR to have industrial use as solvents for cleaning or degreasing have industrial and/ or end use releases that are a relatively high percentage of the volume associated with this use. Higher percentage releases occur when the chemical's intended use is as a solvent that may evaporate into the atmosphere or may be collected and disposed to aqueous media. In some cases, some engineering controls or capture for recycle or reclamation may reduce these losses. The actual percentage and quantity of release of the reported chemical associated with this category is not known but could be high.

Many chemicals designated by IUR to have industrial use as solvents in product formulations or mixtures have industrial and/ or end use releases that are a relatively high percentage of the volume associated with this use. Higher percentage releases occur when the chemical's intended use is as a solvent that may evaporate into the atmosphere or may be collected and disposed to aqueous media. In some cases, some engineering controls or capture for recycle or reclamation may reduce these losses. The actual percentage and quantity of release of the reported chemical associated with this category is not known but could be high.

Many chemicals designated by IUR to have industrial use as solvents for chemical manufacture and processing have industrial and/ or end use releases that are a relatively high percentage of the volume. Higher percentage releases occur when the chemical's intended use is as a solvent that may evaporate into the atmosphere or may be collected and disposed to aqueous media. In some cases, some engineering controls or capture for recycle or reclamation may reduce these losses. The actual percentage and quantity of release of the reported chemical associated with this use category is not known but could be high.

Chemicals designated by IUR to have industrial use as lubricants can have variable release percentages during industrial processing and use. The actual percentage and quantity of release of the reported chemical associated with this use category is not known.

Chemicals designated by IUR to have industrial use as "Not Readily Obtainable" can have variable release percentages during industrial processing and use. The actual percentage and quantity of release of the reported chemical associated with this use category is not known.

According to SIDS report, the chemical is used as a flotation frother for treating copper ores and coal and the IUR reports the chemical is used as a flotation agent. Many chemicals used as a flotation agent are used in aqueous processes and have releases to aqueous media. The actual percentage and quantity of release of the reported chemical associated with this category are not known.

Experience has shown that air releases due to volatilization have not been an issue for chemicals with vapor pressures below 0.01 torr. This chemical's vapor pressure of 5.3 torr could result in significant air releases.

Exposures to the General Population and the Environment

Based on the information under the release section above, it is likely that there would be some releases to water and/or air during manufacturing, processing, and uses such as solvents, intermediates, lubricants and flotation agents. A search of additional relevant databases provides further information on releases of this chemical. EPA identifies a moderate potential that the general population and the environment might be exposed to 4-Methyl-2-Pentanol. The IUR ranking for general population and the environment is medium due to the likelihood that there will be exposure to this chemical based on the use code listed as other under commercial/consumer products in the IUR data.

Persistence and bioaccumulation ratings for this chemical are P1 and B1. These ratings suggest that this chemical is not very persistent in the environment; and is not very bioaccumulative.

Based on the information considered, its potential to be released to water and/or air during manufacturing and processing; its' uses as a solvent, intermediate, lubricant and flotation agent and its low persistence and bioaccumulation, EPA identifies a moderate potential that the general population and the environment might be exposed to this chemical.

Exposures to Consumers

Consumer uses are included in IUR data, and none of these are claimed confidential. Table 2 at the end of this summary provides additional details.

EPA identifies a high potential that consumers might be exposed to this chemical based on their use of products containing this chemical.²⁴

There is also potential for exposure to consumers based on information from public data sources. This chemical can be used as solvent for dye, in oils, gums, resins, waxes, lubricant additives, and lacquers.²⁵ Potential exposure to consumers and children is likely from this airborne chemical when contained in a consumer product.²⁶

Depending on the consumer product, there may be dermal and/or inhalation exposures to consumers from vapors, mists, or particulates. EPA identifies a high potential that consumers might be exposed to this chemical based on IUR data and information from public data sources that indicate this chemical is airborne in consumer products.

²³ HSDB, 2008. Hazardous Substances Data Bank. Accessed, 4/4/08. 4-Methyl-2-Pentanol. http://toxnet.nlm.nih.gov/.

²⁴ USEPA, 2004. Source Ranking Database (SRD). Accessed, 4/4/08. http://www.epa.gov/opptintr/exposure/pubs/srd.htm.

²⁵ HSDB, 2008. Hazardous Substances Data Bank. Accessed, 4/4/08. 4-Methyl-2-Pentanol. http://toxnet.nlm.nih.gov/.

²⁶ USEPA, 2004. Source Ranking Database (SRD). Accessed, 4/4/08. http://www.epa.gov/opptintr/exposure/pubs/srd.htm.

July 2008

Exposures to Children

Persons submitting IUR information reported that children's use information is Not Readily Obtainable. Other data sources did not indicate any uses in children's products, either. EPA identifies, for the purposes of risk-based prioritization, that the potential for exposures to children from products containing this chemical is moderate because there is uncertainty in the IUR data.

Non Confidential IUR Data Summary

Manufacturing Information

Production (including import) volume: 100-500 million lbs List of non-CBI companies/ sites: Shell Chemical LP / TX

Union Carbide Corporation / WV

Celanese / TX

Petrochem Americas LLC / TX

Highest non-CBI maximum concentration: up to 100% Non-CBI physical forms: Liquid

Table 1 Industrial Processing and Use Information Reported in 2006 IUR Processing Industrial Function in				
Processing as a reactant	Other Basic Organic Chemical Manufacturing	Intermediates		
Processingincorporation into formulation, mixture, or reaction product	Other Basic Organic Chemical Manufacturing	Not Readily Obtainable		
Processingincorporation into formulation, mixture, or reaction product	Paint and Coating Manufacturing	Solvents (which become part of product formulation or mixture)		
Processingincorporation into formulation, mixture, or reaction product	All Other Chemical Product and Preparation Manufacturing	Flotation agents		
Processingincorporation into formulation, mixture, or reaction product	All Other Chemical Product and Preparation Manufacturing	Lubricants		
Processingincorporation into formulation, mixture, or reaction product	All Other Chemical Product and Preparation Manufacturing	Solvents (which become part of product formulation or mixture)		
Processingincorporation into formulation, mixture, or reaction product	Other Chemical and Allied Products Merchant Wholesalers	Solvents (for chemical manufacture and processing and are not part of product at greater than 1% by weight)		
Processingrepackaging	Other Basic Organic Chemical Manufacturing	Solvents (which become part of product formulation or mixture)		
Processingrepackaging	Other Chemical and Allied Products Merchant Wholesalers	Solvents (for cleaning or degreasing)		
Claimed confidential				

Table 2 Commercial/ Consumer Uses Information Reported in 2006 IUR				
Highest maximum concentration range	Use in Children's Products			
N/A	No			
N/A	NRO			