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PUBLIC COMMENT ON CERTAIN MEDIUM CHAIN CHLORINATED PARAFFINS
DECEMBER 15, 2020

Contents

EXECUTIVE SUMMARY

Performance Building Solutions (PBS) is a business unit of DuPont Specialty Products USA, LLC, (previously The Dow Chemical's Dow Building Solutions business). PBS appreciates the opportunity to submit our comments concerning potential actions by the ECHA regarding the use of medium-chain chlorinated paraffins (MCCPs).

DuPont believes in providing society with sustainable products and agrees that proper handling and disposal of chemicals is an important environmental issue. As a Responsible Care® company, DuPont is committed to using its resources safely and most efficiently to provide value to our customers and stakeholders by delivering solutions that meet our customer's needs while additionally enhancing the quality of life for current and future generations.

Uses of one component polyurethane foam (OCF) insulating sealants do not result in releases to water, and so do not result in risk to aquatic organisms. The critical nature of MCCPs in these formulations and the lack of water releases clearly demonstrate that there is no unreasonable risk to human health or the environment from their continued use and thus any ECHA action predicated on a claim of "may present an unreasonable risk" would necessarily fail.

Based upon the US EPA definitions of chlorinated paraffins (CP), including short chain CPs (C_{10-13}), medium chain CPs (MCCPs) (C_{14-17}), long chain CPs (LCCPs) (C_{18-20}), and very long chain CPs (vLCCPs) ($C_{>20}$), PBS uses MCCPs in OCF insulating sealants. MCCPs provide critical functional properties to PBS's uses including flame retardancy, viscosity, plasticization, and thermal stability. Risk assessments of MCCPs identify a potential for ecotoxicity risk from the processing or use of these chemicals. However, ECHA may not be aware that DuPont's processing and use of MCCPs in OCF necessarily excludes water at all stages because the formulations are highly water sensitive. Water is a contaminant in DuPont's formulations using MCCPs and is excluded from the process to ensure high quality products. In addition, there is zero discharge of any MCCP to the environment at any DuPont manufacturing site. Finally, the product end uses present neither the potential for direct nor indirect release to water; product containers are sealed and cannot be rinsed, and the final cured products do not leach MCCPs by design, else the products would lose the properties provided by these chlorinated paraffins (CPs) over the functional life of the products. Furthermore, a careful analysis of these CPs show that the MCCPs products that DuPont uses are neither persistent nor bioaccumulative.

OCF insulating sealants are critically important air-sealing products that are used extensively in the residential and commercial construction markets to improve building energy efficiency. The U.S. Department of Energy (DOE) estimates that 42% of total U.S. energy demand is consumed within the commercial and residential building sectors. EPA and DOE both recognize that one of the most effective greenhouse gas (GHG) emission reduction strategies for buildings is achieved through incorporation of energy efficiency measures. As a result, energy codes throughout the United States have become more stringent, requiring in many cases, an increasing use and application of all types of foam insulation, sealants and insulating foam sealants. US EPA estimates a typical home contains a half-mile of cracks and gaps,"[1] and that "the energy savings from comprehensive air sealing can quickly add up when you consider all the places hot or cool air can enter or escape from your home."[1] Additionally, OCF specialty adhesives are critically important products to roofing performance that are used extensively in construction markets to hold roof tiles on in high wind zones in order to mitigate damage and reduce insurance costs. Due to the dangerous potential for great extents of harm, high wind zone applications are stringently overseen by U.S. state and county building regulatory bodies such as Miami-Dade County (wind uplift requirements), and the Texas Department of Insurance.

[1] The United States Environmental Protection Agency, http://www.energystar.gov/ , http://www.energystar.gov/ia/partners/bldrs_lenders_raters/downloads/Thermal_Enclosure_Factsheet.p2730-f9e6

Review of previous draft risk assessments shows vastly over-assumed releases and subsequent environmental impact from at least two end uses, sealants and adhesives. This further supports the need for a closer look at exposure and risk assessment of MCCPs through a transparent assessment.

OCF foams and OCF adhesives are designed and engineered to retain the MCCP content to maintain key performance and safety criteria (flame retardant properties, heat stabilization, and plasticization to boost adhesion). To reach their final state, OCF insulating sealants and OCF adhesives are dispensed from a one-component can or cylinder as a bead and quickly react and cure to form a stable thermoset polymer. Environment Canada, Association of European Adhesives and Sealants Manufacturers, and DuPont have data that demonstrate that these chemicals used in OCFs do not migrate nor are they sources of environmental exposures. As a result, losses of MCCPs to the environment are negligible if at all, in the use phase; negligible use-phase emissions coupled with no releases during processing or use, demonstrate non-dispersive use.

The table below outlines the DuPont product uses, US EPAs comments from 2016 in the PMN risk assessment documents, PBS's response to the comments, and PBS recommendations.

Product Types	**EPA PMN Comments**	**PBS Response**	**PBS Recommendations**
One component polyurethane foams (OCFs): Insulating foam sealants and specialty adhesives.	1. Processing and use of sealants and adhesives can result in large environmental releases of MCCPs. 2. Drop in alternatives exist that can replace MCCPs. 3. MCCPs may present an unreasonable risk as PBTs.	1. Processing and use of MCCPs in OCFs does not result in environmental releases or exposures of concern. 2. No safe, functional alternatives have been identified or currently exist. If alternatives are identified they will require years of testing and approvals in advance of being commercialized. 3. MCCPs used in PBS products have not been shown to present unreasonable risks or be persistent and bioaccumulative.	No restrictions for existing, on-going uses that do not lead to water releases.

At present, there are no proven, widely available candidate replacements for MCCPs that meet established performance criteria for broad use in OCF insulating sealants and OCF specialty adhesives. Any suggestion that polyurethane insulating foam sealant and adhesive plants can be converted to accept alternatives is unrealistic and unsupported. Major issues with some suggested alternatives involve viscosity, unproven thermal performance, and unproven adhesion. The typical North American industry standards for performance of OCF insulating sealants and adhesives alone may include, but are not limited to, those issued by ICC Evaluation Service (covering requirements for the International Building Code as well as the International Residential Code), UL Classified Caulking and Sealants, PFS Corporation, California Bureau of Electronic and Appliance Repair, Home Furnishings and Thermal Insulation, American Architectural Manufacturers Association (812-04 test method), CAN/ULC 710.1-11, Miami-Dade County (wind uplift requirements), and Texas

Department of Insurance. These third-party approval requirements are necessary steps in the process of commercializing new formulations and they all take time to complete. After consideration of these factors, PBS concludes that it is neither feasible nor practical for the one component polyurethane foam insulating sealants and OCF adhesives sectors to shift to non-MCCPs alternatives in the indefinite future. The processing of testing and obtaining approvals after alternatives are identified, if this occurs in the future, would require multiple steps over a number of years to reformulate.

PBS believes that assessments of the persistence and bioaccumulation of MCCPs would only be strengthened if it is based upon an overall weight of evidence (WOE) approach rather than relying on worst-case assumptions for both persistence and bioaccumulation. Such assumptions are inappropriate considering that the most persistent constituent is not expected to bioaccumulate, and the more bioaccumulative constituent is not expected to be highly persistent. There is no constituent that is both very persistent and very bioaccumulative.

Furthermore, environmental monitoring data, including concentrations in soil, sediment, and surface water, do not support the conclusion that MCCPs are highly persistent and highly bioaccumulative. These substances have been in commerce for decades and yet there is no demonstrable evidence and only equivocal evidence, at best, for bioaccumulation. PBS also believes that the US EPA risk assessment did not fully consider the conclusions on persistence and bioaccumulation made by the UK Environmental Agency in 2005 and those submitted to the European Chemicals Agency under REACH. These reviews concluded that some forms of MCCPs, including the type used by PBS, do not meet the PBT criteria.

In summary, PBS believes that there is no precedent for regulating MCCPs. Considering the importance of OCF insulating sealants in meeting the building energy efficiency goals set out by the numerous Climate Action Plans to reduce global energy demand and the associated reduction in GHG emissions, there is no justification that outweighs the benefits these products provide for discontinuing the use of formulations that contain MCCPs in our OCF markets. Likewise, there is no justification for discontinuation that outweighs the important benefits of OCF specialty adhesives in high wind zones. Moreover, there is no demonstrable risk from processing, formulation, and use of MCCPs in OCF insulating sealants or OCF specialty adhesive foams, that would justify any proposed phase-out or cessation of manufacture. Previously the US EPA only identified risk to aquatic species and PBS's processing and use does not lead to any water releases. As stated earlier, readily available "drop in" replacements for MCCPs in OCFs do not currently exist; PBS products must meet many stringent "in-use" performance prerequisites requiring numerous years to reformulate new products to replace the current products that have been successfully deployed in the market for over 20 years. Additionally, a review of the available data does not support the conclusion that MCCPs products used by PBS in OCFs formulation/manufacture and use are PBTs nor do they present any significant potential for environmental exposure or any release.

Supported by the data we reviewed, we challenged the US EPA to utilize the work plan process to properly assess the environmental impacts. Much of our original public comment submission to the US EPA follows as submitted under our previous business name - Performance Building Solutions (PBS) is a business unit of DuPont Specialty Products USA, LLC, (previously The Dow Chemical's Dow Building Solutions business).

DETAILED POSITION STATEMENT

The following sections present detailed points that support our position with regard to the decision regarding MCCPs. These sections encompass general industry considerations, and those relevant to specific products that are produced by PBS.

Important technical considerations are discussed, which is subsequently followed by a final summary and conclusion.

END USES: ONE COMPONENT POLYURETHANE FOAM (OCF) INSULATING SEALANTS, OCF ADHESIVES

The MCCPs required for use in PBS products must meet exacting standards for product consistency and safety. For decades the chemicals have been safely used to formulate and manufacture OCF compounds. Many different facets should be considered including the sites that support local and federal economies, the multiple functions of the MCCPs in the products, the safe handling of the chemicals during formulation/manufacture of the products, the complete lack of emissions (in contrast to incorrect assumptions), and the lack of immediately identified or available alternatives.

FINANCIAL IMPACT TO THE ECONOMY

The risk assessment documents published by US EPA previously did not include any economic analysis of any proposed regulatory action. Understanding the economic impacts of any action taken is critical to help determine whether any risk presented is reasonable or not. Based on the data presented below on actual environmental exposure, it is clear that forcing these markets to move out of a technology with zero environmental exposure is a nonsensical approach especially given the inevitable heavy damage to the economy.

FORMULATING ONE COMPONENT POLYURETHANE PRODUCTS (OCFS)

It is further important to note that the end uses of the PBS products containing MCCPs are not dispersive in nature. The MCCPs are integral to a product and are designed to remain stable in the final product. These chlorinated paraffins are not purposely released to the environment during processing, formulation or use, and they are not in contact with water at any point in the process. Additionally, this means that the MCCPs are not released to water, nor released to wastewater treatment facilities from PBS formulation and processing facilities.

Based on draft risk assessments, US EPA was concerned that use of MCCPs will cause potential harm to the aquatic species in environment due to water releases (both treated and untreated). US EPA's analyses assumed large surface water releases. The fact is, OCF formulations performed by PBS requires a closed-loop system that explicitly precludes water contamination and, therefore, no water cleaning, rinsing, or flushing is performed on any part of the system. If cleaning is required, transportation and processing equipment is cleaned with an organic solvent and the rinsate is disposed of as hazardous waste, either by incineration or to a hazardous waste landfill, according to US EPA regulations.

The OCF pre-polymers are highly reactive to water and water vapor, and actually use water vapor in the air to cure the polyurethane in place when applied. To ensure that there is no contamination of water in the manufacturing process, the plant is highly engineered. As a basic view of the process a schematic is provided, Figure 1, in example of the closed loop system.

At no time is the OCF plant system flushed with water for any reason.

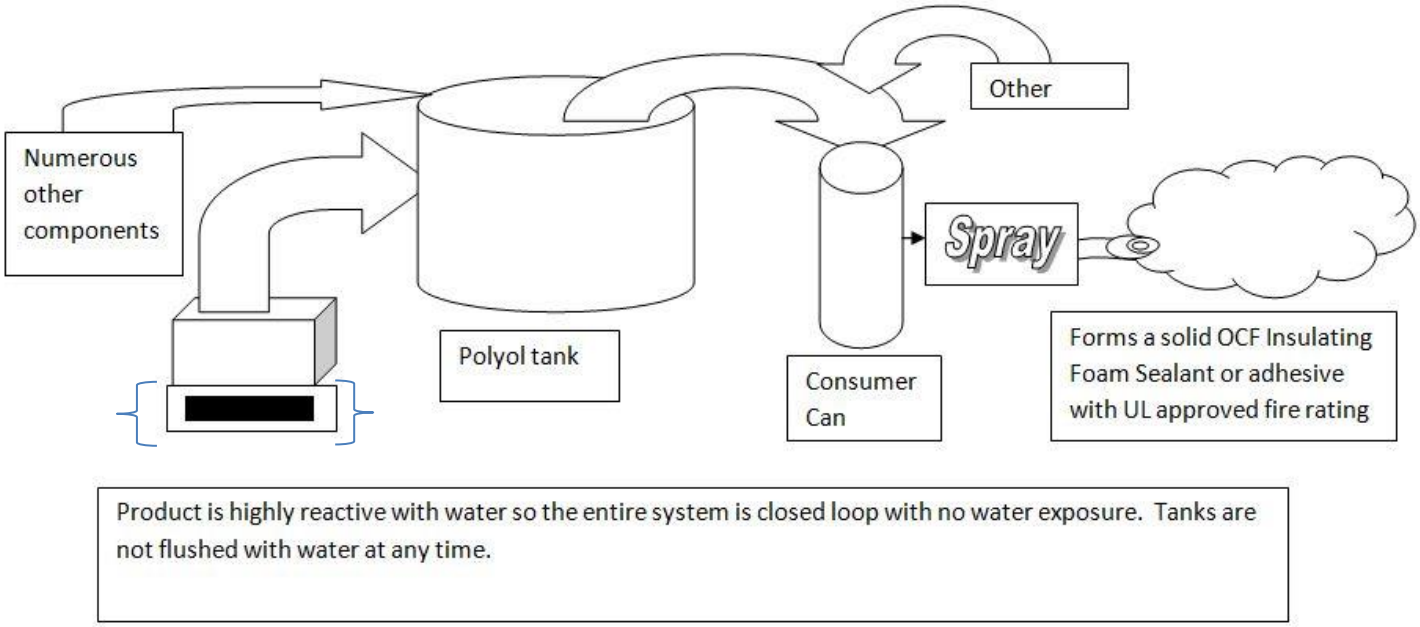

Figure 1. One component polyurethane foam insulating sealant and adhesive closed loop manufacturing process does not involve any exposure to water, including no exposure to public water treatment or public water ways.

PBS's one component polyurethane pre-polymer foams, both insulating sealants and adhesives, are highly water sensitive. All manufacturing activity involving chlorinated paraffins occurs indoors and under roof. At no time is any part of the manufacturing process in contact with any water. The required water-free closed manufacturing system means that all raw materials go from delivery into the final product cans as a component of the product with zero water exposure or release to the environment.

There are no associated drum cleaning waste streams; bulk raw materials containing chlorinated paraffins are unloaded outdoors over a sized secondary containment structure. Any potential leakage within the containment unit would be managed as indicated below. If bulk containers (trucks, rail cars) are cleaned, the rinsate is handled as hazardous waste and is incinerated or sent to a hazardous waste landfill.

Manufacturing process equipment cleaning is rarely needed and would only be done using solvents. All spent cleaning solvents are handled as hazardous waste per EPA regulations by a licensed handler, leading to no releases to water (either untreated or treated wastewater).

Any raw material or final OCF product found to be off-specification is handled as hazardous waste again per EPA regulations by a licensed handler and is incinerated or sent to a hazardous waste landfill.

PBS manufacturing facilities have sealed concrete flooring with no floor drains in close proximity to the manufacturing or storage areas. If there was an accidental spill of any compound in the manufacturing facility, the coated concrete slab floor, or containment area, would be cleaned using sorbents and booms. All used sorbents are promptly collected, drummed and disposed as hazardous waste. All hazardous waste is handled by a licensed, off-site, third party hazardous waste contractor.

CORRECTION OF EPA EMISSION ASSUMPTIONS

The US EPA originally made several emission assumptions in evaluating use of MCCPs in manufacturing OCFs and specialty adhesives. The data and assumptions are grossly in error. In part, this error was made due to the lack of understanding that OCF and specialty adhesive formulating/manufacturing is highly water reactive and therefore meticulously excludes water. Additionally, the OCF products as sold are final formulated products that are non-water based. Tables 2 and 3 compare the EPA assumptions in their risk assessments with precise manufacturing and use data.

Table 2 shows the incorrect EPA rationale that assumes during product formulation a portion of the total MCCPs used at a facility is discharged to water (mostly from cleaning operations such as equipment cleaning, tank/drum cleaning, as well as discharge of off-specification batches) and provides the correct actual manufacturing data and rationale.

Table 3 shows the incorrect EPA rationale that assumes during product use a portion of the total MCCPs used is discharged to water through cleaning losses and provides the correct actual use data and rationale.

Table 2. PBS data versus EPA Environmental Exposure Modeling Assumptions: Sealants and Adhesive Formulation with MCCPs and LCCPs

Source	U.S. EPA Basis	PBS Actual Emission from manufacturing data	Assumption error(s)
Cleaning liquid residuals from drums used to transport raw material	EPA/OPPT Drum Residual Model	**0 released to water**	**PBS raw material is not handled in drums; bags and bulk only. Bags are not rinsed. Bulk containers are washed by specialty firms that subsequently incinerate any washing fluid per EPA RCRA requirements.**
Equipment cleaning losses from blending tank	ESD for adhesives formulation (2009)	**0 released to water**	**Water is never used and any solvent would be handled as hazardous waste under EPA RCRA requirements and is incinerated or sent to hazardous waste landfill.**
Discharge of off-specification material	ESD for adhesives formulation (2009)	**0 released to water**	**All off-specification material is handled as hazardous waste under RCRA requirements and is incinerated or sent to hazardous waste landfill.**

Table 3. PBS data versus EPA Environmental Exposure Modeling Assumptions: Sealants and Adhesive Use of MCCPs

Source	U.S. EPA Basis	PBS Actual Emission from use data	Assumption error(s)
Cleaning liquid residuals from drums used to transport raw material	EPA/OPPT Drum Residual Model	**0 released to water**	**OCF insulating sealants and adhesives are fully formulated and are sold in single-use containers, not drums, and are not raw materials for other products.**
Equipment cleaning losses from multiple vessels	EPA/OPPT Multiple Process Vessel Residual Model	**0 released to water**	**OCF insulating sealants and adhesives are fully formulated and are sold in single-use containers.**

ALTERNATIVES ARE NOT DROP IN REPLACEMENTS IN OCFS

OCF pre-polymer chemistry is a delicate science that has taken many years to perfect. For example, the reaction chemistry during pre-polymer formation requires a delicate balance of reaction rate and heat formation to maintain high quality control. As a complex and highly-engineered formulation, there is no component in the can that can be easily replaced with any "drop-in" compound.

DuPont takes extreme quality and safety measures to ensure consistent product manufacture. There are many things that must be considered for any alternative chemistry. It is important to note the research and qualification for alternatives required for each product formulation. The performance requirements for MCCPs include:

1) Non-reactivity with polyurethane pre-polymer. Any replacement additive must be inert with respect to the reactive function groups on the pre-polymer.

2) Flame retardancy. Qualification of new formulations involves an iterative process with outside 3rd party testing.

3) Solubility. Replacements must be sufficiently soluble to achieve the proper loading in the final formulation. If an additional solubilizing agent is required to get the potential replacement material into the blend, that solubilizing agent must also not interfere with the other functions of the formulation.

4) Emulsification. In addition to impacting fire performance, it acts as an emulsifier of the blowing agent into the pre-polymer. If the replacement material does not also provide emulsification, an additional additive will be required to provide a stable foam. As with the solubilizing agent, the emulsifier must also not interfere with the other functions of the formulation.

5) Viscosity. Potential replacement materials may negatively impact the viscosity of the polyol premix. Again, a separate viscosity modifier may be required. Another avenue would be to consider processing the premix at a higher temperature, which would require additional capital investment, and may degrade the premix.

6) Shelf-life. Reformulating may require a novel polyol or polyurethane to achieve the current performance. The new polymer would have to still meet current shelf-life criteria. Additional time would be required to complete the PMN process for a novel pre-polymer.

7) VOC content. Any new formulation ingredients must not adversely affect volatile organic compound (VOC) content so that the final formulation still meets state and federal VOC standards.

8) Qualification to standards. Once a new formulation is found, third-party testing is required by various building codes including ICC Evaluation Service (covering requirements for the International Building Code as well as the International Residential Code), UL Classified Caulking and Sealants, PFS Corporation, FM, California Bureau of Electronic and Appliance Repair, Home Furnishings and Thermal Insulation, American Architectural Manufacturers Association (812-04 test method), CAN/ULC 710.1-11, Miami-Dade County (wind uplift requirements), and Texas Department of Insurance. Miami-Dade County alone regularly takes 12-15months or more for approvals.

In general, reformulating and qualifying products in this class requires many years. PBS prefers to reformulate with sustainable chemistries and avoid regrettable substitutions, which includes avoiding compounds currently under pressure in industry or those that have been identified as having a potential negative impact as noted on the EPA Work Plan lists. It is difficult to see how the time and expense associated with reformulating away from MCCP products in OCF manufacture can be justified. There have not been any identified human health risks and, since there is no water release associated with PBS's processing or use of MCCPs as functional ingredients, there is no environmental risk.

PBT DATA EVALUATION & RISK ASSESSMENTS

A review of scientifically accepted assessments for MCCPs used in PBS's OCF insulating sealants and adhesives, questions any designation of very persistent and very bioaccumulative and the screening procedure used to achieve those designations. A thorough evaluation of the existing data and information concludes that the environmental fate and effects of short, medium, and long chain chlorinated paraffins are not equivalent. When both laboratory and field information are included, all the MCCP congeners demonstrate significantly less bioaccumulative potential than the SCCP congeners. Some medium chain, lower chlorinated MCCP congeners have been reported to be degraded in standardized biodegradation tests including C_{14} and C_{15} congeners with less than 50% chlorination. Taken together, the compounds used in PBS's one component polyurethane foam insulating sealants do not fit standard persistence criteria or bioaccumulative criteria. Thus, the specific MCCP products used by PBS should not be classified as PBTs. Pragmatically PBT requires all three components- PBT designation falls short if only one (T) or two (T and B) criteria are satisfied.

MEDIUM-CHAIN CHLORINATED PARAFFINS (MCCPS)

The MCCP congeners used by PBS comprise a mixture of linear chlorinated paraffins. The available data for MCCPs with a similar range of chlorination and chain length demonstrates that these materials do not fulfill the criteria for persistence (P) and bioaccumulation (B). This conclusion is clear when using an overall weight of evidence approach. A risk assessment for the chlorinated paraffin (C_{14-17}), CAS Number: 85535-85-9 (with a chlorine content 40-63% by wt.), using a weight of evidence approach was conducted by the UK Environmental Agency in 2005[2] and more recently in a review of the PBT assessment in the REACH Dossiers[3] submitted to the European Chemicals Agency. In both cases the conclusion was that this MCCP did not fit the classification of persistence and bioaccumulative.

Biodegradation studies are available confirming the degradation of MCCPs occurred when chlorination of the chain was 50% or less by weight[4,5]. OECD test guidelines for biodegradation (OECD 301, 302) are frequently used to assess the environmental persistence of a chemical. Information available in the REACH substance evaluation document demonstrates that both a C_{14} chlorinated paraffin (45% chlorination) and C_{14-17} chlorinated paraffins (45.6% chlorination) were rapidly biodegraded (64% and 51% degradation over 28 days, respectively) in the OECD Ready Biodegradability test. These results demonstrate that MCCPs products similar to the material used by PBS would be expected to ultimately biodegrade in the environment and, according to REACH guidance Chapter 11, these C_{14-17} paraffins with a lower degree of chlorination do not meet the Annex XIII persistence criterion.

A sophisticated analysis using both laboratory- and field-derived Biomagnification Factors and field data such as Trophic Magnification Factors (TMFs) demonstrated all the MCCP congeners had little bioaccumulation potential (BMF and TMF <1)[6]. Laboratory bioaccumulation studies for the medium chain chlorinated paraffin (C_{14-17}, chlorine content 40-63% by wt.) have exhibited mixed results but when all studies are considered this group of materials demonstrates low bioaccumulation potential. Arnot[7] conducted a subsequent assessment on the bioaccumulation and biomagnification of

[2] ALKANES, C14-17, CHLORO (MCCP) Part I – Environment: Summary Risk Assessment. 2005. Environment Agency, UK. Compositions Medium Chain Chlorinated Paraffins/Alkanes, C14-C17, chloro : PBT Analysis

[3] (http://apps.echa.europa.eu/registered/data/dossiers/DISS-9ebcd9d5-5f92-56b4-e044-00144f67d031/AGGR-b15a117c-bc8e-4907-b7ab-f6eb8ccc2c25_DISS-9ebcd9d5-5f92-56b4-e044-00144f67d031.html

[4] van Ginkel CG, Belle R. 2010. Biodegradability of polychlorinated tetradecane; closed bottle test method. Arnheim, Netherlands: AkzoNobel. Report ECRAM09.

[5] van Ginkel CG, Louwese A, Geerts R. 2011. Assessment of persistence of chlorinated paraffins using OECD biodegradability tests (ready and enhanced). Poster presentation Society for Environmental Toxicology and Chemistry Europe. Milan, Italy.

[6] Thompson, R., and Vaughan, M. (2014). Medium-chain chlorinated paraffins (MCCPs): A review of bioaccumulation potential in the aquatic environment. Integr. Environ. Assess. Manag. 10 (1):78-86.

[7] Arnot, Jon. 2014. Bioaccumulation Assessment of Medium-chain chlorinated paraffins (MCCPs). April 28, 2014. Unpublished reported provided in Section 13 of the REACH dossier

MCCP using the framework developed by Burkhard and colleagues[8]. This framework originated from a bioaccumulation expert workshop which occurred in 2009 and was co-sponsored by the US EPA, Society of Environmental Toxicology and Chemistry (SETAC) and International Life Sciences Institute, Health and Environmental Sciences Institute (ILSI-HESI). The assessment was conducted with available measured B data for MCCP constituents from various aquatic species (plankton, invertebrates, fish), from laboratory testing and environmental monitoring, with a total of 97 measured data points. The results of this analysis revealed that 93% of the data examined were lower than the threshold criterion for bioaccumulation. Their conclusion was: "*The current weight of evidence indicates that MCCP constituents are not likely to biomagnify in fish and in aquatic food webs."*

Furthermore, the conclusion that MCCPs are highly toxic to aquatic organisms is confounded by the very low water solubility of MCCP congeners. The difficulty in testing MCCPs may be the reason that the lowest daphnia chronic toxicity effect concentration (10 μg/L)[9] is higher than the daphnia acute toxicity effect concentrations (5.9 μg/L)[10]. In addition, the aquatic toxicity varies over many orders of magnitude depending on the degree of chlorination: Daphnia acute toxicity was measured at 9 mg/L for MCCPs with 45% chlorination and greater than 10,000 mg/L for MCCPs with 52% chlorination.[11]

OCFs WITH CHLORINATED PARAFFIN

The final use of PBS's OCF foam insulating foam sealants and adhesives would not result in any significant release of MCCP to the environment. Environment Canada's assessment report for chlorinated paraffins did not identify these products or associated manufacturing and uses as significant sources of release into the environment.[12] With respect to end-of-life disposal of polymeric products containing MCCPs, Environment Canada concluded that chlorinated paraffins are expected to remain stabilized in these products.[13] Additionally, the Association of European Adhesives and Sealants Manufacturers (FEICA) completed a study on the aquatic acute and chronic effects of MCCPs in a generic formulation for one-component polyurethane foams.[14] The position paper summarizing the study concluded that no acute or chronic effects on aquatic life are expected.[15] Evidence that PBS's OCFs are not a significant source to the environment was demonstrated in a recent laboratory study[16] where fish (*Pimephales promelas)* were maintained for 16 days in aquariums lined with GREAT STUFF™ product. The study followed OECD No. 204 guideline and the reported no-effects concentration (*i.e*., NOEC) was > 0.63 g/L, which is approximately 40 times the expected foam loading rate expected to result from use of the foam in construction of a typical ornamental pond.

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[8] Burkhard LP, Arnot JA, Embry MR, Farley KJ, Hoke RA, Kitano M, Leslie HA, Lotufo GR, Parkerton TF, Sappington KG, Tomy GT, Woodburn KB. 2012. Comparing laboratory and field measured bioaccumulation endpoints. Integr Environ Assess Manage 8:17–31

[9] Thompson, R. S., N. J. Williams, and E. Gillings. 1997. *Chlorinated Paraffin (52% Chlorinated, C14-C17): Chronic Toxicity to Daphnia magna*. AstraZeneca Confidential Report, BL 5791/B.

[10] CPA (Chlorinated Paraffins Association). 1996. *Chlorinated Paraffin (52% Chlorinated, C14-17): Chronic Toxicity to Daphnia magna*. Study conducted by Thompson, R. S., A. J. Banner, E. Gillings , and N. R. Gore, Brixham Environmental Laboratory: ZENECA Limited, (October 2, 1996), Brixham, UK. OTS 0573997. Doc ID 88000000085.

[11] Tarkpea, M., E. Linden, B. E. Bengtsson, A. Larsson, and O. Svenberg. 1981. *Products Control Studies at the Brackish Water Toxicology Laboratory 1979-80*. NBL Report 1981-03-23. Swedish Environmental Protection Agency, Nykoping, Sweden.

[12] Environment Canada, Chlorinated Paraffins, Follow-up Report on a PSL1 Assessment for Which Data Were Insufficient to Conclude Whether the Substances Were "Toxic" to the Environment and to the Human Health (August 2008). Available at: http://www.ec.gc.ca/lcpe-cepa/documents/substances/pc-cp/cps_followup-eng.pdf.

[13] Environment Canada, Chlorinated Paraffins, Follow-up Report on a PSL1 Assessment for Which Data Were Insufficient to Conclude Whether the Substances Were "Toxic" to the Environment and to the Human Health (August 2008). Available at: http://www.ec.gc.ca/lcpe-cepa/documents/substances/pc-cp/cps_followup-eng.pdf.

[14] FEICA Position Paper on the classification and labeling of One-Component Foam (OCF) containing Mid Chained Chlorinated Paraffin (MCCP). Available at: http://www.feica.com/library/position-papers/mccp.

[15] Id.

[16] 2009. Great Stuff™ Pond & Stone Waterfall Foam Filler: Evaluation of Potential Prolonged Toxicity to Freshwater Fish. The Dow Chemical Company, Midland MI

ANY POTENTIAL BAN UNNECESSARILY PENALIZES THE POLYURETHANE FOAM INDUSTRY

Because MCCPs have long been in commerce, there is a significant body of toxicological and exposure data for these substances, including data in the public literature and data developed in collaboration with or previously submitted to US EPA. These data should all be carefully considered and subject to the full scrutiny of external peer-review.

DuPont is a global company, and as a result it has structured its research programs around the TSCA Work Plan Chemicals in addition to EU REACH and Environment Canada and Health Canada substance evaluations. This approach allows for alignment with regulatory priorities and complements effective technical agency interactions, as seen with prior industry and PBS discussions with regulatory bodies. Additionally, this approach meets the high sustainability standards and goals of DuPont.

SUMMARY and CONCLUSION

PBS believes that regulatory bodies should exhibit leadership on this issue by utilizing appropriate legal authorities and appropriate procedures to propose and enact environmentally effective, economically sustainable, technically feasible, and reasonable regulations of chlorinated paraffins. The underlying risk assessment should be appropriately peer-reviewed by an external body and proposed regulatory actions should be published for notice and comment. Even if the risk assessment demonstrates that there is potential for unreasonable risk from water releases, the appropriate risk management strategy is to impose restrictions on such releases, not a phase-out or ban of the substances from commerce.

Mandating arbitrary changes in OCF insulating sealant technologies that are already key components to commercial and residential building energy efficiency could result in global consumers being forced to choose less effective alternatives, which is counterproductive to effective national energy strategies as well as counterproductive to a successful environmental preservation strategy. Additionally, OCF adhesive technologies are critical to roofing performance in high wind zones and mandating arbitrary changes to these products would impact building damage and insurance costs. Such disruptions are not appropriate when the use patterns involve zero discharges to water and there would be no discernible environmental benefit.

Research, development and implementation of substitutes and alternative manufacturing methods are expansive in scope, and can take many years. There is no known alternative at the present time. A rapid time-line for implementation of potential alternatives is unreasonable and would be likely to lead to commercially unacceptable replacement products and cause severe impact to an entire industry globally.

PBS believes that a proper scientific review will establish that the use of MCCPs in one component polyurethane foam insulating sealants and adhesives do not present unreasonable risk to human health or the environment.

ADDENDUM –

2009. Great Stuff™ Pond & Stone Waterfall Foam Filler: Evaluation of Potential Prolonged Toxicity to Freshwater Fish. The Dow Chemical Company, Midland, MI