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November 15, 2001

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Research Triangle Park, NC 27709

**RE: Response to NTP-CERHR Expert Panel Draft Report on Reproductive and Developmental Toxicity of 1-Bromopropane**

Dear Dr. Shelby:

By way of background, Enviro Tech International, Inc, is a leading manufacturer of 1 Bromopropane ("1-BP") solvents in the United States, closing the first commercial sale of 1-BP based solvents in 1996. Enviro Tech holds four United States Patents[1] concerning the stabilization of 1-Bromopropane for use as a solvent in industrial vapor degreasers with additional Patent Applications pending[2] as well as multiple European[3] and International Patents[4] concerning 1-BP. Enviro Tech is a Petitioner for the use of 1-BP in the Precision Cleaning Sector before the United States Environmental Protection Agency pursuant to its Significant New Alternatives Program ("SNAP")[5]. We have sponsored toxicological studies of 1-BP[6] and expert assessments of the full toxicological database for 1-BP[7] and have also sponsored many ongoing studies regarding the atmospheric chemistry of 1-BP[8], including the first ozone depletion study of 1-BP [9] as well as subsequent reports.

The following comments regarding the Draft Report referenced above are respectfully submitted for consideration and insertion into the NTP-CERHR public docket concerning the Expert Panel review of 1 Bromopropane ("1-BP") and inclusion in the Expert Panel's Final Report.

1.1.3 Chemical and Physical Properties

**Flash Point/Flammability**

Although 1-Bromopropane has been historically reported in the literature as flammable, there have been numerous flash point tests conducted by such credible organizations as Factory Mutual (Exhibit A) conducted according to ASTM and OSHA standards which clearly establish Bromopropane does not have an identifiable flash point. Therefore, by definition, 1-Bromopropane is not flammable.

1-BP does have a limited range, between 4.6 % and 8.5 % mixture in air, in which vapors may ignite. This is true of many chlorinated solvents, including 1,1,1-trichloroethane (LEL 8% , UEL 13%) and trichloroethylene (LEL 8%, UEL 11%) and methylene chloride (LEL 13%, UEL 23%)[10]. These solvents are also considered non-flammable.

1.1.4

**Contaminants**

The case study's discussion of "contaminants" of 1-BP is incorrect. The so called contaminants are well known additives used as an inhibitor package to stabilize 1-BP[11]. Unstabilized 1-BP is unusable as a solvent. Additives used as stabilizers are well known and have been in use for decades in chlorinated and other solvents.[12]

2 Bromopropane (2-BP) is a true and well known contaminant of 1-BP, with trace amounts found in unstabilized 1-BP after manufacture. Since the first commercial sale of 1-BP solvents, manufacturers have been aware of the potential toxicity of 2-BP (the reports of 2-BP toxicity underlying 2-BP's classification as a contaminant) and have demanded the lowest 2-BP content possible. In 2000, ASTM 6368 was amended to require a 2-BP content of less than $1/10^{th}$ of 1 % (.1%) of 2-BP content (Exhibit B) and quickly became the industry standard and compliance with the standard became a user expectation. Currently, 2-BP content is typically in the range of .03% to .08% by volume as shown on various Certificates of Analysis from manufacturers of neat 1-BP.[13]

**Case Study**

It must be pointed out that the case study's description of "contaminants" in 1-BP provides no scientific or other factual evidence as to how such "contaminants" were identified or how the amount of each additive was quantified. The additives recited are merely recited from one manufacturer's Material Safety Data Sheet[14]. Since there were five major manufacturers of 1-BP based solvents in the United States at that time as well as other smaller solvent manufacturers[15] each of which adds different inhibitors and/or inhibitors similar to those described but at a range of different percentages by volume[16], the actual composition of the particular mixture alleged to be the cause of the subject's medical problems can not be known.

The conclusions of the report are based on the statement of an unidentified subject (who could not be found for subsequent follow up) that he worked with some form of a 1-BP solvent in an undetermined time frame at an unknown exposure level and a comparison of the subject's symptoms with animal effects from a single study where rats were exposed at the level of 1000 ppm 8 hrs/day, 7 days per week for five to seven weeks[17].

NIOSH exposure assessments show that exposures to workers in a cold dip degreaser ranged from undetectable to 4.4 ppm. (Exhibit C) Exposure assessments by Albermarle at three sites involving vapor degreasers found exposures levels in the range of 0.1 ppm to 13 ppm. (Exhibit D).

In exposure assessments in the most emissive application, NIOSH studies of 42 workers in a spray adhesive workplace found exposures up to 190 ppm for over one year without mechanical ventilation (Exhibit E) and exposure levels of under 30 ppm after mechanical ventilation was installed. (Exhibit F) Another NIOSH exposure assessments in the same application found geometric mean exposures of 62.1 ppm without mechanical control present and a subsequent geometric mean exposure of 22.5 ppm after exposure control systems were installed. (Exhibit G) A third exposure NIOSH assessment in the adhesive sector found exposures in the range of 18.1 ppm to 253.9 ppm without adequate exposure controls present. (Exhibit H) Exposure studies of four different adhesive applications by Albermarle, which were filed with the USEPA's SNAP docket, found exposures in the range of 18 to 92 ppm.(Exhibit I) An Albermarle exposure assessment of a refrigeration coil cleaning operation found exposure levels of 42 ppm. (See Exhibit D)

The above studies identify exposures typically found in the workplace to be in a range from undetectable to 253 ppm. Most of these exposure studies were done in the same general time frame as subject's alleged exposure and can be said to be typical exposure levels based on typical circumstances at that time. Further, the studies show the typical range of worker exposure to be undetectable to 13 ppm in vapor degreasing operations, which is where the subject of the case study worked. Therefore, it is highly unlikely that the subject could have been exposed to any *industrial* exposure, much less an exposure from a vapor degreasing operation, at a level equivalent to the dosage level in the Yu (1998)[18] animal study.

Further, NIOSH medical studies show *that workers exposed for up to a year to the highest exposures measured, 190 ppm.* (Exhibit J) It is especially important to note that these workers experienced an unknown level of dermal exposure (from the spray) along with the inhalation exposure measured. However, *none of the exposed workers experienced any comparable symptoms* and in fact experienced no adverse symptoms at all. Similarly, the symptoms of Korean workers exposed to extraordinarily high levels of 2-BP for a much longer period of time *did not show these effects*[19]. Finally, not one other report relating similar physical symptoms has been identified from any source either before the study or after its publication after six years of industry use of 1-BP as a solvent, three years as a carrier and a far longer history of use in the pharmaceutical industry. This calls into serious question the over broad leap to a conclusion included in the case study.

Within the case study, no investigation to confirm the subject's statements regarding 1-BP exposure was described or attempted, no attempt was made to determine the level of the alleged industrial exposure and no investigation was made of possible and more likely alternative exposure scenarios. Further, no medical test was attempted to identify the presence of any toxic chemical in the subject.

There is no credible evidence presented in the case study to connect the subject's maladies with 1-BP, a stabilized 1-BP solvent or any other to a chemical whatsoever. Likewise, there is no credible evidence presented in the case study to connect the subject's maladies with an *industrial workplace exposure to a chemical compound of any kind.* In fact, the described medical problems are consistent with a number of medical conditions, exposures to other toxic compounds outside the workplace, **illegal drug use and/or purposeful misuse/recreational inhalation** of any number of chemical compounds; none of which were researched factually or adequately considered and all of which are just as likely or more likely to be the cause of the subject's symptoms.

Within the Draft Report, the Expert Panel has criticized and questioned the utility of animal studies where details regarding the methodology were unclear[20], where correlation between observed effects with expected effects were lacking[21] and where the conclusions regarding otherwise well conducted studies appeared to be unsupported[22]. Those studies, in comparison, were far more detailed regarding the identity of the material and exposure level than was the cited case study. Therefore, based on the lack of scientific method in determining the cause of the subject's symptoms, the total lack of information regarding the possible dose and route of exposure, the likelihood that any continuous workplace exposure would have been at typical rather than extraordinary levels, the impossibility for further study of the subject and the lack of any previous or subsequent reports of like symptoms, we suggest the study does not meet the minimum standards for scientific data to be included in the Expert Panel's consideration and that the Expert Panel should withdraw this study from any consideration.

1.2.1

**Estimates of Chlorinated Solvent Usage**

In earlier comments to the Expert Panel (Exhibit K), we showed that the OSHA Nomination's (Exhibit L) predictions for the use of 1-BP in the United States were vastly overstated, beginning with the initial over-estimation (by at least a factor of 2) of the amount of chlorinated solvents in use in the United States; the Nomination estimated a *potential* for 1-BP to replace all current use of chlorinated solvents in only *two application sectors*, the vapor degreasing/cold metal cleaning and adhesive (foam fabrication) sectors "over the next several years, perhaps even within months" in an amount of 310 million pounds per year ("lbs/yr").

The failure of the Nomination's estimates is readily seen as it is based on a Comment filed with the USEPA SNAP program by the Institute for Research and Technical Assistance (IRTA)[23]. (Exhibit M) Within the Comment, IRTA advertises itself as non-profit firm assisting firms in adopting non-solvent technologies. Although the Comment quotes a 1988 article which presents estimates of chlorinated solvent usage as of 1988, the Comment's estimates for contemporary chlorinated solvent usage (as of April, 1999) are set forth without authoritative backup of any kind and without description as to their basis. A closer review also shows that the 1988 article cited was authored by the same person who authored the Comment. In effect, the author cites herself from a ten year old article in the sole attempt to support her otherwise unsubstantiated current estimates.

The Nomination's fatal flaw is its lack of due diligence in accepting the Comments's estimates without verifying their accuracy and its failure to do even minimal additional research which would have easily uncovered credible data readily available from well known and respected sources.

A short rebuttal of the Comment is included here as the Comment has been attached for your review. The later section of this letter, **<u>Ozone Depletion Potential and Global Warming</u>** is sufficient to discuss references to the ozone depletion made in the Comment.

The Comment is incorrect in fact and at law in its assertion that the USEPA lacks the authority and/or jurisdiction to regulate 1-BP under its SNAP program. Its contention that SNAP regulation is no longer needed reminds me of the similar rationale behind the proposition to close the United States Patent Office in the 1920's; all inventions that could be invented had, by then, been invented, so the office was unnecessary. In any case, the USEPA intends to regulate 1-BP under its SNAP program[24] and *none of the stakeholders*, either at the raw material manufacturing level or at the solvent manufacturing level, *have ever objected to the jurisdiction of the USEPA's SNAP program over 1-BP.*

The Comment alleges without support that "high concentrations" of butylene oxide in a solvent is offered by "one producer", that "[s]ome of the 1-BP being sold today has high concentrations of other contaminants, including chlorinated and non-chlorinated organic solvents" and that 1-BP solvents had "high concentrations" of 2-BP. The last allegation is especially odd, as industry documents, such as manufacturer's Certificate of Analysis as discussed above, show that 2-BP was already typically at or below .1% by volume at the time[25]. Although it should be easy enough to prove these allegations, even in 1999, by attaching the publically available MSDS of the offending product or products, no such authority is identified. Again, unsubstantiated and unsupported claims, especially where the information is publically available and easily accessible is not offered in any form, should be afforded no consideration in a scientifically based review.

The Comment's other now dated assertions and concerns regarding both toxicity and ozone depletion have been answered in favor of 1-BP.

Credible data from the Halogenated Solvents Industry Association which was available at the time of the Comment's and Nomination's publication showed that chlorinated usage in those two sectors was about half the amount stated in the Nomination. [26]. Subsequent research shows leading third party industry research companies estimating the *total use in all sectors* of chlorinated solvents in 1999 was lower that of the HSIA as stated in the previous correspondence.

The Freedonia Group is a leading international business research company, founded in 1985, that publishes more than 100 industry research studies annually. Freedonia's industry analysis provides an *unbiased* outlook and a reliable assessment of an industry and includes product and market forecasts, industry trends, threats and opportunities, competitive strategies, market share determinations and company profiles. More than 90% of the industrial companies in the Fortune 500 use these research reports.[27]

The reports are authored by a team of analysts from sources such as trade publications, government source books, proprietary databases, product literature and annual and industry reports. Information gained by extensive interviews with major industrial participants as well as knowledgeable industry experts is also added to the reports. The information is then analyzed and distilled into a study, complete with product and market forecasts, critical industry trends, threats and opportunities, competitive strategies and market share determinations. Conclusions are verified through intensive interviewing of top ranking companies in the industry.

ECNext.com is a web based service which provides online access to commercial information from 500 leading publishers, including the Freedonia Group and over 250,000 sources, covering every major industry and country.[28]

The figures below show *total amounts of chlorinated solvents for all sectors* available as reported by ECNext .com comprised of information including information from the Freedonia Group. (Exhibit N)

| | 1995 | 2000 |
|---|---|---|
| Methylene Chloride | 268,000,000 lbs | 167,000,000 lbs |
| Perchloroethylene | 207,000,000 lbs | 140,000,000 lbs |
| Trichloroethylene | 85,000,000 lbs | 97,000,000 lbs |

ECNext/Freedonia estimates total use of these chlorinated solvents for *all* sectors for the year 2000 was 404 million pounds. HSIA estimates that 29 % of all methylene chloride use in the adhesive/foam fabrication and metal cleaning sectors[29], 10 % of perchloroethylene is used in metal cleaning[30] and 42% of trichloroethylene is used in metal cleaning[31]. Applying these percentages results in the following:

| | 1995 | 2000 |
|---|---|---|
| Methylene Chloride | 77,720,000 lbs | 48,430,000 lbs |
| Perchloroethylene | 20,700,000 lbs | 14,000,000 lbs |
| Trichloroethylene | 35,700,000 lbs | 40,740,000 lbs |

Thus, the total estimates for chlorinated solvent use in the adhesive/foam fabrication and metals cleaning sectors total 103,170,000 pounds. This is *less than one third the amount* stated in the Nomination.

Even these numbers may also be unduly high, given that 1-BP is not a viable substitute for these chlorinated solvents in all their applications within the metal cleaning and adhesive sectors. Another important reason for the likelihood of 1-BP to fail to ever reach the Nominations's and other overly high estimates is that 1-BP has been, is now and can be expected to be in the future two and one half to five times the price of any of the three chlorinated solvents discussed herein. In a practical sense, no business would switch to a more expensive alternative if their present process is working. It must also be assumed that mechanical systems are already in place where they are legally required, since the date for meeting legal requirements has long passed. Therefore, no related capital expenditures would be saved by switching to a more expensive solvent. Lastly, companies such as DOW, Dupont and PPG, which produce chlorinated solvents can not be expected to exit the existing solvent marketplace merely because an alternative has become available. In contrast, these industrial giants can only be expected to redouble their sales efforts in the marketplace to counter any loss of market share.

The above discussion shows that 1-BP use estimates in the 300 million pound range are grossly overstated, based on questionable and unsubstantiated data and are unrealistic in view of the realities of the marketplace. Therefore, we respectfully submit that these estimates be granted no weight and be excluded from the Expert Panel's evaluation.

**<u>1-BP Production and Use in the United States</u>**

Based on information gained as the leading supplier of 1-BP based solvents to the precision cleaning sector and discussions with industry sources and associations, it is our estimate that 1.5 million pounds of neat 1-BP were *produced* in the United States in 1999 and 2000, with the bulk of production by Great Lakes Chemical earmarked for the pharmaceutical industry. Great Lakes had offered a 1-BP based solvent for sale prior to 2000, but exited the solvent market. (Exhibit O)

The majority of the 1-BP sold in the United States is imported. The Port Import Export Report Service ("PIERS") is a publically available service which compiles data from public shipping documents for every product imported into or exported from the United States. An accurate estimate of the total 1-BP imported into the United States can be made using PIERS reports. (A sample report is attached as Exhibit P. A full report is available to the Expert Panel upon request) Based on the PIERS reports for the years in question, we estimate 1-BP was *imported* into the United States in the following quantities:

| | |
|---|---|
| 1999 | 2,807,647 lbs |
| 2000 | 2,838,583 lbs |
| 2001 | 2,964,432 lbs |

Thus, we estimate that the total amount of 1-BP *imported and produced* for sale in the United States are as follows :

| | |
|---|---|
| 1999 | 4,307,647 lbs |
| 2000 | 4,338,583 lbs |
| 2001 | 4,464,432 lbs |

Based on the above estimates, the actual average yearly compound growth rate the use of 1-BP in the United States for the period 1999 - 2001 is 2.34%.

Currently, the market for 1-BP as a replacement for chemicals banned by the Montreal Protocol in the United States is declining at a rapid pace, as the majority of banned compounds have already been substituted[32] [33].

Although there is some switching from substitute to substitute, this is not a growth area, as users are reluctant to proceed through an arduous testing and certification process to approve a new solvent when the current solvent has already proved effective. This is especially true when the cost of the new solvent is appreciably higher than that of their current solvent, as in the case of substituting for chlorinated compounds. 1-BP is currently 2.5 to 5 times higher than comparable chlorinated solvents and this cost differential is expected to remain constant for the foreseeable future. This economic consideration alone has proven to be a bar to rapid or extensive replacement of chlorinated compounds by 1-BP.

Further, 1-BP is incompatible with many applications currently using HCFCs which are scheduled to be phased out in the future. Most approved uses for HCFCs are in the refrigerant sector in applications where 1-BP has not proven to be a cost effective or applicable substitute. At the same time, few HCFCs are scheduled to be phased out in the near future.[34]

Production of HCFC-141b is scheduled to end in January 1, 2003.(Exhibit Q) Although1-BP is an acceptable substitute for HCFC-141b as a solvent cleaner, sales of HCFC-141b as a solvent have been restricted since 1994 (before 1-BP solvents were available) and is limited to use in aerosol spray cans for electronics cleaning. (Exhibit Q) This use is responsible for only a small amount of the use HCFC-141b today. 1-BP can be expected to replace a small amount of HCFC-141b in the solvent sector with a resulting small increase in American 1-BP sales; however, the vast majority of HCFC-141b is used in applications for which 1-BP is not a practical or lawful replacement.

Further, under SNAP, sales of 1-BP are allowed only in the solvent cleaning and adhesive, coatings and inks sectors. Although the SNAP consideration has been underway since 1995, no petition for expanding the use sectors for 1-BP to the refrigeration, aerosol propellant, foam, halon or sterilant sectors have been filed. Currently, 1-BP can not be legally used in the refrigeration, aerosol propellant, foam, halon or sterilant sectors even if 1-BP unexpectedly proved to be an acceptable replacement[35].

The effect of USEPA SNAP approval is expected to create a minimal to very modest increase in the amount of 1-BP sold in the United States, although it will increase confidence in customers already using 1-BP solvents. SNAP approval will not have an effect on substitution for banned compounds, as this has already been completed[36]. Neither will SNAP have an effect on replacement of HCFCs, as 1-BP is not an effective replacement for the majority of HCFC applications and few HCFCs are scheduled to be phased out in the near future. Further, HCFCs are already SNAP approved until such time as they are phased out (2020 - 2030)[37] and time has shown few users will substitute for currently effective compounds without over riding economic and business reason to do so.

Our experience has shown that users have switched to 1-BP because there was no other substitute which met the performance requirements for their application. In addition, it can not be overstated that the practical consideration in the real world marketplace of the cost issues of using 1-BP versus the cost consideration of other solvents, particularly the chlorinated solvents, has proven to be a bar to sales of 1-BP. Therefore, we do not anticipate a growth rate for sale of 1-BP in the United States to exceed the current growth rate of 2.34% per year at any time by more than a diminimus amount. In addition, we believe that due to the current recession and business climate in the last half of 2001, which is expected to continue into 2002, the total amount of 1-BP actually imported into the United States will decline in the immediate and foreseeable future.

The Brominated Solvents Consortium ("BSOC"), a trade group consisting of Great Lakes Chemical, Albermarle and Dead Sea Bromine Group, three of the largest brominated product manufacturers in the world, estimated *world wide production* sales of 1-BP as follows:[38]

| | |
|---|---|
| 2000 | 10,645,000 lbs |
| 2001 | 6,934,400 lbs |
| 2002 | 8,219,200 lbs |

These current estimates reflect actual sales data into 2001 and represent up to a 46% reduction from previous BSOC estimates of world wide production of 1-BP made earlier. (Exhibit R) In fact, reported audited world wide consumption of 1-BP for the year 2000, 9.23 million pounds (Exhibit S) shows that the current BSOC estimates of world wide production may still be overly high.

Although it has been estimated that non-Article 5(1)[39] countries use over 50% of the current 1-BP world production[40], Enviro Tech estimates, based on the information below, that approximately 74% of the world production of 1-BP is used in non-Article5(1) countries. Our estimate for US 1-BP usage in 2000 of 4,338,583 pounds based on PIERS reports and industry participation reflects 47 % of the 9.23 million pounds reported to be used world wide in that year. With Europe using another 2.5 million pounds[41], a total of 74% of the total world wide production of 1-BP is accounted for. Therefore, our estimates of United States usage are consistent with the BSOC world wide estimates.

Finally, it must be pointed out that both the industry and the United Nations TEAP committee have found it prudent to revise estimates of 1-BP production downward within the last year.[42]

**Emissive Applications**

Enviro Tech does not support the sale of any solvent into highly emissive applications, such as adhesive carriers. However, NIOSH reports have shown that even in these emissive applications, users have chosen to install exposure control measures such as the expensive mechanical ventilation systems recommended by NIOSH and have been successful in bringing worker exposure to acceptably low levels[43]. Again, the Nomination's fear that exposure levels could not and would not be controlled has proven not to be true.

1.2.2

Based on our experience as the oldest manufacturer of 1-BP based solvents in the marketplace, we believe the majority of 1-BP used in the United States is used as a solvent in vapor degreasing for the precision cleaning sector, oxygen system cleaning, optic cleaning and electronics cleaning. It is also used, to a much lesser extent, as a cold wipe or cold dip cleaning process. Some 1-BP is used as a carrier in the adhesive sector. It has been long used in the pharmaceutical industry.

1.2.3

**Environmental Exposure to 1-BP**

Again, it is questionable whether the use of unsupported statements, no matter what the source, is appropriate for a scientific review. Thus, unspecified levels of environmental exposure from unidentifiable sources as described in the Draft Report's reference to HSDB 2001, add no useful information to the discussion and should not be considered for inclusion in the Expert Panel report. The Draft Report's statement "[n]o information was found that documents exposure to 1-BP through contact with air, water, food or consumer products" is the proper conclusion which can stand on its own.

Historically, solvent usage was uncontrolled and worker misuse of solvents was a common occurrence[44]. Today, environmental and employer consciousness as well as extremely strong product stewardship programs minimize the amount of solvent going into the atmosphere and minimize the likelihood of environmental contamination. As an example, Enviro Tech prepared a spent solvent recovery program even before the first commercial sale of 1-BP as a solvent was completed. Today, all major producers of 1-BP based solvents have in place a waste recovery system and it is well known that *waste streams from spent 1-BP solvents have commercial value as a recycled product*. Given this commercial value, the relatively small quantity of 1-BP that can reasonably be expected to be used by industry (as compared to chlorinated solvents and other solvents such as glycol ethers), 1-BP's short lifetime and its relatively late identification as a useful solvent in a time when environmental issues are at the forefront of industry consciousness, it is highly unlikely that 1-BP will become an environmental contaminant

**Workplace Exposure**

The Nomination states " there is a pressing need to pin down the 'true' NOAEL - even better, to use standard study designs and statistical methods to establish a `benchmark dose' for each compound". As a direct response to the Nomination to fulfill this pressing need, Enviro Tech sponsored Dr. Marc Stelljes of SLR International, Inc. to conduct a benchmark dose method assessment of the toxicological database for 1-BP and to recommend a workplace exposure level.[45]

Dr. Stelljes used the latest computer modeling software which was developed by the USEPA[46] to conduct the assessment and was assisted in the use of the software and computations by USEPA representatives. This Assessment has been submitted to the USEPA as part of the SNAP program consideration of 1-BP. The study is now in preparation for publication in a peer review journal.

In contrast to the scientific assessment of the complete toxicological database contained in Dr. Stelljes' report, the Draft report cites other recommended exposure levels based on the results of only one toxicological study[47] or on an incomplete toxicological database.[48] Dead Sea Bromine Group, probably the major 1-BP producer in the world, explained in a letter to the USEPA that its move to a 25 ppm exposure level was based on solely on legal issues pending a recommendation of an exposure limit by the USEPA. (Exhibit T)

We believe that since Dr. Stelljes' work is a direct reply to OSHA's identification of a "pressing need" to determine a bench mark dose for 1-BP and encompasses a standard study design which uses statistical methods to establish a benchmark dose as described in the Nomination, the assessment should be included in the Expert Panel's review or at the very least to be identified with other descriptions under Section 1.2.3 Occupational Exposure Sources.

**Ozone Depletion Potential and Global Warming**

1-BP is the most extensively studied chemical compound regarding ozone depletion potential. Enviro Tech sponsored the first full study of the ODP of 1-BP by Dr. Donald Wuebbles of the University of Illinois[49], who is known as the creator of the ozone depletion potential concept and who developed the model used by the United Nations when developing the Montreal Protocols[50]. When tested using identical methods and systems to those used to determine the ODP of *every other* chemical compound for which an ODP has been calculated to date, the ODP of 1-BP was calculated at .006[51]. This, in effect, means that 1-BP had only 6/1000 's the adverse effect on stratospheric ozone as CFC-111.

It is known that 1-BP has a very short atmospheric lifetime, between 11 and 19 days[52]. When it was later questioned whether or not the current 2 dimensional ("2D") modeling programs were applicable to compounds with short atmospheric lifetime, 1-BP was subjected to a new modeling system, the 3 dimensional model ("3D"). The 3D model takes into consideration far more information that the previous 2D model and the 3D model used by Dr. Wuebbles for his calculations considers over four hundred more chemical reactions than other 3D models which have been developed[53]. The 3D modeling calculated an ozone depletion potential of .016 for 1-BP in the United States[54].

Dr. Wuebbles has also calculated that an emission of 15,000,000 pounds of 1-BP (over three times the current US usage level and over twice the estimated world production for 2001) from the United States would result in a total change in stratospheric ozone too small to be measured[55].

Dr. Wuebbles has also written that any compound with an atmospheric lifetime of one year or less would benefit from using the 3D model and that compounds with an atmospheric lifetime of less than six months could only be calculated accurately using the 3D method[56]. Methylene chloride and perchloroethylene have atmospheric lifetimes of five to six months, whereas trichloroethylene has an atmospheric lifetime of six to eight days. (Exhibit U) To date, the USEPA continues to tout the benefits of these well known chlorinated solvents because of their short atmospheric lifetimes (Exhibit V) although none of these chlorinated solvents have been tested using the 3D model, even though methylene chloride, perchloroethylene and trichloroethylene all have atmospheric lifetimes within the identified range where an accurate ODP can only be determined through the use of the 3D model and are used in substantially larger quantities which may have more immediate effects on stratospheric ozone. 1-BP remains the only chemical compound in the world that has been subjected to the 3D model testing. Even so, the ODP of .016 is less than HCFC compounds which have already been SNAP approved. (Exhibit W) 1-BP, with its short atmospheric lifetime, can not be expected to be a cause of global warming, unlike most of the already SNAP approved HCFCs and HFCs.

1.4

**Workplace Exposure in the Adhesive Sector**

It should not be over looked that a complete review of all the NIOSH exposure level assessments show that responsible use is the current norm[57]. As discussed above, a number of NIOSH exposure studies show that initial high exposure levels were subsequently controlled by the addition of NIOSH recommended mechanical ventilation systems, which reduced worker exposure dramatically.

**Worker Exposure During Vapor Degreasing**

Most 1-BP is used in vapor degreasers in the United States. In a vapor degreaser, the solvent is heated to its boiling point, forcing the vapors to rise within the machine. The top of the machine is surrounded by cooling coils, which keep the temperature at least 40° F cooler than the vapor. The difference in temperature forces the vapors to remain below the cooling coils. Parts are cleaned by lowering them into the vapor, where the difference in temperature causes the vapor to condense on the parts. Raising the part through the cooling coils causes the now liquid solvent to fall off the part, carrying the dirt back into the machine. With a vapor degreasing system, emissions are reduced as opposed to a cold vapor cleaner. A typical vapor degreaser at idle emits .02 pounds of solvent per hour per square foot of air/solvent interface. (Exhibit X) Typical worker exposures working at the degreaser is expected to be below 15 ppm and is frequently found to be under 10 ppm. (See Exhibit D).

**28 Day Repeated Exposure Study - ClinTrial 1997a**

As reported in the study itself, the draft report notes that microscopic evaluation indicated vacuolation of white and grey matter in the central nervous system for all treated groups. As Doull and Rozman point out, "the lack of vacuolization in the central nervous system even at 600 ppm in the 13 week study when contrasted with the findings of CNS vacuolization at 400 ppm in the 28 day study cannot be easily reconciled."[58]

Although we have no written documentation in our possession, Jeff Cohen of the USEPA SNAP program has publically stated a number of times that USEPA experts had determined that what was previously viewed as CNS vacuolization found in the 28 day study was found to be merely an artifact of slide preparation. We suggest that this information be further investigated by the Expert Panel for clarification if this effect is found to be relevant to the Panel's emphasis on reproductive and developmental effects.

Again, the above comments regarding the NTP-CERHR Expert Panel Draft Report on Reproductive and Developmental Toxicity of 1-Bromopropane are respectfully submitted for consideration and insertion into the NTP public docket concerning the Expert Panel review of 1 Bromopropane ("1-BP") and inclusion in the Panel's Final Report.

**Ichihara Studies**

Over the past several years, Reva Rubenstein, Jeff Cohen and Erin Birgfeld of the USEPA's SNAP program have all publically questioned the Ichihara studies regarding, among other things, GLP and the supervision of students participating in the study. Other industry commentators as well have questioned the validity of some points of these particular studies, pointing out that some effects which were seen in theses studies were not duplicated in similar subsequent studies.[59]

Although we again have no written documentation in our possession, this issue is well known and continually discussed throughout the industry. Because of the nature of these statements made by well known and well respected United States governmental officials, we believe it is extremely important that these issues be fully investigated by the Expert Panel for clarification since the reproductive portion of the Ichihara study has been determined to be useful in the Panel's review. The Expert Panel has an important opportunity to investigate and discuss these matters and use their expertise and the weight and respect of the National Toxicology Project to offer a definitive conclusion to this issue. If this issue as a whole is left unaddressed, it may very well serve to undermine the ultimate summary and conclusions of the Panel's Final Report.

Please do not hesitate to call if you have any comments or questions.

Cordially,

Richard Morford
General Counsel

# REFERENCES


1. US Patents 5616549, 5824162, 5938859 and 6176942. Patents may be viewed at www.ensolv.com.

2. US Patent Application 2001/0000001A1.

3. European Patent 781842.

4. Among others, Germany - Pat. No. 69604477.3; France, United Kingdom , Italy, Netherlands, Sweden - Pat. No. 0781842.

5. Enviro Tech SNAP Petition - Snap Docket No. A-91-42 VI-D-138.

6. As an example: *Human Cell Bioassay of 1-Bromopropane and 2-Bromopropane* EnviroMed Laboratories, Windsor, Ontario, Canada 1997 (K. Adali, B. Hasspieler).

7. Dr. John Doull, Ph.D., M.D. and Karl K. Rozman, Ph.D., D.A.B.T. *Derivation of an Occupational Exposure Limit for n-Propyl Bromide*. Enviro Tech International, Inc. 2001.

   Dr. Marc Stelljes Ph. D. *Inhalation Occupational Exposure Limit for N-Propyl Bromide* Enviro Tech International, Inc. 2001.

8. Dr. Gary Z. Whitten . *The Hydrocarbon Equivalency of 1-Bromopropane*. Enviro Tech International, Inc. 1998.

   Dr. Gary Z. Whitten.. *VOC Reactivity of 1-Bromopropane*. Enviro Tech International, Inc. 1999.

9. Wuebbles, Jain, Patten, Connel. *Evaluation of Ozone Depletion Potential for Chlorobromomethane and 1-Bromopropane*. Atmospheric Environmental Vol. 32, No. 2 107 - 113 1998.

10. A review of physical properties of various chlorinated solvents, including their flammable limits is available from the Halogenated Solvents Industry Alliance at http://www.hsia.org/properties.html.

11. See the bibliography of prior art included in the Enviro Tech Patents referenced in Note 1 above.

12. Ibid.

13. Certificate of Analysis are available to the NTP-CERHR Expert Panel upon request.

14. Sclar, Case Report *Encephalomyeloradiculoneuropahty following exposure to an industrial solvent.* 1999 page199.

15. 1-BP based solvent producers include Enviro Tech International, Petrofirm, Albermarle and Polysystems. Other smaller companies also exist. Great Lakes Chemical produced a 1-BP based solvent on or about September, 2000, when it exited the solvent marketplace. (See Exhibit O)

16. MSDS for all solvent manufacturers are public documents available upon request from the suppliers and , for the most part, from the manufacturer's web sites.

17. Yu X, et. al. *Preliminary Report on the neurotoxicity of 1-Bromopropane, an alternative for chlorofluorocarbons*. J. Occup Health 1998: 40. 234-235.

18. Ibid.

19. Kim, et. al. *Hematopoietic and reproductive hazards of Korean electronic workers exposed to solvents containing 2-Bromopropane.* Scand J Work Environ Health 1996: 22: 387-91.

20. Expert Panel Draft Report. pg 7 re Jones and Walsh 1979.

21. Expert Panel Draft Report. pg 15 re Fueta et. al. 2000.

22. Expert Panel Draft Report. pg 5 re Kim et. al., 1999a.

23. *OSHA Nomination of 1-Bromopropane and 2-Bromopropane for Testing by the National Toxicology Program.* December, 1999. See page 2 and follow reference to Endnote 1.

24. Federal Register: February 18, 1999 (Volume 64, Number 32). Pg 8043 - 8048.

25. Certificate of Analysis are available to the NTP-CERHR Expert Panel upon request.

26. Halogenated Solvent Industry Alliance White Papers for Trichloroethylene, methylene chloride and perchloroethylene are available at www.hsia.org or as an exhibit to Enviro Tech's previous Comment to the Panel regarding the OSHA Nomination..

27. http://www.freedoniagroup.com.

28. http://www.ecnext.com.

29. Halogenated Solvent Industry Alliance Methylene Chloride White Paper. June 1998. Available at www.hsia.org.

30. Halogenated Solvent Industry Alliance Perchloroethylene White Paper. November, 1999. Available at www.hsia.org

31. Halogenated Solvent Industry Alliance Trichloroethylene White Paper. 1996 updated February, 2001. Available at www.hsia.org.

32. See Exhibit M page 1. Although I have criticized the conclusion reached by the author concerning the SNAP program, the author's recitation of these particular facts are correct in that little or no direct substitution for banned compounds is happening currently.

33. See Exhibit Y, a Freedonia Group report showing a current and future estimated zero demand for 1,1,1-trichloroethane, the most widely used banned solvent.

34. 42 USC 7671d.

35. 42 USC §7671k.

36. See references 33 and 34 above.

37. See Reference 35.

38. UNEP Report on the Geographical Market Potential and Estimated Emissions of n-Propyl Bromide. April, 2001. Pg 13 footnote 13.

39. Ibid. See Appendix 2 for list of Article 5(1) and non-Article 5(1) countries.

40. UNEP Report of the Technology and Economic Assessment Panel. April, 2000. Section 4.1.4.

41. Ibid. Section 4.1.3.

42. Compare figures in Reference 39 with Exhibit Q for review of downward estimates of world wide production from the Brominated Solvents Consortium.. The 2000 TEAP report (Reference 41) estimates production of 60,000 to 100,000 metric tonnes of 1-BP in five years, beginning in 1999. The next yearly report (Reference 39) estimates total world wide production of 1-BP at 20,000 to 60,000 metric tonnes in ten years, which encompasses a reduction in the maximum estimated emission of 40,000 metric tonnes and doubles the time frame to reach that maximum to ten years. We believe even these estimates are unrealistically high.

43. Compare NIOSH letter (Reh) to Custom Products, Inc. May 26, 1999 (HETA 98-0153) with NIOSH Letter (Reh) of December 21, 2000 and see NIOSH letter (Harney) to STN Cushion Company of September 12, 2001 (HETA 2000-0410) for discussion of reduction of workplace exposure levels by users.

44. A recent series of articles in The Courier Journal newspaper ( Louisville, Kentucky, a Garnett Newspaper, Sunday May 13, 2001) relate how trichloroethylene was misused in the railroad industry in the period 1960 - 1980. The article chronicles workers use of solvents with little regard to safe workplace practices including splashing and spraying trichloroethylene to clean locomotives over an open maintenance pit where other employees, working in the maintenance pit, would be drenched in the solvent.

45. Dr. Marc Stelljes Ph. D. *Inhalation Occupational Exposure Limit for N-Propyl Bromide* Enviro Tech International, Inc. 2001.

46. U.S. Environmental Protection Agency (USEPA) 2001a *Benchmark Dose Software, Version 1.3.* Available online at http://www.epa.gov

U.S. Environmental Protection Agency (USEPA) 2001b *Help Manual for Benchmark Dose Software Version 1.3* Office of Research and Development. EPA 600/R-00/014F. Washington, D.C. March.

U.S. Environmental Protection Agency (USEPA) 2000 *Benchmark Dose Technical Guidance Document.* External Draft Review. Risk Assessment Forum. EPA/630/R-00/001. Washington, D.C. October.

U.S. Environmental Protection Agency (USEPA) 1995. *The Use of the Benchmark Dose Approach in Health Risk Assessment.* Office of Research and Development. EPA/630/R-94/007. Washington, D.C. February.

47. Albermarle MSDS for Abzol, their 1-BP based solvent, dated 10/17/00 states that 25 ppm is set based on preliminary results of reproductivity tests.

48. ATOFINA's public statements regarding its recommended exposure level contain references to only a small percentage of the available studies on 1-BP

49. See Reference 9.

50. Wuebbles, D.J. *Chlorocarbon Emission scenarios: Potential Impact on Stratospheric Ozone.* J. Geophys. Res. 88, 1433 - 1443, 1983.

51. See Reference 9

52. Wuebbles, Donald. Patten, Kenneth O, Johnson, Matthew T; Kotamarthi, Rao 2001 *New Methodology for Ozone Depletion Potentials of Short-lived Compounds: n-propyl bromide as an example* J. Geophys. Res. Vol 106, No. D13, p. 14,551 (2001JD00008)

53. Private communication with Dr. Donald Wuebbles to Richard Morford.

54. See Reference 53.

55. Wuebbles, Donald. *Expected Response of Stratospheric Ozone to Recent Use of 1-BP in the United States.* Enviro Tech International, Inc. 2001.

56. Wuebbles, Donald. *What Constitutes a Short Lived Gas for Evaluating ODPs?* Enviro Tech International, Inc. 2001.

57. A complete review of all NIOSH initial exposure assessments and their related subsequent assessments by NIOSH at Custom Products, Inc. (see Exhibit e and F) Trilithic, Inc. (see Exhibit C) and STN Cushion Company (Exhibit G) shows that each company worked to provide appropriate ventilation systems and/or exposure controls to dramatically reduce worker exposure to appropriate levels.

58. See Reference 7.

59. As an example, the retained spermatid endpoint in the Ichihara study was not confirmed by the WIL Research two generation reproductivity test. Reduced plasma CPK found in the Ichihara study was not reproduced in any other critical study.