White Paper: Identification of Key Exposure Pathways for 1,3-Butadiene (BD)

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1,3-Butadiene TSCA Risk Evaluation Consortium

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The text below is intended to provide a high-level summary of data and issues related to exposures to 1,3-butadiene (BD) in the United States, including its chemical-physical properties, releases to the environment, historical trends, and identification of important exposure pathways.

1. Chemical-Physical Properties

- Based on physical chemical (PC) properties (high Henry's law, vapor pressure, low-to-insoluble in water; **Table 1**; adapted from USEPA's *Final Scope of the Risk Evaluation for 1,3-Butadiene*) BD is a highly volatile gas at standard temperature and pressure.
- Due to these properties, inhalation of BD in air is expected to be the primary (and near exclusive) route of exposure.
- Due to these properties, BD poses several potential physical hazards:
    - At high air concentrations, it is highly flammable and susceptible to ignition due to its extremely low flash point. Its vapors are heavier than air and a flame can flash back to the source of leak very easily.
    - Contact with the liquid BD, which requires low temperatures and/or high pressure, can cause frostbite.
    - At high air concentrations, BD can cause asphyxiation by displacement of oxygen in air.
- A separate white paper has been prepared that covers the chemical-physical properties of BD (unpublished white paper: *1,3-Butadiene Overview*).

Table 1: Select Physical-Chemical Properties of BD

Property or Endpoint	Value[a]	Reference	Data Quality Rating
Molecular formula	C_4H_6	NA	NA
Molecular weight	54.09 g/mol	NA	NA
Physical state	Colorless gas	Rumble (2018a)	High
Physical properties	Colorless, mildly aromatic or gasoline- like odor	NLM (2003)	High
Melting point	-108.966°C	O'Neil (2013)	High
Boiling point	-4.5°C at 760 mm Hg	O'Neil (2013)	High
Density	0.6149 g/cm3 at 25°C and >1 atm	Rumble (2018a)	High
Vapor pressure	2110 mm Hg	U.S EPA (2019b)	High
Vapor density	1.87 (air = 1)	NLM (2003)	High
Water solubility	735 mg/L at 20°C	NLM (2003)	High
Octanol/water partition coefficient (log Kow)	1.99 at 25°C	Rumble (2018c)	High
Henry's Law constant	0.204 atm·m3 /mol at 25°C	Rumble (2018b)	High
Flash point	-76.111°C	RSC (2019)	High
Auto flammability	420°C	Rumble (2018a)	High
Viscosity	0.00754 cP at 20°C	NLM (2003)	High
Refractive Index	1.4292	Rumble (2018a)	High
Dielectric constant	2.050	Rumble (2018a)	High

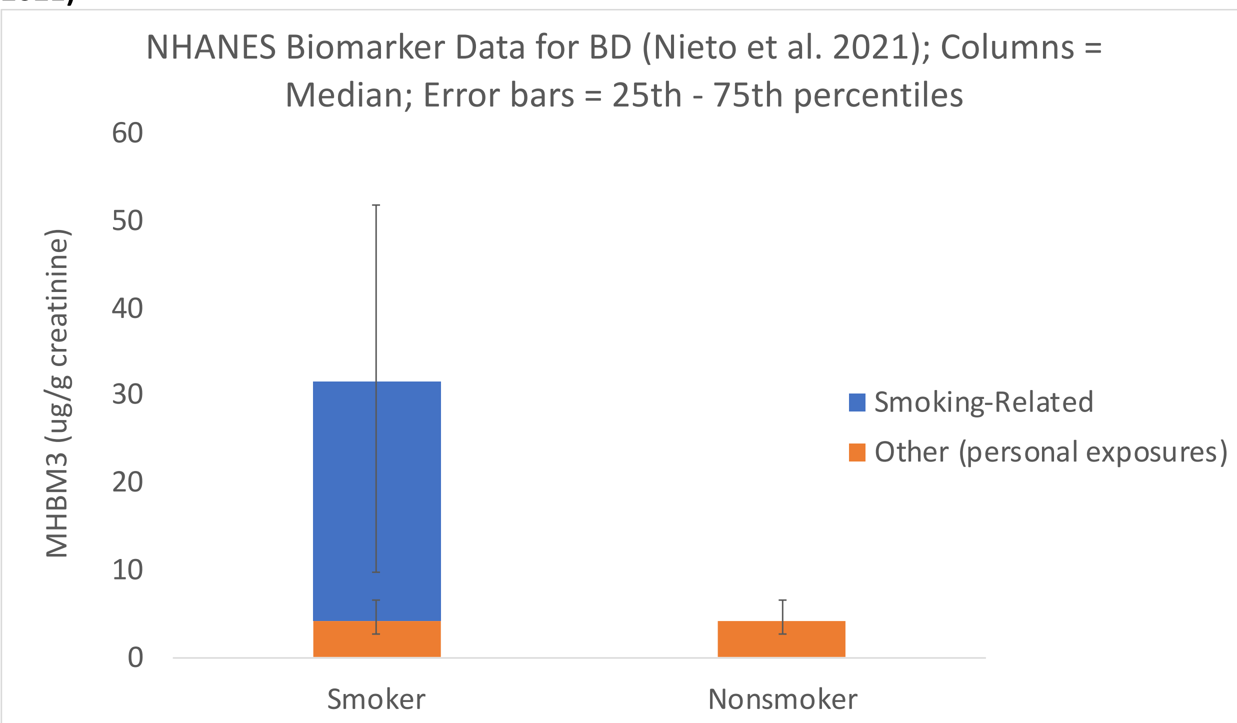
[a] Measured unless otherwise noted.

NA = Not applicable

2. BD Exposure is Ubiquitous and Smoking is the Largest Non-Occupational Source of Exposure in the United States

- Essentially all people are exposed to BD in some manner based on urinary biomarker detection rates greater than 96% of samples collected as part of the Nation Health and Nutrition Examination Survey (NHANES) in United States (Nieto et al. 2021). These biomarker measurements reflect total exposure to BD (i.e., across all exposure pathways for recent exposures to BD).
- Smoking represents the single largest non-occupational source of BD exposure to the US population. Urinary biomarkers (N-acetyl-S-(4-hydroxy-2-buten-1-yl)-L-cysteine or MHBMA3) measured in smokers are on average approximately 7.5-fold higher (31.5 vs 4.11 ug/g creatinine) than corresponding levels measured in nonsmokers (**Figure 1**).
- Biomarker measurements in nonsmokers reflect recent personal exposures to BD (e.g., ambient air, indoor air, in-vehicle air, etc.).

Figure 1. BD Urinary Biomarkers in Nonsmokers and Smokers (NHANES 2011-16; Nieto et al. 2021)



- Smoking exposures to BD in the US have decreased over time due to trends in smoking behaviors (**Table 2**), such that exposures to BD from smoking were considerably larger in the past than were measured in NHANES 2011-2016. This decreasing trend is expected to continue in the future. The estimated mean (based on changes in smoking habit, and a correlation between biomarker concentration in urine and cigarettes per day (CPD)) in this table for smokers in 2015 (25 ug/g creatinine) matches well with measured values reported for smokers in NHANES 2011-16 (median = 31.5 ug/g creatinine; Nieto et al. 2021)

Table 2. Estimated BD Biomarker Based on Trends in Smoking Behavior in the US

	Smoking Intensity (% of smokers that fall into each cigarette-per-day (CPD) category)*				Urinary MHBMA3 (ug/g creatinine)		
Year	**High (>24 CPD)**	**Medium (15-24 CPD)**	**Low (<15 CPD)**	**Smoking Prevalence (%)***	**Smoker Estimated Mean****	**Nonsmoker Estimated Mean*****	**Estimated US Population Mean (smokers and nonsmokers combined)**
1975	25.9	43	31.2	37.1	35	4.1	15.5
1980	29.1	42.1	28.2	33.2	36	4.1	14.7
1985	26.6	41.8	31.6	30.1	35	4.1	13.4
1990	22.9	42.6	34.5	25.5	34	4.1	11.7
1995	20.1	39	40.9	24.7	32	4.1	11.0
2000	15.4	38.8	45.8	23.3	30	4.1	10.2
2005	11.7	36.6	51.7	20.9	28	4.1	9.2
2010	7.4	33.7	58.9	19.3	26	4.1	8.4
2015	6.4	29.7	63.9	15.1	25	4.1	7.3

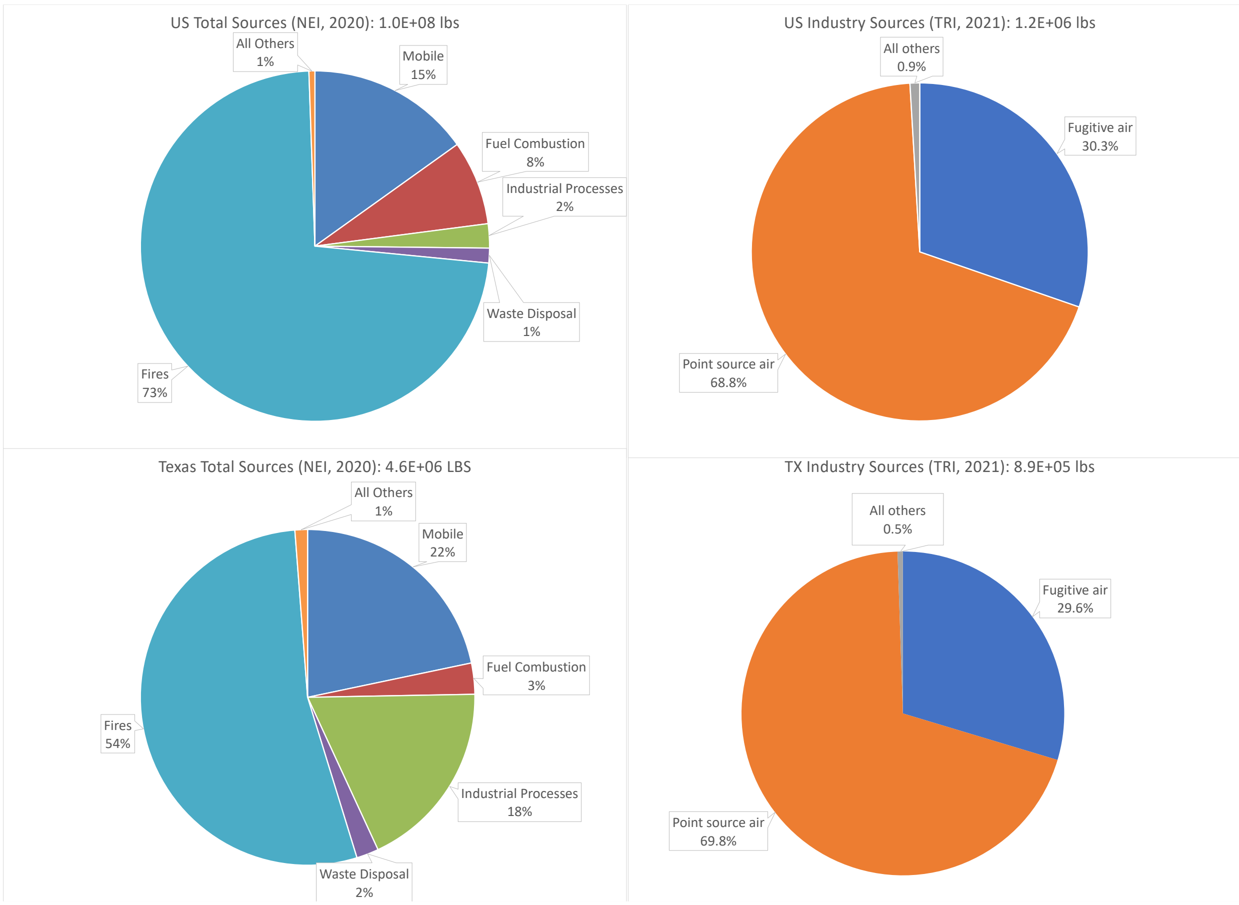
*American Lung Association (ALA, 2020)
**Estimated from smoking intensity data and a correlation between urinary MHBMA3 and CPD based on data reported in Nieto et al. (2021).
***Assumed constant over time

3. Based on Release Data, Inhalation is the Primary Route by Which the US Population is Exposed to BD

- In addition to the physical-chemical properties of BD (**Table 1**) which favor the inhalation pathway, release information indicate that air is the predominant exposure media since >99% of known BD releases are directly to air.
  - US Data:
    - EPA National Emissions Inventory database (NEI, 2020) reports that over 1E+08 lbs of BD were released, of which fires (73%) and mobile sources (e.g., fuel combustion from cars and trucks) (15%) represent the largest sources, and releases associated with industrial processes and disposal (3.6% combined) represent a small source in the US (**Figure 2**).
    - EPA Toxics Release Inventory database (TRI, 2021) reports that over 1.2E+06 lbs of BD were released as a result of industrial processes, of which point source releases (69%) and fugitive air releases (30%) were the largest sources, with all others being negligible (<1%) (**Figure 2**).
    - It should be noted that industrial emission estimates from these two data sources are similar but not an exact match, due to differences in reporting requirements and practices.

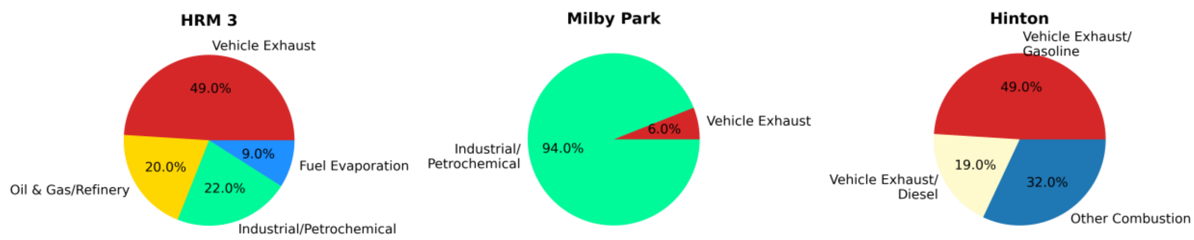
- Texas Data:
  - In Texas, as a state that produces a large portion of BD in the US, NEI (2020) reports that over 4.6E+06 lbs of BD were released, of which fires (54%), mobile sources (22%), and industrial processes and disposal (21% combined) represent the largest sources (**Figure 2**).
  - EPA Toxics Release Inventory database (TRI, 2021) reports that over 8.8E+05 lbs of BD were released in Texas as a result of industrial processes, of which point source releases (70%) and fugitive air releases (30%) were the largest sources, with all others being negligible (<1%) (**Figure 2**).
  - As noted above for national estimates, industrial emission estimates at the state level from these two data sources are similar but not an exact match, due to differences in reporting requirements and practices.

Figure 2. BD Releases Based on (A) EPA National Emissions Inventory (NEI, 2020) and (B) Toxics Release Inventory (TRI, 2021)



- Based on its physical-chemical properties (e.g., boiling point of -4.5 C; **Table 1**), the relatively small amounts of BD released to media other than air (e.g., water, soil) are expected to rapidly volatilize to air.
- At the local level, the relative importance of different emissions sources to air concentrations is highly site-specific, depending on proximity to industrial and other sources (e.g., highways) of BD, as indicated by air modeling results for three locations in the Houston, TX area (**Figure 3**).

Figure 3. Source Apportionment Based on Air Modeling for Three Specific Locations in the Houston, TX Area (AECOM, 2024) (HRM = Houston Regional Monitoring)



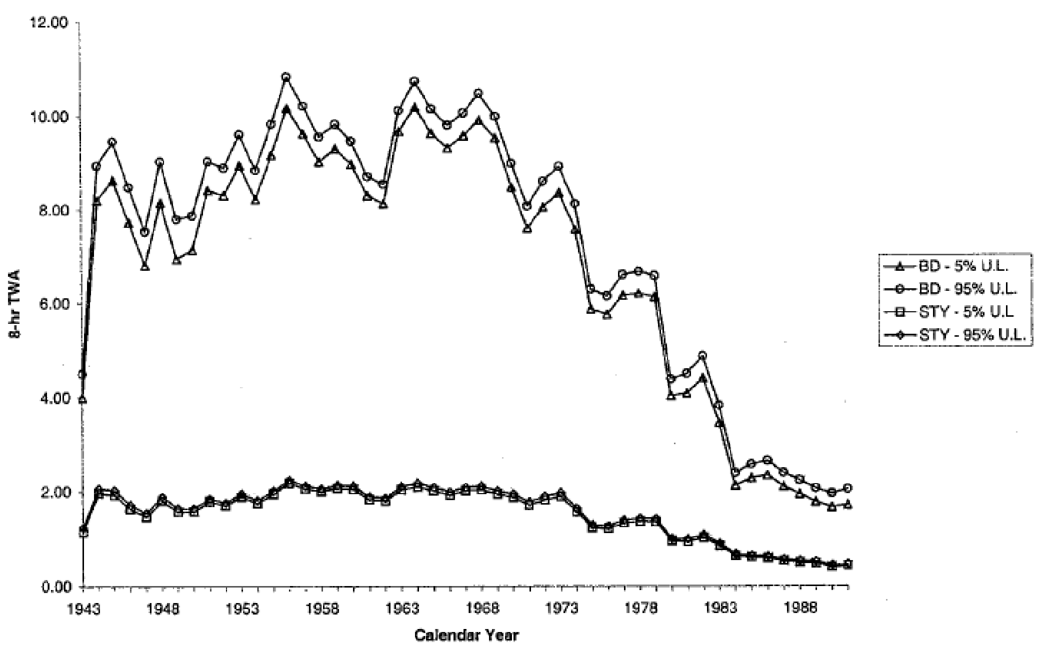
4. Exposures to BD in the U.S. Have Decreased Over Time and are Currently Low

- In addition to the decreasing trends in exposure to BD estimated from smoking noted above (**Table 2**), other BD exposures have generally decreased over time, including those to workers and those associated with ambient air, as summarized below.

4.1 Worker Exposures to BD Have Decreased and Are Low At Present

- In styrene-butadiene rubber (SBR) workers, BD exposures have generally decreased from the 1960s to 1991 as a result of engineering controls and regulation (in particular the establishment of Occupational Safety and Health Administration in 1970) (**Figure 4**).

Figure 4. Historical Trend for Occupational Exposure to BD (ppm) in SBR workers (Macaluso et al. 2004)



- The refined exposure estimates from the Macaluso et al (2004) study, shown in **Figure 4** serve as the exposure basis used to determine a cancer unit risk value for BD based on worker exposures and leukemia mortality (Valdez-Flores et al., 2022).
- Occupational exposures in SBR workers have continued to decrease after 1991, with current exposures to SBR workers typically being below 0.2 ppm (**Table 3;** IISRP, 2020)

Table 3. Summary of a Recent Occupational Exposure Survey for SBR Worker Exposures to BD (IISRP, 2020; rounded to two significant figures)

			Concentration (ppm)	
Activity	**Analytical Method**	**Sampling duration (range)**	**Average**	**Standard Deviation**
Analyze Samples	MDHS 88/ OSHA 7; OSHA 56	8–12 Hours	0.036	0.058
Collect samples	OSHA 56 / MDHS 88	8–12 Hours	0.012	0.021
Connecting/ Disconnecting	MDSH 88/ OSHA 56/ OSHA 7	4–8 Hours	0.0098	0.016
Maintenance Jobs	OSHA 56 / OSHA 7/ MDHS 88/ NIOSH 1024M	4–8 Hours	0.010	0.020
Routine Rounds	MDHS 88/ OSHA 7/ OSHA 56/ NIOSH 1024M	8–12 Hours	0.0087	0.017

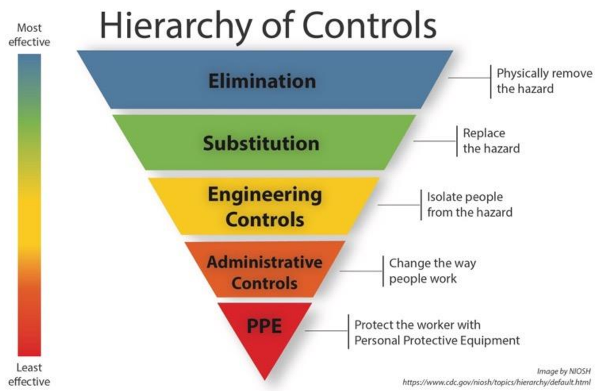
- Similarly, full-shift exposures to BD manufacturing workers are also generally below 0.5 ppm under current routine conditions (**Table 4;** Panko et al. 2023).

Table 4. Full-Shift Exposures in BD Manufacturing Workers (from Panko et al. 2023)

				Full-Shift Personal Air Concentrations (ppm)—Kaplan Meier Statistics								
Job Group	N Samples	% Non-Detects	% DL < 0.1 ppm	Min	50th	90th	95th	KM-Mean	SE	95LCL Mean	95UCL Mean	Max
Infrastructure/Distribution Operations	455	78%	72%	0.006	NA	0.21	0.45	0.12	0.038	0.045	0.19	16.4
Instrument and Electrical	313	91%	63%	0.008	NA	0.021	0.16	0.068	0.033	0.003	0.13	10.0
Laboratory Technician	215	73%	86%	0.006	NA	0.12	0.25	0.063	0.016	0.031	0.094	2.93
Machinery and Specialists Group	222	80%	97%	0.008	NA	0.060	0.28	0.087	0.023	0.042	0.13	3.31
Maintenance	354	69%	46%	0.001	NA	0.23	0.24	0.11	0.010	0.089	0.13	2.10
Occupational Non-User	39	77%	100%	0.008	NA	0.013	0.033	0.012	0.001	0.010	0.014	0.038
Operations Onsite	1952	88%	85%	0.0001	0.001	0.037	0.19	0.074	0.016	0.043	0.11	16.0
Safety Health and Engineering	21	71%	100%	0.038	NA	0.19	0.36	0.16	0.036	0.087	0.23	0.78
Missing Job Group Designation	378	94%	91%	0.002	NA	NA	0.037	0.024	0.004	0.016	0.032	1.3

- To reduce/minimize potential exposures to BD, facilities have implemented a hierarchy of controls that consist of elimination, substitution, engineering controls, administrative controls, and personal protective equipment (PPE) (**Figure 5**).

Figure 5. Hierarchy of Controls to Reduce/Minimize Worker Exposures



- Since 1970, OSHA has required the use of personal protective equipment (PPE) by workers when there is a reasonable probability of injury that can be prevented by such equipment. Respirator use by BD manufacturing workers has been characterized by Panko et al. (2023) (**Table 5**).

Table 5 PPE Use in BD Workers (Panko et al. 2023)

	1,3-BD Workplace air concentration ranges (ppm) reported with respirator use			
Task	Supplied Air	Full-Face APR	Half-Face APR	No Respirator
Unloading & Loading	<0.118–89	<0.06–36	<0.05–2.2	–
Handling Waste	–	<0.25–<3.7	<0.08–<0.1	–
Cleaning & Maintaining Equipment	<0.15–120	<0.02–110	<0.04–<0.7	<0.4–<0.7
Sampling Collection & Analysis	<0.52	<0.06–12	<0.09–7.3	<0.02–4.8
Performing Other Tasks	0.27–4.7	<0.24–<0.42	<0.2–<0.3	<0.39–<0.67

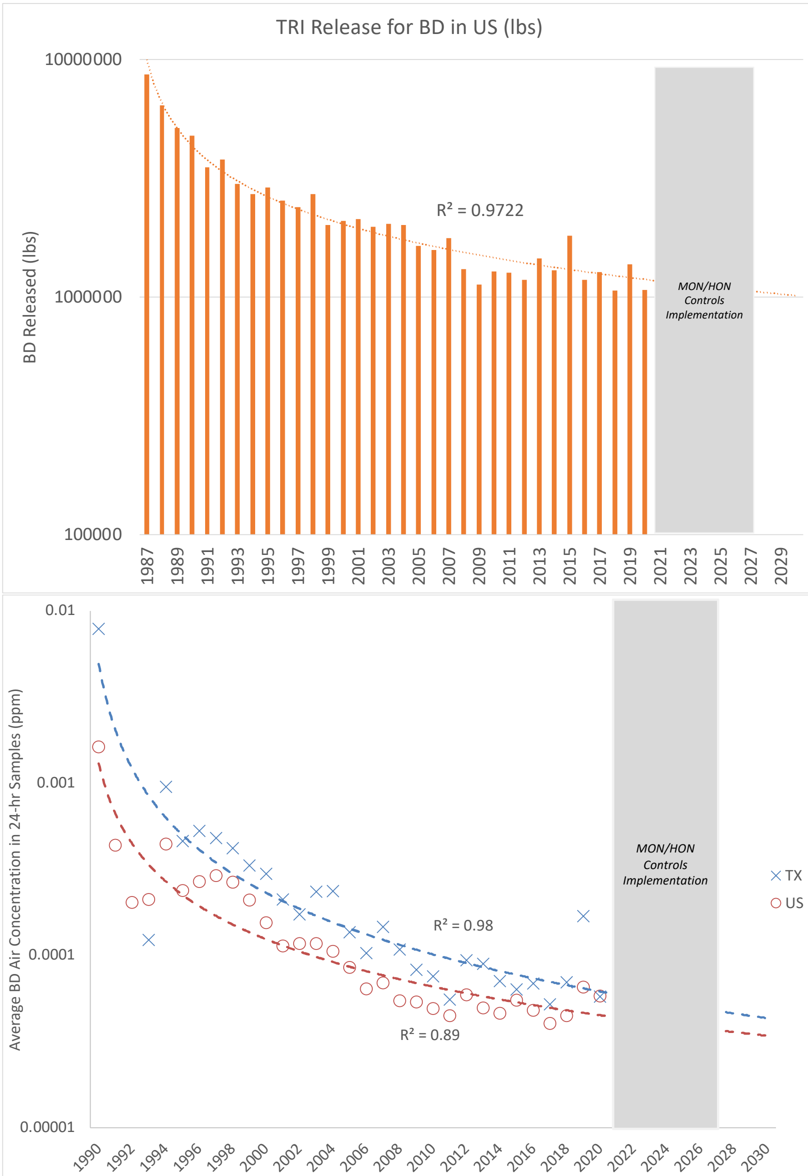
Note: APR = air-purifying respirator.

- Occupational exposures to BD for a wide variety of worker job categories in Italy have been characterized (Scarselli et al. 2017), yielding an overall mean±SD of 0.12±0.37 mg/m3 (0.054±0.17 ppm).

4.2 Ambient Air Release and Concentrations of BD Have Decreased and Are Comparatively Low at Present

- Over the past three decades, industry emissions and ambient concentrations of BD in air have been decreasing (**Figure 6A; TRI, 2020**). National and statewide annual average levels of BD in ambient air in the U.S. and Texas are generally less than 0.0001 ppm and 0.0003 ppm, respectively, at present; **Figure 6B**, EPA AMA, 2020).

Figure 6. Historical Trends for (A) Industry BD Emissions (TRI, 2020) and (B) Concentrations in Ambient Air (EPA AMA, 2020)



- Additional decreases in emissions and resulting air concentrations of BD are expected. For example, recent regulations (EPA 2020 MON final rule; EPA 2023 HON final rule) are expected to reduce emissions of various hazardous air pollutants including BD.
- In 2020, the annual average air concentrations for BD in the US and TX were 0.000058+/-0.00014 ppm and 0.000057+/-0.00013 ppm, respectively.
- Ambient air concentrations of BD can vary from location to location depending upon proximity to important release sources (e.g., BD facilities, highways, wildfires). Measured air concentrations for two air monitoring locations in Houston, Texas near a BD facility are provided in **Table 6** (AECOM, 2024).

Table 6. Measured Air Concentrations at Two Locations near Houston, Texas (AECOM, 2024)

	BD Annual Average (±SD) Air Concentration (ppm; reflects BD from all sources)	
Monitoring Station	**2019**	**2021**
HRM-3 (far from facility)	0.000080± 0.00032	0.00013± 0.00067
HRM-16 (near facility)	0.00018± 0.0025	0.00023 0.00064

5. Indoor Air and In-Vehicle Air Concentrations of BD

- Huy et al. (2018) provides a comprehensive review of 1,3-butadiene concentrations in air for a variety of microenvironments. Studies that measured both indoor and outdoor air concentrations in the U.S. indicate that indoor concentrations are generally higher than outdoor. For example, average residential indoor concentrations in New York ranged from 0.00045-0.00054 ppm compared to an outdoor average concentration of 0.000045 ppm. Similarly for Los Angeles, average indoor air concentrations ranged from 0.000090-0.00022 ppm compared to outdoor average concentrations that range from 0.0000045-0.00014 ppm. Indoor air concentrations of BD are likely higher due to the contribution of a variety of indoor sources of BD (e.g., environmental tobacco smoke, wood-burning, fuel combustion/attached garages, heating some cooking oils).
- Logue et al. (2011) assembled data from seven studies that included 879 samples for BD considered to be representative of U.S. residences. These data yielded a mean indoor air concentration of 0.00021 ppm and a 95th percentile of 0.00059 ppm, which as noted above reflect BD from a variety of sources.
- Other indoor air environments (e.g., restaurants, offices) appear to be of similar magnitude as indoor residential air (reviewed in Huy et al. 2018).
- In-vehicle air samples collected in Sacramento and Los Angeles yielded mean BD concentrations of 0.001-0.0013 ppm, and similar to levels reported in vehicles for other countries (reviewed in Huy et al., 2018). These levels are attributed to fuel combustion since BD was reportedly only observed at significant concentrations inside the cabins of moving vehicles during peak-hour traffic, otherwise in-vehicle levels were near ambient levels and/or the detection limit (Duffy and Nelson, 1997).

6. Non-Inhalation Exposures of Workers to BD are Expected to be Negligible

- Based on physical-chemical properties (e.g., boiling point of -4.5 C; **Table 1**) BD is expected to volatilize from water, other media, and from human skin. BD is a gas at standard temperature and pressure, and can exist in liquid forms only under high pressure/low temperature. Exposure to liquid BD is not expected, as this would result in freeze-related damage to the skin. BD in dilute solutions would be expected to rapidly volatilize from skin.
- BD exposures to workers are expected to be limited due to a hierarchy of controls. In addition, workers currently rely on personal protective equipment (PPE) to prevent cold damage due to frostbite and this will prevent/minimize potential dermal exposures to BD. As stated in Panko et al. (2023), "*The potential dermal exposure of certain workers who may contact liquid streams with trace amounts of 1,3-BD has not been assessed quantitatively; however, streams with trace amounts of BD are likely to be hydrocarbon mixtures. Safe practices in the workplace require the use of dermal protection to prevent contact with hydrocarbon mixtures. The use of gloves that are resistant to hydrocarbons would provide sufficient protection for low concentrations of BD*."
- Historically, dermal and incidental ingestion pathways for BD have not been included in worker exposure assessments for BD. For example, Macaluso et al. (2004) focused exclusively on inhalation exposures to BD to characterize historical exposures to SBR workers (see **Figure 4** above), which is consistent with its chemical-physical properties. In contrast, these authors did estimate dermal co-exposures to workers for a different chemical (dimethyldithiocarbamate or DMDTC), based on a consideration of its chemical-physical properties (i.e., low vapor pressure, low volatility). Because the inhalation exposure estimates of Macaluso et al. (2004) for BD have been used by agencies and risk assessors to characterize the cancer potency of BD, all dependent toxicity values (e.g., cancer unit risk values) are exclusively based on inhalation exposure estimates. For this reason, any future risk assessments for BD workers that consider contributions from dermal or incidental ingestion exposure pathways would create a problematic, inequitable treatment of BD exposures (i.e., to avoid mischaracterization or bias in potential risk estimates, the toxicity assessment and exposure assessment components of a risk assessment should treat exposure pathways equitably).
- Due to its physical-chemical properties, toxicity studies for non-inhalation exposures to BD (ingestion, dermal) are generally not available for this chemical (ATSDR, 2012) (i.e., there are no reliable toxicity studies to which worker oral and/or dermal exposure estimates could be assessed).

7. Non-Inhalation Exposures of the General Public to BD from Other Sources (Food, Water, Consumer Products) Are Expected to be Negligible

- BD Detection in Water:
    - Based on physical-chemical properties (e.g., boiling point of -4.5 C, low water solubility; **Table 1**), significant concentrations of BD in water are not expected to occur.

- BD was rarely detected (1/204) in industry-impacted surface water samples in the 1970s (EPA, 1977). No recent data are available to indicate BD is detected in surface or groundwater at meaningful frequencies or concentrations (ATSDR, 2012).

- BD Detection in and Migration from Consumer Products:
  - The Ministry of Environment and Food of Denmark (MEFD) (MEFD, 2019) recently conducted a survey of BD monomer content and migration in/from polymer-based toy materials (10 products made of ABS plastic, 2 products made of SBC plastic). Using headspace and gas chromatography with mass selective detection, low levels of BD were detected using in ABS plastic samples (mean = 0.6 ug/g) and were below the limit of detection for SBC samples (<0.1 mg/kg) (**Table 7**). However, migrations studies using multiple simulant solutions (including 20% ethanol, artificial saliva, artificial sweat, 0.07 mol/L HCl) for all samples failed to find any concentrations above the limit of detection (<0.01 mg/L), indicating that the low levels of BD detected in plastic have limited to no bioavailability. MEFD assessed the detection limits of their study and concluded there is no risk related to playing with toys containing BD. Based on this study, the mouthing of plastic toys is considered an incomplete pathway for BD.

Table 7. Residual and Migration of BD Monomer from Plastic Toys as Determined by the Ministry of Environment and Food of Denmark (MEFD, 2019).

	Residual BD Monomer			Migration of BD Monomer						
Material	**Samples**	**Measured Mean (Range), mg/kg**	**Range Reported in Other Studies, mg/kg**	**Samples (residual monomer)**	**20 % ethanol 30 minutes at 40°C Stirring**	**Artificial saliva 3 hours at 37°C Stirring**	**Artificial sweat 8 hours at 37°C Static**	**Demineralized water 3 hours at 37°C Static**	**According EN 71-3: Migration to 0.07 mol/L HCl**	**Risk-Based Level for Migration Potential**
ABS	10	0.6 (0.23 - 1.55)	<0.01-5	2 (0.35-1.55 mg/kg)	ND (<0.01 mg/L)	ND (<0.01 mg/L)	ND (<0.01 mg/L)	ND (<0.01 mg/L)	ND (<0.01 mg/L)	0.072 mg/L
SBC	2	0.13 (<0.1-0.2)	--	--	--	--	--	--	--	
SBS	--	--	<0.1	--	--	--	--	--	--	

-- = not tested/reported; ABS = acrylonitrile-butadiene-styrene; SBC = styrene-butadiene block copolymer; SBS = styrene-butadiene-styrene

  - EPA (2019) assessed the emissions of BD from recycled tire crumb rubber using GC-MS. At 25 degrees C, BD emissions were below the limit of detection [not reported, but below the lowest reported value of 0.094 ng/g/h] in 27 samples of tire crumb rubber from recycling plants, and low emissions of BD were detected in 13/38 samples of tire crumb rubber from synthetic turf fields (mean below the limit of detection; maximum = 0.23 ng/g/hr). At 60 degrees C, BD emissions were again below the limit of detection [not reported, but below the lowest reported value of 0.12 ng/g/h] in 27 samples of tire crumb rubber from recycling plants, and low emissions of BD were detected in 11/37 samples of tire crumb rubber from synthetic turf fields (mean below the limit of detection; maximum = 0.81 ng/g/hr). Overall, EPA concluded that BD measurements were above quantifiable limits in only a few samples and the emission factors were low for these few samples (⩽1.0 ng/g/h). As such, BD release from tires is not expected to serve as an important source to BD in air, and to the extent there are releases they are expected to be reflected in available air monitoring data for BD (**Figure 5**).

- Residual monomer data for BD reported in unpublished data continue to show that the levels of BD in materials are very low: mean < 0.05 mg/kg for various synthetic rubbers (**Table 8**); mean values ranging from 0.68-2.14mg/kg for ABS samples (**Tables 9**). Furthermore, the migration/bioavailability of these residuals into simulated food media (solutions of acetic acid, ethanol, or olive oil) is very low (**Table 10**).
- A separate white paper has been prepared that summarizes available information on residual BD monomer (unpublished white paper: *Residual Butadiene in BD-derived polymers and resins – Summary of the evidence*)

Table 8. Survey Results for Residual BD Monomer in Rubber (conducted in the first Quarter 2020 in the US; IISRP, 2020)

Product	Residual BD	Unit	Method, remarks
ESBR	<50	ppb	Head Space-Gas Chromatography /Mass Spectrometry Method
SSBR	<20	ppb	GC/MS Method
SBS	ND	ppb	GC/MS Method and EPA Method 8260
BR	<20	ppb	GC/MS Method
SEBS	ND	ppb	GC/MS Method

Table 9. Unpublished Data for Residual BD Monomer in ABS Plastics

				Residual BD (mg/kg)			
Year of analysis	**Sample**	**Analytical Method**	**Detection Frequency**	**Minimum**	**Maximum**	**Mean**	**SD**
2001	ABS 1	GCMS	0/1	--	--	<1 mg/kg	--
2001	ABS 2	GCMS	0/1	--	--	<1 mg/kg	--
2001	ABS 3	GCMS	0/1	--	--	<1 mg/kg	--
2001	ABS 4	GCMS	1/1	--	--	1 mg/kg	--
2020-2023	ABS 5*	Not specified	53/56	0.2	3.15	0.68	0.71
2020-2023	ABS 6*	Not specified	595/595	0.1	10.4	2.14	1.47

*Statistics are based on detected values only.

Table 10. Unpublished Characterization of Residual BD and Migration of BD into Food Materials (conducted in 2001)

		2 hours @70 degrees C (158 F)			2 days @ 40 degrees C (104 F)			10 days @ 20 degrees C (68 F)		
ABS Sample	Residual monomer	3% Acetic acid	10% ethanol	olive oil	3% Acetic acid	10% ethanol	olive oil	3% Acetic acid	10% ethanol	olive oil
ABS 1	ND*	ND**	ND	ND	ND	ND	ND	--	--	--
ABS 2	ND	ND	ND	ND	ND	ND	ND	--	--	--
ABS 3	ND	--	--	--	--	--	--	ND	ND	ND
ABS 4	1 mg/kg	ND	ND	ND	ND	ND	12 ug/kg	--	--	--

*DL=1 mg/kg
**DL=10 ug/kg;
"—"= not tested

- Limits for residual BD monomer in consumer products include the following:
  - In 2011, EU established a limit of 1 mg/kg in final product for residual BD monomer (and for several other monomers) for materials used for food contact purposes.
  - A limit of 1 mg/kg has been proposed for residual BD in toys, and is applicable for toys intended for use by children below 3 years and for toys which are intended to be placed in the mouth (ANEC, 2018).
  - MEFD (2019) defined a risk-based migration limit of 0.072 mg/L for BD in simulated biological fluids (saliva, sweat, gastric) to be protective of exposures to children (**Table 7**). ABS samples containing 0.35-1.55 mg/kg BD monomer yielded migration measurements that were below the limit of detection (0.01 mg/L), which in turn is more than 7-fold below this risk-based level.

<u>Authoritative Body Conclusions on the Importance of BD Exposures Via Non-Inhalation Pathways</u>

- Health agencies have historically considered non-inhalation exposure pathways to be negligible for BD:
  - Health Canada (2000): "*Although few data were identified regarding levels in drinking water and food, intake of butadiene in these media is expected to be negligible in comparison with that in air because of its physical/chemical properties (e.g., vapour pressure and partition coefficients) and environmental release patterns (i.e., principally atmospheric emissions).*"
  - WHO. (2001): "*The general population is exposed to 1,3-butadiene primarily through ambient and indoor air. In comparison, other media, including food and drinking-water, contribute negligibly to exposure to 1,3-butadiene.*"
  - EPA IRIS (2002): "*The hazard by ingestion is unlikely since 1,3-butadiene is poorly soluble in water. When released in water, 1,3-butadiene rapidly evaporates.*"
  - ATSDR (2012): "*The available data indicate that exposure to 1,3-butadiene through ingestion of food and drinking water is expected to be low relative to inhalation exposure*."

- ECHA (2014): *"...the exposures arising as a result of potential release of monomeric 1,3-butadiene from consumer products give rise to very low doses. The risks to human health under current consumer exposure levels are uncertain, but in view of the very low estimated exposure levels, it is predicted that there would be negligible residual risk."*
- ECHA (2014): "*It is expected that any 1,3-butadiene present in surface water will volatilise rapidly. Therefore, even if 1,3-butadiene is released to surface water from point sources, the concentration would be expected to decrease markedly with increasing distance from the source.*"
- ECHA (2023): *"The potential for oral or dermal exposure cannot be entirely excluded but is considered to represent a very minor route of exposure in comparison to inhalation."*

8. Summary and Conclusions

Based on the data summarized above, the following position statements are proposed to help guide the human health risk assessment for BD:

1. *Inhalation is the primary route of exposure for BD, and should serve as the focus of efforts to quantify potential hazards and risks to human health*
2. *Important exposure sources for BD in air include indoor air (occupational, residential), ambient air, in-vehicle air, and smoking*
3. *The following exposure pathways are considered to be either incomplete or negligible compared to inhalation. As such, these pathways do not require quantification in risk assessment (but could be discussed qualitatively or semi-quantitatively).*
    a. *Ingestion water containing BD*
    b. *Dermal contact with BD (pure liquid and/or dilute solutions)*
    c. *Migration of BD from polymers used in consumer products (e.g., toys, tires)*

A draft exposure pathway summary for BD is provided in **Table 11.**

Table 11. Proposed Exposure Pathways for Human Health Risk Assessment of BD

Life Cycle Stage / Exposure Category	Receptor	Exposure Scenario(s)	Exposure Media	Exposure Route	Evaluation in Risk Assessment	Rationale for Further Evaluation / no Further Evaluation
Manufacture	Manufacturing Workers	- Instrument and Electrical - Laboratory Technician - Machinery and Specialists Group - Maintenance - Operations Onsite - Safety Health and Engineering - Missing Job Group Designation - Occupational Non-User	Workplace Air	Inhalation	Yes (quantitative)	Comprehensive IH data available (**Table 4**; Panko et al. 2023). The effect of PPE on exposure estimates should be considered.
				Dermal vapor	No	The dermal absorption of BD vapor is expected to be orders of magnitude lower than corresponding inhalation exposures. Due to the low expected exposures levels, the dermal vapor pathway has not been explicitly assessed for worker exposures used to characterized BD cancer and noncancer potency.
			Liquid	Dermal contact	No	Due to physical-chemical properties (e.g., boiling point of -4.5 C), the rate of volatilization from skin is expected to far exceed rate of absorption. Due to the low expected exposures levels, the dermal vapor pathway has not been explicitly assessed for worker exposures used to characterized BD cancer and noncancer potency. In addition, due to engineering controls and use of PPE, dermal exposures are not expected to occur.
Industrial Use	SBR Workers	- Analyze samples - Collect samples - Connecting/Disconnecting - Maintenance Jobs - Routine Rounds	Workplace Air	Inhalation	Yes (quantitative)	Limited IH data are available for SBR workers (**Table 3**; IISRP, 2020). The effect of PPE on exposure estimates should be considered.
				Dermal vapor	No	The dermal absorption of BD vapor is expected to be orders of magnitude lower than corresponding inhalation exposures. Due to the low expected exposures levels, the dermal vapor pathway has not been explicitly assessed for worker exposures used to characterized BD cancer and noncancer potency.
			Liquid	Dermal contact	No	Due to physical-chemical properties (e.g., boiling point of -4.5 C), rate of volatilization from skin is expected to far exceed rate of absorption. Due to the low expected exposures levels, the dermal liquid pathway has not been explicitly assessed for worker exposures used to characterized BD cancer and noncancer potency. In addition, due to engineering controls and use of PPE, dermal exposures are not expected to occur.
	Other Downstream Users	From EPA (2020), e.g., Adhesives and Sealants (epoxy resins) Automotive Care Products Fuel and Related Products	Workplace Air	Inhalation	Yes (quantitative)	Occupational exposures to BD for a wide variety of job categories have been characterized in Italy, which reflect BD from a variety of undefined/unspecified sources (Scarselli et al. 2017).

		Laboratory Chemicals Paints and Coatings Processing aids specific to petroleum production (e.g. hydraulic fracturing fluid)				Please see May 26, 2020, ACC 1,3-Butadiene TSCA Risk Evaluation comments on EPA's Draft BD Scope.
				Dermal vapor	No	The dermal absorption of BD vapor is expected to be orders of magnitude lower than corresponding inhalation exposures. Due to the low expected exposures levels, the dermal vapor pathway has not been explicitly assessed for worker exposures used to characterized BD cancer and noncancer potency.
			Liquid	Dermal contact	No	Due to physical-chemical properties (e.g., boiling point of -4.5 C), rate of volatilization from skin is expected to far exceed rate of absorption. Due to the low expected exposures levels, the dermal liquid pathway has not been explicitly assessed for worker exposures used to characterized BD cancer and noncancer potency. In addition, due to engineering controls and use of PPE, dermal exposures are not expected to occur.
Offsite Release from Facilities	General Public	General Public	Ambient Air	Inhalation	Yes (quantitative)	Ambient air monitoring (EPA AMA, 2020) and air modeling data near industrial facilities are available (AECOM, 2024); Contributions from nonindustrial releases are important and should also be considered
Consumer Products			Consumer Goods/Food Packaging	Ingestion	No	Levels of residual monomer in consumer goods (plastic, rubber products) are either low or below limits of detection. Detectable levels do not migrate and therefore are not considered to be bioavailable (see **Table 7**). Agencies have historically considered non-inhalation pathways to be negligible (see Section 7)
Other Sources (e.g., combustion)			Indoor Air	Inhalation	Yes (quantitative)	Publications on indoor air levels of BD are available and reflect BD from a variety of sources (reviewed in Huy et al., 2018; Logue et al. 2011)
			In-vehicle Air	Inhalation	Yes (quantitative)	Publications on in-vehicle air levels of BD are available (reviewed in Huy et al., 2018), and reflect BD produced via combustion (Duffy and Nelson, 1997)
			Smoking	Inhalation	Yes (semi-quantitative)	Biomonitoring data for the U.S. population can be used to make relative comparisons between smokers and nonsmokers (Nieto et al. 2021)

Shaded regions indicate exposure pathways that are considered to be incomplete or negligible.

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