TRICLOCARBAN (CASRN 101-202)

(3,4,4'-Trichlorocarbanilide)
Safety & Exposure Information Related to Potential Designated Chemical
May 24, 2010 Meeting of Scientific Guidance Panel (SGP)
Biomonitoring California

Summary

Triclocarban (TCC) is an antibacterial agent that is currently being considered for inclusion in the California Environmental Contaminant Biomonitoring Program (CECBP). Existing human and environmental health safety information indicates that TCC is safe and does not present an unreasonable risk to human health or the environment. As such, it should receive a low priority for being listed on the CECBP. Information supporting this position is presented below.

Triclocarban has been used safely in consumer products for more than 40 years. Triclocarban is not a pesticide active ingredient and there are no uses regulated by the U.S. Environmental Protection Agency (EPA) under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). In the United States, TCC is primarily regulated as an antibacterial (AB) active ingredient under the Food and Drug Administration's (FDA) Tentative Final Monograph (TFM) for Topical Antimicrobial Drug Products for Over-the-Counter Human Use: Health-Care Antiseptic Drug Products (59 FR 31402, June 17, 1994). FDA is currently reviewing the safety and efficacy of TCC as an antibacterial agent under the TFM for Topical Antiseptic Drug Products.

In the United States, Triclocarban is predominantly used as an antibacterial active ingredient in bar soaps at a typical concentration of 0.6%. It has also used, to a much lesser extent, as a cosmetic ingredient or preservative in deodorant consumer products at a concentration of 0.3% or less. In the U.S., it is estimated that approximately 30% of all bar soaps are antibacterial soaps.

Extensive information exists on human health and environmental safety of Triclocarban. This data is publicly available and has been submitted to numerous government agencies. The safety of TCC has been reviewed by several Authoritative bodies. For example, the European Union Scientific Committee on Consumer Products (SCCP) concluded in 2005 that the use of Triclocarban for non-preservative purposes in cosmetic rinse-off hand and body care products up to a maximum concentration of 1.5% does not pose a direct risk to the health of the consumer. In addition, health and environmental effects data submitted to EPA under EPA's High Production Volume (HPV) Challenge Program show that appropriate margins of safety exist and that the ingredient is safe for its intended uses.

TCC is rapidly metabolized by humans and metabolites are excreted in the urine and feces, an indication that TCC does not bioaccumulate in humans. Human studies evaluating single oral doses of TCC indicates that that 27% of the dose was excreted in the urine within 80 hours; 70% was excreted in the feces within 5 days. Existing biomonitoring studies indicate that blood levels of TCC can be expected to be below 10 parts per billion (ppb) and a study of lipophilic compounds showed that it is not present in human breast milk.

TCC has not been shown to have endocrine disrupting effects in the natural setting. Recently published *in vitro* studies suggest that TCC may amplify the actions of certain steroid hormones. However, such cell culture experiments are not considered to be scientifically representative of human exposure levels. Most of these studies come from *in vitro* systems which are very

difficult to extrapolate to humans. Furthermore, endocrine disruption is not considered a marker of toxicity but a mechanism (or pathway) that could lead to an adverse effect. The marker of toxicity is reproductive effects or infertility. TCC was studied for reproduction in rats exposed to levels well above those typically encountered during normal consumer product use and the results indicated no adverse effects. In addition, The Environmental Defense Fund (EDF) has reviewed this data and has agreed that there are few or no apparent effects observed in the well-conducted reproductive and developmental toxicity studies. Additionally in 2005, the European Scientific Committee on Consumer Products SCCP stated that TCC did not cause carcinogenic or reproductive/developmental effects in *in vivo* animal studies.

Available environmental data indicate that TCC is unlikely to cause harm to human or environmental health. Existing environmental data submitted to EPA under the HPV program shows that TCC is inherently biodegradable and extensively removed during wastewater treatment. These data indicated that up to 98% of TCC is removed by wastewater treatment plants and the remainder undergoes rapidly photodegradation. In addition, TCC in biosolids-amended soil is not bioavailable.

In California, the median TCC concentration has been reported at 0.22 µg/L in recycled water (water reuse). To our knowledge, TCC has not been detected in drinking water. Therefore, exposure of consumers to TCC via drinking water is unlikely.

Worst-case exposure estimates utilizing the current estimated volumes of TCC used in consumer bar soap products in California indicate that there are acceptable Margins of Exposure (MOE) and no risk associated with the use of TCC in antibacterial bar soaps.

Based on this information it is concluded that TCC is safe and does not present any unreasonable risks to human or environmental safety. As such, it is recommended that it receive a low priority for listing under the CECBP. Further details regarding TCC's human and environmental safety may be found below.

Exposure or potential exposure to the public or specific subgroups

Potential exposure to TCC is described below via primary exposure of personal care products and from an indirect exposure via ingestion of contaminated food or drinking water.

Triclocarban use in personal care products – Direct (primary) consumer exposure

In 2010 the annual U.S. volume for TCC was reported at 500,000 pounds (226,796 kg) (US EPA). Exposure to TCC is low, principally from direct skin contact with consumer products which results in an approximate aggregate dose of 32.4 µg/kg/day for a 60-kg adult (SCCP, 2005). This estimate considers exposures from bar and liquid soaps and from body wash products containing a maximum TCC concentration of 1.5%. At these levels, the calculated Margin of Safety is 778 for a 60 kg adult. As previously stated, in the US, TCC is not used in liquid soaps or body wash products.

The 500,000 lbs TCC annual volume represents approx. 334 million AB bar soaps marketed on a National basis and approximately 41.75 million AB bar soap units marketed in California. This amount translates to approximately 11 AB bar soaps per person per year assuming that 10% of the population (3.75 million in California) use AB bar soaps (Appendix 1). Californians would get exposed to approximately 0.35 mg/kg bw/day resulting in a TCC daily dose of 3.5 µg/kg

bw/day). Using a Non-Observed-Effect-Level (NOEL) of 25 mg/kg bw/day, this exposure represents a Margin of Exposure (MOE) of 7,143.

Triclocarban in biosolids-amended soils and potential for uptake by plants resulting in contaminated food – Indirect (secondary) consumer exposure

TCC that enters the WWTP's is sorbed into sludge (approx. 76% sorbed) and the rest is degraded based on the type of sludge treatment with aerobic conditions better than anaerobic. The median biosolid TCC concentration from different treatment plants across the US is 19±11 ppm (Snyder et al., 2010). It is estimated that approximately 7 million tons of sewage sludge is produced in the United States, 50% applied to land as fertilizer or soil amendment and about 45% disposed of in landfills or as landfill cover. It is estimated that approx. 76,000 kg TCC is applied as biosolids per year (O'Connor, 2009). The average sewage sludge application is 2.2 kg/m^2 based on nutrient content. The sludge is applied to one square meter of land around 20-cm topsoil (1/5 cubic meter or 200-kg soil), therefore, assuming thoroughly mixed, the TCC concentration in the biosolids-amended soil is approx. 200-fold lower than biosolids. This results in approximately 0.21 mg TCC/kg biosolid-amended soil.

One question is the potential transfer of TCC from the biosolid-amended soil used as fertilizer to crops for human consumption. The TCC concentration is initially 0.21 mg TCC/kg amended soil (see above). In the unlikely (worst-case) scenario where all of the TCC in the amended soil is bioavailable and taken up by plants (bioconcentration factor, BCF, equals 1.0), the plant tissue concentration (dry weight basis) is the same as in the amended soil or 0.21 mg TCC/ kg plant tissue. Assuming a 60-kg person consumes one kilogram (dry weight basis) of various food stuffs the amount of TCC ingested is 0.21 mg which translate to 3.5 µg/kg body weight. Using the NOEL of 25 mg/kg bw/day, this exposure represents a MOE of 7,143.

Recent research by Dr. O'Connor (2009) indicates that TCC in biosolids is not available (biosolids-bound) and only < 0.2% biosolids-borne TCC leached from amended sandy soil columns (Plants BCF = 0.2). Therefore, a more realistic calculation (assuming all leached TCC is taken up by plants) would result in 0.42 µg TCC/kg plant tissue ingested by a 60-kg person which translates to MOE of > 3.5 million (Similar to recycled drinking water, see below). Water solubility and vapor pressure influence the transfer to plant roots. Therefore, the low water solubility and low vapor pressure of TCC will limit even further the percentage taken up by the plants resulting in a plant BCF < 0.01. This risk for secondary exposure to TCC is lower than direct exposure.

Potential for triclocarban in drinking water – Indirect exposure to TCC

Recent studies report detection of TCC in surface water and in sewage sludge. TCC is efficiently removed by WWTP's with 88 - 97% efficiency rate resulting in extremely low levels in surface waters. The estimated TCC concentration in surface waters (effluents) has been estimated at 0.023 – 0.045 µg/L (parts-per-billion) using E-FAST and iSTREEM (Ayala-Fierro, 2010). In influent water the TCC median concentration has been reported at 4.2 ± 0.8 ppb whereas in effluent water the median concentration was reported at 0.23 ppb (range 0.011 – 1.78 ppb) (Haidler and Halden, 2009). The mean concentration of TCC in effluents collected from the Chicago District's Water Reclamation Plants ranged from 0.09 - 0.30 µg/L (Hundal et al., 2009).

In California, the median TCC concentration has been reported at 0.22 µg/L in recycled water (water reuse) (Anderson et el. 2010). The presence of TCC in reused water may lead to

consumer exposure from indirect potable reuse via surface spreading of recycled water, indirect potable reuse via subsurface injection of recycled water into a potable aquifer, and, urban landscape irritation with recycled water (Anderson et el. 2010). To our knowledge, TCC has not been detected in drinking water. However, assuming the worst-case scenario where a Californian drinks reused water containing 0.22 µg/L (2 liters per day or 0.44 µg TCC), the resulting TCC dose is 0.0073 µg/kg TCC which translated to a MOE of > 3.4 million (Appendix 1).

Potential health effects

TCC is an antibacterial agent used in bar soaps and has had very limited use in cosmetic deodorant products. Extensive data exist on human health and environmental safety for TCC. The data has been submitted to government agencies including EPA under the HPV Program and is publicly available. TCC has a low order of toxicity to mammalians based on a variety of acute, subchronic and chronic toxicity studies. The oral and dermal LD50 (lethal dose) values are greater than 2,000 mg/kg. The contact with eyes may produce slight irritating effects whereas skin contact produces no irritation. Human sensitization patch tests indicate no sensitization. It is also negative in genetic toxicity Ames tests and in a two-year carcinogenicity bioassay in rats. Rats exposed to 1000 mg/kg/day for 30 days showed no adverse effects. The No-Observed-Effect-Level (NOEL) was established at 25 mg/kg/day after some testicular degeneration was found at 75 mg/kg/day in a 24 month-oral study in rats.

OEHHA identified few toxicological studies related to TCC in the scientific literature. Two studies with high-dose feeding experiments are mentioned in the OEHHA TCC document. No details were found for the first study (Wright et al., 1975) since it was presented only as a meeting abstract. The second study (Nole and Dierchman, 1979) reported some reproductive effects of a 2:1 mixture of TCC and 3-trifluoromethyl-4,4'-dichlorocarbanilide. However, reproductive studies with TCC alone did not find any effects. The Environmental Defense Fund (EDF) reviewed and confirmed TCC's safety based on the mammalian toxicity data. EDF concluded that TCC has low acute toxicity, is negative in genetic toxicity tests and is also negative for carcinogenesis in a 2-year bioassay in rats. EDF also agreed that there are few or no apparent effects observed in the well-conducted reproductive and developmental toxicity studies that were preformed.

OEHHA states that recently published *in vitro* studies suggest that TCC may amplify the actions of certain steroid hormones. Ahn et al. 2008, evaluated the *in vitro* biological activity of TCC in a battery of *in vitro* cellular system screening tools (AhR, ER, AR and RyR bioassays) in recombinant rat hepatoma (liver cancer) cells, human ovarian cancer cells, and skeletal myotube primary cultures from mice. The study reported that in the presence of estrogen or testosterone, TCC enhanced the actions of these hormones. The cell cultures were exposed to TCC concentrations ranging from 1 to 10 µM; while *in vitro* exposures are difficult to extrapolate directly to whole body dosages, by rough estimation the cell cultures received an approximate dose of 100-1000 µg/kg-body weight/day. By comparison, a Californian would get an estimated systemic average dose on the order of 0.0035 and 0.035 mg/kg bw/day (Appendix 1).

Chen et al. 2008 reported that TCC enhanced the testosterone-induced androgen receptor (AR)-mediated response. However, in this study TCC did not induce an androgenic response alone in 2933Y cells, did not show affinity for the AR up to tested concentrations of 200 µM in the competitive bind assay, and did not activate cAMP/protein kinase A (PKA)-mediated luciferase in MDA-kb2 cells. In a Hershberger assay on castrated rats TCC did not affect body weight and did not affect weights of androgen-sensitive tissues such as seminal vesicles, glans penis, Cowper's glands and levator ani/bulbocavernous muscles, but increased the absolute

liver and ventral prostate weights. The effects of TCC are observed in the presence of added androgen testosterone suggesting the action of testosterone is enhanced.

The cell culture experiments are not considered representative of human exposure levels. Cell cultures operate in the absence of feedback systems found at normal tissues and lack the metabolic processes and general physiological dynamics that are found in the whole organism. As such, it is generally agreed that the information derived from these types of *in vitro* systems are not relevant for human health risk assessments. Based on the level of activity found in the different cell culture systems, there is little likelihood of human risk based on the concentrations of triclocarban tested.

Global safety review for TCC (Regulatory Agencies)

TCC has been reviewed for safety globally. The European Union Scientific Committee on Consumer Products (SCCP) concluded in 2005 that the use of Triclocarban for non-preservative purposes in cosmetic rinse-off hand and body care products up to a maximum concentration of 1.5% does not pose a direct risk to the health of the consumer. Additionally, TCC is approved as a preservative for cosmetics with a maximum permissible concentration of 0.2% under the European Union Cosmetic Products Directive (EU Directive 76/768/EEC). TCC is approved for use as an antimicrobial in cosmetic products in Switzerland at a maximum use concentration of 0.2%, (Annex 2, Swiss Cosmetic Product Regulation). TCC is also listed in the Japanese Cosmetic Standard as a preservative for cosmetic products with a maximum use concentration of 0.3% for leave-on cosmetics and no specified upper limit for rinse-off cosmetics.

Potential to bioaccumulate

TCC is reported as persistent with estimated half-life in soil of 87 – 231 days, depending on the type of soil (Wu et al., 2009) but the ultimate degradation in land-applied biosolids would require several years (Snider et al., 2010). O'Connor, 2009, reported that TCC is biosolids-bound (not available) with a leaching rate < 0.2, therefore, the potential to leach (available) for uptake by plants or terrestrial animals is extremely low. The toxicity of biosolids-borne TCC to soil microbes and earthworms was tested by Snider et al. 2009 (Micropol and Ecohazard, San Francisco CA). Using the EPA approved method for soil microbial community toxicity test (OPPTS 850.5100) they did not find TCC related effects on microbe's respiration, ammonification, and nitrification with biosolids-amended soil containing up to 7 mg TCC/kg amended soil. Similarly, using the EPA approved method for subchronic earthworm toxicity (OPPTS 850.6200) the authors reported a LC50 of 40 mg/kg biosolids-amended soil containing up to 100 mg TCC/kg amended soil.

Bioaccumulation

The TCC Consortium (2002) reported a bioconcentration factor (BCF) of 137 in catfish. The OEHHA document references other recent studies that reported bioaccumulation of TCC in algae and two freshwater invertebrates (Higgins et al., 2009; Coogan and Point, 2008; Coogan et al., 2007). OEHHA indicates that no studies were identified that investigated the *potential bioaccumulation in terrestrial organisms.* The accumulation of TCC by the *Eisenia* fetida earth worm was studied by Snider et al. 2009 (Micropol and Ecohazard, San Francisco CA). The bioaccumulation factor (BAF) was 5.2 ± 0.22, 18 ± 3.5 and 20 ± 2.1 for the artificial, Immokalee, and Genesse type of soils, respectively. Snider et al. 2009 also studied bioaccumulation of TCC in the *Paspalum notatum* plant from biosolids taken from different WWTP's. The BAF (whole soil) ranged from 0.0004 to 0.0080.

Parmacokinetics and Metabolism

The studies referenced in the OEHHA document are correct. TCC absorption has been measured under product use conditions (showering study) reported by Scharpf et al. (1975) who found minimal percutaneous absorption of TCC after six adult male subjects showered with bar soap containing TCC. In that study, 0.2% and 0.39% of the applied dose was excreted in the first 24 and 48 hrs, respectively. In another study, North-Root et al. 1984, reported that after rinsing off TCC bar soap, a small amount of the applied TCC (1.4%) remained on the skin (n = 12). In conditions where TCC applied to the skin is not rinsed TCC absorption can be higher. Wester et al. (1985) estimated percutaneous absorption in five human subjects to be 7.0 ± 2.8% after urine was collected for 10 days.

TCC is rapidly metabolized by humans and metabolites excreted in the urine and feces. Human metabolism of TCC involves direct glucuronidation to form N- and N'- glucuronides as well as ring hydroxylation to 2'-hydroxy-TCC and 6-hydroxy-TCC, which are further metabolized to sulfate and glucuronide conjugates (Hiles and Birch, 1978). In human subjects given a single oral dose of TCC, Hiles and Birch (1978) found that 27% of the dose was excreted in the urine within 80 hours; 70% was excreted in the feces within 5 days.

Past Biomonitoring studies

As stated above TCC is rapidly metabolized by humans and metabolites are excreted in urine and feces, an indication that TCC does not bioaccumulate in humans. Gruenke et al. 1987 identified TCC metabolites in plasma and urine in subjects who showered with TCC-containing bar soap. In a population, however, only approx. 10% uses antimicrobial bar soaps reducing the number of individuals with potential positive results. Since TCC is rapidly metabolized, a non-regular user of TCC-bar soaps will show TCC in urine only during the active use of the soap. As stated in the OEHHA report, TCC was included in a study investigating the presence of lipophilic compounds in breast milk samples (n=20), but was not detected in any of the samples (Ye et al., 2006).

Need to assess efficacy of public health actions

OEHHA states that TCC is a widely used antimicrobial in consumer products. To our knowledge, in the U.S. TCC is used predominantly as an antimicrobial agent in bar soaps. OEHHA also states that TCC is persistent in the environment. TCC in the environment is biosolids-bound with an extremely low rate to leach as a free TCC, therefore, the risk for toxicity to terrestrial organisms, and the potential for uptake by plants, is considered very low. OEHHA also states that recent studies suggest that TCC could have endocrine disrupting effects. Most of these studies come from *in vitro* systems which are very difficult to extrapolate to humans. In addition, endocrine disruption is not considered a marker of toxicity but a mechanism (or pathway) that could lead to an adverse effect. The marker of toxicity is reproductive effects or infertility. TCC was studied for reproduction in rats exposed to 1000 mg/kg/day for 30 days and results indicated no adverse effects. The EDF reviewed the data and agreed that there are few or no apparent effects observed in the well-conducted reproductive and developmental toxicity studies.

Recommendations

Primary and secondary exposure to TCC by Californians is considered limited due primarily to the low volume of TCC used. Primary exposure to TCC from the use of consumer products

involves the potential absorption through the dermal route. TCC exposure by inhalation is limited due the low vapor pressure. Consumer evaluations indicate that Margins-of-Exposure (MOE) are acceptable (ranging from 7,143 to >3.5 million) and calculations supporting these estimates are conservative (Appendix 1).

Secondary exposure via consumer consumption of contaminated food or water is unlikely. TCC in biosolids-amended soil is not bioavailable. Exposure assessments indicate a very low risk with acceptable MOE's. Exposure of consumers to TCC via drinking water is unlikely. First, TCC has not been detected in drinking water in California. Even in a worst-case using TCC in recycled water the MOE is acceptable and represents no safety issues. Based on these estimates it is concluded that TCC is sufficiently studied and recommended as a low priority for further work.

References

Ahn K.C., Zhao B., Chen J., Cherednichenko G., Sanmarti E., Denison M., Lasley B., Pessah I., Kultz D., Chang D., Gee S., and Hammock B. (2008). In vitro biological activities of the antimicrobials triclocarban, its analogues, and triclosan in bioassay screens: receptor-based bioassay screens. Env. Health. Perspect. 116(9), 1203-1210.

Anderson, P., Denslow, N. Drewes, J.E., Olivieri, A.,Schlenk, D., and Snyder, S. (2010). Monitoring strategies for chemicals of emerging concern (CECs) in recycled water. Recommendations of Science Advisory Panel. California State Water Resources Control Board. April 15, 2010.

Ayala-Fierro, F., Jeram, L., Kretschik, O., and DeLeo, P. Refined predicted no-effect-concentration (PNEC) for triclocarban in freshwater environment. 238th American Chemical Society (ACS) Annual Meeting. Washington, D.C., August 16 – 20, 2009.

Chen, J., Ahn, K.C., Gee, N.A., Ahmed, M.I., Duleba, A.J., Zhao, L., Gee, S.J. Hammock, B.D. and Lasley, B.L. (2008). Triclocarban enhances testosterone action: a new type of endocrine disruptor?. Endocrinology, 149(3): 1173-1179

Directive 76/768/EEC, Annex VI, part 1 n° 23.
http://www.bpfk.gov.my/pdfworddownload/Annex6%20Parts1-2PreservativesList.pdf

European Commission's Scientific Committee on Consumer Products (SCCP) opinion on triclocarban for other uses than as a preservative (2005):
http://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_016.pdf

Gledhill, W.E. (1975). Biodegradation of 3,4,4'-trichlocarbanilide, TCC, in sewage and activated sludge, Water Res. 9, 649-654.

Halden, R.U.; Paull, D.H. (2005). Co-occurrence of triclocarban and triclosan in U.S. water resources. Environ. Sci. Technol. 39(6), 1420-1426.

Haidler J., and Halden, R.U. (2009). Fate of organohalogens in US wastewater treatment plants and estimated chemical releases to soils nationwide from biosolids recycling. J. Environ Monitor 11, 2207-2215.

Hundal, L.S., Kumar, K., Liao, A., Cox, A.E., and Granato, T.C. (2010). Levels of triclocarban and triclosan in the influent, effluent, and waste-activated sludge or biosolids from the Metropolitan Water Reclamation District of greater Chicago's seven water reclamation plants. Monitoring and Research Department, Report No. 09-60, September 2009.

Safety documents on Triclocarban (FDA website): http://www.fda.gov/ohrms/dockets/

Snyder, E. H., O'Connor, G. A., McAvoy, D.C. (2010). Measured physicochemical characteristics and biosolids-borne concentrations of the antimicrobial Triclocarban (TCC). Sci Total Environ. 408(13):2667-2673.

Snyder, E. H., O'Connor, G. A., McAvoy, D.C. (2009). Risk assessment of bisolids-borne Triclocarban (TCC). Micropol & Ecohazard, June 8-10, 2009. San Francisco, California.

O'Connor, G.A. (2009). Fate and transport of biosolids-borne antimicrobials. Society of Environmental Toxicology and Chemistry (SETAC), New Orleans, November 19-22, 2009.

TCC Consortium. High Production Volume (HPV) Chemical Challenge Program Data Availability and Screening Level Assessment for Triclocarban, CAS#: 101-20-2; Report 201-14186A; 2002. http://www.epa.gov/hpv/pubs/summaries/tricloca/c14186tc.htm

Triclocarban [CASRN 101-20-2]. Potential designated chemical. May 24, 2010 meeting of Scientific Guidance Panel (SGP) Biomonitoring California.
http://www.oehha.ca.gov/multimedia/biomon/pdf/052410Triclocarban.pdf

Appendix 1 – Assumptions and Calculations for Consumer Exposure to Triclocarban

Primary (Direct) Exposure to Triclocarban

1. Consumer Products

National TCC Annual Volume and Total AB Bar Soap Units
TCC Annual Volume = 500,000 lbs (226,796 kg)
One bar soap = 4 oz (113.4 grams)
Maximum TCC concentration in bar soaps = 0.6 %
Amount TCC in bar soaps = 113.4 * 0.6% = 0.68 grams
Total AB bar soap units = 226,796,000 / 0.68 = 333,523,529 (assume 334 million units)
Note: This calculation assumes that all TCC is used in bar soaps. However, in reality, this is a worst-case estimate since a portion of the total volume of TCC is also used in cosmetic deodorant products.

California TCC Annual Volume and Number of AB Bar Soaps Used
Population = 37.5 million (12.5% total population)
Estimated TCC Volume = 226.796 * 12.5% = 28,350 kg (62,500 lbs)
Estimate AB bar soaps marketed = 334 million units * 12.5% = 41.75 million units
Percent population using AB bar soaps = 10% representing 3.75 million people
Estimated AB bar soaps per person per year = 41.75 million units / 3.75 million people = 11.1 bar soaps

Exposure to TCC for California Users of AB Bar Soaps
Annual Exposure to TCC= 11 AB bar soaps * 0.68 grams TCC = 7.48 grams/year (0.021 g/day)
Estimated TCC Daily Exposure = 0.021 g/day / 60 kg body weight = 0.00035 g/kg bw/day (0.35 mg/kg/day)

Resulting TCC Dose for Californians Users of AB Bar Soaps
TCC Daily Dose = 0.35 mg/kg bw/day
10% Deposition Factor during Product Use = 0.35 * 0.1 = 0.035 mg
10% Absorption Factor during Product Use = 0.035 * 0.1 = 0.0035 mg

Margin of Exposure (MOE)
TCC NOEL = 25 mg/kg bw/day
MOE for bar soaps = 25 / 0.0035 = 7,143
Note: MOE = The ratio of the no-observed adverse-effect-level to the estimated exposure dose. EPA considers MOE > 100 as acceptable

Secondary (Indirect) Exposure to Triclocarban

1. TCC Removed in WWTP and Used as Biosolids

TCC Efficiency Removal by WWTP's: 95-98%
Sewage sludge produced in the United States annually: 7 million tons
Amount TCC applied as biosolids per year: 76,000 kg
TCC Concentration in biosolids = 19 ± 11 mg/kg

Sludge application = 2.2 kg/m^2 of land
Amount TCC applied/m^2 of land = 2.2 kg * 19 mg/kg = 41.8 mg
TCC mixed around 20-cm (1/5 cubic meter) = 200-kg soil)
Resulting TCC after mixing = 41.8 / 200 = 0.21 mg TCC/kg biosolid-amended soil

2. Drinking Water

TCC is not detectable in drinking water
Worst-case scenario (Recycled or Reused Water)
Median TCC Concentration = 0.22 µg/L
Water Consumption per day = 2 Liters or 0.44 µg TCC
60-kg person = 0.44 µg/60-kg = 0.0073 µg/kg (0.0000073 mg/kg)

Margin of Exposure (MOE)
TCC NOEL = 25 mg/kg bw/day
MOE = 25 / 0.0000073 = > 3.4×10^6

3. Potential Transfer of TCC to Foods

Worst-Case Scenario (Unrealistic)

Amount of TCC in Plant Tissues
TCC concentration in biosolid-amended soil = 0.21 mg
Assume bioconcentration factor, BCF = 1.0 (all TCC is bioavailable)
TCC taken up by plants (dry weight basis) = 0.21 mg TCC/kg plant tissue

Amount Ingested by a 60-kg Person
A 60-kg person consumes 1 kg food stuff daily = 0.21 mg TCC ingested
TCC Dose = 0.21 mg / 60-kg = 0.0035 mg/kg (3.5 µg/kg)

Margin of Exposure (MOE)
TCC NOEL = 25 mg/kg bw/day
MOE for food consumption = 25 / 0.0035 = 7,143 under worst-case scenario

Realistic Scenario

Amount of TCC in Plant Tissues
TCC concentration in biosolid-amended soil = 0.21 mg
% biosolids-borne TCC leached (and bioavailable) = < 0.2%
TCC taken up by plants (dry weight basis) = 0.21 mg * 0.2% = 0.00042 mg TCC/kg plant tissue

Amount Ingested by a 60-kg Person
A 60-kg person consumes 1 kg food stuff daily = 0.00042 mg TCC ingested
TCC Dose = 0.00042 mg / 60-kg = 0.000007 mg/kg (0.007 µg/kg)

Margin of Exposure (MOE)
TCC NOEL = 25 mg/kg bw/day
MOE for food consumption = 25 / 0.000007 = > 3.5×10^6 under realistic conditions