

# OFFICE OF POLLUTION PREVENTION AND TOXICS

WASHINGTON, D.C. 20460

# June 12, 2025

### **MEMORANDUM**

SUBJECT:	Dibutyl Phthalate (DBP) Dermal Absorption Data
FROM:	Collin Beachum, Branch Supervisor Risk Assessment Branch 6 Existing Chemicals Risk Assessment Division
TO:	Jeff Morris, Director Existing Chemicals Risk Assessment Division

### **PURPOSE:**

The *Draft Risk Evaluation for Dibutyl Phthalate (DBP)* (U.S. EPA, 2025c) includes dermal exposure estimates that used empirical dermal absorption data from live guinea pigs (Doan et al., 2010). EPA acknowledges that the rate of dermal absorption used for estimating occupational and consumer dermal exposure can be refined using data that are more relevant to absorption through human skin. This memo describes a proposed refinement of the approach for estimating dermal exposures for DBP, which would incorporate empirical dermal absorption data from human skin. The availability of chemical- and species-specific dermal absorption data will lead to refinement of the dermal risk estimates as part of the final risk evaluation.

#### **REFINED ANALYSIS:**

The Draft Risk Evaluation for Dibutyl Phthalate (DBP) (U.S. EPA, 2025c) calculates dermal exposure estimates using absorption data from live guinea pigs (Doan et al., 2010). In the Draft Environmental Release and Occupational Exposure Assessment for Dibutyl Phthalate (U.S. EPA, 2025b) and the Draft Consumer and Indoor Exposure Assessment for Dibutyl Phthalate (DBP) (U.S. EPA, 2025a), EPA selected the Doan et al. (2010) study for dermal absorption data because it is the most recent publication with DBP-specific information in comparison with Scott et al. (1987), Elsisi et al. (1989), and Janjua et al. (2008). EPA initially considered the study duration from Doan et al. (2010) of 24 hours to be more representative to consumer and occupational dermal scenarios than the 7-day study duration used in other studies.

EPA has reconsidered the selection of the most relevant study to use for dermal absorption, placing more emphasis on data derived from human tissues as opposed to animal models. The Doan *et al.* (2010) study was conducted using live guinea pigs. Though dermal absorption through guinea pig skin may represent an upper bound of potential human dermal absorption

(*i.e.*, absorption through guinea pig skin is expected to be greater than absorption through human skin), human dermal absorption data specific to the chemical are most relevant for calculation of exposure estimates for worker exposures.

EPA has identified one dermal absorption study that received a medium rating through the EPA systematic review process and provides measurement of the *in vitro* dermal absorption of neat DBP through human skin (Scott et al., 1987). EPA is proposing to implement a refinement to the dermal occupational and consumer exposure estimates for the final *Risk Evaluation for Dibutyl Phthalate (DBP)* by incorporating the empirical dermal absorption rates obtained from these *in vitro* human skin experiments (Scott et al., 1987).

In Section 2.4.3.2 of the *Draft Environmental Release and Occupational Exposure Assessment* for Dibutyl Phthalate (U.S. EPA, 2025b), the rate of dermal absorption was estimated as  $2.35 \times 10^{-2}$  mg/cm<sup>2</sup>/hr, based on the rate of dermal absorption in guinea pigs (Doan et al., 2010). However, *in vitro* dermal absorption rate of dermal absorption of DBP through human skin was measured to be  $7.0 \times 10^{-5}$  mg/cm<sup>2</sup>/hr (Scott et al., 1987). Scott (1987) also measured *in vitro* dermal absorption of  $9.33 \times 10^{-3}$  mg/cm<sup>2</sup>/hr for DBP through rat skin, which is two orders of magnitude higher than *in vitro* dermal absorption measured in human skin. The hairless guinea pig skin shares similar absorptive characteristics to rat skin (*i.e.*, absorption through rat and hairless guinea pig skin are noted to be much more rapid than absorption through human skin). Therefore, the results of Scott (1987) support the use of dermal exposure refinement using absorption data from human skin.

# **RESULTS:**

Section 4.3.1 of the Draft Risk Evaluation for Dibutyl Phthalate (U.S. EPA, 2025c) characterized the daily human equivalent dose (HED) value as 2.1 mg/kg-day and the benchmark MOE as 30. As noted in Appendix C.2 of the Draft Environmental Release and Occupational Exposure Assessment for Dibutyl Phthalate (U.S. EPA, 2025b), the occupational dermal exposure assessment assumed that the surface area of absorption is between 535 cm<sup>2</sup> (*i.e.*, surface area of one hand) and 1,070 cm<sup>2</sup> (*i.e.*, surface area of two hands) and that the duration of absorption (*i.e.*, duration that material may be on the skin) is up to 8 hours. Therefore, based on the refined absorption rate of DBP in human skin of  $7.0 \times 10^{-5}$  mg/cm<sup>2</sup>/hr (Scott et al., 1987), the acute levels of occupational dermal exposure after refinement are expected to be between  $3.7 \times 10^{-3}$ and  $7.5 \times 10^{-3}$  mg/kg-day. Consequently, the refined MOEs based on dermal absorption rates of DBP through human skin range from 280 to 560 for acute occupational dermal exposures, compared to a benchmark MOE of 30. The intermediate and chronic MOE values for occupational dermal exposure are greater than acute values (i.e., lower levels of daily dermal exposure over intermediate and chronic time periods) since intermediate and chronic exposures are averaged over time periods where exposure does not occur daily (e.g., weekends, holidays, etc.).

Section 2.3.4 in the *Draft Consumer and Indoor Exposure Assessment for Dibutyl Phthalate* (*DBP*) (U.S. EPA, 2025a) summarizes dermal exposure assessment inputs for each consumer

exposure scenario. Using those inputs and the absorption rate of DBP in human skin of  $7.0 \times 10^{-5}$  mg/cm<sup>2</sup>/hr (<u>Scott et al., 1987</u>), the highest acute dermal consumer exposure dose equals to 7.7 µg/kg-day with a corresponding MOE of 274 compared to a benchmark MOE of 30. All other exposure scenarios for acute, intermediate, and chronic dermal doses result in even larger MOEs.

# **REFERENCES:**

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