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July 7, 2026

To Whom It May Concern:

Subject: Exemption from Safety Data Sheet (SDS) Requirements for Solid Oral Dose Pharmaceutical Products under OSHA Hazard Communication Standard (29 CFR 1910.1200)

Purpose This memo explains why Safety Data Sheets (SDSs) are not required for solid oral dose pharmaceutical products (such as tablets, pills, or capsules in their final form) under OSHA's Hazard Communication Standard (HCS), and clarifies the scope and limitations of this exemption.

SDSs are generally required for hazardous chemicals to which employees may be exposed. However, the standard includes specific exemptions.

Specific Exemption for Solid Oral Dose Pharmaceuticals Under 29 CFR 1910.1200(b)(6)(vii), the HCS **does not** apply to:

"Any drug, as that term is defined in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), when it is in solid, final form for direct administration to the patient (e.g., tablets or pills); drugs which are packaged by the chemical manufacturer for sale to consumers in a retail establishment (e.g., over-the-counter drugs); and drugs intended for personal consumption by employees while in the workplace (e.g., first aid supplies)."

This exemption covers solid oral dosage forms like tablets, pills, and capsules that are in their **final form** intended for direct administration to the patient without further processing (such as crushing or dissolving) by employees.

Rationale for the Exemption: OSHA determined that the potential for employee exposure to hazardous chemicals in these products is minimal when they remain in intact solid final form. The primary intent of the HCS is to protect workers from hazardous exposures; where exposure risk is negligible (e.g., simply dispensing intact tablets), the full requirements of labeling and SDSs are not triggered for these drugs.

This aligns with FDA-regulated drugs designed for direct patient use, distinguishing them from bulk chemicals or other hazardous substances.

In accordance with these regulations, Oliva Therapeutics does not supply an SDS for their solid oral dose products.

Sincerely,

Michael Turnamian

Michael Turnamian
Chief Operating Officer
Oliva Therapeutics