

**CONFIDENTIALITY COMMITMENT
STATEMENT OF LEGAL AUTHORITY
AND COMMITMENT FROM
BUNDESMINISTERIUM FÜR UMWELT, NATURSCHUTZ UND
REAKTORSICHERHEIT
NOT TO PUBLICLY DISCLOSE NON-PUBLIC INFORMATION
SHARED**

**BY THE U. S. FOOD AND DRUG ADMINISTRATION (USFDA), U.S.
DEPARTMENT OF HEALTH AND HUMAN SERVICES**

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Therefore, the Bundesministerium für Umwelt, Naturschutz und Reaktorsicherheit certifies that it:

1. has the authority to protect the non-public information provided to the Bundesministerium für Umwelt, Naturschutz und Reaktorsicherheit in confidence by the USFDA from public disclosure;

2. will not publicly disclose the USFDA-provided non-public information without the written authorization of the owner of the information, the written authorization from the individual who is the subject of the personal privacy information, or a written statement from USFDA that the information no longer has non-public status;
3. will inform USFDA within two working days of any effort made to obtain USFDA-provided non-public information from the Bundesministerium für Umwelt, Naturschutz und Reaktorsicherheit by judicial or legislative mandate. If such judicial or legislative mandate orders disclosure of USFDA-provided non-public information, the Bundesministerium für Umwelt, Naturschutz und Reaktorsicherheit will take all measures in an effort to ensure that the information will be disclosed in a manner that protects the information from public disclosure; and
4. will promptly inform USFDA of any changes to German laws or the Bundesministerium für Umwelt, Naturschutz und Reaktorsicherheit policies or procedures that would affect the Bundesministerium für Umwelt, Naturschutz und Reaktorsicherheit's ability to honor the agreements in this document.



Beglaubigt

Angestellter

Signature Bundesministerium für Umwelt, Naturschutz und Reaktorsicherheit official

Prof. Dr. Schlottmann

Printed name of Bundesministerium für Umwelt, Naturschutz und Reaktorsicherheit official

Head of Division International Chemical Safety

Title of Bundesministerium für Umwelt, Naturschutz und Reaktorsicherheit official

Bundesministerium für Umwelt, Naturschutz und Reaktorsicherheit
Postfach 12 06 29
5300 Bonn 1
Germany

Telephone and facsimile: +49-228-305-2740 / Fax.: -305 -3524