Environmental Protection Agency § 725.94

requested, EPA will review the re-
response. If the submitter’s proposed ge-
neric name is acceptable, EPA will
publish that generic name on the pub-
lic Inventory. If the submitter’s pro-
posed generic name is not acceptable,
EPA will notify the submitter of EPA’s
choice of a generic name. Thirty days
after this notification, EPA will place
the chosen generic name on the public
Inventory.

§ 725.88 Uses of a microorganism.

(a) Assertion of claim. A person who
submits information to EPA under this
part on the categories or proposed cat-
egories of use of a microorganism may
assert a claim of confidentiality for
this information.

(b) Requirements for claim. A sub-
mitter that asserts such a claim must:
(1) Report the categories or proposed
categories of use of the microorganism.
(2) Provide, in nonconfidential form,
a description of the uses that is only as
generic as necessary to protect the
confidential business information. The
generic use description will be included
in the FEDERAL REGISTER notice de-
scribed in § 725.40.

(c) Generic use description. The person
must submit the information required
by paragraph (b) of this section by de-
scribing the uses as precisely as pos-
sible, without revealing the information
which is claimed confidential, to
disclose as much as possible how the
use may result in human exposure to
the microorganism or its release to the
environment.

§ 725.92 Data from health and safety
studies of microorganisms.

(a) Information other than specific
microorganism identity. Except as pro-
vided in paragraph (b) of this section,
EPA will deny any claim of confiden-
tiality with respect to information in-
cluded in a health and safety study of
a microorganism, unless the informa-
tion would disclose confidential busi-
ness information concerning:
(1) Processes used in the manufacture
or processing of a microorganism.
(2) Information which is not in any
way related to the effects of a micro-
organism on health or the environ-
ment, such as, the name of the submit-
ting company, cost or other financial
data, product development or mar-
keting plans, and advertising plans, for
which the person submits a claim of
confidentiality in accordance with
§ 725.80.

(b) Microorganism identity—(1) Claims
applicable to the period prior to com-
 mencement of manufacture or import for
general commercial use. A claim of con-
 fidentiality for the period prior to com-
 mencement of manufacture or import
for general commercial use for the spe-
cific identity of a microorganism for
which a health and safety study was
submitted must be asserted in conjunc-
tion with a claim asserted under
§ 725.85(a). The submitter must substan-
tiate each claim in accordance with
the requirements of § 725.94(a).

(2) Claims applicable to the period after
commencement of manufacture or import
for general commercial use. To maintain
the confidential status of the specific
identity of a microorganism for which
a health and safety study was sub-
mitted after commencement of manu-
facture or import for general com-
mercial use, the claim must be reasserted
and substantiated in conjunction with
a claim under § 725.85(b). The submitter
must substantiate each claim in ac-
 accordance with the requirements of
§ 725.94(b).

(c) Denial of confidentiality claim. EPA
will deny a claim of confidentiality for
microorganism identity under para-
graph (b) of this section, unless:
(1) The information would disclose
processes used in the manufacture or
processing of a microorganism.
(2) The microorganism identity is not
necessary to interpret a health and
safety study.

(d) Use of generic names. When EPA
discloses a health and safety study con-
taining a microorganism identity,
which the submitter has claimed con-
 fidential, and if the Agency has not de-
 nied the claim under paragraph (c) of
this section, EPA will identify the
microorganism by the generic name se-
lected under § 725.85.

§ 725.94 Substantiation requirements.

(a) Claims applicable to the period prior
to commencement of manufacture or im-
port for general commercial use—(1)
MCAN, TME, Tier I certification, and
Tier II exemption request requirements.

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