|  |
| --- |
| Logo AGES |
| Ethylene oxide |
|  |  |
| 05.02.2025 15:08 Uhr |

**Ethylene
oxide**

**Ethylene
oxide**

Last
change:
14.10.2024

**Profile**

**Description**

Ethylene
oxide
is
a
colorless
gas
used
in
some
countries
such
as
India,
USA,
Canada
for
spraying
food
to
kill
bacteria
and
fungi.
It
may
therefore
appear
as
a
residue
in
these
foods.
In
the
EU,
it
has
been
banned
in
plant
protection
products
since
1991.
Ethylene
oxide
is
permitted
as
a
sterilizing
agent
(e.g.,
in
medical
devices)
because,
in
order
to
prevent
damage
to
the
material
or
electronics,
in
many
cases
it
cannot
be
replaced
by
other
sterilization
methods
(hot
steam,
gamma
rays,
etc.).
However,
it
must
not
come
into
contact
with
food,
but
also
must
not
be
applied
to
surfaces
that
come
into
contact
with
food.

**Occurrence**

Residues
of
ethylene
oxide
are
found
mainly
in
sesame
seeds,
in
products
containing
sesame
seeds
such
as
bars,
snacks
or
salad
toppings,
and
in
spices
and
additives,
e.g.
locust
bean
gum
(E410),
guar
gum
(E412).

**Health
risk**

Ethylene
oxide
is
mutagenic
and
carcinogenic

**Situation
in
Austria**

**Antigen
test
systems**

We
have
already
randomly
analyzed
swabs
of
commercially
available
SARS-CoV-2
antigen
test
systems
with
regard
to
ethylene
oxide
residues
in
2021.
For
this
purpose,
we
performed
15
swab
analyses
from
12
different
products/manufacturers.
In
13
swabs,
no
ethylene
oxide
was
detectable.
Ethylene
oxide
was
detectable
in
two
swabs,
but
in
both
cases
the
levels
were
well
below
the
method's
limit
of
quantitation
of
1
µg/swab.
These
two
results
represent
less
than
one-tenth
of
the
limit
allowed
for
medical
devices.

We
also
evaluated
the
health
risk:
To
do
this,
we
assumed
that
a
child
weighing
30
kilograms
would
have
a
test
stick
containing
1
microgram
of
ethylene
oxide
in
his
or
her
nose
for
one
hour
every
day.
Even
under
this
nevertheless
unlikely
duration
of
contact,
the
so-called
"intake
level
of
low
concern"
for
ethylene
oxide
of
0.037
micrograms
per
kilogram
of
body
weight
per
day
is
undercut.
Since
a
test
is
not
performed
every
day
and
the
swab
is
usually
in
contact
with
the
nasal
mucosa
for
about
20
seconds
when
an
antigen
test
is
used,
the
actual
risk
is
much
lower.

**Food**

On
July
16,
2021,
the
European
Commission
reiterated
in
a
letter
addressed
to
European
authorities
and
food
business
operators
that
products
contaminated
with
ethylene
oxide
above
the
applicable
MRL
under
Regulation(EC)
No.
396/2005
will
be
assessed
as
unsafe
throughout
the

EU
and
therefore
unfit
for
human
consumption.

The
responsibility
for
safe
food
lies
primarily
with
food
business
operators.
As
part
of
their
self-monitoring,
they
are
now
called
upon
to
test
their
products
for
this
banned
substance.
In
case
of
contamination
with
ethylene
oxide
above
the
applicable
maximum
residue
level
according
to
Regulation(EC)
No.
396/2005,
these
products
must
not
be
marketed.

Since
contaminated
food
products
were
reported
via
the
European
Rapid
Alert
System,
[controls
by
the
competent
food
authorities](https://www.ages.at/en/human/focus/focus-actions/detail/ethylenoxid-in-auf-sesamsamen-und-gewuerzen-aus-drittlaendern)
have
been
ongoing
throughout
Austria
and
will
continue
to
be
carried
out
in
order
to
ensure
the
greatest
possible
safety
for
consumers.

**Focus
actions
on
ethylene
oxide**

[Ethylene
oxide
in/on
sesame
seeds
and
spices
from
third
countries
2021](https://www.ages.at/mensch/schwerpunkte/schwerpunktaktionen/detail/ethylenoxid-in-auf-sesamsamen-und-gewuerzen-aus-drittlaendern)

**Specialized
information**

Ethylene
oxide
is
a
mutagenic
carcinogen
with
no
threshold
(RAC
2017,
ATP).
Mutagenicity
(the
potential
to
alter
genetic
material)
is
basically
an
acute
effect
occurring
after
a
single
exposure.
However,
secondary
effects,
such
as
tumor
formation
(carcinogenicity),
occur
after
a
delay
and
as
a
result
of
accumulated
exposure
over
a
lifetime.
Therefore,
even
single
high
exposures
by
children
should
be
avoided.
Due
to
the
mutagenic
potential
of
ethylene
oxide,
it
was
not
possible
to
define
a
health-based
guideline
value
without
health
risk
(EFSA,
2012,
BPC
2020).
However,
as
already
stated
in
the
BfR
statement
(BfR,
2020,
2021),
the
data
situation
on
ethylene
oxide
allows
the
derivation
of
intake
levels
below
which
a
"minimal
additional
cancer
risk"
can
be
assumed
(EFSA,
2005).
Following
the
elaboration
of
this
concept
by
EFSA
(2005),
an
intake
level
of
"low
concern"
can
be
estimated
by
applying
an
extrapolation
factor
of
10000
(Margin
of
Exposure,
MoE)
to
the
relevant
BMDL10
value
from
an
appropriate
animal
study
or
from
epidemiological
surveys.
The
BMDL10
value
describes
the
calculated
lower
limit
of
the
confidence
interval
of
that
dose
that
causes
a
10%
increase
in
tumor
incidence
with
lifetime
intake.
In
the
case
of
ethylene
oxide,
the
National
Institute
for
Public
Health
and
the
Environment
(RIVM,
the
Netherlands)
had
available
a
150-week
study
in
rats
(Dunkelberg,
1982)
suitable
for
estimating
cancer
risk
after
oral
intake.
The
findings
from
this
study
were
re-evaluated
with
respect
to
the
dose-response
relationship
according
to
the
state
of
the
art
described
by
EFSA
(2017)
using
benchmark
dose
modeling
and
found
to
be
plausible
by
BfR
(BfR,
2020,
2021).
A
BMDL10
of
0.37
mg/kg
bw/day
was
determined
for
the
increase
in
tumors
in
the
stomach
of
lifelong
exposed
female
animals
(rats)
in
the
study
by
Dunkelberg,
1982.
Thus,
by
including
the
extrapolation
factor
of
10,000,
the
intake
level
of
"low
concern"
for
ethylene
oxide
is
0.037
µg/kg
bw/day.
Regarding
the
ethylene
oxide
degradation
product
2-chloroethanol,
the
data
situation
is
contradictory
and
partly
incomplete.
The
BfR
(BfR,
2020,
2021)
also
concludes
that
no
reliable
statement
can
currently
be
made
on
the
mutagenic
and
carcinogenic
properties
of
2-chloroethanol
and
that
the
risk
assessment
for
2-chloroethanol
should
therefore
follow
the
same
principle
as
for
ethylene
oxide.

The
use
of
ethylene
oxide
for
sterilization
of
medical
devices
is
an
established
procedure.
The
manufacturer
must
prove
that
the
products
are
actually
sterile
after
sterilization
and
that
the
outgassing
time
for
ethylene
oxide
has
been
selected
long
enough
to
ensure
that
limit
values
that
have
been
classified
as
harmless
are
also
complied
with.
In
addition,
the
involvement
of
a
notified
body
(independent
testing
authority)
is
necessary
as
part
of
the
conformity
assessment
procedure.
If
ethylene
oxide
were
no
longer
allowed
to
be
used
for
sterilization,
many
medical
devices,
especially
high-class
ones
(implantable
devices),
would
no
longer
be
available,
as
most
of
them
cannot
be
sterilized
using
other
methods.

**More
information
on
Ethylene
oxide**

[Dunkelberg
H
(1982)
Carcinogenicity
of
ethylene
oxide
and
1,2-propylene
oxide
upon
intragastric
ad-ministration
to
rats.
Br.
J.
Cancer,
46,
924-933.](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2011226/)[RIVM
&
WFSR
(2020)
Risk
Assessment
of
ethylene
oxid
e
in
sesame
seeds.
Project
No.
V/
093130.](https://www.rivm.nl/sites/default/files/2020-11/FO%20beoordeling%20ethyleenoxide%20in%20sesamzaad_final_20201025_anon.pdf)[RAC
Opinion
proposing
harmonised
classification
and
labeling
at
EU
level
of
ethylene
oxide
(oxirane),
2017.](https://echa.europa.eu/documents/10162/d82894c8-9cf1-2c16-d3e6-40cad6ae534f)[Commission
Regulation
(EU)
2020/217
of
October
4,
2020.](https://eur-lex.europa.eu/legal-content/DE/TXT/PDF/?uri=CELEX:32020R0217)[Conclusion
on
the
peer
review
of
the
pesticide
risk
assessment
of
the
active
substance
ethylene,
EFSA
Journal
2012;10(1):2508.](https://www.efsa.europa.eu/de/efsajournal/pub/2508)[Opinion
on
the
application
for
approval
of
the
active
substance:
ethylene
oxide,
ECHA/BPC/272/2020,
BCP
2020.](https://echa.europa.eu/documents/10162/5a3831c0-e6d4-7140-1e1b-2c8e3369edd4) [Health
evaluation
of
ethylene
oxide
residues
in
sesame
seeds,
BfR
2020](https://www.bfr.bund.de/cm/343/gesundheitliche-bewertung-von-ethylenoxid-rueckstaenden-in-sesamsamen_final.pdf).

[Health
evaluation
of
ethylene
oxide
residues
in
sesame
seeds
-
Updated
BfR
Opinion
No.
024/2021
of
01
September
2021.](https://www.bfr.bund.de/cm/343/gesundheitliche-bewertung-von-ethylenoxid-rueckstaenden-in-sesamsamen_final.pdf)[Opinion
of
the
Scientific
Committee
on
a
request
from
EFSA
related
to
A
Harmonised
Approach
for
Risk
Assessment
of
Substances
Which
are
both
Genotoxic
and
Carcinogenic,
EFSA
2005](https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2005.282)[EFSA
guidance
on
benchmark
dose
modelling,
2017,
BMD
approach
in
risk
assessment](https://www.efsa.europa.eu/en/efsajournal/pub/4658)[EFSA
comprehensive
European
food
consumption
database,
2015](https://www.efsa.europa.eu/en/food-consumption/comprehensive-database)

[Ethylene
oxide
-
German
Food
Association](https://www.lebensmittelverband.de/de/lebensmittel/sicherheit/unerwuenschte-stoffe-kontaminanten/ethylenoxid)

[DIN
EN
ISO
10993-7
(Biological
evaluation
of
medical
devices,
Part
7:
Ethylene
oxide
sterilization
residues)](https://shop.austrian-standards.at/search/FastSearch.action?q=H4sIAAAAAAAAACsucq8ocqsoKOdggILiIteKIhegCCNTcZFnRZFHRZEXkMfMwGhYXBReURQA5OgwMzClpDKwux_ek1OSmc7AlJrHwBqWmJOZwsBUVcXAa29vXwbi6RkCWRXFhQx1DFzlthBN3FBN2amZJWCNHGCNmSWVYL3iML1AgbzEssz0xJL8IpAp5ewMrGCJiuKiqAqQkezlIgxCLp5-Cq5-Cp7B_gqGBpaWxrrmUOskGcHWYVEAc5AZxEFsbpk5JalFYLfA2VCXFKcmFiVn6EEooEQuyCVAAAAI0LLCNwEAAA&fromHistory=true&searchTerm=DIN+EN+ISO+10993-7#/)

[European
Commission
(2021):
minutes
to
the
meeting
of
crisis
coordinators
regarding
the
detection
of
ethylene
oxide
in
food
additives
(E410).](https://ec.europa.eu/food/food/rasff-food-and-feed-safety-alerts/ethylene-oxide-incident-food-additive_en)

[European
Commission
(2020):
minutes
to
the
meeting
of
crisis
coordinators
regarding
the
detection
of
ethylene
oxide
in
sesame
imported
from
India.](https://ec.europa.eu/food/safety/rasff-food-and-feed-safety-alerts/ethylene-oxide-incident-sesame-seeds_en)