EtO BPD Consortium

Ethylene Oxide

For use as a gaseous sterilant (PT2)

Document IIIA

Section 7.1 to 7.3

Ecotoxicological profile including environmental fate and behaviour

Part 1

February 2020

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Please refer to “Technical Notes for Guidance on Dossier Preparation including preparation and evaluation of study summaries under Directive 98/8 EC Concerning the Placing of Biocidal Products on the Market (Appendix 7.1 and 7.2)” for a list of the Standard Terms and Abbreviations used in this document.

7.1 Fate and Behaviour in Water

7.1.1 Degradation, initial studies

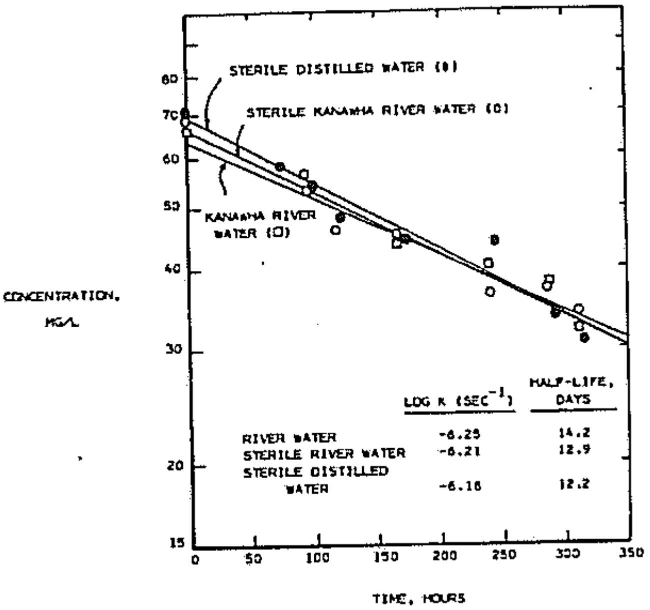
7.1.1.1 Abiotic

7.1.1.1.1 Hydrolysis as a function of pH and identification of breakdown products

Section A7.1.1.1.1/01 **Annex Point IIA 7.6.2.1**	**Hydrolysis as a function of pH and identification of breakdown products**	
	1 Reference	**Official use only**
1.1 Reference	R. A. Conway, G. T. Waggy, M. H. Spiegel, R. L. Berglund (1983) Environmental Fate and Effects of Ethylene Oxide. Published report, J. Environ. Sci. Technol., 1983, Vol. 17, No. 2, 107-112	
1.2 Data protection	None	
1.2.1 Data owner	Public domain	
1.2.3 Criteria for data protection	No data protection claimed	
	2 Guidelines and Quality Assurance	
2.1 Guideline study	Guideline not specified	
2.2 GLP	No	
2.3 Deviations	Not applicable	X
	3 Materials and Methods	
3.1 Test material	Ethylene oxide	
3.1.1 Lot/Batch number	Not specified	
3.1.2 Specification	Not specified	
3.1.3 Purity	Not specified	X
3.1.4 Further relevant properties	Not applicable	
3.2 Reference substance	No	
3.2.1 Initial concentration of reference substance	Not applicable	
3.3 Test solution	The hydrolytic degradation of ethylene oxide was determined in sterile distilled water and in sterile and non-sterile Kanawha River water containing approximately 65 mg/L ethylene oxide at pH 7.4 and 25°C. The hydrolysis of ethylene oxide was also determined in salt water by preparing a pH 7 buffer solution by mixing 30 mL of 0.06 M NaH_2PO_4	

	with 61 mL of 0.067 M K_2HPO_4, which was then diluted 10-fold and sterilised by filtration through a 0.22 µm filter. Buffered solutions containing approximately 200 mg/L ethylene oxide and 0%, 1% and 3% NaCl were tested at 25°C.	
3.4 Testing procedure		
3.4.1 Test system	Ethylene oxide was added to the test solutions via a cylinder containing ethylene oxide gas which was placed in a hood and connected to a swagelock tee equipped with a septum. Gas flowed through the tee to a rotameter and was vented to the hood. A pre-calculated volume of ethylene oxide, depending on the temperature and pressure, was collected in a syringe and injected into a septum-sealed, sterile vial containing a known quantity of solution buffered at the desired pH. Vials were almost completely filled to lessen volatilisation and various concentrations of ethylene oxide were prepared to establish an analytical base. The vials were incubated in the dark in a temperature-controlled, shaken water bath. Samples were removed for analysis at regular intervals during the study using a 10 µl syringe.	x
3.4.2 Temperature	25°C	
3.4.3 pH	7.4 (distilled water and Kanawha River water) and 7.0 (salt water)	
3.4.4 Duration of the test	350 hours	
3.4.5 Number of replicates	Not specified	
3.4.6 Sampling	Samples were removed at the following approximate times; 0 h, 4 d, 5 d, 7 d, 10 d, 12 d and 13 d.	
3.4.7 Analytical methods	Samples were analysed by gas chromatography with the following operating conditions:- injection port, 60°C; column, 60°C; flame ionisation detector, 200°C; helium flow, 22 cm^3/min. A sample size of 5 µL was used in a solvent flush technique, with an approximate retention time of 6.3 mins. The distilled water and river water samples were analysed using 6.1 m x 3.2 mm stainless steel tubing packed with a 30% solution of Tergitol non-ionic surfactant TMN-3% sodium methylate on Chromosorb W, NAW, 60/80 mesh. The salt water samples were analysed using 6.1 m x 3.2 mm stainless steel tubing packed with super PAK-20M (column recommended for ethylene oxide and chlorohydrin with regard to accuracy and elution times).	
3.5 Preliminary test	No	
	4 Results and Discussion	
4.1 Concentration and hydrolysis values	Not specified	
4.2 Hydrolysis rate constant (k_h)	The following Log K values were reported for the fresh water hydrolysis experiment at pH 7.4 and 25°C:	x

	Sterile distilled water = -6.16 sec^{-1} River water (sterile) = -6.21 sec^{-1} River water (non sterile) = -6.25 sec^{-1} Based on a critical review of published studies comparing the rates of hydrolysis of chemicals in natural and pure waters, the authors concluded that the rate constants are the same and that laboratory measurements can provide data for estimating hydrolysis rates in the environment. There were slight differences in the rate constants for the sterilised samples compared to the natural river water, but the authors reported that these were well within the error limits discussed in the published literature. The experimental results were plotted against data available in the published literature to show the data in perspective. This indicated that there were no significant differences in the hydrolysis rate of ethylene oxide at different pH values in the environmentally relevant pH range of 5 – 9. It was concluded that water temperature is likely to have a greater effect on half-life than expected pH differences in natural waters. The following Log K values were reported for the salt water hydrolysis experiment at pH 7 and 25°C: 0% NaCl = -6.21 sec^{-1} 1% NaCl = -6.14 sec^{-1} 3% NaCl = -6.06 sec^{-1} The results for the salt-free solution are in close agreement with those for the fresh water experiment thus lending credibility to the laboratory procedures used and other results achieved.	
4.3 Dissipation time	The following first-order half-lives were reported for the fresh water hydrolysis experiment at pH 7.4 and 25°C: Sterile distilled water = 12.2 days River water (sterile) = 12.9 days River water (non sterile) = 14.2 days The following first-order half-lives were reported for the salt water hydrolysis experiment at pH 7 and 25°C: 0% NaCl = 13.1 days 1% NaCl = 11.0 days 3% NaCl = 9.3 days	

4.4 Concentration – time data	 **Figure 2.** Ethylene oxide hydrolysis in fresh water at pH 7.4 and 25 °C.	
4.5 Specification of the transformation products	Ethylene oxide is hydrolysed in fresh water to ethylene glycol and in salt water to ethylene glycol and ethylene chlorohydrin. During the hydrolysis tests using 1% and 3% NaCl buffer solutions, the loss of ethylene oxide and the formation of ethylene chlorohydrin were determined and chlorohydrin / glycol ratios were therefore calculated. These were 0.11 and 0.23 for the 1% and 3% NaCl solutions, respectively. The ratio is directly proportional to salt concentration.	X
	5 Applicant's Summary and Conclusion	
5.1 Materials and methods	The hydrolytic degradation of ethylene oxide was determined in fresh water and salt water solutions. For the fresh water experiment solutions of sterile distilled water and sterile and non-sterile Kanawha River water containing approximately 65 mg/L ethylene oxide at pH 7.4 were prepared. For the salt water experiment a pH 7 buffer solution was prepared by mixing 30 mL of 0.06 M NaH_2PO_4 with 61 mL of 0.067 M K_2HPO_4, which was then diluted 10-fold and sterilised by filtration through a 0.22 µm filter. Buffered solutions containing approximately 200 mg/L ethylene oxide and 0%, 1% and 3% NaCl were prepared. The solutions were incubated in the dark at 25°C for 350 hours. Samples were taken at regular intervals and analysed by gas chromatography.	
5.2 Results and discussion		X
5.2.1 k_H	Sterile distilled water = -6.16 sec^{-1} River water (sterile) = -6.21 sec^{-1} River water (non sterile) = -6.25 sec^{-1} 0% NaCl = -6.21 sec^{-1} 1% NaCl = -6.14 sec^{-1} 3% NaCl = -6.06 sec^{-1}	
5.2.2 DT_{50}	Sterile distilled water = 12.2 days River water (sterile) = 12.9 days River water (non sterile) = 14.2 days	

	0% NaCl = 13.1 days 1% NaCl = 11.0 days 3% NaCl = 9.3 days	
5.2.3 r^2	Not specified	
5.3 Conclusion	The hydrolysis half-life of ethylene oxide was estimated to be 12-14 days in fresh water and 9-11 days in salt water. Ethylene oxide is hydrolysed in fresh water to ethylene glycol and in salt water to ethylene glycol and ethylene chlorohydrin.	
5.3.1 Reliability	2	x
5.3.2 Deficiencies	Yes The study has not been performed in accordance with any regulatory guideline. However, the data presented from this paper provides valuable information on the hydrolysis of ethylene oxide in the aquatic environment. Direct exposure to the natural aquatic environment following use of ethylene oxide as a gaseous sterilant will not occur and any indirect exposure is expected to be negligible. A guideline compliant study to fulfil this data requirement is therefore not considered necessary.	x
	Evaluation by Competent Authorities	
	Evaluation by Rapporteur Member State	
Date	10 May 2019	
Materials and Methods	**Comment (2.3)**: The eCA agrees that deviations are not applicable, since no guideline was followed. However, if compared with the requirements of OECD test guideline 111, several deviations are identified: testing at only pH value instead of three, no information on recoveries and statistical information are given, etc.). **Comment (3.1.3)**: The purity is not reported in the published article. As discussed in the CAR, section A.1.2. Composition of the substance (reference specifications), the production of ethylene oxide consistently yields the active substance in high purity (generally above 99 %). It is not expected that today's production process is significantly different from the production process at the time when this article was written. The principles of the ethylene oxide production has remained unchanged since the 1930s. In the current production of ethylene oxide, some impurities are identified, but none detected above significant level (all below 0.01 %). Furthermore, based on the identity of these impurities and the hazardous profile of the active substance itself, the eCA has no reason to believe that the impurities will have any impact on the findings of this study. **Comment (3.4.6)**: Ethylene oxide is a highly volatile substance and it is hence important to take extra measures to ensure that the substance is kept in solution during the test. It is essential that the containers are properly sealed. As it is stated that the vials were almost completely filled and that septum-sealed vials were used, the eCA considers that the necessary precautions have been taken.	
Results and discussion	**Comment (4.2)**: According to the authors of the publication, water temperature will have more effect than pH on the hydrolysis of ethylene oxide. The half-life at	

	12 °C can be calculated using the following formula: $DT_{50}\ (12\ °C) = DT_{50}\ (25\ °C) \cdot e^{(0.08 \cdot (25-12))}$ Using half-lives of 12-14 d for 25 °C as a starting point, the half-life in freshwater at 12 °C would be in the range of 34-40 days. **Comment (4.5)**: In freshwater (which is the most relevant compartment for the applied use of ethylene oxide), the hydrolysis of ethylene oxide results in the formation of ethylene glycol. This process is well known from the open literature. However, there is no information in this study on the formation of ethylene glycol in the freshwater study. The eCA is of the opinion that ethylene glycol should be regarded as a relevant transformation product for the environmental assessment. **Comment (5.2)**: Due to the insufficient reporting and limited test setup, these results should be considered as giving basic information on the hydrolysis of ethylene oxide at neutral pH and 25 °C.
Conclusion	**Comment (5.3.2)**: We agree with the reasoning of the applicant. However, it should be noted that the given half-lives relate to a temperature of 25 °C. It can be expected that ethylene oxide will hydrolyse in the aquatic environment, but that the process will be slow. Half-life in freshwater recalculated to 12 °C based on this study would be in the range of 34-40 days.
Reliability	**Comment (5.3.1)**: It may be that the reliability should be set to 3 due to the very limited reporting. Regardless of a reliability of 2 or 3, the eCA is of the opinion that the results can be used as supporting information / together with other information in a weight of evidence approach.
Acceptability	There are several limitations to this study, since it is not a standardised guideline study and the reporting of test conditions, statistical evaluation etc. is not as elaborate as desired. Nevertheless, the test system (a sterile buffered aqueous solution kept at a fixed temperature in the dark, measures taken to prevent evaporation) is considered scientifically acceptable as a basic investigation of the hydrolysis of ethylene oxide at neutral pH and one temperature.
Remarks	-

7.1.1.1.2 Photo-transformation in water including identity of the products of transformation

Section A7.1.1.1.2 **Annex Point IIA7.6.2.2**	**Photo-transformation in water including identity of the products of transformation**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [ ] **Limited exposure [X]**	**Technically not feasible [X]** **Scientifically unjustified [X]** **Other justification [ ]**	
Detailed justification:	Ethylene oxide does not contain chromophores that absorb at wavelengths >290 nm and is therefore not expected to be susceptible to direct photolysis by sunlight (Hazardous Substances Data Bank, 2002)[1]. In addition, direct exposure to the natural aquatic environment following use of ethylene oxide as a gaseous sterilant will not occur and any indirect exposure is expected to be negligible. Studies to investigate the photo-transformation of ethylene oxide in water are therefore not required.	x
Undertaking of intended data submission [ ]	No undertaking provided; submission of further data/information is not considered necessary.	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	10 May 2019	
Evaluation of applicant's justification	The information on ethylene oxide in the Hazardous Substances Data Bank was reviewed by SRP in 2008 and the statement on photolysis was not changed then. The eCA agrees with the statement. Furthermore, the absorption spectrum of ethylene oxide (Doc IIIA3.4) indicates that it does not absorb solar radiation in the wavelengths necessary to reach the earth's surface (absorption maxima at 159, 171 and 174 nm, no absorption above 182 nm). This is in accordance with what could be expected based on the molecular structure of ethylene oxide, given that it does not contain any double bonds and should therefore not absorb radiation with higher wavelengths.	
Conclusion	Agree with applicant. Ethylene oxide is not expected to undergo phototransformation. A study is therefore not considered necessary	
Remarks	-	

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[1] Hazardous Substances Data Bank (2002) Ethylene Oxide CASRN: 75-21-8, Environmental Fate & Exposure: Environmental Fate/Exposure Summary. National Library of Medicine, National Toxicology Information Program, Bethesda, MA 20894

7.1.1.2 Biotic

7.1.1.2.1 Ready biodegradability

Section A7.1.1.2.1/01 **Annex Point IIA 7.6.1.1**	**Biodegradability (ready)**	
	1 Reference	**Official use only**
1.1 Reference	R. A. Conway, G. T. Waggy, M. H. Spiegel, R. L. Berglund (1983) Environmental Fate and Effects of Ethylene Oxide. Published report, J. Environ. Sci. Technol., 1983, Vol. 17, No. 2, 107-112	
1.2 Data protection	None	
1.2.1 Data owner	Public domain	
1.2.3 Criteria for data protection	No data protection claimed	
	2 Guidelines and Quality Assurance	
2.1 Guideline study	"Standard Methods for the Examination of Water and Wastewater", 14th ed.; American Public Health Association, Washington DC, 1975.	X
2.2 GLP	No	
2.3 Deviations	Method changes involved extending the test period to 20 days; maintaining three seed control bottles (2 mL of domestic sewage/bottle) through the test period for calculating seed oxygen demand; accomplishing reaeration, if needed, by dividing the BOD bottle contents between two BOD bottles, sealing, shaking 20 times and returning to the original BOD bottle, reading the oxygen level, resealing, and returning to an incubator.	X
	3 Materials and Methods	
3.1 Test material	Ethylene oxide	
3.1.1 Lot/Batch number	Not specified	
3.1.2 Specification	Not specified	
3.1.3 Purity	Not specified	X
3.1.4 Further relevant properties	Not applicable	
3.1.5 Composition of Product	Not specified	
3.1.6 TS inhibitory to microorganisms	No	

3.1.7 Specific chemical analysis	Not applicable	
3.2 Reference substance	Glucose / monosodium glutamate	x
3.2.1 Initial concentration of reference substance	The standard solutions of glucose/monosodium glutamate were determined with each test series. The theoretical concentration was 215 mg/L, eighteen measurements gave a mean of 215 mg/L, SD 3 mg/L.	
3.3 Testing procedure	The theoretical oxygen demand (ThO_2) was calculated (the oxygen required to completely oxidize the chemical to CO_2 and H_2O), and the chemical oxygen demand (COD) was determined by measuring chromic acid depletion, with standard solutions of potassium hydrogen phthalate as a reference.	
3.3.1 Inoculum / test species	Domestic sewage	
3.3.2 Test system	The biodegradation of ethylene oxide was determined in a lightly seeded biological oxygen demand (BOD) test. Ethylene oxide was incubated with domestic sewage sludge inoculum in airtight bottles under aerobic conditions in the dark for 20 days. The samples were re-aerated when necessary by dividing the contents of each bottle between two BOD bottles which were then sealed and shaken 20 times. After shaking, the bottle contents were transferred back to the original BOD bottle, an oxygen level reading was taken and the bottle was then re-sealed and returned to the incubator. Three seed control bottles (2 mL of domestic sewage per bottle) were included in the study and standard solutions of glucose/monosodium glutamate were determined with each test series for validation purposes. The biodegradation of some possible metabolites of ethylene oxide, ethylene glycol, ethylene chlorohydrin and glyoxal was also determined during the study.	
3.3.3 Test conditions	Details of the test conditions are not specified.	
3.3.4 Method of preparation of test solution	Not specified	
3.3.5 Initial TS concentration	Not specified	
3.3.6 Duration of test	20 days	
3.3.7 Analytical parameter	Oxygen consumption	
3.3.8 Sampling	5, 10, 15 and 20 days	
3.3.9 Intermediates/ degradation products	No intermediates / degradation products were detected.	
3.3.10 Nitrate/nitrite measurement	Not applicable	
3.3.11 Controls	Three seed control bottles (2 mL of domestic sewage per bottle) were included in the study and standard solutions of glucose/monosodium glutamate were determined with each test series for validation purposes.	

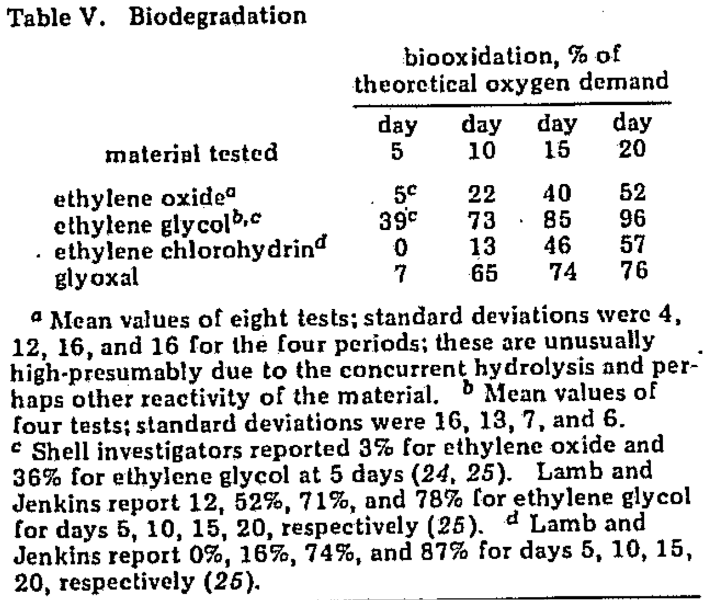
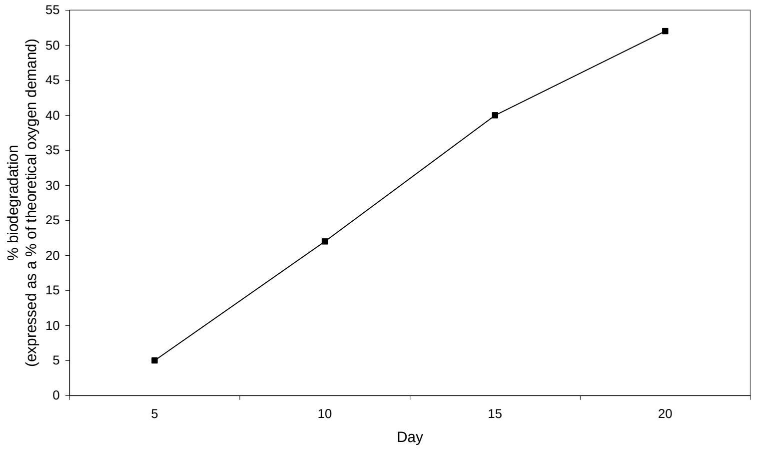
3.3.12 Statistics	Not applicable Mean values and standard deviations were calculated (see Table V)	
	4 Results and Discussion	
4.1 Degradation of test substance		

Table V. Biodegradation

material tested	biooxidation, % of theoretical oxygen demand day 5	day 10	day 15	day 20
ethylene oxide[a]	5[c]	22	40	52
ethylene glycol[b,c]	39[c]	73	85	96
ethylene chlorohydrin[d]	0	13	46	57
glyoxal	7	65	74	76

[a] Mean values of eight tests; standard deviations were 4, 12, 16, and 16 for the four periods; these are unusually high-presumably due to the concurrent hydrolysis and perhaps other reactivity of the material. [b] Mean values of four tests; standard deviations were 16, 13, 7, and 6. [c] Shell investigators reported 3% for ethylene oxide and 36% for ethylene glycol at 5 days (*24*, *25*). Lamb and Jenkins report 12, 52%, 71%, and 78% for ethylene glycol for days 5, 10, 15, 20, respectively (*25*). [d] Lamb and Jenkins report 0%, 16%, 74%, and 87% for days 5, 10, 15, 20, respectively (*25*).

4.1.1 Graph	The biodegradation of ethylene oxide expressed as a percentage of its theoretical oxygen demand is shown in the graph below: 	
4.1.2 Degradation	The bio-oxidation of ethylene oxide was 52% after 20 days. The aqueous aerobic biodegradation half-life of ethylene oxide is therefore estimated to be approximately 20 days. The authors conclude that in a biological waste treatment system with a high concentration of adapted micro-organisms, bio-oxidation is expected to be much faster.	X
4.1.3 Other observations	Bio-oxidation data presented for the possible metabolites of ethylene oxide, ethylene glycol, ethylene chlorohydrin and glyoxal show that these compounds biodegrade in a lightly seeded dilution-bottle test. The bio-oxidation of ethylene glycol, ethylene chlorohydrin and glyoxal was 96%, 57% and 76%, respectively, after 20 days.	

4.1.4 Degradation of TS in abiotic control	Not applicable	
4.1.5 Degradation of reference substance	Degradation of standard solutions of glucose/monosodium glutamate were determined within each test series.	
4.1.6 Intermediates/ degradation products	Analysis for intermediates / degradation products was not carried out.	
	5 Applicant's Summary and Conclusion	
5.1 Materials and methods	The biodegradation of ethylene oxide was determined in a lightly seeded biological oxygen demand (BOD) test over a 20 day test period. The biodegradation of some possible metabolites of ethylene oxide, ethylene glycol, ethylene chlorohydrin and glyoxal was also determined during the study.	
5.2 Results and discussion	Nineteen determinations of the standard (theoretical concentration of 500 mg/L) gave a mean of 504 mg/L, SD 6 mg/L. The bio-oxidation of ethylene oxide was 52% after 20 days. The authors conclude that in a biological waste treatment system with a high concentration of adapted micro-organisms, bio-oxidation is expected to be much faster. The bio-oxidation of ethylene glycol, ethylene chlorohydrin and glyoxal was 96%, 57% and 76%, respectively, after 20 days.	X
5.3 Conclusion	The aqueous aerobic biodegradation half-life of ethylene oxide is approximately 20 days in a lightly seeded biological oxygen demand (BOD) test. The rate of biodegradation in a biological waste treatment system with a high concentration of adapted micro-organisms is expected to be much faster.	X
5.3.1 Reliability	2	X
5.3.2 Deficiencies	Yes The study has not been performed in accordance with any regulatory guideline. However, the data presented from this paper provides valuable information on the aqueous aerobic biodegradation of ethylene oxide. Direct exposure to the natural aquatic environment following use of ethylene oxide as a gaseous sterilant will not occur and any indirect exposure is expected to be negligible. A guideline compliant study to fulfil this data requirement is therefore not considered necessary.	
	Evaluation by Competent Authorities	
	Evaluation by Rapporteur Member State	
Date	17 January 2020	
Materials and Methods	**Comment (2.1)**: This is a BOD test carried out generally following the principles in "Standard Methods for the Examination of Water and Wastewater" (14th ed.; American Public Health Association, Washington DC, 1975). To the eCA's knowledge, these were highly regarded standards at that time, which many of today's test guidelines are based on. Today, the OECD 301 tests should be used for screening biodegradation. However, the eCA considers that a modified BOD test	

	carried out following the mentioned test guideline is sufficient for the purpose of this risk assessment. **Comment (2.3)**: With the mentioned modifications of the test, e.g. the increased duration, the test has many similarities with the OECD 301D (closed bottle) test. However, limited reporting of the performed test disables a full comparison. **Comment (3.1.3)**: The purity is not reported in the published article. As discussed in the CAR, section A.1.2. Composition of the substance (reference specifications), the production of ethylene oxide consistently yields the active substance in high purity (generally above 99 %). It is not expected that today's production process is significantly different from the production process at the time when this article was written. The principles of the ethylene oxide production has remained unchanged since the 1930s. In the current production of ethylene oxide, some impurities are identified, but none detected above significant level (all below 0.01 %). Furthermore, based on the identity of these impurities and the hazardous profile of the active substance itself, the eCA has no reason to believe that the impurities will have any impact on the findings of this study. **Comment (3.2)**: This is not a mentioned reference compound in the OECD 301 test guideline, but the 1975 guideline used for this study specifically recommends a glucose-glumatic acid check.
Results and discussion	**Comment (4.1.2)**: The publication only gives the biooxidation as a percentage of the theoretical oxygen demand. No information on the start and end test concentrations of ethylene oxide are given. This is considered a significant shortcoming with this study.
Conclusion	**Comment (5.2)**: The information on the standard refers to standard solutions of potassium hydrogen phthalate used as a reference (cf. point 3.3). **Comment (5.3)**: It is likely that an environment of highly adapted microorganisms would speed up the biodegradation process of many substances. However, the eCA is of the opinion that even though findings in this test indicate that biodegradation of ethylene oxide does occur, the extrapolation of the results to a functional sewage treatment plant should not be given too much weight. Based on a comparison with pass levels of the OECD 301D test, and based on the finding of this study taking into account its shortcomings, the eCA's conclusion is that it is likely that ethylene oxide does biodegrade in the environment, but it is not readily biodegradable.
Reliability	**Comment (5.3.1)**: It may be that the reliability should be set to 3 due to the very limited reporting. Regardless of a reliability of 2 or 3, the eCA is of the opinion that the results can be used as supporting information / together with other information in a weight of evidence approach.
Acceptability	Acceptable as an indication that biodegradation of ethylene oxide does occur, and no further study is required by the eCA. This is also based on the fact that direct exposure to water is not foreseen, and the indirect exposure via atmosphere is expected to be minimal.
Remarks	-

Section A7.1.1.2.1/02 **Annex Point IIA 7.6.1.1**	**Biodegradability (ready)**	
	1 Reference	**Official use only**
1.1 Reference	A. L. Bridié, C. J. M. Wolff, M. Winter (1979a) BOD and COD of some petrochemicals. Published report, Water Research, 1979, Vol. 13, 627-630	
1.2 Data protection	None	
1.2.1 Data owner	Public domain	
1.2.3 Criteria for data protection	No data protection claimed	
	2 Guidelines and Quality Assurance	
2.1 Guideline study	Standard Dilution Method for BOD (APHA “Standard Methods” No. 219, 1971) Standard Potassium Dichromate Method for COD (ASTM D 1252-67, reapproved 1974)	
2.2 GLP	No	
2.3 Deviations	In the BOD determinations 0.5 mg L^{-1} allylthiourea was added in each test to prevent nitrification.	
	3 Materials and Methods	
3.1 Test material	Ethylene oxide	
3.1.1 Lot/Batch number	Not specified	
3.1.2 Specification	Not specified	
3.1.3 Purity	Not specified	X
3.1.4 Further relevant properties	Not applicable	
3.1.5 Composition of Product	Not specified	
3.1.6 TS inhibitory to microorganisms	Not specified	
3.1.7 Specific chemical analysis	Not applicable	
3.2 Reference substance	Mixture of glucose and glutamic acid	
3.2.1 Initial concentration of reference substance	Not specified	

3.3 Testing procedure		
3.3.1 Inoculum / test species	Effluent from a biological sanitary waste treatment plant	
3.3.2 Test system	The biochemical and chemical oxygen demand (BOD and COD) of a number of industrial chemicals (including ethylene oxide) were determined in the laboratory. For the determination of BOD 500 mL test solutions were seeded with a filtered 10 mL volume of sewage effluent from a biological sanitary waste treatment plant. Allylthiourea was also added to each test solution at a concentration of 0.5 mg/L, to prevent nitrification. Samples were incubated at 20 ± 1°C for a period of 5 days. For each series of determinations duplicate tests were also conducted on a mixture of glucose and glutamic acid for validation purposes. Tests for COD were conducted in accordance with the standard potassium dichromate method described in ASTM D 1252-67.	
3.3.3 Test conditions	In the BOD tests the test solutions were incubated at 20 ± 1°C for 5 days.	
3.3.4 Method of preparation of test solution	Not specified	
3.3.5 Initial TS concentration	Not specified	
3.3.6 Duration of test	5 days	
3.3.7 Analytical parameter	BOD and COD	
3.3.8 Sampling	Not specified	
3.3.9 Intermediates/ degradation products	Not specified	
3.3.10 Nitrate/nitrite measurement	Not applicable	
3.3.11 Controls	For each series of determinations duplicate tests were also conducted on a mixture of glucose and glutamic acid for validation purposes.	
3.3.12 Statistics	Not applicable	
	4 Results and Discussion	
4.1 Degradation of test substance		
4.1.1 Graph	Not applicable	
4.1.2 Degradation	The results of the BOD and COD measurements for ethylene oxide are shown below. The measured values are also compared to the theoretical oxygen demand (ThOD) of ethylene oxide: ThOD = 1.82 g/g	

	BOD = 0.06 g/g (% of ThOD = 3%) COD = 1.74 g/g (% of ThOD = 96%)	
4.1.3 Other observations	Not applicable	
4.1.4 Degradation of TS in abiotic control	Not applicable	
4.1.5 Degradation of reference substance	Not specified	
4.1.6 Intermediates/ degradation products	Not specified	
	5 Applicant's Summary and Conclusion	
5.1 Materials and methods	The biochemical and chemical oxygen demand (BOD and COD) of a number of industrial chemicals (including ethylene oxide) were determined in the laboratory.	
5.2 Results and discussion	The results of the BOD and COD measurements for ethylene oxide are shown below. The measured values are also compared to the theoretical oxygen demand (ThOD) of ethylene oxide: ThOD = 1.82 g/g BOD = 0.06 g/g (% of ThOD = 3%) COD = 1.74 g/g (% of ThOD = 96%)	
5.3 Conclusion	The 5-day biochemical oxygen demand (BOD) of ethylene oxide is 0.06 g/g, which is equivalent to 3% of the theoretical oxygen demand (ThOD) of 1.82 g/g.	
5.3.1 Reliability	3	
5.3.2 Deficiencies	Yes The study has not been performed in accordance with any regulatory guideline. However, the data presented from this paper provides valuable information on the aqueous aerobic biodegradation of ethylene oxide. Direct exposure to the natural aquatic environment following use of ethylene oxide as a gaseous sterilant will not occur and any indirect exposure is expected to be negligible. A guideline compliant study to fulfil this data requirement is therefore not considered necessary.	x
	Evaluation by Competent Authorities	
	Evaluation by Rapporteur Member State	
Date	17 January 2020	
Materials and Methods	Agree with applicant's version.	
Results and discussion	Agree with applicant's version.	
Conclusion	**Comment (3.1.3)**: The purity is not reported in the published article. As discussed in the CAR, section A.1.2. Composition of the substance (reference specifications),	

	the production of ethylene oxide consistently yields the active substance in high purity (generally above 99 %). It is not expected that today's production process is significantly different from the production process at the time when this article was written. The principles of the ethylene oxide production has remained unchanged since the 1930s. In the current production of ethylene oxide, some impurities are identified, but none detected above significant level (all below 0.01 %). Furthermore, based on the identity of these impurities and the hazardous profile of the active substance itself, the eCA has no reason to believe that the impurities will have any impact on the findings of this study. **Comment (5.3.2)**: Test standards (ASTM, APHA) have been used. However, the reporting is very limited. The publication only refers to the test standards and lists the resulting degradation values. Therefore, it is impossible to say whether there are any deficiencies or deviations from the test guidelines. The biooxidation percentage of 3 % of the theoretical oxygen demand is in line with the findings of Conway *et al.* (1983), A.7.1.1.2.1/01, where the percentage after 5 days was 5 %.
Reliability	Agree – 3, due to the very limited reporting.
Acceptability	Acceptable as information supporting the assumption that the biodegradation of ethylene oxide during the first 5 days is low.
Remarks	-

Section A7.1.1.2.1/03 **Annex Point IIA 7.6.1.1**	**Biodegradability (ready)**	
	1 Reference	**Official use only**
1.1 Reference	P. H. Howard, R. S. Boethling, W. F. Jarvis, W. M. Meylan, E. M. Michalenko (1991) Handbook of environmental degradation rates. Published report, Lewis Publishers Inc., Chelsea, Michigan, US, 144-145	
1.2 Data protection	None	
1.2.1 Data owner	Public domain	
1.2.3 Criteria for data protection	No data protection claimed	
	2 Guidelines and Quality Assurance	
2.1 Guideline study	Not applicable	
2.2 GLP	No	
2.3 Deviations	Not applicable	
	3 Materials and Methods	
3.1 Test material	Ethylene oxide	
3.1.1 Lot/Batch number	Not applicable	
3.1.2 Specification	Not applicable	
3.1.3 Purity	Not applicable	X
3.1.4 Further relevant properties	Not applicable	
3.1.5 Composition of Product	Not applicable	
3.1.6 TS inhibitory to microorganisms	Not applicable	
3.1.7 Specific chemical analysis	Not applicable	
3.2 Reference substance	Not applicable	
3.2.1 Initial concentration of reference substance	Not applicable	
3.3 Testing procedure	Environmental rate constants were estimated for a range of chemicals of anthropogenic origin, including ethylene oxide. Rate constants were compiled for individual abiotic and biotic degradation processes, and a	X

	range of half-lives were established for both individual degradation processes and environmental media. The Syracuse Research Corporation's (SRC) Environmental Fate Data Bases (EFDB) were the primary sources of information. DATALOG, CHEMFATE, BIOLOG and BIODEG files were searched for pertinent data. The CHEMFATE and BIODEG files contain actual experimental data and the review of data was greatly facilitated when these files contained records on a chemical. For chemicals not included in CHEMFATE or BIODEG, the reviewer used DATALOG for pointers to references pertaining to abiotic degradation processes and BIOLOG for references with information on biodegradation. Estimates were performed for chemicals for which rate data could not be located in the available literature.	
3.3.1 Inoculum / test species	Not applicable	
3.3.2 Test system	Not applicable	
3.3.3 Test conditions	Not applicable	
3.3.4 Method of preparation of test solution	Not applicable	
3.3.5 Initial TS concentration	Not applicable	
3.3.6 Duration of test	Not applicable	
3.3.7 Analytical parameter	Not applicable	
3.3.8 Sampling	Not applicable	
3.3.9 Intermediates/ degradation products	Not applicable	
3.3.10 Nitrate/nitrite measurement	Not applicable	
3.3.11 Controls	Not applicable	
3.3.12 Statistics	Not applicable	
	4 Results and Discussion	
4.1 Degradation of test substance		
4.1.1 Graph	Not applicable	
4.1.2 Degradation	Based on the BOD test results of Bridié *et al*., (1979a) (summarised in Document IIIA, Section 7.1.1.2.1/02) and Conway *et al*., (1983) (summarised in Document IIIA, Section 7.1.1.2.1/01), the unacclimated aqueous aerobic biodegradation half-life of ethylene oxide was estimated to range from 1 to 6 months. Based on the estimated aerobic biodegradation half-life, the aqueous anaerobic half-life was estimated to be 4 to 24 months.	

4.1.3 Other observations	Not applicable	
4.1.4 Degradation of TS in abiotic control	Not applicable	
4.1.5 Degradation of reference substance	Not applicable	
4.1.6 Intermediates/ degradation products	Not applicable	
	5 Applicant's Summary and Conclusion	
5.1 Materials and methods	Environmental rate constants were estimated for a range of chemicals of anthropogenic origin, including ethylene oxide. Rate constants were compiled for individual abiotic and biotic degradation processes, and a range of half-lives were established for both individual degradation processes and environmental media.	
5.2 Results and discussion	Based on the BOD test results of Bridié *et al.*, (1979a) and Conway *et al.*, (1983), the unacclimated aqueous aerobic biodegradation half-life of ethylene oxide was estimated to range from 1 to 6 months. Based on the estimated aerobic biodegradation half-life, the aqueous anaerobic half-life was estimated to be 4 to 24 months.	
5.3 Conclusion	The unacclimated aqueous aerobic biodegradation half-life of ethylene oxide was estimated to range from 1 to 6 months.	
5.3.1 Reliability	3	X
5.3.2 Deficiencies	Yes The information presented is based on the results of a review of available published literature and scientific databases, and is not a guideline compliant regulatory study. However, the data presented from this source provides valuable supporting information on the aqueous aerobic biodegradation of ethylene oxide. Direct exposure to the natural aquatic environment following use of ethylene oxide as a gaseous sterilant will not occur and any indirect exposure is expected to be negligible. A guideline compliant study to fulfil this data requirement is therefore not considered necessary.	
	Evaluation by Competent Authorities	
	Evaluation by Rapporteur Member State	
Date	17 January 2020	
Materials and Methods	**Comment (3.1.3.)**: The purity is not reported in the published article – or in the articles on which the estimations are based. As discussed in the CAR, section A.1.2. Composition of the substance (reference specifications), the production of ethylene oxide consistently yields the active substance in high purity (generally above 99 %). It is not expected that today's production process is significantly different from the production process at the time when this article was written. The principles of the ethylene oxide production has remained unchanged since the 1930s. In the current production of ethylene oxide, some impurities are identified,	

	but none detected above significant level (all below 0.01 %). Furthermore, based on the identity of these impurities and the hazardous profile of the active substance itself, the eCA has no reason to believe that the impurities will have any impact on the findings. **Comment (3.3)**: In the handbook, on the data for aqueous biodegradation, the only information given related to any methods used for the estimation, is "Scientific judgement based upon unacclimated aerobic aqueous screening test". It is in other words impossible to say anything about how the values are estimated.
Results and discussion	-
Conclusion	-
Reliability	**Comment (5.3.1)**: Reliability must be set to 4 due to lacking reporting – or to 0 (not applicable) due to this being an estimation / scientific judgement and not a study.
Acceptability	The eCA has no way of evaluating these results, since no information is given on how they are estimated. The usefulness of these estimations in risk assessment is therefore considered as very low.
Remarks	-

Section A7.1.1.2.1/04 **Annex Point IIA 7.6.1.1**	**Biodegradability (ready)**	
	1 Reference	**Official use only**
1.1 Reference	Ministry of International Trade and Industry (1995), Microbial degradation study of ethylene oxide (test substance number K-881. Chemicals Inspection & Testing Institute, Japan; Study number 20881; 29 June 1995	
1.2 Data protection	None	
1.2.1 Data owner	Public domain	
1.2.3 Criteria for data protection	No data protection claimed	
	2 Guidelines and Quality Assurance	
2.1 Guideline study	OECD Guidelines for Testing of Chemicals (17 July 1992): Ready Biodegradability: 301C, Modified MITI Test (I) Test Methods for New Chemical Substances (Kanpogyo No. 5, Yakuhatsu No. 615, 49 Kikyoku No. 392, 13 July 1984): Degradation Tests for Chemical Substances Using Microorganisms etc.	
2.2 GLP	Yes	
2.3 Deviations	No toxicity control was included in the study. A number of Figures cited in the text have not been included with the report- these include GC charts, and analytical spectra of the test substance (IR, MS and NMR). It is not expected that these deviations will alter the overall conclusion of this study that ETO can be considered to be Readily Biodegradable.	X
	3 Materials and Methods	
3.1 Test material	Ethylene oxide	
3.1.1 Lot/Batch number	A21	
3.1.2 Specification	Not specified	
3.1.3 Purity	99.9 %	
3.1.4 Further relevant properties	Not applicable	
3.1.5 Composition of Product	Test material consists of ethylene oxide only	
3.1.6 TS inhibitory to microorganisms	Not specified	

3.1.7 Specific chemical analysis	Not specified	x
3.2 Reference substance	Aniline	
3.2.1 Initial concentration of reference substance	100 mg/L	
3.3 Testing procedure		
3.3.1 Inoculum / test species	The sludge was collected from ten locations around Japan from wastewater plants and natural waters and the activity was checked prior to use. Source of inoculum/activated sludge (e.g. location, sampling depth, contamination history, procedure): In March, June, September, and December, sludge was sampled at the following 10 places in Japan: 1. Fukogawa city sewage plant, 2. Fukashiba industry sewage plant, 3. Nakahama city sew age plant, 4. Ochiai city sewage plant, 5. Kitakami river, 6. Shinano river, 7. Yoshino river, 8. Lake Biwa, 9. Hiroshima bay, 10. Dookai bay; sampling: 1. City sewage: Returned sludge from sewage plants was taken. 2. Rivers, lake and sea: Surface water and surface soil which were in contact with atmosphere were collected. Method of cultivation: About 30 minutes after ceasing aeration to the sludge mixture, supernatant corresponding to about 1/3 of the whole volume was removed. Then the equal volume of dechlorinated water was added to the remaining portion and aerated again, followed by addition of synthetic sewage at a concentration of 0.1% (w/v). This procedure was repeated once every day. The culturing was carried out at 25 ± 2 °C. 5 L of the filtrate of the supernatant of old activated sludge was mixed with 500 mL of the filtrate of the supernatant of new sludge and cultured at pH 7.0 ± 1.0 under sufficient aeration using prefiltered open air. During the cultivation, appearance of the supernatant, precipitability, formation of flock, pH, dissolved oxygen concentration in the solution and temperature were checked and necessary adjustments were made, Microflora in the activated sludge was microscopically observed and sludge with no abnormal symptom was used for the test. Concentration of sludge: 30 mg/L	x
3.3.2 Test system	– Culturing apparatus: Closed system oxygen consumption measuring apparatus (Coulometer: Ohkura Electric Co., Ltd.); 300 mL vessel, absorbent for evolving carbon dioxide Soda lime No .l (extra pure reagent, Wako Pure Chemical Industries, Ltd.). – Number of culture flasks/concentration: 1 – Measuring equipment: Coulometer, Okhura Electric Co., Ltd. – Test performed in open system: no – Details of trap for CO_2 and volatile organics if used: soda lime, extra pure, Wako Pure Chemical Industries, Ltd.)	
3.3.3 Test conditions	The summary of test conditions is; 1) Concentration of test substance: 100 mg/L	

	2) Concentration of active sludge: 30 mg/L (suspended substance concentration) 3) Volume of test solution: 300 mL 4) Test solution culture temperature: 25±1°C 5) Test solution culture period: 28 days	
3.3.4 Method of preparation of test solution	The following test solutions were prepared; – Test vessel [1] Sludge + aniline Basic culture medium (300 mL: amount of active sludge solution added (mL)) was placed in the test vessel and 29.5 µL was added to give an aniline concentration of 100 mg/L – Test vessel [2] Sludge blank Basic culture medium 300 mL: amount of active sludge solution added (mL) – Test vessel [3] Water + test substance 297 mL of purified water was placed in the test vessel and 3 mL of 10 g/L test substance solution was added to give a test substance concentration of 100 mg/L. – Test vessels [4], [5] and [6] Sludge + test substance Basic culture medium (297 mL: amount of active sludge solution added (mL)) was placed in the test vessel and 3 mL of 10 g/L test substance solution was added to give a test substance concentration of 100 mg/L.	X
3.3.5 Initial TS concentration	100 mg/L	
3.3.6 Duration of test	28 days	
3.3.7 Analytical parameter	1) Measurement of biological oxygen demand (BOD) using a closed system oxygen demand measuring apparatus 2) Analysis of dissolved organic carbon using total organic carbon (TOC) 3) Analysis of test substance using gas chromatography (GC)	
3.3.8 Sampling	Cf. 3.3.7	X
3.3.9 Intermediates/ degradation products	Not specified	X
3.3.10 Nitrate/nitrite measurement	Not applicable	
3.3.11 Controls	– Inoculum blank: yes – Abiotic sterile control: yes	X

<table>
<tr><td></td><td>– Toxicity control: no</td><td></td></tr>
<tr><td>3.3.12 Statistics</td><td>A simple linear regression was used to calculate a DT_{50} value of 10.8 days for the degradation of ETO (r^2 0.9905).</td><td></td></tr>
<tr><td></td><td>4 Results and Discussion</td><td></td></tr>
<tr><td>4.1 Degradation of test substance</td><td></td><td></td></tr>
<tr><td>4.1.1 Graph</td><td>See Figure A7.1.1.2.1/04-01 below.</td><td></td></tr>
<tr><td>4.1.2 Degradation</td><td>1) Degradation by BOD: 98%, 107%, 115%, mean 107%
2) Degradation by TOC: 96%, 96%, 97%, mean 96%
3) Degradation by GC: 100%, 100%, 100%, mean 100% (based on LOQ of 0.95 mg/L ETO)

In addition the test substance was confirmed to be stable under the storage conditions.
<table>
<tr><th rowspan="2">Analysis</th><th colspan="4">Degradation (in %)</th></tr>
<tr><th>Sample no. 4</th><th>Sample no. 4</th><th>Sample no. 4</th><th>Mean</th></tr>
<tr><td>BOD</td><td>98</td><td>107</td><td>115</td><td>107</td></tr>
<tr><td>TOC</td><td>96</td><td>96</td><td>97</td><td>96</td></tr>
<tr><td>GC</td><td>100</td><td>100</td><td>100</td><td>100</td></tr>
</table>
</td><td></td></tr>
<tr><td>4.1.3 Other observations</td><td>Not applicable</td><td>X</td></tr>
<tr><td>4.1.4 Degradation of TS in abiotic control</td><td>Not specified</td><td>X</td></tr>
<tr><td>4.1.5 Degradation of reference substance</td><td>The results from the reference compound (aniline show rapid consumption in BOD by 28 days) and blank controls (vessels 2 + 3 show low consumption of BOD) are shown in Figure A7.1.1.2.1/04-01 below.</td><td>X</td></tr>
<tr><td>4.1.6 Intermediates/ degradation products</td><td>Not specified</td><td>X</td></tr>
<tr><td></td><td>5 Applicant's Summary and Conclusion</td><td></td></tr>
<tr><td>5.1 Materials and methods</td><td>The study was carried out at the request of the Ministry of International Trade and Industry (at the Japan Chemical Safety Centre, Kurume Laboratory Study number 20881) and a quality assurance certificate is available.

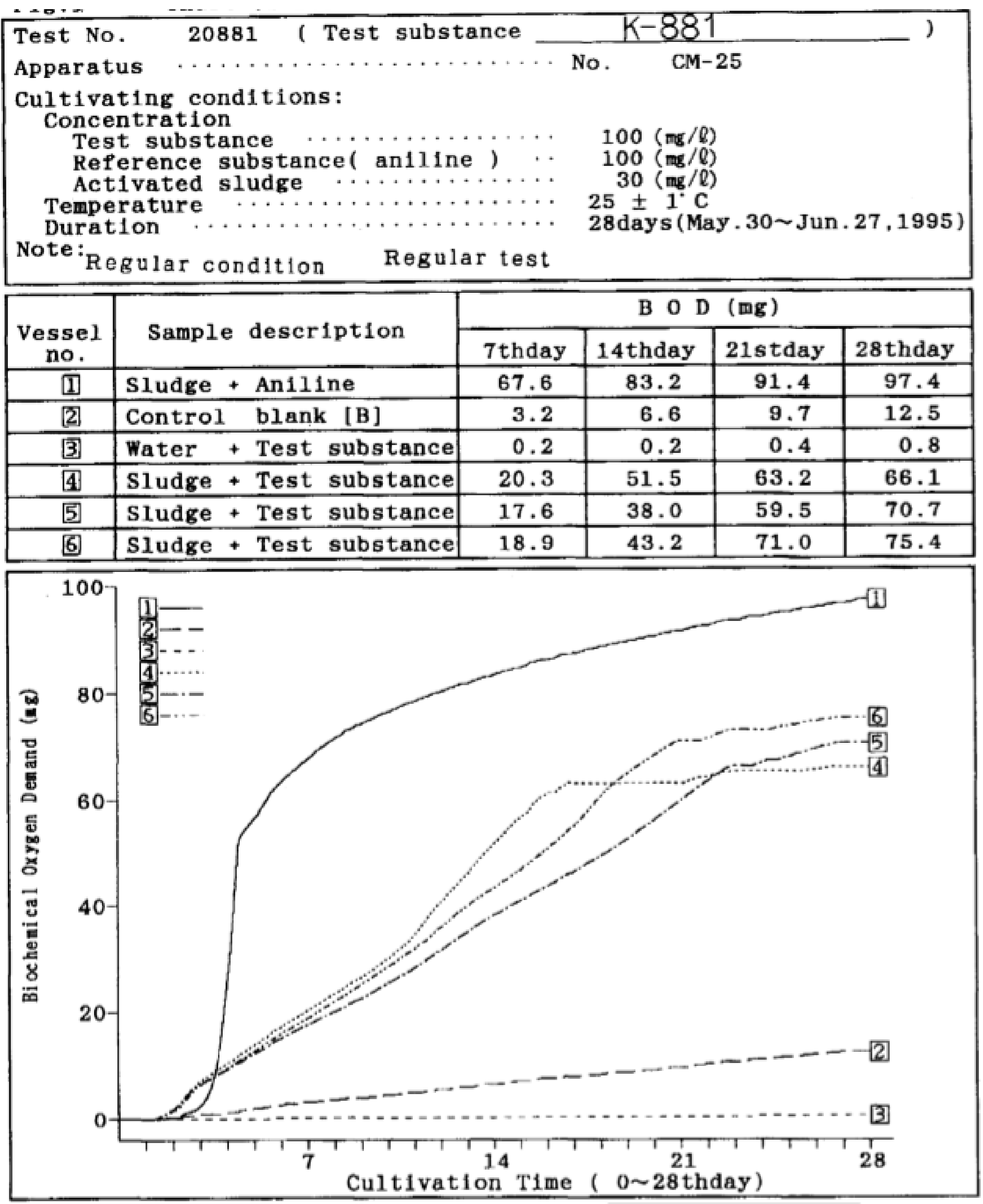
The study conformed with the “Degradation Tests for Chemical Substances Using Microorganisms etc.” stipulated in the “Test Methods for New Chemical Substances” (Kanpogyo No. 5, Yakuhatsu No. 615, 49 Kikyoku No. 392, 13 July 1984) and the “Ready Biodegradability: 301C, Modified MITI Test (I)“ set out in the “OECD Guidelines for Testing of Chemicals” (17 July 1992).</td><td></td></tr>
</table>

5.2 Results and discussion	1) Degradation by BOD: 98%, 107%, 115%, mean 107% 2) Degradation by TOC: 96%, 96%, 97%, mean 96% 3) Degradation by GC: 100%, 100%, 100%, mean 100% (based on LOQ of 0.95 mg/L ETO)	
5.3 Conclusion	Ethylene oxide can be considered to be Readily Biodegradable.	
5.3.1 Reliability	2	
5.3.2 Deficiencies	-	X
	Evaluation by Competent Authorities	
	Evaluation by Rapporteur Member State	
Date	28 October 2020	
Materials and Methods	**Comment (2.3):** Additionally, the following deviations/uncertainties should be mentioned: – During the preparation of the inoculum, the aeration time is not given (according to OECD 301C it should be approx 23.5 h). – It is not known whether the composition of the stock solutions for the mineral medium in the Japanese guideline are identical to the OECD 301C compositions. – It is not known exactly how the test vessels / culture flasks were improved for volatile substances. – It does not seem that specific chemical analyses of t.s. and ethylene glycol were done at the beginning of the test (only at the end of the test). **Comment (3.3.1):** The description in the IUCLID study summary is confusing as the steps seem to be mentioned in the wrong order. We suggest to first describe that a 500 mL filtrate from each of the 10 sludge samples were collected and 5 L of a filtrate of old sludge used in previous tests were mixed to add up to 10 L. This was then aerated in a culture tank (at a pH of 7 ± 1). It it is not stated how long the aeration lasted. Then, the further preparation should be described (removal of supernatant, addition of water, aeration, addition of synthetic sewage water). **Comment (3.1.7):** At the end of the test (28 d), the t.s. and the hydrolysis transformation product ethylene glycol were analysed by GC (Shimadzu Corporation GC-9 A) with a flame ionisation detector. Lower limits of quantification were 0.95 mg/L for the t.s. and 1.8 mg/L for ethylene glycol. **Comment (3.3.4):** The test solutions consist of test substance and mineral medium. The mineral medium was according to the study report prepared in accordance with the JIS K 0102-1993 guideline. The preparation of the medium from the stock solutions (i.e. 3 mL of each of four stock solutions and make up to 1 L) is identical to the description in the OECD 301C guideline, but it is not known to the eCA whether the composition of the stock solutions in the Japanese guideline are identical to the OECD 301C compositions. **Comment (3.3.8):** The flasks / test vessels were kept in an Okhura Electric Coulometer for 28 days and the BOD (in mg) was measured on day 7, 14, 21 and	

	28. After 28 d, total organic carbon (TOC) samples and gas chromatography (GC) samples were prepared by cooling and centrifugation. Dissolved organic carbon (DOC) was measured based on TOC analyses. The concentration of t.s. and ethylene glycol was measured by GC. **Comment (3.3.9):** See comment 4.1.3. **Comment (3.3.11):** In the study report, it is not stated specifically that the abiotic control is sterile (only that it was prepared using purified water). Furthermore, it could be mentioned here that an activity control was included, using aniline as a reference substance.
Results and discussion	**Comment (4.1.3):** The study report mentions that a separate hydrolysis test was performed (due to the expected formation of ethylene glycol by hydrolysis). The only reported conditions for this test is a t.s. concentration of 100 mg/L and a temperature of 25 ± 1 °C. T.s. concentration was measured after what looks like 24, 48, 96, 240 and 360 h (i.e. the last measurement after 15 d, based on eCA's visual inspection of graph) and the half-life was determined by linear regression. Also, a separate retention test (closed system with "no gas phase") with t.s. + water only (abiotic control) was run, due to expected vaporisation of t.s. during the main test. Reported conditions are a t.s. concentration of 100 mg/L, a temperature of 25 ± 1 °C, and a test duration of 28 d. It is unclear to the eCA what precisely is meant by "no gas phase", but we assume that the volume of "dead" gas space was kept to a minimum. **Comment (4.1.4):** Specific chemical analyses of t.s. and ethylene glycol after 28 d (the eCA's understanding of how the percentage remaining t.s. and formed ethylene glycol are calculated): Test vessel 3 (abiotic control): – T.s. amount (mg) measured: 4.0 mg in a 300 mL flask => 13 mg/L (i.e. 13 % of initial nominal concentration) – Ethylene glycol amount (mg) measured: 30.9 mg in a 300 mL flask => 103 mg/L (based on the molecular masses of the two substances, it would take 73 mg/L of t.s. to produce 103 mg/L ethylene glycol, i.e. 73 % of initial nominal concentration) Test vessels 4, 5 and 6 (t.s. in mineral medium): – T.s. and ethylene glycol amount (mg) measured: 0 mg (concentration below the lower quantification limit), hence 0 % remaining and formed, respectively (ethylene oxide could however have been formed and degraded). As noted in the study report, the percentage remaining t.s. and formed ethylene glycol (or rather, percentage of t.s. converted to ethylene glycol) adds up to 86 %. Therefore, the separate renention test (closed system with no gas phase) as described above was run. After 28 days in this test, 11 % of the initial nominal ethylene oxide concentration remained, and the percentage of ethylene glycol formed (percentage t.s. converted to ethylene glycol) was 87 %. This adds up to 98 % in total. **Comment (4.1.5):** The degradation of the reference substance (aniline), calculated from BOD measurements after 7 and 14 days, was 71 and 85 %, respectively.

	Comment (4.1.6): See comment 4.1.3.
Conclusion	**Comment (5.3):** Agree that ethylene oxide can be considered readily biodegradable according to this test. The volatilisation of ethylene oxide should have been taken more closely into account in the main test – even though the study report states that the culture flasks were "improved for volatile substances". However, even though it is expected that some of the removal of the ethylene oxide should be due to vaporisation, this is not considered to affect the overall conclusion of the study, based on the findings of the separate retention test (c.f. comments 4.1.3 and 4.1.4). Even if as a worst case approximately 20 % of the ethylene oxide should have been lost by vaporisation in the main test (given that the percentage of initial ethylene oxide that can be accounted for at the end of the test is 86 %), and if as a worst case one assumes that this would not have been biodegraded if the vaporisation could be prevented, the biodegradation would still be approx. 80 % instead of approx. 100 %. Hence, ethylene oxide would still be considered readily biodegradable.
Reliability	Agree with applicant's version. Reliability 2.
Acceptability	The OECD 301C pass criteria are met: – Oxygen uptake (BOD) in the inoculum blank was 12.5 mg after 28 d. This corresponds to approx. 42 mg/L, and is hence under 60 mg/L. **Criterion passed.** – Replicate values of the removal of the test substance at the end of the test are all below the lower quantification limit, but based on BOD, the difference between the extremes is less than 20 %. **Criterion passed.** – Percentage aniline degradation (from BOD) was 71 % and 85 % after 7 and 14 d, respectively (above the limits of 40 % and 65 % after 7 and 14 days, respectively). **Criterion passed.** The eCA considers that the study is acceptable, taking into account the considerations given above.
Remarks	-

Figure A7.1.1.2.1/04-01



Test No. 20881 (Test substance K-881)
Apparatus .... No. CM-25
Cultivating conditions:
Concentration
Test substance .... 100 (mg/ℓ)
Reference substance(aniline) .. 100 (mg/ℓ)
Activated sludge .... 30 (mg/ℓ)
Temperature .... 25 ± 1°C
Duration .... 28days(May.30~Jun.27,1995)
Note: Regular condition Regular test

Vessel no.	Sample description	B O D (mg)			
		7thday	14thday	21stday	28thday
1	Sludge + Aniline	67.6	83.2	91.4	97.4
2	Control blank [B]	3.2	6.6	9.7	12.5
3	Water + Test substance	0.2	0.2	0.4	0.8
4	Sludge + Test substance	20.3	51.5	63.2	66.1
5	Sludge + Test substance	17.6	38.0	59.5	70.7
6	Sludge + Test substance	18.9	43.2	71.0	75.4

[redacted]

7.1.1.2.2 Inherent biodegradability, where appropriate

Section A7.1.1.2.2 **Annex Point IIA7.6.1.2**	**Inherent Biodegradability, where appropriate**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [X] **Limited exposure [X]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [ ]**	
Detailed justification:	Data on the inherent biodegradability of ethylene oxide are not required as sufficient data on the biodegradation of the compound are available (summarised in Document IIIA, Section 7.1.1.2.1). In addition, direct exposure to the natural aquatic environment following use of ethylene oxide as a gaseous sterilant will not occur, and any indirect exposure is expected to be negligible. Further data to fulfil this data requirement are therefore not considered necessary.	
Undertaking of intended data submission [ ]	No undertaking provided; submission of further data/information is not considered necessary.	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	17 January 2020	
Evaluation of applicant's justification	The eCA agrees that further testing does not seem necessary due to the limited exposure of the substance. Despite deficiencies, the other data submitted for the purpose of assessing ready biodegradation is considered sufficient, due to the limited exposure and with the conclusion that ethylene oxide is not readily biodegradable.	
Conclusion	Agree with applicant's conclusion.	
Remarks		

7.1.1.2.3 Biodegradation in seawater

Section A7.1.1.2.3 **Annex Point x.y**	**Biodegradation in seawater**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [ ] **Limited exposure [X]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [ ]**	
Detailed justification:	Data on the biodegradation of ethylene oxide in seawater are not required as no application is envisaged for use in seawater. Direct exposure to seawater following use of ethylene oxide as a gaseous sterilant will not occur and any indirect exposure is expected to be negligible.	
Undertaking of intended data submission [ ]	No undertaking provided; submission of further data/information is not considered necessary.	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	17 January 2020	
Evaluation of applicant's justification	The eCA agrees that further testing does not seem necessary due to the lack of exposure to seawater.	
Conclusion	Agree with applicant's conclusion.	
Remarks		

7.1.2 Rate and route of degradation in aquatic systems including identification of metabolites and degradation products

7.1.2.1 Biological sewage treatment

7.1.2.1.1 Aerobic biodegradation

Section A7.1.2.1.1 **Annex Point IIIA XII 2.1**	**Aerobic biodegradation**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [X] **Limited exposure [X]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [ ]**	
Detailed justification:	Based on the proposed use of ethylene oxide as a gaseous sterilising agent, environmental exposure is expected to be extremely minimal and exposure of ethylene oxide to sewage treatment plants is not anticipated. During the sterilisation process gaseous ethylene oxide is introduced into a sealed, stainless steel chamber which contains the products for sterilisation. On completion of the process, ethylene oxide from the chamber is exhausted to the atmosphere via a catalytic converter which converts the gas to carbon dioxide and water, typically with efficiency greater than 99.9%. The sterilisation chamber is then repeatedly flushed with nitrogen and air to remove the remaining ethylene oxide from the chamber and the sterilised products are subjected to high rates of air exchange to remove any residual ethylene oxide from the product and packaging. The exhaust from this phase is also treated via the catalytic converter. In a relatively small number of sterilisation plants acid scrubbers containing a solution of water and 5% sulphuric acid are used as an alternative to the catalytic conversion system. Ethylene oxide from the sterilisation chamber is dissolved in the acid solution, which converts ethylene oxide to ethylene glycol with efficiency typically in the range of 99.5 to 99.9%. Neutralised solution from the acid scrubbers is transported to waste water treatment facilities as toxic waste water, where it undergoes specialist handling and treatment, thus minimising any potential environmental exposure. Following use of ethylene oxide as proposed, exposure to sewage treatment plants is therefore not anticipated, and studies to investigate the aerobic biodegradation of the compound in biological sewage treatment systems are not required. In addition, sufficient data on the biodegradation of ethylene oxide are available (summarised in Document IIIA, Section 7.1.1.2.1), and further data to fulfil this data requirement are therefore not considered necessary.	
Undertaking of intended	No undertaking provided; submission of further data/information is not	

data submission [ ]	considered necessary.	

Evaluation by Competent Authorities

	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	17 January 2020
Evaluation of applicant's justification	The eCA agrees that further testing does not seem necessary due to the lack of direct exposure of the substance to STPs. The submitted data on biodegradation in the presence of domestic sewage is considered sufficient, with the conclusion that ethylene oxide is not readily biodegradable.
Conclusion	Agree with applicant's conclusion.
Remarks	

7.1.2.1.2 Anaerobic biodegradation

Section A7.1.2.1.2 **Annex Point XII.2.1**	**Anaerobic biodegradation**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [X] **Limited exposure [X]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [ ]**	
Detailed justification:	Based on the proposed use of ethylene oxide as a gaseous sterilising agent, environmental exposure is expected to be extremely minimal and exposure of ethylene oxide to sewage treatment plants is not anticipated. During the sterilisation process gaseous ethylene oxide is introduced into a sealed, stainless steel chamber which contains the products for sterilisation. On completion of the process, ethylene oxide from the chamber is exhausted to the atmosphere via a catalytic converter which converts the gas to carbon dioxide and water, typically with efficiency greater than 99.9%. The sterilisation chamber is then repeatedly flushed with nitrogen and air to remove the remaining ethylene oxide from the chamber and the sterilised products are subjected to high rates of air exchange to remove any residual ethylene oxide from the product and packaging. The exhaust from this phase is also treated via the catalytic converter. In a relatively small number of sterilisation plants acid scrubbers containing a solution of water and 5% sulphuric acid are used as an alternative to the catalytic conversion system. Ethylene oxide from the sterilisation chamber is dissolved in the acid solution, which converts ethylene oxide to ethylene glycol with efficiency typically in the range of 99.5 to 99.9%. Neutralised solution from the acid scrubbers is transported to waste water treatment facilities as toxic waste water, where it undergoes specialist handling and treatment, thus minimising any potential environmental exposure. Following use of ethylene oxide as proposed, exposure to sewage treatment plants is therefore not anticipated, and studies to investigate the anaerobic biodegradation of the compound in biological sewage treatment systems are not required. In addition, sufficient data on the biodegradation of ethylene oxide are available (summarised in Document IIIA, Section 7.1.1.2.1), and further data to fulfil this data requirement are therefore not considered necessary.	
Undertaking of intended data submission [ ]	No undertaking provided; submission of further data/information is not considered necessary.	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	17 January 2020	
Evaluation of applicant's	The eCA agrees that further testing does not seem necessary due to the lack of	

justification	direct exposure of the substance to STPs. The submitted data on biodegradation in the presence of domestic sewage is considered sufficient, with the conclusion that ethylene oxide is not readily biodegradable.
Conclusion	Agree with applicant's conclusion.
Remarks	

7.1.2.2 Biodegradation in freshwater

7.1.2.2.1 Aerobic aquatic degradation study

Section A7.1.2.2.1 **Annex Point XII.2.1**	**Aerobic aquatic degradation study**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [ ] **Limited exposure [X]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [ ]**	
Detailed justification:	Ethylene oxide is intended for use as a gaseous sterilising agent; no application is envisaged for use in water. During the sterilisation process gaseous ethylene oxide is introduced into a sealed, stainless steel chamber which contains the products for sterilisation. On completion of the process, ethylene oxide from the chamber is exhausted to the atmosphere via a catalytic converter which converts the gas to carbon dioxide and water, typically with efficiency greater than 99.9%. The sterilisation chamber is then repeatedly flushed with nitrogen and air to remove the remaining ethylene oxide from the chamber and the sterilised products are subjected to high rates of air exchange to remove any residual ethylene oxide from the product and packaging. The exhaust from this phase is also treated via the catalytic converter. In a relatively small number of sterilisation plants acid scrubbers containing a solution of water and 5% sulphuric acid are used as an alternative to the catalytic conversion system and ethylene oxide from the sterilisation chamber is dissolved in the acid solution, which converts ethylene oxide to ethylene glycol with efficiency typically in the range of 99.5 to 99.9%. Neutralised solution from the acid scrubbers is transported to waste water treatment facilities as toxic waste water, where it undergoes specialist handling and treatment, thus minimising any potential environmental contamination. Direct exposure to the natural aquatic environment will therefore not occur following use of ethylene oxide as proposed and any indirect exposure is expected to be negligible. The available information summarised in Document IIIA, Sections 7.1.1.1.1 and 7.1.1.2.1 indicates that ethylene oxide will undergo hydrolysis and aerobic and anaerobic degradation in water. The duration of any potential indirect exposure will therefore be short-lived. In addition, volatilization of ethylene oxide from water is also expected to be a significant removal process (volatilization half-life in water ~1 hour). A study to determine the aerobic aquatic degradation of ethylene oxide in freshwater is therefore not required.	
Undertaking of intended data submission [ ]	No undertaking provided; submission of further data/information is not considered necessary.	

	Evaluation by Competent Authorities
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	17 January 2020
Evaluation of applicant's justification	The eCA agrees that further testing does not seem necessary due to the lack of direct exposure of the substance to freshwater and the high vapour pressure leading to rapid volatilisation / minimal deposition from air.
Conclusion	Agree with applicant's conclusion.
Remarks	

7.1.2.2.2 Water/sediment degradation study

Section A7.1.2.2.2 **Annex Point XII.2.1**	**Water/sediment degradation study**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [ ]	**Technically not feasible [ ]** **Scientifically unjustified [ ]**	
Limited exposure [X]	**Other justification [ ]**	
Detailed justification:	Ethylene oxide is intended for use as a gaseous sterilising agent; no application is envisaged for use in water. During the sterilisation process gaseous ethylene oxide is introduced into a sealed, stainless steel chamber which contains the products for sterilisation. On completion of the process, ethylene oxide from the chamber is exhausted to the atmosphere via a catalytic converter which converts the gas to carbon dioxide and water, typically with efficiency greater than 99.9%. The sterilisation chamber is then repeatedly flushed with nitrogen and air to remove the remaining ethylene oxide from the chamber and the sterilised products are subjected to high rates of air exchange to remove any residual ethylene oxide from the product and packaging. The exhaust from this phase is also treated via the catalytic converter. In a relatively small number of sterilisation plants acid scrubbers containing a solution of water and 5% sulphuric acid are used as an alternative to the catalytic conversion system and ethylene oxide from the sterilisation chamber is dissolved in the acid solution, which converts ethylene oxide to ethylene glycol with efficiency typically in the range of 99.5 to 99.9%. Neutralised solution from the acid scrubbers is transported to waste water treatment facilities as toxic waste water, where it undergoes specialist handling and treatment, thus minimising any potential environmental contamination. Direct exposure to the natural aquatic environment will therefore not occur following use of ethylene oxide as proposed and any indirect exposure is expected to be negligible. The available information summarised in Document IIIA, Sections 7.1.1.1.1 and 7.1.1.2.1 indicates that ethylene oxide will undergo hydrolysis and aerobic and anaerobic degradation in water. The duration of any potential indirect exposure will therefore be short-lived. In addition, volatilization of ethylene oxide from water is also expected to be a significant removal process (volatilization half-life in water ~1 hour). A water/sediment degradation study for ethylene oxide is therefore not required.	
Undertaking of intended data submission [ ]	No undertaking provided; submission of further data/information is not considered necessary.	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	17 January 2020	

Evaluation of applicant's justification	The eCA agrees that further testing does not seem necessary due to the lack of direct exposure of the substance to freshwater and the high vapour pressure leading to rapid volatilisation / minimal deposition from air.
Conclusion	Agree with applicant's conclusion.
Remarks	

7.1.3 Adsorption / desorption screening test

Section A7.1.3 **Annex Point IIA7.7**	**Adsorption / desorption screening test**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [X]	**Technically not feasible [ ]** **Scientifically unjustified [ ]**	
Limited exposure [X]	**Other justification [ ]**	
Detailed justification:	Based on the proposed use of ethylene oxide as a gaseous sterilising agent, environmental exposure is expected to be extremely minimal. During the sterilisation process gaseous ethylene oxide is introduced into a sealed, stainless steel chamber containing the products for sterilisation. On completion of the process, ethylene oxide from the chamber is exhausted to the atmosphere via a catalytic converter which converts the gas to carbon dioxide and water, typically with efficiency greater than 99.9%. The sterilisation chamber is then repeatedly flushed with nitrogen and air to remove the remaining ethylene oxide from the chamber and the sterilised products are subjected to high rates of air exchange to remove any residual ethylene oxide from the product and packaging. The exhaust from this phase is also treated via the catalytic converter. In a relatively small number of sterilisation plants acid scrubbers containing a solution of water and 5% sulphuric acid are used as an alternative to the catalytic conversion system and ethylene oxide from the sterilisation chamber is dissolved in the acid solution, which converts ethylene oxide to ethylene glycol with efficiency typically in the range of 99.5 to 99.9%. Neutralised solution from the acid scrubbers is transported to waste water treatment facilities as toxic waste water, where it undergoes specialist handling and treatment, thus minimising any potential environmental contamination. Direct exposure to soil and the natural terrestrial environment will therefore not occur following use of ethylene oxide as proposed, and any indirect exposure is expected to be negligible. Studies to investigate the adsorption and desorption characteristics of the compound in soil are therefore not required. In the absence of laboratory determined adsorption / desorption data for ethylene oxide, a K_{oc} value can be estimated using the PCKOCWIN program, version 2.0 (EPISUITE 4.0, U.S. Environmental Protection Agency, 2009). The Soil Adsorption Coefficient Program (PCKOCWIN) estimates the soil adsorption coefficient of organic compounds and is a reliable and internationally recognised and accepted estimation tool. PCKOCWIN uses a first-order molecular connectivity index (1-MCI) and a series of group contribution factors to predict K_{oc}. The group contribution method outperforms traditional estimation methods based on octanol/water partition coefficients and water solubility. The program requires only a chemical structure to predict K_{oc}, which is entered into PCKOCWIN as a SMILES notation (Simplified Molecular Input Line Entry System). The estimated K_{oc} value for ethylene oxide is 3.237 L/kg, indicating that the compound is not strongly adsorbed to soil or sediment, and would therefore be	

	unlikely to accumulate in these compartments.	
Undertaking of intended data submission [ ]	No undertaking provided; submission of further data/information is not considered necessary.	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	17 January 2020	
Evaluation of applicant's justification	The eCA agrees that an adsorption/desorption screening test does not seem necessary due to the lack of direct exposure of the substance to other compartments than air. The estimation using PCKOCWIN is sufficient.	
Conclusion	Agree with applicant's conclusion.	
Remarks	The eCA has also estimated the log Koc values with the more recent version of KOCWIN, and come to the same result.	

7.1.4 Further studies on adsorption and desorption in water/sediment systems and, where relevant, on the adsorption and desorption of metabolites and degradation products where the preliminary risk assessment indicates that it is necessary

7.1.4.1 Field study on accumulation in the sediment

Section A7.1.4.1 **Annex Point XII.2.1**	**Field study on accumulation in the sediment**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [ ] **Limited exposure [X]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [ ]**	
Detailed justification:	Ethylene oxide is intended for use as a gaseous sterilising agent; no application is envisaged for use in water. During the sterilisation process gaseous ethylene oxide is introduced into a sealed, stainless steel chamber which contains the products for sterilisation. On completion of the process, ethylene oxide from the chamber is exhausted to the atmosphere via a catalytic converter which converts the gas to carbon dioxide and water, typically with efficiency greater than 99.9%. The sterilisation chamber is then repeatedly flushed with nitrogen and air to remove the remaining ethylene oxide from the chamber and the sterilised products are subjected to high rates of air exchange to remove any residual ethylene oxide from the product and packaging. The exhaust from this phase is also treated via the catalytic converter. In a relatively small number of sterilisation plants acid scrubbers containing a solution of water and 5% sulphuric acid are used as an alternative to the catalytic conversion system and ethylene oxide from the sterilisation chamber is dissolved in the acid solution, which converts ethylene oxide to ethylene glycol with efficiency typically in the range of 99.5 to 99.9%. Neutralised solution from the acid scrubbers is transported to waste water treatment facilities as toxic waste water, where it undergoes specialist handling and treatment, thus minimising any potential environmental contamination. Direct exposure to the natural aquatic environment will therefore not occur following use of ethylene oxide as proposed, and any indirect exposure is expected to be negligible. In addition, the estimated K_{oc} value for ethylene oxide is 3.237 L/kg, indicating that the compound is not strongly adsorbed to soil or sediment (see Document IIIA, Section 7.1.3). Significant accumulation in sediment is therefore not expected to occur and a field study to investigate the potential for accumulation of ethylene oxide in sediment is not considered necessary.	
Undertaking of intended data submission [ ]	No undertaking provided; submission of further data/information is not considered necessary.	

Evaluation by Competent Authorities

	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	17 January 2020
Evaluation of applicant's justification	The eCA agrees that further testing does not seem necessary, due to the lack of direct exposure of the substance to freshwater and the high vapour pressure leading to rapid volatilisation / minimal deposition from air.
Conclusion	Agree with applicant's conclusion.
Remarks	-

7.2 Fate and behaviour in soil

7.2.1 Aerobic degradation in soil, initial study

Section A7.2.1 **Annex Point VII.4, XII.1.1**	**Aerobic degradation in soil, initial study**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [ ] **Limited exposure [X]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [ ]**	
Detailed justification:	Based on the proposed use of ethylene oxide as a gaseous sterilising agent, environmental exposure is expected to be extremely minimal. During the sterilisation process gaseous ethylene oxide is introduced into a sealed, stainless steel chamber containing the products for sterilisation. On completion of the process, ethylene oxide from the chamber is exhausted to the atmosphere via a catalytic converter which converts the gas to carbon dioxide and water, typically with efficiency greater than 99.9%. The sterilisation chamber is then repeatedly flushed with nitrogen and air to remove the remaining ethylene oxide from the chamber and the sterilised products are subjected to high rates of air exchange to remove any residual ethylene oxide from the product and packaging. The exhaust from this phase is also treated via the catalytic converter. In a relatively small number of sterilisation plants acid scrubbers containing a solution of water and 5% sulphuric acid are used as an alternative to the catalytic conversion system and ethylene oxide from the sterilisation chamber is dissolved in the acid solution, which converts ethylene oxide to ethylene glycol with efficiency typically in the range of 99.5 to 99.9%. Neutralised solution from the acid scrubbers is transported to waste water treatment facilities as toxic waste water, where it undergoes specialist handling and treatment, thus minimising any potential environmental exposure. Direct exposure to soil and the natural terrestrial environment will therefore not occur following use of ethylene oxide as proposed and any indirect exposure is expected to be negligible. Ethylene oxide is expected to undergo hydrolysis and biological degradation in soil. Howard *et al*., (1991, Document IIIA, Section 7.1.1.2.1/03) estimated the half-life of ethylene oxide in soil to be 10.5-11.9 days based on measured hydrolysis rate constants at pH 5, 7 and 9. Volatilisation is also expected to be a significant removal process from soil and the duration of any potential indirect exposure to soil will therefore be short-lived. The estimated K_{oc} value for ethylene oxide is 3.237 L/kg (Document IIIA, Section 7.1.3), indicating that the compound is not strongly adsorbed to soil or sediment and is therefore unlikely to accumulate in these compartments. A study to investigate the aerobic degradation of ethylene oxide in soil is therefore not required.	
Undertaking of intended data submission [ ]	No undertaking provided; submission of further data/information is not considered necessary.	

Evaluation by Competent Authorities

	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	17 January 2020
Evaluation of applicant's justification	The eCA agrees that further testing does not seem necessary due to the lack of direct exposure of the substance to soil and the high vapour pressure leading to rapid volatilisation / minimal deposition from air.
Conclusion	Agree with applicant's conclusion.
Remarks	

7.2.2 Aerobic degradation in soil, further studies

Section A7.2.2 **Annex Point XII.1.1**	**Aerobic degradation in soil, further studies**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [ ] **Limited exposure [X]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [ ]**	
Detailed justification:	Based on the proposed use of ethylene oxide as a gaseous sterilising agent, environmental exposure is expected to be extremely minimal. During the sterilisation process gaseous ethylene oxide is introduced into a sealed, stainless steel chamber containing the products for sterilisation. On completion of the process, ethylene oxide from the chamber is exhausted to the atmosphere via a catalytic converter which converts the gas to carbon dioxide and water, typically with efficiency greater than 99.9%. The sterilisation chamber is then repeatedly flushed with nitrogen and air to remove the remaining ethylene oxide from the chamber and the sterilised products are subjected to high rates of air exchange to remove any residual ethylene oxide from the product and packaging. The exhaust from this phase is also treated via the catalytic converter. In a relatively small number of sterilisation plants acid scrubbers containing a solution of water and 5% sulphuric acid are used as an alternative to the catalytic conversion system and ethylene oxide from the sterilisation chamber is dissolved in the acid solution, which converts ethylene oxide to ethylene glycol with efficiency typically in the range of 99.5 to 99.9%. Neutralised solution from the acid scrubbers is transported to waste water treatment facilities as toxic waste water, where it undergoes specialist handling and treatment, thus minimising any potential environmental exposure. Direct exposure to soil and the natural terrestrial environment will therefore not occur following use of ethylene oxide as proposed, and any indirect exposure is expected to be negligible. Ethylene oxide is expected to undergo hydrolysis and biological degradation in soil. Howard *et al*., (1991, Document IIIA, Section 7.1.1.2.1/03) estimated the half-life of ethylene oxide in soil to be 10.5-11.9 days based on measured hydrolysis rate constants at pH 5, 7 and 9. Volatilisation is also expected to be a significant removal process from soil and the duration of any potential indirect exposure to soil will therefore be short-lived. The estimated K_{oc} value for ethylene oxide is 3.237 L/kg (Document IIIA, Section 7.1.3), indicating that the compound is not strongly adsorbed to soil or sediment and is therefore unlikely to accumulate in these compartments. Further studies to investigate the aerobic degradation of ethylene oxide in soil are therefore not required.	
Undertaking of intended data submission [ ]	No undertaking provided; submission of further data/information is not considered necessary.	

Evaluation by Competent Authorities

	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	17 January 2020
Evaluation of applicant's justification	The eCA agrees that further testing does not seem necessary due to the lack of direct exposure of the substance to soil and the high vapour pressure leading to rapid volatilisation / minimal deposition from air.
Conclusion	Agree with applicant's conclusion.
Remarks	

7.2.2.1 The rate and route of degradation including identification of the processes involved and identification of any metabolites and degradation products in at least three soil types under appropriate conditions

Section A7.2.2.1 **Annex Point VII.4, XII.1.1, XII.1.4**	**The rate and route of degradation including identification of the processes involved and identification of any metabolites and degradation products in at least three soil types under appropriate conditions**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [ ] **Limited exposure [X]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [ ]**	
Detailed justification:	Based on the proposed use of ethylene oxide as a gaseous sterilising agent, environmental exposure is expected to be extremely minimal. During the sterilisation process gaseous ethylene oxide is introduced into a sealed, stainless steel chamber containing the products for sterilisation. On completion of the process, ethylene oxide from the chamber is exhausted to the atmosphere via a catalytic converter which converts the gas to carbon dioxide and water, typically with efficiency greater than 99.9%. The sterilisation chamber is then repeatedly flushed with nitrogen and air to remove the remaining ethylene oxide from the chamber and the sterilised products are subjected to high rates of air exchange to remove any residual ethylene oxide from the product and packaging. The exhaust from this phase is also treated via the catalytic converter. In a relatively small number of sterilisation plants acid scrubbers containing a solution of water and 5% sulphuric acid are used as an alternative to the catalytic conversion system and ethylene oxide from the sterilisation chamber is dissolved in the acid solution, which converts ethylene oxide to ethylene glycol with efficiency typically in the range of 99.5 to 99.9%. Neutralised solution from the acid scrubbers is transported to waste water treatment facilities as toxic waste water, where it undergoes specialist handling and treatment, thus minimising any potential environmental exposure. Direct exposure to soil and the natural terrestrial environment will therefore not occur following use of ethylene oxide as proposed, and any indirect exposure is expected to be negligible. Ethylene oxide is expected to undergo hydrolysis and biological degradation in soil. Howard *et al*., (1991, Document IIIA, Section 7.1.1.2.1/03) estimated the half-life of ethylene oxide in soil to be 10.5-11.9 days based on measured hydrolysis rate constants at pH 5, 7 and 9. Volatilisation is also expected to be a significant removal process from soil and the duration of any potential indirect exposure to soil will therefore be short-lived. The estimated K_{oc} value for ethylene oxide is 3.237 L/kg (Document IIIA, Section 7.1.3), indicating that the compound is not strongly adsorbed to soil or sediment and is therefore unlikely to accumulate in these compartments. Data on the rate and route of ethylene oxide in soil are therefore not required.	

Undertaking of intended data submission [ ]	No undertaking provided; submission of further data/information is not considered necessary.	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	17 January 2020	
Evaluation of applicant's justification	The eCA agrees that further testing does not seem necessary due to the lack of direct exposure of the substance to soil and the high vapour pressure leading to rapid volatilisation / minimal deposition from air.	
Conclusion	Agree with applicant's conclusion.	
Remarks		

7.2.2.2 Field dissipation and accumulation

Section A7.2.2.2 **Annex Point XII.1.1, Annex VI, para 85**	**Field soil dissipation and accumulation**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [ ]	**Technically not feasible [ ]** **Scientifically unjustified [ ]**	
Limited exposure [X]	**Other justification [ ]**	

Detailed justification:	Based on the proposed use of ethylene oxide as a gaseous sterilising agent, environmental exposure is expected to be extremely minimal. During the sterilisation process gaseous ethylene oxide is introduced into a sealed, stainless steel chamber containing the products for sterilisation. On completion of the process, ethylene oxide from the chamber is exhausted to the atmosphere via a catalytic converter which converts the gas to carbon dioxide and water, typically with efficiency greater than 99.9%. The sterilisation chamber is then repeatedly flushed with nitrogen and air to remove the remaining ethylene oxide from the chamber and the sterilised products are subjected to high rates of air exchange to remove any residual ethylene oxide from the product and packaging. The exhaust from this phase is also treated via the catalytic converter. In a relatively small number of sterilisation plants acid scrubbers containing a solution of water and 5% sulphuric acid are used as an alternative to the catalytic conversion system and ethylene oxide from the sterilisation chamber is dissolved in the acid solution, which converts ethylene oxide to ethylene glycol with efficiency typically in the range of 99.5 to 99.9%. Neutralised solution from the acid scrubbers is transported to waste water treatment facilities as toxic waste water, where it undergoes specialist handling and treatment, thus minimising any potential environmental exposure. Direct exposure to soil and the natural terrestrial environment will therefore not occur following use of ethylene oxide as proposed, and any indirect exposure is expected to be negligible. Ethylene oxide is expected to undergo hydrolysis and biological degradation in soil. Howard *et al*., (1991, Document IIIA, Section 7.1.1.2.1/03) estimated the half-life of ethylene oxide in soil to be 10.5-11.9 days based on measured hydrolysis rate constants at pH 5, 7 and 9. Volatilisation is also expected to be a significant removal process from soil, and the duration of any potential indirect exposure to soil will therefore be short-lived. The estimated K_{oc} value for ethylene oxide is 3.237 L/kg (Document IIIA, Section 7.1.3), indicating that the compound is not strongly adsorbed to soil or sediment and is therefore unlikely to accumulate in these compartments. Further data on the field soil dissipation and accumulation of ethylene oxide in soil are therefore not required.
Undertaking of intended data submission [ ]	No undertaking provided; submission of further data/information is not considered necessary.

Evaluation by Competent Authorities

	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	17 January 2020
Evaluation of applicant's justification	The eCA agrees that further testing does not seem necessary due to the lack of direct exposure of the substance to soil and the high vapour pressure leading to rapid volatilisation / minimal deposition from air.
Conclusion	Agree with applicant's conclusion.
Remarks	

7.2.2.3 Extent and nature of bound residues

Section A7.2.2.3 **Annex Point XII.1.4**	**Extent and nature of bound residues**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [ ] **Limited exposure [X]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [ ]**	
Detailed justification:	Based on the proposed use of ethylene oxide as a gaseous sterilising agent, environmental exposure is expected to be extremely minimal. During the sterilisation process gaseous ethylene oxide is introduced into a sealed, stainless steel chamber containing the products for sterilisation. On completion of the process, ethylene oxide from the chamber is exhausted to the atmosphere via a catalytic converter which converts the gas to carbon dioxide and water, typically with efficiency greater than 99.9%. The sterilisation chamber is then repeatedly flushed with nitrogen and air to remove the remaining ethylene oxide from the chamber and the sterilised products are subjected to high rates of air exchange to remove any residual ethylene oxide from the product and packaging. The exhaust from this phase is also treated via the catalytic converter. In a relatively small number of sterilisation plants acid scrubbers containing a solution of water and 5% sulphuric acid are used as an alternative to the catalytic conversion system and ethylene oxide from the sterilisation chamber is dissolved in the acid solution, which converts ethylene oxide to ethylene glycol with efficiency typically in the range of 99.5 to 99.9%. Neutralised solution from the acid scrubbers is transported to waste water treatment facilities as toxic waste water, where it undergoes specialist handling and treatment, thus minimising any potential environmental exposure. Direct exposure to soil and the natural terrestrial environment will therefore not occur following use of ethylene oxide as proposed, and any indirect exposure is expected to be negligible. Ethylene oxide is expected to undergo hydrolysis and biological degradation in soil. Howard *et al*., (1991, Document IIIA, Section 7.1.1.2.1/03) estimated the half-life of ethylene oxide in soil to be 10.5-11.9 days based on measured hydrolysis rate constants at pH 5, 7 and 9. Volatilisation is also expected to be a significant removal process from soil, and the duration of any potential indirect exposure to soil will therefore be short-lived. The estimated K_{oc} value for ethylene oxide is 3.237 L/kg (Document IIIA, Section 7.1.3), indicating that the compound is not strongly adsorbed to soil or sediment and is therefore unlikely to accumulate in these compartments. Data on the extent and nature of bound residues in soil are therefore not required.	
Undertaking of intended data submission [ ]	No undertaking provided; submission of further data/information is not considered necessary.	

Evaluation by Competent Authorities

	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	17 January 2020
Evaluation of applicant's justification	The eCA agrees that further testing does not seem necessary due to the lack of exposure of the substance to soil or sediment and the high vapour pressure leading to rapid volatilisation / minimal deposition from air.
Conclusion	Agree with applicant's conclusion.
Remarks	

7.2.2.4 Other soil degradation studies

Section A7.2.2.4 **Annex Point XII.1.1**	**Other soil degradation studies**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [ ] **Limited exposure [X]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [ ]**	
Detailed justification:	Based on the proposed use of ethylene oxide as a gaseous sterilising agent, environmental exposure is expected to be extremely minimal. During the sterilisation process gaseous ethylene oxide is introduced into a sealed, stainless steel chamber containing the products for sterilisation. On completion of the process, ethylene oxide from the chamber is exhausted to the atmosphere via a catalytic converter which converts the gas to carbon dioxide and water, typically with efficiency greater than 99.9%. The sterilisation chamber is then repeatedly flushed with nitrogen and air to remove the remaining ethylene oxide from the chamber and the sterilised products are subjected to high rates of air exchange to remove any residual ethylene oxide from the product and packaging. The exhaust from this phase is also treated via the catalytic converter. In a relatively small number of sterilisation plants acid scrubbers containing a solution of water and 5% sulphuric acid are used as an alternative to the catalytic conversion system and ethylene oxide from the sterilisation chamber is dissolved in the acid solution, which converts ethylene oxide to ethylene glycol with efficiency typically in the range of 99.5 to 99.9%. Neutralised solution from the acid scrubbers is transported to waste water treatment facilities as toxic waste water, where it undergoes specialist handling and treatment, thus minimising any potential environmental exposure. Direct exposure to soil and the natural terrestrial environment will therefore not occur following use of ethylene oxide as proposed, and any indirect exposure is expected to be negligible. Ethylene oxide is expected to undergo hydrolysis and biological degradation in soil. Howard *et al*., (1991, Document IIIA, Section 7.1.1.2.1/03) estimated the half-life of ethylene oxide in soil to be 10.5-11.9 days based on measured hydrolysis rate constants at pH 5, 7 and 9. Volatilisation is also expected to be a significant removal process from soil and the duration of any potential indirect exposure to soil will therefore be short-lived. The estimated K_{oc} value for ethylene oxide is 3.237 L/kg (Document IIIA, Section 7.1.3), indicating that the compound is not strongly adsorbed to soil or sediment and is therefore unlikely to accumulate in these compartments. Soil degradation data for ethylene oxide are therefore not required.	
Undertaking of intended data submission [ ]	No undertaking provided; submission of further data/information is not considered necessary.	

Evaluation by Competent Authorities

	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	17 January 2020
Evaluation of applicant's justification	The eCA agrees that further testing does not seem necessary due to the lack of direct exposure of the substance to soil and the high vapour pressure leading to rapid volatilisation / minimal deposition from air.
Conclusion	Agree with applicant's conclusion.
Remarks	

7.2.3 Adsorption and mobility in soil, further studies

7.2.3.1 Adsorption and desorption in accordance with the new test guideline EC C18 or the corresponding OECD 106 and, where relevant, adsorption and desorption of metabolites and degradation products

Section A7.2.3.1 **Annex Point XII.1.1**	**Adsorption and desorption in accordance with the new test guideline EC C18 or the corresponding OECD 106 and, where relevant, adsorption and desorption of metabolites and degradation products**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [X] **Limited exposure [X]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [ ]**	
Detailed justification:	Based on the proposed use of ethylene oxide as a gaseous sterilising agent, environmental exposure is expected to be extremely minimal. During the sterilisation process gaseous ethylene oxide is introduced into a sealed, stainless steel chamber containing the products for sterilisation. On completion of the process, ethylene oxide from the chamber is exhausted to the atmosphere via a catalytic converter which converts the gas to carbon dioxide and water, typically with efficiency greater than 99.9%. The sterilisation chamber is then repeatedly flushed with nitrogen and air to remove the remaining ethylene oxide from the chamber and the sterilised products are subjected to high rates of air exchange to remove any residual gas from the product and packaging. The exhaust from this phase is also treated via the catalytic converter. In a relatively small number of sterilisation plants acid scrubbers containing a solution of water and 5% sulphuric acid are used as an alternative to the catalytic conversion system and ethylene oxide from the sterilisation chamber is dissolved in the acid solution, which converts ethylene oxide to ethylene glycol with efficiency typically in the range of 99.5 to 99.9%. Neutralised solution from the acid scrubbers is transported to waste water treatment facilities as toxic waste water, where it undergoes specialist handling and treatment, thus minimising any potential environmental exposure. Following use of ethylene oxide as proposed, direct exposure to soil and the natural terrestrial environment will therefore not occur and any indirect exposure is expected to be negligible. Studies to investigate the adsorption and desorption characteristics of the compound in soil are therefore not required. A K_{oc} value for ethylene oxide has been estimated using the PCKOCWIN estimation program (EPISUITE 4.0, U.S Environmental Protection Agency, 2009). The estimated K_{oc} value for ethylene oxide is 3.237 L/kg, indicating that the compound is not strongly adsorbed to soil or sediment, and would therefore be unlikely to accumulate in these compartments. Additional details are provided in Document IIIA, Section 7.1.3. Further data on the adsorption and mobility of ethylene oxide in soil are therefore not considered necessary.	

Undertaking of intended data submission [ ]	No undertaking provided; submission of further data/information is not considered necessary.	
	Evaluation by Competent Authorities	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	17 January 2020	
Evaluation of applicant's justification	The eCA agrees that further testing does not seem necessary due to the lack of direct exposure of the substance to soil and the high vapour pressure leading to rapid volatilisation / minimal deposition from air. The Koc estimation is considered sufficient.	
Conclusion	Agree with applicant's conclusion.	
Remarks		

7.2.3.2 Mobility in at least three soil types and where relevant, mobility of metabolites and degradation products

Section A7.2.3.2 **Annex Point XII.1.1**	**Mobility in at least three soil types and where relevant, mobility of metabolites and degradation products**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA *As outlined in the TNsG on data requirements, the applicant must always be able to justify the suggested exemptions from the data requirements. The justifications are to be included in the respective location (section) of the dossier.* *If one of the following reasons is marked, detailed justification has to be given below. General arguments are not acceptable*	Official use only
Other existing data [X] **Limited exposure [X]**	**Technically not feasible [ ]** **Scientifically unjustified [ ]** **Other justification [ ]**	
Detailed justification:	Based on the proposed use of ethylene oxide as a gaseous sterilising agent, environmental exposure is expected to be extremely minimal. During the sterilisation process gaseous ethylene oxide is introduced into a sealed, stainless steel chamber containing the products for sterilisation. On completion of the process, ethylene oxide from the chamber is exhausted to the atmosphere via a catalytic converter which converts the gas to carbon dioxide and water, typically with efficiency greater than 99.9%. The sterilisation chamber is then repeatedly flushed with nitrogen and air to remove the remaining ethylene oxide from the chamber and the sterilised products are subjected to high rates of air exchange to remove any residual gas from the product and packaging. The exhaust from this phase is also treated via the catalytic converter. In a relatively small number of sterilisation plants acid scrubbers containing a solution of water and 5% sulphuric acid are used as an alternative to the catalytic conversion system and ethylene oxide from the sterilisation chamber is dissolved in the acid solution, which converts ethylene oxide to ethylene glycol with efficiency typically in the range of 99.5 to 99.9%. Neutralised solution from the acid scrubbers is transported to waste water treatment facilities as toxic waste water, where it undergoes specialist handling and treatment, thus minimising any potential environmental exposure. Following use of ethylene oxide as proposed, direct exposure to soil and the natural terrestrial environment will therefore not occur and any indirect exposure is expected to be negligible. Studies to investigate the adsorption and desorption characteristics of the compound in soil are therefore not required. A K_{oc} value for ethylene oxide has been estimated using the PCKOCWIN estimation program (EPISUITE 4.0, U.S Environmental Protection Agency, 2009). The estimated K_{oc} value for ethylene oxide is 3.237 L/kg, indicating that the compound is not strongly adsorbed to soil or sediment, and would therefore be unlikely to accumulate in these compartments. Additional details are provided in Document IIIA, Section 7.1.3. Further data on the adsorption and mobility of ethylene oxide in soil are therefore not considered necessary.	
Undertaking of intended data submission [ ]	No undertaking provided; submission of further data/information is not considered necessary.	

Evaluation by Competent Authorities

	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	17 January 2020
Evaluation of applicant's justification	The eCA agrees that further testing does not seem necessary due to the lack of direct exposure of the substance to soil and the high vapour pressure leading to rapid volatilisation / minimal deposition from air. The Koc estimation is considered sufficient.
Conclusion	Agree with applicant's conclusion.
Remarks	

7.3 Fate and behaviour in air

7.3.1 Photo-transformation in air (estimation method), including identification of breakdown products

Section A7.3.1/01 **Annex IIA5**	**Photo-transformation in air (estimation method), including identification of breakdown products**	
	1 Reference	**Official use only**
1.1 Reference	V. Thomas (2009) Ethylene Oxide: Estimation of atmospheric oxidation rate. JSC International Ltd., Simpson House, Windsor Court, Clarence Drive, Harrogate, North Yorkshire, HG1 2PE, England, UK. Unpublished report No.: ETO/02/03. 20 August 2009	
1.2 Data protection	Yes	
1.2.1 Data owner	Ethylene Oxide BPD Consortium	
1.2.3 Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I	
	2 Guidelines and Quality Assurance	
2.1 Guideline study	Not applicable. Calculation only	
2.2 GLP	No. Calculation only	
2.3 Deviations	Not applicable	
	3 Materials and Methods	
3.1 Test material	Not applicable. Calculation only	
3.1.1 Lot/Batch number	Not applicable. Calculation only	
3.1.2 Specification	Not applicable. Calculation only	
3.1.3 Purity	Not applicable. Calculation only	
3.1.4 Further relevant properties	Not applicable. Calculation only	
3.2 Reference substance	Not applicable. Calculation only	
3.2.1 Initial concentration of reference substance	Not applicable. Calculation only	
3.3 Test system	The atmospheric oxidation rate for ethylene oxide was estimated using the Atmospheric Oxidation Program. This estimates the rate constant for the atmospheric, gas-phase reaction between photo-chemically produced hydroxyl radicals and organic chemicals.	
	4 Results and Discussion	
4.1 Estimated half-life	The estimated half-life of ethylene oxide in air based on reaction with hydroxyl radicals (assumed average daylight concentration in the	

	atmosphere 1.5 x 10^6 OH radicals/cm^3) is 38.157 days under environmental conditions with a diurnal cycle of 12 hours.	
	5 Applicant's Summary and Conclusion	
5.1 Materials and methods	The atmospheric oxidation rate for ethylene oxide was estimated based on the Atkinson calculation using the Atmospheric Oxidation Program.	
5.2 Results and discussion	The estimated half-life of ethylene oxide in air based on reaction with hydroxyl radicals (assumed average daylight concentration in the atmosphere 1.5 x 10^6 OH radicals/cm^3) is 38.157 days under environmental conditions with a diurnal cycle of 12 hours.	
5.3 Conclusion	It was estimated that the half-life of ethylene oxide subject to atmospheric oxidation was 38.157 days under environmental conditions with a diurnal cycle of 12 hours. On this basis, it can be concluded that ethylene oxide is relatively persistent in the atmosphere and may have some potential for long-range atmospheric transport and atmospheric accumulation if released into the atmosphere in significant amounts.	
5.3.1 Reliability	1	X
5.3.2 Deficiencies	No	
	Evaluation by Competent Authorities	
	Evaluation by Rapporteur Member State	
Date	17 January 2020	
Materials and Methods	Agree with applicant's version.	
Results and discussion	Agree with applicant's version.	
Conclusion	Agree with applicant's version.	
Reliability	**Comment (5.3.1)**: Changed to 0, not applicable, since this is an estimation method.	
Acceptability	Acceptable.	
Remarks	The same estimate is obtained when using AOPWIN v. 1.92 (September 2010).	

7.3.2 Fate and behaviour in air, further studies

Section A7.3.2/01&02 **Annex Point XII.3**	**Fate and behaviour in air, further studies**	
	1 Reference	**Official use only**
1.1 Reference	A. M. Winer, R. Atkinson, J. Arey, S. M. Aschmann, M. A. Goodman, E. C. Tuazon (1987) Lifetimes and fates of toxic chemicals in California's atmosphere. Statewide Air Pollution Research Centre, University of California, Riverside, California 92521. Published report No.: ARB/R-88/345	
1.2 Data protection	None	
1.2.1 Data owner	Public domain	
1.2.3 Criteria for data protection	No data protection claimed	
	2 Guidelines and Quality Assurance	
2.1 Guideline study	Guideline not specified	
2.2 GLP	No	
2.3 Deviations	Not applicable	
	3 Materials and Methods	
3.1 Test material	Ethylene oxide	
3.1.1 Lot/Batch number	Not specified	
3.1.2 Specification	Not specified	
3.1.3 Purity	Not specified	X
3.1.4 Further relevant properties	Not applicable	
3.2 Reference substance	No	
3.2.1 Initial concentration of reference substance	Not applicable	
3.3 Test system	A series of experiments were conducted to determine the atmospheric loss rates of ethylene oxide as a function of water vapour concentration. The experiments were conducted in a SAPRC 5800-liter evacuable, Teflon-coated environmental chamber, equipped with an in-situ white-type multiple reflection optical system interfaced to an FT-IR absorption spectrometer. Concentrations of ethylene oxide and water were monitored by FT-IR absorption spectroscopy, using a path-length of 62.9 m and a resolution of 1 cm^{-1}. Water vapour concentrations were determined using calibration curves generated by vaporising known amounts of liquid water into the chamber. The initial concentrations of ethylene oxide were approximately 1.4 x 10^{14} molecule cm^{-3} (6 ppm) and	

	all experiments were conducted in the dark at 25°C ± 2°C. The experiments were run at < 1% and 49 % relative humidity over 4 hours (at <1 % humidity) and 2 and 29 hours (at 4 % humidity).	
	4 Results and Discussion	
4.1 Observed atmospheric loss rates due to wet deposition	The experimental conditions and observed atmospheric loss rates of ethylene oxide are presented in Table A7.3.2-01. Minimal hydrolysis of ethylene oxide was observed under the experimental conditions tested and the small losses of ethylene oxide observed were attributed to removal at the chamber walls. The data yield an upper limit loss rate for ethylene oxide of ≤3 x 10^{-5} min^{-1} at ~50% relative humidity and 25°C. Based on this the minimum atmospheric lifetime of ethylene oxide due to hydrolysis is 23 days, with the likelihood of a much longer lifetime due to this removal process.	
	5 Applicant's Summary and Conclusion	
5.1 Materials and methods	A series of experiments were conducted to determine the atmospheric loss rates of ethylene oxide as a function of water vapour concentration. The experiments were conducted in an environmental chamber, equipped with an in-situ white-type multiple reflection optical system interfaced to an FT-IR absorption spectrometer. Concentrations of ethylene oxide and water were monitored by FT-IR absorption spectroscopy.	
5.2 Results and discussion	Measured loss rates for ethylene oxide ranged from ≤3 x 10^{-5} mins^{-1} at a relative humidity of 49% to ≤7 x 10^{-5} mins^{-1}at a relative humidity of <1%. The driest experiment exhibited the largest loss rate, and the data indicated that there was no observable hydrolysis of ethylene oxide under the experimental conditions tested. The small losses of ethylene oxide observed were attributed to removal at the experimental chamber walls.	
5.3 Conclusion	The finding from this paper by *Winer et. al.* (1987)- that ethylene oxide is not expected to be readily wet deposited from the atmosphere is consistent with other literature. An example of this is the publication by *Dana et. al.* (1985), (Hazardous air pollutants: wet removal rates and mechanisms. United States Environmental Protection Agency. Published report No.: EPA-600/3-84-113) where a washout ratio (also given as a dimensionless value for α in this publication) was given ranging from 3.8 (measured at 278 K) to 11.2 (calculated at 303 K). The washout ratio (W) describes the equilibrium partitioning between rain and gas phase is defined below and can also be related to the gas constant (R), temperature (in K) and Henry's Law constant. W = Concentration in rain / Concentration in air = (R x T)/ H This is compared to readily wet deposited species such as phenol where values for α are approximately 10^4 (measured and calculated 293 K to 298 K) and nitrobenzene, where α approximately 10^3 (measured and calculated 293 K to 298 K).	

5.3.1 Reliability	2	
5.3.2 Deficiencies	Yes The study has not been performed in accordance with any regulatory guideline. However, the data presented from this report provides valuable supporting information on the fate and behaviour of ethylene oxide in the atmosphere.	
	Evaluation by Competent Authorities	
	Evaluation by Rapporteur Member State	
Date	17 January 2020	
Materials and Methods	**Comment (3.1.3)**: The purity is not reported in the published article. As discussed in the CAR, section A.1.2. Composition of the substance (reference specifications), the production of ethylene oxide consistently yields the active substance in high purity (generally above 99 %). It is not expected that today's production process is significantly different from the production process at the time when this article was written. The principles of the ethylene oxide production has remained unchanged since the 1930s. In the current production of ethylene oxide, some impurities are identified, but none detected above significant level (all below 0.01 %). Furthermore, based on the identity of these impurities and the hazardous profile of the active substance itself, the eCA has no reason to believe that the impurities will have any impact on the findings of this study.	
Results and discussion	Agree with applicant's version.	
Conclusion	Agree with applicant's version.	
Reliability	**Comment (5.3.1)**: In the study report, the relevant experiment is one of many experiments performed on several substances. The eCA is of the opinion that the findings seem consistent with the expected behaviour of ethylene oxide due to the high vapour pressure. Whether the reliability is set to 2 or 3, it is considered that the results can be used as supporting information to indicate a low degree of wet deposition of ethylene oxide from the atmosphere.	
Acceptability	Acceptable as supporting information to indicate a low degree of wet deposition of ethylene oxide from the atmosphere.	
Remarks	-	

Table A7.3.2-01: Experimental conditions and results for the behaviour of ethylene oxide in the presence of water vapour

EC Run	Diluent gas	Relative humidity (%)	Observed ethylene oxide loss (%)	Loss rate (min^{-1})
1192	N_2	<1	1.5% over 4 hours	$\leq 7 \times 10^{-5}$
1193	N_2	49	<0.5% over 2 hours	$< 4 \times 10^{-5}$
1194	Air	49	4% over 29 hours	$\leq 3 \times 10^{-5}$

Section A7.3.2/03 **Annex Point XII.3**	**Fate and behaviour in air, further studies**	
	1 Reference	**Official use only**
1.1 Reference	L. T. Cupitt (1987) Atmospheric persistence of eight air toxics. Atmospheric Sciences Research Laboratory, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711. Published report No.: EPA/600/3-87/004	
1.2 Data protection	None	
1.2.1 Data owner	Public domain	
1.2.3 Criteria for data protection	No data protection claimed	
	2 Guidelines and Quality Assurance	
2.1 Guideline study	Guideline not specified	
2.2 GLP	No	
2.3 Deviations	Not applicable	
	3 Materials and Methods	
3.1 Test material	Ethylene oxide	
3.1.1 Lot/Batch number	Not applicable	
3.1.2 Specification	Not applicable	
3.1.3 Purity	Not applicable	X
3.1.4 Further relevant properties	Not applicable	
3.2 Reference substance	No	
3.2.1 Initial concentration of reference substance	Not applicable	
3.3 Test system	The atmospheric persistence of eight chemicals (methylene chloride, chloroform, carbon tetrachloride, ethylene dichloride, trichloroethylene, perchloroethylene, 1,3-butadiene and ethylene oxide) was estimated. It was assumed that removal from the atmosphere is primarily due to reaction with hydroxyl radicals (in the case of seven out of eight chemicals, including ethylene oxide). Calculations were then made based on average conditions due to OH reactions over the continental U.S. The calculations were based solely on the reaction with hydroxyl radicals, as this is the dominat removal mechanism for ethylene oxide.	

Uncertainities regarding the rate constant K_{OH} which is a function of temperature (that changes during the day, and varies between latitude and season) and variation in the concentration of hydroxyl radical [OH] were addressed by using reasonable estimates of the average values.

Calculations for ethylene oxide were based on an activation energy of 2.9 kcal mol^{-1} measured over the temperature range of 297 k to 435 K. This value was also assumed to be appropriate for a 260 K, this does lead to some uncertainty in the lifetime estimate as a potentially higher rate constant could lead to a potentially higher DT_{50} (at 260 K).

4 Results and Discussion

4.1 Estimated lifetimes

Estimated lifetimes for ethylene oxide based on average conditions due to OH reactions over the continental U.S. range from 217-578 days. The author reports that due to its relatively high water solubility ethylene oxide is preferentially distributed into the aqueous phase. However, despite this, washout via rainfall is not an effective atmospheric removal process for ethylene oxide, even without taking into account the re-volatilisation of the chemical. Experimental measurements and theoretical modelling of rain out effects conducted by Dana *et al*., (1985), have demonstrated little impact from rain out for gases which are far more soluble than ethylene oxide, and the estimated atmospheric lifetime of ethylene oxide due to rain out is hundreds of years. The author also concludes that ethylene oxide is not expected to distribute into the aqueous phase on ambient aerosols and be removed from the atmosphere by deposition of the aerosol. It is reported that a worst-case aerosol concentration of 150 $\mu g\ m^{-3}$, all of it being water, will only reduce the gas phase concentration of ethylene oxide by one part in one billion.

5 Applicant's Summary and Conclusion

5.1 Materials and methods

The atmospheric persistence of eight chemicals was estimated based on average conditions due to OH reactions over the continental U.S.

5.2 Results and discussion

Estimated lifetimes for ethylene oxide based on average conditions due to OH reactions over the continental U.S. range from 217-578 days.

Ethylene oxide Reaction Rate Constants and Lifetimes

Temperature (K)	OH Reaction rate constant (10^{-14} cm^{3} $molec^{-1}$ s^{-1})	Assumed [OH] 10^{6} molec cm^{-3}	Lifetime (days)
288	*6.9*	*1.0*	*167*[a]
263	4.3	1.0	217
260	4.0	0.5	578

[a] Based on less relevant atmospheric temperature

The dominant removal mechanism for ethylene oxide is reaction with hydroxyl (OH) radicals. The author concludes that washout via rainfall and adsorption into aqueous aerosol particles are not effective atmospheric removal processes for ethylene oxide.

5.3 Conclusion	Reaction with hydroxyl (OH) radicals is the dominant atmospheric removal mechanism for ethylene oxide. Washout from the atmosphere via rainfall and adsorption into aqueous aerosols followed by subsequent aerosol deposition are not significant removal processes for ethylene oxide.	
5.3.1 Reliability	2	
5.3.2 Deficiencies	Yes The study has not been performed in accordance with any regulatory guideline and the estimated atmospheric lifetimes reported are based on average conditions for the continental U.S. However, the data presented from this report provides valuable supporting information on the fate and behaviour of ethylene oxide in the atmosphere.	
	Evaluation by Competent Authorities	
	Evaluation by Rapporteur Member State	
Date	17 January 2020	
Materials and Methods	**Comment (3.1.3)**: The purity is not reported in the published article. As discussed in the CAR, section A.1.2. Composition of the substance (reference specifications), the production of ethylene oxide consistently yields the active substance in high purity (generally above 99 %). It is not expected that today's production process is significantly different from the production process at the time when this article was written. The principles of the ethylene oxide production has remained unchanged since the 1930s. In the current production of ethylene oxide, some impurities are identified, but none detected above significant level (all below 0.01 %). Furthermore, based on the identity of these impurities and the hazardous profile of the active substance itself, the eCA has no reason to believe that the impurities will have any impact on the findings of this study. **Comment (3.3)**: No information is given in the study report on these estimations, other than "Relationships have been developed which describe the atmospheric lifetimes of potentially hazardous chemicals in terms of their probable removal mechanisms."	
Results and discussion	Agree with applicant's version.	
Conclusion	Agree with applicant's version.	
Reliability	**Comment (5.3.1)**: The reasonings of the author are well described in the study report. However, since these are estimations, it might be that the reliability should be set to 0.	
Acceptability	The eCA considers that the results support the assumption that ethylene persists for a long time in the atmosphere, and furthermore that a low degree of wet deposition is to be expected.	
Remarks	-	