SAFETY DATA SHEET

Annex II

Exposure scenario

Substance Name: ethylene oxide

EC Number: 200-849-9

CAS Number: 75-21-8

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1. EXPOSURE ASSESSMENT

General remarks

The technical conditions and risk management measures in EO producing and handling facilities should always be sufficiently efficient to prevent exposure of the workers in concentrations above the DMEL. The intention should be to seek the lowest exposure at any time. Therefore, it can be assumed that a qualitative description of the exposure scenarios is sufficient to ensure that exposure concentrations are at least below the DMEL.

Human health – Worker

Skin and ocular exposure

Ethylene oxide is classified as skin irritant and can cause serious eye irritation. Although ethylene oxide does not exert local irritation at concentrations below exerting systemic toxicity including carcinogenicity, personal protection, technical means and organizational arrangements are required when there is the likelihood of exposure. The likelihood of exposure is considered to be practically negligible for PROC 1 due to the high integrity of closed systems. For PROC 2, 8b and 9 the likelihood of exposure is similarly low, apart from e.g. during maintenance or sampling procedures for which individual considerations should apply. For the other PROCs 3 and 15, exposure can not completely be ruled out.

Ethylene oxide is very volatile and a gas and therefore handled in closed systems under strictly controlled conditions. Thus, dermal and ocular exposure does not occur under normal conditions of use. Nevertheless, workers could be accidentally exposed with liquid ethylene oxide (corrosion may occur) or ethylene oxide gas from the gas phase (transdermal exposure) during monitoring, maintenance, testing, filling, loading, unloading or other procedures such as the incidence of leakages and minor accidents. An effective prevention of potential skin and ocular irritation can be achieved by technical means, supplemented by organizational arrangements and personal protective equipment. Ethylene oxide requires special chemical resistant materials for personal protection to avoid any dermal exposure and which are provided in the protective equipment of workers.

Workers in ethylene oxide producing and handling facilities are usually located in isolated measuring stations with light high pressure conditions to avoid any diffusion of ethylene oxide. Quality control and sampling takes place in a closed system. Workers are located outside of the isolated measuring station for short processes only. Each of the above mentioned processes takes no longer than 5 - 10 minutes and never exceeds a total of 2 hours per day. Each facility is fully equipped with gas sensor heads to detect gas leakage. In case of leakage this system is connected to a water sprinkler system to avoid volatilization of the gaseous phase. Pumps and sampling stations are additionally isolated with a circumfluent water film.

The industrial facility has a thorough training program for employees to practice the appropriate work processes and monitoring in an ethylene oxide producing and handling facility. Workers follow the recommended safety measures in the Extended Safety Data Sheet (eSDS). When workers are located outside of the isolated measuring station during monitoring, they wear overalls, helmets, goggles and safety shoes. Additionally, workers wear portable gas sensors.

During maintenance, leakages and minor accidents workers use suitable respiratory protection (breathing air, full face piece), ethylene oxide resistant and impermeable gloves (e.g. butyl rubber), ethylene oxide resistant and impermeable boots (e.g. nitrile rubber) and ethylene oxide impermeable, special chemical resistant overalls (e.g. Microchem 4000 model 151) and portable gas sensors.

Laboratories have an appropriate and thorough training program for employees to practice the appropriate work processes with ethylene oxide. Only properly trained and authorised personnel should be allowed to handle the substance. Processes are carried out below highly efficient local exhaust ventilations (LEV) only. Employees wear respiratory protection, face shields/goggles and ethylene oxide resistant and impermeable gloves (e.g. butyl rubber) to avoid any skin or ocular contact. Processes with potential contact (e.g. experimental set-up) never exceed a total of 15 minutes to 1 hour per day.

Short-term exposure

If no data are available for the derivation of peak exposure concentration, the 8-hour time weighed average is multiplied by a factor of 4, as recommended by the ECETOC TRA tool 3.0. Therefore, the full shift ECETOC TRA estimate, as well as the actual measured values, were multiplied by a factor of 4 to estimate the 95th percentile of the related short term exposure distribution.
For ethylene oxide, the inhalation DNEL for short-term exposure exceeds the inhalation DNEL for long-term exposure by a factor of 3.13. Thus, it can be concluded that the demonstration of safe use concerning full shift exposure also covers a safe use with regard to short term exposure levels.
Inhalation peak exposure could only occur during maintenance, testing, filling, loading, unloading or the incidence of leakages and minor accidents. To avoid inhalation peak exposure, each facility is fully equipped with gas sensor heads to detect gas leakage. In case of leakage this system is connected to a water sprinkler system to avoid volatilization of the gaseous phase. Additionally, workers wear portable gas sensors secondary to the personal protective equipment when processes are undertaken outside of the isolated measuring stations. In laboratories, inhalation peak exposure could only occur during minor accidents. Therefore, despite the handling of ethylene oxide below highly efficient local exhaust ventilations (LEV) only, employees wear respiratory protection.

Human health – Worker and Consumer

The exposure assessment covers the life cycle of the substance (monomer) until the polymerization reaction. The unreacted residual monomer in a polymer is to be regarded as impurity that need not be critically addressed in the exposure assessment. Also covered is the life cycle of the substance as an intermediate until the respective chemical reaction and finally distillation of the product.

Environment

In the chemical safety assessment performed according to Article 14(3) in connection with Annex I section 3 (Environmental Hazard Assessment) and PBT/ vPvB Assessment no hazard was identified. Therefore according to REACH Annex I (5.0) an exposure estimation is not necessary. Consequently all identified uses of the substance are assessed as safe for the environment.

Ethylene oxide (EO) is only used as an intermediate or as a monomer in polymer production. Both uses are performed in closed systems and under strictly controlled conditions. Unintended releases into the environment are hence not to be expected. Additionally, regular external audits of the facilities, conducted by the national competent authority of the respective country in Europe or an independent organization, ensure that the measured values of air around the highly contained facilities do not exceed the legally permitted thresholds. Therefore, environmental exposure is negligible.

In the Reference Document on Best Available Techniques in the Large Volume Organic Chemical Industry, published by the European Commission (2003) several techniques used inside the EU to prevent and control releases of ethylene oxide and subsequent occupational exposure are discussed. The typical ethylene oxide (EO) production process includes several effluent streams (Reference Document on Best Available Techniques in the Large Volume Organic Chemical Industry, 2003). In some of them ethylene oxide may be found.

- Vent from the carbon dioxide removal unit: Carbon dioxide is produced as a by-product during the manufacture of EO. It is removed from the system by absorption in a hot carbonate solution and is then stripped by means of lower pressure and heat. This gaseous overhead stream is vented to air after partial condensation of water. This stream does not contain ethylene oxide and is not to be considered further.
- Inerts vent: In case of the air-based process the inerts form a large gas stream (due to e.g. the amount of nitrogen), whereas it is a small stream in the oxygen-based process and contains mainly hydrocarbons. This stream is treated by flaring or passes to a fuel gas network for combustion. In the air-based process a part of the recycle gas is routed to a second EO reactor to convert present ethylene and generated EO is absorbed in water. The inert vents are also considered to be free of EO and are

hence not considered further.

- Volatile organic chemicals (VOCs) from cooling towers: In some plants, the water used to absorb EO is cooled down in cooling towers. This water contains some traces of organics and hence the air from the cooling towers contains between 0.015 and 0.6 kg VOC/ton EO. This gas is released to the atmosphere and contains < 0.6 kg VOC/ton EO. EO is generally stripped out and online process analysers check the completeness of EO stripping out of the VOC containing vents. Therefore, off-gases from cooling towers are not expected to contain measurable amounts of EO.
- Scrubber off-gas: EO containing vent gases originate from various sources in the process, such as the EO recovery section, the EO purification section, from process analysers and safety valves. Further, they may originate from associated activities like EO storage or buffer vessels and EO loading/unloading operations. Besides EO these vent gases typically contain non-condensable like argon, ethane, ethylene, methane, carbon dioxide, oxygen and/or nitrogen. To minimize these EO streams most of the vents a routed through a scrubber and EO as well as the overhead gas are recycled to the process and hence no emission occurs. In case of EO streams that do not contain other valuable components. These vents are typically treated by water scrubbing and recovered EO is routed back to the process or the water containing EO is routed to a biological waste water treatment plant. The remaining EO-free inert vent is released to the atmosphere.
- Storage tanks: Losses from storage tanks are considered to only occur during filling operations and only in the absence of specific emission prevention. For such cases Rentz (1999) reports a loss of 2.6 kg ethylene oxide/ton.
- Fugitive/non-channeled emissions: Releases may occur during maintenance procedures or derive from reactor analyser vents. However, such releases are expected to be extremely low, because much attention is paid to the minimization of occupational exposure due to very low threshold limit values for EO because of its toxic and carcinogenic nature of EO.

Water effluents containing EO may derive from the EO recovery where water is used as absorbent for EO. EO is partially hydrolysed to ethylene glycol and the bleed stream is concentrated in organic compounds. The stream is treated in a biological waste water treatment plant, where the low remaining quantities of EO are readily biodegraded or undergo hydrolysis to ethylene glycol which in turn is also readily biodegraded. Generally, all water effluents from the complete plant should also be routed to the waste water treatment plant.

EO will be eliminated from water by three independent processes which are biodegradation, volatilisation and hydrolysis. These processes take place simultaneously. Implemented best available techniques (BAT) concentrate on the transfer of effluent streams to a central or external waste water treatment plant to take the advantage of the high biodegradability of the sum of all containing organic compounds in the stream (mainly glycols). The application of BAT allows an emission level of 10-15 g TOC/t EO ex-reactor to be achieved as stream directed to the waste water treatment plant. This corresponds to a release fraction from the processing site of 0.001 to 0.0015% based on TOC which includes all VOC present in the water bleed and is further subject to biodegradation.

Therefore, the releases of EO into the environment are considered to be negligible and a quantitative exposure assessment for ethylene oxide is not considered to be necessary.

References:
European Commission: Integrated Pollution Prevention and Control (IPPC) – Reference Document on Best Available Techniques in the Large Volume Organic Chemical Industry, February 2003

Rentz, N., Laforsch & Holtmann: Technical background document for the actualisation and assessment of UN/ECE protocols related to the abatement of the transboundary transport of VOCs from stationary sources., French-German Institute for environmental research, 1999.

Short description of all exposure scenarios

Table 1.1. Short description of all exposure scenarios with their use descriptors and life cycle stage

Number (ES)	Short description of exposure scenario	Product Category (PC)	Life cycle stage covered by ES						Sector of use (SU)	Process category (PROC)	Article Category (AC)	Environmental release category (ERC)
			Manufacture	Formulation	End use			Service Life				
					Industrial	Professional	Consumer					
1	Manufacture and distribution of the substance	-	X	-	X	-	-	-	8, 9, 3	1, 2, 3, 8b, 9	-	1
2	Polymer production	-	-	-	X	-	-	-	8, 9, 3	1, 2, 3, 8b, 9	-	6c
3	Use as an intermediate	-	-	-	X	-	-	-	8, 9, 3	1, 2, 3, 8b, 9	-	6a
4	Use as a laboratory agent	-	-	-	X	X	-	-	3, 22	15	-	1

1.1. Manufacture and distribution of the substance

1.1.1. Exposure Scenario

Table 1.2. Description of the ES

1.1.1.1. Title		
Reference number	1	
Free short title	Manufacture and distribution of the substance	
Systematic title based on use descriptor	SU 8, 9 and 3; PROC 1, 2, 3, 8b and 9; ERC 1	
Processes, tasks, activities covered	Use of the substance in a closed process, in closed continuous processes with occasional controlled exposure or in closed batch processes including the transfer of the substance from/to vessels/large containers at dedicated facilities or to small containers (including weighing)	
Environment characteristic covered	-	
1.1.1.2. Operational conditions and risk management measures		
The technical conditions and risk management measures in EO producing and handling facilities need to be always sufficiently efficient to prevent inhalation exposure of workers in concentrations above the DMEL long term- systemic effects for workers (2.0 mg/m³). The intention should be to seek the lowest exposure at any time.		
1.1.1.2.1. Control of workers exposure for PROC 1		
Title information related to contributing scenario		
Workers related free short title	Use in closed process, no likelihood of exposure	
Use descriptor covered	PROC 1	
Processes, tasks, activities covered	Use of the substance in high integrity contained system where little potential exists for exposures, e.g. any sampling via closed loop systems	
Assessment values	measured values*	
Product characteristic		
Physical state	gaseous	
Concentration of substance	100%	
Amounts used		
Not relevant		
Frequency and duration of use/exposure		
Duration of exposure	< =2 hours	hours/day
Frequency of exposure	≤ 240	days/year
Human factors not influenced by risk management		
Not relevant		
Other given operational conditions affecting workers exposure		
Location	Inside or Outside	
Domain	Industrial	
Technical conditions and measures at process level (source) to prevent release		
Processes take place in a high integrity contained and monitored system.		
Technical conditions and measures to control dispersion from source towards the worker		
Sampling takes place in a closed loop system. Samples are taken in steel drums, loaded in a closed process and automatically sent to the laboratory. Each facility is fully equipped with gas sensor heads to detect gas leakage. In case of leakage this system is connected to a water sprinkler system to avoid volatilization of the gaseous phase. Pumps and sampling stations are additionally isolated with a circumfluent water film.		
Organisational measures to prevent /limit releases, dispersion and exposure		
Workers are located in isolated measuring stations with light high pressure conditions to avoid any diffusion of ethylene oxide. They are located outside of the isolated measuring station for short		

monitoring tours and sampling only. Each of these processes takes no longer than 5-10 minutes and never exceeds a total of 2 hours per day. The industrial facility has a thorough training program for employees to practice the appropriate work process and monitoring.		
Conditions and measures related to personal protection, hygiene and health evaluation		
When workers are located outside of the isolated measuring station during monitoring, they wear overalls, helmets, goggles and safety shoes. Additionally, workers wear portable gas sensors. During sampling, they wear overalls, helmets, face shields, ethylene oxide resistant and impermeable gloves (e.g. butyl rubber), safety shoes and portable gas sensors.		
1.1.1.2.2. Control of workers exposure for PROC 2 and PROC 3		
Title information related to contributing scenario		
Workers related free short title	Use in closed, continuous process with occasional controlled exposure (e.g. sampling) or use in closed batch process	
Use descriptor covered	PROC 2 and PROC 3	
Processes, tasks, activities covered	Continuous process but where the design philosophy is not specifically aimed at minimizing emissions. Occasional exposure will arise e.g. through maintenance or sampling; Batch manufacture of a chemical or formulation where the predominant handling is in a contained manner, but where some opportunity for contact with chemicals occurs (e.g. through sampling)	
Assessment values	measured values *	
Product characteristic		
Physical state	gaseous	
Concentration of substance	100%	
Amounts used		
Not relevant		
Frequency and duration of use/exposure		
Duration of exposure	< =2 hours	per day
Frequency of exposure	≤ 240	days/year
Human factors not influenced by risk management		
Not relevant		
Other given operational conditions affecting workers exposure		
Location	Inside or Outside	
Domain	Industrial	
Technical conditions and measures at process level (source) to prevent release		
Processes take place in a high integrity contained and monitored system.		
Technical conditions and measures to control dispersion from source towards the worker		
Each facility is fully equipped with gas sensor heads to detect gas leakage. In case of leakage this system is connected to a water sprinkler system to avoid volatilization of the gaseous phase. Pumps and sampling stations are additionally isolated with a circumfluent water film.		
Organisational measures to prevent /limit releases, dispersion and exposure		
Workers are located outside of the isolated measuring station for short monitoring and maintenance tours only. Pumps and equipment are regularly checked for monitoring purpose and samples are taken from the circumfluent water film of the pumps on first indication of potential leakages. Each of these processes takes no longer than 5-10 minutes and never exceeds a total of 2 hours per day. The industrial facility has a thorough training program for employees to practice the appropriate work process and monitoring.		
Conditions and measures related to personal protection, hygiene and health evaluation		
When workers are located outside of the isolated measuring station during monitoring, they wear overalls, helmets, goggles and safety shoes. Additionally, workers wear portable gas sensors. During maintenance, leakages and minor accidents workers use suitable respiratory protection (breathing air, full face piece), ethylene oxide resistant and impermeable gloves (e.g. butyl rubber), ethylene oxide resistant and impermeable boots (e.g. nitrile rubber) and ethylene oxide impermeable, special chemical resistant overalls (e.g. Microchem 4000 model 151) and portable gas		

sensors.		
1.1.1.2.3. Control of workers exposure for PROC 8b and PROC 9		
Title information related to contributing scenario		
Workers related free short title	Transfer of substance or preparation from/to vessels/large containers at dedicated facilities and transfer into small containers at dedicated facilities (including weighing)	
Use descriptor covered	PROC 8b and PROC 9	
Processes, tasks, activities covered	Sampling, loading, filling, transfer in dedicated facilities. Exposure to the substance and cleaning of equipment to be expected; Filling lines specifically designed to for both, capturing vapour and aerosol emissions and minimise spillage	
Assessment values	measured values *	
Product characteristic		
Physical state	gaseous	
Concentration of substance	100%	
Amounts used		
Not relevant		
Frequency and duration of use/exposure		
Duration of exposure	15 mins – 1 hours	per day
Frequency of exposure	≤ 240	days/year
Human factors not influenced by risk management		
Not relevant		
Other given operational conditions affecting workers exposure		
Location	Inside or Outside	
Domain	Industrial	
Technical conditions and measures at process level (source) to prevent release		
Processes take place in a high integrity contained and monitored system.		
Technical conditions and measures to control dispersion from source towards the worker		
Transfer to dedicated on-site facilities takes place via short pipelines in a highly contained system without workers leaving the isolated measuring stations. Each facility is fully equipped with gas sensor heads to detect gas leakage. In case of leakage this system is connected to a water sprinkler system to avoid volatilization of the gaseous phase. Pumps and sampling stations are additionally isolated with a circumfluent water film. Filling, loading and unloading of special containments (according to the pressure vessel regulation of the respective country) for transfer to destinations outside of the manufacturing facility is carried out under strictly controlled conditions following the strict regulations for the transport of ethylene oxide in pressure vessels of the respective country in Europe. The transport of ethylene oxide in bulk is subject to strict regulations within Europe. In addition, the international movement of ethylene oxide by road, rail or sea is subject to international agreements which lay down specific requirements concerning transport which are observed by all parties involved.		
Organisational measures to prevent /limit releases, dispersion and exposure		
Workers are located outside of the isolated measuring station for short loading and filling processes only. Each of these processes takes no longer than 5-10 minutes and never exceeds a total of 1 hour per day. The industrial facility has a special and thorough training program for employees to practice the appropriate work processes.		
Conditions and measures related to personal protection, hygiene and health evaluation		
When workers are located outside of the isolated measuring station for e.g. cleaning of equipment, they use suitable respiratory protection (breathing air, full face piece), chemical resistant gloves (e.g. butyl rubber), chemical resistant boots (e.g. nitrile rubber) and ethylene oxide impermeable, special chemical resistant overalls (e.g. Microchem 4000 model 151). Additionally, workers wear portable gas sensors.		

* collected during regular external audits of the facilities, conducted by the national competent authority or an independent organization (e.g. TÜV).

1.1.2. Exposure Estimation for workers / PROC 1, 2, 3, 8b, 9

Exposure assessment for systemic (inhalation) exposure was done using actual measured values from regular external audits of the facilities, conducted by the national competent authority. Therefore, no exposure calculation was performed via an exposure assessment tool. The peak value of the last 11 years measurements was taken to reflect the worst case exposure of workers: 0.69 mg/m^3.

1.2. Polymer production

1.2.1. Exposure Scenario

Table 1.3. Description of the ES

1.2.1.1. Title		
Reference number	2	
Free short title	Polymer production	
Systematic title based on use descriptor	SU 8, 9 and 3; PROC 1, 2, 3, 8b and 9; ERC 6c	
Processes, tasks, activities covered	Use of the substance in a closed process, in closed continuous processes with occasional controlled exposure or in closed batch processes including the transfer of the substance from/to vessels/large containers at dedicated facilities or to small containers (including weighing)	
Environment characteristic covered	-	
1.2.1.2. Operational conditions and risk management measures		
The technical conditions and risk management measures in EO producing and handling facilities need to be always sufficiently efficient to prevent inhalation exposure of workers in concentrations above the DMEL long term- systemic effects for workers (2.0 mg/m³). The intention should be to seek the lowest exposure at any time.		
1.2.1.2.1. Control of workers exposure for PROC 1		
Title information related to contributing scenario		
Workers related free short title	Use in closed process, no likelihood of exposure	
Use descriptor covered	PROC 1	
Processes, tasks, activities covered	Use of the substance in high integrity contained system where little potential exists for exposures, e.g. any sampling via closed loop systems	
Assessment values	measured values*	
Product characteristic		
Physical state	gaseous	
Concentration of substance	100%	
Amounts used		
Not relevant		
Frequency and duration of use/exposure		
Duration of exposure	< =2 hours	hours/day
Frequency of exposure	≤ 240	days/year
Human factors not influenced by risk management		
Not relevant		
Other given operational conditions affecting workers exposure		
Location	Inside or Outside	
Domain	Industrial	
Technical conditions and measures at process level (source) to prevent release		
Processes take place in a high integrity contained and monitored system.		
Technical conditions and measures to control dispersion from source towards the worker		
Sampling takes place in a closed loop system. Samples are taken in steel drums, loaded in a closed process and directly sent to the laboratory. Each facility is fully equipped with gas sensor heads to detect gas leakage. In case of leakage this system is connected to a water sprinkler system to avoid volatilization of the gaseous phase. Pumps and sampling stations are additionally isolated with a circumfluent water film.		
Organisational measures to prevent /limit releases, dispersion and exposure		
Workers are located in isolated measuring stations with light high pressure conditions to avoid any diffusion of ethylene oxide. They are located outside of the isolated measuring station for short		

monitoring tours and sampling only. Each of these processes takes no longer than 5-10 minutes and never exceeds a total of 2 hours per day. The industrial facility has a thorough training program for employees to practice the appropriate work process and monitoring.		
Conditions and measures related to personal protection, hygiene and health evaluation		
When workers are located outside of the isolated measuring station during monitoring, they wear overalls, helmets, goggles and safety shoes. Additionally, workers wear portable gas sensors. During sampling, they wear overalls, helmets, face shields, ethylene oxide resistant and impermeable gloves (e.g. butyl rubber), safety shoes and portable gas sensors.		
1.2.1.2.2. Control of workers exposure for PROC 2 and PROC 3		
Title information related to contributing scenario		
Workers related free short title	Use in closed, continuous process with occasional controlled exposure (e.g. sampling) or use in closed batch process	
Use descriptor covered	PROC 2 and PROC 3	
Processes, tasks, activities covered	Continuous process but where the design philosophy is not specifically aimed at minimizing emissions. Occasional exposure will arise e.g. through maintenance or sampling; Batch manufacture of a chemical or formulation where the predominant handling is in a contained manner, but where some opportunity for contact with chemicals occurs (e.g. through sampling)	
Assessment values	measured values *	
Product characteristic		
Physical state	gaseous	
Concentration of substance	100%	
Amounts used		
Not relevant		
Frequency and duration of use/exposure		
Duration of exposure	< =2 hours	per day
Frequency of exposure	≤ 240	days/year
Human factors not influenced by risk management		
Not relevant		
Other given operational conditions affecting workers exposure		
Location	Inside or Outside	
Domain	Industrial	
Technical conditions and measures at process level (source) to prevent release		
Processes take place in a high integrity contained and monitored system.		
Technical conditions and measures to control dispersion from source towards the worker		
Each facility is fully equipped with gas sensor heads to detect gas leakage. In case of leakage this system is connected to a water sprinkler system to avoid volatilization of the gaseous phase. Pumps and sampling stations are additionally isolated with a circumfluent water film.		
Organisational measures to prevent /limit releases, dispersion and exposure		
Workers are located outside of the isolated measuring station for short monitoring and maintenance tours only. Pumps and equipment are regularly checked for monitoring purpose and samples are taken from the circumfluent water film of the pumps on first indication of potential leakages. Each of these processes takes no longer than 5-10 minutes and never exceeds a total of 2 hours per day. The industrial facility has a thorough training program for employees to practice the appropriate work process and monitoring.		
Conditions and measures related to personal protection, hygiene and health evaluation		
When workers are located outside of the isolated measuring station during monitoring, they wear overalls, helmets, goggles and safety shoes. Additionally, workers wear portable gas sensors. During maintenance, leakages and minor accidents workers use suitable respiratory protection (breathing air, full face piece), ethylene oxide resistant and impermeable gloves (e.g. butyl rubber), ethylene oxide resistant and impermeable boots (e.g. nitrile rubber) and ethylene oxide impermeable, special chemical resistant overalls (e.g. Microchem 4000 model 151) and portable gas		

sensors.		
1.2.1.2.3. Control of workers exposure for PROC 8b and PROC 9		
Title information related to contributing scenario		
Workers related free short title	Transfer of substance or preparation from/to vessels/large containers at dedicated facilities and transfer into small containers at dedicated facilities (including weighing)	
Use descriptor covered	PROC 8b and PROC 9	
Processes, tasks, activities covered	Sampling, loading, filling, transfer in dedicated facilities. Exposure to the substance and cleaning of equipment to be expected; Filling lines specifically designed to for both, capturing vapour and aerosol emissions and minimise spillage	
Assessment values	measured values *	
Product characteristic		
Physical state	gaseous	
Concentration of substance	100%	
Amounts used		
Not relevant		
Frequency and duration of use/exposure		
Duration of exposure	15 mins – 1 hours	per day
Frequency of exposure	≤ 240	days/year
Human factors not influenced by risk management		
Not relevant		
Other given operational conditions affecting workers exposure		
Location	Inside or Outside	
Domain	Industrial	
Technical conditions and measures at process level (source) to prevent release		
Processes take place in a high integrity contained and monitored system.		
Technical conditions and measures to control dispersion from source towards the worker		
Transfer to dedicated on-site facilities takes place via short pipelines in a highly contained system without workers leaving the isolated measuring stations. Each facility is fully equipped with gas sensor heads to detect gas leakage. In case of leakage this system is connected to a water sprinkler system to avoid volatilization of the gaseous phase. Pumps and sampling stations are additionally isolated with a circumfluent water film. Filling, loading and unloading of special containments (according to the pressure vessel regulation of the respective country) for transfer to destinations outside of the manufacturing facility is carried out under strictly controlled conditions following the strict regulations for the transport of ethylene oxide in pressure vessels of the respective country in Europe. The transport of ethylene oxide in bulk is subject to strict regulations within Europe. In addition, the international movement of ethylene oxide by road, rail or sea is subject to international agreements which lay down specific requirements concerning transport which are observed by all parties involved.		
Organisational measures to prevent /limit releases, dispersion and exposure		
Workers are located outside of the isolated measuring station for short loading and filling processes only. Each of these processes takes no longer than 5-10 minutes and never exceeds a total of 1 hour per day. The industrial facility has a special and thorough training program for employees to practice the appropriate work processes.		
Conditions and measures related to personal protection, hygiene and health evaluation		
When workers are located outside of the isolated measuring station for e.g. cleaning of equipment, they use suitable respiratory protection (breathing air, full face piece), chemical resistant gloves (e.g. butyl rubber), chemical resistant boots (e.g. nitrile rubber) and ethylene oxide impermeable, special chemical resistant overalls (e.g. Microchem 4000 model 151). Additionally, workers wear portable gas sensors.		

* collected during regular external audits of the facilities, conducted by the national competent authority or independent organization (e.g. TÜV).

1.2.2. Exposure Estimation

Exposure assessment for systemic (inhalation) exposure was done using actual measured values from regular external audits of the facilities, conducted by the national competent authority. Therefore, no exposure calculation was performed via an exposure assessment tool. The peak value of the last 11 years measurements was taken to reflect the worst case exposure of workers: 0.69 mg/m^3.

1.3. Use as an intermediate

1.3.1. Exposure Scenario

Table 1.4. Description of the ES

1.3.1.1. Title		
Reference number	3	
Free short title	Use as an intermediate	
Systematic title based on use descriptor	SU 8, 9 and 3; PROC 1, 2, 3, 8b and 9; ERC 6a	
Processes, tasks, activities covered	Use of the substance in a closed process, in closed continuous processes with occasional controlled exposure or in closed batch processes including the transfer of the substance from/to vessels/large containers at dedicated facilities or to small containers (including weighing)	
Environment characteristic covered	-	
1.3.1.2. Operational conditions and risk management measures		
The technical conditions and risk management measures in EO producing and handling facilities need to be always sufficiently efficient to prevent inhalation exposure of workers in concentrations above the DMEL long term- systemic effects for workers (2.0 mg/m³). The intention should be to seek the lowest exposure at any time.		
1.3.1.2.1. Control of workers exposure for PROC 1		
Title information related to contributing scenario		
Workers related free short title	Use in closed process, no likelihood of exposure	
Use descriptor covered	PROC 1	
Processes, tasks, activities covered	Use of the substance in high integrity contained system where little potential exists for exposures, e.g. any sampling via closed loop systems	
Assessment values	measured values *	
Product characteristic		
Physical state	gaseous	
Concentration of substance	100%	
Amounts used		
Not relevant		
Frequency and duration of use/exposure		
Duration of exposure	< =2 hours	hours/day
Frequency of exposure	≤ 240	days/year
Human factors not influenced by risk management		
Not relevant		
Other given operational conditions affecting workers exposure		
Location	Inside or Outside	
Domain	Industrial	
Technical conditions and measures at process level (source) to prevent release		
Processes take place in a high integrity contained and monitored system.		
Technical conditions and measures to control dispersion from source towards the worker		
Sampling takes place in a closed loop system. Samples are taken in steel drums, loaded in a closed process and directly sent to the laboratory. Each facility is fully equipped with gas sensor heads to detect gas leakage. In case of leakage this system is connected to a water sprinkler system to avoid volatilization of the gaseous phase. Pumps and sampling stations are additionally isolated with a circumfluent water film.		
Organisational measures to prevent /limit releases, dispersion and exposure		
Workers are located in isolated measuring stations with light high pressure conditions to avoid any diffusion of ethylene oxide. They are located outside of the isolated measuring station for short		

monitoring tours and sampling only. Each of these processes takes no longer than 5-10 minutes and never exceeds a total of 2 hours per day. The industrial facility has a thorough training program for employees to practice the appropriate work process and monitoring.		
Conditions and measures related to personal protection, hygiene and health evaluation		
When workers are located outside of the isolated measuring station during monitoring, they wear overalls, helmets, goggles and safety shoes. Additionally, workers wear portable gas sensors. During sampling, they wear overalls, helmets, face shields, ethylene oxide resistant and impermeable gloves (e.g. butyl rubber), safety shoes and portable gas sensors.		
1.3.1.2.2. Control of workers exposure for PROC 2 and PROC 3		
Title information related to contributing scenario		
Workers related free short title	Use in closed, continuous process with occasional controlled exposure (e.g. sampling) or use in closed batch process	
Use descriptor covered	PROC 2 and PROC 3	
Processes, tasks, activities covered	Continuous process but where the design philosophy is not specifically aimed at minimizing emissions. Occasional exposure will arise e.g. through maintenance or sampling; Batch manufacture of a chemical or formulation where the predominant handling is in a contained manner, but where some opportunity for contact with chemicals occurs (e.g. through sampling)	
Assessment values	measured values *	
Product characteristic		
Physical state	gaseous	
Concentration of substance	100%	
Amounts used		
Not relevant		
Frequency and duration of use/exposure		
Duration of exposure	< =2 hours	per day
Frequency of exposure	≤ 240	days/year
Human factors not influenced by risk management		
Not relevant		
Other given operational conditions affecting workers exposure		
Location	Inside or Outside	
Domain	Industrial	
Technical conditions and measures at process level (source) to prevent release		
Processes take place in a high integrity contained and monitored system.		
Technical conditions and measures to control dispersion from source towards the worker		
Each facility is fully equipped with gas sensor heads to detect gas leakage. In case of leakage this system is connected to a water sprinkler system to avoid volatilization of the gaseous phase. Pumps and sampling stations are additionally isolated with a circumfluent water film.		
Organisational measures to prevent /limit releases, dispersion and exposure		
Workers are located outside of the isolated measuring station for short monitoring and maintenance tours only. Pumps and equipment are regularly checked for monitoring purpose and samples are taken from the circumfluent water film of the pumps on first indication of potential leakages. Each of these processes takes no longer than 5-10 minutes and never exceeds a total of 2 hours per day. The industrial facility has a thorough training program for employees to practice the appropriate work process and monitoring.		
Conditions and measures related to personal protection, hygiene and health evaluation		
When workers are located outside of the isolated measuring station during monitoring, they wear overalls, helmets, goggles and safety shoes. Additionally, workers wear portable gas sensors. During maintenance, leakages and minor accidents workers use suitable respiratory protection (breathing air, full face piece), ethylene oxide resistant and impermeable gloves (e.g. butyl rubber), ethylene oxide resistant and impermeable boots (e.g. nitrile rubber) and ethylene oxide impermeable, special chemical resistant overalls (e.g. Microchem 4000 model 151) and portable gas		

sensors.		
1.3.1.2.3. Control of workers exposure for PROC 8b and PROC 9		
Title information related to contributing scenario		
Workers related free short title	Transfer of substance or preparation from/to vessels/large containers at dedicated facilities and transfer into small containers at dedicated facilities (including weighing)	
Use descriptor covered	PROC 8b and PROC 9	
Processes, tasks, activities covered	Sampling, loading, filling, transfer in dedicated facilities. Exposure to the substance and cleaning of equipment to be expected; Filling lines specifically designed to for both, capturing vapour and aerosol emissions and minimise spillage	
Assessment values	measured values *	
Product characteristic		
Physical state	gaseous	
Concentration of substance	100%	
Amounts used		
Not relevant		
Frequency and duration of use/exposure		
Duration of exposure	15 mins – 1 hours	per day
Frequency of exposure	≤ 240	days/year
Human factors not influenced by risk management		
Not relevant		
Other given operational conditions affecting workers exposure		
Location	Inside or Outside	
Domain	Industrial	
Technical conditions and measures at process level (source) to prevent release		
Processes take place in a high integrity contained and monitored system.		
Technical conditions and measures to control dispersion from source towards the worker		
Transfer to dedicated on-site facilities takes place via short pipelines in a highly contained system without workers leaving the isolated measuring stations. Each facility is fully equipped with gas sensor heads to detect gas leakage. In case of leakage this system is connected to a water sprinkler system to avoid volatilization of the gaseous phase. Pumps and sampling stations are additionally isolated with a circumfluent water film. Filling, loading and unloading of special containments (according to the pressure vessel regulation of the respective country) for transfer to destinations outside of the manufacturing facility is carried out under strictly controlled conditions following the strict regulations for the transport of ethylene oxide in pressure vessels of the respective country in Europe. The transport of ethylene oxide in bulk is subject to strict regulations within Europe. In addition, the international movement of ethylene oxide by road, rail or sea is subject to international agreements which lay down specific requirements concerning transport which are observed by all parties involved.		
Organisational measures to prevent /limit releases, dispersion and exposure		
Workers are located outside of the isolated measuring station for short loading and filling processes only. Each of these processes takes no longer than 5-10 minutes and never exceeds a total of 1 hour per day. The industrial facility has a special and thorough training program for employees to practice the appropriate work processes.		
Conditions and measures related to personal protection, hygiene and health evaluation		
When workers are located outside of the isolated measuring station for e.g. cleaning of equipment, they use suitable respiratory protection (breathing air, full face piece), chemical resistant gloves (e.g. butyl rubber), chemical resistant boots (e.g. nitrile rubber) and ethylene oxide impermeable, special chemical resistant overalls (e.g. Microchem 4000 model 151). Additionally, workers wear portable gas sensors.		

* collected during regular external audits of the facilities, conducted by the national competent authority or an independent organization (e.g. TÜV).

1.3.2. Exposure Estimation

Exposure assessment for systemic (inhalation) exposure was done using actual measured values from regular external audits of the facilities, conducted by the national competent authority. Therefore, no exposure calculation was performed via an exposure assessment tool. The peak value of the last 11 years measurements was taken to reflect the worst case exposure of workers: 0.69 mg/m^3.

1.4. Use as laboratory reagent

1.4.1. Exposure Scenario

Table 1.5. Description of the ES

1.4.1.1. Title		
Reference number	4	
Free short title	Use as a laboratory reagent	
Systematic title based on use descriptor	SU 3 and 22; PROC 15; ERC 1	
Processes, tasks, activities covered	Use of substances at small scale laboratory (< 1 l or 1 kg present at workplace).	
Environment characteristic covered	-	
1.4.1.2. Operational conditions and risk management measures		
1.4.1.2.1. Control of workers exposure for PROC 15		
Title information related to contributing scenario		
Workers related free short title	Use as a laboratory reagent	
Use descriptor covered	PROC 15	
Processes, tasks, activities covered	Use of substances at small scale laboratory (< 1 l or 1 kg present at workplace).	
Assessment Method	ECETOC TRA Worker v2.0 with modifications [1]	
Product characteristic		
Physical state	gaseous	
Concentration of substance	100%	
Amounts used		
Not relevant		
Frequency and duration of use/exposure		
Duration of exposure	15min - 1h	Per day
Frequency of exposure	≤ 240	days/year
Human factors not influenced by risk management		
Not relevant		
Other given operational conditions affecting workers exposure		
Location	Inside	
Domain	Industrial and Professional	
Technical conditions and measures at process level (source) to prevent release		
Ethylene oxide is stored in highly contained vessels at any time.		
Technical conditions and measures to control dispersion from source towards the worker		
Appropriate local exhaust ventilation: Effectiveness: 99%		
Organisational measures to prevent /limit releases, dispersion and exposure		
Laboratories have a thorough training program for employees for the appropriate handling of ethylene oxide.		
Conditions and measures related to personal protection, hygiene and health evaluation		
Use of suitable respiratory protection: Effectiveness: 97.5% (full face shield) Use of ethylene oxide impermeable gloves (e.g. butyl rubber)		

[1] Respiratory protection: another effectiveness value was applied

1.4.2. Exposure Estimation

Table 1.6. Estimated exposure for workers / PROC 15

Route of exposure	Concentrations		Justification
	Value	Unit	
Long-term exposure, systemic, inhalative	0.05	mg/m³	
Short-term exposure, systemic, inhalative	0.91	mg/m^3	

2. RISK CHARACTERISATION

General remarks

The technical conditions and risk management measures in EO producing and handling facilities should always be sufficiently efficient to prevent exposure of the workers in concentrations above the DMEL. The intention should be to seek the lowest exposure at any time. Therefore, it can be assumed that a qualitative description of the exposure scenarios is sufficient to ensure that exposure concentrations are at least below the DMEL and the RCR will never be > 1.

Human Health – Worker
Risk characterization for local inhalative effects:
As discussed in the hazard assessment, ethylene oxide does not exert local irritation at concentrations below exerting systemic toxicity including carcinogenicity. The proposed DNEL is therefore a systemic DNEL, however considered to be protective also from local toxicity. Thus the exposure scenarios described by actual measured values (resulting in a RCR < 1: measured values vs. systemic DNELs) also cover local effects.

Human health – Worker and Consumer
The risk characterization covers the life cycle of the substance (monomer) until the polymerization reaction. The unreacted residual monomer in a polymer is to be regarded as impurity that need not be critically addressed in the exposure assessment. Also covered is the life cycle of the substance as an intermediate until the respective chemical reaction and finally distillation of the product.

Environment
In the chemical safety assessment performed according to Article 14(3) in connection with Annex I section 3 (Environmental Hazard Assessment) and PBT/ vPvB Assessment no hazard was identified. Therefore according to REACH Annex I (5.0) an exposure estimation and risk characterization is not necessary. Consequently all identified uses of the substance are assessed as safe for the environment.

Ethylene oxide is only used as an intermediate or as a monomer in polymer production. Both uses are performed in closed systems and under strictly controlled conditions. Unintended releases into the environment are hence not to be expected. Additionally, regular external audits of the facilities, conducted by the national competent authority of the respective country in Europe or an independent organization, ensure that the measured values of air around the highly contained facilities do not exceed the legally permitted thresholds. Therefore, environmental exposure is negligible.

2.1. Manufacture and distribution of the substance

2.1.1. Human Health

2.1.1.1. Workers

Table 2.1. RCRs Worker / PROC 1, 2, 3, 8b, 9

Exposure	Exposure estimate	DMEL	RCR per route	Safe use
Long-term exposure, systemic, inhalative	0.69 mg/m³	2.0 mg/m³	0.345	yes
Short-term exposure, systemic, inhalative	2.76 mg/m³	10.0 mg/m³	0.276	yes

2.1.1.2. Consumers

Not relevant.

2.1.1.3. Indirect exposure to humans via the environment

Ethylene oxide is a reactive chemical and typically employed as a building block in chemical synthesis, usually in closed systems and under strictly controlled conditions. Air measurements in the immediate environment of such plants have not shown detectable amounts of ethylene oxide. Furthermore, ethylene oxide is not considered to be bioaccumulative and is readily biodegradable (see also Chapter 1, General remarks, Environment). Therefore, an indirect environmental exposure of humans from technical processes in chemical industry is highly unlikely.
On the other hand, there is some background exposure to ethylene from environmental sources such as traffic emissions and edible plants and this is endogeneously oxidized to ethylene oxide by living systems including man. This unavoidable exposure to ethylene and endogeneous ethylene oxide appears to the source for the spontaneous background level of hydroxyethyl adducts in DNA and proteins. The present standard of DNA adduct analysis indicates a spontaneous rate of hydroxylation as would be obtained from an air borne exposure to 0.1 ppm ethylene oxide. Therefore, endogeneous hydroxyethylation from spontaneous and environmental ethylene exposure by far exceeds any environmental impact of industrial production and use of ethylene oxide.

2.1.2. Environment

2.1.2.1. Aquatic Compartment (incl. Sediment)

See chapter 1 and 2, General remarks

2.1.2.2. Terrestrial Compartment

See chapter 1 and 2, General remarks

2.1.2.3. Atmospheric Compartment

See chapter 1 and 2, General remarks

2.1.2.4. Microbiological Activity in Sewage Treatment Systems

See chapter 1 and 2, General remarks

2.2. Polymer production

2.2.1. Human Health

2.2.1.1. Workers

Table 2.2. RCRs Worker / PROC 1, 2, 3, 8b, 9

Exposure	Exposure estimate	DMEL	RCR per route	Safe use
Long-term exposure, systemic, inhalative	0.69 mg/m³	2.0 mg/m³	0.345	yes
Short-term exposure, systemic, inhalative	2.76 mg/m³	10.0 mg/m³	0.276	yes

2.2.1.2. Consumers

Not relevant

2.2.1.3. Indirect exposure to humans via the environment

See 2.1.1.3

2.2.2. Environment

2.2.2.1. Aquatic Compartment (incl. Sediment)

See chapter 1 and 2, General remarks

2.2.2.2. Terrestrial Compartment

See chapter 1 and 2, General remarks

2.2.2.3. Atmospheric Compartment

See chapter 1 and 2, General remarks

2.2.2.4. Microbiological Activity in Sewage Treatment Systems

See chapter 1 and 2, General remarks

2.3. Use as an intermediate

2.3.1. Human Health

2.3.1.1. Workers

Table 2.3. RCRs Worker / PROC 1, 2, 3, 8b, 9

Exposure	Exposure estimate	DMEL	RCR per route	Safe use
Long-term exposure, systemic, inhalative	0.69 mg/m³	2.0 mg/m³	0.345	yes
Short-term exposure, systemic, inhalative	2.76 mg/m³	10.0 mg/m³	0.276	yes

2.3.1.2. Consumers

Not relevant

2.3.1.3. Indirect exposure to humans via the environment

See 2.1.1.3

2.3.2. Environment

2.3.2.1. Aquatic Compartment (incl. Sediment)

See chapter 1 and 2, General remarks

2.3.2.2. Terrestrial Compartment

See chapter 1 and 2, General remarks

2.3.2.3. Atmospheric Compartment

See chapter 1 and 2, General remarks

2.3.2.4. Microbiological Activity in Sewage Treatment Systems

See chapter 1 and 2, General remarks

2.4. Use as laboratory reagent

2.4.1. Human Health

2.4.1.1. Workers

Table 2.4. RCRs Worker / PROC 15

Exposure	Exposure estimate	DMEL	RCR per route	Safe use
Long-term exposure, systemic, inhalative	0.05	2.0 mg/m³	0.025	yes
Short-term exposure, systemic, inhalative	0.91	10.0 mg/m³	0.091	yes

2.4.1.2. Consumers

Not relevant

2.4.1.3. Indirect exposure to humans via the environment

See 2.1.1.3

2.4.2. Environment

2.4.2.1. Aquatic Compartment (incl. Sediment)

See chapter 1 and 2, General remarks

2.4.2.2. Terrestrial Compartment

See chapter 1 and 2, General remarks

2.4.2.3. Atmospheric Compartment

See chapter 1 and 2, General remarks

2.4.2.4. Microbiological Activity in Sewage Treatment Systems

See chapter 1 and 2, General remarks

2.5. Overall exposure (combined for all relevant emission /release sources)

2.5.1 Human health (combined for all exposure routes)

The consideration of an overall exposure is considered to be not relevant since none of the PROCs calculated has a RCR close to 1. Furthermore, the general population is not exposed towards ethylene oxide via consumer products.

2.5.2 Environment (combined for all emission sources)

See chapter 1 and 2, General remarks