

CHEMICAL SAFETY REPORT

7 December 2015

PUBLIC VERSION

Authorisation application: Industrial use as a recyclable solvent and extraction agent in a closed system for purification of 1,3,5-trioxane

Substance Name: 1,2-dichloroethane

EC Number: 203-458-1

CAS Number: 107-06-2

Registrant's Identity: BASF SE

9 EXPOSURE ASSESSMENT

9.0 Introduction

9.0.1 Overview of uses and Exposure Scenarios

BASF produces the polymer polyoxymethylene (POM) (trade name Ultraform®) at its site in Ludwigshafen, Germany. This is an integrated process involving production of formaldehyde from methanol, followed by conversion of formaldehyde to yield 1,3,5-trioxane (“trioxane”).

High-purity trioxane monomer is necessary to ensure an efficient polymerisation reaction and EDC is used in two parallel plants, both of which are within the Ultraform® facility at Ludwigshafen. EDC is used in a **closed system**, being delivered from a central storage tank via pipeline into the plant’s closed extraction / distillation system.

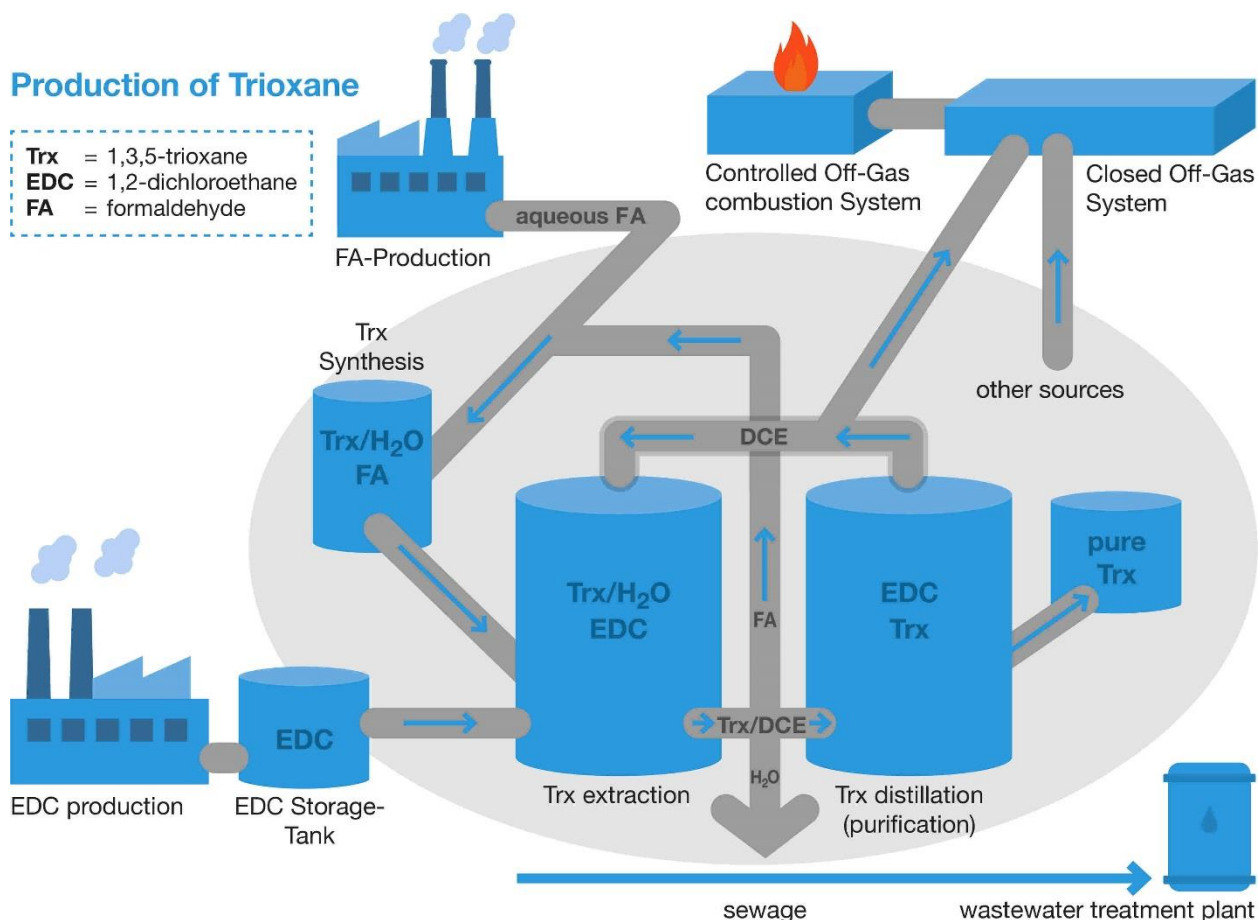
After synthesis, trioxane is solved in water. Because these two substances form an azeotrope, they cannot be separated by simple distillation. Thus, an extraction step is used to transfer trioxane into a solvent which results in a non-azeotropic mixture. In BASF’s process, EDC is this extraction solvent.

In a second step, a distillation process is then applied to extract pure (>99%) trioxane, while the EDC is recycled to the extraction phase.

POM polymerisation is the main purpose of trioxane production at BASF. However, a small proportion of the annual production volume of trioxane – [Claim #1] – is sold as a chemical intermediate (for industrial production of chemicals). As EDC is not present in trioxane (the concentration is below 1 ppm) this minor use is not discussed further here.

Approximately 60 tonnes of EDC needs to be replaced annually, resulting from losses to the closed off-gas incineration system, as well as loss through reaction with sodium hydroxide which is used as a neutralisation agent in the process (details of the apportionment of this 60 tonnes is provided in Appendix F). The total inventory of EDC on site at any one time is around [Claim #1] tonnes.

EDC is recirculated in the plant. The capacity of the trioxane plants adds up to [Claim #1] tonnes trioxane per year. Therefore, the feed to the extraction towers of the plant is also [Claim #1] tonnes per year. This leads to a recycling rate of 780 [Claim #1] i.e. EDC is effectively ‘used’ 780 times. The recirculation rate for EDC in the plant is around 8 tonnes per hour. There are two trioxane monomer plants within the Ultraform® plant. These plants operate in parallel about 11 months per year each. While one plant is down for three weeks to one month each year for maintenance and repair (one plant in spring, one plant in autumn), the other plant continues to operate. The figure below provides an illustration of the trioxane purification process in which EDC is used.

Figure 1: Simplified schematic illustrating use of EDC in trioxane purification


EDC is used in a closed system that is highly automated. Fugitive emissions are minimised through testing the integrity of the system at the start of each production run (i.e. once per year), using water (instead of EDC-containing product-streams) and visual inspection to identify any leaks. Visual inspections are undertaken each day. Transportation within the plant is done through closed pipelines. During storage in tanks, nitrogen is used as an inert blanketing substance, to prevent generation of an explosive atmosphere. The storage tank is double-walled with a vacuum in the space between the walls, the pressure of which is monitored online to confirm that it is airtight. There is a closed connection from the storage tank to the plant off-gas extraction/incineration system which ensures that any EDC released through vaporisation is destroyed.

EDC is used because it forms a non-azeotropic mixture with trioxane; trace impurities in trioxane do not hamper the polymerisation process; and its vapour pressure, melting point and partition coefficients make the whole process, including extraction, efficient.

Purified trioxane is >99% pure, with a range of different impurities, of which EDC is one (present in trioxane below 1 ppm). Because EDC is present in trioxane only in trace quantities, the only hazard of the substance is related to trioxane itself, and not to the presence of EDC.

EDC is present in only trace quantities in the POM polymer (<10 ppb) which leaves the Ultraform® plant, so subsequent use of EDC is not relevant for this authorisation application.

EDC use is only in an industrial process, with no subsequent use by professionals or consumers.

Key risk management measures applied include: use of a closed system; an additional 'leak-free' system for taking samples; fume cupboards/hoods for laboratory sampling; personal protective equipment including respiratory protective equipment during maintenance/repair (full protection suit); and a closed off-gas incineration system which results in complete destruction of EDC before venting to atmosphere. Further details of risk management measures applied are provided in the following sections.

The process is considered to be 'closed' by BASF in that there is no realistic potential for exposure of workers, other than when opening the system for sampling/maintenance, or in relation to wastes arising from the process (which are treated and incinerated on site). The plant does, for example, include several flanged joints in the pipework through which there is theoretically the potential for exposure. In line with TA Luft (BMUB, 2002)) (section 5.2.6.3), the flanged joints are type approved to ensure a specific leakage ratio of no more than 10^{-5} kPa•l/(s•m). BASF has

calculated that the leakage rate from the equipment is no more than 3kg per year (see Appendix A). In practice, this is considered to be negligible in terms of worker exposure and exposure of man via the environment.

Tonnage information:

Assessed tonnage: 60 tonnes per year (confidential average annual tonnage for the use)

Annual tonnage band for use 1: 10-100 tonnes per year

Approximately 60 tonnes of EDC needs to be replaced annually, resulting from losses to the closed off-gas incineration system, as well as loss through reaction with sodium hydroxide which is used as a neutralisation agent in the process. The total inventory of EDC on the Ultraform® plant at any one time is in the range of [Claim #1] tonnes.

The Ultraform® plant operates at close to capacity. Therefore, the quantity of EDC used is not expected to increase in the future. Likewise, the quantity is not expected to decrease because of the need to maintain production near to capacity for commercial reasons (discussed further in the SEA).

The following table lists all the exposure scenarios (ES) assessed in this CSR. There is one exposure scenario and four contributing scenarios, which have been identified by BASF's environment, health and safety specialists.

Potential exposure to EDC in the trioxane product (and hence in the POM polymer) is excluded. EDC cannot be detected in the final POM product (detection limit of 10 ppb).

Table 4: Overview of exposure scenarios and contributing scenarios

Identifiers	Market Sector	Titles of exposure scenarios and the related contributing scenarios	Tonnage (tonnes per year)
I-1	PC40	Industrial use as a recyclable solvent and extraction agent in a closed system for purification of 1,3,5-trioxane	60
I-1a		Sample collection (contributing scenario)	
I-1b		Laboratory use (contributing scenario)	
I-1c		Maintenance/repair (contributing scenario)	
I-1d		Exposure via off-gas incineration system (contributing scenario)	

9.0.2 Introduction to the assessment

9.0.2.1 Environment

Scope and type of assessment:

Exposure assessment and risk characterisation for the environment are not needed. The scope of this authorisation CSR relates to the intrinsic properties of EDC as specified in Annex XIV of the REACH Regulation i.e. carcinogenicity (category 1B).

As set out in the Registration CSR, in the chemical safety assessment performed according to Article 14(3) in connection with Annex I section 3 (Environmental Hazard Assessment) and section 4 (PBT/ vPvB Assessment) no hazard was identified. Therefore according to REACH Annex I (5.0) an exposure estimation and risk characterisation is not necessary. Consequently all identified uses of the substance are assessed as safe for the environment.

Table 5: Type of risk characterisation required for the environment

Protection target	Type of risk characterisation	Hazard conclusion (see section 7)
Freshwater	Not needed	
Sediment (freshwater)	Not needed	
Marine water	Not needed	
Sediment (marine water)	Not needed	
Sewage treatment plant	Not needed	

Protection target	Type of risk characterisation	Hazard conclusion (see section 7)
Air	Not needed	
Agricultural soil	Not needed	
Predator	Not needed	

Comments on assessment approach:

Not assessed.

9.0.2.2 Man via environment

Scope and type of assessment:

Exposure and risk characterisation for ‘man via the environment’ has been undertaken in quantitative terms for potential exposure via atmosphere, while exposure via the water environment is also considered qualitatively. The theoretical potential routes of exposure are:

- Exposure of the general population through releases from the plant to atmosphere.
- Exposure of the general population through releases from the plant to waste water.

Exposure via atmosphere – incinerator efficiency

In relation to releases to *atmosphere*, the trioxane and POM plant are connected to waste gas incineration system (off-gas combustion system). This incinerator was specifically designed for destruction of low-boiling chemicals present, including EDC. Although EDC has not (yet) been directly measured in the exhaust air of the incinerator, based on the following analysis, BASF concludes that the amount of substance which could in theory escape the incineration process is expected to be very low.

All apparatus on the plant is connected to the (closed) incineration system. Following incineration at 1000°C, HCl is generated from the EDC, which can be detected using pH as a proxy (H⁺ and Cl⁻ equivalent). Using a mass balance approach, BASF have used this proxy relationship to estimate the amount passed to the incinerator each year as around 50-60 tonnes, which is comparable to the quantity of EDC added to the plant each year. The incinerator includes a washing plant, and a steam boiler. The steam from the boiler is used in the plant.

EDC has a self-ignition temperature of 440°C, which is substantially lower than the waste gas incineration temperature, ensuring complete combustion/destruction of EDC in the gases released from the incinerator. US EPA (2002) provides an illustration of the effectiveness of this incineration process, indicating that the theoretical destruction of EDC is 99.99% for incineration with a 1s residence time at 742°C (1368°F). The higher temperature and longer residence time for BASF’s incinerator provides further assurance that the EDC will be destroyed.

Ongoing effective destruction of EDC is achieved in the incinerator through use of a programmable logic controller to keep key operating conditions within their given limiting values. Every violation of the limiting values causes an alarm and is documented, with key parameters such as temperature continuously monitored in the control room. If either the temperature or the volume flow to the incinerator drop below their defined operating range, the plant switches over to a standby mode where no EDC containing fuel is consumed. Other parameters are monitored continuously, such as pressure difference between exhaust gas inlet and the combustion chamber; pH of the water from the absorption tower; and amount of fluid fuel (containing EDC), which is measured using a mass flow meter.

Based on the consumption (replenishment rate) of 60 tonnes per year, the maximum amount which could escape through the incinerator is estimated as 6 kg per year based on the value from the US EPA study.

Although BASF has not yet measured EDC emissions directly from the incinerator, the amount released can be estimated based on the measurement of ‘other carbon’, which is undertaken. The exhaust gases of the incinerator are regularly characterised to ensure proper operation of the incinerator and efficient destruction of the exhaust gases. Organic compounds are measured at the exhaust using a flame ionisation detector (FID) as ‘total carbon’. The ‘low-boiling chemicals mixture’, which ultimately acts as a fuel for the incinerator, contains on average 0.122 % EDC. Assuming that all organic compounds are equally efficiently incinerated, it was estimated that the total amount of EDC released is no more than 0.13kg per year¹. This is the value used in the analysis.

¹ Total carbon in the exhaust gas is below 0.2 mg/m³. As a worst case, it is assumed that the total carbon in the exhaust gas will be exactly 0.2 mg/m³. Exhaust gas flow (standard state) during measurement was 10,000 m³/h. As a worst case, we assume an exhaust gas flow of 15,000 m³/h. This indicates that there is a maximum of 3000 mg/h total carbon emitted. Since 0.122 % of the total carbon stems from EDC, an emission of 3.66 mg/h originates from EDC. This leads to 15.1 mg/h expressed as EDC (with a concentration of 0.001 mg/m³). The plant operates 24

Given that the incinerator (a) collects EDC from all of the equipment within the plant; (b) leads to effectively complete destruction of the EDC, it is concluded that any quantities released to the receiving environment will lead to only very small exposure for the surrounding population (these are expected to be negligible).

Exposure via atmosphere – concentrations in the local environment

In order to assess the potential for exposure of workers in the area surrounding the plant, as well as (potentially) the general population, two approaches have been applied:

- Modelling to estimate concentrations in the surrounding area.
- Monitoring of concentrations of EDC in the surrounding area.

In relation to *modelling*, the potential for exposure of people outside the plant via releases from the incinerator has been investigated based on modelling using ADMS 5.0 (see Appendix G²). The maximum annual average concentration at ground level is predicted to be 4.5×10^{-7} ppm (2.0×10^{-6} mg/m³), occurring around 350m from the chimney.

Using ECHA's dose-response relationship (3.45×10^{-6} per $\mu\text{g}/\text{m}^3$), the maximum potential excess cancer risk for man exposed via the environment is therefore 6.8×10^{-9} . This is clearly higher than the amount that any person could realistically be exposed to, given that this assumes that (a) emissions from the incinerator are at $1 \text{ mg}/\text{m}^3$ whereas in reality they are lower i.e. $0.001 \text{ mg}/\text{m}^3$ based on the estimate in the previous section; (b) a person is standing at the point of maximum exposure all day, every day. On this basis, exposure of man via the environment (for both BASF workers outside the plant, and for the general public), is considered to be negligible.

In order to assess the risks to workers outside the Ultraform® plant associated with releases from the incinerator, a quantitative estimate of the potential total risk to people within a 1 km^2 area around the plant. Using the modelling results from above, the *average* concentration within this 1 km^2 area is 2.2×10^{-7} ppm (9.0×10^{-7} mg/m³) (this is the annual average ground-level concentration, averaged across the whole area). This translates to an excess cancer risk of 3.1×10^{-9} over a 40 year period. The average population density of the Ludwigshafen site is estimated as 3921 per km^2 (based on 39,211 employees in 2013, and a 10 km^2 total area). Taking into account that, on average, workers will only be present for around 22% of the time over the course of a year³, the cumulative excess cancer risk across all of these people is calculated as 2.67×10^{-6} . This value is taken forward to the assessment of overall risks⁴.

Note that no estimate has been made for exposure to the general public, given that the Ultraform® plant is over 500m from the nearest residential or commercial areas.

In relation to *monitoring*, in August 2015, BASF undertook monitoring of ambient air in the surroundings of the Ultraform® plant. Measurements were taken both directly downwind of the plant, as well as at (already) established monitoring stations on the Ludwigshafen site. Samples were taken using TENAX tubes, analysed using gas chromatography.

Firstly, measurements were taken at 500m and 800m downwind of the plant (2 samples each), based on the actual wind direction on the day (as well as a sample upwind). The sampling time was 25 minutes. All measurements were below the limit of detection of the equipment, which in this case was $0.06 \mu\text{g}/\text{m}^3$ ($60 \text{ ng}/\text{m}^3$).

hours a day and 365 days a year, so this translates to 132,254 mg/year or 0.132 kg/year.

² ADMS is an advanced dispersion model used to model the air quality impact of existing and proposed industrial installations. It is used extensively by industrial companies and by government regulators for modelling of air pollution dispersion and has been extensively verified (see <http://www.cerc.co.uk/environmental-software/ADMS-model.html>).

³ Assuming an average of 1920 hours worked per person, out of a total of 8760 hours in a year.

⁴ Note that this value is considered to be conservative (i.e. the actual risk will be lower), as the modelling was based on a concentration in the exhaust gas of $1 \text{ mg}/\text{m}^3$, whereas in reality the concentration is lower; furthermore, the estimate does not take into account the fact that many people will be indoors, and hence exposed to lower concentrations of EDC.

Figure 2: Location of air concentration sampling sites



6-hour samples were also taken at five established sites between 1 and 4km of the Ultraform® plant (see Appendix H). All measurements were below the limit of detection (maximum 55 ng/m³).

The above provides confirmation that there is only very low potential for exposure of workers and the general public outside the Ultraform® plant. All measurements were below the detection limit of maximum 60 ng/m³; this detection limit translates to a maximum risk level of 2.0×10^{-7} based on ECHA's dose response relationship. In reality the risks are much lower, for the reasons described above in relation to the modelling results above.

Exposure via atmosphere – fugitive emissions from the plant

As described in Section 9.0.1 above, in line with TA Luft (BMUB, 2002)) (section 5.2.6.3), the flanged joints in the plant are type approved to ensure a specific leakage ratio of no more than 10–5 kPa•l/(s•m). BASF has calculated that the leakage rate from the equipment is no more than 3kg per year based on the inventory of flange connectors and pipe system (see Appendix A).

It is important to highlight that the trioxane plant is essentially open to the atmosphere (i.e. the pipework, vessels, etc. are not located inside a building), so this quantity will be diluted to a very low concentration in the environment.

Exposure via atmosphere – conclusion

Overall, the above provides evidence that there is negligible potential for exposure to EDC via the atmosphere for people outside the plant. However, for the purposes of transparency, the calculated estimate of the excess cancer risk to people outside the plant (2.7×10^{-6} across 3921 workers, over 40 years) is taken forward to the risk characterisation, and subsequently the socio-economic analysis.

Exposure via water

In relation to releases to *water*, the potential release points are water used in the trioxane manufacturing and extraction process and water released from the incinerator. Wastewater from the extraction contains around 1% EDC. This EDC is recovered by distillation ("stripping") before being passed from the Ultraform® plant to the Ludwigshafen site wastewater treatment plant.

Using an online gas chromatography analysis system (head-space technology), the purified waste water is continuously checked for EDC contamination (about every 7 minutes an integral value of the last 7 minutes is generated). The detection limit of the analytical method applied is usually 1 ppm. In case of a failure in the distillation system the EDC-contaminated wastewater would be collected in a quarantine tank to gain time to look

for the source. (There has been no such need to use this quarantine tank due to high EDC concentrations in the last 10 years of operation).

During preparation of this authorisation application, BASF undertook additional monitoring of EDC in waste water using a method with a lower detection limit than usual. During the whole of calendar week 33 of 2015 (when the trioxane plant was in standard operation), samples of the wastewater were taken and analysed for EDC. The detection limit of the method was 0.5 µg EDC / litre wastewater. EDC was not detected in any of the samples. Based on these results, the *maximum*, amount of EDC released to water is estimated as 175 grams per year⁵, and the actual amount will be less than this because this assumes releases at the detection limit.

Furthermore, BASF is required to ensure that releases from the Ludwigshafen site comply with relevant European legislation. Specifically, the environmental quality standard for EDC under the water framework directive (WFD, Directive 2008/15/EC amending Directive 2000/60/EC) is 10 µg/l (0.01ppm) for surface waters. The quality standard for drinking water is 3 µg/l (0.003ppm) under the drinking water directive (98/83/EC). These standards are not breached by BASF's discharges from the Ludwigshafen site, as the concentration of EDC is below these values even before it reaches the Ludwigshafen site WWTP.

Because of the measures described above and in the subsequent sections, there are only negligible emissions to the environment via this route.

Overall summary of releases to the environment

Based on the above analysis, the total releases from the site each year are estimated as:

- 0.13kg per year released in the gas from the incinerator.
- 3kg fugitive emissions from the plant equipment.
- 0.18kg released to waste water (maximum).

The above translates to a maximum loss of 3.5kg per year. This is 0.006% of the total 60t of EDC consumed in / lost from the process each year. However, taking into account the recirculation rate of 780 times for EDC, this translates to a loss of 0.000007% each time the EDC is "used".

Table 6: Type of risk characterisation required for man via the environment

Route of exposure and type of effects	Type of risk characterisation	Hazard conclusion (see section 5.11)
Inhalation: Systemic Long Term	Not needed	
Oral: Systemic Long Term	Not needed	

Comments on assessment approach:

Not assessed.

9.0.2.3 Workers

Scope and type of assessment:

This authorisation CSR considers the risk to workers associated with carcinogenicity. Other endpoints are not considered as they are not relevant for authorisation. However, they were considered in the registration CSR, which demonstrates RCR values below 1.

The assessment is based on ECHA's dose-response relationship for carcinogenicity (June 2015). The relevant hazard conclusions are set out in the table below.

Table 7: Type of risk characterisation required for workers

Route	Type of effect	Type of risk characterisation	Hazard conclusion (see section 5.11)
Inhalation	Systemic Long Term	Quantitative	Lifetime cancer risk = 6×10^{-7} per µg/m ³
	Systemic Acute		
	Local Long Term		

⁵ Based on plant operation for 8760 h / year and a wastewater stream of 40 m³/h, the total amount of wastewater released is 350.4 million litres per year. Based on an EDC concentration of 0.5 µg/litre (assuming concentration at the detection limit), this translates to 175.2 million µg / year or 175.2 grams / year.

Route	Type of effect	Type of risk characterisation	Hazard conclusion (see section 5.11)
	Local Acute		
Dermal	Systemic Long Term	Quantitative	Lifetime cancer risk = 2.1×10^{-6} per $\mu\text{g}/\text{kg}$ bw/day (assumes ECHA's default value of 50% for dermal absorption)
	Systemic Acute		
	Local Long Term		
	Local Acute		
Eye	Local	Not needed	

Comments on assessment approach related to toxicological hazard:

Relevant hazards considered

In the exposure assessment, a quantitative assessment was carried out for long term systemic hazards (carcinogenic) via skin and inhalation. The inhalation exposure concentration for workers was measured directly using a variety of methods. Dermal exposure was modeled using ECETOC TRA (BASF modified version) for the generic Registration CSR, but dermal exposure has been excluded from the scope of the CSR for this specific use, as described below.

Determination of inhalation exposure

For inhalation exposure, measurements have been taken using personal samplers and stationary samplers over the period 2001 to 2010. The method used is described in Appendix D.

In all cases bar one, measured concentrations were below the quantification limit of $0.01 \text{ mg}/\text{m}^3$ (as an 8h TWA) and this covers exposure during normal operation, including sampling / laboratory analysis. In one case, when the closed system was opened to repair a broken pump, the measured exposure was $0.11 \text{ mg}/\text{m}^3$. During such maintenance operations, personal protective equipment (PPE) is applied, as described below.

As these measurements were relatively old, BASF has undertaken additional monitoring in 2015, both in order to increase the number of samples and also to ensure future compliance with the German risk-related concept of measures for activities involving carcinogenic hazardous substances (TRGS 910) (BAUA, 2014). These measurements, from September 2015, included 8 full shift measurements (using personal samplers), and 6 stationary measurements (3 in the laboratory and 3 in the control room). These measurements were undertaken using a different method (carbon tubes rather than tenax tubes), with a detection limit⁶ of $0.06 \text{ mg}/\text{m}^3$. Again all of the measured concentrations were below the detection limit, confirming the low levels of exposure within the plant.

Note that the method used was considered by BASF to have a sufficient detection limit ($0.06 \text{ mg}/\text{m}^3$) to demonstrate compliance with TRGS 910 under which BASF is regulated in Germany. This specifies that the acceptable risk (expressing the statistical probability of developing cancer) limit is set at an interim level of 4:10,000 until 2018 and thereafter at a level of 4:100,000. Based on ECHA's dose-response relationship (see Section 10) this translates to a concentration of EDC of $0.067 \text{ mg}/\text{m}^3$ and therefore exposure below the detection limit of $0.06 \text{ mg}/\text{m}^3$ is sufficient to demonstrate compliance⁷.

The majority of BASF's exposure measurements are based on personal samplers, which better reflect the amount of EDC that an employee could potentially inhale. Fixed place or static monitoring is used to obtain information on the likely sources contributing to exposure, and so is used when significant changes are made to the plant. However, static monitoring does not usually reflect the amount that employees could inhale. Details of the measurements are provided in Appendix K.

Based on the above, BASF concludes that full-shift (8h TWA) exposure within the plant is below $0.01 \text{ mg}/\text{m}^3$ during normal operation. This value is used in the subsequent exposure assessment. However, given that the most recent

⁶ This alternative method was chosen because of the practical challenges of using tenax tubes for taking multiple samples (e.g. tubes need to be changed every 120 minutes), as well as to allow demonstration of compliance with the German regulatory requirements from 2018.

⁷ Note that the German Committee for Hazardous Substances (AGS – UA III) sets exposure-risk relationships for individual substances (<http://www.baua.de/en/Topics-from-A-to-Z/Hazardous-Substances/TRGS/Assessment-criteria.html>). While no such value for EDC has been published at the time of writing, it is understood (from personal communication with BAUA) that the value to be adopted will be $0.08 \text{ mg}/\text{m}^3$ from 2018.

measurements only demonstrated exposure below 0.06 mg/m³, this value is also taken forward for use in sensitivity testing (uncertainty analysis).

BASF will undertake further workplace exposure measurements, in 2016 and annually thereafter, to verify that the exposure is below 0.01 mg/m³ during standard operation on an ongoing basis.

Determination of dermal exposure

The activities with potential for dermal exposure are in quality sampling, laboratory analysis and maintenance of the plant. There are no other potential dermal exposure routes as the plant is essentially a closed loop.

Firstly, the protective equipment used is intended to avoid dermal exposure. The following personal protective equipment is used:

- Sampling: Chemical resistant gloves, goggles, protective boots.
- Laboratory analysis: Gloves, goggles, laboratory coat. Carried out in a fume cupboard.
- Unplanned maintenance / opening of the system: Chemical protection suit with respiratory protection and an assigned protection factor of 40 (used in cases where EDC exposure cannot be ruled out).

Secondly, BASF's internal procedures reduce the potential for dermal exposure during these activities. Specifically, training is given to workers on the use of PPE. Within the regular training on the safe use of dangerous substances (called 'Gefahrstoffunterweisung' within BASF), the correct use of gloves is instructed at least once per year. New workers are instructed before they use gloves for the first time. In addition, there is an annual training on the correct use of personal protection equipment (PPE) conducted by members of BASF's plant fire brigade; gloves are of course covered there too.

Training material is used to illustrate the correct use, for example based on the publication "Chemikalienschutzhandschuhe" (= chemicals resistant gloves) by the DGUV (Deutsche Gesetzliche Unfallversicherung = German statutory accident insurance), the 'Best Practice Guideline 5' (= Safe use of gloves for the handling of solvents) by 'The European Solvents Industry Group' (ESIG) and the guideline issued by the 'Bundesverband Handschutz e.V.' (= Federal Association for Hand Protection) entitled 'BVH Info-Reihe 4 – Chemikalienschutzhandschuhe'. In addition, practical training, for example the correct removal and disposal of the gloves, is performed within the aforementioned training. The training consists of:

- Infrastructure: Where are the gloves stored, how can they be correctly identified, and how and where can they be exposed?
- Pre-use check for cracks, cuts, holes and other damage. Gloves need to be discarded when damaged.
- Recommended maximum use time is one third of the penetration time. This means for the butyl gloves this is 29 minutes and for the fluorocarbon rubber (FKM) gloves this is 485 minutes.
- The cuffs are turned up when working over breast height.
- Colleagues monitor each other to ensure that suitable gloves are used in a correct way.
- Rinsing of contaminated gloves is undertaken.
- Removal of the gloves is undertaken without skin contact.
- Gloves can only be re-used if it is quite certain that contamination did not occur.
- Non-contaminated gloves can be reused but have frequently to be discarded for hygienic reasons or because of damage.
- Gloves which can be reused should be dried after use.
- Gloves, and other PPE, should be stored or transported separately from other equipment; this is especially valid for used PPE.

Thirdly, the correct type and use of gloves is implemented in the SOPs (Arbeitsanweisung mit Gefährdungsbeurteilung), provided in Appendix B. (Note that only SOPs with potential for EDC are included in Appendix B; there are of course other SOPs for the plant, but the activities do not involve potential EDC exposure.)

Fourthly, the suitability of a specific glove is evaluated by a BASF expert together with the supplier. Butyl rubber is considered a suitable material for short-term exposure and splash protection, even though swelling in contact with EDC does happen to some extent, with longer-term exposure.

We note that the GESTIS database suggests that fluoro carbon rubber - FKM (0.4 mm) gloves should be worn, and that butyl rubber gloves are unsuitable for protective gloves because of degradation, severe swelling or low permeation time. However, BASF considers that the butyl rubber gloves are suitable for uses such as those

described above, which involve short-term contact / uses (for example sampling) to protect from (infrequent) splashes/drops, and where gloves are changed immediately in the event of splashing.

BASF also has an internal database ('HandSchuChem') showing suitable gloves for many chemicals. An extract from this is provided in Appendix J.

Given the use of gloves in all critical activities and the additional measures applied above, the potential for actual dermal absorption of EDC is considered to be negligible, as any spills of EDC will evaporate rapidly from the gloves upon contact.

In order to estimate the rate of evaporation, a calculation has been made of the evaporation time from gloves based on Appendix R.14-1 of ECHA's guidance. The evaporation time is calculated as between 10 seconds (assuming 1mg mass) and 50 seconds (assuming 5mg mass)⁸. This exposure-reducing effect due to evaporation is considered appropriate as workers do not have continuous direct contact with EDC. The estimate of 1mg mass is more appropriate for the use of EDC here, as it relates to "non-dispersive use, contact level: intermittent". Therefore, EDC is expected to evaporate from gloves long before the penetration time is reached. This coupled with the procedures in place to change/clean gloves whenever they are splashed, as well as to change them within 1/3 of the penetration time, is considered to exclude the potential for dermal absorption of EDC.

In summary, in relation to potential dermal exposure, BASF considers that this can be excluded on the basis of:

- The use of full protective suits during those activities with greatest potential for dermal exposure (e.g. maintenance with opening of the system).
- The use of gloves for all activities with the potential for dermal exposure. For use in quality sampling and for laboratory work, BASF staff are required to change their gloves in the event of splashing and in any event long before the penetration time of EDC. Moreover, the duration of these activities is substantially less than the breakthrough time of the gloves used, and any EDC splashes would evaporate long before the breakthrough time is reached.

Potential for use of biomonitoring to determine dermal exposure

In addition to static monitoring and personal samplers, BASF has considered the potential use of biomonitoring to assess worker exposure. Appendix O provides further details on BASF's assessment of the current status of biomonitoring for EDC.

At present, biomonitoring is not considered appropriate or useful for exposure of EDC. The options for a human biomonitoring for exposure analysis and assessment of EDC are currently limited to two biomarkers: EDC in blood and the metabolite TDGA (thiodiglycolic acid) in urine.

While an analytical method exists for measuring EDC in blood, the method is outdated. In addition, sampling in blood is invasive and is generally avoided by BASF. Furthermore, there is no known dose-concentration or dose-response relationship for humans for EDC in blood. As a result, no limit values or guidance values exist for the interpretation of EDC concentrations in blood.

The main disadvantages of TDGA in urine as a biomarker of EDC exposure are that it is a non-specific biomarker (i.e. it is also a metabolite of several chemicals, and is discussed as an endogenous metabolic product, possibly from fatty acid metabolism, resulting in a physiological background concentration); and also TDGA has no biological limit value related to EDC exposure.

The German Ordinance on Occupational Health Care (Verordnung zur arbeits-medizinischen Vorsorge, ArbMedVV) asks for two minimum requirements to be met: "Biomonitoring is a part of preventive occupational health care insofar as analytical methods recognised by occupational medicine and suitable evaluation values are available." (ArbMedVV of Dec 18, 2008, Section 6, paragraph 2, published in the German Federal Law Gazette I, p. 2768). These criteria are clearly not met and therefore biomonitoring is clearly not appropriate in this case, based on the German regulatory requirements.

On these grounds, human biomonitoring for EDC is not carried out at BASF in routine examinations. The analysis of EDC in blood is undertaken only under "special circumstances", e.g. accidental exposure, as an instrument for exposure (or non-exposure) confirmation.

An alternative approach to measuring the risks related to dermal exposure would be through 'whole body dosimetry' studies, which BASF uses for some other substances. Operators wear two layers of clothing (i.e. outer dosimeter and inner dosimeter). The outer dosimeter is representative of work clothing and the inner dosimeter is a surrogate for the skin of operators. However, the 'whole body dosimetry' approach is only applicable for substances with low

⁸ Calculations were done using the equations in the guidance document, assuming a molecular mass of 98.97 and a vapour pressure of 10,247 Pa.

vapour pressure, and not for solvents as EDC. Substances with high vapour pressure would disappear before they could be detected.

Given that suitable biomonitoring techniques are not available, exposure is assessed by BASF primarily using personal samplers, and stationary sampling.

Overall approach to assessment of dermal exposure

Although BASF has demonstrated why dermal exposure can be excluded, as a sensitivity test, dermal exposure has also been calculated using BASF's version of ECETOC-TRA (EasyTRA⁹).

Exposure potential during the working day

As part of a “work efficiency programme” (‘Opal 21’), typical activities undertaken by the permanent staff of the Trioxane monomer plant during normal operation were collected (and excludes laboratory workers). Based on 100% representing the time spent on a full shift, the time spent undertaking different activities was as follows:

Mail, Correspondence:	1 %	(office)
Documentation and archiving of plant operation data:	14 %	(office)
Writing of reports and the plant operation ‘diary’:	3 %	(office)
Meetings:	3 %	(office)
Conducting tests / trials (plant modifications):	1 %	(plant)
Solve problems / repair:	6 %	(plant)
Operation of the plant control room:	43 %	(control room)
Operation of the plant on-site:	6 %	(plant)
Inspection tour (plant):	16 %	(plant)
Trainings and organization of work:	7 %	(office)

Based on the above, workers at the plant on average spend around 30% of their time in the plant, and the remaining 70% in the office and control room (where there is negligible potential for exposure).

General information on risk management related to toxicological hazard:

Hazard and risk assessment process

Hazard assessments, standard operating procedures (SOPs), and risk management measures including personal protective equipment (PPE) (i.e. gloves, eye protection, respiratory equipment with a minimum 95% efficiency¹⁰) are used by BASF during any operation where workers may be potentially exposed to EDC, particularly during sampling and maintenance. The specific risk management measures are outlined in the relevant sections below.

BASF has standard operating procedures (SOPs) for all standard activities where potential for exposure to EDC occurs, which is sampling only. Copies of these SOPs are provided in Appendix B. BASF also manages non-standard activities with potential for exposure EDC, through a hazard assessment and protective measures work permit system (Appendix C).

Closed system to avoid emissions from normal plant operation

EDC is used in the Ultraform® monomer plant in a closed system: The substance is delivered from a central storage tank via a system of pipes into the plant’s closed extraction / distillation system and then recycled. A minor part of EDC is released to the closed off-gas system due to vaporisation (within the closed system). As set out above (man via the environment), releases from this closed system are very low.

Specific details of the risk management measures applied are provided in the later sections covering each of the ‘worker contributing scenarios’. The table below provides a summary of the main risk management measures in place for each scenario, for convenience.

⁹ EasyTRA has exactly the same underlying model algorithms as ECETOC-TRA, the only differences being a different user interface and the potential to use other values than certain defaults (e.g. reduction factor for gloves). Calculations and input data are explained in the reports in Appendix L, with any deviations from the standard values included in Annex I (tier 2 justifications) of that document.

¹⁰ Actual efficiency is estimated at > 97.5% based on an assigned protection factor of 40.

Table 8: Summary of the main risk management measures applied for each contributing scenario

Identifier	Titles of contributing scenario	Key RMMs applied
I-1a	Sample collection	<ul style="list-style-type: none"> Closed sample collection system. Chemical resistant gloves, goggles.
I-1b	Laboratory exposure	<ul style="list-style-type: none"> Laboratory gloves, goggles, laboratory coat. Fume cupboard.
I-1c	Maintenance/repair	<ul style="list-style-type: none"> Risk assessment and work permit certificate are required before maintenance takes place. Chemical protection suit (with RPE) (when potential for exposure to EDC exists), chemical resistant gloves, protective boots where potential exposure to EDC exists.
I-1d	Off-gas incineration	<ul style="list-style-type: none"> Closed system without potential for exposure.

Appendix E provides a copy of the specifications for the chemical protection suit used in BASF's Ultraform® plant.

General information on risk management related to physicochemical hazard:

Physicochemical hazard was not assessed as it is not relevant to the authorisation application.

9.0.2.4 Consumers

Scope and type of assessment:

Consumer exposure is not relevant to this use and has not been assessed.

Table 9: Type of risk characterisation required for consumers

Route	Type of effect	Type of risk characterisation	Hazard conclusion (see section 5.11)
Inhalation	Systemic Long Term	Not applicable	
	Systemic Acute	Not applicable	
	Local Long Term	Not applicable	
	Local Acute	Not applicable	
Dermal	Systemic Long Term	Not applicable	
	Systemic Acute	Not applicable	
	Local Long Term	Not applicable	
	Local Acute	Not applicable	
Eye	Local	Not applicable	
Oral	Systemic Long Term	Not applicable	

Comments on assessment approach:

Not assessed.

9.1 Exposure scenario I1 for workers

Market sector: PC40: extraction agents

Sector of use: SU3: Industrial uses: Uses of substances as such or in preparations at industrial sites

Article categories: None

Environment contributing scenario(s):

ERC7: Industrial use of substances in closed systems

ERC4 (Industrial use of processing aids in processes and products, not becoming part of articles).

Worker/Consumer contributing scenario(s):

PROC 1: Use in closed process, no likelihood of exposure

PROC 4: Use in batch and other process (synthesis) where opportunity for exposure arises

PROC8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities

PROC15: Use as laboratory reagent

Note: The above ERCs and PROCs are only provided for illustrative purposes, because the approach to exposure and risk assessment is based on measured data.

Subsequent service life exposure scenario(s): None

Exposure scenario(s) of the uses leading to the inclusion of the substance into the article(s): Not applicable

Description of the activities and technical processes covered in the exposure scenario:

The activities undertaken are described above and, in more detail, in relation to the worker contributing scenarios below. In summary the contributing scenarios include:

I-1a	Sample collection	PROC 1 and PROC 8b
I-1b	Laboratory exposure	PROC 15
I-1c	Maintenance/repair	PROC 4
I-1d	Exposure via off-gas incineration system	PROC 1

Explanation on the approach taken for the ES:

The various contributing scenarios are described in the following sections, including details of the processes and risk management measures in place.

9.1.1 Environmental contributing scenario 1

9.1.1.1 Conditions of use

Product (article) characteristics
Concentration of substance in mixture: Substance as such
Amount used, frequency and duration of use (or from service life)
60 tonnes per year are added to the system. Plant operation 12 months per year (2 plants each operating 49 weeks per year) EDC concentrations during sample collection, laboratory work, maintenance/repair or off-gassing during incineration are usually not detected above the method quantification limit of 0.01 mg/m ³ (based on 2005-10 monitoring data). Sample collection frequency ~20x/week Laboratory – not detected (i.e. < quantification limit of 0.01 mg/m ³) in laboratory atmosphere, according to 2001 analyses (stationary sampling, when laboratory was refurbished) Maintenance/repair – about 1 incidence per month for unplanned maintenance; 5 days per year for planned maintenance.
Technical and organisational conditions and measures
Extraction and distillation take place in a closed system. Only opened for sampling and for maintenance/repair.
Conditions and measures related to sewage treatment plant
None – Wastewater from the extraction process contains 1% EDC. However, the EDC is recovered by stripping (distillation) before entering the plant’s wastewater system, which is then discharged to the site wastewater treatment plant. The purified waste water is continuously checked for EDC contamination (about every 7 minutes) using an online-GC-analysis system (head-space technology). The analytical method detection limit is 1 ppm and all measurements are below the detection limit (also checked with a method using a detection limit of 0.5 µg/l). In the event of a failure in the distillation system, the EDC-contaminated

wastewater is collected in a quarantine tank. The wastewater is continuously monitored and there is no relevant emission to the environment via this route.
Conditions and measures related to treatment of waste (including article waste)
EDC is stripped from wastewater and monitored to ensure concentrations released to WWTP are <0.5ppm (<0.5 µg/l) (detection limit of monitoring in 2015; normal online monitoring is done with detection limit of 1ppm).
Other conditions affecting environmental exposure
None
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply
-

9.1.1.2 Releases

Table 10: Local releases to the environment

Release	Release factor estimation method	Explanation / Justification
Water	Site-specific	<p>Initial release factor: N/A Final release factor: .0003% Local release rate: 0.0005 kg/day (0.18 kg/year)</p> <p>Explanation / Justification: Water from the extraction/distillation process, from the incinerator and used to flush system during maintenance/repair. EDC stripped off prior to reaching wastewater treatment facility. Continuous monitoring of wastewater occurs. Final release factor based on 180g released per year (based on measured values in waste water which are all below detection limit of 0.5 µg/l) and measured flow of 40 m³/h. Final release factor expressed as a percentage of total annual consumption (60t)</p>
Air	Site specific	<p>Initial release factor: ~100% Final release factor: 0.005% Local release rate: 0.0086 kg/day (0.13 kg/year from incinerator and 3kg/year fugitive emissions)</p> <p>Explanation / Justification: EDC is destroyed in the plant incinerator and not released to the environment. Emissions from incinerator are calculated by proxy based on total carbon emissions. Fugitive emissions are calculated based on notional leakage rates for plant equipment. Initial release factor is basically the total amount of EDC that needs to be replaced each year.</p>
Soil	Site specific	<p>Final release factor: 0% Explanation / Justification: No release to soil during normal operations or during maintenance/repair</p>
Waste	Site specific	<p>Release factor to waste from the process: 0% Release factor to waste from on-site treatment: EDC is stripped off prior to reaching wastewater treatment facility. Continuous monitoring of wastewater occurs.</p>

9.1.1.3 Exposure and risks for the environment and man via the environment

As set out previously, exposure and risks for the environment are not relevant to this authorisation CSR and man via the environment is not a relevant exposure route. The original (registration) CSR provides further details.

Conclusion on risk characterisation:

Risk characterisation has not been undertaken for risks to the environment.

Risks for exposure of man via the environment have been assessed on the basis of measured data on atmospheric emissions (below detection limit) and these are considered to be negligible, given the essentially complete destruction of EDC in the thermal incinerator and subsequent dispersion and dilution upon release of the residual low concentration.

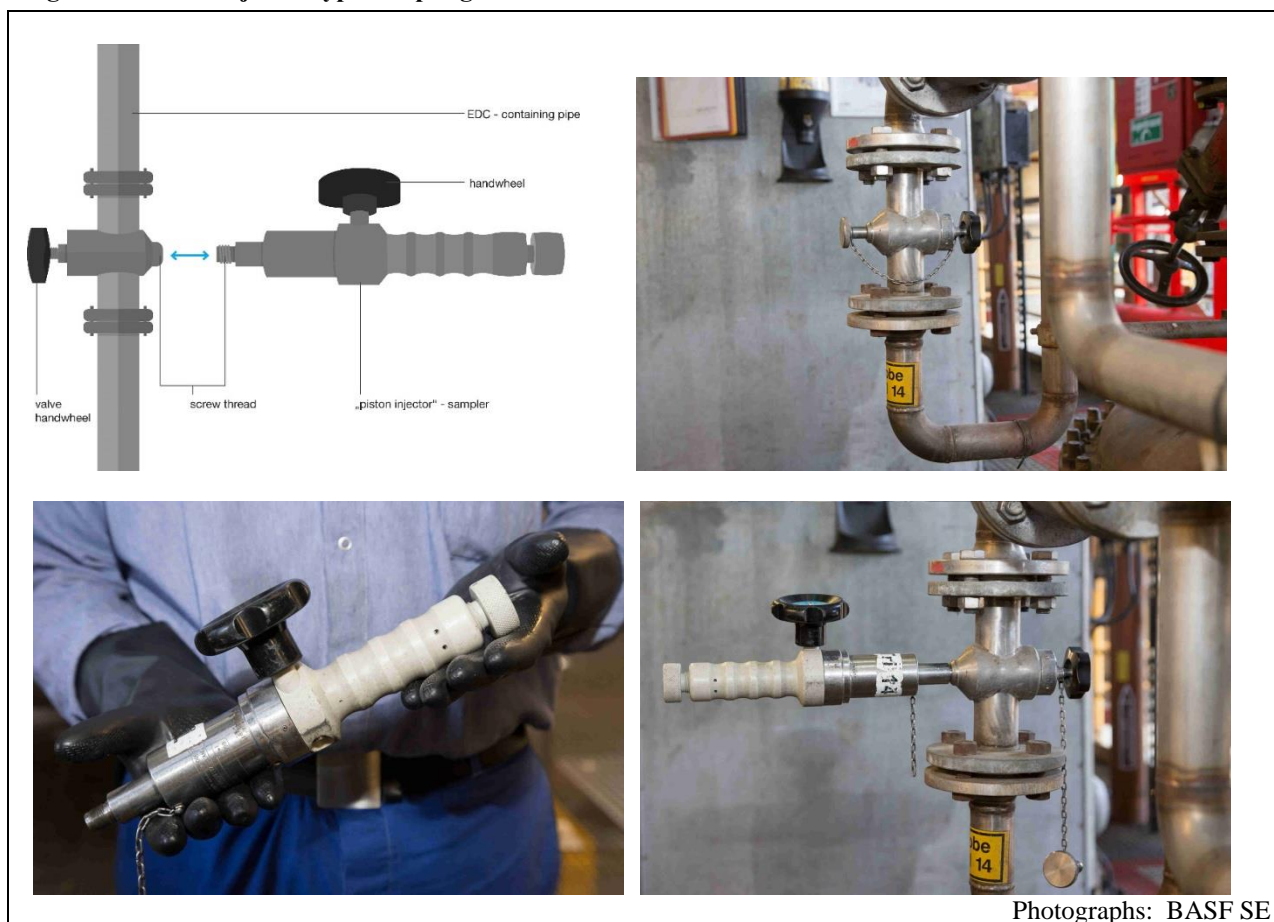
9.1.2 Worker contributing scenario I-1a (sample collection)

9.1.2.1 Overview

This scenario covers potential exposure of workers while taking samples. There are 14 sampling points used for EDC or EDC-containing liquids, including 6 in each plant and 2 at other locations related to both plant. All of them are located outdoors. Eight of these sampling points use a technology to *prevent* exposure (piston injector). The other six sampling points use a standard sampling system designed to *minimise* exposure (plate and screw cap bottle). EDC samples are collected according to a ‘sampling plan’ (Appendix N), and on demand where needed.

The ‘piston injector’ sampling system consists of a syringe-shaped sampling unit that is tightened to the sampling point. After docking, the sampler and the EDC-containing pipe is opened and liquid is transferred. After the transfer is completed, the sampler and the pipe are locked again, and the sampler is loosened and removed. The time needed to take one sample using this method is about 2 minutes.

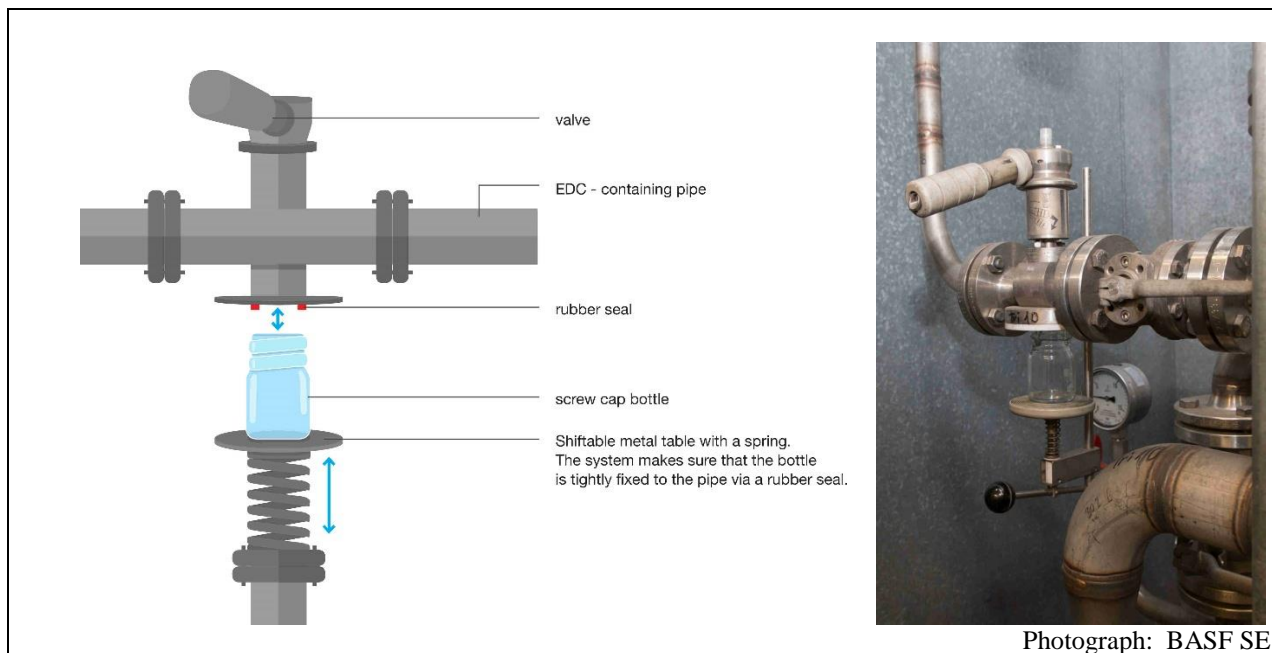
Figure 3: Piston injector type sampling method



Photographs: BASF SE

Screw-cap-bottle sampling consists of an opened screw cap bottle placed on a moveable metal plate and docked to a sampling pipe by pressing the open part of the bottle to a rubber seal. A tap is opened and EDC is transferred into the bottle. The tap is then closed and the open bottle is removed from the plate and sealed (see the figure below). The time needed to take one sample with this method is about 30 seconds.

Figure 4: Screw-cap bottle type sampling method



Where possible, the piston injector sampling system has been implemented at specific sampling points at the plant, taking into account the small quantity (volume) of the sample required (e.g. for GC analysis). At the remaining ‘plate and bottle’ sampling points, the piston injector system cannot be installed mainly because of clogging (as for example Trioxane would precipitate). According to the sampling plan, 16 samples are collected in a week, with a maximum of about 20 (see Appendix N).

Because the sampling points are located directly on the main pipes of the closed system, there is no need to collect and discard liquid present in feed lines (there are no dead spots / spaces).

9.1.2.2 Conditions of use

The details of the conditions during sample taking are summarised below.

	Method
Product (article) characteristics	
Concentration of substance in mixture: Concentration 0.0002% to >90% (depending on sampling location) (see sampling plan in appendix)	-
Amount used, frequency and duration of use (or from service life)	
Sample collection frequency ~20x/week (maximum). Approx. 8 samples per week for piston injector type sampling method and approx. 10 samples per week for screw-cap bottle (flask) method. Exposure duration averages around 3 minutes use per day for screw-cap bottle method (based on 10-11 measurements per week of 2 minutes each sample). EDC concentrations during sample collection (as part of combined exposure measured over 8h TWA) are not detected above the method quantification limit of 0.01 mg/m ³ .	
Technical and organisational conditions and measures	
Hazard assessments and SOPs are applied. A combination of piston injector-type sampling and screw-cap bottle (filled using a rubber seal) are used.	SOPs: Probenahme Tri-10a Probenahme Tri-14
Conditions and measures related to personal protection, hygiene and health evaluation	

	Method
Personal protective equipment is applied during sampling as follows:	
Protection of hands: Chemical resistant protective gloves	EN 374
Eye protection: Goggles	
Body protection: Protective boots	
Other conditions affecting workers exposure	
Trioxane purification is a closed system with regular sampling.	
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	

9.1.2.3 Exposure and risks for workers

Exposure for workers during sample collection is summarised in the table below. Data for inhalation exposure are based on 5 personal sampling regimes undertaken over the period 2005 to 2010, with confirmation that exposure remains below the detection limit in 2015. BASF will undertake further workplace exposure measurements, in 2016 and annually thereafter, to verify that exposure is below 0.01 mg/m³ during standard operation on an ongoing basis.

Table 11: Exposure concentrations and risks for workers (sampling)

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, long-term	< 0.01 mg/m ³ (measured)	Considered at end of this section
Inhalation, systemic, acute	-	
Inhalation, local, long-term	-	
Inhalation, local, acute	-	
Dermal, systemic, long-term	BASF conclude dermal exposure can be excluded. However, exposure is modelled using EasyTRA for sensitivity testing: 0.000429 mg/kg-bw/d for screw-cap bottle method (PROC 8b) 0.000206 mg/kg-bw/day for piston injector method (PROC 1)	Considered at end of this section
Dermal, systemic, acute	-	
Dermal, local, long-term	-	
Dermal, local, acute	-	
Eye, local		
Combined routes, systemic, long-term	-	
Combined routes, systemic, acute	-	

Remarks on exposure data:

Inhalation exposure data for sampling is based on personal sampling. Sampling is one of several activities undertaken by workers while monitoring is being done. Measured data were below the quantification limit of 0.01 mg/m³ expressed as 8h TWA.

Dermal exposure is calculated using BASF's version of ECETOC-TRA (EasyTRA¹¹). These values are lower than that presented in the registration CSR (0.1371 mg/kg-bw/d), as they are more specific to BASF's use in the Ultraform® plant and are specific to sampling. It assumes use of gloves with an assigned protection factor of 100 (i.e. 99% exposure reduction). See Appendix L for details of the EasyTRA modelling.

Given that PPE is applied while sampling takes place, this is expected to be an overestimate (worst case scenario). BASF uses the butyl rubber gloves to ensure that dermal exposure does not occur during sampling and other processes described below. These gloves have a 0.7 mm protection layer, a protection index of 3 and a penetration protection time for EDC of 88 minutes¹².

BASF's overall conclusion is that dermal exposure is not relevant for workers in the Ultraform® plant. However, the results of the exposure modelling are included here to allow for sensitivity testing.

Conclusion on risk characterisation:

Inhalation and dermal DMEL values were calculated in the registration CSR. However, for the purposes of consistency and to aid review by ECHA's committees, in this authorisation CSR risks to workers are calculated using ECHA's reference dose-response relationship as part of a sensitivity test.

Because exposure is assessed over the course of an 8 hour period for inhalation exposure (and for total annual exposure in calculation of risks), conclusions are drawn for all activities combined, rather than for this contributing scenario specifically. This is set out in Section 9.1.6.

9.1.3 Worker contributing scenario I-1b (laboratory use/exposure)

9.1.3.1 Overview

The sampling units (see Section 9.1.2) are transferred to the laboratory within the plant and opened under a flue/fume hood. Using a pipette, EDC is transferred to a gas-chromatography sample unit (a small, sealed glass bottle) and put in the chromatograph for analysis. The waste is properly disposed of as hazardous waste.

The latest specific exposure measurement of EDC in the laboratory was performed in 2001 using a stationary sampler. EDC was not detected (the quantification limit was 0.01 mg/m³ and measurement was done over 8 hours). Personal sampling from other more recent measurement regimes also covered laboratory use, again with exposure not detectable above 0.01 mg/m³. Note that the stationary samples were taken when the new laboratory was installed, and stationary sampling is not undertaken routinely¹³.

9.1.3.2 Conditions of use

The details of the conditions in the laboratory are summarised below.

	Method
Product (article) characteristics	
Concentration of substance in mixture: Concentration 0.0002% to >90% (depending on sampling location) (see sampling plan in appendix)	-
Amount used, frequency and duration of use (or from service life)	
Sample testing frequency ~20x/week (same as scenario I-1a). Duration of laboratory analysis is <15 minutes per day. EDC concentrations in the laboratory have been measured (in 2001, when the current laboratory was installed) and confirmed to be below the quantification limit of 0.01 mg/m ³ . Furthermore measurements between 2005 and 2010 using personal	

¹¹ EasyTRA has exactly the same underlying model calculations as ECETOC-TRA, the only difference being a different user interface. Calculations and input data are explained in the reports in Appendix L.

¹² The breakthrough time of the butyl rubber gloves is stated to be 88 minutes in Appendix J. In practice, this is a generic value for this type of glove, and the actual gloves used have a breakthrough time of 122 min (as is also mentioned in the dermal exposure modelling in Appendix L). According to the available data on the butyl rubber material, without glove supplier-specific statements, the breakthrough time would indeed be considered to be 88 minutes. However, for the actual gloves BASF use for sampling and maintenance, BASF has a supplier statement (based on tests) that the breakthrough time is 122 minutes.

¹³ Fixed place or static monitoring is used to obtain information on the likely sources contributing to exposure, but it does not usually reflect the amount that employees could breathe in. As set out by the UK HSE (2006), fixed place sampling can be used e.g. to check the effectiveness of control measures, identify emission sources, and determine background workplace contaminant concentrations.

	Method
samplers, confirm that levels in the laboratory (as part of combined exposure measured over 8h TWA) are not detected above the method quantification limit of 0.01 mg/m ³ . Further monitoring in 2015 confirms that concentrations are below the quantification limit (though in this case at 0.06 mg/m ³ , as a different method was used).	
Technical and organisational conditions and measures	
Piston injector samplers and screw-cap bottles are opened within the fume cupboard/hood. EDC is transferred to a sealed bottle and analysed in using gas chromatography.	
Conditions and measures related to personal protection, hygiene and health evaluation	
Personal protective equipment is applied in the laboratory as follows:	
Protection of hands: Suitable laboratory gloves (nitrile rubber). They are immediately disposed of and replaced in case of contact with EDC	EN 374
Eye protection: Goggles	EN 166 (goggles)
Body protection: Laboratory coat	
Other conditions affecting workers exposure	
Trioxane purification is a closed system with regular laboratory analysis of samples.	-
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	

9.1.3.3 Exposure and risks for workers

Exposure for workers in the laboratory is summarised in the table below. Data are based on 5 personal sampling regimes undertaken over the period 2005 to 2010 and a stationary sampler in the laboratory itself in 2001, as well as more recent monitoring undertaken in 2015.

Table 12: Exposure concentrations and risks for workers (laboratory)

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, long-term	< 0.01 mg/m ³ (measured)	Considered at end of this section
Inhalation, systemic, acute	-	
Inhalation, local, long-term	-	
Inhalation, local, acute	-	
Dermal, systemic, long-term	BASF conclude dermal exposure can be excluded. However, exposure is modelled using EasyTRA for sensitivity testing: 0.000171 mg/kg-bw/d (PROC 15)	Considered at end of this section
Dermal, systemic, acute	-	
Dermal, local, long-term	-	
Dermal, local, acute	-	
Eye, local		

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Combined routes, systemic, long-term	-	
Combined routes, systemic, acute	-	

Remarks on exposure data:

Inhalation exposure data for sampling is based on 8h TWA personal sampling and 8h TWA stationary sampler. Measured data were below the quantification limit of 0.01 mg/m³.

Dermal exposure is calculated using BASF's version of ECETOC-TRA (EasyTRA). This value is lower than that presented in the registration CSR (0.1371 mg/kg-bw/d), as it is more specific to BASF's use in the Ultraform® plant and is specific to sampling. It assumes use of gloves with an assigned protection factor of 10 (i.e. 95% exposure reduction for nitrile gloves). See Appendix L for details of the EasyTRA modelling.

Given that BASF's operating procedures require operators to change/clean gloves whenever they are splashed, the above is likely to be an overestimate of exposure.

BASF's overall conclusion is that dermal exposure is not relevant for workers in the Ultraform® plant. However, the results of the exposure modelling are included here to allow for sensitivity testing.

Conclusion on risk characterisation:

Inhalation and dermal DMEL values were calculated in the registration CSR. However, for the purposes of consistency and to aid review by ECHA's committee, in this authorisation CSR risks to workers are calculated using ECHA's reference dose-response relationship.

Because exposure is assessed over the course of an 8 hour period for inhalation exposure (and for total annual exposure in calculation of risks), conclusions are drawn for all activities combined, rather than for this contributing scenario specifically. This is set out in Section 9.1.6.

9.1.4 Worker contributing scenario I-1c (maintenance / repair)

9.1.4.1 Overview

There are two types of maintenance activities undertaken at the Ultraform® plant:

1. Unplanned maintenance when something is broken during operation of the plant.
2. Annual (planned) maintenance of the plant.

In case the closed system requires opening for maintenance and/or repair, the affected parts of the system are isolated and flushed with water. Therefore, no EDC should be left in the affected parts of the system, but in reality the flushing is never 100% efficient. For calculation of exposure using ECETOC TRA, an approximate water solubility of EDC (1%) is taken as the 'substance in preparation' input value.

Unplanned maintenance is rare and occurs around 1 time per month. One of BASF's personal sampling results relates to an occasion when unplanned maintenance occurred and indicated exposure *of the sampler* at 0.11 mg/m³ as an 8h TWA. Unplanned maintenance is required particularly when there is a pump failure, which requires repair. There is no leak in the pump, but there is potential for exposure when it is disconnected for repair/replacement.

During these maintenance activities, respiratory protective equipment is used by the maintenance workers, with a specified minimum efficiency of 95%. The actual worker exposure is therefore less than that during normal operations measured with the same personal samplers (i.e. 0.01 mg/m³). As set out above, actual exposure is expected to be substantially less than this, as the actual chemical protection suit / RPE used has an assigned protection factor of 40. However, as stated above, an exposure value of 0.01 mg/m³ is used in the risk estimation.

Prior to opening the system, a hazard assessment is completed including the identification of suitable personal protective equipment (PPE). As per BASF's standard operating procedures, work is permitted only when a work permit certificate is issued for this specific task. Furthermore, BASF has a general guidance document for work that may result in EDC exposure ("Betriebsanweisung nach Gefahrstoffverordnung" and specific workplace safety instructions in accordance with the German "hazardous substance regulation"). These document requires the use of additional PPE (i.e. respiratory protection equipment) during maintenance and repairs.

Appendix C provides details of the "hazard assessment and protective measures work permit" that is completed for each maintenance activity. It also includes a copy of the "permit manual" used to guide this process. Because the maintenance activities are unpredictable, they are not covered by SOPs. The handbook describes how a work permit

is obtained, which includes conducting a risk assessment. The permit form is then completed, specifying which RMMs are to be applied, and is signed off by the responsible expert.

Potential exposure to EDC during planned maintenance/repair at both plants (combined) occurs over approximately five days per year. There are approximately 10 BASF workers who undertake this maintenance, some of whom are permanently based in the Ultraform® plant, and others who undertake wider maintenance across the Ludwigshafen site.

Wastewater from the extraction process contains 1% EDC. However, the EDC is recovered by stripping (distillation) before entering the plant's wastewater system. The purified waste water is continuously checked for EDC contamination (about every 7 minutes) using an online-GC-analysis system (head-space technology) prior to discharge to the Ludwigshafen site waste water treatment plant. The analytical method detection limit is 1 ppm. In the event of a failure in the distillation system, the EDC-contaminated wastewater is collected in a quarantine tank (this has not occurred due to EDC concentrations in at least the last 10 years). Because the wastewater is continuously monitored, there is no relevant emission to the environment via this route.

Because the system is flushed before the maintenance occurs, exposure is much lower than during unplanned maintenance and is comparable to exposure under normal operation (i.e. < 0.01 mg/m³ as the quantification limit). Planned maintenance takes place for around 5 days per year, and involves around 10 workers.

9.1.4.2 Conditions of use

The details of the conditions during maintenance are summarised below.

	Method
Product (article) characteristics	
Concentration of substance in mixture: Maximum 1%	-
Amount used, frequency and duration of use (or from service life)	
Unplanned maintenance: Approximately 1 time per month, typically a few hours.	
Planned maintenance: 5 days per year, involving c. 10 people total	
Total duration estimated at around 10 minutes per day on average over the course of a year	
Technical and organisational conditions and measures	
Risk assessment and work permit certificate are required before maintenance takes place. This specifies the use of suitable PPE.	“Hazard assessment and protective measures work permit” and “permit manual” in Appendix C.
Conditions and measures related to personal protection, hygiene and health evaluation	
Personal protective equipment is applied during maintenance as follows (depending on the actual work and the potential hazard involved):	
Protection of hands: Chemical resistant protective gloves	EN 374
Eye protection: Goggles	EN 166 (goggles)
Body protection: Apron, protective boots, chemical-protection suit	EN 14605 (chemical protection suit)
Respiratory protection: At low concentrations or short-term exposure: Gas filter for organic gases / vapours (boiling point > 65°C). Higher concentrations or prolonged exposure: Self-contained breathing apparatus (isolated).	EN 14387 type A specified in operating instructions according to ordinance on hazardous materials BASF uses a chemical protection suit of the type

		Method
		in Appendix E (as protection in case of accidents)
Other conditions affecting workers exposure		
Trioxane purification is a closed system with infrequent laboratory analysis of samples.		-
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply		

9.1.4.3 Exposure and risks for workers

Exposure for workers during maintenance is summarised in the table below. Data are based on 1 personal sampling activity in 2008 when unplanned maintenance (including opening the closed system) took place. Routine, planned maintenance has exposure comparable to the personal sampling undertaken (5 times) over the period 2005 to 2010, as well as more recent monitoring undertaken in 2015.

Table 13: Exposure concentrations and risks for workers (maintenance)

Route of exposure and type of effects	Exposure concentration	Risk characterisation
Inhalation, systemic, long-term	Unplanned maintenance: 0.11 mg/m ³ (measured) (RPE is worn with APF of 40) Planned maintenance: < 0.01 mg/m ³ (measured)	Considered at end of this section
Inhalation, systemic, acute	-	
Inhalation, local, long-term	-	
Inhalation, local, acute	-	
Dermal, systemic, long-term	BASF conclude dermal exposure can be excluded. However, exposure is modelled using EasyTRA for sensitivity testing: 0.000014 mg/kg-bw/d (PROC 4)	Considered at end of this section
Dermal, systemic, acute	-	
Dermal, local, long-term	-	
Dermal, local, acute	-	
Eye, local		
Combined routes, systemic, long-term	-	
Combined routes, systemic, acute	-	

Remarks on exposure data:

Inhalation exposure data for sampling is based on personal sampling. Measured data were below the quantification limit of 0.01 mg/m³ (8h TWA) for planned maintenance and 0.11 mg/m³ for unplanned maintenance. Because RPE with an efficiency of at least 95% is worn during unplanned maintenance, actual exposure is comparable to the method quantification limit of 0.01 mg/m³.

The efficiency of the RPE is in fact much greater than 90%. BASF uses a chemical protection suit (Appendix E), which has an assigned protection factor¹⁴ of 40. In other words, although the workplace concentration was

¹⁴ UK APF according to Annex C of EN529:2005. The APF means the factor by which the hazard is reduced, i.e. how many times cleaner the air is inside the hood than outside.

measured as 0.11 mg/m³ during unplanned maintenance, the actual exposure of workers would have been less than 0.0028 mg/m³. For convenience, and to take into account potentially higher exposure from different unplanned maintenance activities, a value of 0.01 mg/m³ has been used in the risk estimation,

Dermal exposure is not expected to be relevant for unplanned maintenance, given that a full protection suit is worn. However, an estimate has been modelled using BASF's version of ECETOC-TRA (EasyTRA). This value is lower than that presented in the registration CSR (0.1371 mg/kg-bw/d), as it is more specific to BASF's use in the Ultraform® plant and is specific to maintenance activities in the plant. It assumes respiratory protection with a 95% exposure reduction and gloves with an efficiency of 99% (butyl rubber). See Appendix L for details of the EasyTRA modelling

In any case, as described previously, BASF's overall conclusion is that dermal exposure is not relevant for workers in the Ultraform® plant. However, the results of the exposure modelling are included here to allow for sensitivity testing.

Conclusion on risk characterisation:

Inhalation and dermal DMEL values were calculated in the registration CSR. However, for the purposes of consistency and to aid review by ECHA's committee, in this authorisation CSR risks to workers are calculated using ECHA's reference dose-response relationship.

Because exposure is assessed over the course of an 8 hour period for inhalation exposure (and for total annual exposure in calculation of risks), conclusions are drawn for all activities combined, rather than for this contributing scenario specifically. This is set out in Section 9.1.6.

9.1.5 Worker contributing scenario I-1d (exposure via off-gas system)

The “off-gas incineration system” collects any emission of volatile compounds (including EDC) from the extraction/distillation process in the volatiles tank. This is a completely closed system. This is then incinerated at a temperature of 1000°C. At this temperature EDC is completely destroyed, as described earlier.

The exhaust gases are washed and the resulting hydrogen chloride (HCl) is neutralised. The waste water is released to the site wastewater system and the combined stream is passed (after stripping of EDC from other streams) to BASF's site wastewater treatment plant. The absence of emission into the environment via this route is checked by continuous monitoring as described previously.

The incineration of EDC at 1000°C is complete, so there is no emission to the air environment from the incinerator, nor potential for exposure to workers or the wider population. The temperature of the incinerator is monitored continuously and the outlet of the incinerator (waste gases) are monitored every 3 years by the TUV for dioxin/furan emissions, demonstrating complete destruction of organic compounds.

Exposure around and after the incineration system is therefore expected to be lower than other routine activities at the plant as described in the previous sections i.e. exposure is not expected to exceed the quantification limit of 0.01 mg/m³. The section on man exposed via the environment demonstrates that exposure to waste gas after the incinerator is expected to be several orders of magnitude smaller than this.

9.1.6 Overall conclusions on exposure for workers

Exposure at the Ultraform® plant (specifically the trioxane monomer plant) is summarised in the table below. Inhalation exposure estimates are based on measured concentrations in the workplace environment (personal samplers and stationary samplers), while dermal exposure is estimated using BASF's modified ECETOC-TRA model (Easy-TRA).

Table 14: Summary of expected exposures

Contributing scenario	Exposure (excl. effect of PPE)	Exposure with PPE
I-1a Sample collection	Inhalation: < 0.01 mg/m ³ Dermal: Not estimated	Inhalation: < 0.01 mg/m ³ Dermal: 0.000286 mg/kg-bw/d (dermal figure provided for sensitivity testing only)
I-1b Laboratory exposure	Inhalation: < 0.01 mg/m ³ Dermal: Not estimated	Inhalation: < 0.01 mg/m ³ Dermal: 0.000429 mg/kg-bw/d for screw-cap bottle method; 0.000206 mg/kg-bw/d for piston injector method (dermal figure provided for sensitivity testing only)

Contributing scenario	Exposure (excl. effect of PPE)	Exposure with PPE
I-1c Maintenance/repair	Unplanned maintenance: Inhalation: 0.11 mg/m ³ Dermal: Not estimated	Inhalation: <0.01 mg/m ³ (0.0028 mg/m ³) Dermal: 0.000014 mg/kg-bw/d (dermal figure provided for sensitivity testing only)
	Planned maintenance: Inhalation: < 0.01 mg/m ³ Dermal: Not estimated	Inhalation: < 0.01 mg/m ³ Dermal: 0.000014 mg/kg-bw/d (dermal figure provided for sensitivity testing only)
I-1d Off-gas incineration	Inhalation: < 0.01 mg/m ³ Dermal: Not estimated	Inhalation: < 0.01 mg/m ³ Dermal: Not relevant
Note: Dermal exposure is not considered relevant for any of the contributing scenarios. However, estimates are provided for scenarios 1a, 1b and 1c for the purposes of sensitivity testing.		

Inhalation exposure for all activities except for unplanned maintenance has been measured as being below the analytical quantification limit of 0.01 mg/m³. Exposure during unplanned maintenance is a factor of 10 higher than this at 0.11 mg/m³ (8h TWA); however the use of RPE with an efficiency of at least 90% (in practice over 97.5%) reduces actual exposure to around 0.01 mg/m³. It is therefore reasonable to assume, as a worst case, that exposure for all workers across the site and all activities (contributing scenarios) is a maximum of 0.01 mg/m³ for the purposes of exposure assessment and risk characterisation.

In terms of dermal exposure, values of between 0.000014 and 0.000429 mg/kg-bw/d have been calculated using EasyTRA. As set out previously, BASF does not believe that dermal exposure is relevant for the Ultraform® plant. However, these values are retained for sensitivity analysis purposes.

9.2 Exposure scenarios for consumers

Not applicable. No consumer exposure occurs.

10 RISK CHARACTERISATION

10.1 Human health

10.1.1 Workers

10.1.1.1 Number of people exposed and frequency/duration of exposure

Risk characterisation is only undertaken for carcinogenicity, as this is the only endpoint relevant for this authorisation CSR.

During normal operation of the trioxane purification plant, four workers are on shift at any one time (covering both trioxane production lines – essentially being part of the same plant). Typically, at any one time one worker will be working at the plant and potentially exposed, with the others being present in other parts of the plant (e.g. the control room). In total, 21 workers are allocated to the plant's operation team (i.e. covering multiple shifts), and as a worst case, it is assumed that they are all potentially exposed. Exposure may occur over 365 days a year, given that when one of the two purification plants is closed for annual maintenance, the other is still operational.

Samples are taken and analysed in the plant laboratory; only 1 of the 4 workers on shift in the plant is responsible for taking samples. Four workers are based in the laboratory and 1 of these 4 workers undertakes the analysis on samples containing EDC. Samples are taken and analysed a maximum of 20 times per week (1,040 times per year).

A further 10 workers are involved in scheduled (planned) maintenance. This maintenance involves short-term exposure, including the use of personal protective equipment. During unplanned maintenance PPE including breathing apparatus is applied (typically 1-2 workers are involved in the repair).

Therefore, in total up to 35 workers could be considered as being potentially exposed. As a worst case, for the purposes of estimating excess cancer risks associated with exposure, it is assumed that all of these workers are exposed over the course of the year. However, a more realistic estimate of exposure is also provided, factoring in the approximate time that workers are present in areas of the plant where exposure could potentially occur, and the duration that they are involved in those activities.

Details of numbers of workers exposed and the duration of exposure is set out below. This is the worst case, assuming that all workers are exposed and that measured exposure levels *below* the quantification limit actually lead to exposure *at* the quantification limit of 0.01 mg/m³ for inhalation exposure. Since only one exposure value for inhalation exposure has been derived (Section 9.1.6) i.e. 0.01 mg/m³, exposure is not broken down into the separate contributing scenarios.

Table 15: Summary of numbers of workers exposed and duration

Parameter	Value
Number of workers potentially exposed (all activities)	35
Number of hours worked per year	1700 (Note that ECHA dose-response is based on 1920h)
Number of years worked	40 years (worst-case assumption)

10.1.1.2 Approach to risk characterisation

Excess cancer risk for EDC has been estimated in the following section based on ECHA's (2015) reference dose response relationship for carcinogenicity of 1,2-dichloroethane (EDC). While the reference dose-response relationship is somewhat different to that included in BASF's registration CSR, the two are in reasonable agreement and so it is used here for convenience and to aid comparability of authorisation applications by ECHA's committees.

The excess cancer risks in the ECHA (2015) document are summarised below.

Route of exposure	Population	T25 Descriptor	Cancer risk for 1 unit amount
Oral	General population	T25 _(oral, human) 20.7 mg/kg bw/day	1.2 x 10⁻⁵ per µg/kg bw/day
Inhalation	Workers	T25 _(inhalation, human) 100.8 ppm (414.4 mg/m ³)	6.0 x 10⁻⁷ per µg/m³
	General population	T25 _(inhalation, human) 17.6 ppm (72.5 mg/m ³)	3.45 x 10⁻⁶ per µg/m³
Dermal	Workers	T25 _(dermal, human) 118.4 mg/kg bw/day	2.1 x 10⁻⁶ per µg/kg bw/day
	General population	T25 _(dermal, human) 41.4 mg/kg bw/day	6 x 10⁻⁶ per µg/kg bw/day

Based on the approach set out in Section 9, the maximum potential exposure of any one worker has been estimated based on data from personal sampling of employees undertaking typical plant activities, including those with potential for exposure to EDC (e.g. sampling) whilst undertaking activities with potential for exposure.

Only inhalation exposure is considered relevant for workers in the Ultraform® plant. However, for the purpose of sensitivity testing, dermal exposure during sampling (the activity with greatest calculated dermal exposure), has also been estimated.

The individual risk is calculated assuming that a worker is exposed over the full course of the working year. The estimate of excess cancer risk for the Ultraform® plant as a whole is calculated taking into account the time worked in the Ultraform® plant, in areas where there is potential for exposure. This is highlighted in the table below.

Table 16: Summary of worst-case and more realistic estimate of worker exposure over a year

	No of workers	% of time in relevant areas ^[1]	Effective no of workers per year
Worst case estimate			
Permanent Ultraform® plant employees	25	100%	25
Other BASF staff involved in routine maintenance	10	100%	10
Total	35		35
Number of hours worked = 1920 hours per year			
Realistic case estimate			
Permanent Ultraform® plant employees – plant	21	30% ^[2]	6.3
Permanent Ultraform® plant employees – laboratory	4	3,1% ^[3]	0.125
Other BASF staff involved in routine maintenance	10	3,1% ^[4]	0.3
Total	35		6.7
Number of hours worked = 1700 hours per year			
Notes:			
[1] These are areas of the plant where exposure may potentially occur. This is the average value across the workforce.			

	No of workers	% of time in relevant areas ^[1]	Effective no of workers per year
<p>[2] On each shift, on average only 1 in 4 of the workers is present in parts of the plant where exposure may occur. Other workers are present e.g. in the plant control room. 30% is based on exposure potential during the working day (section 9.0.2.3).</p> <p>[3] Laboratory staff will not process EDC samples all the time and so potential exposure will only occur for part of the time. It is assumed that exposure may occur for about 15 minutes per day, that would account for 3.2% of the working time (based on an 8 hour working day).</p> <p>[4] Routine maintenance of the plant with potential for exposure is undertaken for a period of 5 days per year (i.e. assumed maximum 60 hours out of 1920 assuming a 12h shift).</p>			

10.1.1.3 Risk characterisation for inhalation exposure

(a) Individual excess cancer risk:

Based on an assumed exposure time of 8 h/day, 5 days/week, 48 weeks/year for 40 years out of a lifetime of 75 years, ECHA's reference dose-response relationship gives an estimate for excess cancer risk of:

$$\text{Cancer risk for 1 unit amount} = 6.0 \times 10^{-7} \text{ per } \mu\text{g}/\text{m}^3 = 6.0 \times 10^{-4} \text{ per mg}/\text{m}^3$$

The relationship is assumed to be linear. Based on the exposure estimate set out in Section 9.1.6, the individual excess cancer risk for the BASF Ultraform® plant is:

$$\text{Excess lifetime cancer risk} = 0.01 \text{ mg}/\text{m}^3 \times 6.0 \times 10^{-4} \text{ per mg}/\text{m}^3 = 6.0 \times 10^{-6}$$

(b) Total excess cancer risk for the applied for use (whole plant):

Based on the assumption that effectively 6.7 workers (Table 16:) are exposed at a comparable level over their lifetime, and that 1700 hours are worked per year instead of the 1920 assumed in the ECHA dose-response relationship, the excess cancer risk for the Ultraform® plant as a whole is:

$$\text{Plant excess lifetime cancer risk} = 6.7 \times (6.0 \times 10^{-6}) \times (1700/1920) = 3.6 \times 10^{-5}$$

10.1.1.4 Risk characterisation for dermal exposure

As set out in Section 9 of this document, dermal exposure in the trioxane plant is considered to be negligible. Therefore no quantitative estimate of the excess cancer risks has been undertaken. However, as a sensitivity test the excess cancer risk related to dermal exposure has been estimated based on the values calculated for sampling (the activity / contributing scenario with greatest potential for exposure).

(a) Individual excess cancer risk:

Based on an assumed exposure time of 8 h/day, 5 days/week, 48 weeks/year for 40 years out of a lifetime of 75 years, ECHA's (2015) reference dose-response relationship gives an estimate for excess cancer risk of:

$$\text{Assuming 50\% absorption: Cancer risk for 1 unit amount} = 2.1 \times 10^{-6} \text{ per } \mu\text{g}/\text{kg bw}/\text{day}$$

According to ECHA, 1% absorption, may be a better estimate when exposure is likely to be for neat 1,2-dichloroethane (EDC) and absorption is low (perhaps due to volatilisation) whereas the default assumption of 50% will be made when absorption is potentially higher as exposure is via 1,2-dichloroethane in aqueous solution. It is our understanding that the preferred value for a process such as the Ultraform® plant is to assume 50% absorption, although BASF believes that this figure is actually probably too high: specific analysis using the "Dermwin v2.02" model suggests a "low" dermal exposure of around 10% (Appendix M). Nonetheless, a conservative approach is taken here, assuming 50% absorption as proposed by ECHA.

The relationship is assumed to be linear. Based on the highest exposure estimate set out in Section 9.1.6 (for sampling using the screw-cap bottle method), the individual excess cancer risk for the BASF Ultraform® plant is:

$$\text{Excess lifetime cancer risk} = (0.000429 \text{ mg}/\text{kg-bw}/\text{day}) \times (2.1 \times 10^{-6} \text{ per } \mu\text{g}/\text{kg bw}/\text{day}) \times (1000 \mu\text{g}/\text{mg}) = 9.0 \times 10^{-7}$$

(b) Total excess cancer risk for the applied for use (whole plant):

Based on the assumption that effectively 6.7 workers (Table 16:) are exposed at a comparable level over their lifetime, and that 1700 hours are worked per year instead of the 1920 assumed in the ECHA dose-response relationship, the excess cancer risk for the Ultraform® plant as a whole is:

$$\text{Plant excess lifetime cancer risk} = 6.7 \times (9.0 \times 10^{-7}) \times (1700/1920) = 5.4 \times 10^{-6}$$

However, as detailed above, it is argued that dermal exposure is not relevant to the real excess cancer risks at the plant. This value is therefore only used for sensitivity testing.

10.1.1.5 Risk characterisation for combined exposure

Overview

Individual excess cancer risk for inhalation exposure is derived above as 6.0×10^{-6} (lifetime excess cancer risk). Since dermal exposure is negligible, this is also the estimate for individual risk from combined exposure. However, an estimate of the risk from combined exposure taking into account dermal exposure has been included, for the purposes of sensitivity testing.

(a) Individual excess cancer risk:

The individual excess cancer risk is calculated by adding the values for inhalation and dermal exposure as follows:

$$\text{Excess lifetime cancer risk} = (6.0 \times 10^{-6}) + 0 = 6.0 \times 10^{-6}$$

As a sensitivity test, the (modelled) estimate of excess cancer risk from dermal exposure during sampling can be added, giving an estimate of:

$$\text{Excess lifetime cancer risk} = (6.0 \times 10^{-6}) + (9.0 \times 10^{-7}) = 6.9 \times 10^{-6}$$

Based on the above and the preceding sections, BASF believes it is clear that the operational conditions and risk management measures in place are appropriate and effective in limiting the risks from EDC. As a further illustration, the above individual risk estimate of 6.9×10^{-6} is within the current “acceptable risk” interim level of 4×10^{-4} , and also the acceptable risk level that applies from 2018 of 4×10^{-5} , under the relevant German regulation¹⁵. In any case, this estimate of the level of risk is an overestimate because it assumes that inhalation exposure is at the quantification limit of 0.01 mg/m^3 whereas in reality all measurements were below the quantification limit.

(b) Total excess cancer risk for the applied for use (whole plant):

It is not appropriate to assume a lower level of exposure than 0.01 mg/m^3 (the quantification limit) because actual measurement data are not available. However, it is possible to account for the fact that numbers of people exposed and duration of exposure are expressed as a worst case above.

Based on the assumption that effectively 6.7 workers (Table 16:) are exposed at a comparable level over their lifetime, the excess cancer risk for the Ultraform® plant as a whole is:

$$\text{Plant excess lifetime cancer risk} = (3.6 \times 10^{-5}) + 0 = 3.6 \times 10^{-5}$$

This number is only used for the later calculation of the potential health benefits of reduced exposure. It represents the total excess cancer risk across the whole potentially-exposed workforce.

As a sensitivity test, if the calculated risk from dermal exposure (highest value, from sampling activities) is added to the risk from inhalation exposure, the excess cancer risk for the Ultraform® plant as a whole is:

$$\text{Plant excess lifetime cancer risk} = (3.6 \times 10^{-5}) + (5.4 \times 10^{-6}) = 4.1 \times 10^{-5}$$

10.1.2 Consumers

Consumer exposure is not relevant for this use

10.2 Environment

As set out in the preceding sections, exposure of the environment is considered negligible and is not assessed here.

In terms of humans exposed via the environment, the potential risk to people outside the plant from exposure to EDC from the plant incinerator has been estimated for a 1 km^2 area around the Ultraform® plant. Based on this analysis the calculated excess cancer risk to people outside the plant is 2.7×10^{-6} across 3921 workers, over 40 years. However, this value is considered to be an overestimate, as described in Section 9.0.2.2.

¹⁵ Technical Rules for Hazardous Substances: Risk-related concept of measures for activities involving carcinogenic hazardous substances (TRGS 910, English Version), February 2014. This refers to a working lifetime of 40 years and exposure for 8h every working day which is equivalent to the time worked by staff at BASF's Ultraform plant.

11 REFERENCES

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