Conforms to Regulation (EC) No. 1907/2006 (REACH), Annex II, as amended by Regulation (EU) No. 2015/830

SAFETY DATA SHEET

FOR INDUSTRIAL USE ONLY

EPIKOTE™ Resin 862

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Product name	:	EPIKOTE™ Resin 862
SDS Number	:	L1262
Index number	:	Not available
EC number	:	500-006-8
CAS number	:	9003-36-5
REACH Registration number	:	01-2119454392-40-0000
Product type	:	Epoxy Resin

1.2 Relevant identified uses of the substance or mixture and uses advised against

Industrial use

Identified use	Process Category (PROC)	Sector of Use (SU)	Environmental Release Category (ERC)*
ES BPFDGE 1.1S			
Industrial manufacturing including synthesis of the substance and blending, or use as an intermediate or monomer in reactions by the manufacturer or DU.	PROC 1 PROC 2 PROC 3	SU 3 SU 8 SU 9 SU 11 SU 12	mERC 1.1 mERC 1.2
ES BPFDGE 1.2S			
Industrial manufacturing including synthesis of the substance and blending, or use as an intermediate or monomer in reactions by the manufacturer or DU.	PROC 4 PROC 8a PROC 8b PROC 9	SU 3 SU 8 SU 9 SU 11 SU 12	mERC 1.1 mERC 1.2
ES BPFDGE 2.1S			
Industrial processes for blending or formulation into a mixture, and packaging of the product or mixtures, including transfers of material or mixtures between vessels, containers and/or shipping tanks. This includes dedicated as well as non-dedicated facilities. This ES covers the activities of most or all of our direct customer DU's.	PROC 5 PROC 8a PROC 8b	SU 3 SU 10	mERC 1.2
ES BPFDGE 3.1S			

Industrial processes for use and end use in manufacture of an article or finished product, including mixtures and formulations. This includes also blending or formulation into a mixture, and packaging of the product or mixtures as well as packaging into small containers for whole sale or retail sales, including transfers of material or mixtures between vessels, containers and/or shipping tanks for both dedicated and non-dedicated facilities.	PROC 5 PROC 6 PROC 7 PROC 8a PROC 8b PROC 9 PROC 10 PROC 13 PROC 14 PROC 15 PROC 16 PROC 19	SU 1 SU 2a SU 2b SU 3 SU 5 SU 6a SU 6b SU 7 SU 8 SU 9 SU 10 SU 11 SU 12 SU 13 SU 15 SU 16 SU 17 SU 18 SU 19 SU 23 SU 24	mERC 1.2

Professional use

Identified use	Process Category (PROC)	Sector of Use (SU)	Environmental Release Category (ERC)*
ES BPFDGE 3.2S			
Professional uses and end uses of an article or product, including mixtures, formulations and transfers of material or mixtures between containers and packaging into containers for whole sale or retail sales.	PROC 5 PROC 6 PROC 8a PROC 8b PROC 9 PROC 10 PROC 11 PROC 13 PROC 14 PROC 15 PROC 16 PROC 19 PROC 20	SU 1 SU 5 SU 6a SU 6b SU 7 SU 8 SU 9 SU 10 SU 11 SU 12 SU 13 SU 15 SU 16 SU 17 SU 18 SU 19 SU 22 SU 24	mERC 1.2

The Enviromental Release Category also includes mERC (modified ERC) and spERC (specific ERC)

See Section 16 for the full text of the PROCs, SUs and ERCs declared above.

1.3 Details of the supplier of the safety data sheet

Manufacturer/Supplier/Importer : Hexion B.V.
Seattleweg 17
3195 ND Pernis - Rotterdam
The Netherlands

Contact person : 4information@hexion.com

Telephone	:	General information +31 (0)10 295 4000
1.4 Emergency telephone number		
Supplier	:	CARECHEM24
Telephone number	:	+44 (0) 1235 239 670

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP/GHS]

Skin Corr./Irrit. 2 H315
Skin Sens. 1 H317
Aquatic Chronic 2 H411

See Section 16 for the full text of the H statements declared above.

2.2 Label elements

Hazard pictograms :

Signal word : Warning

Hazard statements :
Causes skin irritation.
May cause an allergic skin reaction.
Toxic to aquatic life with long lasting effects.

Precautionary statements

Prevention :
Wear protective gloves.
Avoid release to the environment.
Avoid breathing vapor.

Response :
IF ON SKIN:
Wash with plenty of soap and water.
If skin irritation or rash occurs:
Get medical attention.

Storage : Not applicable.

Disposal :
Dispose of contents and container in accordance with all local, regional, national and international regulations.

Hazardous ingredients :
Formaldehyde, polymer with (chloromethyl)oxirane and phenol, mw <=700

Supplemental label elements : Not applicable.

2.3 Other hazards

Substance meets the criteria for : No.

PBT according to Regulation (EC) No. 1907/2006, Annex XIII

Substance meets the criteria for vPvB according to Regulation (EC) No. 1907/2006, Annex XIII : Not available

Other hazards which do not result in classification : None known.

SECTION 3: Composition/information on ingredients

Substance/mixture : Mono-constituent substance

Product/ingredient name	Identifiers	% by weight	Classification Regulation (EC) No. 1272/2008 [CLP]	Type
Formaldehyde, polymer with (chloromethyl)oxirane and phenol, mw <=700	RRN : 01-2119454392-40 EC:500-006-8 CAS : 9003-36-5 Index:	100	Skin Corr./Irrit. 2, H315 Skin Sens. 1, H317 Aquatic Chronic 2, H411	[A]

Type
[A] Constituent
[B] Impurity
[C] Stabilizing additive

Type
[1] Substance classified with a health or environmental hazard
[2] Substance with a workplace exposure limit
[3] Substance meets the criteria for PBT according to Regulation (EC) No. 1907/2006, Annex XIII
[4] Substance meets the criteria for vPvB according to Regulation (EC) No. 1907/2006, Annex XIII

See Section 16 for the full text of the H statements declared above.
There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment and hence require reporting in this section.
Occupational exposure limits, if available, are listed in Section 8.

SECTION 4: First aid measures

4.1 Description of first aid measures

Eye contact : Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for at least 10 minutes. Get medical attention.

Inhalation : Remove victim to fresh air and keep at rest in a position comfortable for breathing. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Get medical attention if adverse health effects persist or are severe. If unconscious, place in recovery

position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.

Skin contact : Wash with plenty of soap and water. Remove contaminated clothing and shoes. Wash contaminated clothing thoroughly with water before removing it, or wear gloves. Continue to rinse for at least 10 minutes. Get medical attention. In the event of any complaints or symptoms, avoid further exposure. Wash clothing before reuse. Clean shoes thoroughly before reuse.

Ingestion : Wash out mouth with water. Remove dentures if any. Remove victim to fresh air and keep at rest in a position comfortable for breathing. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. Do not induce vomiting unless directed to do so by medical personnel. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Get medical attention if adverse health effects persist or are severe. Never give anything by mouth to an unconscious person. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.

Protection of first aid personnel : No action shall be taken involving any personal risk or without suitable training. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Wash contaminated clothing thoroughly with water before removing it, or wear gloves.

4.2 Most important symptoms and effects, both acute and delayed

Potential acute health effects

Eye contact : No known significant effects or critical hazards.
Inhalation : No known significant effects or critical hazards.
Skin contact : Causes skin irritation. May cause an allergic skin reaction.
Ingestion : No known significant effects or critical hazards.

Over-exposure signs/symptoms

Eye contact : Adverse symptoms may include the following:
pain or irritation
watering
redness

Inhalation : No specific data.

Skin contact : Adverse symptoms may include the following:
irritation
redness

Ingestion : No specific data.

4.3 Indication of any immediate medical attention and special treatment needed

Notes to physician : Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.

Specific treatments : No specific treatment.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media	:	Use water spray, fog or foam.Use an extinguishing agent suitable for the surrounding fire.
Unsuitable extinguishing media	:	Do not use water jet.None known.

5.2 Special hazards arising from the substance or mixture

Hazards from the substance or mixture	:	In a fire or if heated, a pressure increase will occur and the container may burst. This material is toxic to aquatic life with long lasting effects. Fire water contaminated with this material must be contained and prevented from being discharged to any waterway, sewer or drain.
Hazardous thermal decomposition products	:	Decomposition products may include the following materials: carbon dioxide carbon monoxide halogenated compounds

5.3 Advice for firefighters

Special protective actions for fire-fighters	:	Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.
Special protective equipment for fire-fighters	:	Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode. Clothing for fire-fighters (including helmets, protective boots and gloves) conforming to European standard EN 469 will provide a basic level of protection for chemical incidents.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel	:	No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilled material. Avoid breathing vapor or mist. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment.
For emergency responders	:	If specialised clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".

6.2 Environmental precautions	:	Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air). Water polluting material. May be harmful to the environment if released in large quantities. Collect spillage.

6.3 Methods and material for containment and cleaning up

Small spill	:	Stop leak if without risk. Move containers from spill area. Dilute with water and mop up if water-soluble. Alternatively, or if water-insoluble, absorb with an inert dry material and place in an appropriate waste disposal container. Dispose of via a licensed waste disposal contractor.
Large spill	:	Stop leak if without risk. Move containers from spill area. Approach release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Contain and collect spillage

with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations. Dispose of via a licensed waste disposal contractor. Contaminated absorbent material may pose the same hazard as the spilled product.

6.4 Reference to other sections : See Section 1 for emergency contact information.
See Section 8 for information on appropriate personal protective equipment.
See Section 13 for additional waste treatment information.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Protective measures : Put on appropriate personal protective equipment (see section 8 of SDS). Persons with a history of skin sensitization problems should not be employed in any process in which this product is used. Do not get in eyes or on skin or clothing. Do not ingest. Avoid breathing vapor or mist. Avoid release to the environment. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Empty containers retain product residue and can be hazardous. Do not reuse container.

Advice on general occupational hygiene : Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.

7.2 Conditions for safe storage, including any incompatibilities

Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see section 10 of SDS) and food and drink. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination.

7.3 Specific end use(s)

Recommendations : Not available

Industrial sector specific solutions : Not available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational exposure limits

No exposure limit value known.

Recommended monitoring procedures : If this product contains ingredients with exposure limits, personal, workplace atmosphere or biological monitoring may be required to determine the effectiveness of the ventilation or other control measures and/or the necessity to use respiratory protective equipment. Reference should be made to monitoring standards, such as the following: European Standard EN 689 (Workplace atmospheres - Guidance for the assessment of exposure by

inhalation to chemical agents for comparison with limit values and measurement strategy) European Standard EN 14042 (Workplace atmospheres - Guide for the application and use of procedures for the assessment of exposure to chemical and biological agents) European Standard EN 482 (Workplace atmospheres - General requirements for the performance of procedures for the measurement of chemical agents) Reference to national guidance documents for methods for the determination of hazardous substances will also be required.

DNELs/DMELs

Product/ingredient name	Type	Exposure	Value	Population	Effects
Formaldehyde, polymer with (chloromethyl)oxirane and phenol, mw <=700	DNEL	Short term Dermal	8.3 µg/cm²	Workers	Local
Formaldehyde, polymer with (chloromethyl)oxirane and phenol, mw <=700	DNEL	Long term Dermal	104.15 mg/kg bw/day	Workers	Systemic
Formaldehyde, polymer with (chloromethyl)oxirane and phenol, mw <=700	DNEL	Long term Inhalation	29.39 mg/m³	Workers	Systemic
Formaldehyde, polymer with (chloromethyl)oxirane and phenol, mw <=700	DNEL	Long term Dermal	62.5 mg/kg bw/day	General	Systemic
Formaldehyde, polymer with (chloromethyl)oxirane and phenol, mw <=700	DNEL	Long term Inhalation	8.7 mg/m³	General	Systemic
Formaldehyde, polymer with (chloromethyl)oxirane and phenol, mw <=700	DNEL	Long term Oral	6.25 mg/kg bw/day	General	Systemic

DNEL/DMEL Summary : Not available

PNECs

Product/ingredient name	Type	Compartment Detail	Value	Method Detail
Formaldehyde, polymer with (chloromethyl)oxirane and phenol, mw <=700	PNEC	Fresh water	0.003 mg/l	
Formaldehyde, polymer with (chloromethyl)oxirane and phenol, mw <=700	PNEC	Marine	0.0003 mg/l	
Formaldehyde, polymer with (chloromethyl)oxirane and	PNEC	Sewage Treatment Plant	10 mg/l	

phenol, mw <=700				
Formaldehyde, polymer with (chloromethyl)oxirane and phenol, mw <=700	PNEC	Fresh water sediment	0.294 mg/kg dwt	
Formaldehyde, polymer with (chloromethyl)oxirane and phenol, mw <=700	PNEC	Marine water sediment	0.0294 mg/kg dw	
Formaldehyde, polymer with (chloromethyl)oxirane and phenol, mw <=700	PNEC	Soil	0.237 mg/kg dwt	
Formaldehyde, polymer with (chloromethyl)oxirane and phenol, mw <=700	PNEC	Intermittent Releases	0.0254 mg/l	

PNEC Summary : Not available

Derived No-Effect Levels' (DNEL's) and Predicted No-Effect Concentrations' (PNEC's)

Explanatory note:
REACH requires manufacturers and importers to establish and report 'Derived No-Effect Levels' (DNEL's) for humans by inhalation, ingestion and dermal routes of exposure and 'Predicted No-Effect Concentrations' (PNEC's) for environmental exposure. DNEL's and PNEC's are established by the registrant without an official consultation process, and are not intended to be directly used for setting workplace or general population exposure limits. They are primarily used as input values in running Quantitative Risk Assessment models (like the ECETOC-TRA model).

Due to differences in calculation methodology the DNEL will tend to be lower (sometimes significantly) than any corresponding health-based OEL for that chemical substance. Further although DNEL's (and PNEC's) are an indication for setting risk reduction measures, it should be recognized that these limits do not have the same regulatory application as officially endorsed governmental OEL's.

8.2 Exposure controls

Appropriate engineering controls : No special ventilation requirements. Good general ventilation should be sufficient to control worker exposure to airborne contaminants. If this product contains ingredients with exposure limits, use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure below any recommended or statutory limits.

Individual protection measures

Hygiene measures : Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

Eye/face protection : Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: chemical splash goggles.

Skin protection

Hand protection	:	Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated. Material: 730 Camatril Minimum break through time: 480 min Material: 898 Butoject Minimum break through time: 480 min Producer: This recommendation is valid only for our Product as delivered. If this product will be mixed with other substances you need to contact a supplier of CE approved protective gloves (e.g. KCL GmbH, D-36124 Eichenzell, Tel. 0049 (0) 6659 87300, Fax. 0049 (0) 6659 87155, email: vertrieb@kcl.de).
Body protection	:	Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
Other skin protection	:	Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
Respiratory protection	:	Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.
Environmental exposure controls	:	Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance

Physical state	:	Liquid
Color	:	Light yellow
Odor	:	Not available
Odor threshold	:	Not available
pH	:	Estimated. 7
Melting point/freezing point	:	Not determined
Initial boiling point and boiling range	:	Greater than 200 °C
Flash point	:	Greater than 150 °C
Evaporation rate	:	Not available
Upper/lower flammability or	:	**Lower:** Not available

explosive limits		**Upper:** Not available
Vapor pressure	:	82 Pa @ 20 °C
Vapor density	:	Not available
Relative density	:	Not available
Density	:	1,180 kg/m3 (ASTM D 4052)
Solubility(ies)	:	Not available
Solubility in water	:	Negligible
Partition coefficient: n-octanol/water	:	3
Auto-ignition temperature	:	Greater than 300 °C
Decomposition temperature	:	Not available
Viscosity	:	**Dynamic:** 2.5 - 4.5 Pa·s @ 25 °C **Kinematic:** Not available
Explosive properties	:	Not available
Oxidizing properties	:	Not available

9.2 Other information

No additional information.

SECTION 10: Stability and reactivity

10.1 Reactivity	:	Stable under normal conditions.
10.2 Chemical stability	:	The product is stable.
10.3 Possibility of hazardous reactions	:	Hazardous reactions or instability may occur under certain conditions of storage or use.
10.4 Conditions to avoid	:	Caustic soda (sodium hydroxide) can induce vigorous polymerisation at temperatures around 200 °C. No specific data.
10.5 Incompatible materials	:	No specific data.
10.6 Hazardous decomposition products	:	Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

Product/ingredient name	Result	Species	Dose	Exposure
Formaldehyde, polymer with (chloromethyl)oxirane and phenol, mw <=700				
	LD50 Oral	Rat	> 2,000 mg/kg	-
Remarks - Oral:	The acute oral median lethal dose (LD50) in the Fischer 344 strain rat was found to be greater than 2000 mg/kg bodyweight.			
Remarks - Inhalation:	REACH Ek VII'ye göre, akut soluma çalışmasının oral olarak yapılması gerekmez ve bu madde için dermal çalışmalar mevcuttur.			
	LD50 Dermal	Rabbit	> 2,000 mg/kg	-

Conclusion/Summary : Not available

Acute toxicity estimates

Not available

Irritation/Corrosion

Product/ingredient name	Result	Species	Score	Exposure	Observation
Formaldehyde, polymer with (chloromethyl)oxirane and phenol, mw <=700	Skin - Erythema/Eschar 404 Acute Dermal Irritation/Corrosion	Rabbit	0.7	4 hrs	72 hrs
	Skin - Edema 404 Acute Dermal Irritation/Corrosion	Rabbit	0	4 hrs	4 - 504 hrs
	eyes - Cornea opacity 405 Acute Eye Irritation/Corrosion	Rabbit	0		1 - 168 hrs
	eyes - Iris lesion 405 Acute Eye Irritation/Corrosion	Rabbit	0		1 - 168 hrs
	eyes - Redness of the conjunctivae 405 Acute Eye Irritation/Corrosion	Rabbit	0		1 - 168 hrs
	eyes - Edema of the conjunctivae 405 Acute Eye Irritation/Corrosion	Rabbit	0		1 - 168 hrs
	Skin - Mild irritant	Rabbit		24 hrs	-

Conclusion/Summary

Skin : Not available
eyes : Not available
Respiratory : Not available

Sensitization

Product/ingredient name	Route of exposure	Species	Result
Formaldehyde, polymer with (chloromethyl)oxirane and phenol, mw <=700	Skin	-	-
Remarks:	The Buehler method was employed to evaluate the dermal sensitization potential of Liquid BPFDGE Epoxy Resin. Ten male guinea pigs received 0.4 ml of test substance topically once a week for three weeks. A positive control of Liquid BPFDGE Epoxy Resin was used on ten additional animals. The challenge phase began two weeks later with an addition 5 animals exposed to 0.4 ml of Liquid BPFDGE Epoxy Resin. The negative control had 0 positive reactions; the Liquid BPFDGE Epoxy Resin had 4 of 10 with positive reactions and the positive control had 8 of ten positive reactions. Under the conditions of this study, the test material caused delayed hypersensitivity in guinea pigs.		

Conclusion/Summary

Skin : Not available
Respiratory : Not available

Mutagenicity

Product/ingredient name	Test	Experiment	Result

Formaldehyde, polymer with (chloromethyl)oxirane and phenol, mw <=700	-	; -	-
Remarks:	Bisphenol F Diglycidylether induced gene-mutation in the Ames/Salmonella mutation test and chromosomal aberrations in human lymphocytes in multiple independent testing guideline GLP studies. Furthermore, the structural analog, Bisphenol A Diglycidylether (BPADGE) induce a significant increase of the mutant frequency in L5178Y mouse lymphoma cells in culture supporting the other findings. Therefore, BPFDGE is genotoxic in vitro. When Bisphenol F Diglycidylether was evaluated for genotoxicity potential in multiple GLP in vivo assays including the mouse micronucleus, rat in vivo/in vitro UDS and MutaMouse tests no evidence of genotoxicity was observed. The results of other in vivo tests for genotoxicity also supported these negative findings for BPFDGE. Therefore, Bisphenol F Diglycidylether is not genotoxic in vivo.		

Conclusion/Summary : Not available

Carcinogenicity

Product/ingredient name	Result	Species	Dose	Exposure
Formaldehyde, polymer with (chloromethyl)oxirane and phenol, mw <=700	- - - - -	-		
Remarks:	Bisphenol F Diglycidylether (BPFDGE) was evaluated for the potential to induce local and systemic tumors in a mouse skin-painting 24 month study. Dermal treatment of mice twice a week with up to a 10% solution of Bisphenol F Diglycidylether (BPFDGE) did not induce any adverse findings of tumor incidence or local dermal effects. Therefore, BPFDGE is not a mouse carcinogen under the conditions of this study. The NOAEL was estimated to be approximately 800 mg/kg/day.			

Conclusion/Summary : Not available

Reproductive toxicity

Conclusion/Summary : Not available

Teratogenicity

Product/ingredient name	Result	Species	Dose	Exposure
Formaldehyde, polymer with (chloromethyl)oxirane and phenol, mw <=700	- - -	-	-	-
Remarks:	Diglycidyl ether of bisphenol A (DGEBPA) was tested for its embryo/fetal toxicity and teratogenicity in pregnant rabbits. DGEBPA was applied daily to the backs (clipped free of hair) of New Zealand White rabbits at dose levels of 0 (polyethylene glycol, vehicle control), 30, 100 or 300 mg/kg body weight/day at a dose volume of 1 ml/kg body weight/day on days 6 through 18 of gestation. Twenty six inseminated rabbits were used per dose group resulting in a minimum of 20 pregnant rabbits per exposure level. An occlusive bandage of absorbent gauze and non-absorbent cotton was placed over the dosing area on the back of each rabbit. The bandage was held in place for a minimum of 6 hours/day using a lycra/spandex jacket. Following the occlusion period the bandage and jacket were removed. Maternal toxicity was observed among pregnant rabbits in the 300 mg/kg dose group as evidenced by moderate to severe erythema, fissures, hemorrhage and slight edema at the exposure site. Similar, but less severe skin lesions were observed in pregnant rabbits in the 100 mg/kg/day exposure group. Skin effects (slight erythema) observed in pregnant rabbits in the 30 mg/kg/day dose group were not considered toxicicologically significant. No evidence of embryo/fetal toxicity or teratogenicity was observed at any dose level resulting in a embryo/fetal no-observed-effect			

	level of 300 mg/kg body weight/day.

Conclusion/Summary : Not available

Specific target organ toxicity (single exposure)

Not available

Specific target organ toxicity (repeated exposure)

Not available

Aspiration hazard

Not available

Information on likely routes of exposure : Not available

Potential acute health effects

Eye contact : No known significant effects or critical hazards.
Inhalation : No known significant effects or critical hazards.
Skin contact : Causes skin irritation. May cause an allergic skin reaction.
Ingestion : No known significant effects or critical hazards.

Symptoms related to the physical, chemical and toxicological characteristics

Eye contact : Adverse symptoms may include the following:
pain or irritation
watering
redness
Inhalation : No specific data.
Skin contact : Adverse symptoms may include the following:
irritation
redness
Ingestion : No specific data.

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Short term exposure

Potential immediate effects : Not available
Potential delayed effects : Not available

Long term exposure

Potential immediate effects : Not available
Potential delayed effects : Not available

Potential chronic health effects

Conclusion/Summary : Not available

General : Once sensitized, a severe allergic reaction may occur when subsequently exposed to very low levels.
Carcinogenicity : No known significant effects or critical hazards.
Mutagenicity : No known significant effects or critical hazards.
Teratogenicity : No known significant effects or critical hazards.
Developmental effects : No known significant effects or critical hazards.
Fertility effects : No known significant effects or critical hazards.

SECTION 12: Ecological information

12.1 Toxicity

Product/ingredient name	Result	Species	Exposure
Formaldehyde, polymer with (chloromethyl)oxirane and phenol, mw <=700			
	Acute LC50 2.54 mg/l -	Fish - Fish	96 h
	Acute EC50 2.55 mg/l - 202 Daphnia sp. Acute Immobilization Test and Reproduction Test	Aquatic invertebrates. Water flea	48 h
	Acute EC50 > 1,000 mg/l - 201 Alga, Growth Inhibition Test	Aquatic plants - Algae	72 h

Conclusion/Summary : Not available

12.2 Persistence and degradability

Product/ingredient name	Test	Result	Dose	Inoculum
Formaldehyde, polymer with (chloromethyl)oxirane and phenol, mw <=700		-		
Remarks:	Bisphenol F Diglycidylether was not readily biodegradable under the conditions of the O.E.C.D. 301 B and 301 D screening studies. The maximum percent biodegradation observed in one of the O.E.C.D. 301 B studies was 16% for 10 mg/L at 28 days of contact.			

Conclusion/Summary : Not available

12.3 Bioaccumulative potential

Product/ingredient name	LogPow	BCF	Potential
Formaldehyde, polymer with (chloromethyl)oxirane and phenol, mw <=700	3.3	150 150.00	low
EPIKOTE™ Resin 862	3	-	high

12.4 Mobility in soil

Soil/water partition coefficient (KOC) : Not available

Mobility : Not available

12.5 Results of PBT and vPvB assessment

PBT : P: Not available
B: Not available
T: No.

vPvB : vP: Not available
vB: Not available

12.6 Other adverse effects

: No known significant effects or critical hazards.
No known significant effects or critical hazards.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product

Methods of disposal : The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction.

Hazardous waste : The classification of the product may meet the criteria for a hazardous waste.

Packaging

Methods of disposal : The generation of waste should be avoided or minimized wherever possible. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible.

Special precautions : This material and its container must be disposed of in a safe way. Care should be taken when handling emptied containers that have not been cleaned or rinsed out. Empty containers or liners may retain some product residues. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

SECTION 14: Transport information

Regulatory information	14.1. UN number	14.2. UN proper shipping name	14.3. Transport hazard class(es)	14.4. Packing group
ADR/ADN	3082	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (LIQUID EPOXY RESIN)	9	III
RID	3082	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (LIQUID EPOXY RESIN)	9	III
ADN	3082	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (LIQUID EPOXY RESIN)	9	III
ICAO/IATA	3082	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (LIQUID EPOXY RESIN)	9	III
IMO/IMDG	3082	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (LIQUID EPOXY RESIN)	9	III

14.5. Environmental hazards

Environmentally hazardous and/or Marine Pollutant : Yes.

14.6 Special precautions for user : Transport within user's premises: always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

EU Regulation (EC) No. 1907/2006 (REACH)
Annex XIV - List of substances subject to authorization
Substances of very high concern

Carcinogen: Not listed
Mutagen: Not listed
Toxic to reproduction: Not listed
PBT: Not listed
vPvB: Not listed

Other EU regulations

REACH Status	:	The substance(s) in this product has (have) been Pre-Registered and/or Registered, or are exempted from registration, according to Regulation (EC) No. 1907/2006 (REACH).
Aerosol dispensers	:	Not applicable.
Annex XVII - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles	:	Not applicable.
EU - Prior Informed Consent. List of chemicals subject to the international PIC procedure (Annex I - Part 1)	:	Not listed
EU - Prior Informed Consent. List of chemicals subject to the international PIC procedure (Annex I - Part 2)	:	Not listed
EU - Prior Informed Consent. List of chemicals subject to the international PIC procedure (Annex I - Part 3)	:	Not listed

Seveso Directive
This product is controlled under the Seveso Directive.

National regulations

International regulations

International lists : Australia inventory (AICS) All components are listed or exempted.
Canada inventory All components are listed or exempted.
Japan inventory All components are listed or exempted.
China inventory (IECSC) All components are listed or exempted.
Korea inventory All components are listed or exempted.
New Zealand Inventory (NZIoC) All components are listed or exempted.
Philippines inventory (PICCS) All components are listed or exempted.
United States inventory (TSCA 8b) All components are listed or exempted.
Taiwan inventory (CSNN) All components are listed or exempted.

Chemical Weapons Convention List Schedule I Chemicals : Not listed

: Not listed

Chemical Weapons Convention List Schedule II Chemicals : Not listed

: Not listed

Chemical Weapons Convention List Schedule III Chemicals : Not listed

: Not listed

15.2 Chemical Safety Assessment : This product contains substances for which Chemical Safety Assessments are still required.

SECTION 16: Other information

Abbreviations and acronyms : ATE = Acute Toxicity Estimate
CLP = Classification, Labelling and Packaging Regulation [Regulation (EC) No. 1272/2008]
DNEL = Derived No Effect Level
DMEL = Derived Minimal Effect Level
EUH statement = CLP-specific Hazard statement
PNEC = Predicted No Effect Concentration
RRN = REACH Registration Number
PBT = Persistent, Bioaccumulative and Toxic
vPvB = Very Persistent and Very Bioaccumulative

Procedure used to derive the classification according to Regulation (EC) No. 1272/2008 [CLP/GHS]

Classification	Justification
Skin Corr./Irrit. 2, H315	Calculation method
Skin Sens. 1, H317	Calculation method
Aquatic Chronic 2, H411	Calculation method

Full text of abbreviated H statements :

H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H411	Toxic to aquatic life with long lasting effects.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.

H411	Toxic to aquatic life with long lasting effects.

Full text of classifications [CLP/GHS] :

Skin Corr./Irrit. 2, H315	SKIN CORROSION/IRRITATION - Category 2
Skin Sens. 1, H317	SKIN SENSITIZATION - Category 1
Aquatic Chronic 2, H411	AQUATIC HAZARD (LONG-TERM) - Category 2
Skin Corr./Irrit. 2, H315	SKIN CORROSION/IRRITATION - Category 2
Skin Sens. 1, H317	SKIN SENSITIZATION - Category 1
Aquatic Chronic 2, H411	AQUATIC HAZARD (LONG-TERM) - Category 2

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Annex: Exposure Scenario BPFDGE 1.1S

1. Title	
	Exposure Scenario BPFDGE 1.1S Closed Process Industrial Manufacturing
Systematic title based on use descriptor	SU 3 SU 8 SU 9 SU 11 SU 12 PROC 1 PROC 2 PROC 3 mERC 1.1 - Environmental releases related to manufacture and use of the substance by the Registrant. mERC 1.2 - Environmental releases related to use of the substance as a reactant, monomer or blending in a mixture by a DU.
Processes, tasks and activities	Industrial manufacturing including synthesis of the substance and

covered	blending, or use as an intermediate or monomer in reactions by the manufacturer or DU.
Assessment Method	ECETOC-TRA modelling, using DNEL's and PNEC's derived from the REACH Registration IUCLID dossier.

2. Operational conditions and risk management measures

RMM's and OC's apply to all SU and PROC/ERC categories listed above. The user should select whichever combination of RMM's and OC's are necessary to reduce worker and environmental exposure to the level required to achieve <1.0 Risk Ratios. Risk Ratios can be calculated using PNEC and DNEL values listed in the SDS.

RMM's - See section 2.1
Operational Controls - See sections 2.1 and 2.2

Number of sites: Not applicable to this risk management modelling. Modelling based on conservative assumption of 100% use at manufacturing site ('worst case' assumptions).

2.1 Control of workers exposure

Product characteristic

There are no specific product characteristics relevant to this exposure scenario. ES assumes substance is 100% concentration ('worst case').

Amounts used

ES and risk assessment modelling assumes total EU production volume of the legal entity at a single site (actual volume is confidential). DU's will be using only a fraction of this total volume ('worst case').

Frequency and duration of use/exposure

365 days/year, 24 hours/day operations ('worst case'). Worker risk assessment assumes 4-8 hour/day and 220 days/yr maximum default value in ECETOC-TRA, which is a 'worst case'. Actual employee exposure duration is much less.

Human factors not influenced by risk management

None specifically known or relevant. Risk modelling does not use any additional exposure mitigation factors (worst case).
Risk assessment utilized standard ECETOC modelling parameters for worker respiratory volume (10M3/day), skin contact area and body weight. Standard values also used for room size and ventilation, but not generally applicable to this ES.

Other given operational conditions affecting workers exposure

Operators should be isolated from the process area, and most of working time should be in a control room remote from the process equipment.

Technical conditions and measures at process level (source) to prevent release

Conditions and Measures to be selected to reduce exposure and risk:
Closed process.
Continuous or batch substance flow from reactor or mixing vessels to storage or distribution tanks.
Low emission permanent installation pipe connections and flanges emission control system
Double sealed pumps.
Overhead vapour recovery and removal system.
Sealed tanks and reactor vessel with safety releases.
Safety releases and venting done to specific controlled emission points or to emission control equipment.
Remotely operated values and process equipment to isolate worker from process operation
Product quality sampling system to minimize worker exposure. (i.e. closed bottle filling systems)
For laboratory analysis, positive flow fume hoods.
Purging and venting procedures prior to maintenance work.

Technical conditions and measures to control dispersion from source towards the worker

Workers remotely control the manufacturing process and are generally not in the area of process equipment.

Organisational measures to prevent /limit releases, dispersion and exposure

Must utilize a combination of operational risk management measures or procedures typically including:
Worker training in process operations.
Workers safety training.
Process Safety Management reviews to identify and minimize risk of process releases and accidents.
Job Hazard Analysis
Spill Control and Countermeasures plan.
Preventative maintenance program.
Safety valve monitoring and replacement procedure.
Accident reporting, investigation and remedial action program.

Leak detection and monitoring program.
Site industrial hygiene and PPE procedure.
Permit to Work and Equipment Safe Isolation program

Conditions and measures related to personal protection, hygiene and health evaluation

Employees must be trained in the proper use of PPE, and when to use it.

Skin protection :

Minimum efficiency for PPE	PROC 1 PROC 2 PROC 3
50%	Not recommended - Sensitizer
90%	Not recommended - Sensitizer
95%	> 4 hrs

Respiratory protection :

Minimum efficiency for PPE	PROC 1 PROC 2 PROC 3
50%	Not needed
90%	Not needed
95%	Not needed
99%	Not needed

Skin protection:
For any more specific recommendations consult the SDS.

RMM SK3
Protection efficiency: 95%
ECETOC-TRA risk modelling results based upon a minimum required protective factor of 0.95 for skin protection. Engineering controls, PPE and work practices should provide the highest level of protection. If a user wants to utilize Tier 2 site-specific worker exposure calculations, this value is used to calculate the allowable skin exposure area (cm2) for each applicable PROC.

The primary RMM is avoidance of skin contact through Operational Controls, procedures and process equipment design. If accidental contact occurs product must be immediately removed from the skin. Recommended or required PPE must be chosen based upon the duration and extent of worker exposure. Employees must be instructed on the use and removal of PPE.
PPE recommendations:
Gloves: Use long gauntlet type gloves where hand contact is possible.
For longer term contact (BTT 4+ hours): Butyl rubber (minimum 0.5-0.6 mm), EVAL ethylene vinyl alcohol laminate (typically 0.10-0.15 mm) only. For short term or incidental contact: Butyl rubber, EVAL, Nitrile
Use gloves approved to relevant standards (e.g. EN 374, ASTM F739). Glove thickness will be related to the breakthrough time (BTT) and to specific supplier's glove design. Suitability and durability of a glove is dependent on the usage, e.g. frequency and duration of contact, chemical resistance of glove material, dexterity, and physical wear and tear. Always seek specific advice from glove supplier. Where tasks result in physical damage or where the gloves become excessively contaminated with surface debris double-gloving is recommended. In that case the outer glove may be of a less protective material such as PVC or neoprene based upon the substance and the glove suppliers recommendation. See SDS for any specific recommendation.
Face shield: Full face shield meeting industry standards (EN 166 a/o ANSI Z87.1) in combination with neck protection (PVC).
Protective clothing: Butyl rubber apron, boots without laces, protective arm sleeves and full body suit required if applicable to the specific use and tasks performed.
In case of vapours use a splash hood.
Secondary contact from vapours and mists may be a significant source of secondary skin contact. Contact must be eliminated through the use of engineering controls or LEV.

Eye Protection:

RMM EY3
Maximum recommended protection:
Anytime when there is a severe risk of splash or spray or if the material in use is highly hazardous the use of a Face shield is necessary. (Full-face supplied air respiratory protection might be needed instead to prevent inhalation risks). Face shields protect the eyes, face, and neck from chemical splashes and spray as well as flying particles. Face shields should not be worn independently. Therefore safety glasses or goggles must be worn underneath face shields for complete protection.
Safety glasses, splash goggles and Face shields must meet EN 166 a/o ANSI Z87.1 standards.

Respiratory protection:
For all respiratory protection equipment training on proper usage is recommended.

Good work practices and PPE should be used as appropriate and is recommended whenever there is potential for exposure.

General comment:
These practices are designed for normal working conditions and operations. For emergency situations additional measures may be needed and the highest level of protection would generally be recommended.

2.2 Control of environmental exposure

Product characteristic

ES covers substance at 100% concentration (‘worst case’).

Amounts used

ES and risk modelling covers total annual production of this substance for this legal entity at a single site. DU’s would be using only a fraction of this total production, and hence the risk ratios at SU3, SU8, SU9, SU11 or SU12 closed process manufacturing plants would be lower than at the plant manufacturing the substance under the same conditions of use (‘worst case’).

Frequency and duration of use/exposure

365 days/year, continuous use (‘worst case’).

Environment factors not influenced by risk management

High flow rate of receiving water body at the “Local” level in the EUSES/ECETOC-TRA model. Flow rate chosen for consistency with actual manufacturing site of substance.

Other given operational conditions affecting environmental exposure

Closed process.
Process equipment is indoors.
Full liquid containment process and spills collected and directed to waste water treatment.
Vapour and overhead recovery system, with collected substance directed to waste water treatment.
Modelling procedure for mERC 1.1 used environmental release values of 10exp-5 for uncontrolled air releases, 10exp-6 for waste water releases to treatment plant, and 10exp-4 for uncontrolled releases to soil.
For ECETOC model, fraction of total production at source = 100%
ECETOC default values for waste water treatment plant were used (EUSES is similar or identical).
Environmental risk assessment done at “Local”, “Regional” and “Continental” levels.
Modelling procedure for mERC 1.2 used environmental release values of 10exp-2 for uncontrolled air releases, 10exp-4 for waste water releases to treatment plant, 0.8 for fraction connected to sewer system, 10exp-2 for uncontrolled releases to soil and 10exp-2 for fraction directly emitted to Regional marine systems. 365days/year releases (‘worst case’).
For mERC 1.2 DU environmental releases, assumption was used that maximum quantity at a single user site was 10% of total Registered substance production (‘worst case’).

Technical conditions and measures at process level (source) to prevent release

Conditions and Measures to be selected to reduce exposure and risk:
Closed process.
Continuous or batch substance flow from reactor or mixing vessels to storage or distribution tanks.
Low emission permanent installation pipe connections and flanges; emission control system
Double sealed pumps.
Overhead vapour recovery and removal system.
Sealed tanks and reactor vessel with safety releases.
Safety releases and venting done to specific controlled emission points or to emission control equipment.
Purging and venting procedures prior to maintenance work.

Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil

Conditions and Measures to be selected to reduce exposure and risk:
Closed process.
Continuous or batch substance flow from reactor or mixing vessels to storage or distribution tanks.
Low emission permanent installation pipe connections and flanges
Double sealed pumps.
Overhead vapour recovery and removal system.
Sealed tanks and reactor vessel with safety releases.
Remotely operated values and process equipment to isolate worker from process operation
Product quality sampling system to minimize worker exposure.
Sludge removal from waste water treatment plant, incinerated.
Risk assessment used conservative (worst case) default assumptions for removal and degradation efficiency.
Treatment plant size and input parameters used ECETOC-TRA conservative default assumptions.

Organizational measures to prevent/limit release from site

Must utilize a combination of operational risk management measures or procedures typically including:
Worker training in process operations.
Workers safety training.
Process Safety Management reviews to identify and minimize risk of process releases and accidents.
Spill Control and Countermeasures plan.
Preventative maintenance program.
Accident reporting, investigation and remedial action program.
Leak detection and monitoring program.
On-site waste water treatment system utilizing solids separation, aeration and biological treatment.
Energy recovery waste treatment.

Conditions and measures related to municipal sewage treatment plant

Risk assessment assumes that waste water is treated on-site. However, treatment may also be accomplished using a municipal sewage treatment plant if the input variables and treatment plant parameters are consistent with substance releases.

Conditions and measures related to external treatment of waste for disposal

Non-aqueous process losses, spill recovery material or waste should be disposed of e.g. by incineration or another destructive process. Another option would be external treatment like for instance via distillation for raw material recovery.

Conditions and measures related to external recovery of waste

Waste recovery is not necessary and is not feasible for this substance, other than the recovery of energy value by incineration.

3. Exposure estimation and reference to its source

All Risk Characterisation Ratios (RCR) derived from ECETOC-TRA model.

Workers exposure

Applicable duration of activity indicated in tables in section 2.1

	RCR
Oral	N/A
Dermal	<1.0
Inhalation	<1.0
Total exposure	<1.0 Dermal + Inhalation

Environmental exposure

	RCR
In STP	<0.01
Local freshwater	<1.0
Freshwater sediment	N/A
Local terrestrial	N/A
Local marine water	N/A
Local marine sediment	N/A
Human via environment	<0.1

4. Guidance to DU to evaluate whether he works inside the boundaries set by the ES
Risk Management Measures (RMM's) and Operational Controls (OC's) listed in this ES would usually be adequate to control risks to risk ratios <1.0. Risk assessment above was done using conservative input values and assumptions, and is generally applicable to DU's for the indicated SU's. Not all the indicated RMM's and OC's may be necessary in a specific manufacturing plant or under specific circumstances of use. The DU must determine for their own operations the required measures. ECETOC-TRA model was used for risk assessment, but EUSES model may also be used for environmental risk. DU's can calculate their own Risk Ratios and/or PEC/PNEC ratios using DNEL's and PNEC's listed in the SDS, as well as the actual quantities of the substance, daily usage pattern, substance concentration, etc.

Annex: Exposure Scenario BPFDGE 1.2S

1. Title	
	Exposure Scenario BPFDGE 1.2S Industrial manufacturing, batch processes, substance transfers, packaging, blending.
Systematic title based on use descriptor	SU 3 SU 8 SU 9 SU 11 SU 12 PROC 4 PROC 8a PROC 8b PROC 9 mERC 1.1 - Environmental releases related to manufacture and use of the substance by the Registrant. mERC 1.2 - Environmental releases related to use of the substance as a reactant, monomer or blending in a mixture by a DU.
Processes, tasks and activities covered	Industrial manufacturing including synthesis of the substance and blending, or use as an intermediate or monomer in reactions by the manufacturer or DU.
Assessment Method	ECETOC-TRA modelling, using DNEL's and PNEC's derived from the REACH Registration IUCLID dossier.
2. Operational conditions and risk management measures	
RMM's and OC's apply to all SU and PROC/ERC categories listed above. The user should select whichever combination of RMM's and OC's are necessary to reduce worker and environmental exposure to the level required to achieve <1.0 Risk Ratios. Risk Ratios can be calculated using PNEC and DNEL values listed in the SDS. RMM's - See section 2.1 Operational Controls - See sections 2.1 and 2.2	
Number of sites: Not applicable to this risk management modelling. Modelling based on conservative assumption of 100% use at manufacturing site ('worst case' assumptions).	
2.1 Control of workers exposure	
Product characteristic	
There are no specific product characteristics relevant to this exposure scenario. ES assumes substance is 100% concentration ('worst case').	
Amounts used	
ES and risk assessment modelling assumes total EU production volume of the legal entity at a single site (actual volume is confidential). DU's will be using only a fraction of this total volume ('worst case').	
Frequency and duration of use/exposure	
365 days/year, 24 hours/day operations ('worst case'). Worker risk assessment assumes 4-8 hour/day (unless otherwise indicated in tables under "Conditions and measures related to personal protection, hygiene and health evaluation") and 220 days/yr maximum default value in ECETOC-TRA, which is a 'worst case'. Actual employee exposure duration is much less.	

Human factors not influenced by risk management

None specifically known or relevant. Risk modelling does not use any additional exposure mitigation factors (worst case).
Risk assessment utilized standard ECETOC modelling parameters for worker respiratory volume (10M3/day), skin contact area and body weight. Standard values also used for room size and ventilation, but not generally applicable to this ES.

Other given operational conditions affecting workers exposure

Operators should be isolated from the process area, and most of working time should be in a control room remote from the process equipment.

Technical conditions and measures at process level (source) to prevent release

Conditions and Measures to be selected to reduce exposure and risk:
Indoor operations with LEV.
Closed or semi-closed process continuous or batch substance flow from reactor or mixing vessels to storage or distribution tanks.
Low emission permanent installation pipe connections and flanges; emission control system
Double sealed pumps.
Overhead vapour recovery and removal system.
Sealed tanks and reactor vessel with safety releases.
Safety releases and venting done to specific controlled emission points or to emission control equipment.
Remotely operated values and process equipment to isolate worker from process operation
Product quality sampling system to minimize worker exposure. (i.e. closed bottle filling systems)
Automated or semi-automated container filling equipment. For container filling systems designed to reduce splashing and vaporization. For example, 'bottom filling' of trucks, railcars and large Isotanks, or use of filling lances for any container.
For laboratory analysis, positive flow fume hoods.
Purging and venting procedures prior to maintenance work.

Technical conditions and measures to control dispersion from source towards the worker

Workers remotely control the manufacturing process and are generally not in the area of process equipment.
Indoors with LEV.

Organisational measures to prevent /limit releases, dispersion and exposure

Must utilize a combination of operational risk management measures or procedures typically including:
Worker training in process operations.
Workers safety training.
Process Safety Management reviews to identify and minimize risk of process releases and accidents.
Job Hazard Analysis
Spill Control and Countermeasures plan.
Preventative maintenance program.
Safety valve monitoring and replacement procedure.
Accident reporting, investigation and remedial action program.
Leak detection and monitoring program.
Site industrial hygiene and PPE procedure.
Permit to Work and Equipment Safe Isolation program

Conditions and measures related to personal protection, hygiene and health evaluation

Employees must be trained in the proper use of PPE, and when to use it.

Skin protection :

Minimum efficiency for PPE	PROC 4 PROC 8a PROC 8b PROC 9
50%	Not recommended - Sensitizer
90%	Not recommended - Sensitizer
95%	> 4 hrs

Respiratory protection :

Minimum efficiency for PPE	PROC 4 PROC 8a

	PROC 8b PROC 9
50%	Not needed
90%	Not needed
95%	Not needed
99%	Not needed

Skin protection:
For any more specific recommendations consult the SDS.

RMM SK3
Protection efficiency: 95%
ECETOC-TRA risk modelling results based upon a minimum required protective factor of 0.95 for skin protection. Engineering controls, PPE and work practices should provide the highest level of protection. If a user wants to utilize Tier 2 site-specific worker exposure calculations, this value is used to calculate the allowable skin exposure area (cm2) for each applicable PROC.

The primary RMM is avoidance of skin contact through Operational Controls, procedures and process equipment design.If accidental contact occurs product must be immediately removed from the skin. Recommended or required PPE must be chosen based upon the duration and extent of worker exposure. Employees must be instructed on the use and removal of PPE.
PPE recommendations:
Gloves: Use long gauntlet type gloves where hand contact is possible.
For longer term contact (BTT 4+ hours): Butyl rubber (minimum 0.5-0.6 mm), EVAL ethylene vinyl alcohol laminate (typically 0.10-0.15 mm) only. For short term or incidental contact: Butyl rubber, EVAL, Nitrile
Use gloves approved to relevant standards (e.g. EN 374, ASTM F739). Glove thickness will be related to the breakthrough time (BTT) and to specific supplier's glove design. Suitability and durability of a glove is dependent on the usage, e.g. frequency and duration of contact, chemical resistance of glove material, dexterity, and physical wear and tear. Always seek specific advice from glove supplier. Where tasks result in physical damage or where the gloves become excessively contaminated with surface debris double-gloving is recommended. In that case the outer glove may be of a less protective material such as PVC or neoprene based upon the substance and the glove suppliers recommendation. See SDS for any specific recommendation.
Face shield: Full face shield meeting industry standards (EN 166 a/o ANSI Z87.1) in combination with neck protection (PVC).
Protective Clothing: Butyl rubber apron, boots without laces, protective arm sleeves and full body suit required if applicable to the specific use and tasks performed.
In case of vapours use a splash hood.
Secondary contact from vapours and mists may be a significant source of secondary skin contact. Contact must be eliminated through the use of engineering controls or LEV.

Eye Protection:

RMM EY3
Maximum recommended protection:
Anytime when there is a severe risk of splash or spray or if the material in use is highly hazardous the use of a Face shield is necessary. (Full-face supplied air respiratory protection might be needed instead to prevent inhalation risks). Face shields protect the eyes, face, and neck from chemical splashes and spray as well as flying particles. Face shields should not be worn independently. Therefore safety glasses or goggles must be worn underneath face shields for complete protection.
Safety glasses, splash goggles and Face shields must meet EN 166 a/o ANSI Z87.1 standards.

Respiratory protection:
For all respiratory protection equipment training on proper usage is recommended.

Good work practices and PPE should be used as appropriate and is recommended whenever there is potential for exposure.

General comment:

These practices are designed for normal working conditions and operations. For emergency situations additional measures may be needed and the highest level of protection would generally be recommended.
2.2 Control of environmental exposure
Product characteristic
ES covers substance at 100% concentration (‘worst case’).
Amounts used
ES and risk modelling covers total annual production of this substance for this legal entity at a single site. DU’s would be using only a fraction of this total production, and hence the risk ratios at SU3, SU8, SU9, SU11 or SU12 closed process manufacturing plants would be lower than at the plant manufacturing the substance under the same conditions of use (‘worst case’).
Frequency and duration of use/exposure
365 days/year, continuous use (‘worst case’).
Environment factors not influenced by risk management
High flow rate of receiving water body at the “Local” level in the EUSES/ECETOC-TRA model. Flow rate chosen for consistency with actual manufacturing site of substance.
Other given operational conditions affecting environmental exposure
Closed or semi-closed process. Process equipment is indoors with LEV. Full liquid containment process and spills collected and directed to waste water treatment. Vapour and overhead recovery system, with collected substance directed to waste water treatment. Modelling procedure for mERC 1.1 used environmental release values of 10exp-5 for uncontrolled air releases, 10exp-6 for waste water releases to treatment plant, and 10exp-4 for uncontrolled releases to soil. For ECETOC model, fraction of total production at source = 100% ECETOC default values for waste water treatment plant were used (EUSES is similar or identical). Environmental risk assessment done at “Local”, “Regional” and “Continental” levels. Modelling procedure for mERC 1.2 used environmental release values of 10exp-2 for uncontrolled air releases, 10exp-4 for waste water releases to treatment plant, 0.8 for fraction connected to sewer system, 10exp-2 for uncontrolled releases to soil and 10exp-2 for fraction directly emitted to Regional marine systems. 365days/year releases (‘worst case’). For mERC 1.2 DU environmental releases, assumption was used that maximum quantity at a single user site was 10% of total Registered substance production (‘worst case’).
Technical conditions and measures at process level (source) to prevent release
Conditions and Measures to be selected to reduce exposure and risk: Closed or semi-closed process. Continuous or batch substance flow from reactor or mixing vessels to storage or distribution tanks. Low emission permanent installation pipe connections and flanges; emission control system Double sealed pumps. Overhead vapour recovery and removal system. Sealed tanks and reactor vessel with safety releases. Safety releases and venting done to specific controlled emission points or to emission control equipment. Purging and venting procedures prior to maintenance work.
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil
Conditions and Measures to be selected to reduce exposure and risk: Closed or semi-closed process. Continuous or batch substance flow from reactor or mixing vessels to storage or distribution tanks. Low emission permanent installation pipe connections and flanges Double sealed pumps. Overhead vapour recovery and removal system. Sealed tanks and reactor vessel with safety releases. Remotely operated values and process equipment to isolate worker from process operation Product quality sampling system to minimize worker exposure. Sludge removal from waste water treatment plant, incinerated. Risk assessment used conservative (worst case) default assumptions for removal and degradation efficiency. Treatment plant size and input parameters used ECETOC-TRA conservative default assumptions.
Organizational measures to prevent/limit release from site
Must utilize a combination of operational risk management measures or procedures typically including: Worker training in process operations. Workers safety training.

Process Safety Management reviews to identify and minimize risk of process releases and accidents.
Spill Control and Countermeasures plan.
Preventative maintenance program.
Accident reporting, investigation and remedial action program.
Leak detection and monitoring program.
On-site waste water treatment system utilizing solids separation, aeration and biological treatment.
Energy recovery waste treatment.

Conditions and measures related to municipal sewage treatment plant

Risk assessment assumes that waste water is treated on-site. However, treatment may also be accomplished using a municipal sewage treatment plant if the input variables and treatment plant parameters are consistent with substance releases.

Conditions and measures related to external treatment of waste for disposal

Non-aqueous process losses, spill recovery material or waste should be disposed of e.g. by incineration or another destructive process. Another option would be external treatment like for instance via distillation for raw material recovery.

Conditions and measures related to external recovery of waste

Waste recovery is not necessary and is not feasible for this substance, other than the recovery of energy value by incineration.

3. Exposure estimation and reference to its source

All Risk Characterisation Ratios (RCR) derived from ECETOC-TRA model.

Workers exposure

Applicable duration of activity indicated in tables in section 2.1

	RCR
Oral	N/A
Dermal	<1.0
Inhalation	<1.0
Total exposure	<1.0 Dermal + Inhalation

Environmental exposure

	RCR
In STP	<0.01
Local freshwater	<1.0
Freshwater sediment	N/A
Local terrestrial	N/A
Local marine water	N/A
Local marine sediment	N/A
Human via environment	<0.1

4. Guidance to DU to evaluate whether he works inside the boundaries set by the ES

Risk Management Measures (RMM's) and Operational Controls (OC's) listed in this ES would usually be adequate to control risks to risk ratios <1.0. Risk assessment above was done using conservative input values and assumptions, and is generally applicable to DU's for the indicated SU's. Not all the indicated RMM's and OC's may be necessary in a specific manufacturing plant or under specific circumstances of use. The DU must determine for their own operations the required measures. ECETOC-TRA model was used for risk assessment, but EUSES model may also be used for environmental risk. DU's can calculate their own Risk Ratios and/or PEC/PNEC ratios using DNEL's and PNEC's listed in the SDS, as well as the actual quantities of the substance, daily usage pattern, substance concentration, etc.

Annex: Exposure Scenario BPFDGE 2.1S (Industrial)

1. Title	
	Exposure Scenario BPFDGE 2.1S Industrial mixing, formulation and packaging.

Systematic title based on use descriptor	SU 3 SU 10 PROC 5 PROC 8a PROC 8b mERC 1.2 - Environmental releases related to use of the substance as a reactant, monomer or blending in a mixture by a DU.
Processes, tasks and activities covered	Industrial processes for blending or formulation into a mixture, and packaging of the product or mixtures, including transfers of material or mixtures between vessels, containers and/or shipping tanks. This includes dedicated as well as non-dedicated facilities. This ES covers the activities of most or all of our direct customer DU's.
Assessment Method	ECETOC-TRA modelling, using DNEL's and PNEC's derived from the REACH Registration IUCLID dossier.

2. Operational conditions and risk management measures

RMM's and OC's apply to all SU and PROC/ERC categories listed above. The user should select whichever combination of RMM's and OC's are necessary to reduce worker and environmental exposure to the level required to achieve <1.0 Risk Ratios. Risk Ratios can be calculated using PNEC and DNEL values listed in the SDS.

RMM's - See section 2.1
Operational Controls - See sections 2.1 and 2.2

Number of sites: Not applicable to this risk management modelling. Modelling based on conservative assumption that 10% of total substance production is used at a single DU industrial site ('worst case' assumptions).

2.1 Control of workers exposure

Product characteristic

There are no specific product characteristics relevant to this exposure scenario. ES assumes substance is 25 - 100% concentration ('worst case').

Amounts used

ES and risk assessment modelling assumes 10 % of total EU production volume of the legal entity's Registration at a single DU site (actual volume and DU percentages are confidential) ('worst case').

Frequency and duration of use/exposure

24 hours/day operations ('worst case'). Worker risk assessment assumes 4-8 hour/day (unless otherwise indicated in tables under "Conditions and measures related to personal protection, hygiene and health evaluation") and 220 days/yr maximum default value in ECETOC-TRA, which is a 'worst case'. Actual employee exposure duration is usually much less.

Human factors not influenced by risk management

None specifically known or relevant. Risk modelling does not use any additional exposure mitigation factors (worst case).
Risk assessment utilized standard ECETOC modelling parameters for worker respiratory volume (10M3/day), skin contact area and body weight. Standard values also used for room size and ventilation, but not generally applicable to this ES.

Other given operational conditions affecting workers exposure

Risk assessment used ECETOC-TRA model without changing assumptions on worker exposure. This is a conservative model for estimating exposure, and would generally over-estimate versus the actual exposure. In particular, workers would rarely be exposed >4hr/day.

Technical conditions and measures at process level (source) to prevent release

Conditions and Measures to be selected to reduce exposure and risk:
Standard conditions and assumptions from ECETOC-TRA model.
Indoor operations with LEV.
Semi-closed continuous or batch substance flow from reactor or mixing vessels to storage or distribution tanks.
Low emission permanent installation pipe connections and flanges
Double sealed pumps.
Overhead vapour recovery and removal system.
Sealed tanks and reactor vessel with safety releases.

Safety releases and venting done to specific controlled emission points or to emission control equipment.
Remotely operated values and process equipment to isolate worker from process operation
Product quality sampling system to minimize worker exposure.
Automated or semi-automated container filling equipment. For container filling systems designed to reduce splashing and vaporization. For example, 'bottom filling' of trucks, railcars and large Isotanks, or use of filling lances for any container.
For laboratory analysis, positive flow fume hoods.
Purging and venting procedures prior to maintenance work.

Technical conditions and measures to control dispersion from source towards the worker

Indoors with LEV.

Organisational measures to prevent /limit releases, dispersion and exposure

Must utilize a combination of operational risk management measures or procedures typically including:
Worker training in process operations.
Workers safety training.
Process Safety Management reviews to identify and minimize risk of process releases and accidents.
Job Hazard Analysis
Spill Control and Countermeasures plan.
Preventative maintenance program.
Safety valve monitoring and replacement procedure.
Accident reporting, investigation and remedial action procedure.
Leak detection and monitoring procedure.
Site industrial hygiene and PPE procedure.
Permit to Work and Equipment Safe Isolation program.

Conditions and measures related to personal protection, hygiene and health evaluation

Employees must be trained in the proper use of PPE, and when to use it.

Skin protection :

Minimum efficiency for PPE	PROC 5 PROC 8a PROC 8b
50%	Not recommended - Sensitizer
90%	Not recommended - Sensitizer
95%	> 4 hrs

Respiratory protection :

Minimum efficiency for PPE	PROC 5 PROC 8a PROC 8b
50%	Not needed
90%	Not needed
95%	Not needed
99%	Not needed

Skin protection:
For any more specific recommendations consult the SDS.

RMM SK3
Protection efficiency: 95%
ECETOC-TRA risk modelling results based upon a minimum required protective factor of 0.95 for skin protection. Engineering controls, PPE and work practices should provide the highest level of protection. If a user wants to utilize Tier 2 site-specific worker exposure calculations, this value is used to calculate the allowable skin exposure area (cm2) for each applicable PROC.

The primary RMM is avoidance of skin contact through Operational Controls, procedures and process equipment design. If accidental contact occurs product must be immediately removed from the skin. Recommended or required PPE must be chosen based upon the duration and extent of worker exposure. Employees must be instructed on the use and removal of PPE.

PPE recommendations:
Gloves: Use long gauntlet type gloves where hand contact is possible.
For longer term contact (BTT 4+ hours): Butyl rubber (minimum 0.5-0.6 mm), EVAL ethylene vinyl alcohol laminate (typically 0.10-0.15 mm) only. For short term or incidental contact: Butyl rubber, EVAL, Nitrile
Use gloves approved to relevant standards (e.g. EN 374, ASTM F739). Glove thickness will be related to the breakthrough time (BTT) and to specific supplier's glove design. Suitability and durability of a glove is dependent on the usage, e.g. frequency and duration of contact, chemical resistance of glove material, dexterity, and physical wear and tear. Always seek specific advice from glove supplier. Where tasks result in physical damage or where the gloves become excessively contaminated with surface debris double-gloving is recommended. In that case the outer glove may be of a less protective material such as PVC or neoprene based upon the substance and the glove suppliers recommendation. See SDS for any specific recommendation.
Face shield: Full face shield meeting industry standards (EN 166 a/o ANSI Z87.1) in combination with neck protection (PVC).
Protective clothing: Butyl rubber apron, boots without laces, protective arm sleeves and full body suit required if applicable to the specific use and tasks performed.
In case of vapours use a splash hood.
Secondary contact from vapours and mists may be a significant source of secondary skin contact. Contact must be eliminated through the use of engineering controls or LEV.

Eye Protection:

RMM EY3
Maximum recommended protection:
Anytime when there is a severe risk of splash or spray or if the material in use is highly hazardous the use of a Face shield is necessary. (Full-face supplied air respiratory protection might be needed instead to prevent inhalation risks). Face shields protect the eyes, face, and neck from chemical splashes and spray as well as flying particles. Face shields should not be worn independently. Therefore safety glasses or goggles must be worn underneath face shields for complete protection.
Safety glasses, splash goggles and Face shields must meet EN 166 a/o ANSI Z87.1 standards.

Respiratory protection:
For all respiratory protection equipment training on proper usage is recommended.

Good work practices and PPE should be used as appropriate and is recommended whenever there is potential for exposure.

General comment:
These practices are designed for normal working conditions and operations. For emergency situations additional measures may be needed and the highest level of protection would generally be recommended.

2.2 Control of environmental exposure

Product characteristic

ES covers mixtures at 25 -100% concentration ('worst case').

Amounts used

ES and risk modelling covers DU using up to 10% of total substance production at a single site. This percentage fraction is greater than the actual amount purchased by any DU legal entity ('worst case').

Frequency and duration of use/exposure

365 days/year, continuous use ('worst case').

Environment factors not influenced by risk management

Standard ECETOC-TRA modelling parameters used with a conservative dilution factor of only 10X for water discharge to receiving body (i.e. river).

Other given operational conditions affecting environmental exposure

Semi-Closed Process
Process equipment is indoors with LEV.
Full liquid and solid containment process and spills collected and directed to waste water treatment.
Modelling procedure for mERC 1.2 used environmental release values of 10exp-2 for uncontrolled air releases, 10exp-4 for waste water releases to treatment plant, 0.8 for fraction connected to sewer system, 10exp-2 for uncontrolled releases to soil and 10exp-2 for fraction directly emitted to Regional marine systems. 365days/year releases ('worst case').

ECETOC default values for waste water treatment plant were used (EUSES is similar or identical).
Environmental risk assessment done at "Local", "Regional" and "Continental" levels.

Technical conditions and measures at process level (source) to prevent release

Conditions and Measures to be selected to reduce exposure and risk:
Semi-Closed Process
Continuous or batch substance flow from reactor or mixing vessels to storage or distribution tanks.
Low emission pipe connections and flanges; emission control system
Double sealed pumps.
Valves and process equipment to isolate worker from process operation.
Product quality sampling system to minimize worker exposure.
Safety releases and venting done to specific controlled emission points or to emission control equipment.
Purging and venting procedures prior to maintenance work.

Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil

Conditions and Measures to be selected to reduce exposure and risk:
Semi-Closed Process
Risk assessment used conservative (worst case) default assumptions for removal and degradation efficiency.
Treatment plant size and input parameters used ECETOC-TRA conservative default assumptions.

Organizational measures to prevent/limit release from site

Must utilize a combination of operational risk management measures or procedures typically including:
Worker training in process operations.
Workers safety training.
Process Safety Management reviews to identify and minimize risk of process releases and accidents.
Spill Control and Countermeasures plan.
Preventative maintenance program.
Accident reporting, investigation and remedial action program.
Leak detection and monitoring program.
On-site waste water treatment system utilizing solids separation, aeration and biological treatment.
Energy recovery waste treatment.

Conditions and measures related to municipal sewage treatment plant

Treatment may be accomplished using either on-site or a municipal sewage treatment plant if the input variables and treatment plant parameters are consistent with substance releases.

Conditions and measures related to external treatment of waste for disposal

Non-aqueous process losses, spill recovery material or waste should be disposed of e.g. by incineration.
Another option would be external treatment like for instance via distillation for raw material recovery.

Conditions and measures related to external recovery of waste

Waste recovery is not necessary and is not feasible for this substance, other than the recovery of energy value by incineration.

3. Exposure estimation and reference to its source

All Risk Characterisation Ratios (RCR) derived from ECETOC-TRA model.

Workers exposure
Applicable duration of activity indicated in tables in section 2.1

	RCR
Oral	N/A
Dermal	<1.0
Inhalation	<1.0
Total exposure	<1.0 Dermal + Inhalation

Environmental exposure

	RCR
In STP	<0.01
Local freshwater	<1.0
Freshwater sediment	N/A
Local terrestrial	N/A
Local marine water	N/A

Local marine sediment	N/A
Human via environment	<0.1

4. Guidance to DU to evaluate whether he works inside the boundaries set by the ES
Risk Management Measures (RMM's) and Operational Controls (OC's) listed in this ES would usually be adequate to control risks to risk ratios <1.0. Risk assessment above was done using conservative input values and assumptions, and is generally applicable to DU's for the indicated SU's. Not all the indicated RMM's and OC's may be necessary in a specific manufacturing plant or under specific circumstances of use. The DU must determine for their own operations the required measures. ECETOC-TRA model was used for risk assessment, but EUSES model may also be used for environmental risk. DU's can calculate their own Risk Ratios and/or PEC/PNEC ratios using DNEL's and PNEC's listed in the SDS, as well as the actual quantities of the substance, daily usage pattern, substance concentration, etc.

Annex: Exposure Scenario BPFDGE 3.1S (Industrial)

1. Title	
	Exposure Scenario BPFDGE 3.1S Industrial Use Applications
Systematic title based on use descriptor	SU 1 SU 2a SU 2b SU 3 SU 5 SU 6a SU 6b SU 7 SU 8 SU 9 SU 10 SU 11 SU 12 SU 13 SU 15 SU 16 SU 17 SU 18 SU 19 SU 23 SU 24 PROC 5 PROC 6 PROC 7 PROC 8a PROC 8b PROC 9 PROC 10 PROC 13 PROC 14 PROC 15 PROC 16 PROC 19 mERC 1.2 - Environmental releases related to use of the substance as a reactant, monomer or blending in a mixture by a DU.
Processes, tasks and activities covered	Industrial processes for use and end use in manufacture of an article or finished product, including mixtures and formulations. This includes also blending or formulation into a mixture, and packaging of the product or mixtures as well as packaging into small containers

	for whole sale or retail sales, including transfers of material or mixtures between vessels, containers and/or shipping tanks for both dedicated and non-dedicated facilities.
Assessment Method	ECETOC-TRA modelling, using DNEL's and PNEC's derived from the REACH Registration IUCLID dossier.

2. Operational conditions and risk management measures

RMM's and OC's apply to all SU and PROC/ERC categories listed above. The user should select whichever combination of RMM's and OC's are necessary to reduce worker and environmental exposure to the level required to achieve <1.0 Risk Ratios. Risk Ratios can be calculated using PNEC and DNEL values listed in the SDS.

RMM's - See section 2.1
Operational Controls - See sections 2.1 and 2.2

Number of sites: Not applicable to this risk management modelling. Modelling based on conservative assumption that 10% of total substance production is used at a single DU industrial site ('worst case' assumptions).

2.1 Control of workers exposure

Product characteristic

There are no specific product characteristics relevant to this exposure scenario. ES assumes substance is 25 - 100% concentration ('worst case').

Amounts used

ES and risk assessment modelling assumes a certain volume of the legal entity's Registration at a single DU site (actual volume and DU percentages are confidential) ('worst case').

Frequency and duration of use/exposure

Worker risk assessment assumes >4 hour/day (unless otherwise indicated in tables under "Conditions and measures related to personal protection, hygiene and health evaluation") maximum default value in ECETOC-TRA, which is a 'worst case'. Actual employee exposure duration is much less.

Human factors not influenced by risk management

None specifically known or relevant. Risk modelling does not use any additional exposure mitigation factors (worst case).
Risk assessment utilized standard ECETOC modelling parameters for worker respiratory volume (10M3/day), skin contact area and body weight. Standard values also used for room size and ventilation, but not generally applicable to this ES.

Other given operational conditions affecting workers exposure

Risk assessment used ECETOC-TRA model without changing assumptions on worker exposure. This is a conservative model for estimating exposure, and would generally over-estimate versus the actual exposure. In particular, workers would rarely be exposed >4hr/day.

Technical conditions and measures at process level (source) to prevent release

Conditions and Measures to be selected to reduce exposure and risk:
Standard conditions and assumptions from ECETOC-TRA model.
Indoor operations with LEV.

Technical conditions and measures to control dispersion from source towards the worker

Indoors with LEV.

Organisational measures to prevent /limit releases, dispersion and exposure

Must utilize a combination of operational risk management measures or procedures typically including:
Worker training in process operations.
Workers safety training.
Site industrial hygiene and PPE procedure.

Conditions and measures related to personal protection, hygiene and health evaluation

Employees must be trained in the proper use of PPE, and when to use it.

Skin protection :

Minimum efficiency for PPE	PROC 5 PROC 6 PROC 7 PROC 8a PROC 8b PROC 9	PROC 19

	PROC 10 PROC 13 PROC 14 PROC 15 PROC 16	
50%	Not recommended - Sensitizer	Not recommended - Sensitizer
90%	Not recommended - Sensitizer	Not recommended - Sensitizer
95%	> 4 hrs	15 min – 1 hr

Respiratory protection :

Minimum efficiency for PPE	PROC 5 PROC 6 PROC 8a PROC 8b PROC 9 PROC 10 PROC 13 PROC 14 PROC 15 PROC 16 PROC 19	PROC 7
50%	Not needed	1 – 4 hrs
90%	Not needed	> 4 hrs
95%	Not needed	Not needed
99%	Not needed	Not needed

Skin protection:
For any more specific recommendations consult the SDS.

RMM SK3
Protection efficiency: 95%
ECETOC-TRA risk modelling results based upon a minimum required protective factor of 0.95 for skin protection. Engineering controls, PPE and work practices should provide the highest level of protection. If a user wants to utilize Tier 2 site-specific worker exposure calculations, this value is used to calculate the allowable skin exposure area (cm2) for each applicable PROC.

The primary RMM is avoidance of skin contact through Operational Controls, procedures and process equipment design. If accidental contact occurs product must be immediately removed from the skin. Recommended or required PPE must be chosen based upon the duration and extent of worker exposure. Employees must be instructed on the use and removal of PPE.
PPE recommendations:
Gloves: Use long gauntlet type gloves where hand contact is possible.
For longer term contact (BTT 4+ hours): Butyl rubber (minimum 0.5-0.6 mm), EVAL ethylene vinyl alcohol laminate (typically 0.10-0.15 mm) only.
For short term or incidental contact: Butyl rubber, EVAL, Nitrile

Use gloves approved to relevant standards (e.g. EN 374, ASTM F739). Glove thickness will be related to the breakthrough time (BTT) and to specific supplier's glove design. Suitability and durability of a glove is dependent on the usage, e.g. frequency and duration of contact, chemical resistance of glove material, dexterity, and physical wear and tear. Always seek specific advice from glove supplier. Where tasks result in physical damage or where the gloves become excessively contaminated with surface debris double-gloving is recommended. In that case the outer glove may be of a less protective material such as PVC or neoprene based upon the substance and the glove suppliers recommendation. See SDS for any specific recommendation.
Face shield: Full face shield meeting industry standards (EN 166 a/o ANSI Z87.1) in combination with neck protection (PVC).
Protective clothing: Butyl rubber apron, boots without laces, protective arm sleeves and full body suit required if applicable to the specific use and tasks performed.
In case of vapours use a splash hood.

Secondary contact from vapours and mists may be a significant source of secondary skin contact.
Contact must be eliminated through the use of engineering controls or LEV.

Eye Protection:

RMM EY3
Maximum recommended protection:
Anytime when there is a severe risk of splash or spray or if the material in use is highly hazardous the use of a Face shield is necessary. (Full-face supplied air respiratory protection might be needed instead to prevent inhalation risks). Face shields protect the eyes, face, and neck from chemical splashes and spray as well as flying particles. Face shields should not be worn independently. Therefore safety glasses or goggles must be worn underneath face shields for complete protection.
Safety glasses, splash goggles and Face shields must meet EN 166 a/o ANSI Z87.1 standards.

Respiratory protection:
For all respiratory protection equipment training on proper usage is recommended.

RMM IN1
Protection efficiency: 50%
At this level work functions preclude any potential for unexpected inhalation of hazardous levels of any chemicals.
Good work practices and PPE should be used as appropriate and is recommended whenever there is potential for exposure (i.e. during sampling or maintenance etc.).
ECETOC-TRA risk modelling results based upon a required protective factor (PF) of 0.50 to a Risk Ratio of <1.0 (DNEL to Estimated Exposure ratio) if using LEV.

RMM IN2
Protection efficiency: 90%
ECETOC-TRA risk modelling results based upon a minimum required protective factor (PF) of 0.90 for respiratory protection. This PF level is required to reduce worker risk to a Risk Ratio <1.0 (DNEL to Estimated Exposure ratio).
The primary RMM is avoidance of inhalation exposure through operational procedures and process equipment design. Risk modelling assumes the usage is Indoors with LEV. Where worker exposure may occur or in emergency situations PPE is required.
Recommended PPE:
Respiratory Protective Equipment: Use Respiratory Protective Equipment with an APF of at least 10 for liquids; for dust FFP2 is acceptable. Half-face or full-face twin cartridge mask respirators with an organic vapour cartridge will generally be acceptable for this level of protection efficiency.Powered or air-fed Respiratory Protective Equipment is more comfortable to wear.
In case of expected vapours use a splash hood.

General comment:
These practices are designed for normal working conditions and operations. For emergency situations additional measures may be needed and the highest level of protection would generally be recommended.

2.2 Control of environmental exposure

Product characteristic

ES covers mixtures at 25 -100% concentration (‘worst case’).

Amounts used

ES and risk modelling covers a percentage fraction that is greater than the actual amount purchased by any DU legal entity (‘worst case’).

Frequency and duration of use/exposure

365 days/year, continuous use (‘worst case’).

Environment factors not influenced by risk management

Standard ECETOC-TRA modelling parameters used with a conservative dilution factor of only 10X for water discharge to receiving body (i.e. river).

Other given operational conditions affecting environmental exposure

Conditions and Measures to be selected to reduce exposure and risk:
Manufacturing equipment is Indoors with LEV.
Full liquid and solid containment process and spills collected and directed to disposal. All wastes are incinerated and substance is fully destroyed.

Modelling procedure for mERC 1.2 used environmental release values of 10exp-2 for uncontrolled air releases, 10exp-4 for waste water releases to treatment plant, 0.8 for fraction connected to sewer system, 10exp-2 for uncontrolled releases to soil and 10exp-2 for fraction directly emitted to Regional marine systems. 365days/year releases ('worst case').
ECETOC default values for waste water treatment plant were used (EUSES is similar or identical).
Environmental risk assessment done at "Local", "Regional" and "Continental" levels.

Technical conditions and measures at process level (source) to prevent release

None additional. Used standard conditions of model.

Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil

None additional. Used standard conditions of model.

Organizational measures to prevent/limit release from site

Must utilize a combination of operational risk management measures including:
Worker training in process operations.
Workers safety training.
Spill Control and Countermeasures plan.

Conditions and measures related to municipal sewage treatment plant

Standard conditions of modelling applied.

Conditions and measures related to external treatment of waste for disposal

Non-aqueous process losses, spill recovery material or waste should be disposed of e.g. by incineration or another destructive process. Another option would be external treatment like for instance via distillation for raw material recovery.

Conditions and measures related to external recovery of waste

Waste recovery is not necessary and is not feasible for this substance, other than the recovery of energy value by incineration.

3. Exposure estimation and reference to its source

All Risk Characterisation Ratios (RCR) derived from ECETOC-TRA model.

Workers exposure
Applicable duration of activity indicated in tables in section 2.1

	RCR
Oral	N/A
Dermal	<1.0
Inhalation	<1.0
Total exposure	<1.0 Dermal + Inhalation

Environmental exposure

	RCR
In STP	<0.01
Local freshwater	<1.0
Freshwater sediment	N/A
Local terrestrial	N/A
Local marine water	N/A
Local marine sediment	N/A
Human via environment	<0.1

4. Guidance to DU to evaluate whether he works inside the boundaries set by the ES

Risk Management Measures (RMM's) and Operational Controls (OC's) listed in this ES would usually be adequate to control risks to risk ratios <1.0. Risk assessment above was done using conservative input values and assumptions, and is generally applicable to DU's for the indicated SU's. Not all the indicated RMM's and OC's may be necessary in a specific manufacturing plant or under specific circumstances of use. The DU must determine for their own operations the required measures. ECETOC-TRA model was used for risk assessment, but EUSES model may also be used for environmental risk. DU's can calculate their own Risk Ratios and/or PEC/PNEC ratios using DNEL's and PNEC's listed in the SDS, as well as the actual quantities of the substance, daily usage pattern, substance concentration, etc.

Annex: Exposure Scenario BPFDGE 3.2S (Professional Users)

1. Title	
	Exposure Scenario BPFDGE 3.2S Professional Use Applications
Systematic title based on use descriptor	SU 1 SU 5 SU 6a SU 6b SU 7 SU 8 SU 9 SU 10 SU 11 SU 12 SU 13 SU 15 SU 16 SU 17 SU 18 SU 19 SU 22 SU 24 PROC 5 PROC 6 PROC 8a PROC 8b PROC 9 PROC 10 PROC 11 PROC 13 PROC 14 PROC 15 PROC 16 PROC 19 PROC 20 mERC 1.2 - Environmental releases related to use of the substance as a reactant, monomer or blending in a mixture by a DU.
Processes, tasks and activities covered	Professional uses and end uses of an article or product, including mixtures, formulations and transfers of material or mixtures between containers and packaging into containers for whole sale or retail sales.
Assessment Method	ECETOC-TRA modelling, using DNEL's and PNEC's derived from the REACH Registration IUCLID dossier.
2. Operational conditions and risk management measures	
RMM's and OC's apply to all SU and PROC/ERC categories listed above. RMM's - See section 2.1 Operational Controls - See sections 2.1 and 2.2	
Number of sites: Not applicable to this risk management modelling. Modelling based on conservative assumption that 10% of total substance production is used at a single DU industrial site ('worst case' assumptions).	
2.1 Control of workers exposure	
Product characteristic	
There are no specific product characteristics relevant to this exposure scenario. ES assumes substance is 25 - 100% concentration ('worst case').	

Amounts used
ES and risk assessment modelling assumes a certain volume of the legal entity's Registration at a single DU site (actual volume and DU percentages are confidential) ('worst case').
Frequency and duration of use/exposure
Worker risk assessment assumes >4 hour/day (unless otherwise indicated in tables under "Conditions and measures related to personal protection, hygiene and health evaluation") maximum default value in ECETOC-TRA, which is a 'worst case'. Actual employee exposure duration is usually much less.
Human factors not influenced by risk management
None specifically known or relevant. Risk modelling does not use any additional exposure mitigation factors (worst case). Risk assessment utilized standard ECETOC modelling parameters for worker respiratory volume (10M3/day), skin contact area and body weight. Standard values also used for room size and ventilation, but not generally applicable to this ES.
Other given operational conditions affecting workers exposure
Risk assessment used ECETOC-TRA model without changing assumptions on worker exposure. This is a conservative model for estimating exposure, and would generally over-estimate versus the actual exposure. In particular, workers would rarely be exposed >4hr/day.
Technical conditions and measures at process level (source) to prevent release
Standard conditions and assumptions from ECETOC-TRA model. Indoor operations with LEV.
Technical conditions and measures to control dispersion from source towards the worker
Indoors with LEV.
Organisational measures to prevent /limit releases, dispersion and exposure
Must utilize a combination of operational risk management measures or procedures typically including: Worker training in application and use Workers safety training. Industrial hygiene and PPE procedure

Conditions and measures related to personal protection, hygiene and health evaluation
Employees must be trained in the proper use of PPE, and when to use it. Skin protection :

Minimum efficiency for PPE	PROC 5 PROC 6 PROC 8a PROC 8b PROC 9 PROC 10 PROC 11 PROC 13 PROC 14 PROC 15 PROC 16 PROC 19 PROC 20
50%	Not recommended - Sensitizer
90%	Not recommended - Sensitizer
95%	> 4 hrs

Respiratory protection :

Minimum efficiency for PPE	PROC 5 PROC 6 PROC 8b PROC 9 PROC 13 PROC 14 PROC 15	PROC 8a PROC 10 PROC 19	PROC 11

	PROC 16 PROC 20		
50%	Not needed	1 – 4 hrs	15 min – 1 hr
90%	Not needed	> 4 hrs	> 4 hrs
95%	Not needed	Not needed	Not needed
99%	Not needed	Not needed	Not needed

Skin protection:
For any more specific recommendations consult the SDS.

RMM SK3
Protection efficiency: 95%
ECETOC-TRA risk modelling results based upon a minimum required protective factor of 0.95 for skin protection. Engineering controls, PPE and work practices should provide the highest level of protection. If a user wants to utilize Tier 2 site-specific worker exposure calculations, this value is used to calculate the allowable skin exposure area (cm2) for each applicable PROC.

The primary RMM is avoidance of skin contact through Operational Controls, procedures and process equipment design. If accidental contact occurs product must be immediately removed from the skin. Recommended or required PPE must be chosen based upon the duration and extent of worker exposure. Employees must be instructed on the use and removal of PPE.
PPE recommendations:
Gloves: Use long gauntlet type gloves where hand contact is possible.
For longer term contact (BTT 4+ hours): Butyl rubber (minimum 0.5-0.6 mm), EVAL ethylene vinyl alcohol laminate (typically 0.10-0.15 mm) only. For short term or incidental contact: Butyl rubber, EVAL, Nitrile

Use gloves approved to relevant standards (e.g. EN 374, ASTM F739). Glove thickness will be related to the breakthrough time (BTT) and to specific supplier's glove design. Suitability and durability of a glove is dependent on the usage, e.g. frequency and duration of contact, chemical resistance of glove material, dexterity, and physical wear and tear. Always seek specific advice from glove supplier. Where tasks result in physical damage or where the gloves become excessively contaminated with surface debris double-gloving is recommended. In that case the outer glove may be of a less protective material such as PVC or neoprene based upon the substance and the glove suppliers recommendation. See SDS for any specific recommendation.
Face shield: Full face shield meeting industry standards (EN 166 a/o ANSI Z87.1) in combination with neck protection (PVC).
Protective clothing: Butyl rubber apron, boots without laces, protective arm sleeves and full body suit required if applicable to the specific use and tasks performed. In case of vapours use a splash hood. Secondary contact from vapours and mists may be a significant source of secondary skin contact. Contact must be eliminated through the use of engineering controls or LEV.

Eye Protection:

RMM EY3
Maximum recommended protection:
Anytime when there is a severe risk of splash or spray or if the material in use is highly hazardous the use of a Face shield is necessary. (Full-face supplied air respiratory protection might be needed instead to prevent inhalation risks). Face shields protect the eyes, face, and neck from chemical splashes and spray as well as flying particles. Face shields should not be worn independently. Therefore safety glasses or goggles must be worn underneath face shields for complete protection.
Safety glasses, splash goggles and Face shields must meet EN 166 a/o ANSI Z87.1 standards.

Respiratory protection:
For all respiratory protection equipment training on proper usage is recommended.

RMM IN1
Protection efficiency: 50%
At this level work functions preclude any potential for unexpected inhalation of hazardous levels of any chemicals.

Good work practices and PPE should be used as appropriate and is recommended whenever there is potential for exposure (i.e. during sampling or maintenance etc.).
ECETOC-TRA risk modelling results based upon a required protective factor (PF) of 0.50 to a Risk Ratio of <1.0 (DNEL to Estimated Exposure ratio) if using LEV.

RMM IN2
Protection efficiency: 90%
ECETOC-TRA risk modelling results based upon a minimum required protective factor (PF) of 0.90 for respiratory protection. This PF level is required to reduce worker risk to a Risk Ratio <1.0 (DNEL to Estimated Exposure ratio).
The primary RMM is avoidance of inhalation exposure through operational procedures and process equipment design. Risk modelling assumes the usage is Indoors with LEV.Where worker exposure may occur or in emergency situations PPE is required.
Recommended PPE:
Respiratory Protective Equipment: Use Respiratory Protective Equipment with an APF of at least 10 for liquids; for dust FFP2 is acceptable. Half-face or full-face twin cartridge mask respirators with an organic vapour cartridge will generally be acceptable for this level of protection efficiency.Powered or air-fed Respiratory Protective Equipment is more comfortable to wear.
In case of expected vapours use a splash hood.

General comment:
These practices are designed for normal working conditions and operations. For emergency situations additional measures may be needed and the highest level of protection would generally be recommended.

2.2 Control of environmental exposure

Product characteristic

ES covers mixtures at 25 -100% concentration (‘worst case’).

Amounts used

ES and risk modelling covers a percentage fraction that is greater than the actual amount purchased by any DU legal entity (‘worst case’).

Frequency and duration of use/exposure

365 days/year, continuous use (‘worst case’).

Environment factors not influenced by risk management

Standard ECETOC-TRA modelling parameters used with a conservative dilution factor of only 10X for water discharge to receiving body (i.e. river).

Other given operational conditions affecting environmental exposure

Conditions and Measures to be selected to reduce exposure and risk:
Manufacturing equipment is Indoors with LEV.
Full liquid and solid containment process and spills collected and directed to disposal. All wastes are incinerated and substance is fully destroyed.
Modelling procedure for mERC 1.2 used environmental release values of 10exp-2 for uncontrolled air releases, 10exp-4 for waste water releases to treatment plant, 0.8 for fraction connected to sewer system, 10exp-2 for uncontrolled releases to soil and 10exp-2 for fraction directly emitted to Regional marine systems. 365days/year releases (‘worst case’).
ECETOC default values for waste water treatment plant were used (EUSES is similar or identical).
Environmental risk assessment done at “Local”, “Regional” and “Continental” levels.

Technical conditions and measures at process level (source) to prevent release

None additional. Used standard conditions of model.

Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil

None additional. Used standard conditions of model.

Organizational measures to prevent/limit release from site

Must utilize a combination of operational risk management measures including:
Worker training in process operations.
Workers safety training.
Spill Control and Countermeasures plan.

Conditions and measures related to municipal sewage treatment plant

Standard conditions of modelling applied.

Conditions and measures related to external treatment of waste for disposal

Non-aqueous process losses, spill recovery material or waste should be disposed of e.g. by incineration or another destructive process. Another option would be external treatment like for instance via distillation for raw material recovery.

Conditions and measures related to external recovery of waste

Waste recovery is not necessary and is not feasible for this substance, other than the recovery of energy value by incineration.

3. Exposure estimation and reference to its source

All Risk Characterisation Ratios (RCR) derived from ECETOC-TRA model.

Workers exposure

Applicable duration of activity indicated in tables in section 2.1

	RCR
Oral	N/A
Dermal	<1.0
Inhalation	<1.0
Total exposure	<1.0 Dermal + Inhalation

Environmental exposure

	RCR
In STP	<0.01
Local freshwater	<1.0
Freshwater sediment	N/A
Local terrestrial	N/A
Local marine water	N/A
Local marine sediment	N/A
Human via environment	<0.1

4. Guidance to DU to evaluate whether he works inside the boundaries set by the ES

Risk Management Measures (RMM's) and Operational Controls (OC's) listed in this ES would usually be adequate to control risks to risk ratios <1.0. Risk assessment above was done using conservative input values and assumptions, and is generally applicable to DU's for the indicated SU's. Not all the indicated RMM's and OC's may be necessary in a specific manufacturing plant or under specific circumstances of use. The DU must determine for their own operations the required measures. ECETOC-TRA model was used for risk assessment, but EUSES model may also be used for environmental risk. DU's can calculate their own Risk Ratios and/or PEC/PNEC ratios using DNEL's and PNEC's listed in the SDS, as well as the actual quantities of the substance, daily usage pattern, substance concentration, etc.