SAFETY DATA SHEET

AMMONIUM BIFLUORIDE FLAKE

Compilation date: 29/11/2010

Revision date: 24/06/2013

Revision No: 6

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

1.1. Product identifier

Product name: AMMONIUM BIFLUORIDE FLAKE

REACH registered number(s): 01-2119489180-38-XXXX

CAS number: 1341-49-7

EINECS number: 215-676-4

Index number: 009-009-00-4

Product code: 0560-025

Synonyms: AMMONIUM HYDROGEN DIFLUORIDE
AMMONIUM ACID FLUORIDE
AMMONIUM BIFLUORIDE SOLID

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

Use of substance / mixture: * PC8: Biocidal products (e.g. Disinfectants, pest control). PC14: Metal surface treatment products, including galvanic and electroplating products. PC15: Non-metal-surface treatment products. PC19: Intermediate.

1.3. Details of the supplier of the safety data sheet

Company name: Resource Chemical Ltd
Resource House
76 High Street
Brackley
Northants
NN13 7DS

Tel: +44(0)1280 843800

Fax: +44(0)1280 701745

Email: sales@resourcechemical.ltd.uk

1.4. Emergency telephone number

Emergency tel: +44(0)1270 502891

Section 2: Hazards identification

2.1. Classification of the substance or mixture

Classification under CLP: Acute Tox. 3: H301; Skin Corr. 1B: H314

Classification under CHIP: T: R25; C: R34

Most important adverse effects: Toxic if swallowed. Causes severe skin burns and eye damage.

[cont...]

2.2. Label elements

Label elements under CLP:

Hazard statements: H301: Toxic if swallowed.
H314: Causes severe skin burns and eye damage.

Signal words: Danger

Hazard pictograms: GHS05: Corrosion
GHS06: Skull and crossbones

Precautionary statements: P260: Do not breathe dust.
P280: Wear protective gloves/protective clothing/eye protection/face protection.
P301+330+331: IF SWALLOWED: rinse mouth. Do NOT induce vomiting.
P305+351+338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P303+361+353: IF ON SKIN (or hair): Remove immediately all contaminated clothing. Rinse skin with water.
P309+311: IF exposed or if you feel unwell: Call a POISON CENTER or doctor.

2.3. Other hazards

PBT: This product is not identified as a PBT substance.

Section 3: Composition/information on ingredients

3.1. Substances

Chemical identity: AMMONIUM BIFLUORIDE FLAKE

Section 4: First aid measures

4.1. Description of first aid measures

Skin contact: Remove all contaminated clothes and footwear immediately unless stuck to skin. Drench the affected skin with running water for 10 minutes or longer if substance is still on skin. Transfer to hospital if there are burns or symptoms of poisoning.

Eye contact: Bathe the eye with running water for 15 minutes. Transfer to hospital for specialist examination.

Ingestion: Do not induce vomiting. Give 1 cup of water to drink every 10 minutes. If unconscious, check for breathing and apply artificial respiration if necessary. If unconscious and breathing is OK, place in the recovery position. Transfer to hospital as soon as possible.

Inhalation: Remove casualty from exposure ensuring one's own safety whilst doing so. If unconscious, check for breathing and apply artificial respiration if necessary. If unconscious and breathing is OK, place in the recovery position. If conscious, ensure the casualty sits or lies down. If breathing becomes bubbly, have the casualty sit and provide oxygen if available. Transfer to hospital as soon as possible.

[cont...]

4.2. Most important symptoms and effects, both acute and delayed

Skin contact: Irritation or pain may occur at the site of contact. Severe burns may occur.

Eye contact: There may be irritation and redness. There may be severe pain. Corneal burns may occur.

Ingestion: Nausea and stomach pain may occur. There may be vomiting. Blood may be vomited. The breathing may become shallow and rapid. Severe poisoning can cause shock, unconsciousness and convulsions.

Inhalation: Exposure may cause coughing or wheezing. There may be congestion of the lungs causing severe shortness of breath. Convulsions may occur.

Delayed / immediate effects: Immediate effects can be expected after short-term exposure.

4.3. Indication of any immediate medical attention and special treatment needed

Immediate / special treatment: * Immediate medical attention is required. Use the following antidotes: Calcium gluconate. Show this safety data sheet to the doctor in attendance. Eye bathing equipment should be available on the premises.

Section 5: Fire-fighting measures

5.1. Extinguishing media

Extinguishing media: * Suitable extinguishing media for the surrounding fire should be used.

5.2. Special hazards arising from the substance or mixture

Exposure hazards: Toxic. Corrosive. In combustion emits toxic fumes.

5.3. Advice for fire-fighters

Advice for fire-fighters: Wear self-contained breathing apparatus. Wear protective clothing to prevent contact with skin and eyes.

Section 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions: * Do not create dust. If outside keep bystanders upwind and away from danger point. Eliminate all sources of ignition. Mark out the contaminated area with signs and prevent access to unauthorised personnel. Refer to section 8 of SDS for personal protection details.

6.2. Environmental precautions

Environmental precautions: Do not discharge into drains or rivers. Contain the spillage using bunding.

6.3. Methods and material for containment and cleaning up

Clean-up procedures: * Transfer to a closable, labelled salvage container for disposal by an appropriate method.

[cont...]

6.4. Reference to other sections

Reference to other sections: Refer to section 8 of SDS. Refer to section 13 of SDS.

Section 7: Handling and storage

7.1. Precautions for safe handling

Handling requirements: * Use only with closed system ventilation. Ensure there is sufficient ventilation of the area. Avoid direct contact with the substance. Prevent contact with water.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions: * Store in cool, well ventilated area. Keep container tightly closed. Avoid contact with water or humidity. Avoid incompatible materials and conditions - see section 10 of SDS.

Suitable packaging: Do not use glass. Must only be kept in original packaging.

7.3. Specific end use(s)

Specific end use(s): No data available.

Section 8: Exposure controls/personal protection

8.1. Control parameters

Workplace exposure limits: **Respirable dust**

State	8 hour TWA	15 min. STEL	8 hour TWA	15 min. STEL
UK	2.5 mg/m3	-	-	-

8.1. DNEL/PNEC Values

AMMONIUM BIFLUORIDE FLAKE

Type	Exposure	Value	Population	Effect
DNEL	Inhalation	3.8mg/m3	Workers	Local
DNEL	Inhalation	2.3mg/m3	Workers	Systemic
DNEL	Oral	0.015mg/m3	Consumers	Systemic
DNEL	Inhalation	0.045mg/m3	Consumers	Systemic

8.2. Exposure controls

Engineering measures: * Ensure there is sufficient ventilation of the area. Ensure all engineering measures mentioned in section 7 of SDS are in place.

Respiratory protection: * Respiratory protective device with particle filter. Particle filter class P2S (EN143). Self-contained breathing apparatus must be available in case of emergency.

Hand protection: * Neoprene gloves.

Eye protection: Safety goggles. Face-shield. Ensure eye bath is to hand.

Skin protection: Protective clothing with elasticated cuffs and closed neck. Boots made of PVC. PVC apron covering the tops of the boots. Ensure safety shower is to hand.

[cont...]

Section 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

State: Flakes

Colour: White

Odour: Pungent

Oxidising: Non-oxidising (by EC criteria)

Solubility in water: Soluble

Also soluble in: Ethanol.

Boiling point/range°C: * 239

Melting point/range°C: 125

Vapour pressure: * 1.08hPa

Relative density: 1.5

pH: * 3.5

9.2. Other information

Other information: No data available.

Section 10: Stability and reactivity

10.1. Reactivity

Reactivity: Stable under recommended transport or storage conditions.

10.2. Chemical stability

Chemical stability: Stable under normal conditions.

10.3. Possibility of hazardous reactions

Hazardous reactions: Hazardous reactions will not occur under normal transport or storage conditions. Decomposition may occur on exposure to conditions or materials listed below.

10.4. Conditions to avoid

Conditions to avoid: Heat. Moist air. Humidity.

10.5. Incompatible materials

Materials to avoid: Water. Acids. Bases.

10.6. Hazardous decomposition products

Haz. decomp. products: In combustion emits toxic fumes of hydrogen fluoride. In combustion emits toxic fumes of nitrogen oxides.

Section 11: Toxicological information

11.1. Information on toxicological effects

[cont...]

*** Toxicity values:**

Route	Species	Test	Value	Units
ORL	RAT	LD50	130	mg/kg

Relevant hazards for substance:

Hazard	Route	Basis
Acute toxicity (ac. tox. 3)	ING	Based on test data
Skin corrosion/irritation	DRM	Based on test data
Serious eye damage/irritation	OPT	Based on test data

Symptoms / routes of exposure

Skin contact: Irritation or pain may occur at the site of contact. Severe burns may occur.

Eye contact: There may be irritation and redness. There may be severe pain. Corneal burns may occur.

Ingestion: Nausea and stomach pain may occur. There may be vomiting. Blood may be vomited. The breathing may become shallow and rapid. Severe poisoning can cause shock, unconsciousness and convulsions.

Inhalation: Exposure may cause coughing or wheezing. There may be congestion of the lungs causing severe shortness of breath. Convulsions may occur.

Delayed / immediate effects: Immediate effects can be expected after short-term exposure.

Section 12: Ecological information

12.1. Toxicity

*** Ecotoxicity values:**

Species	Test	Value	Units
FATHEAD MINNOWS	96H LC50	422	mg/l

12.2. Persistence and degradability

Persistence and degradability: Not applicable.

12.3. Bioaccumulative potential

Bioaccumulative potential: No bioaccumulation potential.

12.4. Mobility in soil

Mobility: Soluble in water.

12.5. Results of PBT and vPvB assessment

PBT identification: This product is not identified as a PBT substance.

12.6. Other adverse effects

Other adverse effects: No data available.

[cont...]

Section 13: Disposal considerations

13.1. Waste treatment methods

Disposal operations: Mix or disolve with a combustible material and burn in a chemical incinerator equipped with afterburners and scrubbers.

Disposal of packaging: Dispose of in a regulated landfill site or other method for hazardous or toxic wastes.

NB: The user's attention is drawn to the possible existence of regional or national regulations regarding disposal.

Section 14: Transport information

14.1. UN number

UN number: UN1727

14.2. UN proper shipping name

Shipping name: AMMONIUM HYDROGENDIFLUORIDE, SOLID

14.3. Transport hazard class(es)

Transport class: 8

14.4. Packing group

Packing group: II

14.5. Environmental hazards

Environmentally hazardous: No **Marine pollutant:** No

14.6. Special precautions for user

Special precautions: No special precautions.

Tunnel code: E

Transport category: 2

Section 15: Regulatory information

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

Specific regulations: * This product is a Seveso category/named substance in Annex I of Council Directive 96/82/EC.

15.2. Chemical Safety Assessment

Chemical safety assessment: * A chemical safety assessment has been carried out for the substance or the mixture by the supplier.

Section 16: Other information

Other information

Other information: This safety data sheet is prepared in accordance with Commission Regulation (EU) No 453/2010.

[cont...]

This safety data sheet is prepared in accordance with Commission Regulation (EC) No 1272/2008.

Phrases used in s.2 and 3: H301: Toxic if swallowed.
H314: Causes severe skin burns and eye damage.
R25: Toxic if swallowed.
R34: Causes burns.

Legal disclaimer: The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. This company shall not be held liable for any damage resulting from handling or from contact with the above product.

Downstream user exposure scenario for Ammonium hydrogendifluoride (AMBI)

1	Exposure Scenario 1: Production of ammonium hydrogendifluoride

Production of ammonium hydrogendifluoride

Environmental Release and Worker Processes Covered:

Environmental Releases

ERC01: Production of chemicals

Worker Processes

PROC01: Use in closed process, no likelihood of exposure
PROC02: Use in closed, continuous process with occasional controlled exposure
PROC03: Use in closed batch process (synthesis or formulation)
PROC05: Mixing or blending in batch process for formulation of preparations and articles (multistage and/or significant contact)
PROC08a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities
PROC08b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities
PROC09: Transfer of substance or preparation into small containers (dedicated filling line, including weighing)

Product Category

Not applicable.

Due to the nature of ammonium hydrogendifluoride, production systems are highly controlled, with a high degree of system closure and extremely limited environmental emissions.

Contributing Environmental Scenario: CES 1: Environmental exposure arising due to production of ammonium hydrogendifluoride (ERC 1).

2.1	Controlling environmental exposure for ES 1

ES1: Contributing exposure scenario (CES) 1 Environmental exposure arising due to production of ammonium hydrogendifluoride.

Section 2.1 describes the environmental releases that may occur during the production of ammonium hydrogendifluoride. These releases may occur due to emission to the atmosphere and release to wastewater.

Liquid wastes are generally treated prior to emission to remove any ammonium hydrogendifluoride in the waste water.

Emissions to air are treated by scrubbers. Emissions to local air (after scrubbing) should be no more than 37.7 kg per day.

AMBI, when in contact with water, converts to ammonium and fluoride ions and is fully miscible in water its actual conversion, neutralisation and removal from the waste stream is expected to be extremely rapid.

Product characteristics

AMBI is a white crystalline solid at 20°C and 101.3 kPa with a vapour pressure of 1.08 Pa at 20°C. It is highly soluble in water and is not considered flammable. AMBI is not considered to be potentially explosive or an oxidising agent. The product used is in flake form or in the form of a solution.

Amounts used

Production sites may use up to 500 tonnes per annum as a worst case assumption with up to 330 emission days per year. Facilities that formulate ammonium hydrogendifluoride may consume quantities approaching two tonnes per day.

Frequency and duration of use

Continuous production and with up to 330 emission days per year.

Environmental factors influenced by risk management

Flow rate of receiving water at least 10,000 m^3 per day. Dilution of (theoretical) STP emissions at least 10 fold.

Other operational conditions affecting environmental exposure

Production of ammonium hydrogendifluoride generally occurs indoors, with a high degree of system closure. Emissions to air are scrubbed before release and waste would primarily be directed to the waste stream.

Technical conditions and measures at process level (source) to prevent release
All production operations, including mixing and blending and transfer processes, are carried out indoors in dedicated facilities with closed systems. Total losses to air are measured.
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil
During the production of AMBI, scrubbers are used for waste air treatment. There are no emissions to wastewater.
Organizational measures to prevent/limit releases from site
Workers are fully trained in order to prevent accidental release. The processes are generally fully enclosed (air tight) and the integrity of the enclosure is monitored.
Conditions and measures related to municipal STP
There is no loss to wastewater and therefore no emission to the STP.
Conditions and measures related to external treatment of waste for disposal
No external treatment of waste is expected.
Conditions and measures related to external recovery of waste
There is no envisaged external recovery of waste. Sludge from the waste water treatment plant is sent for recovery, incineration or landfill and is not used for agricultural spreading.

2.2	**Controlling worker exposure for ES 1**

ES1: CES 2: Worker exposure arising due to use in closed processes (PROC 1), CES 3: worker exposure arising due to use in closed continuous processes with occasional controlled exposure (PROC 2), CES 4: worker exposure arising due to use in closed batch process (PROC 3) CES 5: worker exposure arising due to mixing or blending (PROC 5), CES 6: worker exposure arising due to transfer of substance or preparations from/to vessels/large containers at non-dedicated or dedicated facilities (PROC 8a and PROC 8b) and CES 7: worker exposure arising due to transfer of the substance or preparation into small containers (PROC 9).

Ammonium bifluoride is produced by reacting NH_3 and HF in gas phase. The generated molten salt is solidified into flakes. The stringent process tolerances, safety standards and a variety of quality control procedures result in a product of the highest quality and consistency.

During the production of ammonium hydrogendifluoride, workers wear protective clothing (respiratory mask with E-P2 filter, eye protective goggles/face shield and protective gloves). A safety shower is required nearby in case of accidental spillage.

Product characteristics
AMBI is a white crystalline solid at 20°C and 101.3 kPa with a vapour pressure of 1.08 Pa at 20°C. It is highly soluble in water and is not considered flammable. AMBI is not considered to be potentially explosive or an oxidising agent. The produced substance is in solid/flake form.
Amounts used
Production sites may manufacture up to 5,500 tonnes per annum with up to 330 emission days per year. As much as 5,500 tonnes may be produced in a single region per year.

Frequency and duration of use exposure
Workers perform standard shifts of 8 hours per day and have standard working years of 220 days per year. However, some tasks such as sampling and cleaning of the operational machinery and transfer of the substance may be shorter duration tasks.
Human factors not influence by risk management
Respiration volume under conditions of use is $10m^3/d$ (default value for a worker breathing for an 8h work day in Guidance Section R 8.4.2). Area of skin contact with the substance under the conditions of use is $0cm^2$ as all dermal contact must be prevented due to the corrosive nature of AMBI.
Other given operational conditions affecting worker exposure
All operations associated with the production of ammonium hydrogendifluoride are conducted indoors, in highly controlled systems, with a high degree of closure due to its corrosive nature. The possibility for exposure is limited where possible to prevent potential exposure.
Technical conditions and measures at process level (source) to prevent release
Primary emission sources are mostly not located in the breathing zone of the worker. The handling of ammonium hydrogendifluoride is such that contact between product and adjacent air is reduced and controlled loading is sometimes used reducing the amount of aerosol/dust formation. Emission can be limited by ensuring the machinery used in the production process is completely isolated and housed separately from the work environment.
Technical conditions to control dispersion from source towards worker
Emission sources can be completely or partially segregated from the work environment by isolating the source in a fully enclosed and separate room, which is airtight. The integrity of the enclosure is also monitored.
Organizational measures to prevent/limit release
Workers involved in production, handling and transfer of materials are trained in the procedures and protective equipment is intended to cope with the worst case scenario, in order to minimise exposure and risks.
Conditions and measures related to personal protection, hygiene and health.
Personal protective clothing, including the use of a respiratory mask with E-P2 filter, eye protective goggles or face shield and protective gloves (butyl-rubber) are worn by all operators in the production of ammonium hydrogendifluoride. Due to the nature of the materials the level of control is extremely high and so in reality exposure is highly unlikely.

3	Exposure estimation and reference to its source

Environmental Exposure

For the environmental exposure assessment in EUSES refined inputs are chosen to best suit the description of the production and uses of ammonium hydrogendifluoride. Emission defaults are those specified by the ECHA "Guidance on information requirements and chemical safety assessment: Chapter R.16: Environmental Exposure Estimation". Regional data and emission fractions were calculated using EUSES. Full EUSES inputs are shown below. The ERC based tier 1 assessment was not considered to give a realistic exposure estimation and so only the results of the refined tier 2 model using EUSES are shown below.

EUSES inputs for ES1 production exposure assessment

Input parameter:	Value:	Unit:	ERC default (if applicable)
Molecular Weight	57.04	g/mol	
Vapour Pressure (at 20 °C)	1.08	Pa	
Water Solubility	100,000 (Fully miscible)	mg/L	The maximum water solubility in EUSES is chosen here.
Octanol/water partition coefficient	-1 (inorganic estimate)	logKow	
Koc	3.16 (Estimated in EUSES based on log kow)		
Biodegradability	Not biodegradable (inorganic acids cannot be considered biodegradable)		
Life Cycle Step	Production		
Environmental Release Class	ERC1		
Fraction of Tonnage for Region (1st Tier)			1
STP			Yes
Emission events per year	330 (manufacturer information)	Days	300
Default Release to Air	5	%	5
Default Release to water	6	%	6
Dilution factor applied for PEC derivation			10 (20,000 m^3/d)
Tonnage assessed	Local: 5,500 Regional: 10,500	tonnes/annum	Worst case local and total regional production tonnage.

Based on these inputs the following predicted environmental exposure concentrations (PECs) were derived

Predicted Releases to the Environment Tier 2

ERC	Compartments	Predicted releases	Measured release	Explanation
1	Wastewater	0 kg/d	-	Tier 2 assessments are not necessary for ERC 1 as there is no loss of the substance to wastewater.
	Release to air	10 kg/d	-	Worst case assumption
	Soil (direct only) Agricultural soil	0 kg/d	-	No direct loss to soil is expected for this ERC and no sludge spreading.

Tier 2 Concentrations in sewage

ERC for Compartment:	Estimated exposure concentrations		Explanation
	value	unit	
Sewage (STP effluent)	0	mg/L	Tier II assessments are not necessary for ERC 1 as there is no loss of the substance to wastewater.
Sewage sludge	0	mg/kg	There is no spreading of sludge to soil so for the purposes of this assessment the concentration in sewage sludge should be considered to be 0

Tier 2 Predicted Environmental Concentrations (PEC) in aquatic compartment

Compartments	PEC aquatic (local mg/L)	Justification
Freshwater (in mg/L)	2.75×10^{-4}	
Marine water (in mg/L)	2.75×10^{-5}	
Intermittent releases to water (in mg/L)	NA	Intermittent release not relevant

Tier 2 Predicted Environmental Concentrations (PEC) in aquatic sediment compartment

Compartments	PEC aquatic (local)
Freshwater sediment (in mg/kg wwt)	2.34×10^{-4}
Marine sediment (in mg/kg wwt)	2.33×10^{-5}

Tier 2 Predicted Environmental Concentrations (PEC) in the soil and groundwater compartment

Compartments	PEC (local)
Agricultural soil (averaged over 30 days (in mg/kg)	0.0015
Groundwater (in mg/L)	0.0087

Tier 2 Predicted Exposure Concentration (PEC) in air

ERC		Local concentration	PEC air (local+regional)	Justification
1	Annual average PEC in air, total (mg/m^3)	0.0025	0.0025	Estimated using EUSES 2.1.

Based on these PECs the following risk characterization ratios are derived

Compartment	**PEC mg/L**	**PNEC mg/L**	**RCR**	**Comments**
Tier 2 Freshwater	2.75×10^{-4}	1.3	0.0002	Safe use demonstrated
Tier 2 Soil	0.015	22	0.0006	Safe use demonstrated
Tier 2 STP	0	0	0	No second tier assessment required as no wastewater is released to the STP. As such there is no indicated risk.

Worker Exposure:

The assessment of worker exposure to ammonium hydrogendifluoride from production (ES1) was carried for processes relevant to this use scenario as identified by PROC codes. Initially, a screening-level (Tier 1) assessment was carried out using the MEASE model instead of ECETOC. The ECETOC model was not deemed appropriate for this substance. A higher tier (Tier 2) refinement of the Tier 1 assessment was carried out using the Advanced REACH Tool (ART).

The effects of exposure to ammonium hydrogendifluoride dermal exposures are likely to be local irritation and corrosivity of the skin. There is no evidence of systemic effects following dermal exposures to ammonium hydrogendifluoride. Estimates of systemic dermal doses associated with acute/short-term and long-term exposures to ammonium hydrogendifluoride were not therefore derived. Furthermore all dermal exposure is ruled out by the exposure limiting methods in place.

A screening-level assessment of inhalation exposure concentrations potentially associated with processes in ES1 was carried out using the MEASE model and the parameters shown in the tables below. The MEASE model was considered more appropriate to use for AMBI than ECETOC as it incorporates measured data from the metals industry and takes into account operational conditions and RMM that are more relevant.
The tables below show the estimated exposure concentration to ammonium hydrogendifluoride for processes associated with ES1.

The MEASE model was not considered to give a reasonable screening-level assessment of exposures associated processes involved in ES1 that are closed and well-controlled and present no real potential for inhalation exposures in workers.
As such the unsuitable tier 1 assessment of inhalation exposures associated with ES 1 derived using the MEASE model were refined using the higher tier inhalation model: the Advanced REACH tool (ART). In the ART model, a mechanistic model of inhalation exposure and expert judgement were used to predict more realistic estimates of inhalation exposure concentrations associated with processes involving ammonium hydrogendifluoride in ES 1. The Tier 2 assessment was carried out using the parameters and assumptions in the tables below. The predicted 50^{th} and 90^{th} (worst case) percentile acute/short-term (e.g. exposure over a full-shift) and long-term inhalation exposure concentrations derived using these parameters for processes associated with ES1 are presented in the tables below.

	Parameter	Explanation/source of data
Molecular weight	57.04 g/mol	
Vapour Pressure	1.08 Pa	
Is the substance a solid?	Yes	The substance is produced in flake form with slow dustiness
Dustiness during process	Inhalable fraction: ≤ 100 mg/kg	Product does not result in dust emission without intentional breakage of products: e.g., firm polymer granules, granules covered with a layer of wax, a woodblock, a brick).
Duration of activity	>4 hours (default)	Worst case
Use of respiratory protection	No	Worst case
Content in preparation	Dry product (<5 % moisture content)	

First tier screening level exposure concentrations to workers

Description of activity	PROC	Physical state of material	Estimated Exposure Concentrations for flake	
			value	unit
Use in closed process, no likelihood of exposure	1	Flake	0.01	mg/m^3
Use in closed, continuous process with occasional controlled exposure	2	Flake	0.01	mg/m^3
Use in closed batch process (synthesis or formulation)	3	Flake	0.1	mg/m^3
Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact)	5	Flake	0.5	mg/m^3
Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities	8a	Flake	0.5	mg/m^3
Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities	8b	Flake	0.1	mg/m^3
Transfer of substance or preparation into small containers (dedicated filling line, including weighing)	9	Flake	0.1	mg/m^3

Parameters and assumptions used in the ART model to conduct a Tier 2 assessment of inhalation exposure concentrations

	PROC	Parameters/ assumptions for flake
Exposure duration	All	480 min
Product type	All	Powders, granules or pelletised material
Process temperature	All	Room temperature (15-25°C)
Vapour pressure	All	1.08 Pa
Liquid weight fraction	All	N/A
Dustiness	All	Product does not result in dust emission without intentional breakage of products: e.g., firm polymer granules, granules covered with a layer of wax, a woodblock, a brick). Inhalable fraction: ≤ 100 mg/kg

Primary emission source proximity	PROC 8a, 8b and 9	Primary emission source located in the breathing zone of the workers (i.e. Within 1 metre)
	PROC 1, 2, 3, and 5	Primary emission source is not located in the breathing zone of the worker- the assessment for this activity involves a primary far-field emission source only (workers are in a control room)
Activity class	PROC 1 and 2	Transfer of powders, granules or pelletised material- falling powders, granules or pelletised material > 1000 kg/minute (e.g. Large scale transfer with big bags)
	PROC 3	Transfer of powders, granules or pelletised material- falling powders, granules or pelletised material 100 – 1000 kg/minute. Automated dumping of powders (e.g. auger or conveyer belt)
	PROC 5	Movement and agitation of powders, granules or pelletised material- Movement and agitation of 100-1000 kg
	PROC 8a and 8b	Transfer of powders, granules or pelletised material- Vacuum transfer of powders, granules or pelletised material > 1000 kg/minute (Large scale vacuum transfer from large vessels)
	PROC 9	Transfer of powders, granules or pelletised material- falling powders, granules or pelletised material- Transferring 0.1 – 1 kg/minute (e.g. Filling bottles)
Containment	PROC 1, 2, 3 and 9	Routine transfer. Drop height > 0.5 m, Handling reduces contact between product and adjacent air.
	PROC 5	Other handling with high level of agitation- Handling that reduces contact between product and adjacent air
	PROC 8a and 8b	Handling reduces contact between product and adjacent air.
Segregation	PROC 1 and 2	Complete segregation with ventilation and filtration of recirculation (sources are completed segregated from the work environment by isolating the source in a fully enclosed and separate room. Personal enclosure: complete personal enclosure with ventilation (enclosed cabin)
	PROC 3 and 5	Sources are partially segregated from the work environment by isolating the source in a separate room (with open doors and/or windows). Personal Enclosure: Partial personal enclosure with ventilation.
Localised controls	All	No localised controls
Fugative emission source	PROC 1, 3, 8b, 9	Process fully enclosed (air tight) and the integrity of the enclosure is monitored. The containment is not breached for sampling o routine cleaning
	PROC 2, 5, 8a	Process not fully enclosed but effective housekeeping practises are in place
Dispersion	All	Indoors, any size workroom, good natural ventilation

Description of activity	PROC	Physical state of material	Estimated Short-term Exposure Concentrations (mg/m^3)		Estimated Long-term Exposure Concentration (mg/m^3)	
			50^{th} percentile value	90^{th} percentile value	50^{th} percentile value	90^{th} percentile value
Use in closed process, no likelihood of exposure	1	Flake	0.054	0.21	0.073	0.18
Use in closed, continuous process with occasional controlled exposure	2	Flake	0.054	0.21	0.073	0.18
Use in closed batch process (synthesis or formulation)	3	Flake	0.16	0.63	0.22	0.55
Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact)	5	Flake	0.16	0.63	0.22	0.54
Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities	8a	Flake	0.3	1.2	0.42	1
Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities	8b	Flake	0.3	1.2	0.42	1
Transfer of substance or preparation into small containers (dedicated filling line, including weighing)	9	Flake	0.091	0.36	0.12	0.31

Based on these exposure concentrations the following RCRs are derived for worker exposure. Only the second tier RCRs as derived using ART are presented below.

	Route	PROC Code	ES 1- 90th exposure concentrations (mg/m3)	Leading toxic end point / Critical effect	DNEL (mg/m3)	Risk characterisation ratio- No RPE assumed	Risk characterisation ratio- RPE : 95% protection
Acute effects- Flake	Inhalation	PROC 1	2.1 x 10^{-1}	Respiratory irritation and corrositivity	3.8	5.5 x 10^{-2}	2.8 x 10^{-3}
		PROC 2	2.1 x 10^{-1}			5.5 x 10^{-2}	2.8 x 10^{-3}
		PROC 3	6.3 x 10^{-1}			1.7 x 10^{-1}	8.3 x 10^{-3}
		PROC 5	6.3 x 10^{-1}			1.7 x 10^{-1}	8.3 x 10^{-3}
		PROC 8a	1.2			3.2 x 10^{-1}	1.6 x 10^{-2}
		PROC 8b	1.2			3.2 x 10^{-1}	1.6 x 10^{-2}
		PROC 9	3.6 x10^{-1}			9.5 x 10^{-2}	4.7 x 10^{-3}
Long term effects- Flake	Inhalation	PROC 1	1.8 x 10^{-1}	Respiratory irritation and corrositivity	2.3	7.8 x 10^{-2}	3.9 x 10^{-3}
		PROC 2	1.8 x 10^{-1}			7.8 x 10^{-2}	3.9 x 10^{-3}
		PROC 3	5.5 x 10^{-1}			2.4 x 10^{-1}	1.2 x 10^{-2}
		PROC 5	5.4 x10^{-1}			2.3 x 10^{-1}	1.2 x 10^{-2}
		PROC 8a	1.0			4.3 x 10^{-1}	2.2 x 10^{-2}
		PROC 8b	1.0			4.3 x 10^{-1}	2.2 x 10^{-2}
		PROC 9	3.1 x 10^{-1}			1.3 x 10^{-1}	6.7 x 10^{-3}

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

Environmental releases:

In order to work within the boundaries of the ES the following conditions should be met:

- Emission to air after scrubbing less than 10 kg per day
- There should be no emissions to wastewater
- Any measured emissions should be confirmed to be less than the relevant PNECs in section 3 above.

5	**Additional good practice advice beyond the REACH CSA.**

- Do not eat, drink or smoke when working with AMBI.
- Always wash hands and exposed skin thoroughly after using AMBI surfaces/machinery that may have come into contact with AMBI.
- Workers should be suitably trained in all safety procedures
- Procedural and safety compliance should be routinely assessed by management
- Machinery should be regularly maintained and checked for proper function
- Efficacy of all emission RMMs and waste treatment procedures should be routinely assessed and confirmed to be functioning correctly
- Details on scaling and control technologies are provided at: http://cefic.org/Industry-support/Implementing-reach/Libraries/

Downstream user exposure scenario for Ammonium hydrogendifluoride (AMBI)

1	Exposure Scenario 2: Formulation of ammonium hydrogendifluoride

Formulation of ammonium hydrogendifluoride

Environmental Release and Worker Processes Covered:

Environmental Releases

ERC02: Formulation of preparations

Worker Processes

PROC01: Use in closed process, no likelihood of exposure
PROC02: Use in closed, continuous process with occasional controlled exposure
PROC05: Mixing or blending in batch process for formulation of preparations and articles (multistage and/or significant contact)
PROC08a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities
PROC08b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities
PROC09: Transfer of substance or preparation into small containers (dedicated filling line, including weighing)

Product Category

Not applicable.

Due to the nature of ammonium hydrogendifluoride, formulation systems are highly controlled, with a high degree of system closure and extremely limited environmental emissions.

Contributing Environmental Scenario: CES 1: Environmental exposure arising due to formulation of ammonium hydrogendifluoride (ERC 1).

2.1	Controlling environmental exposure for ES 2

ES2: Contributing exposure scenario (CES) 1 Environmental exposure arising due to formulation of ammonium hydrogendifluoride.

Section 2.1 describes the environmental releases that may occur during the formulation of ammonium hydrogendifluoride. These releases may occur due to emission to the atmosphere and release to wastewater.

Liquid wastes are generally treated prior to emission to remove any ammonium hydrogendifluoride in the waste water.

Emissions to air are treated by scrubbers. Emissions to local air (after scrubbing) should be no more than 37.7 kg per day.

AMBI, when in contact with water, converts to ammonium and fluoride ions and is fully miscible in water its actual conversion, neutralisation and removal from the waste stream is expected to be extremely rapid.

Product characteristics

AMBI is a white crystalline solid at 20°C and 101.3 kPa with a vapour pressure of 1.08 Pa at 20°C. It is highly soluble in water and is not considered flammable. AMBI is not considered to be potentially explosive or an oxidising agent. The product used is in flake form or in the form of a solution.

Amounts used

Formulation sites may use up to 500 tonnes per annum as a worst case assumption with up to 330 emission days per year. Facilities that formulate ammonium hydrogendifluoride may consume quantities approaching two tonnes per day.

Frequency and duration of use

Continuous production and with up to 330 emission days per year.

Environmental factors influenced by risk management

Flow rate of receiving water at least 10,000 m^3 per day. Dilution of (theoretical) STP emissions at least 10 fold.

Other operational conditions affecting environmental exposure

Formulation of ammonium hydrogendifluoride generally occurs indoors, with a high degree of system closure. Emissions to air are scrubbed before release and waste would primarily be directed to the waste stream.

Technical conditions and measures at process level (source) to prevent release
All formulation operations, including mixing and blending and transfer processes, are carried out indoors in dedicated facilities with closed systems. Total losses to air are measured.
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil
During the formulation of AMBI, scrubbers are used for waste air treatment. Liquid wastes would generally be treated by neutralisation to neutral pH and/or precipitation prior to emission to remove any ammonium hydrogendifluoride in the waste water, ensuring the maximum concentration of fluorides in the effluent can be no higher than the low solubility of the formed precipitates. Sludge from the waste water treatment plant is sent for recovery, incineration or landfill and is not used for agricultural spreading.
Organizational measures to prevent/limit releases from site
Workers are fully trained in order to prevent accidental release. The processes are generally fully enclosed (air tight) and the integrity of the enclosure is monitored.
Conditions and measures related to municipal STP
The emission volume of the (theoretical) STP should be at least the default of 2,000 m^3 per day though no actual loss to the STP is envisaged.
Conditions and measures related to external treatment of waste for disposal
No external treatment of waste is expected.
Conditions and measures related to external recovery of waste
There is no envisaged external recovery of waste. Sludge from the waste water treatment plant is sent for recovery, incineration or landfill and is not used for agricultural spreading.

2.2	**Controlling worker exposure for ES 2**

ES2: CES 2: Worker exposure arising due to use in closed processes (PROC 1), CES 3: worker exposure arising due to use in closed continuous processes with occasional controlled exposure (PROC 2), CES 4: worker exposure arising due to mixing or blending (PROC 5), CES 5: worker exposure arising due to transfer of substance or preparations from/to vessels/large containers at non-dedicated or dedicated facilities (PROC 8a and PROC 8b) and CES 6: worker exposure arising due to transfer of the substance or preparation into small containers (PROC 9).

During the industrial formulation of ammonium hydrogendifluoride, workers wear protective clothing (respiratory mask with E-P2 filter, eye protective goggles/face shield and protective gloves). A safety shower is required nearby in case of accidental spillage.

Product characteristics
AMBI is a white crystalline solid at 20°C and 101.3 kPa with a vapour pressure of 1.08 Pa at 20°C. It is highly soluble in water and is not considered flammable. AMBI is not considered to be potentially explosive or an oxidising agent. The product used is in flake form or in the form of a solution.
Amounts used
Formulation sites may use up to 500 tonnes per annum as a worst case assumption with up to 330 emission days per year. Facilities that formulate ammonium hydrogendifluoride may consume quantities approaching two tonnes per day.

Frequency and duration of use exposure
Workers perform standard shifts of 8 hours per day and have standard working years of 220 days per year. However, some tasks such as sampling and cleaning of the operational machinery and transfer of the substance may be shorter duration tasks.
Human factors not influence by risk management
Respiration volume under conditions of use is $10m^3/d$ (default value for a worker breathing for an 8h work day in Guidance Section R 8.4.2). Area of skin contact with the substance under the conditions of use is $0cm^2$ as all dermal contact must be prevented due to the corrosive nature of AMBI.
Other given operational conditions affecting worker exposure
All operations associated with the production of ammonium hydrogendifluoride are conducted indoors, in highly controlled systems, with a high degree of closure due to its corrosive nature. The possibility for exposure is limited where possible to prevent potential exposure.
Technical conditions and measures at process level (source) to prevent release
Primary emission sources are mostly not located in the breathing zone of the worker. The handling of ammonium hydrogendifluoride is such that contact between product and adjacent air is reduced and controlled loading is sometimes used reducing the amount of aerosol/dust formation. Emission can be limited by ensuring the machinery used in the production process is completely isolated and housed separately from the work environment.
Technical conditions to control dispersion from source towards worker
Emission sources can be completely or partially segregated from the work environment by isolating the source in a fully enclosed and separate room, which is airtight. The integrity of the enclosure is also monitored.
Organizational measures to prevent/limit release
Workers involved in production, handling and transfer of materials are trained in the procedures and protective equipment is intended to cope with the worst case scenario, in order to minimise exposure and risks.
Conditions and measures related to personal protection, hygiene and health.
Personal protective clothing, including the use of a respiratory mask with E-P2 filter, eye protective goggles or face shield and protective gloves (butyl-rubber) are worn by all operators in the production of ammonium hydrogendifluoride. Due to the nature of the materials the level of control is extremely high and so in reality exposure is highly unlikely.

3	Exposure estimation and reference to its source

Environmental Exposure

For the environmental exposure assessment in EUSES refined inputs are chosen to best suit the description of the production and uses of ammonium hydrogendifluoride. Emission defaults are those specified by the ECHA "Guidance on information requirements and chemical safety assessment: Chapter R.16: Environmental Exposure Estimation". Regional data and emission fractions were calculated using EUSES. Full EUSES inputs are shown below. The ERC based tier 1 assessment was not considered to give a realistic exposure estimation and so only the results of the refined tier 2 model using EUSES are shown below.

EUSES inputs for ES2 formulation exposure assessment

Input parameter:	Value:	Unit:	ERC default (if applicable)
Molecular Weight	57.04	g/mol	
Vapour Pressure (at 20 °C)	1.08	Pa	
Water Solubility	100,000 (Fully miscible)	mg/L	The maximum water solubility in EUSES is chosen here.
Octanol/water partition coefficient	-1 (inorganic estimate)	logKow	
Koc	3.16 (Estimated in EUSES based on log kow)		
Biodegradability	Not biodegradable (inorganic acids cannot be considered biodegradable)		
Life Cycle Step	Formulation		
Environmental Release Class	ERC2		
Fraction of Tonnage for Region (1st Tier)			1
STP			Yes
Emission events per year	330 (manufacturer information)	Days	300
Default Release to Air	2.5	%	2.5
Default Release to water	2	%	2
Dilution factor applied for PEC derivation			10 (20,000 m^3/d)
Tonnage assessed	Local: 500 Regional: 4700	tonnes/annum	Worst case local and total regional/EU tonnage.

Based on these inputs the following predicted environmental exposure concentrations (PECs) were derived

ERC	Compartments	Predicted releases	Measured release	Explanation
2	Wastewater	14.6 kg/d	-	Based on the on-site treatment process
	Release to air	37.7 kg/d	-	ERC default loss
	Soil (direct only) Agricultural soil	0 kg/d	-	No direct loss to soil is expected for this ERC and no sludge spreading.

Tier 2 Concentrations in sewage

ERC for Compartment:	Estimated exposure concentrations		Explanation
	value	unit	
Sewage (STP effluent)	7.3	mg/L	Set to 7.3 due to on-site treatment and removal
Sewage sludge	0	mg/kg	There is no spreading of sludge to soil so for the purposes of this assessment the concentration in sewage sludge should be considered to be 0

Tier 2 Predicted Environmental Concentrations (PEC) in aquatic compartment

Compartments	PEC aquatic (local mg/L)	Justification
Freshwater (in mg/L)	0.734	
Marine water (in mg/L)	0.0734	
Intermittent releases to water (in mg/L)	NA	Intermittent release not relevant

Tier 2 Predicted Environmental Concentrations (PEC) in aquatic sediment compartment

Compartments	PEC aquatic (local)
Freshwater sediment (in mg/kg wwt)	0.625
Marine sediment (in mg/kg wwt)	0.0625

Tier 2 Predicted Environmental Concentrations (PEC) in the soil and groundwater compartment

Compartments	PEC (local)
Agricultural soil (averaged over 30 days (in mg/kg)	0.0253
Groundwater (in mg/L)	0.0933

Tier 2 Predicted Exposure Concentration (PEC) in air

ERC		Local concentration	PEC air (local+regional)	Justification
2	Annual average PEC in air, total (mg/m^3)	0.00949	0.00949	Estimated using EUSES 2.1.

Based on these PECs the following risk characterization ratios are derived.

Risk characterisation

Compartment	**PEC mg/L**	**PNEC mg/L**	**RCR**	**Comments**
Tier 2 Freshwater	0.734	1.3	0.5646	Safe use demonstrated
Tier 2 Soil	0.0253	22	0.00115	Safe use demonstrated
Tier 2 STP	7.3	76	0.096	Safe use demonstrated

Worker Exposure:

The assessment of worker exposure to ammonium hydrogendifluoride during formulation (ES2) was carried out for processes relevant to this use scenario as identified by PROC codes. Initially, a screening-level (Tier 1) assessment was carried out using the MEASE model instead of ECETOC. The ECETOC model was not deemed appropriate for this substance. A higher tier (Tier 2) refinement of the Tier 1 assessment was carried out using the Advanced REACH Tool (ART).

The effects of exposure to ammonium hydrogendifluoride dermal exposures are likely to be local irritation and corrosivity of the skin. There is no evidence of systemic effects following dermal exposures to ammonium hydrogendifluoride. Estimates of systemic dermal doses associated with acute/short-term and long-term exposures to ammonium hydrogendifluoride were not therefore derived. Furthermore all dermal exposure is ruled out by the exposure limiting methods in place.

A screening-level assessment of inhalation exposure concentrations potentially associated with processes in ES2 was carried out using the MEASE model and the parameters shown in the tables below. The MEASE model was considered more appropriate to use for AMBI than ECETOC as it incorporates measured data from the metals industry and takes into account operational conditions and RMM that are more relevant.

The tables below show the estimated exposure concentration to ammonium hydrogendifluoride for processes associated with ES2.

The MEASE model was not considered to give a reasonable screening-level assessment of exposures associated processes involved in ES2 that are closed and well-controlled and present no real potential for inhalation exposures in workers.

As such the unsuitable tier 1 assessment of inhalation exposures associated with ES 2 derived using the MEASE model were refined using the higher tier inhalation model: the Advanced REACH tool (ART). In the ART model, a mechanistic model of inhalation exposure and expert judgement were used to predict more realistic estimates of inhalation exposure concentrations associated with processes involving ammonium hydrogendifluoride in ES2. The Tier 2 assessment was carried out using the parameters and assumptions in the tables below. The predicted 50^{th} and 90^{th} (worst case) percentile acute/short-term (e.g. exposure over a full-shift) and long-term inhalation exposure concentrations derived using these parameters for processes associated with ES 2 are presented in the tables below.

Parameters used in the MEASE model to conduct a Tier 1 assessment of inhalation exposure concentrations

	Parameter for Solution	Explanation/source of data for solution	Parameter for Flakes	Explanation/source of data for flake
Molecular weight	57.04 g/mol		57.04 g/mol	
Vapour Pressure	1.08 Pa		1.08 Pa	
Water solubility	100,000 mg/L		100,000 mg/L	
Is the substance a solid?	No – liquid	>25% (worst case)	Yes	The substance is produced in flake form
Dustiness during process	n/a	Only in the case of solid	Inhalable fraction: ≤ 100 mg/kg	Product does not result in dust emission without intentional breakage of products: e.g., firm polymer granules, granules covered with a layer of wax, a woodblock, a brick).
Duration of activity	>4 hours (default)	Worst case	>4 hours (default)	Worst case
Use of respiratory protection	No	Worst case	No	Worst case

First tier screening level exposure concentrations to workers

Description of activity	PROC	Physical state of material	Estimated Exposure Concentrations	
			value	unit
Use in closed process, no likelihood of exposure	1	Liquid	0.001	mg/m^3
Use in closed, continuous process with occasional controlled exposure	2	Liquid	0.001	mg/m^3
Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact)	5	Liquid	0.05	mg/m^3
Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities	8a	Liquid	0.05	mg/m^3
Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities	8b	Liquid	0.01	mg/m^3
Transfer of substance or preparation into small containers (dedicated filling line, including weighing)	9	Liquid	0.01	mg/m^3
Use in closed process, no likelihood of exposure	1	Flake	0.01	mg/m^3
Use in closed, continuous process with occasional controlled exposure	2	Flake	0.01	mg/m^3
Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact)	5	Flake	0.5	mg/m^3

Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities	8a	Flake	0.5	mg/m^3
Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities	8b	Flake	0.1	mg/m^3
Transfer of substance or preparation into small containers (dedicated filling line, including weighing)	9	Flake	0.1	mg/m^3

Parameters and assumptions used in the ART model to conduct a Tier 2 assessment of inhalation exposure concentrations

	PROC	Parameters/ assumptions for Flake	PROC	Parameters/ assumptions for Solution
Exposure duration	All	480 min	All	480 min
Product type	All	Powders, granules or pelletised material	All	Powders dissolved in a liquid or incorporated in a liquid matrix (e.g. copper in anti-fouling paint)
Process temperature	All	Room temperature (15-25°C)	All	Room temperature (15-25°C)
Vapour pressure	All	1.08 Pa	All	1.08 Pa
Liquid weight fraction	All	N/A	All	Substantial (10-50%)
Primary emission source proximity	PROC 1, 2, 5	Primary emission source is not located in the breathing zone of the worker- the assessment for this activity involves a primary far-field emission source only (workers are in a control room)	PROC 1, 2, 5	Primary emission source is not located in the breathing zone of the worker- the assessment for this activity involves a primary far-field emission source only (workers are in a control room)
	PROC 8a, 8b and 9	Primary emission source located in the breathing zone of the workers (i.e. Within 1 metre)	PROC 8a, 8b and 9	Primary emission source located in the breathing zone of the workers (i.e. Within 1 metre)
Activity class	PROC 1 and 2	Transfer of powders, granules or pelletised material- falling powders, granules or pelletised material > 1000 kg/minute (e.g. Large scale transfer with big bags)	PROC 1, 2, 8a, 8b	Transfer of liquid products- falling liquids >1000 L/minutes- worst case. (e.g. Loading of tanker at bulk terminal (boats, rail car or truck))
	PROC 5	Movement and agitation of powders, granules or pelletised material- Movement and agitation of 100- 1000 kg	PROC 5,	Activities with open liquid surfaces- activities with agitated surfaces- Open surface > 3 m²
	PROC 8a and 8b	Transfer of powders, granules or pelletised material- Vacuum transfer of powders, granules or pelletised material > 1000 kg/minute (Large scale vacuum transfer from large vessels)	Proc 9	Transfer of liquid products (Falling liquids) 1-10L/min- filling bottles
	PROC 9	Transfer of powders, granules or pelletised material- falling powders, granules or pelletised material- Transferring 0.1 – 1		

		kg/minute (e.g. Filling bottles)		
Containment	PROC 1, 2, and 9	Routine transfer. Drop height > 0.5 m, Handling reduces contact between product and adjacent air.	PROC 1, 2 and 9	Handling reduces contact between product and adjacent air. Transfer loading type: Splash loading, where the liquid dispenser remains at the top of the reservoir and the liquid splashes freely
	PROC 5	Other handling with high level of agitation- Handling that reduces contact between product and adjacent air	PROC 5, 8a, 8b	N/A
	PROC 8a, 8b	Handling reduces contact between product and adjacent air.		
Localised controls	All	No localised controls	All	No localised controls
Segregation	PROC 1, 2	Complete segregation with ventilation and filtration of recirculation (sources are completed segregated from the work environment by isolating the source in a fully enclosed and separate room. Personal enclosure: complete personal enclosure with ventilation (enclosed cabin)	PROC 1 and 2	Complete segregation with ventilation and filtration of recirculation (sources are completed segregated from the work environment by isolating the source in a fully enclosed and separate room. Personal enclosure: complete personal enclosure with ventilation (enclosed cabin)
	PROC 5	Sources are partially segregated from the work environment by isolating the source in a separate room (with open doors and/or windows). Personal Enclosure: Partial personal enclosure with ventilation.	PROC 5	Sources are partially segregated from the work environment by isolating the source in a separate room (with open doors and/or windows). Personal Enclosure: Partial personal enclosure with ventilation.
			PROC 8a, 8b and 9	N/A
	PROC 8a, 8b and 9	N/A		
Fugative emission source	PROC 1, 8b and 9	Process fully enclosed (air tight) and the integrity of the enclosure is monitored. The containment is not breached for sampling o routine cleaning	PROC 1, 8b and 9	Process fully enclosed (air tight) and the integrity of the enclosure is monitored. The containment is not breached for sampling o routine cleaning
	PROC 2, 5 and 8a	Process not fully enclosed but effective housekeeping practises are in place	PROC 2, 5, 8a	Process not fully enclosed but effective housekeeping practises are in place
Dispersion	All	Indoors, any size workroom, good natural ventilation	All	Indoors, any size workroom, good natural ventilation

Tier 2 acute/short-term and long-term inhalation exposure concentrations derived using the ART model

Description of activity	PROC	Physical state of material	Estimated Short-term Exposure Concentrations (mg/m^3)		Estimated Long-term Exposure Concentration (mg/m^3)	
			50^{th} percentile value	90^{th} percentile value	50^{th} percentile value	90^{th} percentile value
Use in closed process, no likelihood of exposure	1	Flake	0.054	0.21	0.073	0.18
Use in closed, continuous process with occasional controlled exposure	2	Flake	0.054	0.21	0.073	0.18
Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact)	5	Flake	0.16	0.63	0.22	0.54
Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities	8a	Flake	0.3	1.2	0.42	1
Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities	8b	Flake	0.3	1.2	0.42	1
Transfer of substance or preparation into small containers (dedicated filling line, including weighing)	9	Flake	0.091	0.36	0.12	0.31
Use in closed process, no likelihood of exposure	1	Liquid	0.0024	0.0097	0.0034	0.0084
Use in closed, continuous process with occasional controlled exposure	2	Liquid	0.0024	0.0098	0.0034	0.0084
Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact)	5	Liquid	0.074	0.29	0.1	0.25
Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities	8a	Liquid	0.0046	0.018	0.0064	0.016
Transfer of substance or preparation (charging/discharging) from/to vessels/large	8b	Liquid	0.0046	0.018	0.0064	0.016

containers at dedicated facilities						
Transfer of substance or preparation into small containers (dedicated filling line, including weighing)	9	Liquid	0.012	0.049	0.017	0.043

Based on these exposure concentrations the following RCRs are derived for worker exposure. Only the second tier RCRs as derived using ART are presented below.

Quantitative risk characterisation for worker

	Route	**PROC Code**	**ES 1- 90th exposure concentrations (mg/m3)**	**Leading toxic end point / Critical effect**	**DNEL (mg/m3)**	**Risk characterisation ratio- No RPE assumed**	**Risk characterisation ratio- RPE : 95% protection**
Acute effects- Solution	Inhalation	PROC 1	9.7×10^{-3}	Respiratory irritation and corrosivity	3.8	2.6×10^{-3}	1.3×10^{-4}
		PROC 2	9.8×10^{-3}			2.6×10^{-3}	1.3×10^{-4}
		PROC 5	2.9×10^{-1}			7.6×10^{-2}	3.8×10^{-3}
		PROC 8a	1.8×10^{-2}			4.7×10^{-3}	2.4×10^{-4}
		PROC 8b	1.8×10^{-2}			4.7×10^{-3}	2.4×10^{-4}
		PROC 9	4.9×10^{-2}			1.3×10^{-2}	6.4×10^{-4}
Long term effects- Solution	Inhalation	PROC 1	8.4×10^{-3}	Respiratory irritation and corrosivity	2.3	3.7×10^{-3}	1.8×10^{-4}
		PROC 2	8.4×10^{-3}			3.7×10^{-3}	1.8×10^{-4}
		PROC 5	2.5×10^{-1}			1.1×10^{-1}	5.4×10^{-3}
		PROC 8a	1.6×10^{-2}			7.0×10^{-3}	3.5×10^{-4}
		PROC 8b	1.6×10^{-2}			7.0×10^{-3}	3.5×10^{-4}
		PROC 9	4.3×10^{-2}			1.9×10^{-2}	9.3×10^{-4}
Acute effects- Flake	Inhalation	PROC 1	2.1×10^{-1}	Respiratory irritation and corrosivity		5.5×10^{-2}	2.8×10^{-3}
		PROC 2	2.1×10^{-1}			5.5×10^{-2}	2.8×10^{-3}
		PROC 5	6.3×10^{-1}			1.7×10^{-1}	8.3×10^{-3}
		PROC 8a	1.2			3.2×10^{-1}	1.6×10^{-2}
		PROC 8b	1.2			3.2×10^{-1}	1.6×10^{-2}
		PROC 9	3.6×10^{-1}			9.5×10^{-2}	4.7×10^{-3}

Long term effects-Flake	Inhalation	PROC 1	1.8×10^{-1}	Respiratory irritation and corrositivity		7.8×10^{-2}	3.9×10^{-3}
		PROC 2	1.8×10^{-1}			7.8×10^{-2}	3.9×10^{-3}
		PROC 5	5.4×10^{-1}			2.3×10^{-1}	1.2×10^{-2}
		PROC 8a	1.0			4.3×10^{-1}	2.2×10^{-2}
		PROC 8b	1.0			4.3×10^{-1}	2.2×10^{-2}
		PROC 9	3.1×10^{-1}			1.3×10^{-1}	6.7×10^{-3}

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

Environmental releases:

In order to work within the boundaries of the ES the following conditions should be met:

- Emission to air after scrubbing should be less than 37.7 kg per day
- Waste water should be treated by neutralization or precipitation prior to release to the environment, ensuring the maximum concentration of fluorides in the effluent can be no higher than the low solubility of the formed precipitates.
- Local emissions to air and water should be no more than those specified in section 3 above.
- Any measured emissions should be confirmed to be less than the relevant PNECs in section 3 above.

Worker exposure:

In order to work within the boundaries of the ES the following conditions should be met:

- Worker segregation and LEV should be in place to prevent contact with the AMBI source during activities associated with formulation using AMBI.
- Workers should wear respiratory mask with E-P2 filter, eye protective goggles or face shield and protective gloves (butyl-rubber) at all times during the use of AMBI during formulation activities.
- Any measured exposure should be confirmed to be less than the relevant DNELs as listed in section 3 above

5 Additional good practice advice beyond the REACH CSA.

- Do not eat, drink or smoke when working with AMBI.
- Always wash hands and exposed skin thoroughly after using AMBI surfaces/machinery that may have come into contact with AMBI.
- Workers should be suitably trained in all safety procedures
- Procedural and safety compliance should be routinely assessed by management
- Machinery should be regularly maintained and checked for proper function
- Efficacy of all emission RMMs and waste treatment procedures should be routinely assessed and confirmed to be functioning correctly
- Details on scaling and control technologies are provided at: http://cefic.org/Industry-support/Implementing-reach/Libraries/

Downstream user exposure scenario for Ammonium hydrogendifluoride (AMBI)

1	Exposure Scenario 3: Metal surface treatment

Metal Surface treatment

Environmental Release and Worker Processes Covered:

Environmental Releases

ERC6B: Industrial use of reactive processing aids

Worker Processes

PROC07: Industrial spraying
PROC13: Treatment of articles by dipping or pouring.

Product Category

PC14: Metal-surface treatment products

Due to the nature of ammonium hydrogendifluoride, the systems are highly controlled.

Ammonium bifluoride used to treat metals during cleaning, pickling and etching of metallic surfaces in preparation for surface coating processes (i.e. galvanization, electroplating) as an adjuvant for electrolytic solutions for galvanization. Aqueous solutions are used with a maximum AMBI concentration of 50%, possibly in combination with other chemicals.

Contributing Environmental Scenario: CES 1: Environmental exposure arising due to metal surface treatment (ERC 6B).

Contributing Worker Scenario: CES 2: Worker exposure arising due to use in industrial spraying processes (PROC 7) and CES 3: worker exposure arising due to treatment of articles by dipping or pouring (PROC 13).

2.1	Controlling environmental exposure for ES 3

ES3: Contributing exposure scenario (CES) 1 Environmental exposure arising due to metal surface treatment.

Section 2.1 describes the environmental releases that may occur during the use of ammonium hydrogendifluoride in metal surface treatment. These releases may occur due to emission to the atmosphere and release to wastewater.

Liquid wastes are generally treated prior to emission to remove any ammonium hydrogendifluoride in the waste water.

Emissions to air are treated by scrubbers. Emissions to local air (after scrubbing) should be no more than 1.52 kg per day.

AMBI, when in contact with water, converts to ammonium and fluoride ions and is fully miscible in water its actual conversion, neutralisation and removal from the waste stream is expected to be extremely rapid.

Product characteristics

AMBI is a white crystalline solid at 20°C and 101.3 kPa with a vapour pressure of 1.08 Pa at 20°C. It is highly soluble in water and is not considered flammable. AMBI is not considered to be potentially explosive or an oxidising agent. The product used is in flake form or in the form of a solution.

Amounts used

Sites may use up to 500 tonnes per annum as a worst case assumption with up to 330 emission days per year. Facilities that use ammonium hydrogendifluoride in metal surface treatment may consume quantities approaching two tonnes per day. The regional tonnage for this use is 4,700 tonnes per annum.

Frequency and duration of use

Continuous production and with up to 330 emission days per year.

Environmental factors influenced by risk management

Flow rate of receiving water at least 10,000 m^3 per day. Dilution of (theoretical) STP emissions at least 10 fold. Wastewater should be treated in an industrial WWTP.

Other operational conditions affecting environmental exposure

The use of ammonium hydrogendifluoride in metal surface treatment generally occurs indoors, in processes that are usually open and continuous. Emissions to air are scrubbed before release and waste would primarily be directed to the waste stream.

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

All processes associated with the use of ammonium hydrogendifluoride in metal surface treatment, including industrial spaying and treating articles by dipping and pouring, are carried out indoors in open continuous systems. The use of ammonium hydrogendifluoride when spraying, the spray is directed downwards.

Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil
During the use of AMBI in metal surface treatment, scrubbers are used for waste air treatment. Liquid wastes would generally be treated by chemical neutralisation to neutral pH and/or precipitation prior to emission to remove any ammonium hydrogendifluoride in the waste water, ensuring the maximum concentration of fluorides in the effluent can be no higher than the low solubility of the formed precipitates. Sludge from the waste water treatment plant is sent for recovery, incineration or landfill and is not used for agricultural spreading.
Organizational measures to prevent/limit releases from site
Workers are fully trained in order to prevent accidental release. The uses of ammonium hydrogendifluoride is sprayed downward only in industrial spraying.
Conditions and measures related to municipal STP
The emission volume of the (theoretical) STP should be at least the default of 2,000 m^3 per day though no actual loss to the municipal STP is envisaged.
Conditions and measures related to external treatment of waste for disposal
No external treatment of waste is expected.
Conditions and measures related to external recovery of waste
There is no envisaged external recovery of waste. Sludge from the waste water treatment plant is sent for recovery, incineration or landfill and is not used for agricultural spreading.

2.2	**Controlling worker exposure for ES 3**

ES3: CES 2: Worker exposure arising due to use in industrial spraying processes (PROC 7) and CES 3: worker exposure arising due to treatment of articles by dipping or pouring (PROC 13).

Ammonium bifluoride used to treat metals during cleaning, pickling and etching of metallic surfaces in preparation for surface coating processes (i.e. galvanization, electroplating) as an adjuvant for electrolytic solutions for galvanization. Aqueous solutions are used with a maximum AMBI concentration of 50%, possibly in combination with other chemicals.

During metal surface treatment using ammonium hydrogendifluoride, workers wear protective clothing (respiratory mask with E-P2 filter, eye protective goggles/face shield and protective gloves). A safety shower is required nearby in case of accidental spillage.

Product characteristics
AMBI is a white crystalline solid at 20°C and 101.3 kPa with a vapour pressure of 1.08 Pa at 20°C. It is highly soluble in water and is not considered flammable. AMBI is not considered to be potentially explosive or an oxidising agent. The product used is in flake form or in the form of a solution.
Amounts used
Sites may use up to 500 tonnes per annum as a worst case assumption with up to 330 emission days per year. Facilities that use ammonium hydrogendifluoride in metal surface treatment may consume quantities approaching two tonnes per day.
Frequency and duration of use exposure
Workers perform standard shifts of 8 hours per day and have standard working years of 220 days per year.

Human factors not influence by risk management
Respiration volume under conditions of use is $10m^3/d$ (default value for a worker breathing for an 8h work day in Guidance Section R 8.4.2). Area of skin contact with the substance under the conditions of use is $0cm^2$ as all dermal contact must be prevented due to the corrosive nature of AMBI.
Other given operational conditions affecting worker exposure
All operations associated with the use of ammonium hydrogendifluoride in metal surface treatment are conducted indoors in open continuous processes. The possibility for exposure is limited where possible to prevent potential exposure.
Technical conditions and measures at process level (source) to prevent release
Primary emission sources are mostly not located in the breathing zone of the worker. When using the solution form of ammonium hydrogendifluoride in industrial spraying, this activity is carried out in one of two ways. The substance can be applied indoors using downward spraying in a workroom with natural ventilation, or in a down-flow spray room using horizontal or downward spraying. When using the flake form of ammonium hydrogendifluoride in industrial spraying, this activity is carried out using a dusting technique or by powder coating.
Technical conditions to control dispersion from source towards worker
When used in industrial spraying, ensure the spray is directed downwards in a workroom with natural ventilation, or in a downflow spray room using horizontal or downward spraying.
Organizational measures to prevent/limit release
Workers involved in production, handling and transfer of materials are trained in the procedures and protective equipment is intended to cope with the worst case scenario, in order to minimise exposure and risks.
Conditions and measures related to personal protection, hygiene and health.
Personal protective clothing, including the use of a respiratory mask with E-P2 filter, eye protective goggles or face shield and protective gloves (butyl-rubber) are worn by all operators in the production of ammonium hydrogendifluoride. Due to the nature of the materials the level of control is extremely high and so in reality exposure is highly unlikely.

3	**Exposure estimation and reference to its source**

Environmental Exposure

For the environmental exposure assessment in EUSES refined inputs are chosen to best suit the description of the production and uses of ammonium hydrogendifluoride. Emission defaults are those specified by the ECHA "Guidance on information requirements and chemical safety assessment: Chapter R.16: Environmental Exposure Estimation". Regional data and emission fractions were calculated using EUSES. Full EUSES inputs are shown below. The ERC based tier 1 assessment was not considered to give a realistic exposure estimation and so only the results of the refined tier 2 model using EUSES are shown below.

EUSES inputs for ES3 metal surface treatment exposure assessment

Input parameter:	Value:	Unit:	ERC default (if applicable)
Molecular Weight	57.04	g/mol	
Vapour Pressure (at 20 °C)	1.08	Pa	
Water Solubility	100,000 (Fully miscible)	mg/L	
Octanol/water partition coefficient	-1 (inorganic estimate)	logKow	
Koc	3.16 (Estimated in EUSES based on log kow)		
Biodegradability	Not biodegradable (inorganic acids cannot be considered biodegradable)		
Life Cycle Step	Industrial use		
Environmental Release Class	ERC 6b		
Fraction of Tonnage for Region (1st Tier)			1
STP			Yes
Emission events per year	330 (manufacturer information)	Days	300
Default Release to Air	0.1	%	0.1
Default Release to water	5	%	5
Dilution factor applied for PEC derivation			10 (20,000 m^3/d)
Tonnage assessed	Local: 500 Regional: 2000	tonnes/annum	Worst case local and total regional/EU tonnage.

Based on these inputs the following predicted environmental exposure concentrations (PECs) were derived

Predicted Releases to the Environment Tier 2

ERC	Compartments	Predicted releases	Measured release	Explanation
6b	Wastewater	14.6 kg/d	-	Tier 2 value based on the specialised waste water treatment procedures in the industrial WWTP.
	Release to air	1.52 kg/d	-	
	Soil (direct only) Agricultural soil	0 kg/d	-	No direct loss to soil is expected for this ERC and no sludge spreading.

Tier 2 Concentrations in sewage

ERC	Compartment:	Estimated exposure concentrations		Explanation
		value	unit	
6b	Sewage (STP effluent)	7.3	mg/L	Set to 7.3 due to on-site treatment and removal
	Sewage sludge	0	mg/kg	There is no spreading of sludge to soil so for the purposes of this assessment the concentration in sewage sludge should be considered to be 0

Tier 2 Predicted Environmental Concentrations (PEC) in aquatic compartment

ERC	Compartments	PEC aquatic (local mg/L)	Justification
6b	Freshwater (in mg/L)	0.733	
	Marine water (in mg/L)	0.0733	
	Intermittent releases to water (in mg/L)	NA	Intermittent release not relevant

Tier 2 Predicted Environmental Concentrations (PEC) in aquatic sediment compartment

ERC	Compartments	PEC aquatic (local)
6b	Freshwater sediment (in mg/kg wwt)	0.624
	Marine sediment (in mg/kg wwt)	0.0624

Tier 2 Predicted Environmental Concentrations (PEC) in the soil and groundwater compartment

ERC	Compartments	PEC (local)
6b	Agricultural soil (averaged over 30 days (in mg/kg)	0.052
	Groundwater (in mg/L)	0.176

Tier 2 Predicted Exposure Concentration (PEC) in air

ERC		Local concentration	PEC air (local+regional)	Justification
6b	Annual average PEC in air, total (mg/m^3)	0.000381	0.000381	Estimated using EUSES 2.1.

Based on these PECs the following risk characterization ratios are derived.

Risk characterisation

Compartment	**PEC mg/L**	**PNEC mg/L**	**RCR**	**Comments**
Tier 2 Freshwater	0.733	1.3	0.564	Safe use demonstrated
Tier 2 Soil	0.052	22	0.0024	Safe use demonstrated
Tier 2 STP	7.3	76	0.096	Safe use demonstrated

Worker Exposure:

The assessment of worker exposure to ammonium hydrogendifluoride from metal surface treatment use (ES3) was carried for processes relevant to this use scenario as identified by PROC codes. Initially, a screening-level (Tier 1) assessment was carried out using the MEASE model instead of ECETOC. The ECETOC model was not considered appropriate for this substance. A higher tier (Tier 2) refinement of the Tier 1 assessment was carried out using the Advanced REACH Tool (ART).

The effects of exposure to ammonium hydrogendifluoride dermal exposures are likely to be local irritation and corrosivity of the skin. There is no evidence of systemic effects following dermal exposures to ammonium hydrogendifluoride. Estimates of systemic dermal doses associated with acute/short-term and long-term exposures to ammonium hydrogendifluoride were not therefore derived. Furthermore all dermal exposure is ruled out by the exposure limiting methods in place.

A screening-level assessment of inhalation exposure concentrations potentially associated with processes in ES3 was carried out using the MEASE model and the parameters shown in the tables below. The MEASE model was considered more appropriate to use for AMBI than ECETOC as it incorporates measured data from the metals industry and takes into account operational conditions and RMM that are more relevant.

The tables below show the estimated exposure concentration to ammonium hydrogendifluoride for processes associated with ES3.

The MEASE model was not considered to give a reasonable screening-level assessment of exposures associated processes involved in ES3 for inhalation exposures in workers.

As such the unsuitable tier 1 assessment of inhalation exposures associated with ES3 derived using the MEASE model were refined using the higher tier inhalation model: the Advanced REACH tool (ART). In the ART model, a mechanistic model of inhalation exposure and expert judgement were used to predict more realistic estimates of inhalation exposure concentrations associated with processes involving the use of ammonium hydrogendifluoride in ES3. The Tier 2 assessment was carried out using the parameters and assumptions in the tables below. The predicted 50^{th} and 90^{th} (worst case) percentile acute/short-term (e.g. exposure over a full-shift) and long-term inhalation exposure concentrations derived using these parameters for processes associated with ES3 are shown in the tables below.

Parameters used in the MEASE model to conduct a Tier 1 assessment of inhalation exposure concentrations

	Parameter for Solution	Explanation/source of data for solution	Parameter for Flakes	Explanation/source of data for flake
Molecular weight	57.04 g/mol		57.04 g/mol	
Vapour Pressure	1.08 Pa		1.08 Pa	
Water solubility	100,000 mg/L		100,000 mg/L	
Is the substance a solid?	No – liquid	>25% (worst case)	Yes	The substance is produced in flake form
Dustiness during process	n/a	Only in the case of solid	Inhalable fraction: ≤ 100 mg/kg	Product does not result in dust emission without intentional breakage of products: e.g., firm polymer granules, granules covered with a layer of wax, a woodblock, a brick).
Duration of activity	>4 hours (default)	Worst case	>4 hours (default)	Worst case
Use of respiratory protection	No	Worst case	No	Worst case

First tier screening level exposure concentrations to workers

Description of activity	PROC	Physical state of material	Estimated Exposure Concentrations for solution		Estimated Exposure Concentrations for flake	
			value	unit	value	unit
Industrial Spraying	7	Liquid/Flake	2.0*	mg/m^3	1.00	mg/m^3
Treatment of articles by dipping and pouring	13	Liquid/Flake	0.01	mg/m^3	0.1	mg/m^3

* RPE – 90 % protection

Parameters and assumptions used in the ART model to conduct a Tier 2 assessment of inhalation exposure concentrations

	PROC	Parameters/ assumptions for solution	Parameters/ assumptions for flake
Exposure duration	All	480 min	480 min
Product type	All	Powders dissolved in a liquid or incorporated in a liquid matrix (e.g. copper in anti-fouling paint)	Powders, granules or pelletised material
Process temperature	All	Room temperature (15-25°C)	Room temperature (15-25°C)
Vapour pressure	All	1.08 Pa	1.08 Pa
Liquid weight fraction	All	Substantial (10-50%)	N/A
Dustiness	PROC7	N/A	Product does not result in dust emission without intentional breakage of products: e.g., firm polymer granules, granules covered with a layer of wax, a woodblock, a brick). Inhalable fraction: ≤ 100 mg/kg
Primary emission source proximity	All	Primary emission source located in the breathing zone of the workers (i.e. Within 1 metre)	Primary emission source located in the breathing zone of the workers (i.e. Within 1 metre)
Activity class	PROC7	Spray application of liquids-surface spraying: moderate application rate (0.3-3 L/min). Only horizontal or downward spraying, with no or low compressed air use. A low application rate (0.03-0.3 L/min) with no or low compressed air is also utilised.	Spray application of powders (powder coating)-Dusting using blower- Only horizontal or downward spraying
	PROC13	Activities with open liquid surfaces-activities with undisturbed surfaces-open surface >3 m2	N/A
Containment	All	N/A	N/A
Localised controls	All	No localised controls	No localised controls
Segregation	All	N/A	N/A
Fugative emission source	All	Process not fully enclosed but effective housekeeping practises are in place	Process not fully enclosed but effective housekeeping practises are in place
Dispersion	PROC7	Down-flow spray room	Down-flow spray room
	PROC13	Indoors, any size workroom, good natural ventilation	

Tier 2 acute/short-term and long-term inhalation exposure concentrations derived using the ART model

Description of activity	PROC	Physical state of material	Estimated Short-term Exposure Concentrations (mg/m3)		Estimated Long-term Exposure Concentration (mg/m3)	
			50th percentile value	90th percentile value	50th percentile value	90th percentile value
Industrial Spraying – Low application rate, Downward Spraying, Workroom and natural ventilation	7	Liquid	0.41	1.6	0.58	1.4
Industrial Spraying – Moderate application rate, Horizontal or Downward spraying, Down-flow spray room	7	Liquid	0.56	2.2	0.77	1.9
Treatment of articles by dipping and pouring	13	Liquid	0.0046	0.018	0.0063	0.016
Industrial Spraying- Powder Coating	7	Flake	0.41	1.6	0.56	1.4
Industrial Spraying- Dusting	7	Flake	0.12	0.48	0.17	0.42

Based on these exposure concentrations the following RCRs are derived for worker exposure. Only the second tier RCRs as derived using ART are presented below.

Quantitative risk characterisation for worker

	Route	PROC Code	ES 3- 90th exposure concentrations (mg/m3)	Leading toxic end point / Critical effect	DNEL (mg/m3)	Risk characterisation ratio – No RPE assumed	Risk characterisation ratio – 95 % protection
Acute effects-liquid	Inhalation	PROC 7-Industrial Spraying – Low application rate, Downward Spraying, Workroom and natural ventilation	1.6	Respiratory irritation and corrositivity	3.8	0.42	0.0021
		PROC 7-Industrial Spraying – Moderate application rate, Horizontal or Downward spraying, Down-flow spray room	2.2			0.58	0.0029
		PROC 13-Treatment of articles by dipping and pouring	0.018			0.0047	0.00024
Long-Term effects-liquid	Inhalation	PROC 7-Industrial Spraying-Powder Coating	1.4	Respiratory irritation and corrositivity		0.61	0.003
		PROC 7-Industrial Spraying-Dusting	1.9			0.83	0.0041
		PROC 13-Treatment of articles by dipping and pouring	0.016			0.007	0.00035

Acute effects-flake		PROC 7-Industrial Spraying – Low application rate, Downward Spraying, Workroom and natural ventilation	1.6	Respiratory irritation and corrositivity	2.3	0.42	0.021	
		PROC 7-Industrial Spraying – Moderate application rate, Horizontal or Downward spraying, Down-flow spray room	0.48			0.13	0.0063	
Long-Term effects-flake	Inhalation	PROC 7-Industrial Spraying-Powder Coating	1.4	Respiratory irritation and corrositivity		0.61	0.03	
		PROC 7-Industrial Spraying-Dusting	0.42			0.18	0.0091	

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

Environmental releases:

In order to work within the boundaries of the ES the following conditions should be met:

- Emission to air after scrubbing should be less than 1.52 kg per day
- Waste water should be treated by neutralization or precipitation prior to release to the environment, ensuring the maximum concentration of fluorides in the effluent can be no higher than the low solubility of the formed precipitates.
- Any measured emissions should be confirmed to be less than the relevant PNECs in section 3 above.

Worker exposure:

In order to work within the boundaries of the ES the following conditions should be met:

- When using industrial spraying of AMBI in the treatment of metal surfaces, it should be applied downward in a workroom with natural ventilation or in a downflow spray room using horizontal or downward spraying.
- Workers should wear respiratory mask with E-P2 filter, eye protective goggles or face shield and protective gloves (butyl-rubber) at all times during the use of AMBI in metal surface treatment.
- Any measured exposure should be confirmed to be less than the relevant DNELs as listed in section 3 above

5	**Additional good practice advice beyond the REACH CSA.**

- Do not eat, drink or smoke when working with AMBI.
- Always wash hands and exposed skin thoroughly after using AMBI surfaces/machinery that may have come into contact with AMBI.
- Workers should be suitably trained in all safety procedures
- Procedural and safety compliance should be routinely assessed by management
- Machinery should be regularly maintained and checked for proper function
- Efficacy of all emission RMMs and waste treatment procedures should be routinely assessed and confirmed to be functioning correctly
- Details on scaling and control technologies are provided at: http://cefic.org/Industry-support/Implementing-reach/Libraries/

Downstream user exposure scenario for Ammonium hydrogendifluoride (AMBI)

1	Exposure Scenario 4: Industrial cleaning products

Use of Ammonium hydrogendifluoride in industrial cleaning products

Environmental Release and Worker Processes Covered:

Environmental Releases

ERC8b: Wide dispersive indoor use of reactive substances in open systems
ERC8e: Wide dispersive outdoor use of reactive substances in open systems

Worker Processes

PROC10: Roller application or brushing
PROC19: Hand-mixing with intimate contact and only PPE available.

Product Category

PC15: Non-Metal-Surface treatment products
PC35: Washing and cleaning products (including solvent based products)

The processes involved in the handling of ammonium hydrogendifluoride as an industrial cleaning product are indoors or outdoors in any size workroom with natural ventilation. The activity is not carried out in an entirely enclosed area but effective housekeeping practices are employed.

Due to the hazardous and corrosive nature of ammonium hydrogendifluoride the handling systems are highly controlled. Workers are suitably trained and wear appropriate PPE and RPE during the times when very limited (not intended) contact may occur.

Contributing Environmental Scenario: CES 1: Environmental exposure arising due to use in industrial cleaning (ERC 8b and ERC 8e).

Contributing Worker Scenario: CES 2: Worker exposure arising due to use in roller and brushing application (PROC 10) and CES 3: worker exposure arising due to Hand-mixing with intimate contact and only PPE available (PROC 19).

2.1	Controlling environmental exposure for ES 4

ES3: Contributing exposure scenario (CES) 1 Environmental exposure arising due to use in industrial cleaning.

Section 2.1 describes the environmental releases that may occur during the use of ammonium hydrogendifluoride in industrial cleaning products. These releases may occur due to emission to the atmosphere and potential release to wastewater.

As a wide dispersive use with multiple sources located within one region diffuse wide dispersive release into the environment has been considered to this use as the pathway of environmental release may not always be direct, as for the industrial scenarios.

AMBI, when in contact with water, converts to ammonium and fluoride ions and is fully miscible in water its actual conversion, neutralisation and removal from the waste stream is expected to be extremely rapid.

Product characteristics

AMBI is a white crystalline solid at 20°C and 101.3 kPa with a vapour pressure of 1.08 Pa at 20°C. It is highly soluble in water and is not considered flammable. AMBI is not considered to be potentially explosive or an oxidising agent. The product used is in flake form or in the form of a solution.

Amounts used

Sites may use up to 484 tonnes per annum as a worst case assumption with 365 emission days per year. The considered regional assessment is 2200 tonnes per annum.

Frequency and duration of use

Continuous wide dispersive use with up to 365 emission days per year.

Environmental factors influenced by risk management

Wide dispersive dilution rate: 25×10^9 m^3/year.

Other operational conditions affecting environmental exposure

The use of ammonium hydrogendifluoride in industrial cleaning may be indoor and outdoor. Releases to the environment are determined by the terms of the ERC and other specific operational conditions are not considered.

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

All processes associated with the use of ammonium hydrogendifluoride in industrial cleaning employ good housekeeping practices but, as a wide dispersive use, specific technical conditions beyond these are not required.

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

Further technical onsite conditions are not specified for this wide dispersive use with regards to environmental emissions.

Organizational measures to prevent/limit releases from site

Workers are fully trained in order to prevent accidental release. Further specific organizational measures are not required.

Conditions and measures related to municipal STP

No significant emissions to the STP are expected during this wide dispersive use.

Conditions and measures related to external treatment of waste for disposal
No external treatment of waste is expected.
Conditions and measures related to external recovery of waste
There is no envisaged external recovery of waste.

2.2	Controlling worker exposure for ES 4

ES4: CES 2: Worker exposure arising due to use in roller and brushing application (PROC 10) and CES 3: worker exposure arising due to Hand-mixing with intimate contact and only PPE available (PROC 19).

Ammonium bifluoride is used as a cleaning agent for industrial boilers, heat exchangers and general pipe work and may be used in both industrial and professional environments.

The substance is applied using a roller or brushing the surfaces or work pieces > 3 m^2/hr. During mixing, activities are performed with agitated surfaces. These activities are not carried out in fully enclosed areas but effective housekeeping practices are in place.

Product characteristics
AMBI is a white crystalline solid at 20°C and 101.3 kPa with a vapour pressure of 1.08 Pa at 20°C. It is highly soluble in water and is not considered flammable. AMBI is not considered to be potentially explosive or an oxidising agent. The product used is in flake form or in the form of a solution.
Amounts used
Sites may use up to 484 tonnes per annum as a worst case assumption. The considered regional assessment is 2200 tonnes per annum.
Frequency and duration of use exposure
Workers perform standard shifts of 8 hours per day and have standard working years of 220 days per year.
Human factors not influence by risk management
Respiration volume under conditions of use is 10m^3/d (default value for a worker breathing for an 8h work day in Guidance Section R 8.4.2). Area of skin contact with the substance under the conditions of use is 0cm^2 as all dermal contact must be prevented due to the corrosive nature of AMBI.
Other given operational conditions affecting worker exposure
All operations associated with the use of ammonium hydrogendifluoride in industrial cleaning are not carried out in fully enclosed areas but effective housekeeping practices are in place.
Technical conditions and measures at process level (source) to prevent release
Due to the nature of the materials the level of control is extremely high and so in reality exposure is highly unlikely. Primary emission sources are mostly located in the breathing zone of the worker. The substance is applied using a roller or brushing the surfaces or work pieces > 3 m^2/hr. During mixing, activities are performed with agitated surfaces. These activities are not carried out in fully enclosed areas but effective housekeeping practices are in place.
Technical conditions to control dispersion from source towards worker
All dermal exposure is ruled out by exposure limiting methods. Roller or brushing applications take place in closed systems with little or no exposure expected.

Organizational measures to prevent/limit release
Workers involved in production, handling and transfer of materials are trained in the procedures and protective equipment is intended to cope with the worst case scenario, in order to minimise exposure and risks.
Conditions and measures related to personal protection, hygiene and health.
Personal protective clothing, including the use of a respiratory mask with E-P2 filter, eye protective goggles or face shield and protective gloves (butyl-rubber) are worn by all operators during the use of ammonium hydrogendifluoride in industrial cleaning products. Due to the nature of the materials the level of control is extremely high and so in reality exposure is highly unlikely. For PROC 10 operations the use is in closed processes with no likelihood of exposure.

3 Exposure estimation and reference to its source

Environmental Exposure

The environmental releases are determined primarily by tonnage and the ERC in the first tier with conservative estimations and defaults being implemented by the terms of the ERC. Emission defaults are those specified by the ECHA "Guidance on information requirements and chemical safety assessment: Chapter R.16: Environmental Exposure Estimation". No significant loss of the substance to the STP is expected to be associated with this ES as it is a wide dispersive use with diffuse release into the environment from multiple sources within a region and as such any local point source emissions to the STP would be minimal. As such no PECs for the STP have been derived.

EUSES inputs for ES4 industrial cleaning exposure assessment.

Input parameter:	Value:	Unit:	ERC default (if applicable)
Molecular Weight	57.04	g/mol	
Vapour Pressure (at 20 °C)	1.08	Pa	
Water Solubility	100,000 (Fully miscible)	mg/L	
Octanol/water partition coefficient	-1 (inorganic estimate)	logKow	
Koc	3.16 (Estimated in EUSES based on log kow)		
Biodegradability	Not biodegradable (inorganic acids cannot be considered biodegradable)		
Life Cycle Step	Industrial Use		
Environmental Release Class	ERC8b ERC 8E		Wide dispersive uses
Fraction of Tonnage for Region (1st Tier)			1
STP			Yes

Emission events per year	365 (wide dispersive use)	Days	365
Default Release to Air	0. 1	%	Value for both ERCs
Default Release to Water	5	%	Value for both ERCs
Default Release to Soil	1	%	ERC 8E only
Dilution factor applied for PEC derivation	Wide dispersive dilution		25 x 10^9 m^3/year
Tonnage assessed	Local: 484 Regional: 2200	tonnes/annum	Worst case local and total regional tonnage.

Based on these inputs the following predicted environmental exposure concentrations (PECs) were derived

Predicted Releases to the Environment

ERC	Compartments	Predicted releases	Measured release	Explanation / source of measured data
8b and 8e	Wastewater	26.5 kg/d	-	Wide dispersive release
8b and 8e	Release to air	1.33 kg/d	-	
8e only	Soil (direct only) Regional soil	60.3 kg/d	-	No direct loss to soil is expected for ERC 8b

Tier 2 Predicted Environmental Concentrations (PEC) in aquatic compartment

ERC	Compartments	Local concentration aquatic (local mg/L)	Justification
8b	Freshwater (in mg/L)	0.004	
	Marine water (in mg/L)	4 x 10^{-4}	As a wide dispersive emission scenario a further dilution factor of 10 has been applied to the surface water PEC in order to derive the marine PEC
	Intermittent releases to water (in mg/L)	NA	
8e	Freshwater (in mg/L)	0.0056	
	Marine water (in mg/L)	5.6 x 10^{-4}	As a wide dispersive emission scenario a further dilution factor of 10 has been applied to the surface water PEC in order to derive the marine PEC
	Intermittent releases to water (in mg/L)	NA	

Tier 2 Predicted Environmental Concentrations (PEC) in aquatic sediment compartment

ERC	Compartments	Local concentration aquatic (local)	Justification
8b	Freshwater sediment (in mg/kg)	0.0047	
	Marine sediment (in mg/kg)	4.71×10^{-4}	As a wide dispersive emission scenario a further dilution factor of 10 has been applied to the freshwater sediment PEC in order to derive the marine PEC
8e	Freshwater sediment (in mg/kg)	0.0048	
	Marine sediment (in mg/kg)	4.8×10^{-4}	As a wide dispersive emission scenario a further dilution factor of 10 has been applied to the freshwater sediment PEC in order to derive the marine PEC

Tier 2 Predicted Environmental Concentrations (PEC) in the soil and groundwater compartment

ERC	Compartments	PEC (local)
8b	Agricultural soil (averaged over 30 days (in mg/kg)	0.0175
	Groundwater (in mg/L)	0.546
8e	Agricultural soil (averaged over 30 days (in mg/kg)	0.0175
	Groundwater (in mg/L)	0.547

Tier 2 Predicted Exposure Concentration (PEC) in air

ERC		Local concentration	PEC air (local+regional)	Justification
8b	Annual average PEC in air, total (mg/m^3)	0.000369	0.000369	Estimated using EUSES 2.1.
8e	Annual average PEC in air, total (mg/m^3)	0.000369	0.000369	Estimated using EUSES 2.1.

Based on these PECs the following risk characterization ratios are derived.

Risk characterisation

ERC	Compartment	**PEC mg/L**	**PNEC mg/L**	**RCR**	**Comments**
8b	Tier 1 Freshwater	0.004	1.3	0.003	Safe use demonstrated in tier 1
8e	Tier 1 Freshwater	0.0056	1.3	0.004	Safe use demonstrated in tier 1

Ammonium hydrogendifluoride is used as an industrial cleaning product with a wide dispersive pattern of emission into the envrionment. There is therefore no direct exposure of soils, and no significant risk of contamination of groundwater (or of waters extracted from underground for drinking water), or via soils of crops or animals used in food production. Equally, wildlife will not be exposed via the soil or groundwater, and there is no potential for accumulation (secondary poisoning) through the wildlife food chain. As such for a wide dispersive diffuse emission pattern an assessment of the exposure to the local soil is not relevant and exposure contribution towards the regional scale should be assessed only this is presented in the risk assessment below.

Atmospheric contamination is minimal with a wide dispersive pattern, with either the use of sealed systems or the use of emission control measures at industrial distribution sites. Given that any ammonium hydrogendifluoride present in the atmosphere will be broken down into ions on contact with moisture any incident on soils as a result of precipitation will be very dilute, and will be rapidly broken down to harmless constituent ions. No atmospheric PNECs are derived and no atmospheric risk characterisation is required.

Worker Exposure:

The assessment of worker exposure to ammonium hydrogendifluoride from use in industrial cleaning (ES4) was carried for processes relevant to this use scenario as identified by PROC codes. Initially, a screening-level (Tier 1) assessment was carried out using the MEASE model instead of ECETOC. The ECETOC model was not considered appropriate for this substance. A higher tier (Tier 2) refinement of the Tier 1 assessment was carried out using the Advanced REACH Tool (ART).

The effects of exposure to ammonium hydrogendifluoride dermal exposures are likely to be local irritation and corrosivity of the skin. There is no evidence of systemic effects following dermal exposures to ammonium hydrogendifluoride. Estimates of systemic dermal doses associated with acute/short-term and long-term exposures to ammonium hydrogendifluoride were not therefore derived. Furthermore all dermal exposure is ruled out by the exposure limiting methods in place.

A screening-level assessment of inhalation exposure concentrations potentially associated with processes in ES4 was carried out using the MEASE model and the parameters shown in the tables below. The tables below show the estimated exposure concentration to ammonium hydrogendifluoride for processes associated with ES4.

The MEASE model was not considered to give a reasonable screening-level assessment of exposures associated processes involved in ES4 that are closed and well-controlled and present no real potential for inhalation exposures in workers.

As such the unsuitable tier 1 assessment of inhalation exposures associated with ES4 derived using the MEASE model were refined using the higher tier inhalation model: the Advanced REACH tool (ART). In the ART model, a mechanistic model of inhalation exposure and expert judgement were used to predict more realistic estimates of inhalation exposure concentrations associated with processes involving ammonium hydrogendifluoride in ES4.

The Tier 2 assessment was carried out using the parameters and assumptions in the tables below. The predicted 50th and 90th (worst case) percentile acute/short-term (e.g. exposure over a full-shift) and long-term inhalation exposure concentrations derived using these parameters for processes associated with ES4 are presented in the tables below.

Parameters used in the MEASE model to conduct a Tier 1 assessment of inhalation exposure concentrations

	Parameter for Solution	**Explanation/source of data for solution**	**Parameter for Flakes**	**Explanation/source of data for flake**
Molecular weight	57.04 g/mol		57.04 g/mol	
Vapour Pressure	1.08 Pa		1.08 Pa	
Water solubility	100,000 mg/L		100,000 mg/L	
Is the substance a solid?	No – liquid	>25% (worst case)	Yes	The substance is produced in flake form
Dustiness during process	n/a	Only in the case of solid	Inhalable fraction: ≤ 100 mg/kg	Product does not result in dust emission without intentional breakage of products: e.g., firm polymer granules, granules covered with a layer of wax, a woodblock, a brick).
Duration of activity	>4 hours (default)	Worst case	>4 hours (default)	Worst case
Use of respiratory protection	No	Worst case	No	Worst case

First tier screening level exposure concentrations to workers

Description of activity	**PROC**	**Physical state of material**	**Estimated Exposure Concentrations**	
			value	**unit**
Roller application or brushing	10	Liquid	0.05	mg/m^3
Hand-mixing with intimate contact and only PPE available.	19	Liquid	0.05	mg/m^3
Roller application or brushing	10	Flake	0.5	mg/m^3
Hand-mixing with intimate contact and only PPE available.	19	Flake	0.5	mg/m^3

Parameters and assumptions used in the ART model to conduct a Tier 2 assessment of inhalation exposure concentrations

	PROC	Parameters/ assumptions for Flake	PROC	Parameters/ assumptions for Solution
Exposure duration	19	480 min	All	480 min
Product type	19	Powders, granules or pelletised material	All	Powders dissolved in a liquid or incorporated in a liquid matrix (e.g. copper in anti-fouling paint)
Process temperature	19	Room temperature (15-25^{o}C)	All	Room temperature (15-25^{o}C)
Vapour pressure	19	1.08 Pa	All	1.08 Pa
Dustiness	19	Product does not result in dust emission without intentional breakage of products: e.g., firm polymer granules, granules covered with a layer of wax, a woodblock, a brick). Inhalable fraction: ≤ 100 mg/kg		N/A
Liquid weight fraction	19	N/A	All	Substantial (10-50%)
Primary emission source proximity	19	Primary emission source located in the breathing zone of the workers (i.e. Within 1 metre)	All	Primary emission source located in the breathing zone of the workers (i.e. Within 1 metre)
Activity class	19	Movement and agitation of powders, granules or pelletised material- Movement and agitation of 100- 1000 kg	10	Spreading of liquid products: spreading of liquids at surfaces or work pieces > 3 m^2 /hr
			19	Activities with open liquid surfaces- activities with agitated surfaces- Open surface 1- 3 m²
Containment	19	Other handling with high level of agitation- Handling that reduces contact between product and adjacent air	All	N/A
Localised controls	19	No localised controls	All	No localised controls
Segregation	19	N/A	All	N/A
Fugative emission source	19	Process not fully enclosed but effective housekeeping practises are in place	All	Process not fully enclosed but effective housekeeping practises are in place
Dispersion	19	Indoors or outdoors , any size workroom, good natural ventilation	All	Indoors or outdoors, any size workroom, good natural ventilation

Tier 2 acute/short-term and long-term inhalation exposure concentrations derived using the ART model

Description of activity	PROC	Physical state of material	Estimated Short-term Exposure Concentrations (mg/m3)		Estimated Long-term Exposure Concentration (mg/m3)	
			50th percentile value	90th percentile value	50th percentile value	90th percentile value
Use in closed process, no likelihood of exposure	19	Flake	0.3	1.2	0.42	1
Use in closed process, no likelihood of exposure	10	Liquid	0.46	1.8	0.63	1.6
Use in closed, continuous process with occasional controlled exposure	19	Liquid	0.46	1.8	0.64	1.6

Based on these exposure concentrations the following RCRs are derived for worker exposure. Only the second tier RCRs as derived using ART are presented below.

Quantitative risk characterisation for worker

	Route	PROC Code	ES 4- 90th exposure concentrations (mg/m3)	Leading toxic end point / Critical effect	DNEL (mg/m3)	Risk characterisation ratio – No RPE assumed	Risk characterisation ratio – RPE 95% protection
Acute effects-Liquid	Inhalation	PROC 10	1.8	Respiratory irritation and corrositivity	3.8	0.47	0.024
		PROC 19	1.8			0.47	0.024
Long term effects-Liquid	Inhalation	PROC 10	1.6	Respiratory irritation and corrositivity	2.3	0.7	0.035
		PROC 19	1.6			0.7	0.035
Acute effects-Flake	Inhalation	PROC 19	1.2	Respiratory irritation and corrositivity	3.8	0.32	0.016
Long term effects-Flake	Inhalation	PROC 19	1	Respiratory irritation and corrositivity	2.3	0.43	0.022

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

Environmental releases:

In order to work within the boundaries of the ES the following conditions should be met:

- Local emissions to air and water should be no more than those specified in section 3 above.
- Any measured emissions should be confirmed to be less than the relevant PNECs in section 3 above.

Worker exposure:

In order to work within the boundaries of the ES the following conditions should be met:

- Workers should wear suitable personal protective equipment and roller or brushing application should be carried out in closed systems.
- Dermal exposure should be prevented
- Any measured exposure should be confirmed to be less than the relevant DNELs as listed in section 3 above

5	Additional good practice advice beyond the REACH CSA.

- Do not eat, drink or smoke when working with AMBI.
- Always wash hands and exposed skin thoroughly after using AMBI surfaces/machinery that may have come into contact with AMBI.
- Workers should be suitably trained in all safety procedures
- Procedural and safety compliance should be routinely assessed by management
- Machinery should be regularly maintained and checked for proper function
- Efficacy of all emission RMMs and waste treatment procedures should be routinely assessed and confirmed to be functioning correctly
- Details on scaling and control technologies are provided at: http://cefic.org/Industry-support/Implementing-reach/Libraries/

Downstream user exposure scenario for Ammonium hydrogendifluoride (AMBI)

1	Exposure Scenario 5: Glass etching

Use of Ammonium hydrogendifluoride in glass etching

Environmental Release and Worker Processes Covered:

Environmental Releases

ERC06b: Industrial use of reactive processing aids

Worker Processes

PROC7: Industrial Spraying
PROC13: Treatment of articles by dipping and pouring

Product Category

PC15: Non-metal-surface treatment products

Ammonium hydrogendifluoride is used in glass and non-metal product etching on an industrial scale. The use of the substance approaches two tonnes per day, during a working year of up to 330 days. The processes involved in glass etching with ammonium hydrogendifluoride are not fully enclosed, indoors in any size workroom with natural ventilation or in a spray room if required.

Environmental emissions of ammonium hydrogendifluoride from glass etching processes are extremely limited (almost no emissions) and are generally treated on-site at the industrial facility before release to the waste system.

Due to the hazardous and corrosive nature of Ammonium hydrogendifluoride the handling systems are highly controlled. Workers are suitably trained and wear appropriate PPE and RPE during the times when very limited (not intended) contact may occur.

Ammonium bifluoride is used in the etching and surface treatment as part of the industrial production and processing of glass products. Aqueous solutions with maximum concentration of 50% are used, possibly in combination with other chemicals.

Contributing Environmental Scenario: CES 1: Environmental exposure arising due to use as a reactive process aid during glass etching.

Contributing Worker Scenario: CES 2: worker exposure arising due to use in industrial spraying (PROC 7), and CES 3: worker exposure arising due to treatment of articles by dipping and pouring (PROC 13).

2.1 Controlling environmental exposure for ES 5

ES5: Contributing Environmental Scenario: CES 1: Environmental exposure arising due to use as a reactive process aid during glass etching.

Section 2.1 describes the environmental releases that may occur during the use of AMBI during glass etching where AMBI is used as a reactive process aid to treat glass surfaces during the etching process.

Ammonium hydrogendifluoride dissociates rapidly and completely when released into waste water. Therefore instead of the substance p*er se*, ammonium and fluoride are released into the environment after the glass etching processes. As such the environmental exposure pathways and risk assessment are based on the specifics and ecological properties of the dissociation products. However, the risk of ammonium salts to the environment is very low. Therefore, the main concern is the release of fluoride.

Product characteristics
AMBI is a white crystalline solid at 20°C and 101.3 kPa with a vapour pressure of 1.08 Pa at 20°C. It is highly soluble in water and is not considered flammable. AMBI is not considered to be potentially explosive or an oxidising agent. The product used may be a liquid or a flake.
Amounts used
Up to 504 tonnes per annum at the highest tonnage single site, with up to 2 tonnes used per day in some cases.
Frequency and duration of use
Continuous use and release with up to 330 emission days per year.
Environmental factors influenced by risk management
Flow rate of receiving water at least 10,000 m^3 per day. Dilution of STP or WWTP emissions at least 10 fold.
Other operational conditions affecting environmental exposure
Environmental emissions are limited by designated waste treatment process designed to limit environmental exposure to all relevant compartments.
Technical conditions and measures at process level (source) to prevent release
Controlled systems are in place and waste is monitored and directed for proper treatment. Environmental emissions are limited by designated waste treatment process designed to limit environmental exposure to all relevant compartments.

Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil
Atmospheric emissions are monitored and controlled. Liquid wastes would generally be treated (neutralisation to neutral pH and/or precipitation) prior to emission to remove any ammonium hydrogendifluoride in the waste water. Sludge from the waste water treatment plant is sent for recovery, incineration or landfill and is not used for agricultural spreading. This precludes any contamination of soil by sludge spreading.
Organizational measures to prevent/limit releases from site
Workers are fully trained in order to prevent accidental release.
Conditions and measures related to municipal STP
The emission volume of the industrial WWTP or STP should be at least the default of 2,000 m^3 per day though no actual loss to the STP is envisaged.
Conditions and measures related to external treatment of waste for disposal
Waste sludge should not be spread to soil but should be sent for specialized recovery.
Conditions and measures related to external recovery of waste
There is no envisaged external recovery of waste.

2.2	**Controlling worker exposure for ES 5**

ES5: Contributing Worker Scenario: CES 2: worker exposure arising due to use in industrial spraying (PROC 7), and CES 3: worker exposure arising due to treatment of articles by dipping and pouring (PROC 13).

The use of AMBI during glass etching is either in industrial spraying or dipping and pouring operations. When using the solution form of ammonium hydrogendifluoride in industrial spraying, this activity is carried out in one of two ways. The substance can be applied indoors using downward spraying in a workroom with natural ventilation, or in a down-flow spray room using horizontal or downward spraying.

When using the flake form of ammonium hydrogendifluoride in industrial spraying, this activity is carried out using a dusting technique or by powder coating.

During dipping and pouring techniques the glass items to be treated are immersed or covered in the solution under low energy and low pressure processes.

Product characteristics
AMBI is a white crystalline solid at 20°C and 101.3 kPa with a vapour pressure of 1.08 Pa at 20°C. It is highly soluble in water and is not considered flammable. AMBI is not considered to be potentially explosive or an oxidising agent. The product used may be a liquid or a flake.
Amounts used
Up to 504 tonnes per annum at the highest tonnage single site.
Frequency and duration of use exposure
Workers generally perform standard shifts of 8 hours per day and have standard working years of 220 days per year.

Human factors not influenced by risk management
Respiration volume under conditions of use is $10m^3/d$ (default value for a worker breathing for an 8h work day in Guidance Section R 8.4.2). Area of skin contact with the substance under the conditions of use is $0cm^2$ as all dermal contact must be prevented due to the corrosive nature of AMBI.
Other given operational conditions affecting worker exposure
Operations associated with the use of AMBI during glass etching are generally carried out indoors. Due to the hazardous and corrosive nature of ammonium hydrogendifluoride the handling systems are highly controlled. The potential for exposure is limited where possible to prevent potential exposure.
Technical conditions and measures at process level (source) to prevent release
The handling of ammonium hydrogendifluoride is such that contact between product and adjacent air is reduced. Emission sources can be completely or partially segregated from the work environment by isolating the source in a fully enclosed and separate room and using complete personal enclosure with ventilation where necessary.
Technical conditions to control dispersion from source towards worker
Dispersion may be controlled by using high integrity contained systems to prevent uncontrolled discharge towards the worker.
Organizational measures to prevent/limit release
Workers involved in the handling, use and transfer of materials are trained in the procedures and protective equipment is intended to cope with the worst case scenario, in order to minimise exposure and risks.
Conditions and measures related to personal protection, hygiene and health.
Personal protective equipment, including the use of protective clothing, gloves and respiratory protection are worn by all operators in the facility. This includes a respiratory mask with E-P2 filter, eye protective goggles or face shield and protective gloves (butyl-rubber). Due to the nature of the materials the level of control is extremely high and so in reality exposure is highly unlikely.

3	**Exposure estimation and reference to its source**

Environmental Exposure

For the environmental exposure assessment in EUSES refined inputs are chosen to best suit the description of uses of ammonium hydrogendifluoride in glass ethcing operations. Emission defaults are those specified by the ECHA “Guidance on information requirements and chemical safety assessment: Chapter R.16: Environmental Exposure Estimation”. Regional data and emission fractions were calculated using EUSES. Full EUSES inputs are shown below. The ERC based tier 1 assessment was not considered to give a realistic exposure estimation and so only the results of the refined tier 2 model using EUSES are shown below..

EUSES inputs for the ES5 exposure assessment

Input parameter:	Value:	Unit:	ERC default (if applicable)
Molecular Weight	57.04	g/mol	
Vapour Pressure (at 20 °C)	1.08	Pa	
Water Solubility	100,000 (Fully miscible)	mg/L	
Octanol/water partition coefficient	-1 (inorganic estimate)	logKow	
Koc	3.16 (Estimated in EUSES based on log kow)		
Biodegradability	Not biodegradable (inorganic acids cannot be considered biodegradable)		
Life Cycle Step	Industrial use		
Environmental Release Class	ERC 6b		
Fraction of Tonnage for Region (1st Tier)			1
STP			Yes
Emission events per year	330 (manufacturer information)	Days	300
Default Release to Air	0.1	%	0.10
Default Release to water	5	%	5
Dilution factor applied for PEC derivation			10 (20,000 m^3/d)
Tonnage assessed	Local: 500 Regional: 6300	tonnes/annum	Worst case local and total regional/EU tonnage.

Based on these inputs the following daily emissions and predicted environmental exposure concentrations (PECs) were derived.

Predicted Releases to the Environment Tier 2

ERC	Compartments	Predicted releases	Measured release	Explanation / source of measured data
6b	Wastewater	14.6 kg/d*	-	Based on efficient waste water treatment in the industrial WWTP with neutralization and precipitation.
	Release to air	1.53 kg/d	-	
	Soil (direct only) Agricultural soil	0 kg/d	-	No direct loss to soil is expected for this ERC and no sludge spreading.
	*The predicted releases were estimated using the EUSES 2.1 program inputting a value of 7.3 mg/L (worst case fluoride concentration after pre-treatment) for the waste water.			

Tier 2 Concentrations in sewage

ERC	ERC for Compartment:	Estimated exposure concentrations		Explanation
		value	unit	
6b	Sewage (STP effluent)	7.3	mg/L	Set to 7.3 due to on-site treatment and removal
	Sewage sludge	0	mg/kg	There is no spreading of sludge to soil so for the purposes of this assessment the concentration in sewage sludge should be considered to be 0

Tier 2 Predicted Environmental Concentrations (PEC) in aquatic compartment

ERC	Compartments	Local concentration aquatic (local mg/L)	Justification
6b	Freshwater (in mg/L)	0.74	
	Marine water (in mg/L)	0.074	10-fold dilution by receiving waters
	Intermittent releases to water (in mg/L)	NA	Intermittent release not relevant

Tier 2 Predicted Environmental Concentrations (PEC) in aquatic sediment compartment

ERC	Compartments	PEC aquatic (local)
6b	Freshwater sediment (in mg/kg)	0.63
	Marine sediment (in mg/kg)	0.063

Tier 2 Predicted Environmental Concentrations (PEC) in the soil and groundwater compartment

ERC	Compartments	PEC (local)
6b	Groundwater (in mg/L)	0.177
	Agricultural soil (averaged over 30 days (in mg/kg)	0.0525

Tier 2 Predicted Exposure Concentration (PEC) in air

ERC		Local concentration	PEC air (local+regional)	Justification
6b	Annual average PEC in air, total (mg/m^3)	0.000384	0.000384	Estimated using EUSES 2.1.

Based on these PECs the following risk characterization ratios are derived

Risk characterisation

Compartment	PEC mg/L	PNEC mg/L	RCR	Comments
Tier 2 Freshwater	0.74	1.3	0.569	Safe use demonstrated in tier 2
Tier 2 Soil	0.0525	22	0.0023	Safe use demonstrated in tier 2
Tier 2 STP	7.3	76	0.096	Safe use demonstrated.

Atmospheric contamination is minimal, with either the use of sealed systems or the use of emission control measures at industrial formulation sites. Given that any ammonium hydrogendifluoride present in the atmosphere will be broken down into ions on contact with moisture any incident on soils as a result of precipitation will be very dilute, and will be rapidly broken down to harmless constituent ions. No atmospheric PNECs are derived and no atmospheric risk characterisation is required.

Worker exposure

The assessment of worker exposure to ammonium hydrogendifluoride from glass etching (ES5) was carried for processes relevant to this use scenario as identified by PROC codes. Initially, a screening-level (Tier 1) assessment was carried out using the MEASE model. A higher tier (Tier 2) refinement of the Tier 1 assessment was carried out using the Advanced REACH Tool (ART).

The effects of exposure to ammonium hydrogendifluoride dermal exposures are likely to be local irritation and corrosivity of the skin. There is no evidence of systemic effects following dermal exposures to ammonium hydrogendifluoride. Estimates of systemic dermal doses associated with acute/short-term and long-term exposures to ammonium hydrogendifluoride were not therefore derived. Furthermore all dermal exposure is ruled out by the exposure limiting methods in place.
A screening-level assessment of inhalation exposure concentrations potentially associated with processes in ES 5 was carried out using the MEASE model and the parameters shown in the tables below. The MEASE model was considered more appropriate to use for AMBI rather than ECETOC as it incorporates measured data from the metals industry and takes into account operational conditions and RMM that are more relevant.

The tables below show the estimated exposure concentration to ammonium hydrogendifluoride for processes associated with ES 5.

The MEASE model was not considered to give a reasonable screening-level assessment of exposures associated processes involved in ES 5 for inhalation exposures in workers.

As such the unsuitable tier 1 assessment of inhalation exposures associated with ES 5 derived using the MEASE model were refined using the higher tier inhalation model: the Advanced REACH tool (ART). In the ART model, a mechanistic model of inhalation exposure and expert judgement were used to predict more realistic estimates of inhalation exposure concentrations associated with processes involving the use of ammonium hydrogendifluoride in ES 5. The Tier 2 assessment was carried out using the parameters and assumptions in the tables below. The predicted 50^{th} and 90^{th} (worst case) percentile acute/short-term (e.g. exposure over a full-shift) and long-term inhalation exposure concentrations derived using these parameters for processes associated with ES 5 are shown in the tables below.

Parameters used in the MEASE model model to conduct a Tier 1 assessment of inhalation exposure concentrations

	Parameter for Solution	Explanation/source of data for solution	Parameter for Flakes	Explanation/source of data for flake
Molecular weight	57.04 g/mol		57.04 g/mol	
Vapour Pressure	1.08 Pa		1.08 Pa	
Water solubility	100,000 mg/L		100,000 mg/L	
Is the substance a solid?	No – liquid	>25% (worst case)	Yes	The substance is produced in flake form
Dustiness during process	n/a	Only in the case of solid	Inhalable fraction: ≤ 100 mg/kg	Product does not result in dust emission without intentional breakage of products: e.g., firm polymer granules, granules covered with a layer of wax, a woodblock, a brick).
Duration of activity	>4 hours (default)	Worst case	>4 hours (default)	Worst case
Use of ventilation	Indoors without LEV	Worst case	Indoors without LEV	Worst case
Use of respiratory protection	No	Worst case	No	Worst case

First tier screening level exposure concentrations to workers

Description of activity	PROC	Physical state of material	Estimated Exposure Concentrations for solution		Estimated Exposure Concentrations for flake	
			value	unit	value	unit
Industrial Spraying	7	Liquid/Flake	2.0*	mg/m^3	1.0	mg/m^3
Treatment of articles by dipping and pouring	13	Liquid/Flake	0.01	mg/m^3	0.10	mg/m^3

* RPE – 95 % protection

Parameters and assumptions used in the ART model to conduct a Tier 2 assessment of inhalation exposure concentrations

	PROC	Parameters/ assumptions for solution	Parameters/ assumptions for flake
Exposure duration	All	480 min	480 min
Product type	All	Powders dissolved in a liquid or incorporated in a liquid matrix (e.g. copper in anti-fouling paint)	Powders, granules or pelletised material
Process temperature	All	Room temperature (15-25^{o}C)	Room temperature (15-25^{o}C)
Vapour pressure	All	1.08 Pa	1.08 Pa
Liquid weight fraction	All	Substantial (10-50%)	N/A
Dustiness	All	N/A	Product does not result in dust emission without intentional breakage of products: e.g., firm polymer granules, granules covered with a layer of wax, a woodblock, a brick). Inhalable fraction: ≤ 100 mg/kg
Primary emission source proximity	All	Primary emission source located in the breathing zone of the workers (i.e. Within 1 metre)	Primary emission source located in the breathing zone of the workers (i.e. Within 1 metre)
Activity class	PROC7	Spray application of liquids-surface spraying: moderate application rate (0.3-3 L/min). Only horizontal or downward spraying, with no or low compressed air use. A low application rate (0.03-0.3 L/min) with no or low compressed air is also utilised.	Spray application of powders-Dusting using blower- Only horizontal or downward spraying
	PROC13	Activities with open liquid surfaces-activities with undisturbed surfaces-open surface >3 m^2	N/A
Containment	All	N/A	N/A
Localised controls	All	No localised controls	No localised controls
Segregation	All	N/A	N/A
Fugative emission source	All	Process not fully enclosed but effective housekeeping practises are in place	Process not fully enclosed but effective housekeeping practises are in place
Dispersion	PROC7	Down-flow spray room	Down-flow spray room
	PROC13	Indoors, any size workroom, good natural ventilation	

Tier 2 acute/short-term and long-term inhalation exposure concentrations derived using the ART model

Description of activity	PROC	Physical state of material	Estimated Short-term Exposure Concentrations (mg/m3)		Estimated Long-term Exposure Concentration (mg/m3)	
			50th percentile value	90th percentile value	50th percentile value	90th percentile value
Industrial Spraying – Low application rate, Downward Spraying, Workroom and natural ventilation	7	Liquid	0.41	1.6	0.58	1.4
Industrial Spraying – Moderate application rate, Horizontal or Downward spraying, Down-flow spray room	7	Liquid	0.56	2.2	0.77	1.9
Treatment of articles by dipping and pouring	13	Liquid	0.0046	0.018	0.0063	0.016
Industrial Spraying- Powder Coating	7	Flake	0.41	1.6	0.56	1.4
Industrial Spraying- Dusting	7	Flake	0.12	0.48	0.17	0.42

Based on these exposure concentrations the following RCRs are derived for worker exposure. Only the second tier RCRs as derived using ART are presented below.

Quantitative risk characterisation for worker

	Route	PROC Code	ES 5- 90th exposure concentrations (mg/m3)	Leading toxic end point / Critical effect	DNEL (mg/m3)	Risk characterisation ratio – No RPE assumed	Risk characterisation ratio – 95 % protection
Acute effects-liquid	Inhalation	PROC 7- Industrial Spraying/Powder Coating – Low application rate, Downward Spraying, Workroom and natural ventilation	1.6	Respiratory irritation and corrositivity	3.8	0.42	0.021
		PROC 7- Industrial Spraying/Dusting – Moderate application rate, Horizontal or Downward spraying, Down-flow spray room	2.2			0.58	0.029

		PROC 13- Treatment of articles by dipping and pouring	0.018			0.0047	0.00024
Long-Term effects-liquid	Inhalation	PROC 7- Industrial Spraying/Powder Coating – Low application rate, Downward Spraying, Workroom and natural ventilation	1.4	Respiratory irritation and corrositivity		0.61	0.03
		PROC 7- Industrial Spraying/Dusting – Moderate application rate, Horizontal or Downward spraying, Down-flow spray room	1.9			0.83	0.041
		PROC 13- Treatment of articles by dipping and pouring	0.016			0.007	0.00035
Acute effects-flake		PROC 7- Industrial Spraying/Powder Coating – Low application rate, Downward Spraying, Workroom and natural ventilation	1.6	Respiratory irritation and corrositivity	2.3	0.42	0.021
		PROC 7- Industrial Spraying/Dusting – Moderate application rate, Horizontal or Downward spraying, Down-flow spray room	0.48			0.13	0.0063

Long-Term effects-flake	Inhalation	PROC 7-Industrial Spraying/Powder Coating – Low application rate, Downward Spraying, Workroom and natural ventilation	1.4	Respiratory irritation and corrositivity		0.61	0.03
		PROC 7-Industrial Spraying/Dusting – Moderate application rate, Horizontal or Downward spraying, Down-flow spray room	0.42			0.18	0.0091

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

Environmental releases:

In order to work within the boundaries of the ES the following conditions should be met:

- Local emissions to air and water should be no more than those specified in section 3 above.
- Emissions to the industrial WWTP should be effectively treated by neutralization and precipitation before release to the environment
- Any measured emissions should be confirmed to be less than the relevant PNECs in section 3 above.

Worker exposure:

In order to work within the boundaries of the ES the following conditions should be met:

- Worker segregation should be in place to prevent direct contact with the AMBI source.
- Workers should wear protective gloves, and respiratory equipment at all times during the use of AMBI during glass etching use.
- Any measured exposure should be confirmed to be less than the relevant DNELs as listed in section 3 above

5	Additional good practice advice beyond the REACH CSA.

- Do not eat, drink or smoke when working with AMBI.
- Always wash hands and exposed skin thoroughly after using AMBI surfaces/machinery that may have come into contact with AMBI.
- Workers should be suitably trained in all safety procedures
- Procedural and safety compliance should be routinely assessed by management
- Machinery should be regularly maintained and checked for proper function
- Efficacy of all emission RMMs and waste treatment procedures should be routinely assessed and confirmed to be functioning correctly
- Details on scaling and control technologies are provided at: http://cefic.org/Industry-support/Implementing-reach/Libraries/

Downstream user exposure scenario for Ammonium hydrogendifluoride (AMBI)

1	Exposure Scenario 6: Drilling

Use of Ammonium hydrogendifluoride in drilling

Environmental Release and Worker Processes Covered:

Environmental Releases

ERC04: Industrial use of processing aids in processes and products, not becoming part of articles

Worker Processes

PROC25: Other hot work operations with metals

Product Category

PC38: Welding and soldering products (with flux coatings or flux cores.), flux products.

Ammonium hydrogendifluoride is used during drilling processes with the activity generally being outdoors. Drilling processes usually operate more or less continuously at approximately 330 days/year (depending on market demands).

The process is not entirely closed as environmental emissions of ammonium hydrogendifluoride are usually not treated on-site. For use during drilling operations AMBI is used as a constituent in drilling fluids for deep boreholes as functional agent to soften silic rock (for example in oil exploration).

Contributing Environmental Scenario: CES 1: Environmental exposure arising due to use as a process aid during drilling.

Contributing Worker Scenario: CES 2: worker exposure arising due to use in hot work operations (PROC 25).

2.1	Controlling environmental exposure for ES 6

ES6: Contributing Environmental Scenario: CES 1: Environmental exposure arising due to use as a process aid during drilling.

Section 2.1 describes the environmental releases that may occur during the use of AMBI during drilling processes where AMBI is used as a process aid to, for example, soften silica containing rocks. This would be carried out during process and exploratory drilling in oil extraction or discovery processes.

Ammonium hydrogendifluoride dissociates rapidly and completely when released into waste water. Therefore instead of the substance p*er se*, ammonium and fluoride are released into the environment after the drilling processes. As such the environmental exposure pathways and risk assessment are based on the specifics and ecological properties of the dissociation products.

However, the risk of ammonium salts to the environment is very low. Therefore, the main concern is the release of fluoride. As the emissions from drilling involve use in ground based drilling actual exposure to the STP is not expected however for the purposes of a worst case assessment complete loss to the STP is considered below to derive a PEC in STP effluent. This will allow safe use in all potential types of drilling to be determined.

Product characteristics
AMBI is a white crystalline solid at 20°C and 101.3 kPa with a vapour pressure of 1.08 Pa at 20°C. It is highly soluble in water and is not considered flammable. AMBI is not considered to be potentially explosive or an oxidising agent. The product used may be a liquid or a flake.
Amounts used
Up to 7.5 tonnes per annum at the highest tonnage single site with up to 20 tonnes per annum in a region.
Frequency and duration of use
Continuous use and release with up to 330 emission days per year.
Environmental factors influenced by risk management
Flow rate of receiving water at least 10,000 m^3 per day. Dilution of (theoretical) STP emissions at least 10 fold.
Other operational conditions affecting environmental exposure
The drilling use of AMBI is carried out outdoors and as a worst case assessment complete loss to air and water (as described by ERC4) are considered.
Technical conditions and measures at process level (source) to prevent release
There are no specific measures designed to prevent release to the environment required to demonstrate safe use.
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil
There are no specific onsite technical conditions designed to prevent release to the environment required to demonstrate safe use.
Organizational measures to prevent/limit releases from site
Workers are fully trained in order to prevent accidental release.

Conditions and measures related to municipal STP
The emission volume of the (theoretical) STP should be at least the default of 2,000 m^3 per day though no actual loss to the STP is envisaged.
Conditions and measures related to external treatment of waste for disposal
No external treatment of waste is expected.
Conditions and measures related to external recovery of waste
There is no envisaged external recovery of waste.

2.2	Controlling worker exposure for ES 6

ES6: Contributing Worker Scenario: CES 2: worker exposure due to use in hot work operations.

The use AMBI during drilling operations takes place outdoors. Due to the hazardous and corrosive nature of ammonium hydrogendifluoride the handling systems are highly controlled. Workers are suitably trained and wear appropriate PPE and RPE during the times when very limited (not intended) contact may occur.

Product characteristics
AMBI is a white crystalline solid at 20°C and 101.3 kPa with a vapour pressure of 1.08 Pa at 20°C. It is highly soluble in water and is not considered flammable. AMBI is not considered to be potentially explosive or an oxidising agent. The product used may be a liquid or a flake.
Amounts used
Up to 7.5 tonnes per annum at the highest tonnage single site with up to 20 tonnes per annum in a region.
Frequency and duration of use exposure
Workers generally perform standard shifts of 8 hours per day and have standard working years of 220 days per year.
Human factors not influenced by risk management
Respiration volume under conditions of use is $10m^3/d$ (default value for a worker breathing for an 8h work day in Guidance Section R 8.4.2). Area of skin contact with the substance under the conditions of use is $0cm^2$ as all dermal contact must be prevented due to the corrosive nature of AMBI.
Other given operational conditions affecting worker exposure
All operations associated with the use AMBI during drilling are carried out outdoors. Due to the hazardous and corrosive nature of ammonium hydrogendifluoride the handling systems are highly controlled. The potential for exposure is limited where possible to prevent potential exposure.
Technical conditions and measures at process level (source) to prevent release
The handling of ammonium hydrogendifluoride is such that contact between product and adjacent air is reduced. Emission sources can be completely or partially segregated from the work environment by isolating the source in a fully enclosed and separate room and using complete personal enclosure with ventilation where necessary.
Technical conditions to control dispersion from source towards worker
Dispersion may be controlled by housing the drilling material in a fully enclosed and separate room and using complete personal enclosure with ventilation where necessary.

Organizational measures to prevent/limit release
Workers involved in the handling, use and transfer of materials are trained in the procedures and protective equipment is intended to cope with the worst case scenario, in order to minimise exposure and risks.
Conditions and measures related to personal protection, hygiene and health.
Personal protective equipment, including the use of protective clothing, gloves and respiratory protection are worn by all operators in the facility. This includes a respiratory mask with E-P2 filter, eye protective goggles or face shield and protective gloves (butyl-rubber). Due to the nature of the materials the level of control is extremely high and so in reality exposure is highly unlikely.

3	**Exposure estimation and reference to its source**

Environmental Exposure

For the environmental exposure assessment in EUSES refined inputs are chosen to best suit the description of uses of ammonium hydrogendifluoride in drilling operations. Emission defaults are those specified by the ECHA "Guidance on information requirements and chemical safety assessment: Chapter R.16: Environmental Exposure Estimation". Regional data and emission fractions were calculated using EUSES. Full EUSES inputs are shown below. The ERC based tier 1 assessment was not considered to give a realistic exposure estimation and so only the results of the refined tier 2 model using EUSES are shown below.

EUSES inputs for the ES6 exposure assessment

Input parameter:	**Value:**	**Unit:**	**ERC default (if applicable)**
Molecular Weight	57.04	g/mol	
Vapour Pressure (at 20 °C)	1.08	Pa	
Water Solubility	100,000 (Fully miscible)	mg/L	
Octanol/water partition coefficient	-1 (inorganic estimate)	logKow	
Koc	3.16 (Estimated in EUSES based on log kow)		
Biodegradability	Not biodegradable (inorganic acids cannot be considered biodegradable)		
Life Cycle Step	Industrial Use		
Environmental Release Class	ERC 4		
Fraction of Tonnage for Region (1st Tier)			1
STP			Yes
Emission events per year	330 (manufacturer information)	Days	300
Default Release to Air	100	%	100
Default Release to water	100	%	100

Dilution factor applied for PEC derivation			10 (20,000 m^3/d)
Tonnage assessed	Local: 7.5 Regional: 20	tonnes/annum	Worst case local and total regional tonnage.

Based on these inputs the following predicted environmental exposure concentrations (PECs) were derived

Exposure concentration in sewage treatment plants (STP)

ERC	ERC for Compartment:	Estimated exposure concentrations		Explanation
		value	unit	
4	Sewage (STP effluent)	12.5	mg/L	Tier II assessments are not necessary for this ES

Tier 2 Predicted Environmental Concentrations (PEC) in aquatic compartment

ERC	Compartments	Local concentration aquatic (local mg/L)	Justification
4	Freshwater (in mg/L)	1.25	
	Marine water (in mg/L)	0.125	
	Intermittent releases to water (in mg/L)	n/a	Intermittent release not relevant

Tier 2 Predicted Environmental Concentrations (PEC) in aquatic sediment compartment

ERC	Compartments	PEC aquatic (local)
4	Freshwater sediment (in mg/kg)	1.06
	Marine sediment (in mg/kg)	0.106

Tier 2 Predicted Environmental Concentrations (PEC) in the soil and groundwater compartment

ERC	Compartments	PEC (local)
4	Agricultural soil (averaged over 30 days (in mg/kg)	0.00312
	Groundwater (in mg/L)	0.018

Tier 2 Predicted Exposure Concentration (PEC) in air

ERC		Local concentration	PEC air (local+regional)	Justification
4	Annual average PEC in air, total (mg/m^3)	0.00571	0.00571	Estimated using EUSES 2.1.

Based on these PECs the following risk characterization ratios are derived

Risk characterisation

Compartment	**PEC mg/L**	**PNEC mg/L**	**RCR**	**Comments**
Tier 2 Freshwater	1.25	1.3	0.961	Safe use demonstrated
Tier 2 Soil	0.00312	22	1.41×10^{-4}	Safe use demonstrated
Tier 2 STP	12.5	76	0.096	As discussed previously actual emission to the municipal STP is not expected. However theoretical safe use is demonstrated.

Worker exposure

The assessment of worker exposure to ammonium hydrogendifluoride from distribution (ES6) was carried for processes relevant to this use scenario as identified by PROC codes. Initially, a screening-level (Tier 1) assessment was carried out using the MEASE model. A higher tier (Tier 2) refinement of the Tier 1 assessment was carried out using the Advanced REACH Tool (ART).

The effects of exposure to ammonium hydrogendifluoride dermal exposures are likely to be local irritation and corrosivity of the skin. There is no evidence of systemic effects following dermal exposures to ammonium hydrogendifluoride. Estimates of systemic dermal doses associated with acute/short-term and long-term exposures to ammonium hydrogendifluoride were not therefore derived. Furthermore all dermal exposure is ruled out by the exposure limiting methods in place.

A screening-level assessment of inhalation exposure concentrations potentially associated with processes in ES6 was carried out using the MEASE model and the parameters shown in the tables below. The MEASE model was considered more appropriate to use for AMBI rather than ECETOC as it incorporates measured data from the metals industry and takes into account operational conditions and RMM that are more relevant.

The MEASE model was not considered to give a reasonable screening-level assessment of exposures associated processes involved in ES6.

As such the unsuitable tier 1 assessment of inhalation exposures associated with ES 6 derived using the MEASE model were refined using the higher tier inhalation model: the Advanced REACH tool (ART). In the ART model, a mechanistic model of inhalation exposure and expert judgement were used to predict more realistic estimates of inhalation exposure concentrations associated with processes involving ammonium hydrogendifluoride in ES 6. The Tier 2 assessment was carried out using the parameters and assumptions in the tables below. The predicted 50^{th} and 90^{th} (worst case) percentile acute/short-term (e.g. exposure over a full-shift) and long-term inhalation exposure concentrations derived using these parameters for processes associated with ES 6 are shown in the tables below.

Parameters used in the MEASE model model to conduct a Tier 1 assessment of inhalation exposure concentrations

	Parameter for Solution	Explanation/source of data for solution	Parameter for Flakes	Explanation/source of data for flake
Molecular weight	57.04 g/mol		57.04 g/mol	
Vapour Pressure	1.08 Pa		1.08 Pa	
Water solubility	100,000 mg/L		100,000 mg/L	
Is the substance a solid?	No – liquid	>25% (worst case)	Yes	The substance is produced in flake form
Dustiness during process	n/a	Only in the case of solid	Inhalable fraction: ≤ 100 mg/kg	Product does not result in dust emission without intentional breakage of products: e.g., firm polymer granules, granules covered with a layer of wax, a woodblock, a brick).
Duration of activity	>4 hours (default)	Worst case	>4 hours (default)	Worst case
Use of ventilation	Indoors without LEV	Worst case	Indoors without LEV	The actual use is outdoors however indoors without LEV represents a worst case assessment in this case
Use of respiratory protection	No	Worst case	No	Worst case

First tier screening level exposure concentrations to workers

Description of activity	PROC	Physical state of material	Estimated Exposure Concentrations	
			value	unit
Other hot work operations with metals	25	Flake	2	mg/m^3
Other hot work operations with metals	25	Liquid	n/a	mg/m^3

Parameters and assumptions used in the ART model to conduct a Tier 2 assessment of inhalation exposure concentrations

	PROC	Parameters/ assumptions for Solution
Exposure duration	PROC 25	480 min
Product type	PROC 25	Powders dissolved in a liquid or incorporated in a liquid matrix (e.g. copper in anti-fouling paint)
Process temperature	PROC 25	Room temperature (15-25^{o}C)
Vapour pressure	PROC 25	1.08 Pa
Liquid weight fraction	PROC 25	Substantial (10-50%)
Primary emission source proximity	PROC 25	Primary emission source is not located in the breathing zone of the worker- the assessment for this activity involves a primary far-field emission source only (workers are in a control room)

Activity class	PROC 25	Application of liquids in high speed processes (e.g. rotating tools), Large-scale activities involving high speed movements
Containment	PROC 25	Handling that reduces contact between product and adjacent air
Localised controls	PROC 25	No localised controls
Segregation	PROC 25	Sources are partially segregated from the work environment by isolating the source in a separate room (with open doors and/or windows). Personal Enclosure: Partial personal enclosure with ventilation.
Fugative emission source	PROC 25	Process not fully enclosed but effective housekeeping practises are in place
Dispersion	PROC 25	Indoors, any size workroom, good natural ventilation

Tier 2 acute/short-term and long-term inhalation exposure concentrations derived using the ART model

Description of activity	**PROC**	**Physical state of material**	**Estimated Short-term Exposure Concentrations (mg/m3)**		**Estimated Long-term Exposure Concentration (mg/m3)**	
			50th percentile value	**90th percentile value**	**50th percentile value**	**90th percentile value**
Other hot work operations with metals	25	Liquid	0.22	0.88	0.30	0.75

Based on these exposure concentrations the following RCRs are derived for worker exposure. Only the second tier RCRs as derived using ART are presented below.

Quantitative risk characterisation for worker

	Route	**PROC Code**	**ES 6- 90th exposure concentrations (mg/m^3)**	**Leading toxic end point / Critical effect**	**DNEL (mg/m^3)**	**Risk characterisation ratio – No RPE**	**Risk characterisation ratio – 95 % protection**
Acute effects-liquid	Inhalation	PROC 25	0.88	Respiratory irritation and corrositivity	3.8	0.23	0.012
Long term effects-liquid	Inhalation	PROC 25	0.75	Respiratory irritation and corrositivity	2.3	0.33	0.016

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

Environmental releases:

In order to work within the boundaries of the ES the following conditions should be met:

- Local emissions to air and water should be no more than those specified in section 3 above.
- Any measured emissions should be confirmed to be less than the relevant PNECs in section 3 above.

Worker exposure:

In order to work within the boundaries of the ES the following conditions should be met:

- Worker segregation and LEV should be in place to prevent contact with the AMBI source.
- Workers should wear protective gloves, and respiratory equipment at all times during the use of AMBI during drilling use.
- Any measured exposure should be confirmed to be less than the relevant DNELs as listed in section 3 above

5	Additional good practice advice beyond the REACH CSA.

- Do not eat, drink or smoke when working with AMBI.
- Always wash hands and exposed skin thoroughly after using AMBI surfaces/machinery that may have come into contact with AMBI.
- Workers should be suitably trained in all safety procedures
- Procedural and safety compliance should be routinely assessed by management
- Machinery should be regularly maintained and checked for proper function
- Efficacy of all emission RMMs and waste treatment procedures should be routinely assessed and confirmed to be functioning correctly
- Details on scaling and control technologies are provided at: http://cefic.org/Industry-support/Implementing-reach/Libraries/