EXPOSURE ASSESSMENT

The following identified uses of the substance MAHP were considered in the exposure assessment.

Table 1 Overview on exposure scenarios and coverage of substance life cycle

Short use description	ES number	Manufacture	Identified uses			Linked to Identified Use	Sector of Use (SU)		Product category (PC)	Process category (PROC)*	Article category (AC)	Environmental release category (ERC)
			Formulation	End use	Consumer use		Main user groups	Sector of end use				
Synthesis of adhesives	1	na	x	na	na	1	3	8, 10	na	3, 4, 8b, 9, 15	na	ERC: 2, 6c spERC: 2.1a.v1 (FEICA)
Formulation of adhesives	1	na	x	na	na	2	3	10	na	3, 4, 8b, 9, 15	na	ERC: 2, 6c spERC: 2.1a.v1 (FEICA)
Industrial use of adhesives	2	na	na	x	na	3	3	0, 19	na	5, 8a, 8b, 9, 10, 13, 14, 15, 19	na	ERC: 2, 5, 6d spERC: 5.1a.v1 and 5.1b.v1 (FEICA)

* The given process categories for industrial use of adhesives seem to not describe activities leading to direct contact of workers with the substance. They are meant to describe single steps of the application process occurring in a dedicated application device.

Scenario 1: Manufacturing (synthesis) and formulation of adhesives in batch process

Main user group: SU 3
Sector of end use: SU 8, 10
Product categories: not applicable
Process categories: PROC 3, 4, 8b, 9, 15
Article categories: not applicable
Environmental release categories: ERC 2, 6c; FEICA spERC 2.1a.v1

Exposure scenario 1: Synthesis of adhesives in batch process/Formulation of adhesives

The substance is manufactured outside the European Economic Area (EEA) and imported to the EEA where it is used in the synthesis and formulation of curable laminate adhesives at one site. This exposure scenario covers the identified uses no. 1 and 2.

For the purpose of the environmental exposure assessment is has been assumed that the substance is imported to a single site to synthesise or formulate adhesive mixtures in closed or open batch processes. These adhesives then are shipped and distributed further along the supply chain.
The following characterisation of operational conditions during synthesis and formulation of adhesives is based on specific information provided by the importer of the substance, generic use descriptor lists and specific Environmental Release Categories published by the Association of European Adhesive and Sealant Industry (FEICA). The FEICA spERC 2.1a.v1 was identified as most appropriate to describe the potential environmental release.

Controlling environmental exposure

Product characteristics

MAHP is imported as a neat substance with a purity of more than 94% (w/w).

Amounts used

The total amount of substance used in the synthesis and formulation of adhesives is 100 tonnes per year. It was assumed in the present assessment that the total amount is imported to a single site, where the substance is used in the synthesis and formulation of adhesive products, i.e. the regional fraction and the fraction of the main local source are both 1 in the present assessment. The number of release days is given with 220 in the spERC published by FEICA. The amount of substance processed at a single day can be calculated from the annual tonnage and the number of release day: it may reach approximately 450 kg/day. This is clearly below the typical maximum tonnage given in the FEICA spERC.

Frequency and duration of use

Environmental release may occur on 220 days according to the specific release scenario developed by FEICA. Release occurs continuously during the emission day.

Environmental factors not influenced by risk management

Generic environmental factors were taken into account in the exposure assessment, i.e. environmental dimensions as defined in the EUSES model and a dilution rate of 10 for freshwater and 100 for seawater.

Other given operational conditions affecting environmental exposure

Not reported

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

The processes normally operate in contained systems reducing emissions of substance into the air. The processes operate without water contact leading to negligible waste water emissions.

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

The typical release fraction to air from the process prior to risk management measures is given as 0.000097 in the FEICA spERC. Exhaust air from the processes is collected and treated to provide a typical removal efficiency of 99%. The final release fraction thus is 9.7×10^{-7}.
The typical release fraction to waste water from the process prior to risk management measures is given as “zero” and specific waste water emission controls are not applicable as there is no direct release to waste water.

Organisational measure to prevent/limit release from site

Due to the corrosive properties of the substance, workers have to follow good industrial practice.

Conditions and measures related to municipal sewage treatment plant

It is assumed that synthesis and formulation of adhesives operate without water contact resulting in negligible emissions of substance into waste water. Onsite treatment of industrial waste water may occur but is not explicitly taken into account in the exposure assessment due to non-existing waste water emissions.

Conditions and measures related to external treatment of waste for disposal

Contaminated containers or spillages of solutions mixed with inert material (e.g. clay) may be disposed of by incineration at an authorised tip in accordance with local regulations.

Conditions and measures related to external recovery of waste
No external recovery of waste occurs.

Controlling worker exposure

Based on the volatility of the sensitizing impurity HHPA, a separate exposure scenario was created to ensure safe exposure to the impurity.

Product characteristics
MAHP is imported as a neat substance with a purity of more than 92% (w/w). MAHP contains up to 0.9% HHPA (cyclohexane-1,2-dicarboxylic anhydride, EC# 201-604-9).

Amounts used
A worker may handle amounts of the substance in the range of tens to hundreds of kilograms per working day.

Frequency and duration of use/exposure
A worker in this industry may be exposed on 220 days a year. Direct exposure may occur during loading and discharging activities during a period of approximately 35 minutes per working day. It is anticipated that no exposure occurs during the remaining 445 minutes of a full working shift of 8 hours under regular conditions.

Human factors not influenced by risk management
The worker has a breathing rate of 10 m^3 per 8-hour working shift. The exposed skin surface area is as described in ECETOC TRA (version 2010). The estimates are based on the skin surface areas given in the ECHA technical guidance document (R.14: Occupational exposure estimation, ECHA 2010). The bodyweight of the worker used in calculations is 70 kg.

Other given operational conditions affecting worker exposure
Not reported.

Technical conditions and measures at process level (source) to prevent release
The processes normally operate in contained systems preventing direct worker exposure.

Technical conditions and measures to control dispersion from source towards worker
Exhaust air from the processes is collected by local exhaust ventilation. Since the FEICA exposure scenario does not give the removal efficiency of the LEV, a conservative value of 80% efficiency is used in the ART tool.

Organisational measures to prevent/limit releases, dispersion and exposure
Due to the corrosive properties of the substance, workers have to follow good industrial practice.

Conditions and measures related to personal protection, hygiene and health evaluation
Workers wear chemical resistant gloves, appropriate clothes and boots in the working area. Workers may also wear personal respiratory equipment according to the FEICA exposure scenario. In addition, workers who may come into direct contact with the substance wear chemical resistant safety goggles or use face shields.

Table 2. Conditions of occupational exposure to HHPA in MAHP for synthesis/formulation of adhesive

Exposure estimated with the ART tool on the basis of the following information	
Charging: 15 minutes	Discharging: 20 minutes
Liquid substance	Liquid substance
Room temperature (15 to 25 °C)	Room temperature (15 to 25 °C)
Vapour pressure: 93 Pa	Vapour pressure: 93 Pa
0.9%	0.4% (final formulation)
Medium viscosity (like oil)	Medium viscosity (like oil)
Primary emission source not in breathing zone	Primary emission source not in breathing zone
Transfer of falling liquids	Transfer of falling liquids
10 to 100 L/minute	10 to 100 L/minute
Open process/splash loading	Handling that reduces contact between product and adjacent air/splash loading

LEV installed (80%)	LEV installed (80%)
No secondary controls	No secondary controls
Not fully enclosed, general housekeeping practices in place	Not fully enclosed, general housekeeping practices in place
Indoor activity in room with 1000 m^3 volume, mechanical ventilation giving at least 3 ACH	Indoor activity in room with 1000 m^3 volume, mechanical ventilation giving at least 3 ACH
0.0048 mg/m^3 HHPA in MAHP. RCR = 0.96	0.00013 mg/m^3 HHPA in MAHP. RCR = 0.026

Scenario 2: Industrial application of adhesives

Main user group: SU 3

Sector of end use: SU 0 (other: packaging industry), SU 19

Product categories: not applicable

Process categories: PROC 5, 8a, 8b, 9, 10, 13, 14, 15, 19

Article categories: not applicable

Environmental release categories: ERC 2, 5, 6d, FEICA spERC 5.1a.v1 and 5.1b.v1

Exposure scenario 2: Industrial application of adhesives

The substance is contained in curable laminating adhesives used for bonding of substrates such as paper, board, aluminium foil and various plastic films. The formulated adhesives are delivered to downstream users in pails, drumsor IBCs. Transfer of adhesive from transportation containers to the application stations is done with automated pumping systems in most cases. Manual pouring of products and filling of application stations may occur in a few cases. The products are ready-to-use and addition of or blending with other materials is not required. The adhesive is applied using a coating method in a dedicated device. Curing is accomplished by UV or electron beam (EB) irradiation using commercial self-shielded curing equipment. The curing converts the adhesive to a high molecular weight cross-linked polymer with only trace levels of free substance remaining in the polymer.

Controlling environmental exposure

The following characterisation of operational conditions during industrial use of adhesives is based on specific information provided by the importer of the substance, generic use descriptor lists and specific Environmental Release Categories published by the Association of European Adhesive and Sealant Industry (FEICA). The FEICA spERCs 5.1a.v1 and 5.1b.v1 were identified as most appropriate to describe the potential environmental release.

Product characteristics

The substance is contained in liquid curable laminating adhesives at a maximum concentration of approximately 35% (w/w).

Amounts used

In this exposure scenario it was assumed that the use of adhesive is well-distributed over Europe, which is reflected by a regional fraction of 0.1. Since information on the reasonable size of a local site was unavailable, a fraction of the main local source of 1 was assumed. On the basis of the available information on tonnages it is estimated that industrial sites may use amounts of the substance in the range of tens of kilograms per day. This is clearly below the typical maximum tonnage given in the FEICA spERC.

Frequency and duration of use

Industrial use of adhesives typically occurs on 220 days a year according to the FEICA spERCs.

Environmental factors not influenced by risk management

Generic environmental factors were taken into account in the exposure assessment, i.e. environmental dimensions as defined in the EUSES model and a dilution rate of 10 for freshwater and 100 for seawater.

Other given operational conditions affecting environmental exposure

Instantaneous curing of adhesives is accomplished by UV or electron beam irradiation. It converts the adhesive mixture to a high molecular weight cross-linked polymer with only trace levels of free substance remaining in the polymer.

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

The processes operate without water contact leading to negligible waste water emissions. All adhesive in the shipping container is usable. This also applies to the adhesive remaining in the system during start-up and stopping.

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

The typical release fraction to air from the process prior to risk management measures is given as 0.009 to 0.017. Exhaust air from the processes is collected and treated to provide a typical removal efficiency of 80%. The final reasonable worst case release fraction hence is 0.017 x 0.2 = 0.0034.

The typical release fraction to waste water from the process prior to risk management measures is given as "zero" and specific waste water emission controls are not applicable as there is no direct release to waste water.

Organisational measure to prevent/limit release from site

The potential for environmental release is very little as the waste quantities are small.

Conditions and measures related to municipal sewage treatment plant

Industrial use of these types of adhesives operates without water contact leading to minimal emissions into waste water. Onsite treatment of industrial waste water may occur but is not explicitly taken into account in the exposure assessment due to non-existing waste water emissions.

Conditions and measures related to external treatment of waste for disposal

In the unlikely event that a disposal of unused adhesive is needed it will be incinerated with no hazardous combustion products expected to be generated.

Conditions and measures related to external recovery of waste

No external recovery of waste occurs.

Controlling worker exposure

Product characteristics

The substance is contained in liquid curable laminating adhesives at a maximum concentration of approximately 35% (w/w). Hence, HHPA in MAHP is contained in the final adhesives at <0.4%.

Amounts used

The products are delivered to downstream users in 20 kg pails, drums or IBCs. Industrial workers may handle amounts in the range of kilograms per day.

Frequency and duration of use

A single industrial worker may be exposed on 220 days a year. The application station must be filled by pump rather than manual pouring. Some activities resulting in exposure in the "near-field", i.e. in the personal breathing zone of a worker, such as changing and cleaning rollers may take 15 minutes during a shift. Workers must wear a half- or full-face respirator with type A (organic vapour) cartridges during such "near-field" work as transient excursions beyond the 0.005 mg/m^3 threshold for HHPA exposure cannot be completely eliminated by the model. Application of adhesives onto surfaces resulting in exposure in the "far-field", i.e. in a broader area around the application station, would then be performed for the remaining duration of the shift, i.e. 465 minutes. In case of automated transfer, worker exposure in the "far-field" is anticipated for the duration of the full working shift, i.e. 480 minutes.

Human factors not influenced by risk management

The worker has a breathing rate of 10 m^3 per 8-hour working shift. The exposed skin surface area is as described in ECETOC TRA. The estimates are based on the skin surface areas given in the ECHA technical guidance

document (R.14: Occupational exposure estimation, ECHA 2010). In this assessment, the bodyweight of the worker is 70 kg.

Other given operational conditions affecting worker exposure

Instantaneous curing of adhesives is accomplished by UV or electron beam irradiation. It converts the adhesive mixture to a high molecular weight cross-linked polymer with only trace levels of free substance remaining in the polymer.

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

The product is delivered to customers in pails, drums or IBCs. Generally, adhesives are directly pumped from the containers to the application system. Curing occurs in commercial self-shielded curing equipment.

Technical conditions and measures to control dispersion from source towards worker

Exhaust air from the processes is collected by local exhaust ventilation. Since the FEICA exposure scenario does not give the removal efficiency of the LEV, the default values given in the respective modelling tools were used (90% in ECETOC TRA and ART tool).

Organisational measures to prevent/limit releases, dispersion and exposure

Due to the corrosive properties of the substance, workers have to follow good industrial practice.

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

Workers wear chemical resistant gloves, appropriate clothes and boots in the working area. Workers may also wear personal respiratory equipment according to the FEICA exposure scenario. In addition, workers who may come into direct contact with the substance wear chemical resistant safety goggles or use face shields.

Table 3. Occupational exposure for industrial use of adhesive

Estimated TWA 8-hour long-term inhalation exposure to HHPA in MAHP for industrial use
0.0032 mg/m^3 estimated air concentration. RCR = 0.64
Exposure estimated with the ART tool on the basis of the following information
Application: 480 minutes
Liquid substance
Room temperature (15 to 25 °C)
Vapour pressure: 93 Pa
0.4%
Medium viscosity (like oil)
Primary emission source not in breathing zone
Spreading of liquid products
>3 m^2/hour
LEV installed/fixed capturing hood (90%)
No secondary controls
Partial segregation with ventilation and filtration of recirculated air
No personal enclosure
Not fully enclosed, no demonstrable effective housekeeping practices in place, general housekeeping rules in practice
Indoor activity in room with 1000 m^3 volume, mechanical ventilation giving at least 3 ACH