ANHYDRIDES
JOINT INDUSTRY
TASKFORCE

Exposure and Medical Inventory Report

Updated Report v1.1

Date: *26-8-2016*

Executive Summary

Hexahydrophthalic Anhydride (HHPA) and Methylhexahydrophthalic Anhydride (MHHPA) (hereinafter collectively referred to as Anhydrides) have been included in the draft prioritisation for authorisation by the European Chemicals Agency (ECHA) for their respiratory sensitising properties, which is regarded an equivalent level of concern as defined in REACH art 57(f).

This report was developed by the Anhydrides Joint Industry Taskforce (AJIT), a joint initiative of Manufacturers/Importers, Formulators, and Downstream Users of the Anhydrides, and contains the results of an exposure measurement campaign and a medical investigation conducted by AJIT.

Three exposure groups can be identified based on uses and the currently obtained measurements: 1) manufacturers/formulators, 2) producers of switchgear, and 3) producers of high voltage rotating devices.

Manufacturers/Formulators observe concentrations in the range of 4.6 – 9.7 µg/m³. Amongst the reporting plants occupying 192 workers, there is no evidence of occupational asthma related to anhydrides.

Producers of switchgear face anhydrides exposure of 4.6 – 69.2 µg/m³. Amongst the reporting plants occupying 74 workers, there is no evidence of occupational asthma related to anhydrides.

Several plant managers indicated that they were planning to reduce exposure following these results. Measures that are being contemplated include: closing of purge buckets and the improvement of local exhaust ventilation.

Producers of high voltage rotating machines typically observe exposure ranging from <0.2 (in a control room) – 284 (in the production hall) µg/m³, with short term peaks up to 3670 µg/m³. The use of Respiratory Protective Equipment reduces exposure during peaks to 0.034 (calculated) – 23 (measured) µg/m³. Amongst the reporting plants occupying 99 workers, there is only one plant where there is evidence that occupational asthma has occurred. In this plant 4 cases could be identified which occurred in 2004, 2005, 2006, and 2010. In two of these cases the workers had a severe atopic condition and might have developed asthma irrespective of whether they had been exposed to anhydrides or not. The workers were removed from exposure to different work places.

Two plants have demonstrated through historic measurements **that it is possible to reduce exposure** through various interventions: improvements in the separation of the workers from the process (under pressure working halls, over pressure control rooms), scrubbers to prevent exhaust systems contaminating other parts of the plants, improvements in local exhaust ventilation, reduction of exposure times, and the use of respiratory protective equipment (RPE).

A review of the standards for RPE revealed that through an upgrade to a higher level RPE, it should be possible to reduce peak exposure by a factor of up to 2000.

Furthermore, this report gives an overview of limit values reported in literature. The American Conference of Governmental Industrial Hygienists (ACGIH) recommends a limit of 5 µg/m³ short term exposure ceiling to prevent sensitisation, which has been adopted in several member states. Within literature

there seems to be consensus that a limit value of 10-20 µg/m³ at which no clinical symptoms occur exists.

AJIT is aware that correlation of the exposure findings reported in this review are difficult to correlate with those reported in earlier scientific literature on the subject and the reasons for this are being examined.

Lastly, the AJIT acknowledges that occupational asthma related to anhydride exposure is something that can, and should, be prevented in industry. It is preparing a **voluntary commitment** which aims as a precautionary measure to further minimize risk by decrease exposure to levels as low as reasonably achievable.

The voluntary commitment will be reinforced through updates of the registration dossier and the exposure scenario annex of the safety data sheet that are communicated downstream, thus ensuring that the entire value chain complies with the voluntary commitment developed by the Anhydrides Joint Industry Taskforce.

The AJIT believes this to be the best risk management option to prevent potential adverse health effects related to the use of anhydrides.

Contents

1. Introduction

Hexahydrophthalic Anhydride (HHPA) and Methylhexahydrophthalic Anhydride (MHHPA) (hereinafter collectively referred to as Anhydrides) have been included in the draft prioritisation for authorisation by the European Chemicals Agency (ECHA) for their respiratory sensitising properties, and are regarded by the European Chemicals Agency as constituting an equivalent level of concern to Carcinogenic, Mutagenic and Toxic to Reproduction (CMR) substances.

The Anhydrides Joint Industry Taskforce (AJIT) is a joint initiative of Manufacturers, Formulators, and Downstream Users of the Anhydrides used as epoxy hardeners (member companies listed in annex I). The purpose of the AJIT is:

1. To evaluate socio-economic impacts of an authorisation.
2. To gather information on current exposure levels and risks associated with Anhydrides and promote best practice regarding protective measures.
3. To inform authorities of possible risk management options for the use of Anhydrides

The current report will focus on the latter two objectives; the socio-economic consequences can be reviewed in the public consultation report which was submitted to the public consultation on the draft prioritisation for authorisation.

2. Exposure Measurement Program

In the public consultation report the AJIT reported measurement values obtained in a limited number of member company plants, which were obtained through various measurement methodologies. These measurements methodologies resulted in a high variability in the limit of detection and potentially in sensitivity/accuracy.

Therefore, the Anhydrides Joint Industry Taskforce developed a harmonised measurement methodology and vowed to implement it in all the member company's plants across the EU.

The exposure measurement methodology is currently being reviewed by the Finnish Competent Authority for its accuracy. The Anhydrides Joint Industry Taskforce welcomes this activity and look forward to the results of this review.

The harmonisation was completed on 11 April 2016 and the first results are currently being reported to the AJIT project manager Polymer Comply Europe. This report will include the currently available information on exposure.

3. Medical Investigation Program

To complement the exposure measurements, medical data have been gathered to facilitate/enable interpretation.

During the previous industry consultation which was used to produce the public consultation report companies were asked the question: "Has any worker health issue occurred in the last ten years that can be linked or associated to handling anhydrides?". This is the first piece of information that will be used for the medical investigation.

In order to facilitate the collection of medical data in a harmonised way a Medical Diagnostic Guidance[1] Document was developed in cooperation with Professor Paul Cullinan of the National Heart & Lung Institute at Imperial College, London following the principle of evidence based medicine[2]. This Medical Diagnostic Guideline is currently being implemented by the AJIT member companies as the centrepiece of a prospective study.

However, as the implementation of the Medical Diagnostic Guideline takes time a simultaneous retrospective study was launched to ascertain the number, if any, of previously diagnosed cases.

This report will mainly contain results from the retrospective study.

4. Results

Medical information that was presented in the previous medical inventory and newly obtained medical information for 11 new plants will be presented in detail in annex II. The focus of this report will be exposure and where necessary the feasibility of exposure reduction.

A total of 226 worker exposure measurements were analysed by the AJIT consortium manager from 13 plants within the consortium. Based on this information one can distinguish three groups of users in the value chain: manufacturers/formulators, producers of switchgear, and producers of high voltage rotating devices.

A complete overview of which plant provided which data can be found in Table 1.

Table 1 Complete overview of the submitted data

Plant	Sector	Number of potentially exposed workers	Measurements performed	Type of medical data submitted
A	Manufacturer/ Formulator	30	Yes	Retrospective Study, Medical Statement
B	Manufacturer/ Formulator	32	Yes	Medical Statement
C	Manufacturer/ Formulator	84	Yes	Medical Statement
D	Manufacturer/ Formulator	13	No	Retrospective Study, Medical Statement
E	Switchgear	6	Yes	Medical Statement
F	Switchgear	6	No	Retrospective Study, Insurance Company Report

[1] A copy of which can be obtained here: http://ow.ly/A9Dl301rh2D
[2] A good definition of evidence based medicine see: Evidence based medicine: what it is and what it isn't by Sackett et al.

Plant	Sector	Number of potentially exposed workers	Measurements performed	Type of medical data submitted
G	Switchgear	4	Yes	Prospective Study
H	High Voltage Rotating Machines	10	Yes	Prospective Study
I	High Voltage Rotating Machines	41	Yes	Industry Consultation
J	High Voltage Rotating Machines	4	Yes	Industry Consultation
K	High Voltage Rotating Machines	4	No	Retrospective Study
L	High Voltage Rotating Machines	19	Yes	Retrospective Study, Interviews with Company Doctor
M	Switchgear	18	Yes	Retrospective Study
N	Manufacture/ Formulator	36	No	
O	Switchgear	10	Yes	Industry Consultation
P	High Voltage Rotating Machines	11	Yes	
Q	Manufacture/ Formulator	33	Yes	Medical Statement
R	Switchgear	16	No	Retrospective Study
S	Switchgear	2	No	Retrospective Study
T	Switchgear	7	No	Retrospective Study
U	High Voltage Rotating Machines	10	No	Retrospective Study
V	Switchgear	5	No	Retrospective Study

In detail, findings were as follows:

Manufacturers/Formulators

86 measurements from four plants were submitted to the consortium manager. Each plant submitted a detailed measurement report and, where necessary,

additional clarification was sought with the plant management via phone interviews.

Plant A

Plant A operates a process with HHPA and MHHPA. Within plant A static samples were collected using the harmonised methodology of all areas of the plant with potential exposure. These included: material handling, reactors, mixing units, and preparation for transport. These samples were taken for 480 minutes during the process.

As stipulated in the harmonised methodology a positive control was included in the measurement protocol. A measured quantity of HHPA and MHHPA was placed in an open container under a fume hood with the suction off. Sampling occurred above this container.

No plant measurement revealed a concentration above the limit of detection of 4 µg/m³. The positive control revealed a concentration of 22 – 28 µg/m³ HHPA and 29 – 31 µg/m³ of MHHPA.

Plant B

Plant B operates a process with HHPA and MHHPA. Within plant B personal as well as static samples were collected using a method that is similar to the harmonised method. Three operations were measured: materials handling, mixing, and reactor operation. The measurements were not encompassing a full shift and were therefore accompanied by an analysis developed together with the plant management to ascertain the exposure during a full 8 hour shift.

Table 2 Exposure and frequency of three critical steps in plant B. * This indicates the number of times this step is done per year in this plant.

Task	Times per year*	Type	Duration (min)	HHPA (µg/m³)	MHHPA (µg/m³)	Extrapolated 8-hour average exposure to anhydrides (µg/m³)
Materials handling	6 – 7	Personal	290	2.5	2.5	3.0
		Static	290	2.0	1.7	2.2
		Static	290	3.5	4.1	4.6
Mixing	2 – 3	Personal	70	4.4	4.2	1.2
		Static	70	3.8	3.5	1.0
		Static	70	3.6	< 3.9	< 1.1
Reactor Operation	5 – 6	Personal	85	2.5	< 2.7	< 0.9
		Static	85	3.5	< 3.0	< 1.1
		Static	85	3.5	< 2.9	< 1.0

Plant C

Plant C operates a process with HHPA and MHHPA. Within plant C personal as well as static samples were collected using a method that is similar to the harmonised method. In this plant the material is handled in 5 different loading/unloading locations after/before which a closed process without exposure occurs. The measurements were not encompassing a full shift and were therefore accompanied by an analysis developed together with the plant management to ascertain the exposure during a full 8 hour shift.

Table 3 Exposure and frequency of five critical steps in plant C. * This indicates the number of times this step is done per year in this plant.

Task	Times per year*	Type	Duration (min)	HHPA (µg/m³)	MHHPA (µg/m³)	Extrapolated 8-hour average exposure to anhydrides (µg/m³)
Loading 1	1 – 2	Personal	100	33.9	33.7	26.5
		Static	100	66.3	61.0	19.2
		Static	100	47.1	45.1	14.1
Loading 2	1 – 2	Personal	100	21.4	16.5	7.9
		Static	100	16.3	18.6	7.3
		Static	100	13.7	16.2	6.2
Unloading 1	1 – 2	Personal	55	21.4	24.3	5.3
		Static	55	19.6	22.9	4.9
		Static	55	17.4	20	4.3
Unloading 2	43	Personal	120	8.5	10	4.6
		Static	120	28.2	34.8	15.8
		Static	120	13.5	14.7	7.1
Unloading 3	1- 2	Personal	400	5.4	6.3	9.7
		Static	400	4.5	4.3	7.3
		Static	400	3.7	3.1	5.6

Plant management has clarified that following the measurements the Loading 1 step has been fully automated and no longer requires a worker to operate. This exposure thus no longer occurs.

Plant Q

Plant Q operates a process with HHPA and MHHPA. Within plant Q personal as well as static samples were collected using the harmonised methodology. Personal samples were collected of operators involved in materials handling and static samples were positioned next to the reactors.

Table 4 Exposure Measurements in plant Q

Operation	Type	Duration (min)	HHPA (µg/m³)	MHHPA (µg/m³)
Materials handling 1	Personal	485	<4	<4
Materials handling 2	Personal	600	<3	<3
Laboratory Analysis	Personal	519	<4	<4
Reactor Operation 1	Static	612	<3	<3
Reactor Operation 2	Static	606	<3	<3
Reactor Operation 3	Static	600	<3	<3

Summary of medical information

Plants A, B, C, D, and Q are operating in this part of the value chain with a total potentially exposed population of 192 workers. In none of these plants there is evidence of occupational asthma related to anhydrides.

Producers of switchgear

35 measurements from four plants were submitted to the consortium manager. Measurements were submitted either in a measurement report, via email, or phone. The latter two options only occurred when the final report was not finished.

Switchgear can be produced using two different processes: Automatic Pressure Gelation (APG) and Vacuum Casting (VC). In the APG process epoxy-anhydride mixture is injected into a closed mould which is heated to initiate the polymerisation reaction (curing). After curing the object is removed from the mould. During VC a mould is placed under vacuum and epoxy-anhydride mixture is poured into the mould and the product is heated to start the polymerisation reaction. These processes are described in more detail in Annex III. These two closed processes are expected to produce similar exposure and are both used to produce switchgear, therefore they are grouped here.

Plant E

Plant E operates a process involving HHPA and MHHPA. A detailed measurement report, performed according to the harmonised method, was shared with the consortium manager. The results include measurements performed on two workers operating different production machinery. As recommended in the measurement methodology two positive controls were included which measured the concentration of anhydrides over an open bucket

Table 5 Exposure Measurements in Plant E

Operation	Type	Duration (min)	HHPA (µg/m³)	MHHPA (µg/m³)
Operator of machine 1	Personal	222	18.4	9.2
Operator of machine 2	Personal	222	20.5	10.5
Positive control	Static	17	125	43.3
Positive control	Static	17	110.8	40.8

Plant G

Plant G operates a process involving MHHPA. A detailed measurement report, performed according to the harmonised method, was shared with the consortium manager. Operators of two machines were measured and two samples were collected on the same individuals.

Table 6 Exposure Measurements in Plant G

Operation	Type	Duration (min)	MHHPA (µg/m³)
Operator of machine 1 Sample 1	Personal	270	20.1
Operator of machine 1 Sample 2	Personal	270	20.9
Operator of machine 2 Sample 1	Personal	258	60.7
Operator of machine 2 Sample 2	Personal	258	69.2
Positive Control 1	Static	15	4900
Positive Control 2	Static	15	4400

Plant M

Plant M operates a process involving HHPA and MHHPA. A measurement report was submitted that was created using the harmonised method. Here

measurements were taken during different process steps: flooding of the mould and opening of the mould. The step in between these two steps the curing of the mixture was not measured. An additional static measurement was performed on the tank containing anhydride.

Table 7 Exposure Measurements in Plant M

Operation	Type	Duration (min)	HHPA (µg/m³)	MHHPA (µg/m³)
Flooding of moulds	Personal	330	<5	30.6
Opening of moulds	Personal	330	6	47.9
On tank	Static	330	<5	48.2

Plant O

Plant O operates a process involving HHPA. Preliminary results generated with the harmonised method were shared with the consortium manger. Here a large number of samples were taken on two subsequent days. All measurements are full shift measurements.

Table 8 Exposure Measurements in Plant O

Operation	Day	Type	HHPA (µg/m³)
Machine 1 Operator 1 Sample 1	1	Personal	16.2
Machine 1 Operator 1 Sample 2	1	Personal	17.8
Machine 1 Operator 2 Sample 1	1	Personal	4.6
Machine 1 Operator 2 Sample 2	1	Personal	6.2
Machine 2 Operator 3 Sample 1	1	Personal	19.7
Machine 2 Operator 3 Sample 2	1	Personal	22.4
Machine 2 Operator 4 Sample 1	2	Personal	28.3
Machine 2 Operator 4 Sample 2	2	Personal	18.4
Quality Control Sample 1	1	Personal	7.7
Quality Control Sample 2	1	Personal	7.4
Team Leader Sample 1	1	Personal	10
Team Leader Sample 2	1	Personal	11.1
Team Leader Sample 3	2	Personal	8.2
Measurements at potential emission sources			
Above basin that contained residual mixture from the night before	2	Static	15.3
Above barrel that collects residual mixture from fresh preparations (with breakthrough of sample)	2	Static	543
Exhaust air above Machine 6 (Dysfunctional LEV & Breakthrough of sample)	2	Static	305
Next to Oven	2	Static	39.9
Framework Measurements			
Office in separate building	1	Static	<0.12
Positive control	1	Static	27000
Epoxy shop hall	2	Static	12.6

Summary of medical information

Plants E, F, G, M, O, R, S, T, and V are operating in this part of the value chain with a total potentially exposed population of 74 workers. In none of these plants there is evidence of occupational asthma related to anhydrides.

Producers of high voltage rotating devices

86 measurements from five plants were submitted to the consortium manager. When necessary, additional clarification was sought with the plant management via phone interviews.

High voltage rotating devices are manufactured with a process called vacuum pressure impregnation (VPI). During a VPI process

1. a device is placed in an impregnation chamber;
2. the chamber is placed under vacuum to remove moisture;
3. the device is flooded with epoxy-anhydride mixture;
4. the impregnation chamber is put under high pressure to force the epoxy anhydride mixture into the insulation of the copper windings thus impregnating the device;
5. the pressure is lowered and the chamber opened; and
6. the wet device is moved to an oven for curing

This semi-open process is described in annex III. The process steps 5 & 6 are expected to produce the most exposure.

Plant H

Plant H operates a process with MHHPA. An extensive measurement report was submitted that was created using the harmonised method. Within plant H the following process steps occurred in detail during the measurement:

I. Placing the devices to be impregnated into a molding tool
II. Placing the molding tool into an impregnation cart (pan)
III. Transfer of the impregnation cart into the impregnation chamber and closing the impregnation chamber
IV. In the impregnation chamber the following steps occur (VPI-Process):
    a. The device is heated to impregnation temperature
    b. The chamber is placed under vacuum
    c. The device is flooded with epoxy-anhydride mixture
    d. The impregnation chamber is put under pressure to force impregnation
    e. The pressure is lowered and epoxy-anhydride mixture is moved back to reservoir
V. Opening of the chamber and moving out of the impregnation cart (pan)
VI. Transfer of the molding tool from impregnation cart (pan) to curing cart
VII. Transfer of the curing cart into an oven
VIII. Curing of the device in the molding tool at high temperature
IX. Cooling of the device in the oven
X. Movement of the curing cart out of the oven
XI. Removal of the impregnated devices form the molding tool

During the measurement (one shift) the following steps occurred in this sequence:

Table 9 Timing of activities on the day of measurements

t (min)	Activity
0	Start of Measurements • Impregnation chamber is closed in Process step IVc • Oven 1 is closed and empty • Oven 2 is closed and contains a device in process phase VIII • In an adjacent hall step XI is started
205	Opening of oven 2 for cooling (IX); device remains in oven
285	Refilling of the epoxy-anhydride mixture (occurs once per week)
295	Removal of curing cart from oven 2 (X)
345	Opening of the Impregnation chamber. V, VI, and VII are performed.
360	Oven is closed and process stage VIII is started; at the impregnation chamber II and III occur
380	Impregnation chamber is closed and process IV is started

The plant supplied personal measurements of two workers operating in the most critical steps (V, VI and VII), which occur once per shift. These measurements were performed both outside and inside of the mask. The measurements were complemented with 8 hour static measurements. Furthermore two positive control measurements were carried out.

Table 10 Exposure Measurements in Plant H

Operation	Type	Duration (min)	MHHPA (µg/m³)
Opening impregnation chamber Operator 1	Personal (inside of mask)	44	23
Opening impregnation chamber Operator 1	Personal (outside of mask)	45	2538
Opening impregnation chamber Operator 2	Personal (inside of mask)	39	133
Opening impregnation chamber Operator 2	Personal (outside of mask)	39	2069
Location 1 next to impregnation chamber	Static	470	152
Location 2 middle of the hall	Static	470	270
Location 3 next to oven 2	Static	470	284
Positive Control 1	Static	120	142
Positive Control 2	Static	120	147

Furthermore, the plant submitted detailed timed static samples which allow for an analysis of the exposure that occurs during the different process steps.

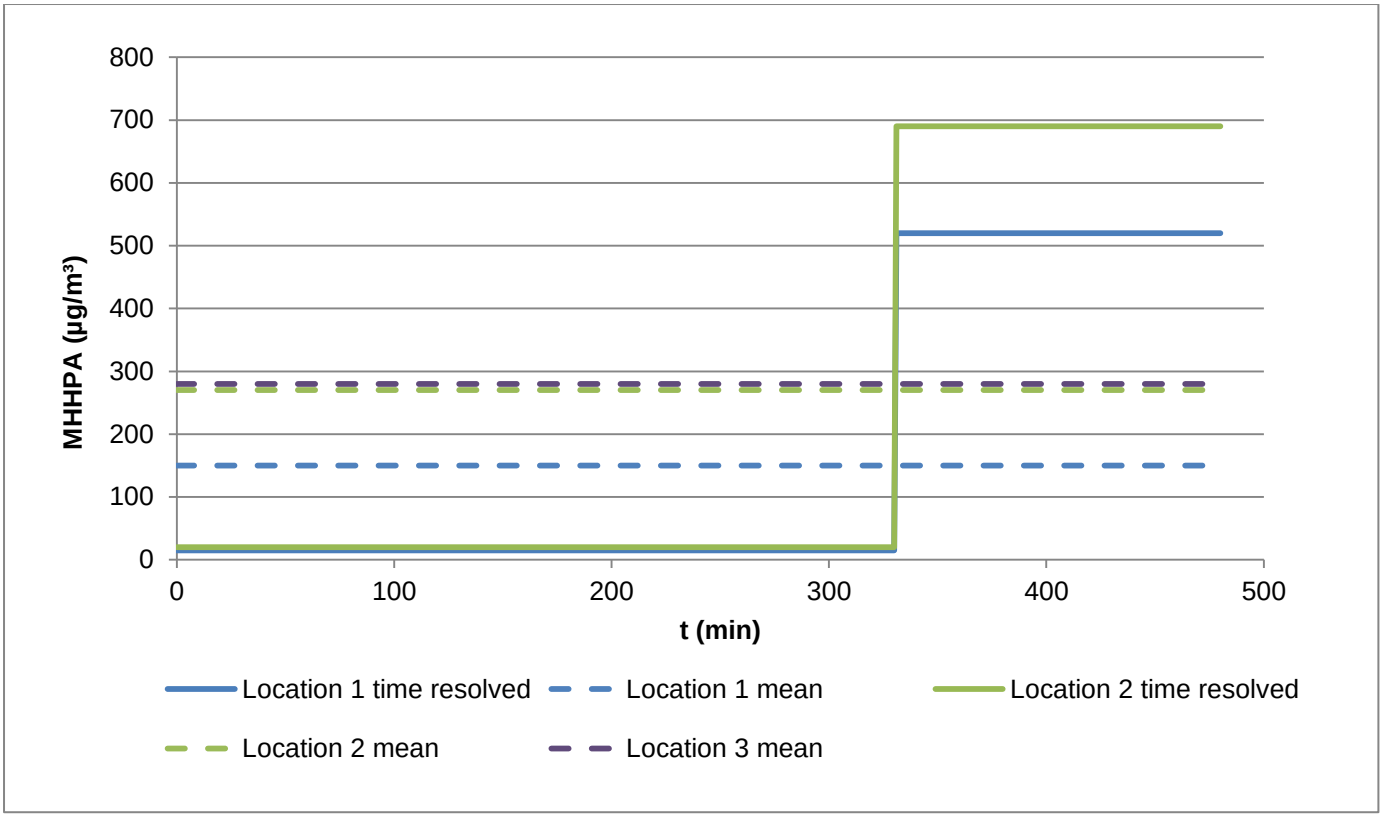

Figure 1 Time series analysis of static samples in plant H. Please note that every horizontal line segment represents one measurement and are thus average concentrations for this period.

One can see that within the plant up until t ≈ 325 exposure is rather limited (12 – 25 µg/m³). Therefore, within this plant it is possible to conclude that exposure from a closed impregnation chamber, from the opening of a finished oven, and the refilling of the epoxy-anhydride mixture is rather low. The critical step in this process is clearly the opening of the impregnation chamber.

Within the plant the following mask is used: 3M M-100 Series face shield (M-106 | M-107) with a 3M Jupiter Powered Air Turbo Unit and AP2R Filters

This combination of face shield and turbo unit is EN 12941 TH2 certified. The nominal protection factor of this combination is thus 50. However, based on the measurements that were performed the protection factor ranged from 15.6 to 110. The lower protection factor can be due to a number of things:

- Improper use of the mask
- The presence of the measuring device

Therefore, it should be possible to achieve a protection factor of 110 if workers are provided with sufficient instructions on how to use the device. Which would result in exposures of around 20 µg/m³ during peak exposure and based on the three static samples an 8-hour time weighted average exposure of between 1.4 – 2.6 µg/m³.

Plant I

Plant I operates a process with MHHPA. Exposure measurements at plant I are based on a pre-existing non-harmonised method as well as new measurements with a modified version of the AJIT methodology to test the efficacy of the used masks.

Table 11 Exposure Measurements in Plant I. * Measurement next to the oven. + Value below the limit of detection.

Operation	Type	Duration (min)	MHHPA (µg/m³)
Working at VPI vessel 1	Personal (outside of mask)	74	3670
Working at VPI vessel 1	Static	150	1700
Working at VPI vessel 1	Static	190	1750
Working at VPI vessel 1	Static	120	2290
Working at VPI vessel 2	Personal (outside of mask)	79	3810
Working at VPI vessel 2	Personal (inside of mask)	79	<40+
Curing in oven* (12:48 – 13:48)	Static	60	750
Curing in oven* (14:00 – 15:00)	Static	60	1310
Curing in oven* (15:08 – 16:08)	Static	60	1610
Curing in oven* (18:38 – 19:56)	Static	78	250
Curing in oven* (04:53 – 6:11)	Static	78	70
Outside of VPI* hall	Static	74	<40+
Outside of VPI* hall	Static	77	<40+

Within the plant the following mask is used:3M Versoflow M-306 Face cover, with 2 A2P R filters, and a Jupiter Turbo Unit (flow rate 150 l/m). This combination of face shield and turbo unit is EN 12941 TH2 certified. The nominal protection factor of this combination is thus 50. Based on the data in the measurement report generated with the non-harmonised method it can be concluded that the protection factor of this mask is >95.

Within the plant another test was performed with a modified version of the harmonised method (air flow rate was set to 150 l/m), which demonstrated that the mask is capable of reducing an exposure of 2250 µg/m³ to 5 µg/m³ thus providing an protection factor of 450, 9 times greater that for what the device is certified.

Plant J

Plant J operates a process involving HHPA. It submitted measurements to the public consultation report generated by a non-harmonised method and since then has submitted detailed measurement reports from 2002, 2005, 2007, 2011, 2012, 2014, and 2015.

Initial measurements were performed in 2002.

Table 12 Exposure measured in Plant J in 2002

Operation	Type	Duration (min)	HHPA (µg/m³)
Peak exposure operation, worker 1	Personal	60	13
Peak exposure operation, worker 2	Personal	60	21
Peak exposure operation	Static	60	13
Adjoining hall during peak exposure operation	Static	60	1.6

At the time there was no exposure limit, however it was advised that a limit of 10 µg/m³ should be strived for. Furthermore, it is noted that the current exposure is peak exposure and that this should be averaged over the full 8-hour shift. It recommended to implement complementary measures.

After improvements in local exhaust ventilation and better separation of the work hall from the rest of the plant new measurements were taken in 2005.

Table 13 Exposure measured in Plant J in 2005

Operation	Type	Duration (min)	HHPA (µg/m³)
Pre-peak exposure operation, worker 1	Personal	138	10.9
Peak exposure operation, worker 1	Personal	25	32.0
Measurement at the control panel	Static	144	6.9
Measurement at the control panel	Static	222	4.5
Measurement at the control panel	Static	290	5.2
Adjoining hall during peak exposure operation	Static	166	<0.7

The separation of the work hall was shown to be effective. The peak worker exposure was higher, however, it was noted that the operation lasted shorter than normal and therefore the exposure during the most critical steps was not averaged out of the measurement. The measurement report recommended the use of powered respirators.

A separate control room was built which is supplied with outside air. To investigate its effectiveness in reducing exposure measurements were performed in 2007. The use of powered respirators was implemented.

Table 14 Exposure measured in Plant J in 2007.* Calculated based on nominal protection factor.

Operation	Type	Duration (min)	HHPA (µg/m³)	HHPA in mask* (µg/m³)
Peak exposure operation	Personal	62	63	1.26
Measurement in control room during peak exposure	Static	68	1.5	

The effectiveness of the control room was confirmed as the exposure was reduced compared to that previously experienced at the control panel and reduced compared to the personal measurement taken in 2007.

In 2011 new measurements were taken as a result of upcoming national legislation in the form of a limit value.

Table 15 Exposure measured in Plant J in 2011.* Calculated based on nominal protection factor.

Operation	Type	Duration (min)	HHPA (µg/m³)	HHPA in mask* (µg/m³)
Material handling	Personal	43	3.8	0.076
Full shift including opening of the impregnation chamber	Personal	300	10	0.2
Control room	Static	315	2.1	

It was noted that there is a steady deterioration in the exposure observed in the control room and measures were advised. Furthermore, the use of masks during the key steps was recommended.

In 2012 two rounds of measurements were performed. The second round was performed as in the first round the sampling tube for the full shift sample was broken and to check the effectiveness of the improved control room.

Table 16 Exposure measured in Plant J in 2012.* Calculated based on nominal protection factor.

Operation	Type	Duration (min)	HHPA (µg/m³)	HHPA in mask* (µg/m³)
Material handling	Personal	50	3.8	0.076
Peak exposure	Personal	22	29	0.58
Control room	Static	498	1.5	
On an overhead crane	Static	36	1.4	
2 – 3 meters from impregnation chamber at 1.4 m height	Static	60	23.8	
Full shift (round 2)	Personal	310	1	0.02
Control room (round 2)	Static	56	0.3	

The report of the first round noted that the following could reduce exposure: specific engineering controls should be developed for the critical steps of the process (e.g. local exhaust ventilation, isolation of process from workers), exposure time reduction, the use of mask (which was already implemented), and improvements in the control room.

During the second round exposure in the control room was reduced to 0.3 which probably helped to reduce the full shift exposure to the level of 1 µg/m³.

In 2014 a round of measurements were performed.

Table 17 Exposure measured in Plant J in 2014.* Calculated based on nominal protection factor.

Operation	Type	Duration (min)	HHPA (µg/m³)	HHPA in mask* (µg/m³)
Full shift	Personal	379	11	0.22
Full shift	Personal	376	8.3	0.166
Control room	Static	345	2.4	

A noticeable increase in exposure was observed. Especially in the control room exposure was considered to be too high as here exposure should be kept close to zero. The recommendation was to periodically inspect the ventilation system.

In 2015 a new work protocol was established which limited the amount of time workers typically work in different areas (total 4 hours per workday). These areas were sampled for the level of HHPA.

Table 18 Exposure measured in Plant J in 2015.* Calculated based on nominal protection factor.

Operation	Type	Duration (min)	HHPA (µg/m³)	HHPA in mask* (µg/m³)
Location 1 after 1 hour	Static	60	3.9	0.078
Location 2 between 1 - 2 hours	Static	60	6.2	0.124
Location 3 between 2 - 3 hour	Static	60	11.2	0.226
Location 4 between 3 - 4 hours	Static	60	8.2	0.164

The mask that is used in plant J is the ProFlow SC with a FH31 Faceshield and PRO2000 CF22 A2B2-P3/PSL R filter. This combination of blower and headpiece is CE certified to EN12941 TH2, meaning that it offers a calculated protection factor of 50.

Plant L

Plant L operates a process with MHHPA. The plant has measured the concentration of anhydrides in 2002, 2007, 2012, 2014, February 2015, and December 2015 using the same non-harmonised method. Each time the purpose of the measurements was different and the level of detail was heterogeneous.

Plant L has two VPI halls: Hall A and Hall B both constructed during the 90's. Both halls have seen considerable improvements in operating conditions and risk management measures.

Table 19 Measurements in Plant L in 2002

Location	Day	MHHPA (µg/m³)
Hall A General Air	17-9-2002	4270
Hall A General Air	8-10-2002	140
Hall A General Air	15-10-2002	37
Hall A General Air – during the opening of the impregnation chamber	17-9-2002	>37000
Hall A Control Room	8-10-2002	17
Hall B General Air	17-9-2002	120
Hall B General Air	8-10-2002	440
Hall B General Air – during the opening of the impregnation chamber	17-9-2002	1120
Hall B General Air – during the opening of the impregnation chamber	15-10-2002	940
Hall B Control Room	15-10-2002	8

As a result of these measurements the plant implemented improvements such as the pressurisation of the VPI halls, more exacting PPE instructions, and informative meetings with employees.

In 2007 a test was performed of the plants emission to air. Due to high values the plant developed scrubbers which were tested in 2012. These tests protocol measured the concentration in the stack before the scrubber, in the stack after the scrubber and at the top of the stack (see Figure 2). The effectiveness of this scrubber was between 82 and 99% and thus deemed sufficiently effective.

During the 2012 measurements the control and break room were measured as well. The concentrations were measured to be 5 and 4 µg/m³, respectively.

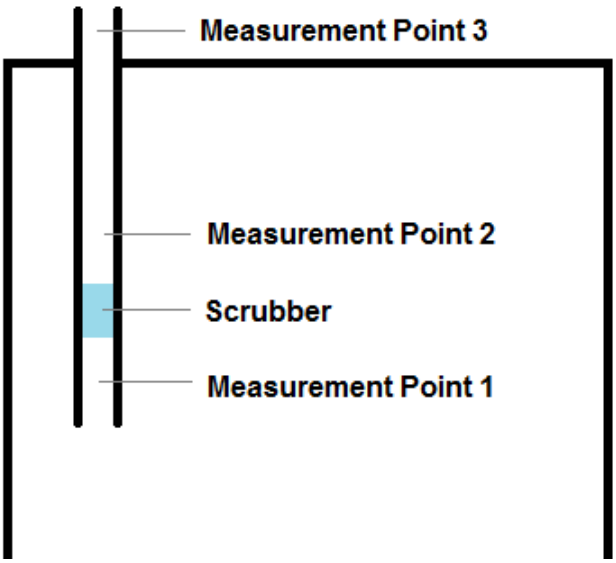

Figure 2 Schematic Diagram of the test to ascertain the effectiveness of the emission scrubber.

In December 2015 in both Hall A and Hall B measurements were carried out of the impregnation step and of the oven curing step. All samples were static samples.

Table 20 Measurements in Plant L in 2015. * Calculated based on nominal protection factor.

Hall	Operation	Duration (min)	MHHPA (µg/m³)	MHHPA in Mask* (µg/m³)
A	Impregnation reference location	115	410	0.82
	Impregnation right after opening of the chamber	18	670	1.34
	Impregnation Control Room	123	1.3	
	Impregnation Break Room	123	<0.2	
	Oven Opening	27	17	0.034
	Oven Opening Control Room	111	0.7	
B	Impregnation reference location	60	270	0.54
	Impregnation right after opening of the chamber	16	1500	3

Hall	Operation	Duration (min)	MHHPA (µg/m³)	MHHPA in Mask* (µg/m³)
	Impregnation Control Room	126	1.4	
	Impregnation Break Room	134	3.7	
	Impregnation Winding Area (outside of VPI hall)	135	1.8	
	Oven Opening	55	150	0.3
	Oven Opening Control Room	91	8.3	
	Oven Opening Packaging and Shipping (outside of VPI hall)	102	1.3	
	Oven Opening Packaging and Shipping (Door opened two times)	45	7.6	
	Oven Opening Winding Area(outside of VPI hall)	105	1.5	

Within the plant the following respirator is used: Proflow EX turbo unit and FM4 headtop is combined with Pro2000 CF22 A2-P3 PSL R filter. This respirator is certified under EN 12942 TM3 and has a calculated protection factor of 2000.

In plant L significant improvements in operating conditions and risk management measures have been made. If we compare the exposure measured in 2002 with the one measured in 2015 we can see drastic decreases in measured exposure in Hall A and reasonable decreases in Hall B (see Table 21).

Table 21 Comparison of exposure. * Bases on calculated protection factor. + This value might be due to longer sampling times in 2002 resulting in a lower average and the 2015 measurement was taken right next to the impregnation chamber.

Operation Identifier (2002)	Operation Identifier (2015)	MHHPA 2002 (µg/m³)	MHHPA 2015 (in mask*) (µg/m³)	Improvement Factor
Hall A General Air	Impregnation reference location	4270	410 (0.21)	11.5
Hall A General Air – during the opening of the impregnation chamber	Impregnation right after opening of the chamber	>37000	670 (0.34)	>55
Hall A Control Room	Impregnation Control Room	17	1.3	13.1
Hall B General Air	Impregnation reference location	440	270 (0.14)	1.6
Hall B General Air – during the opening of the impregnation chamber	Impregnation right after opening of the chamber	1120	1500 (0.75)	0.75+
Hall B Control Room	Impregnation Control Room	8	1.4	5.7

Plant P

Plant P operates a process with MHHPA. It submitted preliminary measurements performed according to the harmonised methodology. The measurements were personal measurements of two workers operating in a VPI plant. Their activities were described in the measurement report:

Activities of operators during the measurement from 9:04 till 10:10

- Opening of the vertical impregnation chamber
- Attaching the devices to the hall crane
- Removing by crane the devices and moving them to the washing location
- At the washing location the device remains attached to the crane
- Removal of epoxy-anhydride mixture from certain location of the device using detergent and air pressure
- Transport by crane of device to oven cart
- Placing of the device on the oven cart
- Final check of device and closing of the oven door

Activities of operators during the measurement from 13:54 till 15:10

- Simulating the reloading of the oven (13:56 – 14:02)
    - Opening of the oven door, removing the oven cart with the device
    - Linger outside, normally the device would now be reloaded
    - Placing the oven chart with the same device back into the oven
- Half opening of the impregnation vessel to allow for the reduction of vapours, followed by fully opening the chamber to and attaching the hall crane connectors
- Transport to washing location
- Placing of the device on wood block and disconnecting the crane
- Cleaning epoxy-hardener mixture from certain locations of the device
- Connection of the crane and transport to oven cart
- Final check, placing in the oven, and closing the oven door

Furthermore two positive control measurements were carried out.

Table 22 Exposure in plant P. Values for the mask are indicative of the exposure that would be experienced when using these masks for the entire duration of the measurement period. Half mask according to the HSE Guidance protection factor and full mask according to the nominal protection factor specified in standard BS EN 12941.

Operation	Type	Duration (min)	MHHPA (µg/m³)	Half Mask (µg/m³)	Full Mask (µg/m³)
VPI Operator 1	Personal	142	234	23.4	4.68
VPI Operator 2	Personal	142	218	21.8	4.36
Positive Control	Static	17	8400		
Positive Control	Static	17	10000		

During most operations a 3M 6200 Reusable half mask respirators with 3M 6055 A2 filter (applicable standards BS EN 140 and BS 3; BS EN 405; BS EN 1827) is used and during steps where the devices are washed MSA OptimAir® 3000 Powered Respirators (applicable standards BS EN 12941) with appropriate filter

is used. The UK Health Safety and Environment has assigned the protection factor of 10 to the former and 20 to the latter mask. The relevant standard specifies that a nominal protection factor of 50 can be reached with the MSA OptimAir 3000. The actual protection factor of these masks for anhydrides is being investigated.

Summary of medical information

Plants H, I, J, K, L, P, and U are operating in this part of the value chain with a total potentially exposed population of 99 workers. Only in plant L there is evidence that occupational asthma has occurred. In this plant 4 cases could be identified which occurred in 2004, 2005, 2006, and 2010. In two of these cases the workers had a severe atopic condition and might have developed asthma irrespective of whether they had anhydrides exposure or not. The other two workers were removed from exposure which caused the symptoms to dissipate.

Other use

One other use for anhydrides has been identified which will be communicated in a separate confidential report, as it occurs in just one company in the EU.

5. Conclusions and Discussion

Producers/formulators

Within the premises of manufacturers/formulators only one plant showed exposure above 5 µg/m³. Within this plant personal 8-hours exposure ranged from 4.6 - 26.5 µg/m³. Since these measurements were taken, the operator of the plant has fully automated the highest exposure step, which thus reduces the exposures experienced in the plant to 4.6 – 9.7 µg/m³. Such improvements highlight the fact that exposure reduction in feasible.

Producers of switchgear

The plants producing switchgear seem to be operating with exposures ranging from 4.6 – 69.2 µg/m³.

Table 23 Exposure experienced in plants producing switchgear. The ranges were generated by reviewing personal exposure measurements

Plant	Range HHPA (µg/m³)	Range MHHPA (µg/m³)
E	18.4 – 20.5	9.2 – 10.5
G	-	20.1 – 69.2
M	<5 – 6	30.6 – 48.2
O	4.6 – 28.3	-

In a phone interview the operator of plant G declared to be planning to implement improved risk management measures with the aim of reaching a level of 10 µg/m³. He stated that he was confident that such a level should be attainable.

The operator of Plant O has clarified that they are, based on the measurements performed, planning to implement improvements in risk management measures to reduce the exposure observed in their plant. The mentioned options for improvements include:

- Closing of purge buckets (buckets into which superfluous epoxy-anhydride mixture flows from the machines)
- Additional exhaust systems

Furthermore, given the variation in different measured values it seems that an exchange of best practices could improve the level of exposure considerably.

Producers of High Voltage Rotating Devices

Exposures observed in the production of High Voltage Rotating Devices are typically the highest of all processes (see Table 24), due to the semi-open nature of the process. Measurements in various plants show that the opening of the impregnation chamber and the transport of the impregnated device to an oven is the most critical step.

Table 24 Typical and Peak Exposure in plants producing High Voltage Rotating Devices.

Plant	Typical Exposure HHPA (µg/m³)	Typical Exposure MHHPA (µg/m³)	Peak HHPA (µg/m³)	Peak MHHPA (µg/m³)	Maximum Anhydrides in Mask (µg/m³)
H	NU	152 – 284[a]	NU	2538	23 - 133[b]*
I	NU	NM	NU	3670	5*
J	3 – 7.1	NU	22	NM	0.44[+]
L (Hall A)	NU	<0.2 – 1.3[c]	NU	17 – 670	< 0.34[+]
L (Hall B)	NU	1.4 – 8.3[c]	NU	150 – 270	< 0.14[+]
P	NU	218 – 234	NU	NM	4.68 - 4.36[a+]

NU = Not Used; NM = Not Measured. a) 8-hours measurements. b) 133 is probably due to inappropriate use of the mask. c) Typical exposure for workers of plant L is the exposure observed in the control room as workers are in the typically only in the VPI hall for 2 hours per day. *) measured concentration [+]) calculated concentration

Several plants performing vacuum pressure impregnation have implemented risk management measures and have measurements proving their effectiveness. These measures include:

- Improving the separation of the workers from the process
  - Under pressure work halls
  - Over pressure control rooms
- Scrubbers to prevent exposure from exhausts in different parts of the plant
- Improvements in Local Exhaust Ventilation
- Exposure time reduction
- Personal protective equipment

Respiratory Protective Equipment

Although all the above measures are possible solutions for improving the exposure of workers to anhydrides, one is of particular importance due to the speed at which it can be implemented: Respiratory Protective Equipment (RPE).

Currently, there is little harmonisation in the type and level of RPE. The relevant standards for RPE that could be used are EN 12941 and EN 12942.

Table 25 Respiratory Protective Equipment. Calculated protection factors are derived from the first table in both standards based on the maximum tolerated inward leakage requirements for certification.

Standard	Level	Calculated Protection Factor
EN 12941	TH1	10
	TH2	50
	TH3	500
EN 12942	TM1	20
	TM2	200
	TM3	2000

Currently two of the reporting plants are using RPE certified under EN 12941 TH2 which should provide a minimal protection factor of 50. Measurements of 3M M-100 Series face shield (M-106 | M-107) with a 3M Jupiter Powered Air Turbo Unit and AP2R Filters show that this RPE with this certification can reach a protection factor of 110 - 450 and indicate that these protection factors can be conservative.

Depending on the protection factor of RPE that should be used during peak exposure, peak exposures can be reduced to the values given in Table 26 calculated for the different plants. A voluntary commitment and/or update of exposure scenario annexes of the suppliers' safety data sheets can enforce the selection of RPE."

Table 26 Peak Exposure Scenarios. In µg/m³

Plant	No RPE	TH1	TH2	TH3	TM1	TM2	TM3
H	2538	253.80	50.76	5.08	126.90	12.69	1.27
I	3670	367.00	73.40	7.34	183.50	18.35	1.84
J	22	2.20	0.44	0.04	1.10	0.11	0.01
L (Hall A)	670	67.00	13.40	1.34	33.50	3.35	0.34
L (Hall B)	270	27.00	5.40	0.54	13.50	1.35	0.14

Scientific Evidence Review

Within literature there are 5 studies that report on a dose response relationship between exposure to HHPA and/or MHHPA and respiratory sensitisation (see Table 27).

Table 27 Reported exposure-response in literature. * mean (range). + n=5 therefore not reliable

Study	Substance	Exposure (µg/m³)	Sensitisation
Welinder et al. (1994) (2)	HHPA	0	0%
		<10 (without Intermittent peak exposure)	0%
		<10 (with Intermittent peak exposure)	26%
		10 – 50	34%
		>50	19%
Welinder et al. (2001) (1)	HHPA, MHHPA, and another acid anhydride	0-5	5%
		5 – 10	10%
		10 – 15	15%
		>15	25%
Nielsen et al. (2001) (4)	HHPA	<10	13%
		10 – 50	26%
		>50	21%
	MHHPA	<10	15%
		10 - 50	26%
		>50	17%
Rosqvist et al. (2003) (3)	HHPA	<1	5.7%
		1 - 3	18.9 %
		3-9	25.0%
		>9	28.6%
	MHHPA	<1	24.2%
		1-3	9.1%
		1-15	20%
		>15	23.7%
Yokota (2002) (5)	HHPA	33.0 (24.0 - 62.4)*	19%
		12.0 (4.6 - 25)*	36%
		3.8 (1.9 - 7.0)*	20%+

Discussion

The first 4 publications in Table 27 were developed by authors of the Department of Occupational and Environmental Medicine, University Hospital, Lund, Sweden. This is the institute that developed the measurement methodology that is being used in one of the plants. At the time in which most of their studies were published using this measurement methodology they measured a peak exposure during a vacuum pressure impregnation process in the range of 20 µg/m³, which is around one to two orders of magnitude lower than the values reported for the same process using different methodologies.

This makes it difficult to correlate current findings with those reported in the literature, certainly in the first four publications. To clarify these differences contact has been initiated with the Department of Occupational and Environmental Medicine, University Hospital, Lund, Sweden.

Furthermore, measurements in the mentioned plant are scheduled in mid-August with the AJIT harmonised measurement methodology to further clarify the differences. The AJIT expects that the measured values will be higher with the harmonised methodology[3].

Limit Values

As mentioned in the public consultation report there are a number of limit values currently being discussed/implemented in different member states.

Health Council of the Netherlands

The Health Council of the Netherlands has performed a dose response curve fitting (6) based on the data developed by Rosqvist et al. (2003) (3) and calculated a concentration at which 10% of the population would be sensitised (0.73 µg HHPA/m³). This level was then divided by 10 and by 100 to determine a concentration at which 1 and 0.1% of the population would become sensitized to arrive at levels of 0.073 and 0.0073 µg HHPA/m³.

Firstly, it should be noted that the exposure in the measured plant was decreased significantly in the years preceding the study (50% for HHPA and 80% for MHHPA), thus raising the problem of "residual sensitisation", i.e. sensitisation incurred when exposure was much higher.

Secondly, it should be noted that in the study by Rosqvist et al. workers were classified in exposure groups based on the concentration of total plasma protein adducts (TPPA). It is unclear how it was determined that a certain level of TPPA correspond to the exposure figures expressed in µg/m³. The study that is referred to correlates the level of TPPA for HHPA and MHHPA to urine metabolite excretion (7). In the discussion of this TPPA-Urine metabolite study a link is developed between the TPPA for MHHPA and exposure by referencing a study that correlated urine metabolites of MHHPA with measured exposure (8). No such link was given for HHPA. Furthermore, even with this combined body of literature, it was not possible for AJIT experts to reproduce the MHHPA air levels corresponding to the levels of TPPA of MHHPA reported in Table 1 of Rosqvist et al (summarised in Table 28).

Table 28 Levels of TPPA and their corresponding exposure according to Rosqvist et al. (3)

HHPA		MHHPA	
TPPA of HHPA	Corresponding air levels	TPPA of MHHPA	Corresponding air levels
<40 fmol/ml	<1 µg/m³	<100 fmol/ml	<1 µg/m³
40 – 100 fmol/ml	1 – 3 µg/m³	100 – 300 fmol/ml	1 – 3 µg/m³
100 – 300 fmol/ml	3 – 9 µg/m³	300 – 1500 fmol/ml	3 – 15 µg/m³
>300 fmol/ml	>9 µg/m³	> 1500 fmol/ml	>15 µg/m³

[3] A measurement report of another anhydride (not HHPA/MHHPA) previously reported in the public consultation report showed that anhydride concentrations were below the limit of detection, while in the same plant in the same process new measurements following the harmonised methodology showed concentrations 1 order of magnitude above the detection limit of the previously used method.

Lastly, the reported data conflicts in the adverse effect outcome of other studies (see Table 27). For example Welinder et al. demonstrated with direct measurements that: if no intermittent peak exposure occurs, a level below 10 µg/m³ does not lead to sensitisation.

Therefore, the data used to derive the proposed level would need critical review. Furthermore, implementation of either of these values would result in a situation which would be unenforceable as there is no method currently available able to detect these low values.

The American Conference of Governmental Industrial Hygienists (ACGIH)

A thorough evidence review was conducted by the ACGIH. Based on the evidence provided by Welinder et al. (1994) that showed that when there is less than 10 µg/m³ exposure without intermittent peaks no sensitisation occurs, it recommended that a short term Occupational Exposure Limit (OEL) for HHPA of 5 µg/m³ should be applied.

Limit values in literature

Welinder et al. (1994) stated:

The results of this investigation suggest that permissible average exposure levels for HHPA should not be above 10-20 µg/m³ and that short time peak exposures may have a great impact on the production of IgE antibodies. Thus ceiling values are very important for protection against IgE sensitization. This finding emphasizes a need for good methods for monitoring peak exposures and also places great emphasis on the importance of extensive preventive measures in the work environment.

Nielsen et al. (2001) declared:

Yokota et al proposed that the permissible exposure limit for MTHPA should not exceed 10–20 µg/m³; our data indicate that this limit would prevent symptoms, but not sensitization to HHPA.

There thus seems to be a consensus that there is: a level at which sensitisation occurs and a level at which symptoms develop. These observations concur with the evidence gathered by the AJIT which shows that within the switchgear producing sector there is a similar level of exposure and an absence of cases of occupational asthma.

National Occupational Exposure Limits

Belgium, Canada, Ireland, and Spain have adopted a 5 µg/m³ short term limit value for HHPA, either based on their own assessment or based on the ACGIH recommendation. Finland has adopted an 8-hour time weighted average value for HHPA of 10 µg/m³.

In Sweden the regulation governing limit values specifies no limits of HHPA or MHHPA[4] (9). However, Sweden has initiated a process whereby it is mandatory to apply for a permit to use anhydrides. The regulation governing the application of such a permit furthermore specifies that regular medical examination of the employees should be performed (10, 11).

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[4] Although for MHHPA a "guideline value" of 5 µg/m³ is mentioned in the notes of AFS 2015:7. In AFS 2014:43 a "guidance value" of 5 µg/m³ for a total of all

AJIT Voluntary Commitment

The AJIT does acknowledge that the use of respiratory sensitizers results in the risk of workers developing occupational asthma, which, all AJIT member companies agree, should be prevented.

Therefore the AJIT has agreed to develop a voluntary commitment to manage the risks involved in the use of anhydrides, which aims as a precautionary measure to further minimize risk by decreasing exposure to levels as low as reasonably achievable.

The voluntary commitment will be reinforced through **updates of the registration dossier and the exposure scenario annex of the safety data sheet** that are communicated downstream. Article 39 of REACH imposes on downstream users the requirement of implementing the RMM reported in exposure scenarios within one year after receiving the (extended) safety data sheet, thus ensuring that the entire value chain is covered by the voluntary commitment.

The exact content of the voluntary commitment will be determined by the AJIT, which will also develop guidance and advice on best practice for the members in order to enable them to reduce exposure to acceptable levels.

The AJIT believes this to be the best risk management option to prevent adverse health effects related to the use of anhydrides.

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7. Disclaimer

This work is based on the input provided by the members of the Anhydrides Joint Industry Taskforce. Information presented in this document is to the best knowledge of the Anhydrides Joint Industry Taskforce correct and valid for industry.

The Anhydrides Joint Industry Taskforce and its project manager Polymer Comply Europe do not accept any liability resulting from any of this data being proven incorrect.

Annex I List of AJIT Members

Polynt	Polynt
Hitachi Chemical Working On Wonders	Hitachi Chemical Europe
Dixie Chemical The Element of Open Innovation	Dixie Chemical represented by REACH-Chemadvice
New Japan Chemical Co., Ltd.	New Japan Chemical represented by Envigo
HEXION	Hexion
ELANTAS Electrical Insulation	ELANTAS Europe
HUNTSMAN Enriching lives through innovation	Huntsman
ABB	ABB
Schneider Electric	Schneider-Electric
EPOXONIC® innovative epoxies	EPOXONIC
SIEMENS	Siemens

Veneta Isolatori

Andritz Hydro

DIAB International

VEM Sachsenwerk

ELIN Motoren GmbH

DRIESCHER WEGBERG

Aditya Birla Chemicals (Europe)

I.S.E.P.

BRUSH HMA

MGC Moser - Glaser

Solid Cure

Participatory Sponsors:

T&D Europe

CEMEP

Annex II Medical Data per Plant

Plant A

In plant A a closed process involving HHPA and MHHPA occurs. The owner of plant A has provided a statement from the Company doctor performing the medical investigation.

30 workers are operating in this plant that could be potentially exposed to Anhydrides.

The employees of this plant are checked on a yearly basis for respiratory symptoms by, amongst other things, spirometry. If the medical professional has any reason to believe a worker has been sensitised the worker is sent to a specialist tertiary care facility for further evaluation.

Currently no cases of occupational asthma have been diagnosed at this plant.

Plant B

In plant B a closed process involving HHPA and MHHPA occurs. Information provided was a detailed medical statement from the doctor providing the annual medical check-ups.

32 workers are operating in this plant that could be potentially exposed to Anhydrides.

Employees receive yearly medical check-ups which include:

- Anamnesis
- Physical examination
- Spirometry
- Blood analysis (blood count, liver values, kidney values)
- Urine analysis (Combur-test)
- Skin examination (for possible allergic contact symptoms)
- Questions regarding possible allergic symptoms

The above examinations have in the past 21 years not led to a diagnosis of occupational asthma related to anhydrides.

Plant C

In plant C a closed process involving HHPA and MHHPA occurs. Information provided was a detailed medical statement.

84 workers are operating in this plant that could be potentially exposed to Anhydrides.

Workers in this plant undergo regular medical examinations. The examinations include:

- **Anamnesis**, consisting of medical interviews with physician(s), using general and focused questions. In this phase questions are raised related to a possible sensitisation to different substances, including anhydrides. Focused questions are targeting, in particular, the respiratory system (lower and upper airways), dermatological and neurological system;
- **Physical Medical examination**, using general and focused approach, depending on the presumptions collected in the anamnesis;
- **Lab tests**, as full blood count, glycemic level, hepatic function (GGT, PA, GPT, GOT), renal-urinary function (Urea, Creatinine, urinary sediment);
- **Functional exploring tests** question pulmonary (spirometry and peak-flow), hearing and sight functions.

Results are logged in an electronic patient database, which was used for the retrospective study. The algorithms used were:

- Occupational asthma (evidence: FEV1/FVC<0.70, positive medical interrogatory, positive occupational history and serial medical examinations; +/- seek for medical expert evidence);
- Occupational Rhinitis (evidence: positive medical interrogatory, positive occupational history and serial medical examinations; +/- seek for medical expert evidence);

Of the analysis of a cohort of 84 individuals some cases of respiratory disease were further examined, however no clear role of anhydrides could be identified in the disease's pathogenesis.

Plant D

Within plant D HHPA and MHHPA are being used closed process. Information provided was a medical statement.

13 workers are operating in this plant that could be potentially exposed to Anhydrides.

Employees receive yearly medical check-ups which include:

- Anamnesis
- Physical examination
- Spirometry
- Blood analysis (blood count, liver values)
- Urine analysis

No cases of occupational asthma have been detected.

Plant E

Within Plant E 6 workers are employed in a closed process occurs involving HHPA and MHHPA. Limited medical information was provided.

Reports from on-site doctors report that they are not aware of any respiratory health problems in workers.

Plant F

Within Plant F a closed process occurs involving HHPA and MHHPA in which 6 people are directly involved. Information provided includes a response to the retrospective study and a detailed report by their medical insurance company.

Response to the retrospective questionnaire stated that the company had been performing medical surveillance since its inception because this is mandatory by local legislation. They perform yearly check-ups of the personnel. The standard procedure is to refer a worker with even the slightest indication of respiratory symptoms to a tertiary specialist care centre. The submitted detailed report for the period 2009 – 2014 stated that no respiratory symptoms occurred during this period.

Plant G

Within Plant G a closed process occurs involving HHPA and MHHPA. Medical information was provided on their workers.

4 workers are operating in this plant that could be potentially exposed to Anhydrides.

Details submitted included gender, age, period of employment, and any relevant symptoms. One of their 4 workers was identified as an "allergy sufferer" that experienced no change in his condition when at or away from work. Therefore there is no indication that there is any occupational asthma among the four workers that have each worked in the plant for over 10 years (range 10 – 24).

Plant H

Within Plant H a semi-open process occurs involving MHHPA. The results of the implementation of the Medical Diagnostic Guideline (i.e. prospective study) were submitted.

10 workers were enrolled in the prospective study. The participation rate was 100%. None of the workers presented with symptoms of rhinitis or respiratory issues that get better during periods away from work. Therefore it was concluded that there is no evidence of occupational asthma.

Plant I

Plant I is performing a semi-open process. A response to the industry consultation included some medical details.

41 workers are operating in this plant that could be potentially exposed to Anhydrides.

The company to which this plant belongs submitted a response to the industry consultation. 4 employees out of a population of 41 presented with allergic reactions over the past 10 years. HHPA or MHHPA could not be identified as the root cause.

Plant J

Plant J is performing a semi-open process. Medical data were reported during the initial industry consultation.

4 workers are operating in this plant that could be potentially exposed to Anhydrides.

Medical data is kept by a third party health services provider. The following symptoms are checked:

- Asthma
- Ocular inflammation
- Eczema
- Rhinitis
- Other symptoms

The plant reports no adverse health effects related to the use of anhydrides.

Plant K

Plant K is performing a semi-open process. A response to the retrospective medical study was provided.

4 workers are operating in this plant that could be potentially exposed to Anhydrides.

In this plant regular medical checks are required by law. Respiratory symptoms are regularly checked. Examinations by specialists are performed if there is a hint of respiratory problems. This approach has not led to the diagnosis of occupational asthma since 2010 (the year medical examination begun).

Plant L

Plant L is performing a semi-open process. A response to the retrospective medical study was provided. As this response indicated that there were cases of Occupational Asthma related to Anhydrides, follow up interviews were undertaken with the: plant management, HSE responsible, and Medical Doctor.

19 workers are operating in this plant that could be potentially exposed to Anhydrides.

Yearly medical check-ups until 2014 included an interview to ascertain if there were any symptoms of respiratory disease, every other years the check-up contains also spirometry and clinical examination. If respiratory symptoms were identified a sIgE test for all respiratory sensitizers that the worker was exposed to would be performed together with other respiratory tests to determine if occupational asthma related to anhydrides has occurred. Post 2014 this approach is complemented with sIgE for anhydride determinations every two years. Once a sensitised worker is identified he/she is relocated to a job without exposure to anhydrides.

In the period 2002 till 2016 4 cases of occupational asthma related to anhydrides were identified. The cases occurred in 2004, 2005, 2006, and 2010. During and following this time the following measures have been introduced:

- Improvements in protective clothing
- Improvements in respiratory protection

    - Workers operate using a full mask with a calculated protection factor of 2000
- Improvements in worker training
- Reduction in exposure time
    - Workers typically work for 2 hours a day in the under pressure hall where exposure can take place
- Health check-ups
    - Once every two years all workers receive sIgE determination
    - Workers with an atopic constitution[5] are strictly allocated with none exposure duties.
- Exposure reduction through technical improvements

sIgE determination of all workers was initiated in 2014 and in 2015, on a population of 19 exposed workers, 2 cases of sensitisation were discovered. These workers were moved to areas without exposure, thereby preventing the development of occupational asthma.

Based on the worker patient records all work related symptoms disappeared after removal from exposure. The workers diagnosed in 2006 and 2010 still have symptoms of general asthma, however these workers could have developed asthma even without exposure to anhydrides, as these workers have a severely atopic constitution.

Plant M

Plant M submitted a response to the retrospective questionnaire, which stated that there have been no cases of occupational asthma in this plan.

In plant M 18 workers are potentially exposed to anhydrides.

Plant N

No medical data yet

Plant O

Plant O submitted an answer to the industry consultation stating to have no evidence of any health issue that can be linked to the use of anhydrides.

In plant O 10 workers are potentially exposed to anhydrides.

Plant P

In plant P participation in the prospective medical investigation is voluntary as obliging the participation is in violation with local legislation. For one of the employees a blood test has been ordered as he was diagnosed with hay fever/asthma in the past year. However, as of yet there is no evidence that occupational asthma has occurred.

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[5] Defined as positive results on a general skin-prick allergy test, a worker interview asking for preexisting allergies and asthma symptoms going back to early childhood (workers are asked to contact their parents for the earliest life phases), or positive blood test (total IgE, sIgE for common allergens, or sIgE for anhydrides). All tests are performed before worker is allowed to work in the exposure area.

Plant Q

Plant Q is performing a closed process using HHPA and MHHPA. Plant supplied a medical statement provided to them by the medical doctor that performs the medical surveillance since the company started using anhydrides, which confirmed that since the start of the use of the substances until now there is no evidence of any adverse health effects that have occurred as a result of the use of HHPA and MHHPA and of liquid Cyclic Anhydrides, in general.

Plant management clarified that there are 33 workers operating in the facility in total and could thus potentially be exposed to anhydrides.

Plant R

Plant R is performing a closed process using anhydrides (no further details provided). The plant replied to the retrospective medical study. The medical service provider stated that its records go back to 2006 and that since that time no cases of occupational asthma were identified.

Plant management informed the consortium manager that 16 workers are operating in this plant.

Plant S

Plant S is performing a closed process using anhydrides (no further details provided). The plant provided input to the retrospective medical study. The medical service provider stated that since 1994 no cases of occupational asthma were identified.

Plant management stated that 2 workers are currently potentially exposed to anhydrides.

Plant T

Plant T is performing a closed process using anhydrides (no further details provided). The plant provided input to the retrospective medical study. The medical service provider clarified that the plant started using anhydrides in 2015 and since then no cases or occupational asthma were identified.

Plant management stated that 7 workers are potentially exposed to anhydrides.

Plant U

Plant U is performing an open process using anhydrides (no further details provided). The plant provided input to the retrospective medical study. The medical service provider stated that it has been performing the medical check-ups of the plants workers since before 2000 and that no cases of occupational asthma were ever identified.

Within the company the following respiratory protection was used: 3M 6800 with filters 3M 6055 A2.

Plant management stated that 10 workers are potentially exposed to anhydrides in this plant.

Plant V

Plant V is performing a closed process using anhydrides (no further details provided). The plant provided input to the retrospective medical study. The

medical service provider declared that since 2002 it has not seen any case of occupational asthma related to anhydrides.

Plant management stated that 5 workers are potentially exposed to anhydrides.

Annex III Process Descriptions

Below you will find a description of the processes used in industry

Automatic Pressure Gelation

The process of Automatic Pressure Gelation involves the injection under high pressure of an epoxy/hardener mixture into a mould. Most often this is a 2 part mould clamped under high pressure. This mould is then heated to accelerate polymerisation. See Figure 3.

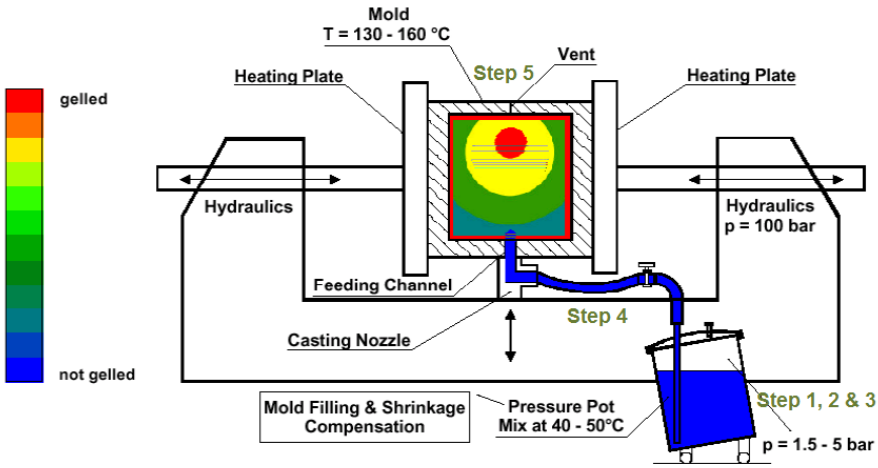

Figure 3 Automatic Pressure Gelation. Source: AJIT

The epoxy and hardener can also be mixed in a continuous system which is displayed in Figure 4.

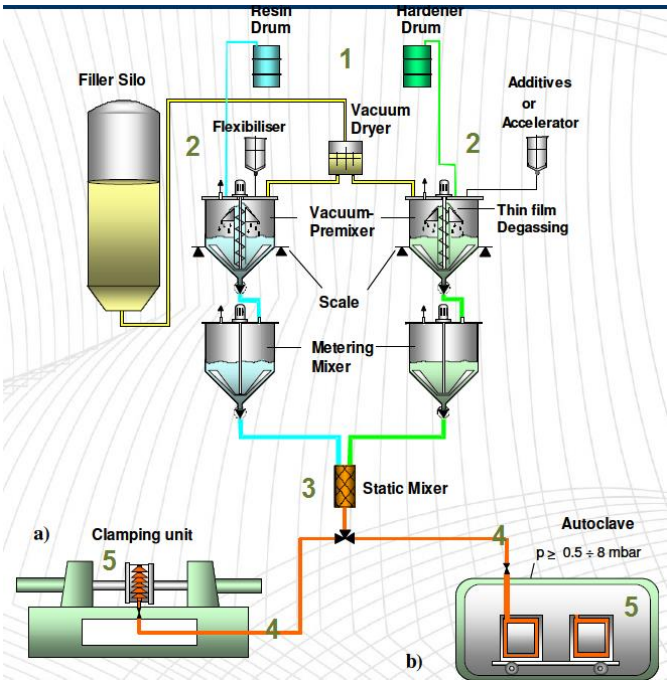

Figure 4 Continuous processing. Source: AJIT

Vacuum Casting

A Vacuum Casting process employs a continuous mixing system under vacuum as described in Figure 5. Epoxy and hardener are mixed in predefined proportions under vacuum and injected into moulds in a vacuum chamber.

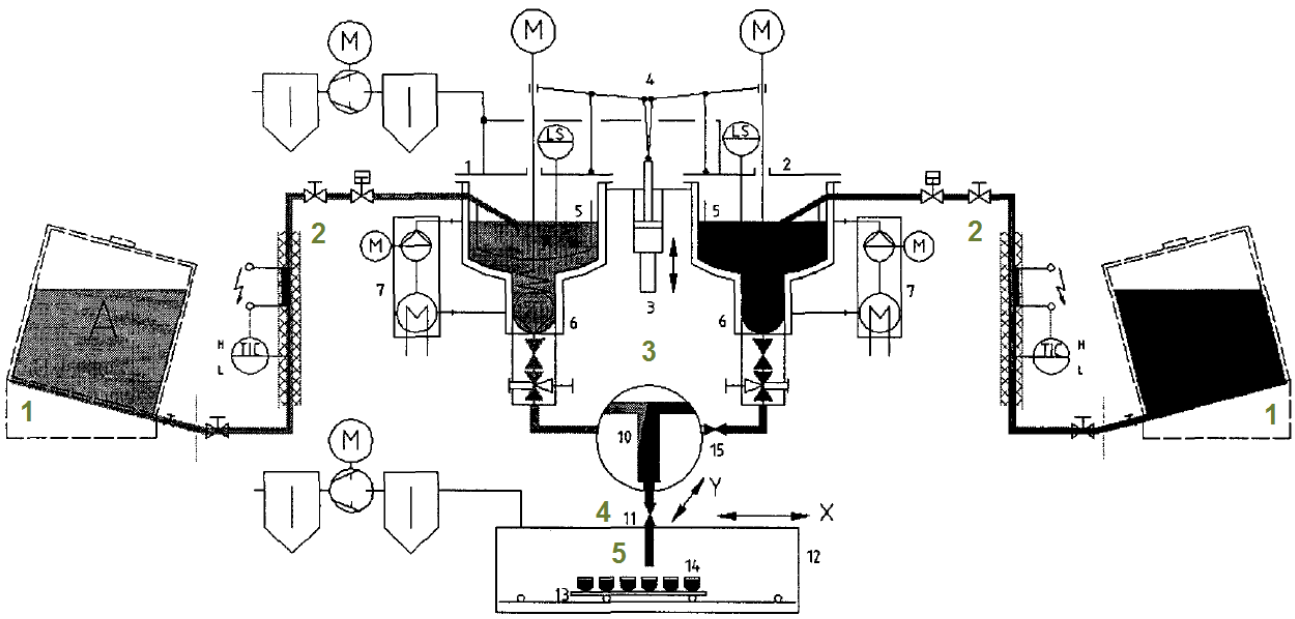

Figure 5 Continuous vacuum preparation and casting system. (1) Vacuum metering mixer, resin component; (2) Vacuum metering mixer, hardener component; (3) Pneumatic central drive; (4) Lever arm system; (5) Stirrer; (6) Metering pumps; (7) Heat exchanger; (10) Static mixer; (11) Reactive mix outlet valve; (12) Vacuum casting chamber; (13) Pallet; (14) Casting mould; and (15) Resin flush valve. Source: (13)

Vacuum Pressure Impregnation

During Vacuum Pressure Impregnation an object is placed in an impregnation chamber (Figure 6). The impregnation chamber is placed under vacuum and the resin/hardener mixture and impregnation chamber are preheated (Figure 7). This removes any moisture from the object. Subsequently, the object in the pressure chamber is flooded with the resin/hardener mixture, followed by the application of high pressure (Figure 8). Finally the resin/hardener mixture is evacuated to the storage tank and the impregnated object is moved to an oven for curing (Figure 9). During the movement of the impregnated object from the impregnation chamber to the curing oven the impregnated object is not in a closed environment, therefor the VPI process is categorized as a “semi-open” process.

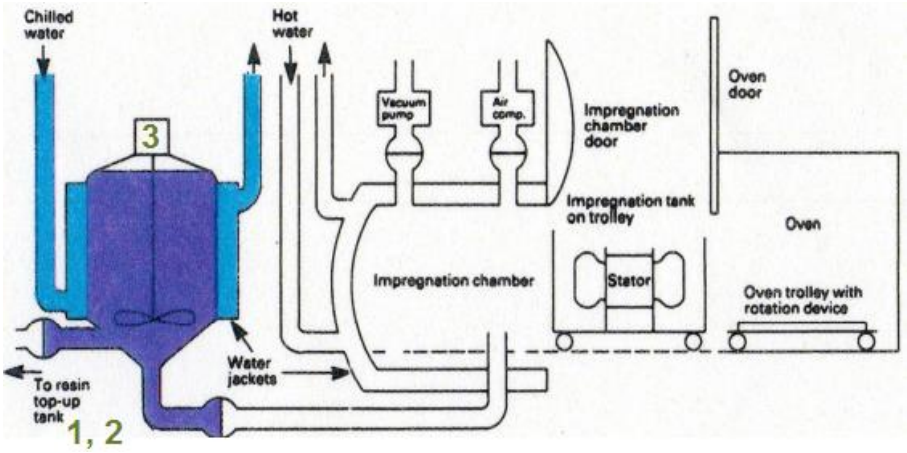

Figure 6 Vacuum Pressure Impregnation Step 1. Source: AJIT

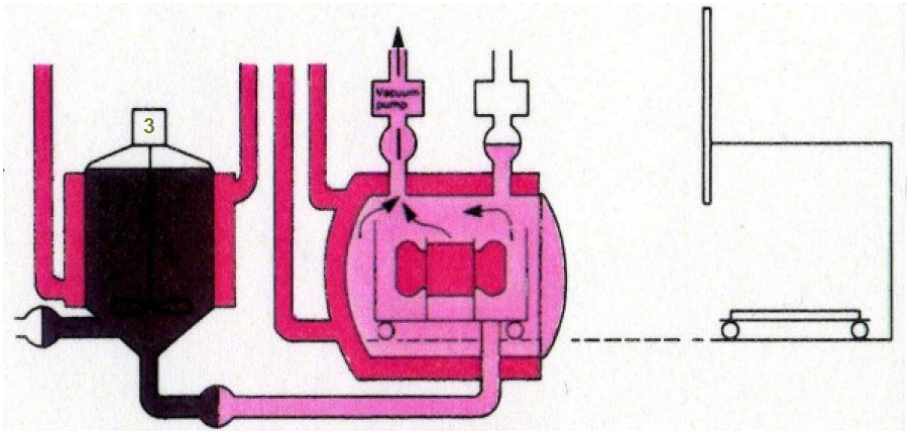

Figure 7 Vacuum Pressure Impregnation Step 2. Source: AJIT

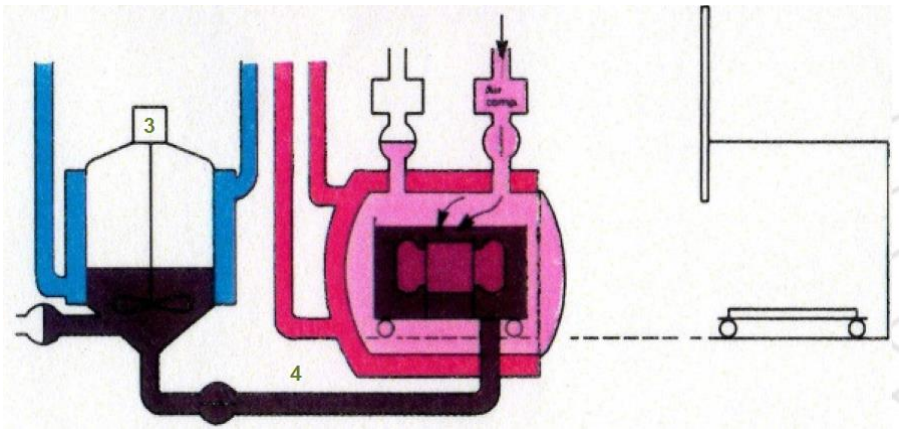

Figure 8 Vacuum Pressure Impregnation Step 3. Source: AJIT

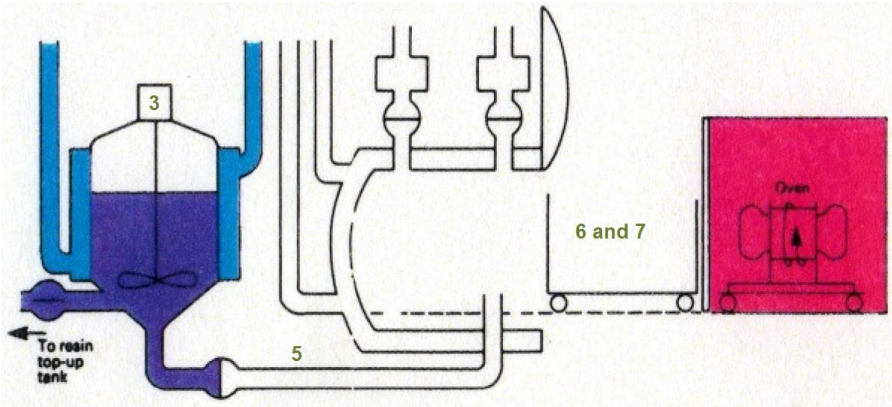

Figure 9 Vacuum Pressure Impregnation Step 4. Source: AJIT