

**Measured Substance Class:** IPI / Dust Measurements

## Dust Measurements during Charging and Discharging of the mechanical Dryer in Building 20 of TIC 1097 in ILC-Dover G2Pac™

**Location:** mechanical dryer A052M 20 00 03

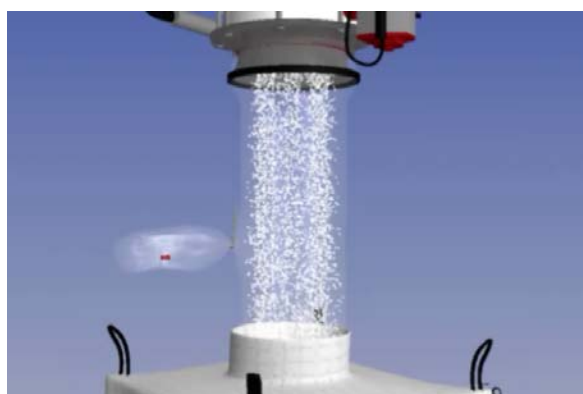
**Production process:** 54461 TIC 1097

**Assessed operations:** charging and discharging of the mechanical dryer.  
Discharging is done directly into the ILC-Dover G2Pacs

### 1 Executive Summary

An Intermediate Product 54661 TIC 1097 is partly produced for Janssen Cork (Ireland). For this purpose another packaging technology needs to be applied. In Janssen Cork TIC 1097 shall be directly charged from ILC-Dover G2Pac's into the reactor for the next chemical step (coupling to Darunavir Ethanolate TMC 114). TIC 1097 has strong skin sensitizing properties.

During a trial repacking campaign TIC 1097 was directly discharged from the Mechanical dryer into ILC-Dover G2Pac's. IH-measurements show a good improvement compared to the conventional method of discharging from the same type of dryer. Nevertheless additional measures need to be taken to obtain constantly low exposure results in the future.



**Packaging-System  
ILC Dover G2Pac™**

Erstellung und Prüfung	Datum:	Unterschrift:
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Eingesehen: Daniel Linder Betriebsleiter Chemieproduktion		

## INHALT

<b>1</b>	<b>Executive Summary</b> .....	<b>1</b>
<b>2</b>	<b>Introduction</b> .....	<b>2</b>
	<b>Substanzeigenschaften</b> .....	Fehler! Textmarke nicht definiert.
2.1	TIC 1097.....	3
<b>3</b>	<b>Material and Methods</b> .....	<b>3</b>
3.1	Air resp. Dust Measurements.....	3
3.2	Minimum Run Time of the GilAir Pumps for the MAK Value Registration .....	3
<b>4</b>	<b>Description of the assessed Operation</b> .....	<b>4</b>
4.1	Charging of the mechanical Dryer.....	4
4.2	Discharging of the mechanical Dryer into in ILC-Dover G2Pac™ .....	4
<b>5</b>	<b>Personal Safety Gear:</b> .....	<b>5</b>
5.1	During Charging .....	5
5.2	During Discharging.....	5
<b>6</b>	<b>Performance of the Dust Measurements</b> .....	<b>5</b>
6.1	Charging:.....	5
6.2	Discharging: .....	6
<b>7</b>	<b>Results</b> .....	<b>7</b>
7.1	Sorted by Sampling Locations .....	7
7.2	Sorted by Event.....	8
<b>8</b>	<b>Assessment of the Measuring Results by Arithmetic Mean</b> .....	<b>9</b>
8.1	During Charging: .....	9
8.2	During Discharging:.....	10
<b>1</b>	<b>Basic Information to the statistical Assessment of the Measuring Results</b> .....	<b>11</b>
<b>9</b>	<b>Assessment of the Situation based on the Measurement Results</b> .....	<b>14</b>
<b>10</b>	<b>Discussion and recommended measures</b> .....	<b>18</b>
10.1	Recommended Measures .....	18

## 2 Introduction

The intermediate 54661 TIC 1097 is partially produced for the external further processing for Janssen Cork in Ireland. For the coupling to the subsequent step (Darunavir Ethanolate TMC 114), in Cork TIC 1097 is charged directly from a packaging system, ILC-Dover G2Pacs into the reactor. Thus during a trial repacking campaign several batches of TIC 1097 were repacked in ILC-Dover G2Pac. This repacking process was performed by charging the product into the mechanical dryer A052M from the usual blue 120L Lupolen drums (plastic drum with lid) then discharged into the G2Pacs.

TIC 1097 has strong skin sensitizing properties.

During charging of the mechanical dryer in the usual way as well as during the discharging into the ILC-Dover G2Pacs, IH dust measurements were performed.

### 3 Substance properties

#### 3.1 TIC 1097

Medium	IPI	Produktionsprozess (sofern zutreffend)				
EDV-Nr.	54661	EDV-Nr.	54661			
Name:	TIC 1097	Name:	TIC 1097			
CAS-Nr.:	169280-56-2	Form:	fest			
Summenformel	C20 H29 N3 O3 S		Molmasse	391.52 g / mol		
PB-OEL:	3A	Dampfdruck 20°C:	-- hPa	Gefahren- Diamant		
OEL:	0.005 mg / m3	Siedepunkt:	-- °C		Gesundheitsgefahr:	2
AL	2.5 µg / m3	Schmelzpunkt:	136.6 °C		Brandgefahr:	-
AL = 50 % des OEL		Zündtemperatur:	420 °C		Explosionsgefahr:	2
Filtermedium:	IOM 4	Nachweisgrenze der Analysenmethode in µg:	0.1			
Flow:	2000 ml / min	Minimale Messdauer in Minuten:	20			

Bei einer Konzentration an der Aktionslimite (AL)

### 4 Material and Methods

#### 4.1 Air resp. Dust Measurements

The measurements were performed with the aid of Gilian pumps (GilAir 5) and IOM measurement heads loaded with Teflon filters (IOM 4). The pumps were calibrated prior to and after the measurement. The air flow rate was 2000 mL / min (+/- 50 mL / min).

Analysis of the dust filters were performed by a third party lab, NATLSCO (a company of Bureau Veritas), Lake Zurich, IL, USA.

#### 4.2 Minimum Run Time of the GilAir Pumps for the MAK Value Registration

With a (given) pump performance of 2000 mL / min, 0,12 m<sup>3</sup> air per hour are pumped through the IOM filter. For the analytical limit of quantitation (LOQ) with the analytical method of NATLSCO thus the following minimum run times for the air pumps are found in order to assure the statement that the action limit (AL) is not exceeded:

$$Laufzeit[\text{min}] = \frac{LOQ[\mu\text{g}] \times 1000[\text{L}]}{AL[\mu\text{g} / \text{m}^3] \times Pumpvolumen[\text{L} / \text{min}]}$$

TIC 1097: 20 min

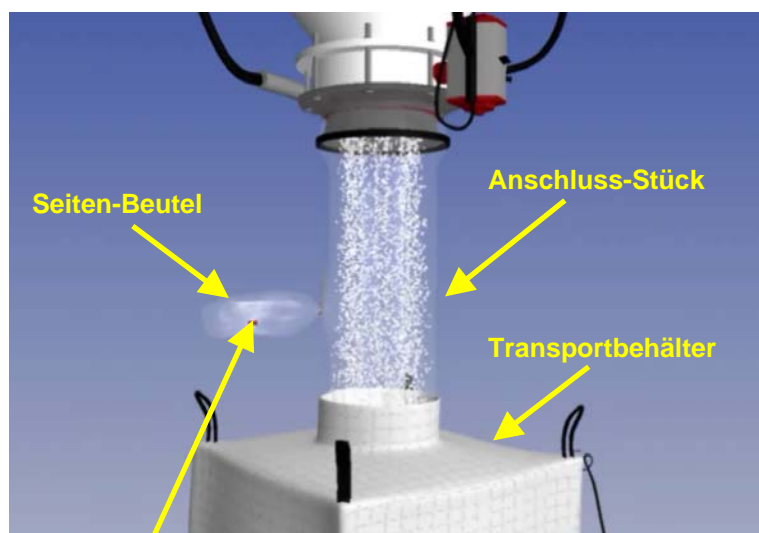
## 5 Description of the assessed Operation

### 5.1 Charging of the mechanical Dryer

Charging of the mechanical dryer is done in the „usual way“ by manually charging the intermediate TIC 1097 (50 kg per container) from the blue 120 L Lupolen drums. Analogously to this procedure, charging of TIC 1097 into the reactor for the in-house coupling to Darunavir Ethanolate TMC 114 is performed.

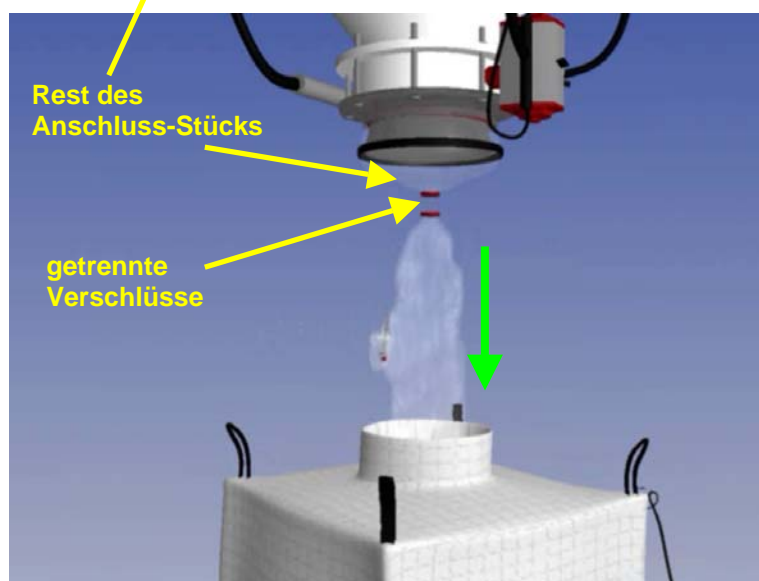
### 5.2 Discharging of the mechanical Dryer into in ILC-Dover G2Pac™

As described, the mechanical dryer was discharged directly into ILC-Dover G2Pacs. In opposition to usual packaging e.g. plastic drums with lid, this packaging system has the advantage that due to the practically closed procedure the dust exposition can be kept very low (see schematic picture).



The transportation container is equipped with an inner bag (primary packaging) incl. connection.

Prior to discharging, the connection is tightly secured to the discharging nozzle with a V-band.



After discharging the outlet is sealed with a closure. Subsequently this closure is cut. The connection thus closed is enclosed in the transportation container.

The remaining rest of the connection on the outlet is enclosed the side bag of the connection of the following container.

## 6 Personal Safety Gear:

### 6.1 During Charging

Charging was performed manually from opened 120 L Lupolen drums with PE internal bags into the open charging nozzle. Thus the operators are equipped with an externally ventilated yellow Tyvek full protection overall.

### 6.2 During Discharging

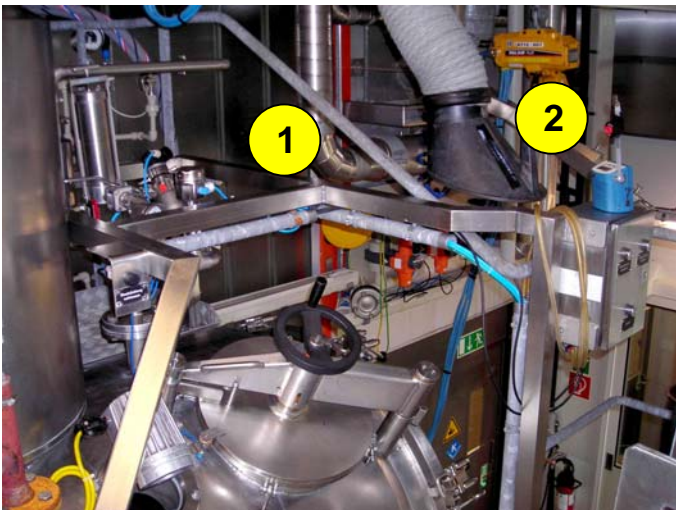
The personal safety gear during discharging consists of the basic gear (white overall, boots and goggles). In addition, the operators are equipped with a white Tyvek overall incl. hood, P3 dust mask and nitrile gloves.

## 7 Performance of the Dust Measurements

In the following pictures it is marked and described in which locations the IOM filters were placed.

### 7.1 Charging:

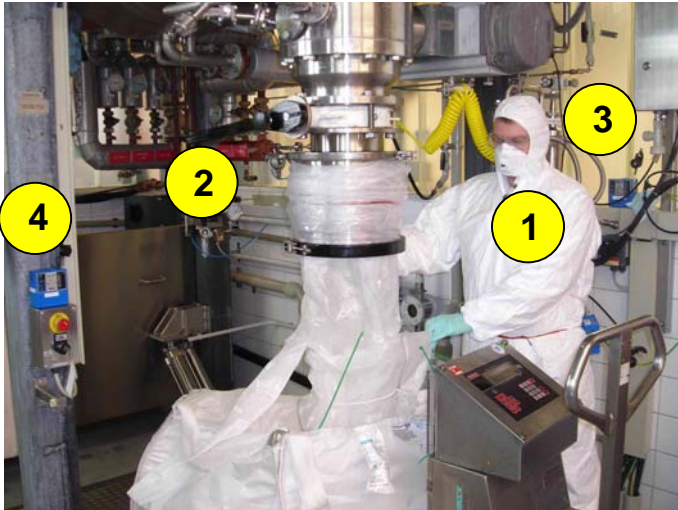
To record the dust exposition during charging, the job was measured during three batches (events). Thus a personal monitoring outside of the protection overall and a stationary monitoring each were performed.



- 1 personal monitoring outside of the protection overall (not shown in picture)
- 2 stationary, 100-150 cm distance from charging opening

## 7.2 Discharging:

To record the dust exposition during discharging, the job was measured during four batches (events). Thus two personal monitorings outside of the protection overall for both operators each and two stationary monitorings each were performed.



- 1 personal monitoring outside of the protection overall 1st. operator
- 2 personal monitoring outside of the protection overall (not shown in picture) 2nd. operator
- 3 stationary, 100-150 cm distance, windowsill
- 4 stationary, 100-150 cm distance, emergency switch

## 8 Results

### 8.1 Sorted by Sampling Locations

Date	Sample No.	Task	Description of sample point	Operator	Begin	End	Duration [min]	Volume [Liter]	Sample-ID	Analytical Results	Actual Concentration			TWA (8 h)			
										[µg]	µg/m <sup>3</sup>	Relation to STEL	Arithm. Mean	µg/m <sup>3</sup>	Relation to OEL	Arithm. Mean	
21.02.2007	1.1	Beschickung mech. Trockner (1.4)	Persönliches Monitoring	Westermann, F	10:50	11:15	25	50	26083205	5.5	110	11.00		5.7	1.15		
21.02.2007	2.1	Beschickung mech. Trockner (1.4)	Persönliches Monitoring	Ravalli, M	16:50	17:05	15	30	26083248	0.1	3.3	0.33		0.1	0.02		
22.02.2007	3.1	Beschickung mech. Trockner (1.4)	Persönliches Monitoring	Isler, G	9:30	9:50	20	40	26083241	36.4	910	91.00	34.1	37.9	7.58	2.9	
21.02.2007	1.2	Beschickung mech. Trockner (1.4)	Stationär, 100-150 cm Abstand von Zugabeöffnung	Bongiorno, F	10:50	11:15	25	50	26083245	0.6	12	2.40		0.6	0.13		
21.02.2007	2.2	Beschickung mech. Trockner (1.4)	Stationär, 100-150 cm Abstand von Zugabeöffnung	Ravalli, M	16:50	17:05	15	30	26083230	0.3	11	2.20		0.3	0.07		
22.02.2007	3.2	Beschickung mech. Trockner (1.4)	Stationär, 100-150 cm Abstand von Zugabeöffnung	Isler, G	9:30	9:50	20	40	26083202	8.4	210	21.00	8.5	8.8	1.75	0.6	
21.02.2007	4.1 A	Austragen (1.9)	Persönliches Monitoring	Bongiorno, F	12:30	14:00	90	180	26083243	1.5	8.6	0.86		1.6	0.32		
21.02.2007	4.1 B	Austragen (1.9)	Persönliches Monitoring	Westermann, F	12:30	14:00	90	180	26083247	1.6	9	0.90		1.7	0.34		
21.02.2007	5.1 A	Austragen (1.9)	Persönliches Monitoring	Bello, A	18:30	19:45	75	150	26083229	0.1	0.67	0.07		0.1	0.02		
21.02.2007	5.1 B	Austragen (1.9)	Persönliches Monitoring	Zimmermann, H	18:30	19:45	75	150	26083224	0.1	0.67	0.07		0.1	0.02		
22.02.2007	6.1 A	Austragen (1.9)	Persönliches Monitoring	Bongiorno, F	11:15	12:20	65	130	26083239	0.3	2.38	0.24		0.3	0.06		
22.02.2007	6.1 B	Austragen (1.9)	Persönliches Monitoring	Isler, G	11:15	12:20	65	130	26083226	1.3	10.00	1.00		1.4	0.27		
22.02.2007	7.1 A	Austragen (1.9)	Persönliches Monitoring	Bello, A	16:05	17:50	105	210	26083242	1.2	5.8	0.58		1.3	0.25		
22.02.2007	7.1 B	Austragen (1.9)	Persönliches Monitoring	Wolf, Th	16:05	17:50	105	210	26083238	1.0	4.6	0.46	0.5	1.0	0.20	0.2	
21.02.2007	4.3	Austragen (1.9)	Stationär, 100-150 cm Abstand, Fensterbrüstung	Bongiorno, F	12:30	14:00	90	180	26083215	0.0	0.056	0.01		0.0	0.00		
21.02.2007	5.3	Austragen (1.9)	Stationär, 100-150 cm Abstand, Fensterbrüstung	Zimmermann, H	18:30	19:45	75	150	26083246	0.1	0.67	0.07		0.1	0.02		
22.02.2007	6.3	Austragen (1.9)	Stationär, 100-150 cm Abstand, Fensterbrüstung	Bongiorno, F	11:15	12:20	65	130	26083236	0.1	0.77	0.08		0.1	0.02		
22.02.2007	7.3	Austragen (1.9)	Stationär, 100-150 cm Abstand, Fensterbrüstung	Wolf, Th	16:05	17:50	105	210	26083209	0.6	3	0.30		0.7	0.13		
21.02.2007	4.4	Austragen (1.9)	Stationär, 100-150 cm Abstand, Notschalter	Westermann, F	12:30	14:00	90	180	26083235	0.2	1.3	0.13		0.2	0.05		
21.02.2007	5.4	Austragen (1.9)	Stationär, 100-150 cm Abstand, Notschalter	Bello, A	18:30	19:45	75	150	26083213	0.1	0.67	0.07		0.1	0.02		
22.02.2007	6.4	Austragen (1.9)	Stationär, 100-150 cm Abstand, Notschalter	Isler, G	11:15	12:20	65	130	26083223	0.1	0.77	0.08		0.1	0.02		
22.02.2007	7.4	Austragen (1.9)	Stationär, 100-150 cm Abstand, Notschalter	Bello, A	16:05	17:50	105	210	26083210	0.9	4.5	0.45	0.1	1.0	0.20	0.1	
22.02.2007	8.2	Raumhintergrund	Stationär, 100-150 cm Abstand von Zugabeöffnung	Kramer,HL	14:15	15:50	95	190	26083240	0.1	0.53	0.05		0.1	0.02		
22.02.2007	8.4	Raumhintergrund	Stationär, 100-150 cm Abstand Ausgabeöffnung, Notschalter	Kramer,HL	14:15	15:50	95	190	26083231	0.2	0.81	0.08	0.1	0.2	0.03	0.0	
											Censored data (below LOQ / LOD)						
											LOD [µg]	STEL [µg/m <sup>3</sup> ]	OEL [µg/m <sup>3</sup> ]	AL [µg/m <sup>3</sup> ]			
											0.1	10.0	5.0	2.5			
LOD: Limit of Detection											Below the AL						
STEL: Short time exposure limit (max. 4 x 15 min per day)											Between AL and OEL						
OEL: Occupational exposure limit											Above the OEL						
AL: Action limit (50 % of the OEL, 10 % in case of carcinogens)																	

8.2 Sorted by Event

Date	Sample No.	Task	Description of sample point	Operator	Begin	End	Duration [min]	Volume [Liter]	Sample-ID	Analytical Results	Concentration		TWA (8 h)		
										[µg]	µg/m <sup>3</sup>	Relation to STEL	µg/m <sup>3</sup>	Relation to OEL	
21.02.2007	1.1	Beschickung mech. Trockner (1.4)	Persönliches Monitoring	Westermann, F	10:50	11:15	25	50	26083205	5.5	110	11.00	5.7	1.15	
21.02.2007	1.2	Beschickung mech. Trockner (1.4)	Stationär, 100-150 cm Abstand von Zugabeöffnung	Bongiorno, F	10:50	11:15	25	50	26083245	0.6	12	1.20	0.6	0.13	
21.02.2007	2.1	Beschickung mech. Trockner (1.4)	Persönliches Monitoring	Ravalli, M	16:50	17:05	15	30	26083248	0.1	3.3	0.33	0.1	0.02	
21.02.2007	2.2	Beschickung mech. Trockner (1.4)	Stationär, 100-150 cm Abstand von Zugabeöffnung	Ravalli, M	16:50	17:05	15	30	26083230	0.3	11	1.10	0.3	0.07	
22.02.2007	3.1	Beschickung mech. Trockner (1.4)	Persönliches Monitoring	Isler, G	9:30	9:50	20	40	26083241	37.0	910	91.00	37.9	7.58	
22.02.2007	3.2	Beschickung mech. Trockner (1.4)	Stationär, 100-150 cm Abstand von Zugabeöffnung	Isler, G	9:30	9:50	20	40	26083202	9.0	210	21.00	8.8	1.75	
21.02.2007	4.1 A	Austragen (1.9)	Persönliches Monitoring	Bongiorno, F	12:30	14:00	90	180	26083243	1.5	8.6	0.86	1.6	0.32	
21.02.2007	4.1 B	Austragen (1.9)	Persönliches Monitoring	Westermann, F	12:30	14:00	90	180	26083247	1.6	9	0.90	1.7	0.34	
21.02.2007	4.3	Austragen (1.9)	Stationär, 100-150 cm Abstand, Fensterbrüstung	Bongiorno, F	12:30	14:00	90	180	26083215	0.1	0.056	0.01	0.0	0.00	
21.02.2007	4.4	Austragen (1.9)	Stationär, 100-150 cm Abstand, Notschalter	Westermann, F	12:30	14:00	90	180	26083235	0.2	1.3	0.13	0.2	0.05	
21.02.2007	5.1 A	Austragen (1.9)	Persönliches Monitoring	Bello, A	18:30	19:45	75	150	26083229	0.1	0.67	0.07	0.1	0.02	
21.02.2007	5.1 B	Austragen (1.9)	Persönliches Monitoring	Zimmermann, H	18:30	19:45	75	150	26083224	0.1	0.67	0.07	0.1	0.02	
21.02.2007	5.3	Austragen (1.9)	Stationär, 100-150 cm Abstand, Fensterbrüstung	Zimmermann, H	18:30	19:45	75	150	26083246	0.1	0.67	0.07	0.1	0.02	
21.02.2007	5.4	Austragen (1.9)	Stationär, 100-150 cm Abstand, Notschalter	Bello, A	18:30	19:45	75	150	26083213	0.1	0.67	0.07	0.1	0.02	
22.02.2007	6.1 A	Austragen (1.9)	Persönliches Monitoring	Bongiorno, F	11:15	12:20	65	130	26083239	0.3	2.38	0.24	0.3	0.06	
22.02.2007	6.1 B	Austragen (1.9)	Persönliches Monitoring	Isler, G	11:15	12:20	65	130	26083226	1.3	10.00	1.00	1.4	0.27	
22.02.2007	6.3	Austragen (1.9)	Stationär, 100-150 cm Abstand, Fensterbrüstung	Bongiorno, F	11:15	12:20	65	130	26083236	0.1	0.77	0.08	0.1	0.02	
22.02.2007	6.4	Austragen (1.9)	Stationär, 100-150 cm Abstand, Notschalter	Isler, G	11:15	12:20	65	130	26083223	0.1	0.77	0.08	0.1	0.02	
22.02.2007	7.1 A	Austragen (1.9)	Persönliches Monitoring	Bello, A	16:05	17:50	105	210	26083242	1.2	5.8	0.58	1.3	0.25	
22.02.2007	7.1 B	Austragen (1.9)	Persönliches Monitoring	Wolf, Th	16:05	17:50	105	210	26083238	1.0	4.6	0.46	1.0	0.20	
22.02.2007	7.3	Austragen (1.9)	Stationär, 100-150 cm Abstand, Fensterbrüstung	Wolf, Th	16:05	17:50	105	210	26083209	0.6	3	0.30	0.7	0.13	
22.02.2007	7.4	Austragen (1.9)	Stationär, 100-150 cm Abstand, Notschalter	Bello, A	16:05	17:50	105	210	26083210	0.9	4.5	0.45	1.0	0.20	
22.02.2007	8.2	Raumhintergrund	Stationär, 100-150 cm Abstand von Zugabeöffnung	Kramer,HL	14:15	15:50	95	190	26083240	0.1	0.53	0.05	0.1	0.02	
22.02.2007	8.4	Raumhintergrund	Stationär, 100-150 cm Abstand Ausgabeöffnung, Notschalter	Kramer,HL	14:15	15:50	95	190	26083231	0.2	0.81	0.08	0.2	0.03	
											Censored data (below LOQ / LOD)				
					LOD [µg]	STEL [µg/m <sup>3</sup> ]	OEL [µg/m <sup>3</sup> ]	AL [µg/m <sup>3</sup> ]							
					0.1	10.0	5.0	2.5							
LOD: Limit of Detection											Below the AL				
STEL: Short time exposure limit (max. 4 x 15 min per day)											Between AL and OEL				
OEL: Occupational exposure limit											Above the OEL				
AL: Action limit (50 % of the OEL, 10 % in case of carcinogens)															



## 9 Assessment of the Measuring Results by Arithmetic Mean

Date	Sample No.	Task	Description of sample point	Duration [min]	Volume [Liter]	Analytical Results		Actual Concentration			TWA (8 h)									
						[µg]	µg/m <sup>3</sup>	Relation to STEL	Arithm. Mean	µg/m <sup>3</sup>	Relation to OEL	Arithm. Mean								
21.02.2007	1.1	Beschickung mech. Trockner (1.4)	Persönliches Monitoring	25	50	5.5	110	11.00		5.7	1.15									
21.02.2007	2.1	Beschickung mech. Trockner (1.4)	Persönliches Monitoring	15	30	0.1	3.3	0.33		0.1	0.02									
22.02.2007	3.1	Beschickung mech. Trockner (1.4)	Persönliches Monitoring	20	40	36.4	910	91.00	34.1	37.9	7.58	2.9								
21.02.2007	1.2	Beschickung mech. Trockner (1.4)	Stationär, 100-150 cm Abstand von Zugabeöffn	25	50	0.6	12	2.40		0.6	0.13									
21.02.2007	2.2	Beschickung mech. Trockner (1.4)	Stationär, 100-150 cm Abstand von Zugabeöffn	15	30	0.3	11	2.20		0.3	0.07									
22.02.2007	3.2	Beschickung mech. Trockner (1.4)	Stationär, 100-150 cm Abstand von Zugabeöffn	20	40	8.4	210	21.00	8.5	8.8	1.75	0.6								
21.02.2007	4.1 A	Austragen (1.9)	Persönliches Monitoring	90	180	1.5	8.6	0.86		1.6	0.32									
21.02.2007	4.1 B	Austragen (1.9)	Persönliches Monitoring	90	180	1.6	9	0.90		1.7	0.34									
21.02.2007	5.1 A	Austragen (1.9)	Persönliches Monitoring	75	150	0.1	0.67	0.07		0.1	0.02									
21.02.2007	5.1 B	Austragen (1.9)	Persönliches Monitoring	75	150	0.1	0.67	0.07		0.1	0.02									
22.02.2007	6.1 A	Austragen (1.9)	Persönliches Monitoring	65	130	0.3	2.38	0.24		0.3	0.06									
22.02.2007	6.1 B	Austragen (1.9)	Persönliches Monitoring	65	130	1.3	10.00	1.00		1.4	0.27									
22.02.2007	7.1 A	Austragen (1.9)	Persönliches Monitoring	105	210	1.2	5.8	0.58		1.3	0.25									
22.02.2007	7.1 B	Austragen (1.9)	Persönliches Monitoring	105	210	1.0	4.6	0.46	0.5	1.0	0.20	0.2								
21.02.2007	4.3	Austragen (1.9)	Stationär, 100-150 cm Abstand, Fensterbrüstun	90	180	0.0	0.056	0.01		0.0	0.00									
21.02.2007	5.3	Austragen (1.9)	Stationär, 100-150 cm Abstand, Fensterbrüstun	75	150	0.1	0.67	0.07		0.1	0.02									
22.02.2007	6.3	Austragen (1.9)	Stationär, 100-150 cm Abstand, Fensterbrüstun	65	130	0.1	0.77	0.08		0.1	0.02									
22.02.2007	7.3	Austragen (1.9)	Stationär, 100-150 cm Abstand, Fensterbrüstun	105	210	0.6	3	0.30		0.7	0.13									
21.02.2007	4.4	Austragen (1.9)	Stationär, 100-150 cm Abstand, Notschalter	90	180	0.2	1.3	0.13		0.2	0.05									
21.02.2007	5.4	Austragen (1.9)	Stationär, 100-150 cm Abstand, Notschalter	75	150	0.1	0.67	0.07		0.1	0.02									
22.02.2007	6.4	Austragen (1.9)	Stationär, 100-150 cm Abstand, Notschalter	65	130	0.1	0.77	0.08		0.1	0.02									
22.02.2007	7.4	Austragen (1.9)	Stationär, 100-150 cm Abstand, Notschalter	105	210	0.9	4.5	0.45	0.1	1.0	0.20	0.1								
22.02.2007	8.2	Raumhintergrund	Stationär, 100-150 cm Abstand von Zugabeöffn	95	190	0.1	0.53	0.05		0.1	0.02									
22.02.2007	8.4	Raumhintergrund	Stationär, 100-150 cm Abstand Ausgabeöffn	95	190	0.2	0.81	0.08	0.1	0.2	0.03	0.0								
						Censored data (below LOQ / LOD)														
LOD: Limit of Detection						Below the AL														
STEL: Short time exposure limit (max. 4 x 15 min per day)						Between AL and OEL														
OEL: Occupational exposure limit						Above the OEL														
AL: Action limit (50 % of the OEL, 10 % in case of carcinogens)																				
						<table border="1"> <thead> <tr> <th>LOD [µg]</th> <th>STEL [µg/m<sup>3</sup>]</th> <th>OEL [µg/m<sup>3</sup>]</th> <th>AL [µg/m<sup>3</sup>]</th> </tr> </thead> <tbody> <tr> <td>0.1</td> <td>10.0</td> <td>5.0</td> <td>2.5</td> </tr> </tbody> </table>							LOD [µg]	STEL [µg/m <sup>3</sup> ]	OEL [µg/m <sup>3</sup> ]	AL [µg/m <sup>3</sup> ]	0.1	10.0	5.0	2.5
LOD [µg]	STEL [µg/m <sup>3</sup> ]	OEL [µg/m <sup>3</sup> ]	AL [µg/m <sup>3</sup> ]																	
0.1	10.0	5.0	2.5																	

Officially for TIC 1097 there is no Short time exposure limit (STEL) described. According to J & J Guidelines in this case as a limit for maximum 4 x 15 min per day the double or triple amount of the OEL may be assumed. For safety reasons the STEL was assumed as the double value of the OEL, thus 10 µg / m<sup>3</sup>.

### 9.1 During Charging:

Due to the uncontained handling during charging, a certain dust generation cannot be avoided. The relative mean to the STEL is 34.1. The TWA with 2.9 times the OEL is still high. Astonishing is the large distribution of the measuring results. This can be an indication of a varying work practice. In stationary measurements, the relative average of 8.5 to the STEL shows the distribution of the generated dust within the immediate working range on the platform near the charging nozzle of the mechanical dryer.

Due to the high exposition values which are factors above the OEL, there is no sense in calculation of additional statistical values.

With the personal protection gear resp. wearing of the forced ventilated Tyvek full protection overall the operator's respiratory protection is sufficient.



## 9.2 During Discharging:

During discharging also, the results of the personal monitoring show a relatively large distribution. In one event the values are under the limit of quantitation. The three remaining events are distributed within values from 2.38 to 10  $\mu\text{g} / \text{m}^3$ . The arithmetic mean relative to the STEL is 0.5, the TWA to the OEL is 0.2.

The values of the stationary measurements are distributed also. The relative means to STEL and OEL although are low with factor 0.1.

The wide distribution of the data is an index for the varying working practice and performance of the operators in this job also. The reason is found in the technology of the packaging system ILC-Dover G2Pac. This system is new and in the trial state yet. Further training of the operators regarding a uniform working performance thus is to be done in any case.

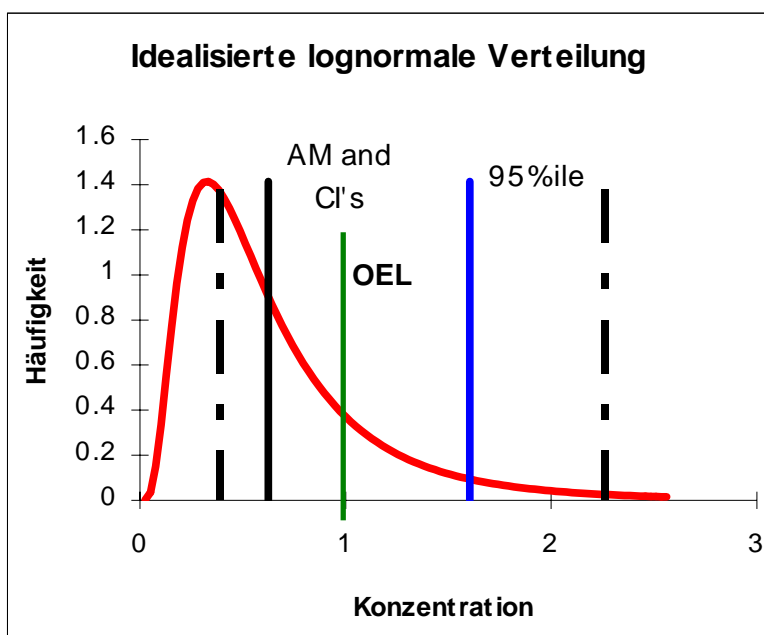
E.g. the reason for an individual high value of 10  $\mu\text{g} / \text{m}^3$  for personal monitoring is not known but nevertheless shows that the system is not as rugged yet and still has functional weaknesses.

The respiration protection resp. the P3 dust mask provides sufficient operator protection but has to be kept as „last barrier“ under any circumstances.

A further statistic assessment of the measuring results is described in chapters 9 and 10.

## 1 Basic Information to the statistical Assessment of the Measuring Results

According to “good IH-practice“ and the J&J standards the simple comparison of the arithmetic mean of the IH results to the OEL resp. MAK value is not sufficient for further decisions resp. often leads to an underestimation of the actual exposition. Because the IH measurements are influenced by several factors, their distribution can be relatively wide and asymmetrical. The distribution of the measurement values thus is often not normal but log-normal (according to following example).



AM = arithmetic mean  
CI = Confidence Interval  
OEL = Occupational Exposure Limit

Assuming the arithmetic mean clearly would lead to an underestimation of the actual exposition in the shown example. Thus the following initiated measures could be possibly insufficient.

According to J&J IH-Guidelines the probability of 95 % of the measured exposition values during a certain task being lower than the OEL has to be  $\geq 95\%$ . In the graph shown above the arithmetic mean of the measured values is significantly lower than the OEL, while the 95 % are clearly higher than the OEL.

A statement regarding the meeting of OELs and MAK values thus is often too insecure when based on means of some measured values only.

### Bayesian Decision Analysis (BDA)

According to & Johnson the Industrial Hygiene is meant to assess ICH measuring values - if possible - with a probability calculation, e.g. according to Bayes (english mathematic, 1702-1762).

For interpretation and assessment of the IH measuring data various software tools are available, such as „IHDataAnalyst“<sup>1</sup> etc.

This tool offers the possibility to assign exposition values and their distribution to a category (exposition category) according to a known classification in the following table. Therein the requested 95 % confidence can be considered.

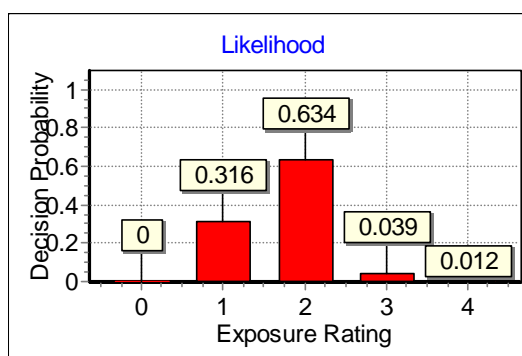
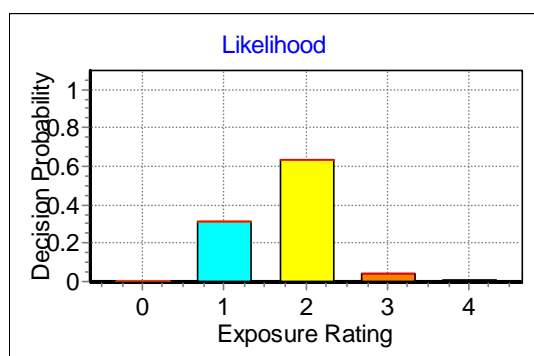
**Exposition categories / Exposure ratings with the further measures**

Expositions-Kategorie		Zusätzliche / weiterführende Massnahmen
0	< 1 % des OEL	keine Massnahmen
1	< 10 % des OEL	Generelle Information betreffend Gefahren im Umgang mit Chemikalien
2	10 - 50 % des OEL	+ Schadstoff-spezifische Information betreffend Gesundheitsgefahren
3	50 - 100 % des OEL	+ Expositionsüberwachung des Arbeitsplatzes, medizinische Kontrolle, Verbesserung der Arbeitspraxis
4	> 100 % des OEL	+ Geschlossenes Handling, verbesserte Schutzausrüstung, Atemschutz, Kontrolle der Arbeitspraxis
	> 50 x OEL	+ Dringende Verbesserung des Containments, evtl. Änderung des Prozesses, Überprüfung des Atemschutzes

OEL: Occupational Exposure Limit / MAK-value

The categories describe the probability of an exposition with a confidence of 95 % (95 % Confidence Level).

After assessment of the data, based on the exposition and its distribution a rating into the categories listed above with their measures can be done according to the following example.

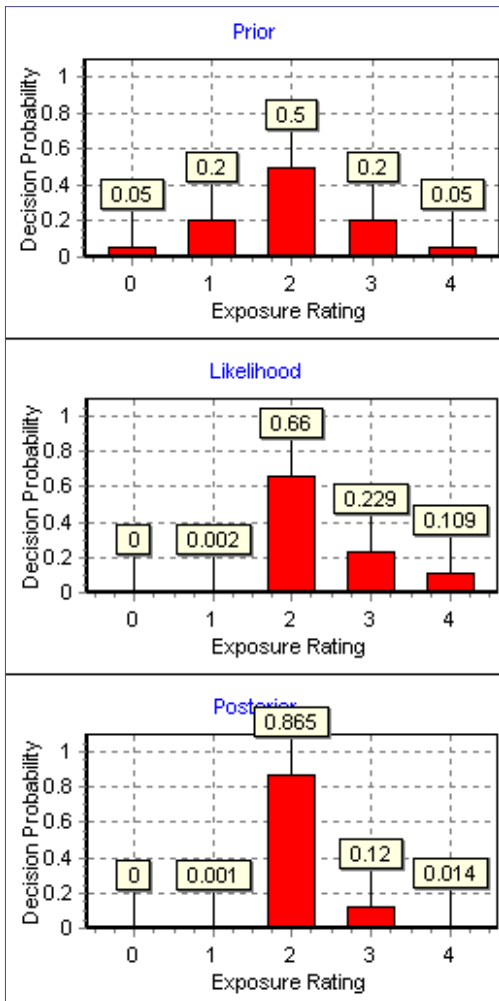


Likelihood = probability

If in the example above the two categories 1 and 2 are added, the result is 0.95 (see graph on the right: 0.316 + 0.634). The probability of the actual exposition to be in the range of < 10% up to 50% of the OEL thus is 95 %.

<sup>1</sup> Paul Hewett Ph.D. CIH © 2006 Exposure Assessment Solutions, Inc.

The software already mentioned, the Bayesian Statistics Tool „IHDataAnalyst“ offers the possibility to monitor the criticality of the exposition (assigned based on a risk assessment) during a certain task.



In the shown example according to „professional judgement“ a task was classified as uncritical, which would correspond to handling with a solvent and a well functioning local exhaust.

With the assignment „Prior“, thus „before“ knowledge of the measurement data, the probability of an exposition of category 4 would be 0.05, thus 5%.

Due to the measurement results the possibility „Likelihood“ of an OEL excess during the assumed task is almost at 11% (0.109).

Classification only based on a few – under certain circumstances very few – measurement data can be relativated by consideration of the first assessment of a situation („Prior“), only. This leads to the „Posterior“- thus final classification.

If compared to the actual measurements results „Likelihood“ the assessment „Prior“ is extremely different, then the base of the risk assessment should be checked or an unplanned state (e.g. leakage) should be corrected. Further measurements for confirmation of the corrective actions (repair of the leak) would be necessary then.

## 10 Assessment of the Situation based on the Measurement Results

As already described in chapter 8, only the measurement data of discharging are further investigated statistically because the measurement data during charging are known to be high. In the following table based on the data distribution of the personal and stationary monitoring the expositions to be expected are described. The probability of the classification into a certain category is 95 % as described.

- low category 0 to 2:      exposition lower than 50 % of OEL
- medium category 3:      exposition between 50 % and OEL possible
- high category 4:      exposition higher than OEL possible

### Personal Monitoring / Acute Exposition (STEL = 10 µg / m<sup>3</sup>)

Measuring point / category	Exposure Rating by IHDataAnalyst	IHData Analyst Values / Remarks																																																																		
Personal monitoring 8 measurement values  category 3 / 4 4 at approx. 76 %	<p><b>Prior</b></p> <table border="1"> <tr><th>Exposure Rating</th><td>0</td><td>1</td><td>2</td><td>3</td><td>4</td></tr> <tr><th>Decision Probability</th><td>0.03</td><td>0.17</td><td>0.6</td><td>0.17</td><td>0.03</td></tr> </table> <p><b>Likelihood</b></p> <table border="1"> <tr><th>Exposure Rating</th><td>0</td><td>1</td><td>2</td><td>3</td><td>4</td></tr> <tr><th>Decision Probability</th><td>0</td><td>0</td><td>0.000</td><td>0.051</td><td>0.949</td></tr> </table> <p><b>Posterior</b></p> <table border="1"> <tr><th>Exposure Rating</th><td>0</td><td>1</td><td>2</td><td>3</td><td>4</td></tr> <tr><th>Decision Probability</th><td>0</td><td>0</td><td>0.002</td><td>0.234</td><td>0.764</td></tr> </table>	Exposure Rating	0	1	2	3	4	Decision Probability	0.03	0.17	0.6	0.17	0.03	Exposure Rating	0	1	2	3	4	Decision Probability	0	0	0.000	0.051	0.949	Exposure Rating	0	1	2	3	4	Decision Probability	0	0	0.002	0.234	0.764	<p>OEL = 10 µg/m<sup>3</sup></p> <hr/> <p>Order Statistics:</p> <p>N = 8 Min = 0.67 Max = 10 Median = 5.2000</p> <hr/> <p>Decriptive Statistics:</p> <p>Mean = 5.2100 SD = 3.7600 GM = 3.4900 GSD = 3.058</p> <hr/> <p>Compliance Statistics (lognormal):</p> <p>X0.95 = 22.0000 95%LCL = 10.2000 95%UCL = 123.0000 ExcFrac = 0.173 95%LCL = 0.052 95%UCL = 0.418</p> <hr/> <p>Compliance Statistics (non-parametric):</p> <hr/> <p>Goodness-of-fit Tests:</p> <p>Fillibens Test: R = 0.925 critical R = 0.905 Interpretation: the lognormal distribution hypothesis is not rejected.</p> <hr/> <p>Bayesian Decision Charts:</p> <p>Type of prior decision distribution: Professional judgment prior Initial Rating = 2 - Well-controlled Certainly Level = 1 - High</p> <table border="1"> <tr> <td>Rating:</td> <td>0-T</td> <td>1-HC</td> <td>2-WC</td> <td>3-C</td> <td>4-PC</td> </tr> <tr> <td>Cutoff (%OEL):</td> <td>1.0</td> <td>10.0</td> <td>50.0</td> <td>100.0</td> <td>&gt;100.0</td> </tr> </table> <table border="1"> <tr> <td>Prior</td> <td>0.030</td> <td>0.170</td> <td>0.600</td> <td>0.170</td> <td>0.030</td> </tr> <tr> <td>Likelihood</td> <td>0.000</td> <td>0.000</td> <td>0.000</td> <td>0.051</td> <td>0.949</td> </tr> <tr> <td>Posterior</td> <td>0.000</td> <td>0.000</td> <td>0.002</td> <td>0.234</td> <td>0.764</td> </tr> </table>	Rating:	0-T	1-HC	2-WC	3-C	4-PC	Cutoff (%OEL):	1.0	10.0	50.0	100.0	>100.0	Prior	0.030	0.170	0.600	0.170	0.030	Likelihood	0.000	0.000	0.000	0.051	0.949	Posterior	0.000	0.000	0.002	0.234	0.764
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**Personal Monitoring / TWA 8 h (OEL = 5 µg / m<sup>3</sup>)**

Measuring point / category	Exposure Rating by IHDataAnalyst	IHData Analyst Values / Remarks																																																																		
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**Stationary Monitoring / Acute Exposition (STEL = 10 µg / m<sup>3</sup>)**

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**Stationary Monitoring / TWA 8 h (OEL = 5 µg / m<sup>3</sup>)**

Measuring point / category	Exposure Rating by IHDataAnalyst	IHData Analyst Values / Remarks																																																																		
<p>Stationary monitoring 8 measurement values</p> <p>category 1 / 2 total at 99 %</p>	<p><b>Prior</b></p> <table border="1"> <tr><th>Exposure Rating</th><td>0</td><td>1</td><td>2</td><td>3</td><td>4</td></tr> <tr><th>Decision Probability</th><td>0.03</td><td>0.17</td><td>0.6</td><td>0.17</td><td>0.03</td></tr> </table> <p><b>Likelihood</b></p> <table border="1"> <tr><th>Exposure Rating</th><td>0</td><td>1</td><td>2</td><td>3</td><td>4</td></tr> <tr><th>Decision Probability</th><td>0</td><td>0.069</td><td>0.899</td><td>0.032</td><td>0.001</td></tr> </table> <p><b>Pos</b></p> <table border="1"> <tr><th>Exposure Rating</th><td>0</td><td>1</td><td>2</td><td>3</td><td>4</td></tr> <tr><th>Decision Probability</th><td>0</td><td>0.021</td><td>0.969</td><td>0.01</td><td>0</td></tr> </table>	Exposure Rating	0	1	2	3	4	Decision Probability	0.03	0.17	0.6	0.17	0.03	Exposure Rating	0	1	2	3	4	Decision Probability	0	0.069	0.899	0.032	0.001	Exposure Rating	0	1	2	3	4	Decision Probability	0	0.021	0.969	0.01	0	<p>OEL = 5 µg/m<sup>3</sup></p> <p>-----</p> <p><b>Order Statistics:</b>  N = 8  Min = 0.01  Max = 0.98  Median = 0.1000</p> <p>-----</p> <p><b>Decriptive Statistics:</b>  Mean = 0.2860  SD = 0.3460  GM = 0.1410  GSD = 4.092</p> <p>-----</p> <p><b>Compliance Statistics (lognormal):</b>  X0.95 = 1.4300  95%LCL = 0.5430  95%UCL = 12.6000  ExcFrac = 0.006  95%LCL = &lt;0.001  95%UCL = 0.105</p> <p>-----</p> <p><b>Compliance Statistics (non-parametric):</b></p> <p>-----</p> <p><b>Goodness-of-fit Tests:</b>  Fillibens Test:  R = 0.937  critical R = 0.905  Interpretation: the lognormal distribution hypothesis is not rejected.</p> <p>-----</p> <p><b>Bayesian Decision Charts:</b></p> <p>Type of prior decision distribution:  Professional judgment prior  Initial Rating = 2 - Well-controlled  Certainly Level = 1 - High</p> <table border="1"> <tr> <td>Rating:</td> <td>0-T</td> <td>1-HC</td> <td>2-WC</td> <td>3-C</td> <td>4-PC</td> </tr> <tr> <td>Cutoff (%OEL):</td> <td>1.0</td> <td>10.0</td> <td>50.0</td> <td>100.0</td> <td>&gt;100.0</td> </tr> </table> <table border="1"> <tr> <td>Prior</td> <td>0.030</td> <td>0.170</td> <td>0.600</td> <td>0.170</td> <td>0.030</td> </tr> <tr> <td>Likelihood</td> <td>0.000</td> <td>0.069</td> <td>0.899</td> <td>0.032</td> <td>0.001</td> </tr> <tr> <td>Posterior</td> <td>0.000</td> <td>0.021</td> <td>0.969</td> <td>0.010</td> <td>0.000</td> </tr> </table>	Rating:	0-T	1-HC	2-WC	3-C	4-PC	Cutoff (%OEL):	1.0	10.0	50.0	100.0	>100.0	Prior	0.030	0.170	0.600	0.170	0.030	Likelihood	0.000	0.069	0.899	0.032	0.001	Posterior	0.000	0.021	0.969	0.010	0.000
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## 11 Discussion and recommended Measures

The exposition values during charging of TIC 1097 into the mechanical dryer under consideration of the open handling are expectably high. This is also due to the product was not being charged water wet as in the usual procedure but in dry state. To enable a definite statement regarding the exposition during charging of water wet TIC 1097, additional measurements during a following campaign are necessary. Nevertheless in the range of the current campaign the measurements performed upon charging were very informative for comparison. Further punctual measures are not necessary for the time being because they will be assessed nevertheless in the range of upgrade projects within the Powder Handling Unit Building 20.

In comparison with the usual procedure, the discharging process of the mechanical dryer into the ILC-Dover G2Pacs is a clear progress regarding the exposition values. Due to the practically closed handling the generation of dust can be kept at a minimum. The most critical point is the cutting of the connection and the sealing of the separation point after discharging. With the aid of some optimization measures the liberation of dust probably can be lowered to a rate that the exposition is definitely lower than the OEL.

### 11.1 Recommended Measures

- Additional training of the operators regarding this new technology to achieve a safe and routine working procedure.
- Assurance of the availability and correct function of the tools and auxiliary tools needed for all individual steps of the discharging procedure.
- Upgrade of the current data by additional measurements during a following campaign