PAVING UNDER REACH AND THE IARC DECISION

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ABSTRACT

The European REACH regulation requires manufacturers and importers of chemical substances to evaluate the risks associated with the use of their chemicals. During the REACH-registration process, bitumen producers have taken into account all available toxicological data about vapours and aerosols of bitumen. These data were the result of numerous studies, many of which were coordinated and co-financed by the German BITUMEN Forum. These studies have in common that they show the absence of any long term health effects on workers.

However, some studies show that during high exposures irritation of the respiratory tract occurred. Although this health effect is of short term and reversible nature, the asphalt industry in Germany has reacted to reduce mastic asphalt application temperatures, and hence exposure, with additives to temperatures below 230°C (warm mix mastic asphalt). This takes exposure to vapours and aerosols to the same order as during laying of hot-mix asphalt.

Review of all available bitumen studies has lead to the conclusion that bitumen is not classified as hazardous to health under EU legislation. Therefore many aspects of REACH are not applicable to bitumen, inter alia the duty to provide a safety data sheet, or exposure scenarios. The observed occasional, short term, reversible irritation of the respiratory tract has however led to a DNEL (derived no effect level) being introduced by REACH registrants. In the voluntarily provided safety data sheet for vapours and aerosols of bitumen a DNEL of 2.9mg/m³ for occupational exposure is given, based on an 8hr time weighed average (TWA) exposure.

In many European countries exposure measurements were carried out at work places, the German BG Bau possesses a huge data base. It must be recognised, that different measurement protocols and references have been used. Therefore, available data can not be compared easily. For Germany, the BITUMEN Forum has proposed a unique way to monitor any long term health effects: employees will be examined medically every two years.

This approach is possible because in Germany the DNEL is not regarded as an OEL, but as guidance for workplace risk assessment. However, other countries might use the DNEL to define an OEL and which could result it becoming a OEL for the whole of Europe.

In October 2011, IARC published their evaluation as to the possible cancer hazard of vapours and aerosols of bitumen. The distinction between hazard and risk is important, and the IARC Monographs identify cancer hazards even when risks are very low at current exposure levels. Without questioning the IARC decisions, some questions remain which hopefully are resolved upon publication of the final report.

The BITUMEN Forum is ready to make this decision transparent and continue to support safe paving.

Keywords: REACH, IARC, DNEL, Exposure

1. INTRODUCTION

On 1st December 2010 the producers and importers of bitumen were obliged to register the product and its uses according to the European REACH Regulation. During the REACH registration a lot of toxicological and ecotoxicological data must be presented for all substances from which are produced more than 1,000 tons.

Numerous studies have been conducted concerning bitumen, from which many were coordinated and co-financed by the German BITUMEN Forum. All these studies show that vapours and aerosols of bitumen are not carcinogenic, nor do they lead to long term health effects. The only health impact occasionally observed was a short term, reversible irritation of the upper respiratory tract. The asphalt industry has responded to these results that occur only at high exposures to vapours and aerosols during applications at very high temperatures. These high exposures no longer exist since several years. Since 2008 in Germany mastic asphalt is only used with additives at application temperatures below 230°C.

As a result of the numerous studies conducted in Europe it can be noted that vapours and aerosols of bitumen are not deemed to be hazardous. They are neither carcinogenic, corrosive, irritant, toxic nor have any other characteristics that would lead to a health hazard classification. Even the irritations of the respiratory system at higher exposures, identified in the Human Bitumen Study (Raulf-Heimsoth et al., 2011), the Fraunhofer Study (Fuhst et al., 2007) and the Rumler Study (Rumler et al., 2007), were too weak to lead to a classification.

Thus many aspects of the REACH Regulation, including the obligation to provide a safety data sheet, are not applicable to bitumen as the substance is not classified. However, the reversible irritation effects of the respiratory tracts have lead to a DNEL (derived no effect level) to be calculated and published. For workers the DNEL is 2.9 mg/m³ (time weighed 8hr average) vapours and aerosols of bitumen and for the general population 0.6 mg/m³(24hr average).

In October 2011 IARC conducted its review of “bitumen and its emissions” (Monograph 103). An international panel of independent scientists re-evaluated all the available scientific studies on vapours and aerosols of bitumen. The final Monograph report has yet to be published and the the overall evaluation shall not be questioned but it has already raised some specific questions on its interpretation. This paper will review some of these points.

2. THE "SUBSTANCE" BITUMEN

Bitumen is not a pure substance like toluene or benzyl alcohol but a complex combination of many hundreds, even thousands of individual hydrocarbon constituents. There exist numerous CAS-No that can be used to describe bitumen (Table 1). CAS numbers usually refer to pure substances, so it is not surprising that for many people it is not clear that bitumen is a complex mixture of many substances even if they see it described under one particular CAS-No.

What sometimes adds to the confusion and leads to further discussions is an unclear description of the *emissions* from bitumen. The solid or liquid state of a pure chemical substance has the same composition as the vapours and/or aerosols derived from this substance. For bitumen, the vapours and aerosols which occur when bitumen is heated have a very different composition than the solid or liquid bitumen. This is a very important consideration when it comes to hazard and risk assessment of vapours and aerosols from bitumen.

Table 1: CAS-No for commonly used bitumen

Asphalt (8052-42-4)
Residues (petroleum), vacuum (64741-56-6)
Residues (petroleum), hydrodesulfurized vacuum (64742-85-4)
Asphalt, oxidized (64742-93-4)
Asphaltenes (petroleum) (91995-23-2)
Residues (petroleum), thermal cracked vacuum (92062-05-0)
Residues (petroleum), dewaxed heavy paraffinic, vacuum (94114-22-4)
Residues (petroleum), distn. residue hydrogenation (100684-39-7)
Residues (petroleum), vacuum distn. residue hydrogenation (100684-40-0)

A possible classification can only refer to vapours and aerosols of bitumen since only these can be inhaled by workers. More importantly only the effects of vapours and aerosols have been considered in the toxicological

and human studies. Consequently any classification does not refer to the solid bitumen but to its vapours and aerosols: it is therefore not a problem to walk on an asphalt pavement barefoot.

Hence it is very important for bitumen producers, users and regulators to separate bitumen on the one hand, and vapours and aerosols of bitumen on the other hand and to use a proper terminology. There are no bitumen vapours and bitumen aerosols as such. There are only vapours and aerosols (out) of (hot) bitumen.

3. DNEL AND EXPOSURE ON CONSTRUCTION SITES

Having analysed the available studies for vapours and aerosols of bitumen manufacturers have derived the DNEL for workers (2.9 mg/m³) and for the general population (0.6 mg/m³), based on the mild irritant effects on the respiratory tract seen in rats.

In the Fraunhofer Study (Fuhst et al., 2007) on rats, from which the DNEL results were derived, the concentration of vapours and aerosols of bitumen were determined on the basis of a bitumen condensate standard. The concentrations measured by the German BITUMEN Forum at construction sites are based on a mineral oil standard (Kriech et al., 2010). To compare values from the different methods, accounting for the influence of the mineral oil standard, a factor of 1.46 applies (Breuer and Engel, 2010; Kriech et al., 2010).

It must further be recognised, that data from German BITUMEN Forum are task related exposures. The DNEL for occupational exposures is based on an eight hours shift value (8h TWA). It is worthwhile to investigate on how exactly to transform all available data into a comparable system.

Producers and users of bitumen need to agree on a standard procedure how to handle hot bitumen safely. Above all it is necessary, that the producers not only specify the DNEL but also provide guidance and assistance how to interpret the DNEL for bitumen vapours and aerosols.

For materials classified as hazardous, the safety data sheet should not only mention a DNEL, but also provide exposure scenarios and risk management measures (RMM). The RMM specify how to deal with the DNEL in practice. For non hazardous substances, such as bitumen, safety data sheets do not have to be created. Many producers of chemicals voluntarily provide information and the format of this information is not specified. It is, however, often based on the basic structure of the safety data sheets. It may list generic safe handling advice to help users in their own workplace risk assessments. Currently in many bitumen safety data sheets, a DNEL of 2.9 mg/m³ is published without risk management measures. Asphalt companies consequently feel left alone with the problem of how to manage the DNEL.

In Germany, the BITUMEN Forum has found a way out of this dilemma. Since the field experience over many years show no effects by the workers during paving, employees are examined every two years to determine, whether any health effects occur due to working occasionally above the DNEL. This approach is possible because in Germany the DNEL is not regarded as an OEL (Occupational Exposure Limit), but as an instrument in workplace risk assessments.

The BITUMEN Forum has asked the producer of bitumen, to add the following sentence in the saty data sheet: "The DNEL is no limit by law, but must be considered in the risk assessment. In Germany, this has the consequence that all asphalt workers are examined every two years."

However, there is a risk that some European countries will set the DNEL as an occupational exposure limit and then the DNEL is discussed as a limit value for all of Europe. German BITUMEN Forum is in contact with the REACH agency on setting the right steps to continue providing safe working conditions and to provide scientific information and background in this complex topic.

4. IARC MONOGRAPH ABOUT BITUMEN

The International Agency for Research of Cancer (IARC) regularly publishes monographs about substances. In these monographs all available publications about the effects of the particular substance on humans and about the exposures are summarized and evaluated from a scientific point of view on hazards. During this evaluation the IARC classifies the substances by putting them into one of the following five categories:

Group 1 Carcinogenic to humans

Group 2A	Probably carcinogenic to humans
Group 2B	Possibly carcinogenic to humans
Group 3	Not classifiable as carcinogenic to humans
Group 4	Probably not carcinogenic to humans

In October 2011 the IARC has re-evaluated the studies on vapours and aerosols of bitumen and concluded that:

- occupational exposures to oxidized bitumens and their emissions during roofing are 'probably carcinogenic to humans' (Group 2A);
- occupational exposures to hard bitumens and their emissions during mastic asphalt work are 'possibly carcinogenic to humans' (Group 2B); and
- occupational exposures to straight-run bitumens and their emissions during road paving are 'possibly carcinogenic to humans' (Group 2B).

The outcome of the evaluation is not questioned here in this paper. However, it should be ensured that the future classification or the substances referred to in the classification are more clearly defined. At this time, the outcome of the IARC evaluation poses many questions:

Should solid oxidized bitumen, solid hard bitumen and solid straight-run bitumen now be classified?

> As all studies were performed with condensates of vapours and aerosols of oxidized and/or straight-run bitumen and because the composition of the condensates is not identical to the composition of the solid substance, there is good reason to ask for guidance on the interpretation of the current wording used.

Why is the evaluation related to the application (i.e expressed by sector – paving, roofing and mastic)?

> Different bitumens are used across a range of applications. For example, straight run bitumen is used in roofing applications. How should occupational exposure to vapours and aerosols from straight run bitumen in roofing be considered? How should hard bitumen used in paving applications be considered? How should air rectified bitumen (a mildly oxidised bitumen, CAS number equivalent to fully oxidised bitumen) be considered in paving application?
> Perhaps in the United States there may be a strong linking between the typpe of bitumen and the sector of ist use. But in Europe the different types of bitumen are used widley spread in the various sectors and it is not understandable, why the sector of use shall have an influence on the toxikological effects.

The bitumen producers physically distinguish between air rectified bitumen and fully oxidised bitumen by considering the Penetration Index of bitumen. Although the same CAS number, the PI reflects differences in manufacturing of fully oxidised bitumen which are often used for roofing applications (often incorporating fluxes) and mildly oxidised bitumen sometimes used for paving applications. Will IARC distinguished between these two obviously different types of materials ?

> IARC may probably define the boundary between these two oxidized bitumen by a factor of ring and ball penetration experiment. How can we ensure that this factor can not be manipulated? The viscosity is certainly not only dependent on the degree of oxidation of the bitumen. Perhaps the difference between semiblown bitumen and oxidized bitumen may better be defined by the addition of flux oil.

Publication of the full Monograph report should hopefully shed some light on the above questions and provide some clarity for those areas not covered by the initial communications. The German BITUMEN Forum is ready to help make the outcome of the IARC evaluation transparent and to continues supporting safe work with bitumen.

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