

## DNEL FAQs

### **Q. Bitumen is not hazardous - why do I need a safety data sheet (SDS)?**

**A.** In the EU, it is mandatory for suppliers of hazardous substances to provide SDSs that meet the format and content requirements of REACH Annex II. Although there is no legal requirement to provide an SDS for substances that are not classified as hazardous, it is generally recognised that this is an effective method for the provision of health, safety, environmental (HSE) and regulatory information to downstream users.

Even though substances are not classified as hazardous, there may still be a need to warn users about potential hazards that arise during use. REACH SDS requirements are primarily directed at suppliers of substances and mixtures. Safety data sheets are product specific and usually do not contain specific information for a given workplace where the product may be used. The documents do, however, provide general information that will help the downstream user organisation meet its obligations under Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

### **Q. On the SDS, section 8, there is mention of a DNEL. What is a DNEL?**

**A.** The term DNEL is an abbreviation for “Derived No Effect Level”. The terminology and concept was introduced by the REACH regulation and represents “the level of exposure above which humans should not be exposed” [REACH Annex 1, Chapter 1 “Human health hazard assessment”, article 1.0.1 (EC, 2006)].

### **Q. What is the purpose of a DNEL?**

**A.** DNELs are calculated health “reference” values, based on health effects observed during experimental studies or human investigations, for which an effect threshold can be identified. The value reflects the level of human exposure at which no health effects are expected and are in effect an estimation of the “safe” level of human exposure to a chemical i.e. that which should not be associated with health effects in an exposed population

### **Q. What is the difference between a DNEL and an Occupational Exposure Limit?**

**A:** The DNEL is not a workplace occupational exposure limit (OEL). It is a health “reference” value used to inform the chemical safety assessment in REACH and, where appropriate, drive the need for risk reduction measures. DNELs are derived from toxicity data, using methodology provided in REACH technical guidance documents. They are intended to cover all potentially exposed populations, not just workers, and also consider inhalation as well as other routes of exposure. In the workplace, DNELs need to be considered during health risk assessments and provide a basis for establishing protective measures.

OELs may be recommended by an individual company, or established by a governmental regulatory body or an expert organisation, such as the Scientific Committee for Occupational Exposure Limits (SCOEL) or the American Conference of Governmental Industrial Hygienists (ACGIH). They are derived following systematic review of the relationship between exposure (normal inhalation) and health effect. OELs are considered to represent safe levels of airborne exposure for a typical worker in an occupational setting (8-hour work shift, 40 hour work week). Compliance with regulatory OELs is an important workplace health protection control measure.

Although the aim of both DNELs and OELs is to protect health, the processes for deriving them are very different and, as a result, the values may differ for the same chemical.

## Q. What are DNELs used for?

A. In REACH, DNELs are used to help characterise the risk to human health from exposure to chemicals that are classified as Dangerous according to the European CLP Regulation [EC No 1272/2008]. They are also used to define appropriate risk management measures. Actual or predicted human exposure is compared with the calculated DNEL and if exposure is greater than the relevant DNEL then action is needed to reduce exposure. If exposure is less than the relevant DNEL then health risks are considered to be adequately controlled.

## Q. Why is a DNEL established?

A. Manufacturers of chemical substances are required to establish DNELs if appropriate under REACH, if they manufacture an amount > 10 tonnes per annum (tpa). DNELs have to be calculated as part of the mandatory health hazard assessment. Note: DNEL values may also be required for chemicals which are not classified as hazardous, since effects may occur at levels of exposure which are higher than the classification threshold.

## Q. How is a DNEL established?

A. The methodology for calculating DNELs is subject to comprehensive guidance issued by the European Chemicals Agency (Guidance on information requirements and chemical safety assessment. Chapter R.8: Characterisation of dose [concentration]-response for human health. Version 2, Dec 2010).

The key steps are summarised as follows:

- Evaluate the key study for the specified health endpoint.
- Identify the threshold concentration or dose associated with either:
  - The lowest “effect” level, or
  - The clear “no effect” level.
- Apply appropriate “Assessment Factors” to take account of uncertainties in the health effects data and extrapolation of effects from animals to man. This includes consideration of effects in susceptible individuals or populations.

Note: the better the quality of the health effects data, the smaller the overall assessment factor that needs to be applied.

## Q. Is there only one DNEL value?

A. No. DNELs must reflect the likely routes, duration and frequency of exposure. Depending upon the substance and how it is used, there may be a need to develop a number of distinct DNEL values. These values need to cover relevant exposed human populations, including, where appropriate, known susceptible or vulnerable populations such as children or pregnant women.

## Q. Who is responsible for establishing DNELs?

A. Under REACH, registrants (manufacturers or importers of a chemical) are legally required to calculate appropriate DNEL values for any chemical that they manufacture or import in quantities > 10 tpa. DNELs are developed as part of the mandatory human health hazard assessment and relevant values must be included in both the REACH Registration Dossier and the Chemical Safety Report, and be communicated to downstream users.

## Q. How were the DNELs for bitumen derived?

A. The DNELs for bitumen were based on evaluation of the known available and relevant health effects data. The key health data for bitumen were identified from a 2-year inhalation study of bitumen fumes in rats, in which the main finding was mild irritation of the nose and upper respiratory tract. This effect was used to calculate the DNEL values for long-term, local effects for both workers and the general population, following inhalation exposure to bitumen fumes.

## Q. What DNEL values are identified for bitumen?

A. The relevant Inhalation DNEL values for bitumen fumes are as follows:

- Worker, Long-term, Local effects - 2.9 mg/m<sup>3</sup> of Total Hydrocarbon (8 hr TWA)
- General population, Long-term, Local Effects - 0.6 mg/m<sup>3</sup> of Total Hydrocarbon (24 hr TWA)

Note: Total Hydrocarbon includes hydrocarbons in aerosol, semi-volatile and vapour forms. A suitable method for collection and measurement of bitumen fume can be downloaded from [www.eurobitume.eu](http://www.eurobitume.eu)

## Q. What health effect does the bitumen DNEL protect against?

A. Results of studies in which animals were exposed repeatedly to fumes from hot bitumen show that the only health effect is mild irritation of the nose and other areas of the upper respiratory system. The calculated DNEL values provide an estimate of the level of exposure at which irritation of the respiratory system is not expected in humans.

## Q. What are the potential consequences of the DNEL? E.g. regular medical surveillance of staff, workplace monitoring ...?

A. The primary purpose of the DNEL in REACH is to help identify any health risks associated with use of a chemical. In the absence of a hazard classification, formal exposure assessment and risk characterisation is not required.

Under the Chemical Agents Directive (98/24/EC), Article 4, employers have a duty, however, to determine whether hazardous chemical agents are present in the workplace and, if so, assess and document any risk to the safety and health of workers during use. If risks are identified, then appropriate measures shall be adopted to eliminate these, or reduce them to a minimum. Article 5 provides a list of general risk reduction measures that should be considered by the employer:

- The design and organisation of systems of work at the workplace;
- The provision of suitable equipment for work with chemical agents and maintenance procedures which ensure the health and safety of workers at work;
- Reducing to a minimum the number of workers exposed or likely to be exposed;
- Reducing to a minimum the duration and intensity of exposure;
- Appropriate hygiene measures;
- Reducing the quantity of chemical agents present at the workplace to the minimum required for the type of work concerned;
- Suitable working procedures including arrangements for the safe handling, storage and transport within the workplace;

**Q. What should a customer do to determine if they are operating within or exceeding the DNEL?**

A. Customers need to assess the potential for exposure of their workers to bitumen emissions during use and the likelihood of irritation of the respiratory tract occurring. This could (or may) include monitoring exposure (8 hour time weighted average) of workers involved in roles with the highest exposure potential. Reports of significant respiratory tract irritation should be investigated. The workplace risk assessment may need to be updated and action taken if necessary.

**Q. The DNEL relates to bitumen fume. How does this relate to bitumen applications?**

A. DNELs are defined for substances and provide a reference value for use in assessing health risk, regardless of the form in which the substance is being used (as a pure substance or in a mixture). Therefore the bitumen DNEL is applicable to those work situations where exposure to fume and aerosol from hot asphalt mixtures is likely.

**Q. There are potentially a number of factors contributing to the presence of fumes in the work place. How can you compare the DNEL with actual measurements?**

A. The methods available for monitoring and quantifying exposure are not specific to bitumen fume. In the workplace atmosphere there may be many other materials or confounding factors, such as dust, tobacco smoke, diesel exhaust fumes, which may be captured during air monitoring. Exposure levels also depend greatly on the worksite conditions (indoor, outdoor, operating temperature, etc.). Comparing a DNEL (calculated values) with actual worker exposure data must be done carefully, taking these and other factors into account.

**Q. How should a customer (e.g. asphalt contractor) compare the DNEL value with published (individual) exposures measured in the field?**

A. The DNEL value for bitumen worker is expressed as the average personal exposure over an 8 hour work period, measured as Total Hydrocarbon. The actual level of personal exposure will fluctuate during the working day and also vary with the job task, working environment, operating temperature etc. It is important to recognise that direct comparison of the DNEL with measured or published data may not be possible, due to differences in measurement method, operating conditions and the time period over which exposure is averaged.

**Q. What should a customer do to establish whether his employees are operating within the DNEL?**

A. The potential for bitumen fumes and aerosol causing irritation of the respiratory tract needs to be considered by employers as part of their workplace risk assessment under the Chemical Agents Directive. In the absence of a recognised Occupational Exposure Limit, the DNEL provides a “reference” exposure level, at which effects in workers are not expected. Customers need to assess the intensity and duration of exposure of their workers to bitumen emissions and consider the likelihood of irritation of the respiratory tract occurring. Reports of significant respiratory tract irritation should be investigated. The workplace risk assessment may need to be updated and action taken if necessary.

**Q. What workplace controls or monitor should/must to be implemented?**

A. Workplace controls and any workplace exposure monitoring strategy will be worksite specific and can only be determined following a structured assessment of the working environment, operating conditions and task involved. This should include a qualitative assessment of the intensity and duration of exposure to bitumen emissions and the likelihood of respiratory tract irritation. Qualitative assessments may be complemented by actual workplace exposure monitoring,

**Q. What can a customer do to lower exposure of staff to bitumen fumes if required by the risk assessment?**

A. Operating temperature is a key factor in determining the amount of fume emissions. In addition to working within recommended temperatures, the following measures should be considered to help reduce exposure:

- Rotate work tasks;
- Stand upwind / avoid standing close to, or downwind of emission sources;
- Take breaks away from emission source;
- Provide protective masks for use in high emission areas;
- Avoid standing in high emission zones;
- Minimise time spent in emission zone;
- Minimise number of workers in the emission zone;
- Provide fume extraction / forced ventilation to remove fumes from work area.

**Note:** Selection of the most appropriate measures to reduce exposure will depend upon the specific worksite and operating conditions.

**Q. Why, in section 1.1 of the SDS, is the product name “Asphalt” and not Bitumen?**

A. As from 1<sup>st</sup> December 2010, REACH Annex II requires that the identification of the substance in Section 1.1 of the SDS be consistent with the substance identification provided in the REACH registration dossier; the process to be followed for identification of registered substances is defined in REACH Annex VI, Section 2.1.

For example, the official CAS RN and EINECS names are Asphalt (CAS 8052-42-4) and Asphalt, oxidized (CAS 64742-93-4). As these “official” names may not be easily recognised, other common names or synonyms may appear in section 1.1, under the heading “Other means of identification”.

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