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Derived No-Effect Levels (DNELs) of Solvent Black 29

EC 938-781-3

Exposure pattern	DNEL	
	Workers	**General population**
Acute - inhalation, systemic effects	No hazard identified	
Acute - dermal, local effects	No hazard identified	
Acute - inhalation, local effects	No hazard identified	
Long-term - dermal, systemic effects	0.13 mg/kg bw/day	0.07 mg/kg bw/d
Long-term - dermal, local effects	No hazard identified	No hazard identified
Long-term - inhalation, systemic effects	0.94 mg/m^3	0.166 mg/m^3
Long-term - inhalation, local effects	No hazard identified	No hazard identified
Long-term - oral, systemic effects	Not relevant	0.07 mg/kg bw/day

1. Toxicological profile

The toxicological profile of Solvent Black 29 has been described in detail in the disseminated ECHA dossier[i]. The substance EC 938-781-3 has no harmonized classification according to Regulation (EC) No. 1272/2008 and is self-classified as Repr 1B.

1.1. Toxicokinetics

Specific toxicokinetic or dermal absorption studies are not available for Solvent Black 29. The product is a UVCB mixture of anionic chrome-azo complexes that form salts with a UVCB mixture of highly branched N-cationic trialkyl amines. The molecular weights range between 851.53 - 949.67 g/mol. A molecular weight of > 500 g/mol is generally considered unfavourable for skin penetration.

Determination of the log Pow with the HPLC-method (OECD 117) showed values between 2.29 and 3.66. The log Pow values are less than 4, therefore the default assumption of 10% permeability cannot be applied. No bioaccumulation is expected.

The vapour pressure of the substance is negligible, therefore exposure via the gas phase is not relevant. Inhalation to mist or fine dusts is expected to result in particle deposition in the respiratory tract. Systemic uptake from there is at least possible after mucociliary clearance to the stomach.

1.2. Acute toxicity

Solvent Black 29 is of low acute toxicity. In an acute oral toxicity study (OECD 401, GLP), the median lethal dose (LD50) in Wistar rats was > 5000 mg/kg bw. In addition, the dermal LD50 value was reported as > 2000 mg/kg bw in rats according to OECD 402, GLP.

1.3. Corrosion / Irritation

Three NZW rabbits were dermally exposed to Solvent Black 29 for 4 hours (OECD 404, GLP). Animals then were observed for three days and additional observations were made on day 4. The single semiocclusive application elicited very slight oedema in all animals at the 48 and/or 72 hour reading, but no erythema. All reactions had been resolved by day 4. The observed signs of skin irritation were not relevant for classification and labelling. Therefore, the test substance is not irritating or corrosive to the rabbit skin. Moreover, Solvent Black 29 is not irritating to eye in an eye irritation study conducted according to OECD TG 405 and GLP.

1.4. Sensitization

Solvent Black has no skin sensitizing potential when tested in guinea pigs (OECD 406, GLP).

1.5. Repeated dose toxicity

The oral administration of Solvent Black 29 to male and female Wistar rats via gavage over a 4-week period, following OECD Guideline 407 (Repeated Dose 28-Day Oral Toxicity Study in Rodents), was conducted at dose levels of 1000, 200, and 40 mg/kg bw/day (corrected to 32 mg/kg bw/day based on concentration analysis). Systemic toxicity was observed at doses of 200 mg/kg bw/day and above. Consequently, the No Observed Adverse Effect Level (NOAEL) was established at 32 mg/kg bw/day for both sexes, as only 80% of the nominal 40 mg/kg bw/day dose was confirmed during concentration control analysis.
In a second subacute 28-day oral toxicity study conducted in Sprague-Dawley rats according to OECD Test Guideline 407 and under GLP conditions, Solvent Black 29 was administered daily by gavage at dose levels of 0, 50, 200, and 1000 mg/kg bw/day. Treatment-related effects were observed at 200 and

1000 mg/kg bw/day. At the highest dose, animals of both sexes exhibited whole-body purple/blue discoloration, haematological changes (including increased unstained cells and reduced reticulocytes), elevated serum bilirubin levels, and increased urinary white blood cells in males. Additionally, focal cortical hypertrophy in the adrenal glands was observed microscopically in two females. At 200 mg/kg bw/day, a reduction in reticulocyte count was noted in males. No treatment-related effects were observed at 50 mg/kg bw/day, which was therefore identified as the No Observed Adverse Effect Level (NOAEL).

1.6. Genetic toxicity

Solvent Black 29 was found to be positive in three standard Ames test. No genotoxic potential was found in the Chromosomal Aberration Test *in vitro*, in the Mammalian Cell Gene Mutation Test *in vitro* and in the Erythrocyte Micronucleus Test *in vivo*. Based on these results, Solvent Black 29 is not classified as genotoxic according to current regulatory criteria.

Table 1: Summary of Mutagenicity studies

Study	Type	OECD Guideline	Result
In vitro	Bacterial Reverse Mutation Assay	OECD TG 471	Positive
	In Vitro Mammalian Cell Gene Mutation Test	OECD TG 476	Negative
	In Vitro Mammalian Chromosome Aberration Test	OECD TG 473	Negative
In vivo	Mammalian Erythrocyte Micronucleus Test	OECD TG 474	Negative

1.7. Toxicity to reproduction

In a GLP-compliant OECD 421 study, Solvent Black 29 was administered daily by gavage to male and female Wistar rats at doses of 0, 40, 200, and 1000/500 mg/kg bw/day. Systemic toxicity was observed at 1000 and 500 mg/kg bw/day in both sexes, and at 200 mg/kg bw/day in females, as evidenced by reduced food consumption, impaired body weight gain, and discoloration of eyes, skin, and faeces. Due to early mortality and systemic effects, the high dose was reduced from 1000 to 500 mg/kg bw/day on day 7. Based on these findings, the NOAEL for systemic toxicity was established at 200 mg/kg bw/day for males and 40 mg/kg bw/day for females.

Despite the absence of adverse histopathological findings in reproductive organs, developmental toxicity was evident at the high dose, with a markedly reduced gestation index, increased postimplantation loss (74.2%), and decreased postnatal viability. Discoloration and impaired body weight development were also noted in F1 pups at 200 and 500/1000 mg/kg bw/day. These effects were considered treatment related. However, since only one litter was affected at 200 mg/kg bw/day and the findings were likely secondary to maternal toxicity, the NOAEL for developmental toxicity was considered to be 200 mg/kg bw/day.

Mating and fertility parameters were unaffected at all dose levels except in the high-dose group, where effects were attributed to maternal toxicity rather than impaired fertility. Therefore, the NOAEL for reproductive performance and fertility was set at 200 mg/kg bw/day for both sexes.

2. DNELs (Derived No-Effect Levels)

Adverse effects on development (increased post-implantation loss, reduced gestation index and postnatal viability index) were observed at the high dose group, and therefore, the NOAEL (OECD TG 421) of 40 mg/m³ was chosen as the most relevant dose descriptor.

Therefore, the following DNELs have been established for Solvent Black 29, reflecting the likely route(s), duration and frequency of exposure:

2.1. Workers - Hazard via inhalation route

2.1.1. Systemic effects

Relevant dose descriptor: NOAEL (OECD 421) = 40 mg/kg bw/d

Conversion of an oral rat NOAEL into a corrected inhalatory NOAEC to assess human inhalatory exposure:

Corrected NOAEC = Oral NOAEL $* \frac{1}{0.38\ m^3/kg/d} * \frac{6.7\ \mathrm{m3(8h)}}{10\ \mathrm{m3(8h)}} = 71\ \mathrm{mg/m^3}$

The oral dose for the rat is converted to the corresponding air concentration using a standard breathing volume for the rat (0.38 m3/kg for 8 hours exposure of workers). Moreover, for workers the resulting air concentration needs to be additionally corrected for the difference between basal caloric demand and caloric demand under light activity. This correction factor derives from the respiratory volumes in 8 hours under the respective conditions (6.7 m^3 for base level, 10 m^3 for light activity).

Assessment factors (AF) based on ECHA Guidance document[ii]:

AF for		Value
interspecies differences	Differences in metabolic rate (rat)	not applicable[1]
	Remaining uncertainties[2]	2.5
intraspecies differences	Workers	5
duration of exposure transfer	Sub-acute to Chronic	6
dose-response	NOAEL -> NOAEC	1
data base quality	Good quality	1
Other		1
Total		75

[1] It is assumed to be already scaled according to the allometric principle, since ventilation rate and food intake directly depend on the basal metabolic rate.

[2] It is assumed that humans would be more sensitive than animals to effects on the respiratory tract.

The DNEL is calculated using the values given above as

$$Workers - Inhalation - Systemic\ DNEL = \frac{\text{NOAEC}}{\text{Overall AF}} = \frac{\frac{71\text{mg}}{\text{m}^3}}{75} = 0.94\ \text{mg/m}^3$$

2.2. Workers - Hazard via dermal route

2.2.1. Systemic effects

Relevant dose descriptor: NOAEL (OECD 421) = 40 mg/kg/day

The molecular weight is high and the water solubility is low. As a worst-case equal absorption for the dermal and oral routes are assumed.

Assessment factors (AF) based on ECHA Guidance document:

AF for		Value
interspecies differences	Differences in metabolic rate (rat)	4
	Remaining uncertainties [2]	2.5
intraspecies differences	Workers	5
duration of exposure transfer	Sub-acute to Chronic	6
dose-response	NOAEL -> NOAEL	1
data base quality	Good quality	1
Other		1
Total		300

The DNEL is calculated using the values given above as

$$Workers - Dermal - Systemic\ DNEL = \frac{\text{NOAEL}}{\text{Overall AF}} = \frac{40\ \frac{\text{mg}}{\text{kg}}\text{bw}}{300} = 0.13\ mg/kg\ bw/d$$

3.1. Consumers - Hazard via inhalation route

3.1.1. Systemic effects

Relevant dose descriptor: NOAEL (OECD 421) = 40 mg/kg/day

Conversion of an oral rat NOAEL into a corrected inhalatory NOAEC to assess human inhalatory exposure:

$$\text{Corrected NOAEC} = \text{Oral NOAEL} * \frac{1}{\frac{1.15\frac{m^3}{kg}}{d}} * \frac{5d}{7d} = 24.8\ \text{mg/m}^3$$

The oral dose for the rat is converted to the corresponding air concentration using a standard breathing volume for the rat (1.15 m3/kg for 24 hours exposure to the general population).

Assessment factors (AF) based on ECHA Guidance document:

AF for		Value
interspecies differences	Differences in metabolic rate (rat)	not applicable[1]
	Remaining uncertainties [2]	2.5
intraspecies differences	Consumers	10
duration of exposure transfer	Sub-acute to Chronic	6
dose-response	NOAEL -> NOAEL	1
data base quality	Good quality	1
Other		1
Total		150

The DNEL is calculated using the values given above as

$$Consumers - Inhalation - Systemic\ DNEL = \frac{\text{NOAEC}}{\text{Overall AF}} = \frac{\frac{24.8\text{mg}}{\text{m}^3}}{150} = 0.166\ \text{mg/m}^3$$

3.2. Consumers- Hazard via dermal route

3.2.1. Systemic effects

Relevant dose descriptor: NOAEL (OECD 421) = 40 mg/kg/day

The molecular weight is high and the water solubility is low. As a worst case equal absorption for the dermal and oral routes are assumed.
Assessment factors (AF) based on ECHA Guidance document:

AF for		Value
interspecies differences	Differences in metabolic rate (rat)	4
	Remaining uncertainties [2]	2.5
intraspecies differences	Consumers	10
duration of exposure transfer	Sub-acute to Chronic	6
dose-response	NOAEL -> NOAEL	1
data base quality	Good quality	1
Other		1
Total		600

The DNEL is calculated using the values given above as

$$Consumers - Dermal - Systemic\ DNEL = \frac{\text{NOAEL}}{\text{Overall AF}} = \frac{40\ \frac{\text{mg}}{\text{kg}}\text{bw}}{600} = 0.07\ mg/kg\ bw/d$$

3.3. Consumers- Hazard via oral route

3.3.1. Systemic effects

Relevant dose descriptor: NOAEL (OECD 421) = 40 mg/kg/day

Assessment factors (AF) based on ECHA Guidance document:

AF for		Value
interspecies differences	Differences in metabolic rate (rat)	4
	Remaining uncertainties [2]	2.5
intraspecies differences	Consumers	10
duration of exposure transfer	Sub-acute to Chronic	6
dose-response	NOAEL -> NOAEL	1
data base quality	Good quality	1
Other		1
Total		600

The DNEL is calculated using the values given above as

$$Consumers - Oral - Systemic\ DNEL = \frac{\text{NOAEL}}{\text{Overall AF}} = \frac{40\ \frac{\text{mg}}{\text{kg}}\text{bw}}{600} = 0.07\ mg/kg\ bw/d$$

References

[i] ECHA. (2025b). *ECHA CHEM EC 938-781-3*. Europa.eu. https://chem.echa.europa.eu/100.221.283/dossier-view/5a11c20c-6c2e-47b8-b09f9ba987500a51/IUC5-cd5fb633-e344-4d4f-b69a-9284b247106a_903f50ca-c8e5-403d-8489e13399d7f050?searchText=938-781-3

[ii] ECHA. (2012). *Guidance on information requirements and chemical safety assessment Chapter R.8: Characterisation of dose [concentration]-response for human health*. https://echa.europa.eu/documents/10162/13632/information_requirements_r8_en.pdf/e153243a-03f044c5-8808-88af66223258