# n-Butyl lactate

| CAS number: | 138-22-7 |
| --- | --- |
| Synonyms: | Butyl alpha-hydroxypropionate, butyl lactate, 2‑hydroxypropanoic acid butyl ester, lactic acid butyl ester |
| Chemical formula: | C7H14O3 |
| Structural formula: |  |

Workplace exposure standard (retained)

| TWA: | **5 ppm (30 mg/m3)** |
| --- | --- |
| STEL: | **—** |
| Peak limitation: | **—** |
| Notations: | **—** |
| IDLH:  Sampling and analysis: | **—**  The recommended value is quantifiable through available sampling and analysis techniques. |
|  |

## Recommendation and basis for workplace exposure standard

A TWA of 5 ppm (30 mg/m3) is recommended to protect for irritation of the upper respiratory tract in exposed workers.

## Discussion and conclusions

N-Butyl lactate is typically encountered as a solvent for processing cellulose derivatives, natural gums, oils, dyes, paints and polymers.

Critical effects of exposure are irritation of the upper respiratory tract, headache and coughing. These effects are likely caused by the action of the hydrolysis product, lactic acid (HCOTN, 2001).

There are limited exposure data available. A NOAEL of 7 ppm (42 mg/m3) is reported for upper respiratory tract effects and objectionable odour in exposed workers (ACGIH, 2018). A NOAEL of 200 mg/m3 for hyperplasia of the nasal epithelium is reported in rats (HCOTN, 2001). The proposed HCOTN TWA of 20 mg/m3 is derived by applying a safety factor of 10 to the animal NOAEL to account for inter and intra species variation (HCOTN, 2001).

The recommended TWA of 5 ppm (30 mg/m3) is derived by rounding down the reported NOAEL in human to allow for experimental uncertainty. This is the same value as the ACGIH (2018) and is considered sufficiently low to minimise potential respiratory tract irritation in exposed workers.

## Recommendation for notations

Not classified as a carcinogen according to the Globally Harmonized System of Classification and Labelling of Chemicals (GHS).

Not classified as a skin sensitiser or respiratory sensitiser according to the GHS.

Insufficient data available to recommend a skin notation.

# Appendix

### Primary sources with reports

| Source Year set Standard |
| --- |
| SWA Year TWA: 5 ppm (30 mg/m3) | |
|  |
| ACGIH 2001 TLV-TWA: 5 ppm (30 mg/m3) |
| TLV-TWA intended to minimise potential for headaches, irritation to mucous membranes and coughing.  Insufficient data to recommend a TLV-STEL, skin, sensitiser and carcinogenicity notations.  No animal data are discussed, TLV-TWA is based on an occupational exposure study that determined a NOAEL of 7 ppm for objectionable odour and clinical symptoms.  Summary of data:  Human data:   * Odour threshold reported at 5.8 ppm * Prolonged exposures at ≈ 7 ppm (duration not specified) with short peak exposures at 11 ppm caused irritation of the upper respiratory mucous membranes with coughing and headaches * sleepiness and headache reported in evening after exposure * nausea and vomiting reported * workers exposed at these levels returned normal blood/urine analyses * NOAEL of 7 ppm for injury from critical effects and objectionable odour * noted that odour was perceived at 7 ppm, but not injurious. |
| DFG NA NA |
| No report. |
| SCOEL NA NA |
| No report. |
| OARS/AIHA NA NA |
| No report. |
| HCOTN 2001 8-hour TWA: 25 mg/m3 |
| DECOS proposed to amend the current administrative TWA of 25 mg/m3 to 20 mg/m3 based on a health-based evaluation of animal inhalational data.  Summary of additional data:   * Assessed together with other alkyl lactate esters * Proposed TWA of 20 mg/m3 derived from inhalational NOAEL of 200 mg/m3 for upper respiratory tract effects in rats * An overall safety factor of 10 is applied to account for intra- and interspecies variability, and exposure duration variability in the available studies * approach is used for other low MW lactate esters * Enzymatic hydrolysis forms lactic acid and corresponding alcohol upon inhalation or topical application (no further information provided) * critical effects likely caused by action of lactic acid * No quantitative kinetic data available * may be expected to have similar effects to lactate and corresponding alcohol due to rapid enzymatic hydrolysis upon absorption   Human data:   * Positive patch test result in one subject for ethyl lactate (induction with 10% in gel, challenge with 1% after 6 wk, methodology not specified)   Animal data:   * No contact sensitisation for related lauryl- and cetyl-lactate esters in maximisation test (guinea pigs, n=10, Magnusson-Kligman procedure, no further information provided) * LC50:> 401 ppm (2,400 mg/m3, no further information provided) * LD50: > 5,000 mg/kg (oral and dermal, no further information provided) * Inhalational study reported NOAEL of 200 mg/m3 for hyperplasia of the nasal respiratory epithelium (rats, n=10, 6 h, 5 d/wk, 4 wk) * LOAEL of 600 mg/m3. |

### Secondary source reports relied upon

| Source |  | Year | Additional information |
| --- | --- | --- | --- |
| HSE |  | 2002 | * 8 hour TWA: 5 ppm (30 mg/m3) |
| NICNAS |  | 2018 | * Only tier I assessment available: identified as low concern to human health |

### Carcinogenicity — non-threshold based genotoxic carcinogens

| Is the chemical mutagenic? | Insufficient data |
| --- | --- |
| Is the chemical carcinogenic with a mutagenic mechanism of action? | Insufficient data |
| **Insufficient data are available to determine if the chemical is a non-threshold based genotoxic carcinogen.** | |

## Notations

| Source | Notations |
| --- | --- |
| SWA | — |
| HCIS | NA |
| NICNAS | — |
| EU Annex | NA |
| ECHA | NA |
| ACGIH | — |
| DFG | NA |
| SCOEL | NA |
| HCOTN | — |
| IARC | NA |
| US NIOSH | NA |

NA = not applicable (a recommendation has not been made by this Agency); — = the Agency has assessed available data for this chemical but has not recommended any notations

### Skin notation assessment

| Calculation |
| --- |
| Insufficient data to assign a skin notation |

### IDLH

| Is there a suitable IDLH value available? | No |
| --- | --- |

## Additional information

| Molecular weight: | 146.19 |
| --- | --- |
| Conversion factors at 25°C and 101.3 kPa: | 1 ppm = Number mg/m3; 1 mg/m3 = Number ppm |
| This chemical is used as a pesticide: |  |
| This chemical is a biological product: |  |
| This chemical is a by-product of a process: |  |
| A biological exposure index has been recommended by these agencies: | ACGIH  DFG  SCOEL |

## Workplace exposure standard history

| Year | Standard |
| --- | --- |
| Click here to enter year |  |

## References

American Conference of Industrial Hygienists (ACGIH®) (2018) TLVs® and BEIs® with 7th Edition Documentation, CD-ROM, Single User Version. Copyright 2018. Reprinted with permission. See the [*TLVs® and BEIs® Guidelines section*](http://www.acgih.org/tlv-bei-guidelines/policies-procedures-presentations) on the ACGIH website.

UK Health and Safety Executive (HSE) (2002) EH40/2005 Workplace exposure limits.

Health Council of the Netherlands (HCOTN) (2001) Lactate esters. Health-based recommended occupational exposure limit. The Hague: Health Council of the Netherlands; publication no. 2001/04OSH.

National Industrial Chemicals Notification and Assessment Scheme (NICNAS) (2018) Propanoic acid, 2-hydroxy-, butyl ester: Human health tier I assessment – IMAP report.