

SAFETY DATA SHEET

Based upon Regulation (EC) No 1907/2006, as amended by Regulation (EU) No 2015/830

NOVAKLEEN

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product name : NOVAKLEEN
Registration number REACH : Not applicable (mixture)
Product type REACH : Mixture

1.2. Relevant identified uses of the substance or mixture and uses advised against

1.2.1 Relevant identified uses

Detergent according to Regulation (EC) No 648/2004

1.2.2 Uses advised against

No uses advised against known

1.3. Details of the supplier of the safety data sheet

Supplier of the safety data sheet

Novatio*
Industrielaan 5B
B-2250 Olen
☎ +32 14 25 76 40
☎ +32 14 22 02 66
info@novatio.be
*NOVATIO is a registered trademark of Novatech International N.V.

Manufacturer of the product

Novatech International N.V.
Industrielaan 5B
B-2250 Olen
☎ +32 14 85 97 37
☎ +32 14 85 97 38
info@novatech.be

1.4. Emergency telephone number

24h/24h (Telephone advice: English, French, German, Dutch) :
+32 14 58 45 45 (BIG)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classified as dangerous according to the criteria of Regulation (EC) No 1272/2008

| Class | Category | Hazard statements |
|------------|------------|--------------------------------------|
| Eye Irrit. | category 2 | H319: Causes serious eye irritation. |

2.2. Label elements



Signal word : Warning

H-statements

H319 Causes serious eye irritation.

P-statements

P280 Wear eye protection.

P264 Wash hands thoroughly after handling.

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P337 + P313 If eye irritation persists: Get medical advice/attention.

2.3. Other hazards

No other hazards known

NOVAKLEEN

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

| Name REACH Registration No | CAS No EC No | Conc. (C) | Classification according to CLP | Note | Remark |
|-------------------------------------|-----------------------|-----------|---|------------|-------------|
| 2-butoxyethanol 01-2119475108-36 | 111-76-2 203-905-0 | C<5% | Acute Tox. 4; H332 Acute Tox. 4; H302 Skin Irrit. 2; H315 Eye Irrit. 2; H319 | (1)(2)(10) | Constituent |
| alcohols, C9-11, ethoxylated | 68439-46-3 | C<5% | Acute Tox. 4; H302 Eye Dam. 1; H318 Skin Irrit. 2; H315 | (1)(10) | Constituent |
| propan-2-ol 01-2119457558-25 | 67-63-0 200-661-7 | C<5% | Flam. Liq. 2; H225 Eye Irrit. 2; H319 STOT SE 3; H336 | (1)(2)(10) | Constituent |

(1) For H- and EUH-statements in full: see section 16

(2) Substance with a Community workplace exposure limit

(10) Subject to restrictions of Annex XVII of Regulation (EC) No. 1907/2006

SECTION 4: First aid measures

4.1. Description of first aid measures

General:

Observe (own) safety. If possible, approach victim and check vital functions. In case of injury and/or intoxication, call the European emergency number 112. Treat symptoms starting with most life-threatening injuries and disorders. Keep victim under observation, possibility of delayed symptoms.

After inhalation:

Remove victim into fresh air. In case of respiratory problems, consult a doctor/medical service.

After skin contact:

If possible, wipe up/dry remove chemical. Then rinse/shower immediately with (lukewarm) water. If irritation persists, consult a doctor/medical service.

After eye contact:

Rinse immediately with plenty of water. Remove contact lenses, if present and easy to do. Continue rinsing. If irritation persists, consult a doctor/medical service.

After ingestion:

Rinse mouth with water. If you feel unwell, consult a doctor/medical service. Do not wait for symptoms to occur to consult Poison Center.

4.2. Most important symptoms and effects, both acute and delayed

4.2.1 Acute symptoms

After inhalation:

No effects known.

After skin contact:

No effects known.

After eye contact:

Irritation of the eye tissue.

After ingestion:

AFTER INGESTION OF HIGH QUANTITIES: Vomiting. Abdominal pain. Diarrhoea. Dizziness. Headache.

4.2.2 Delayed symptoms

No effects known.

4.3. Indication of any immediate medical attention and special treatment needed

If applicable and available it will be listed below.

SECTION 5: Firefighting measures

5.1. Extinguishing media

5.1.1 Suitable extinguishing media:

Small fire: Quick-acting ABC powder extinguisher, Quick-acting BC powder extinguisher, Quick-acting class B foam extinguisher, Quick-acting CO2 extinguisher.

Major fire: Class B foam (alcohol-resistant), Water spray if puddle cannot expand.

5.1.2 Unsuitable extinguishing media:

Small fire: Water (quick-acting extinguisher, reel); risk of puddle expansion.

Major fire: Water; risk of puddle expansion.

5.2. Special hazards arising from the substance or mixture

In case of fire: possible release of toxic/corrosive gases/vapours.

NOVAKLEEN

5.3. Advice for firefighters

5.3.1 Instructions:

No specific fire-fighting instructions required.

5.3.2 Special protective equipment for fire-fighters:

Gloves (EN 374). Safety glasses (EN 166). Protective clothing (EN 14605 or EN 13034). Heat/fire exposure: self-contained breathing apparatus (EN 136 + EN 137).

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

No naked flames.

6.1.1 Protective equipment for non-emergency personnel

See section 8.2

6.1.2 Protective equipment for emergency responders

Gloves (EN 374). Safety glasses (EN 166). Protective clothing (EN 14605 or EN 13034).

Suitable protective clothing

See section 8.2

6.2. Environmental precautions

Contain released product, pump into suitable containers. Plug the leak, cut off the supply.

6.3. Methods and material for containment and cleaning up

Take up liquid spill into inert absorbent material. Scoop absorbed substance into closing containers. Clean contaminated surfaces with an excess of water. Wash clothing and equipment after handling.

6.4. Reference to other sections

See section 13.

SECTION 7: Handling and storage

The information in this section is a general description. If applicable and available, exposure scenarios are attached in annex. Always use the relevant exposure scenarios that correspond to your identified use.

7.1. Precautions for safe handling

Keep away from naked flames/heat. In finely divided state: use spark-/explosionproof appliances. Finely divided: keep away from ignition sources/sparks. Observe normal hygiene standards. Keep container tightly closed.

7.2. Conditions for safe storage, including any incompatibilities

7.2.1 Safe storage requirements:

Meet the legal requirements. Keep container in a well-ventilated place. Protect against frost. Keep out of direct sunlight. Max. storage time: 365 day(s).

7.2.2 Keep away from:

Heat sources.

7.2.3 Suitable packaging material:

Synthetic material.

7.2.4 Non suitable packaging material:

Metal.

7.3. Specific end use(s)

If applicable and available, exposure scenarios are attached in annex. See information supplied by the manufacturer.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 Occupational exposure

a) Occupational exposure limit values

If limit values are applicable and available these will be listed below.

EU

| | | |
|-----------------|---|-----------------------|
| 2-Butoxyethanol | Time-weighted average exposure limit 8 h (Indicative occupational exposure limit value) | 20 ppm |
| | Time-weighted average exposure limit 8 h (Indicative occupational exposure limit value) | 98 mg/m ³ |
| | Short time value (Indicative occupational exposure limit value) | 50 ppm |
| | Short time value (Indicative occupational exposure limit value) | 246 mg/m ³ |

Belgium

NOVAKLEEN

| | | |
|----------------------|--|------------------------|
| 2-Butoxyéthanol | Time-weighted average exposure limit 8 h | 20 ppm |
| | Time-weighted average exposure limit 8 h | 98 mg/m ³ |
| | Short time value | 50 ppm |
| | Short time value | 246 mg/m ³ |
| Alcool isopropylique | Time-weighted average exposure limit 8 h | 200 ppm |
| | Time-weighted average exposure limit 8 h | 500 mg/m ³ |
| | Short time value | 400 ppm |
| | Short time value | 1000 mg/m ³ |

The Netherlands

| | | |
|-----------------|---|-----------------------|
| 2-Butoxyéthanol | Time-weighted average exposure limit 8 h (Public occupational exposure limit value) | 20 ppm |
| | Time-weighted average exposure limit 8 h (Public occupational exposure limit value) | 100 mg/m ³ |
| | Short time value (Public occupational exposure limit value) | 50 ppm |
| | Short time value (Public occupational exposure limit value) | 246 mg/m ³ |

France

| | | |
|----------------------|--|-----------------------|
| 2-Butoxyéthanol | Time-weighted average exposure limit 8 h (VRC: Valeur réglementaire contraignante) | 10 ppm |
| | Time-weighted average exposure limit 8 h (VRC: Valeur réglementaire contraignante) | 49 mg/m ³ |
| | Short time value (VRC: Valeur réglementaire contraignante) | 50 ppm |
| | Short time value (VRC: Valeur réglementaire contraignante) | 246 mg/m ³ |
| Alcool isopropylique | Short time value (VL: Valeur non réglementaire indicative) | 400 ppm |
| | Short time value (VL: Valeur non réglementaire indicative) | 980 mg/m ³ |

Germany

| | | |
|-----------------|---|-----------------------|
| 2-Butoxyéthanol | Time-weighted average exposure limit 8 h (TRGS 900) | 10 ppm |
| | Time-weighted average exposure limit 8 h (TRGS 900) | 49 mg/m ³ |
| Propan-2-ol | Time-weighted average exposure limit 8 h (TRGS 900) | 200 ppm |
| | Time-weighted average exposure limit 8 h (TRGS 900) | 500 mg/m ³ |

UK

| | | |
|-----------------|---|------------------------|
| 2-Butoxyéthanol | Time-weighted average exposure limit 8 h (Workplace exposure limit (EH40/2005)) | 25 ppm |
| | Time-weighted average exposure limit 8 h (Workplace exposure limit (EH40/2005)) | 123 mg/m ³ |
| | Short time value (Workplace exposure limit (EH40/2005)) | 50 ppm |
| | Short time value (Workplace exposure limit (EH40/2005)) | 246 mg/m ³ |
| Propan-2-ol | Time-weighted average exposure limit 8 h (Workplace exposure limit (EH40/2005)) | 400 ppm |
| | Time-weighted average exposure limit 8 h (Workplace exposure limit (EH40/2005)) | 999 mg/m ³ |
| | Short time value (Workplace exposure limit (EH40/2005)) | 500 ppm |
| | Short time value (Workplace exposure limit (EH40/2005)) | 1250 mg/m ³ |

USA (TLV-ACGIH)

| | | |
|-----------------|--|---------|
| 2-Butoxyéthanol | Time-weighted average exposure limit 8 h (TLV - Adopted Value) | 20 ppm |
| 2-propanol | Time-weighted average exposure limit 8 h (TLV - Adopted Value) | 200 ppm |
| | Short time value (TLV - Adopted Value) | 400 ppm |

b) National biological limit values

If limit values are applicable and available these will be listed below.

Germany

| | | | |
|---|---|--------------------|--|
| 2-Butoxyéthanol (Butoxyessigsäure (nach Hydrolyse)) | Urin: expositionsende, bzw. schichtende bei langzeitexposition: nach mehreren vorangegangenen schichten | 150 mg/g Kreatinin | |
| Propan-2-ol (Aceton) | Urin: expositionsende, bzw. schichtende | 25 mg/l | |
| Propan-2-ol (Aceton) | Vollblut: expositionsende, bzw. schichtende | 25 mg/l | |

UK

| | | | |
|-------------------------------------|-------------------|-------------------------|--|
| 2-Butoxyéthanol (butoxyacetic acid) | Urine: post shift | 240 mmol/mol creatinine | |
|-------------------------------------|-------------------|-------------------------|--|

USA (BEI-ACGIH)

| | | | |
|---|--|---------------------|-------------------------|
| 2-butoxyéthanol (Butoxyacetic acid (BAA)) | urine: end of shift | 200 mg/g creatinine | With hydrolysis |
| 2-Propanol (Acetone) | Urine: end of shift at end of workweek | 40 mg/L | Background, Nonspecific |

8.1.2 Sampling methods

| Product name | Test | Number |
|--|-------|--------|
| 2-Butoxyéthanol (Alcohols IV) | NIOSH | 1403 |
| 2-Butoxyéthanol (Butyl Cellosolve solvent) | OSHA | 83 |

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4 / 17

NOVAKLEEN

| Product name | Test | Number |
|---|-------|--------|
| Butoxyacetic acid | NIOSH | 8316 |
| Butyl cellosolve (Volatile Organic compounds) | NIOSH | 2549 |
| Butyl Cellosolve | OSHA | 83 |
| Isopropanol (Volatile Organic compounds) | NIOSH | 2549 |
| Isopropyl Alcohol (Alcohols I) | NIOSH | 1400 |
| Isopropyl Alcohol | OSHA | 109 |

8.1.3 Applicable limit values when using the substance or mixture as intended

If limit values are applicable and available these will be listed below.

8.1.4 Threshold values

DNEL/DMEL - Workers

2-butoxyethanol

| Effect level (DNEL/DMEL) | Type | Value | Remark |
|--------------------------|---------------------------------------|------------------------|--------|
| DNEL | Long-term systemic effects inhalation | 98 mg/m ³ | |
| | Acute systemic effects inhalation | 1091 mg/m ³ | |
| | Acute local effects inhalation | 246 mg/m ³ | |
| | Long-term systemic effects dermal | 125 mg/kg bw/day | |
| | Acute systemic effects dermal | 89 mg/kg bw/day | |

propan-2-ol

| Effect level (DNEL/DMEL) | Type | Value | Remark |
|--------------------------|---------------------------------------|-----------------------|--------|
| DNEL | Long-term systemic effects inhalation | 500 mg/m ³ | |
| | Long-term systemic effects dermal | 888 mg/kg bw/day | |

DNEL/DMEL - General population

2-butoxyethanol

| Effect level (DNEL/DMEL) | Type | Value | Remark |
|--------------------------|---------------------------------------|-----------------------|--------|
| DNEL | Long-term systemic effects inhalation | 59 mg/m ³ | |
| | Acute systemic effects inhalation | 426 mg/m ³ | |
| | Acute local effects inhalation | 147 mg/m ³ | |
| | Long-term systemic effects dermal | 75 mg/kg bw/day | |
| | Acute systemic effects dermal | 89 mg/kg bw/day | |
| | Long-term systemic effects oral | 6.3 mg/kg bw/day | |
| | Acute systemic effects oral | 26.7 mg/kg bw/day | |

propan-2-ol

| Effect level (DNEL/DMEL) | Type | Value | Remark |
|--------------------------|---------------------------------------|----------------------|--------|
| DNEL | Long-term systemic effects inhalation | 89 mg/m ³ | |
| | Long-term systemic effects dermal | 319 mg/kg bw/day | |
| | Long-term systemic effects oral | 26 mg/kg bw/day | |

PNEC

2-butoxyethanol

| Compartments | Value | Remark |
|-------------------------------------|------------------------|--------|
| Fresh water | 8.8 mg/l | |
| Marine water | 0.88 mg/l | |
| Fresh water (intermittent releases) | 26.4 mg/l | |
| STP | 463 mg/l | |
| Fresh water sediment | 34.6 mg/kg sediment dw | |
| Marine water sediment | 3.46 mg/kg sediment dw | |
| Soil | 2.33 mg/kg soil dw | |
| Oral | 20 mg/kg food | |

propan-2-ol

| Compartments | Value | Remark |
|-------------------------------------|-----------------------|--------|
| Fresh water | 140.9 mg/l | |
| Fresh water (intermittent releases) | 140.9 mg/l | |
| Marine water | 140.9 mg/l | |
| STP | 2251 mg/l | |
| Fresh water sediment | 552 mg/kg sediment dw | |
| Marine water sediment | 552 mg/kg sediment dw | |
| Soil | 28 mg/kg soil dw | |
| Oral | 160 mg/kg food | |

8.1.5 Control banding

If applicable and available it will be listed below.

8.2. Exposure controls

The information in this section is a general description. If applicable and available, exposure scenarios are attached in annex. Always use the relevant exposure scenarios that correspond to your identified use.

8.2.1 Appropriate engineering controls

Keep away from naked flames/heat. In finely divided state: use spark-/explosionproof appliances. Finely divided: keep away from ignition sources/sparks. Measure the concentration in the air regularly. Carry operations in the open/under local exhaust/ventilation or with respiratory protection.

8.2.2 Individual protection measures, such as personal protective equipment

Observe normal hygiene standards. Do not eat, drink or smoke during work.

NOVAKLEEN

a) Respiratory protection:

Full face mask with filter type A at conc. in air > exposure limit.

b) Hand protection:

Protective gloves against chemicals (EN 374).

c) Eye protection:

Safety glasses (EN 166).

d) Skin protection:

Protective clothing (EN 14605 or EN 13034).

8.2.3 Environmental exposure controls:

See sections 6.2, 6.3 and 13

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

| | |
|---------------------------|-------------------------------------|
| Physical form | Liquid |
| Odour | Characteristic odour |
| Odour threshold | No data available in the literature |
| Colour | Colourless |
| Particle size | Not applicable (liquid) |
| Explosion limits | 0.85 - 24.6 vol % |
| Flammability | Not classified as flammable |
| Log Kow | Not applicable (mixture) |
| Dynamic viscosity | 1 mPa.s ; 20 °C |
| Kinematic viscosity | 1 mm ² /s ; 20 °C |
| Melting point | 0 °C |
| Boiling point | 76 °C - 360 °C |
| Evaporation rate | 1.3 ; Butyl acetate |
| Relative vapour density | No data available in the literature |
| Vapour pressure | No data available in the literature |
| Solubility | Water ; soluble |
| Relative density | 1.02 ; 20 °C |
| Decomposition temperature | No data available in the literature |
| Auto-ignition temperature | 200 °C |
| Flash point | No data available in the literature |
| Explosive properties | Not classified |
| Oxidising properties | Not classified |
| pH | 9.1 |

9.2. Other information

| | |
|------------------|--------------------------------|
| Absolute density | 1018 kg/m ³ ; 20 °C |
|------------------|--------------------------------|

SECTION 10: Stability and reactivity

10.1. Reactivity

Heating increases the fire hazard. Basic reaction.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No data available.

10.4. Conditions to avoid

Precautionary measures

Keep away from naked flames/heat. In finely divided state: use spark-/explosionproof appliances. Finely divided: keep away from ignition sources/sparks.

10.5. Incompatible materials

No data available.

10.6. Hazardous decomposition products

No data available.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

11.1.1 Test results

Acute toxicity

NOVAKLEEN

No (test)data on the mixture available

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6 / 17

NOVAKLEEN

Judgement is based on the relevant ingredients

2-butoxyethanol

| Route of exposure | Parameter | Method | Value | Exposure time | Species | Value determination | Remark |
|----------------------|-----------|------------------------|-----------------|---------------|----------------------------|---------------------|--------|
| Oral | ATE | | 1200 mg/kg bw | | | Annex VI | |
| Oral | LD50 | Equivalent to OECD 401 | 1746 mg/kg bw | | Rat (male) | Experimental value | |
| Oral | LD50 | OECD 401 | 1414 mg/kg bw | | Guinea pig (male / female) | Experimental value | |
| Dermal | LD50 | OECD 402 | > 2000 mg/kg bw | | Rat (male / female) | Experimental value | |
| Inhalation (vapours) | LC50 | | > 4.26 mg/l | 4 h | Rat (male / female) | Experimental value | |

The acute toxicity of this substance to rats, mice and rabbits is higher than it is to humans. Rats, mice and rabbits are highly susceptible to haemolysis following exposure to this substance and data from such species will overestimate the hazard to humans. Humans are not prone to such effects. The guinea pig is a much better model for predicting the hazard to humans.

alcohols, C9-11, ethoxylated

| Route of exposure | Parameter | Method | Value | Exposure time | Species | Value determination | Remark |
|-------------------|-----------|--------|------------|---------------|---------|---------------------|--------|
| Oral | | | category 4 | | | Literature study | |

propan-2-ol

| Route of exposure | Parameter | Method | Value | Exposure time | Species | Value determination | Remark |
|----------------------|-----------|------------------------|----------------|---------------|---------------------|---------------------|-----------------|
| Oral | LD50 | Equivalent to OECD 401 | 5840 mg/kg bw | | Rat | Experimental value | |
| Dermal | LD50 | Equivalent to OECD 402 | 16400 ml/kg bw | 24 h | Rabbit | Experimental value | |
| Dermal | LD50 | Equivalent to OECD 402 | 12882 mg/kg bw | 24 h | Rabbit | Experimental value | Converted value |
| Inhalation (vapours) | LC50 | Equivalent to OECD 403 | > 10000 ppm | 6 h | Rat (male / female) | Experimental value | |

Conclusion

Not classified for acute toxicity

Corrosion/irritation

NOVAKLEEN

No (test)data on the mixture available

Classification is based on the relevant ingredients

2-butoxyethanol

| Route of exposure | Result | Method | Exposure time | Time point | Species | Value determination | Remark |
|-------------------|------------|---------------|---------------|------------------|---------|---------------------|-------------------------------|
| Eye | Irritating | OECD 405 | 24 h | 24; 48; 72 hours | Rabbit | Experimental value | Single treatment with rinsing |
| Skin | Irritating | EU Method B.4 | 4 h | 24; 48; 72 hours | Rabbit | Experimental value | |

alcohols, C9-11, ethoxylated

| Route of exposure | Result | Method | Exposure time | Time point | Species | Value determination | Remark |
|-------------------|--------------------------------|--------|---------------|------------|---------|---------------------|--------|
| Eye | Serious eye damage; category 1 | | | | | Literature study | |
| Skin | Irritating; category 2 | | | | | Literature study | |

propan-2-ol

| Route of exposure | Result | Method | Exposure time | Time point | Species | Value determination | Remark |
|-------------------|----------------|------------------------|---------------|---------------------|---------|---------------------|------------------|
| Eye | Irritating | Equivalent to OECD 405 | | 24 hours | Rabbit | Experimental value | Single treatment |
| Skin | Not irritating | | 4 h | 4; 24; 48; 72 hours | Rabbit | Experimental value | |

Conclusion

Causes serious eye irritation.

Not classified as irritating to the skin

Not classified as irritating to the respiratory system

Respiratory or skin sensitisation

NOVAKLEEN

No (test)data on the mixture available

Judgement is based on the relevant ingredients

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7 / 17

NOVAKLEEN

2-butoxyethanol

| Route of exposure | Result | Method | Exposure time | Observation time point | Species | Value determination | Remark |
|-------------------|-----------------|----------|---------------|------------------------|----------------------------|---------------------|--------|
| Skin | Not sensitizing | OECD 406 | | | Guinea pig (male / female) | Experimental value | |

propan-2-ol

| Route of exposure | Result | Method | Exposure time | Observation time point | Species | Value determination | Remark |
|-------------------|-----------------|----------|---------------|------------------------|----------------------------|---------------------|--------|
| Skin | Not sensitizing | OECD 406 | | | Guinea pig (male / female) | Experimental value | |

Conclusion

Not classified as sensitizing for skin

Not classified as sensitizing for inhalation

Specific target organ toxicity

NOVAKLEEN

No (test)data on the mixture available

Judgement is based on the relevant ingredients

2-butoxyethanol

| Route of exposure | Parameter | Method | Value | Organ | Effect | Exposure time | Species | Value determination |
|-----------------------|-----------|------------------------|--------------------|-------|-----------|------------------------------------|------------------------|---------------------|
| Oral (drinking water) | NOAEL | Equivalent to OECD 408 | < 69 mg/kg bw/day | | No effect | 90 days (continuous) | Rat (male) | Experimental value |
| Oral (drinking water) | NOAEL | Equivalent to OECD 408 | < 82 mg/kg bw/day | | No effect | 90 day(s) | Rat (female) | Experimental value |
| Dermal | NOAEL | Equivalent to OECD 411 | > 150 mg/kg bw/day | | No effect | 13 weeks (5 days / week) | Rabbit (male / female) | Experimental value |
| Inhalation (vapours) | NOAEC | Equivalent to OECD 413 | < 31 ppm | | No effect | 14 weeks (6h / day, 5 days / week) | Rat (female) | Experimental value |
| Inhalation (vapours) | NOAEC | Equivalent to OECD 413 | 62.5 ppm | | No effect | 14 weeks (6h / day, 5 days / week) | Rat (male) | Experimental value |

propan-2-ol

| Route of exposure | Parameter | Method | Value | Organ | Effect | Exposure time | Species | Value determination |
|----------------------|------------|------------------------|----------|------------------------|-----------------------|-------------------------------------|---------------------|---------------------|
| Oral | | | | | | | | Data waiving |
| Dermal | | | | | | | | Data waiving |
| Inhalation (vapours) | NOAEC | OECD 451 | 5000 ppm | | No effect | 104 weeks (6h / day, 5 days / week) | Rat (male / female) | Experimental value |
| Inhalation (vapours) | Dose level | Equivalent to OECD 403 | 5000 ppm | Central nervous system | Drowsiness, dizziness | 6 h | Rat (male / female) | Experimental value |

Conclusion

Not classified for subchronic toxicity

Mutagenicity (in vitro)

NOVAKLEEN

No (test)data on the mixture available

Judgement is based on the relevant ingredients

2-butoxyethanol

| Result | Method | Test substrate | Effect | Value determination | Remark |
|---|------------------------|-----------------------------|--------|---------------------|--------|
| Negative with metabolic activation, negative without metabolic activation | Equivalent to OECD 471 | Bacteria (S.typhimurium) | | Experimental value | |
| Negative with metabolic activation, negative without metabolic activation | Equivalent to OECD 476 | Chinese hamster ovary (CHO) | | Experimental value | |

propan-2-ol

| Result | Method | Test substrate | Effect | Value determination | Remark |
|---|------------------------|-----------------------------|-----------|---------------------|--------|
| Negative with metabolic activation, negative without metabolic activation | Equivalent to OECD 471 | Bacteria (S.typhimurium) | No effect | Experimental value | |
| Negative with metabolic activation, negative without metabolic activation | Equivalent to OECD 476 | Chinese hamster ovary (CHO) | No effect | Experimental value | |

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8 / 17

NOVAKLEEN

Mutagenicity (in vivo)

NOVAKLEEN

No (test)data on the mixture available

Judgement is based on the relevant ingredients

2-butoxyethanol

| Result | Method | Exposure time | Test substrate | Organ | Value determination |
|----------------------------|------------------------|----------------------------|----------------|-------|---------------------|
| Negative (Intraperitoneal) | Equivalent to OECD 474 | 3 dose(s)/24-hour interval | Mouse (male) | | Experimental value |

propan-2-ol

| Result | Method | Exposure time | Test substrate | Organ | Value determination |
|----------------------------|------------------------|---------------|-----------------------|-------|---------------------|
| Negative (Intraperitoneal) | Equivalent to OECD 474 | | Mouse (male / female) | | Experimental value |

Conclusion

Not classified for mutagenic or genotoxic toxicity

Carcinogenicity

NOVAKLEEN

No (test)data on the mixture available

Judgement is based on the relevant ingredients

2-butoxyethanol

| Route of exposure | Parameter | Method | Value | Exposure time | Species | Effect | Organ | Value determination |
|----------------------|-----------|------------------------|-----------|-------------------------------------|---------------------|------------------------|-------|---------------------|
| Inhalation (vapours) | NOAEC | Equivalent to OECD 451 | > 125 ppm | 104 weeks (6h / day, 5 days / week) | Rat (male / female) | No carcinogenic effect | | Experimental value |

propan-2-ol

| Route of exposure | Parameter | Method | Value | Exposure time | Species | Effect | Organ | Value determination |
|----------------------|-----------|----------|----------|-------------------------------------|---------------------|------------------------|-------|---------------------|
| Inhalation (vapours) | NOEL | OECD 451 | 5000 ppm | 104 weeks (6h / day, 5 days / week) | Rat (male / female) | No carcinogenic effect | | Experimental value |

Conclusion

Not classified for carcinogenicity

Reproductive toxicity

NOVAKLEEN

No (test)data on the mixture available

Judgement is based on the relevant ingredients

2-butoxyethanol

| | Parameter | Method | Value | Exposure time | Species | Effect | Organ | Value determination |
|--|-----------|------------------------|------------------|---------------------------|-----------------------|-----------|-------|---------------------|
| Developmental toxicity (Oral (stomach tube)) | NOAEC | Equivalent to OECD 414 | 200 mg/kg bw/day | 3 days (gestation, daily) | Rat | No effect | | Experimental value |
| Maternal toxicity (Oral (stomach tube)) | NOAEL | Equivalent to OECD 414 | 30 mg/kg bw/day | 3 days (gestation, daily) | Rat | No effect | | Experimental value |
| Effects on fertility (Oral (drinking water)) | NOAEL | Fertility Assessment | 720 mg/kg bw/day | 14 weeks (daily) | Mouse (male / female) | No effect | | Experimental value |

propan-2-ol

| | Parameter | Method | Value | Exposure time | Species | Effect | Organ | Value determination |
|--|-----------|------------------------|------------------|-----------------------|---------------------|-----------|--------|---------------------|
| Developmental toxicity (Oral (stomach tube)) | NOAEL | Equivalent to OECD 414 | 400 mg/kg bw/day | 10 day(s) | Rat | No effect | Foetus | Experimental value |
| Maternal toxicity (Oral (stomach tube)) | NOAEL | Equivalent to OECD 414 | 400 mg/kg bw/day | 10 day(s) | Rat | No effect | | Experimental value |
| Effects on fertility (Oral (drinking water)) | NOAEL | Equivalent to OECD 415 | 853 mg/kg bw/day | 21 day(s) - 70 day(s) | Rat (male / female) | No effect | | Experimental value |

Conclusion

Not classified for reprotoxic or developmental toxicity

Toxicity other effects

NOVAKLEEN

No (test)data on the mixture available

Chronic effects from short and long-term exposure

NOVAKLEEN

No effects known.

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9 / 17

NOVAKLEEN

SECTION 12: Ecological information

12.1. Toxicity

NOVAKLEEN

No (test)data on the mixture available

Judgement of the mixture is based on the relevant ingredients

2-butoxyethanol

| | Parameter | Method | Value | Duration | Species | Test design | Fresh/salt water | Value determination |
|---|--------------------|---------------------------|------------|-----------|---------------------------------|--------------------|------------------|---|
| Acute toxicity fishes | LC50 | OECD 203 | 1474 mg/l | 96 h | Oncorhynchus mykiss | Static system | Fresh water | Experimental value; Nominal concentration |
| Acute toxicity crustacea | EC50 | OECD 202 | 1550 mg/l | 48 h | Daphnia magna | Static system | Fresh water | Experimental value; Locomotor effect |
| Toxicity algae and other aquatic plants | ErC50 | OECD 201 | 1840 mg/l | 72 h | Pseudokirchneriella subcapitata | Static system | Fresh water | Experimental value; Nominal concentration |
| | NOEC | OECD 201 | 286 mg/l | 72 h | Pseudokirchneriella subcapitata | Static system | Fresh water | Experimental value; Growth rate |
| Long-term toxicity fish | NOEC | Equivalent to OECD 204 | > 100 mg/l | 21 day(s) | Danio rerio | Semi-static system | Fresh water | Experimental value; Nominal concentration |
| Long-term toxicity aquatic crustacea | NOEC | OECD 211 | 100 mg/l | 21 day(s) | Daphnia magna | Semi-static system | Fresh water | Experimental value; Reproduction |
| Toxicity aquatic micro-organisms | Toxicity threshold | Equivalent to DIN 38412/8 | 700 mg/l | 16 h | Pseudomonas putida | Static system | Fresh water | Experimental value; Nominal concentration |

propan-2-ol

| | Parameter | Method | Value | Duration | Species | Test design | Fresh/salt water | Value determination |
|---|--------------------|---------------------------|------------------------|------------|-------------------------|---------------------|------------------|--------------------------------------|
| Acute toxicity fishes | LC50 | Equivalent to OECD 203 | 9640 mg/l - 10000 mg/l | 96 h | Pimephales promelas | Flow-through system | Fresh water | Experimental value; Lethal |
| Acute toxicity crustacea | LC50 | Equivalent to OECD 202 | > 10000 mg/l | 24 h | Daphnia magna | Static system | Fresh water | Experimental value; Locomotor effect |
| Toxicity algae and other aquatic plants | Toxicity threshold | | 1800 mg/l | 7 day(s) | Scenedesmus quadricauda | Static system | Fresh water | Experimental value; Toxicity test |
| Long-term toxicity fish | | | | | | | | Data waiving |
| Long-term toxicity aquatic crustacea | NOEC | | 2344 µmol/l | 16 day(s) | Daphnia magna | | Fresh water | Experimental value; Growth |
| Toxicity aquatic micro-organisms | Toxicity threshold | Equivalent to DIN 38412/8 | 1050 mg/l | 16 h | Pseudomonas putida | Static system | Fresh water | Experimental value; Toxicity test |
| | EC50 | ISO 8192 | 41676 mg/l | 30 minutes | Activated sludge | | | Experimental value |

Conclusion

Not classified as dangerous for the environment according to the criteria of Regulation (EC) No 1272/2008

12.2. Persistence and degradability

2-butoxyethanol

Biodegradation water

| Method | Value | Duration | Value determination |
|-----------|------------------------|-----------|---------------------|
| OECD 301B | 90.4 %; Carbon dioxide | 28 day(s) | Experimental value |

Phototransformation air (DT50 air)

| Method | Value | Conc. OH-radicals | Value determination |
|--------------|---------|------------------------|---------------------|
| AOPWIN v1.90 | 5.459 h | 1.5E6 /cm ³ | QSAR |

alcohols, C9-11, ethoxylated

Biodegradation water

| Method | Value | Duration | Value determination |
|-----------|-------|-----------|---------------------|
| ISO 14593 | 72 % | 28 day(s) | Weight of evidence |

propan-2-ol

Biodegradation water

| Method | Value | Duration | Value determination |
|---------------|--------------------------|----------|---------------------|
| EU Method C.5 | 53 %; Oxygen consumption | 5 day(s) | Experimental value |

Phototransformation air (DT50 air)

| Method | Value | Conc. OH-radicals | Value determination |
|--------------|----------|------------------------|---------------------|
| AOPWIN v1.92 | 17.668 h | 1.5E6 /cm ³ | Calculated value |

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10 / 17

NOVAKLEEN

Conclusion

Water

The surfactant(s) is/are biodegradable according to Regulation (EC) No 648/2004

12.3. Bioaccumulative potential

NOVAKLEEN

Log Kow

| Method | Remark | Value | Temperature | Value determination |
|--------|--------------------------|-------|-------------|---------------------|
| | Not applicable (mixture) | | | |

2-butoxyethanol

BCF fishes

| Parameter | Method | Value | Duration | Species | Value determination |
|-----------|--------|-------|----------|---------|---------------------|
| | | | | | Data waiving |

Log Kow

| Method | Remark | Value | Temperature | Value determination |
|-----------|--------|-------|-------------|---------------------|
| BASF test | | 0.81 | 25 °C | Experimental value |

alcohols, C9-11, ethoxylated

BCF fishes

| Parameter | Method | Value | Duration | Species | Value determination |
|-----------|--------|----------------------|----------|---------------------|---------------------|
| BCF | | 12.7 l/kg - 237 l/kg | 72 h | Pimephales promelas | Read-across |

Log Kow

| Method | Remark | Value | Temperature | Value determination |
|--------|--------|------------|-------------|---------------------|
| KOWWIN | | 3.3 - 3.73 | | QSAR |

propan-2-ol

Log Kow

| Method | Remark | Value | Temperature | Value determination |
|--------|--------|-------|-------------|-----------------------------|
| | | 0.05 | 25 °C | Weight of evidence approach |

Conclusion

Does not contain bioaccumulative component(s)

12.4. Mobility in soil

2-butoxyethanol

(log) Koc

| Parameter | Method | Value | Value determination |
|-----------|-------------------|---------------|---------------------|
| log Koc | SRC PCKOCWIN v2.0 | 0.451 - 0.882 | Calculated value |

Percent distribution

| Method | Fraction air | Fraction biota | Fraction sediment | Fraction soil | Fraction water | Value determination |
|----------------|--------------|----------------|-------------------|---------------|----------------|---------------------|
| Mackay level I | 0.31 % | 0 % | 0.01 % | 0.59 % | 99.09 % | QSAR |

alcohols, C9-11, ethoxylated

(log) Koc

| Parameter | Method | Value | Value determination |
|-----------|-------------------|---------------|---------------------|
| log Koc | SRC PCKOCWIN v2.0 | 1.399 - 1.656 | Calculated value |

propan-2-ol

(log) Koc

| Parameter | Method | Value | Value determination |
|-----------|-------------------|---------------|---------------------|
| log Koc | SRC PCKOCWIN v2.0 | 0.185 - 0.541 | Calculated value |

Conclusion

Contains component(s) with potential for mobility in the soil

12.5. Results of PBT and vPvB assessment

Does not contain component(s) that meet(s) the criteria of PBT and/or vPvB as listed in Annex XIII of Regulation (EC) No 1907/2006.

12.6. Other adverse effects

NOVAKLEEN

Greenhouse gases

None of the known components is included in the list of fluorinated greenhouse gases (Regulation (EU) No 517/2014)

Ozone-depleting potential (ODP)

Not classified as dangerous for the ozone layer (Regulation (EC) No 1005/2009)

2-butoxyethanol

Groundwater

Groundwater pollutant

alcohols, C9-11, ethoxylated

Groundwater

Groundwater pollutant

NOVAKLEEN

propan-2-ol

Groundwater

Groundwater pollutant

SECTION 13: Disposal considerations

The information in this section is a general description. If applicable and available, exposure scenarios are attached in annex. Always use the relevant exposure scenarios that correspond to your identified use.

13.1. Waste treatment methods

13.1.1 Provisions relating to waste

European Union

Can be considered as non hazardous waste according to Directive 2008/98/EC, as amended by Regulation (EU) No 1357/2014 and Regulation (EU) No 2017/997.

Waste material code (Directive 2008/98/EC, Decision 2000/0532/EC).

20 01 30 (separately collected fractions (except 15 01): detergents other than those mentioned in 20 01 29). Depending on branch of industry and production process, also other waste codes may be applicable.

13.1.2 Disposal methods

Remove waste in accordance with local and/or national regulations. Do not discharge into drains or the environment. Dispose of at authorized waste collection point.

13.1.3 Packaging/Container

European Union

Waste material code packaging (Directive 2008/98/EC).

15 01 02 (plastic packaging).

SECTION 14: Transport information

Road (ADR)

14.1. UN number

| | |
|-----------|-------------|
| Transport | Not subject |
|-----------|-------------|

14.2. UN proper shipping name

14.3. Transport hazard class(es)

| | |
|------------------------------|--|
| Hazard identification number | |
|------------------------------|--|

| | |
|-------|--|
| Class | |
|-------|--|

| | |
|---------------------|--|
| Classification code | |
|---------------------|--|

14.4. Packing group

| | |
|---------------|--|
| Packing group | |
|---------------|--|

| | |
|--------|--|
| Labels | |
|--------|--|

14.5. Environmental hazards

| | |
|--|----|
| Environmentally hazardous substance mark | no |
|--|----|

14.6. Special precautions for user

| | |
|--------------------|--|
| Special provisions | |
|--------------------|--|

| | |
|--------------------|--|
| Limited quantities | |
|--------------------|--|

Rail (RID)

14.1. UN number

| | |
|-----------|-------------|
| Transport | Not subject |
|-----------|-------------|

14.2. UN proper shipping name

14.3. Transport hazard class(es)

| | |
|------------------------------|--|
| Hazard identification number | |
|------------------------------|--|

| | |
|-------|--|
| Class | |
|-------|--|

| | |
|---------------------|--|
| Classification code | |
|---------------------|--|

14.4. Packing group

| | |
|---------------|--|
| Packing group | |
|---------------|--|

| | |
|--------|--|
| Labels | |
|--------|--|

14.5. Environmental hazards

| | |
|--|----|
| Environmentally hazardous substance mark | no |
|--|----|

14.6. Special precautions for user

| | |
|--------------------|--|
| Special provisions | |
|--------------------|--|

| | |
|--------------------|--|
| Limited quantities | |
|--------------------|--|

Inland waterways (ADN)

14.1. UN number

| | |
|-----------|-------------|
| Transport | Not subject |
|-----------|-------------|

14.2. UN proper shipping name

14.3. Transport hazard class(es)

| | |
|-------|--|
| Class | |
|-------|--|

| | |
|---------------------|--|
| Classification code | |
|---------------------|--|

14.4. Packing group

| | |
|---------------|--|
| Packing group | |
|---------------|--|

| | |
|--------|--|
| Labels | |
|--------|--|

14.5. Environmental hazards

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BIG number: 54677

12 / 17

NOVAKLEEN

| | |
|--|--|
| Environmentally hazardous substance mark | no |
| 14.6. Special precautions for user | |
| Special provisions | |
| Limited quantities | |
| Specific mention | Dangerous only when carried in tank vessels. |

Sea (IMDG/IMSBC)

| | |
|--|---|
| 14.1. UN number | |
| Transport | Not subject |
| 14.2. UN proper shipping name | |
| 14.3. Transport hazard class(es) | |
| Class | |
| 14.4. Packing group | |
| Packing group | |
| Labels | |
| 14.5. Environmental hazards | |
| Marine pollutant | |
| Environmentally hazardous substance mark | no |
| 14.6. Special precautions for user | |
| Special provisions | |
| Limited quantities | |
| 14.7. Transport in bulk according to Annex II of Marpol and the IBC Code | |
| Annex II of MARPOL 73/78 | Not applicable, based on available data |

Air (ICAO-TI/IATA-DGR)

| | |
|--|-------------|
| 14.1. UN number | |
| Transport | Not subject |
| 14.2. UN proper shipping name | |
| 14.3. Transport hazard class(es) | |
| Class | |
| 14.4. Packing group | |
| Packing group | |
| Labels | |
| 14.5. Environmental hazards | |
| Environmentally hazardous substance mark | no |
| 14.6. Special precautions for user | |
| Special provisions | |
| Passenger and cargo transport | |
| Limited quantities: maximum net quantity per packaging | |

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

European legislation:

VOC content Directive 2010/75/EU

| VOC content | Remark |
|-------------|--------|
| 1.78 % | |
| 18.12 g/l | |

Indicative occupational exposure limit values (Directive 98/24/EC, 2000/39/EC and 2009/161/EU)

2-butoxyethanol

| Product name | Skin resorption |
|-----------------|-----------------|
| 2-Butoxyethanol | Skin |

Ingredients according to Regulation (EC) No 648/2004 and amendments

<5% phosphates, <5% non-ionic surfactants, perfumes

REACH Annex XVII - Restriction

Contains component(s) subject to restrictions of Annex XVII of Regulation (EC) No 1907/2006: restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles.

| | Designation of the substance, of the group of substances or of the mixture | Conditions of restriction |
|--|--|---|
| <ul style="list-style-type: none"> 2-butoxyethanol alcohols, C9-11, ethoxylated propan-2-ol | Liquid substances or mixtures fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008: (a) hazard classes 2.1 to 2.4, 2.6 and 2.7, 2.8 types A and B, 2.9, 2.10, 2.12, 2.13 categories 1 and 2, 2.14 categories 1 and 2, 2.15 types A to F; (b) hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on | 1. Shall not be used in: — ornamental articles intended to produce light or colour effects by means of different phases, for example in ornamental lamps and ashtrays, — tricks and jokes, — games for one or more participants, or any article intended to be used as such, even with ornamental aspects, 2. Articles not complying with paragraph 1 shall not be placed on the market. 3. Shall not be placed on the market if they contain a colouring agent, unless required for fiscal reasons, or perfume, or both, if they: — can be used as fuel in decorative oil lamps for supply to the general public, and, |

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13 / 17

NOVAKLEEN

| | | | |
|------------------------------------|--|--|---|
| | | development, 3.8 effects other than narcotic effects, 3.9 and 3.10; (c) hazard class 4.1; (d) hazard class 5.1. | <p>— present an aspiration hazard and are labelled with H304,</p> <p>4. Decorative oil lamps for supply to the general public shall not be placed on the market unless they conform to the European Standard on Decorative oil lamps (EN 14059) adopted by the European Committee for Standardisation (CEN).</p> <p>5. Without prejudice to the implementation of other Community provisions relating to the classification, packaging and labelling of dangerous substances and mixtures, suppliers shall ensure, before the placing on the market, that the following requirements are met:</p> <p>a) lamp oils, labelled with H304, intended for supply to the general public are visibly, legibly and indelibly marked as follows: “Keep lamps filled with this liquid out of the reach of children”; and, by 1 December 2010, “Just a sip of lamp oil — or even sucking the wick of lamps — may lead to life- threatening lung damage”;</p> <p>b) grill lighter fluids, labelled with H304, intended for supply to the general public are legibly and indelibly marked by 1 December 2010 as follows: “Just a sip of grill lighter may lead to life threatening lung damage”;</p> <p>c) lamp oils and grill lighters, labelled with H304, intended for supply to the general public are packaged in black opaque containers not exceeding 1 litre by 1 December 2010.</p> |
| · propan-2-ol | | Substances classified as flammable gases category 1 or 2, flammable liquids categories 1, 2 or 3, flammable solids category 1 or 2, substances and mixtures which, in contact with water, emit flammable gases, category 1, 2 or 3, pyrophoric liquids category 1 or pyrophoric solids category 1, regardless of whether they appear in Part 3 of Annex VI to that Regulation or not. | <p>1. Shall not be used, as substance or as mixtures in aerosol dispensers where these aerosol dispensers are intended for supply to the general public for entertainment and decorative purposes such as the following:</p> <p>— metallic glitter intended mainly for decoration,</p> <p>— artificial snow and frost,</p> <p>— “whoopee” cushions,</p> <p>— silly string aerosols,</p> <p>— imitation excrement,</p> <p>— horns for parties,</p> <p>— decorative flakes and foams,</p> <p>— artificial cobwebs,</p> <p>— stink bombs.</p> <p>2. Without prejudice to the application of other Community provisions on the classification, packaging and labelling of substances, suppliers shall ensure before the placing on the market that the packaging of aerosol dispensers referred to above is marked visibly, legibly and indelibly with:</p> <p>“For professional users only”.</p> <p>3. By way of derogation, paragraphs 1 and 2 shall not apply to the aerosol dispensers referred to Article 8 (1a) of Council Directive 75/ 324/EEC.</p> <p>4. The aerosol dispensers referred to in paragraphs 1 and 2 shall not be placed on the market unless they conform to the requirements indicated.</p> |
| · 2-butoxyethanol · propan-2-ol | | <p>Substances falling within one or more of the following points:</p> <p>(a) substances classified as any of the following in Part 3 of Annex VI to Regulation (EC) No 1272/2008:</p> <p>— carcinogen category 1A, 1B or 2, or germ cell mutagen category 1A, 1B or 2, but excluding any such substances classified due to effects only following exposure by inhalation</p> <p>— reproductive toxicant category 1A, 1B or 2 but excluding any such substances classified due to effects only following exposure by inhalation</p> <p>— skin sensitiser category 1, 1A or 1B</p> <p>— skin corrosive category 1, 1A, 1B or 1C or skin irritant category 2</p> <p>— serious eye damage category 1 or eye irritant category 2</p> <p>(b) substances listed in Annex II to Regulation (EC) No 1223/2009 of the European Parliament and of the Council</p> <p>(c) substances listed in Annex IV to Regulation (EC) No 1223/2009 for which a condition is specified in at least one of the columns g, h and i of the table in that Annex (d) substances listed in Appendix 13 to this Annex.</p> <p>The ancillary requirements in paragraphs 7 and 8 of column 2 of this entry apply to all mixtures for use for tattooing purposes, whether or not they contain a substance falling within points (a) to (d) of this column of this entry.</p> | <p>1. Shall not be placed on the market in mixtures for use for tattooing purposes, and mixtures containing any such substances shall not be used for tattooing purposes, after 4 January 2022 if the substance or substances in question is or are present in the following circumstances:</p> <p>(a) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as carcinogen category 1A, 1B or 2, or germ cell mutagen category 1A, 1B or 2, the substance is present in the mixture in a concentration equal to or greater than 0,00005 % by weight;</p> <p>(b) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as reproductive toxicant category 1A, 1B or 2, the substance is present in the mixture in a concentration equal to or greater than 0,001 % by weight;</p> <p>(c) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as skin sensitiser category 1, 1A or 1B, the substance is present in the mixture in a concentration equal to or greater than 0,001 % by weight;</p> <p>(d) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as skin corrosive category 1, 1A, 1B or 1C or skin irritant category 2, or as serious eye damage category 1 or eye irritant category 2, the substance is present in the mixture in a concentration equal to or greater than:</p> <p>(i) 0,1 % by weight, if the substance is used solely as a pH regulator;</p> <p>(ii) 0,01 % by weight, in all other cases;</p> <p>(e) in the case of a substance listed in Annex II to Regulation (EC) No 1223/2009 (*), the substance is present in the mixture in a concentration equal to or greater than 0,00005 % by weight;</p> <p>(f) in the case of a substance for which a condition of one or more of the following kinds is specified in column g (Product type, Body parts) of the table in Annex IV to Regulation (EC) No 1223/2009, the substance is present in the mixture in a concentration equal to or greater than 0,00005 % by weight:</p> <p>(i) “Rinse-off products”;</p> <p>(ii) “Not to be used in products applied on mucous membranes”;</p> <p>(iii) “Not to be used in eye products”;</p> <p>(g) in the case of a substance for which a condition is specified in column h (Maximum concentration in ready for use preparation) or column i (Other) of the table in Annex IV to Regulation (EC) No 1223/2009, the substance is present in the mixture in a concentration, or in some other way, that does not accord with the condition specified in that column;</p> <p>(h) in the case of a substance listed in Appendix 13 to this Annex, the substance is present in the mixture in a concentration equal to or greater than the concentration limit specified for that substance in that Appendix.</p> <p>2. For the purposes of this entry use of a mixture “for tattooing purposes” means injection or introduction of the mixture into a person’s skin, mucous membrane or eyeball, by any process or procedure (including procedures commonly referred to as L 423/12 EN Official Journal of the European Union 15.12.2020 permanent make-up, cosmetic tattooing, micro-blading and micro-pigmentation), with the aim of making a mark or design on his or her body.</p> <p>3. If a substance not listed in Appendix 13 falls within more than one of points (a) to (g) of paragraph 1, the strictest concentration limit laid down in the points in question shall apply to that substance. If a substance listed in Appendix 13 also falls within one or more of points (a) to (g) of paragraph 1, the concentration limit laid down in point (h) of</p> |

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14 / 17

NOVAKLEEN

paragraph 1 shall apply to that substance.

4. By way of derogation, paragraph 1 shall not apply to the following substances until 4 January 2023:

(a) Pigment Blue 15:3 (CI 74160, EC No 205-685-1, CAS No 147-14-8);

(b) Pigment Green 7 (CI 74260, EC No 215-524-7, CAS No 1328-53-6).

5. If Part 3 of Annex VI to Regulation (EC) No 1272/2008 is amended after 4 January 2021 to classify or re-classify a substance such that the substance then becomes caught by point (a), (b), (c) or (d) of paragraph 1 of this entry, or such that it then falls within a different one of those points from the one within which it fell previously, and the date of application of that new or revised classification is after the date referred to in paragraph 1 or, as the case may be, paragraph 4 of this entry, that amendment shall, for the purposes of applying this entry to that substance, be treated as taking effect on the date of application of that new or revised classification.

6. If Annex II or Annex IV to Regulation (EC) No 1223/2009 is amended after 4 January 2021 to list or change the listing of a substance such that the substance then becomes caught by point (e), (f) or (g) of paragraph 1 of this entry, or such that it then falls within a different one of those points from the one within which it fell previously, and the amendment takes effect after the date referred to in paragraph 1 or, as the case may be, paragraph 4 of this entry, that amendment shall, for the purposes of applying this entry to that substance, be treated as taking effect from the date falling 18 months after entry into force of the act by which that amendment was made.

7. Suppliers placing a mixture on the market for use for tattooing purposes shall ensure that, after 4 January 2022, the mixture is marked with the following information:

(a) the statement "Mixture for use in tattoos or permanent make-up";

(b) a reference number to uniquely identify the batch;

(c) the list of ingredients in accordance with the nomenclature established in the glossary of common ingredient names pursuant to Article 33 of Regulation (EC) No 1223/2009, or in the absence of a common ingredient name, the IUPAC name. In the absence of a common ingredient name or IUPAC name, the CAS and EC number. Ingredients shall be listed in descending order by weight or volume of the ingredients at the time of formulation.

"Ingredient" means any substance added during the process of formulation and present in the mixture for use for tattooing purposes. Impurities shall not be regarded as ingredients. If the name of a substance, used as ingredient within the meaning of this entry, is already required to be stated on the label in accordance with Regulation (EC) No 1272/2008, that ingredient does not need to be marked in accordance with this Regulation;

(d) the additional statement "pH regulator" for substances falling under point (d)(i) of paragraph 1;

(e) the statement "Contains nickel. Can cause allergic reactions." If the mixture contains nickel below the concentration limit specified in Appendix 13;

(f) the statement "Contains chromium (VI). Can cause allergic reactions." if the mixture contains chromium (VI) below the concentration limit specified in Appendix 13;

(g) safety instructions for use insofar as they are not already required to be stated on the label by Regulation (EC) No 1272/2008. The information shall be clearly visible, easily legible and marked in a way that is indelible.

The information shall be written in the official language(s) of the Member State(s) where the mixture is placed on the market, unless the Member State(s) concerned provide(s) otherwise. Where necessary because of the size of the package, the information listed in the first subparagraph, except for point (a), shall be included instead in the instructions for use. Before using a mixture for tattooing purposes, the person using the mixture shall provide the person undergoing the procedure with the information marked on the package or included in the instructions for use pursuant to this paragraph.

8. Mixtures that do not contain the statement "Mixture for use in tattoos or permanent make-up" shall not be used for tattooing purposes.

9. This entry does not apply to substances that are gases at temperature of 20 °C and pressure of 101,3 kPa, or generate a vapour pressure of more than 300 kPa at temperature of 50 °C, with the exception of formaldehyde (CAS No 50-00-0, EC No 200-001-8).

10. This entry does not apply to the placing on the market of a mixture for use for tattooing purposes, or to the use of a mixture for tattooing purposes, when placed on the market exclusively as a medical device or an accessory to a medical device, within the meaning of Regulation (EU) 2017/745, or when used exclusively as a medical device or an accessory to a medical device, within the same meaning. Where the placing on the market or use may not be exclusively as a medical device or an accessory to a medical device, the requirements of Regulation (EU) 2017/745 and of this Regulation shall apply cumulatively.

National legislation Belgium NOVAKLEEN

No data available

2-butoxyethanol

| | |
|-----------------|--|
| Résorption peau | 2-Butoxyéthanol; D; La mention "D" signifie que la résorption de l'agent, via la peau, les muqueuses ou les yeux, constitue une partie importante de l'exposition totale. Cette résorption peut se faire tant par contact direct que par présence de l'agent dans l'air. |
|-----------------|--|

National legislation The Netherlands NOVAKLEEN

| | |
|----------------------|---|
| Waterbezwaarlijkheid | B (4); Algemene Beoordelingsmethodiek (ABM) |
|----------------------|---|

2-butoxyethanol

| | |
|------------------------|--------------------|
| Huidopname (wettelijk) | 2-Butoxyethanol; H |
|------------------------|--------------------|

National legislation France NOVAKLEEN

Reason for revision: 9, 12, 15

Publication date: 2014-01-20

Date of revision: 2021-04-30

Revision number: 0300

BIG number: 54677

15 / 17

NOVAKLEEN

No data available

2-butoxyethanol

| | |
|----------------------------------|--|
| Risque de pénétration percutanée | 2-Butoxyéthanol; Risquedepénétrationpercutanée |
|----------------------------------|--|

National legislation Germany

NOVAKLEEN

| | |
|-----------------------|--|
| Lagerklasse (TRGS510) | 10: Brennbare Flüssigkeiten die keiner der vorgenannten LGK zuzuordnen sind |
| WGK | 1; Verordnung über Anlagen zum Umgang mit wassergefährdenden Stoffen (AwSV) - 18. April 2017 |

2-butoxyethanol

| | |
|---------------------------------------|--|
| TA-Luft | 5.2.5/I |
| TRGS900 - Risiko der Fruchtschädigung | 2-Butoxyethanol; Y; Risiko der Fruchtschädigung braucht bei Einhaltung des Arbeitsplatzgrenzwertes und des biologischen Grenzwertes nicht befürchtet zu werden |
| Hautresorptive Stoffe | 2-Butoxyethanol; H; Hautresorptiv |

alcohols, C9-11, ethoxylated

| | |
|---------|---------|
| TA-Luft | 5.2.5/I |
|---------|---------|

propan-2-ol

| | |
|---------------------------------------|--|
| TA-Luft | 5.2.5 |
| TRGS900 - Risiko der Fruchtschädigung | Propan-2-ol; Y; Risiko der Fruchtschädigung braucht bei Einhaltung des Arbeitsplatzgrenzwertes und des biologischen Grenzwertes nicht befürchtet zu werden |

National legislation United Kingdom

NOVAKLEEN

No data available

2-butoxyethanol

| | |
|-----------------|---------------------|
| Skin absorption | 2-Butoxyethanol; Sk |
|-----------------|---------------------|

Other relevant data

NOVAKLEEN

No data available

2-butoxyethanol

| | |
|-----------------------|---------------------|
| IARC - classification | 3; 2-butoxyethanol |
| TLV - Carcinogen | 2-Butoxyethanol; A3 |

propan-2-ol

| | |
|-----------------------|----------------|
| IARC - classification | 3; Isopropanol |
| TLV - Carcinogen | 2-propanol; A4 |

15.2. Chemical safety assessment

No chemical safety assessment has been conducted for the mixture.

SECTION 16: Other information

Full text of any H-statements referred to under section 3:

- H225 Highly flammable liquid and vapour.
- H302 Harmful if swallowed.
- H315 Causes skin irritation.
- H318 Causes serious eye damage.
- H319 Causes serious eye irritation.
- H332 Harmful if inhaled.
- H336 May cause drowsiness or dizziness.

| | |
|--------------|--|
| (*) | INTERNAL CLASSIFICATION BY BIG |
| ADI | Acceptable daily intake |
| AOEL | Acceptable operator exposure level |
| ATE | Acute Toxicity Estimate |
| CLP (EU-GHS) | Classification, labelling and packaging (Globally Harmonised System in Europe) |
| DMEL | Derived Minimal Effect Level |
| DNEL | Derived No Effect Level |
| EC50 | Effect Concentration 50 % |
| Erc50 | EC50 in terms of reduction of growth rate |
| LC50 | Lethal Concentration 50 % |
| LD50 | Lethal Dose 50 % |
| NOAEL | No Observed Adverse Effect Level |
| NOEC | No Observed Effect Concentration |
| OECD | Organisation for Economic Co-operation and Development |
| PBT | Persistent, Bioaccumulative & Toxic |
| PNEC | Predicted No Effect Concentration |
| STP | Sludge Treatment Process |
| vPvB | very Persistent & very Bioaccumulative |

The information in this safety data sheet is based on data and samples provided to BIG. The sheet was written to the best of our ability and according to the state of knowledge at that time. The safety data sheet only constitutes a guideline for the safe handling, use, consumption, storage, transport and disposal of the substances/preparations/mixtures mentioned under point 1. New safety data sheets are written from

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16 / 17

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