



Safety Data Sheet

REV. : 1
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SAFETY DATA SHEET

SAV LP is the legal manufacturer of Sterilant for "Getinge" branded Formaldehyde Gas Sterilizers (as shown in the table below), manufactured for Maquet GmbH.

The following Safety Data Sheet (SDS) attached herein, is applicable to said Sterilant products.

Item	Description	For use in sterilizer
466745810	400 ML IN 500 ML GLASSBOTTLE (12 BOTTLES/BOX) - 37%	HS6613 LTSF
466745809	300 ML IN 500 ML GLASSBOTTLE (12 BOTTLES/BOX) - 37%	HS6610 LTSF
6014449070	FORMALDEHYDE PLASTIC 400ML (12 BOTTLES/BOX) - 35%	HS66T LTSF / GSS67F

Manufacturer's Address:



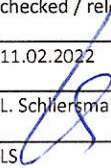
SAV Liquid Production GmbH
Hochriesstrasse 2
D-83126 Flintsbach am Inn

Date: 11.02.2022

Signature:

Name: Leonhard Schliersmaier jun.

Position: Geschäftsführer

	launched	changed	checked / released
Datum	11.02.2022	11.02.2022	11.02.2022
Name	Dr. Angela Wölfel 	Dr. Angela Wölfel 	L. Schliersmaier jun. 
	AW	AW	LS

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 21.09.2020

Version number 306

Revision: 17.04.2020

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

- 1.1 Product identifier

- Trade name: **Formaldehyde 37%**

- CAS Number:

50-00-0

- EC number:

200-001-8

- REACH-Registration number 01-2119488953-20

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

No further relevant information available.

- Application of the substance / the mixture *Disinfectant*

- 1.3 Details of the supplier of the safety data sheet

- Manufacturer/Supplier:

SAV LP GmbH
Hochriesstrasse 2
D-83126 Flintsbach am Inn
Tel.: +49 80 34 909 80 - 0
Fax: +49 80 34 909 80 -70
e-Mail: info@sav-lp.de

Supplier Australia: Getinge Australia Pty Ltd
Suite 701, Level 7, 11 Help Street
Chatswood, NSW 2067 Australia
Phone: 1800 438 464

Supplier New Zealand: Getinge Australia (NZ Branch)
600 Great South Road, Bldng B, Level 2
Ellersie, Auckland 1051, New Zealand
Phone: 0800 1 438 464

- Informing department:

Department: Quality assurance
e-Mail: info@sav-lp.de

- 1.4 Emergency telephone number:

Poison Control Center, Mainz
Tel. 0049 / 61 31 / 19 240

Emergency Contacts: Australia +61 280 144 558
New Zealand +64 9 929 1484

SECTION 2: Hazards identification

- 2.1 Classification of the substance or mixture

- Classification according to Regulation (EC) No 1272/2008

Acute Tox. 3 H301 Toxic if swallowed.

Acute Tox. 3 H311 Toxic in contact with skin.

Acute Tox. 2 H330 Fatal if inhaled.

Skin Corr. 1B H314 Causes severe skin burns and eye damage.

Skin Sens. 1 H317 May cause an allergic skin reaction.

Muta. 2 H341 Suspected of causing genetic defects.

Carc. 1B H350 May cause cancer.

- 2.2 Label elements

- Labelling according to Regulation (EC) No 1272/2008

The substance is classified and labelled according to the CLP regulation.

- Hazard pictograms



GHS05 GHS06 GHS08

- Signal word *Danger*

- Hazard statements

H330 - Fatal if inhaled.

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H301 + H311 - Toxic if swallowed or in contact with skin.

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H314 - Causes severe skin burns and eye damage.

H317 - May cause an allergic skin reaction.

H350 - May cause cancer.

H341 - Suspected of causing genetic defects.

H371 - May cause damage to organs.

H335 - May cause respiratory irritation.

- Precautionary statements

P271 - Use only outdoors or in a well-ventilated area.

P280 - Wear protective gloves/protective clothing/eye protection/face protection.

P303 - IF ON SKIN (or hair):

P361 - Remove/Take off immediately all contaminated clothing.

P353 - Rinse skin with water [or shower].

P304 - IF INHALED:

P340 - Remove victim to fresh air and keep at rest in a position comfortable for breathing.

P305 - IF IN EYES:

P351 - Rinse cautiously with water for several minutes.

P338 - Remove contact lenses, if present and easy to do. Continue rinsing.

P310 - Immediately call a POISON CENTER or physician.

P405 - Store locked up.

P501 - Dispose of contents and container in accordance with all local, regional, national and international regulations.

- 2.3 Other hazards**- Results of PBT and vPvB assessment****- PBT:** Not applicable.**- vPvB:** Not applicable.

* SECTION 3: Composition/information on ingredients

- 3.1 Substances**- CAS No. Designation:**

50-00-0 Formaldehyd 37 %

- Identification no(s):**- EC number:** 200-001-8**- Dangerous components:**

CAS: 50-00-0	formaldehyde	37%
EINECS: 200-001-8	Flam. Liq. 3, H226; Acute Tox. 3, H301; Acute Tox. 3, H311; Acute Tox. 2, H330; Muta. 2, H341; Carc. 1B, H350; Skin Corr. 1B, H314; Skin Sens. 1, H317	
Reg.nr.: 01-2119488953-20		

CAS: 67-56-1	methanol	8% <-15%
EINECS: 200-659-6	Flam. Liq. 2, H225; Acute Tox. 3, H301; Acute Tox. 3, H311; Acute Tox. 3, H331; STOT SE 1, H370	
Reg.nr.: 01-2119433307-44		

- Composition/Ingredients Disinfectant,

* SECTION 4: First aid measures

- 4.1 Description of first aid measures**- General advice:**

Instantly remove any clothing soiled by the product.

Remove breathing apparatus only after soiled clothing has been completely removed.

- After inhalation

Take affected persons into the open air and position comfortably.

Call a doctor immediately.

In case of respiratory failure or breathing irregularities, commence resuscitation or oxygen inhalation and immediately consult a doctor. In case of unconsciousness, place and transport the patient in a recovery position.

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- **After skin contact**
Instantly wash with water and soap and rinse thoroughly. If skin irritation persists, seek medical advice.
- **After eye contact**
Rinse immediately opened eye for several minutes under running water. Then consult doctor.
- **After swallowing** *Do not induce vomiting. Drink plenty of water. Call for medical help.*
- **4.2 Most important symptoms and effects, both acute and delayed**
Cough, lacrimation, irritation of nose, throat and respiratory tract, nausea, impaired vision.
- **Information for doctor** *Symptomatic treatment.*
- **4.3 Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

* SECTION 5: Firefighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents**
*Water haze
Foam
Fire-extinguishing powder*
- **For safety reasons unsuitable extinguishing agents** *Water with a full water jet.*
- **5.2 Special hazards arising from the substance or mixture**
*Can be released in case of fire:
carbon oxides (COx)
Formaldehyde (HCHO)*
- **5.3 Advice for firefighters**
- **Protective equipment:** *Wear self-contained breathing apparatus.*

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**
*Wear protective equipment and keep unprotected persons away.
Do not breathe vapours.*
- **6.2 Environmental precautions:**
*Do not allow product to reach sewage system or water bodies.
If large amounts are released, the authorities must be informed.*
- **6.3 Methods and material for containment and cleaning up:**
*Collect mechanically.
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
Dispose of the material collected according to regulations.
Treat the residues with diluted ammonia.*
- **6.4 Reference to other sections**
*See Section 7 for information on safe handling
See Section 8 for information on personal protection equipment.
See Section 13 for information on disposal.*

* SECTION 7: Handling and storage

- **7.1 Precautions for safe handling**
*Ensure good ventilation/exhaustion at the workplace. Avoid repeated or long-term skin contact.
Open and handle container with care.*
- **Information about protection against explosions and fires:**
Keep ignition sources away - Do not smoke.

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Protect against electrostatic charges.

- **7.2 Conditions for safe storage, including any incompatibilities**- **Storage**- **Requirements to be met by storerooms and containers:**

Observe official regulations on storage and handling of water hazardous substances

- **Information about storage in one common storage facility:**

Do not store together with strong oxidizing agents.

Do not store together with alkalis (caustic solutions).

- **Further information about storage conditions:** Keep container tightly sealed.- **Recommended storage temperature:**

Storage stability: > 14 d at +40°C

Instable at < +20°C (formation of paraformaldehyde).

- **7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see item 7.- **8.1 Control parameters**- **Components with critical values that require monitoring at the workplace:** Not required.- **DNELs**

50-00-0 formaldehyde

Oral	DNEL (population)	4.1 mg/kg bw/day (Long-term, systemic effects)
Dermal	DNEL (worker)	240 mg/kg bw/day (Long-term, systemic effects)
	DNEL (population)	102 mg/kg bw/day (Long-term, systemic effects)
Inhalative	DNEL (population)	0.012 mg/cm ² (Long-term - local effects)
	DNEL (worker)	0.5 mg/m ³ (Long-term - systemic + local effects)
		1 mg/m ³ (Acute - systemic + local effects)
	DNEL (population)	3.2 mg/m ³ (Long-term, systemic effects)
		0.1 mg/m ³ (Long-term - local effects)

67-56-1 methanol

Dermal	DNEL (worker)	20 mg/kg bw/day (Acute, systemic effects)
		20 mg/kg bw/day (Long-term, systemic effects)
	DNEL (population)	4 mg/kg bw/day (Acute, systemic effects)
Inhalative		4 mg/kg bw/day (Long-term, systemic effects)
	DNEL (worker)	130 mg/m ³ (Acute, systemic effects)
		130 mg/m ³ (Long-term, systemic effects)
		130 mg/m ³ (Long-term - systemic + local effects)
		130 mg/m ³ (Acute - systemic + local effects)
	DNEL (population)	26 mg/m ³ (Acute, systemic effects)
		26 mg/m ³ (Long-term, systemic effects)
		26 mg/m ³ (Long-term - systemic + local effects)
		26 mg/m ³ (Acute - systemic + local effects)

- **PNECs**

50-00-0 formaldehyde

PNEC water	0.47 mg/l (freshwater)
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PNEC	0.47 mg/l (Seawater) 4.7 mg/l (intermittent releases) 0.19 mg/l (p37)
67-56-1 methanol	
PNEC water	20.8 mg/l (freshwater) 2.08 mg/l (marine water)
PNEC	1,540 mg/l (intermittent releases)
PNEC sediment	77 mg/kg dw (freshwater) 7.7 mg/kg dw (marine water)
PNEC soil	100 mg/kg dw (soil)
PNEC STP	100 mg/l (sewage plant)

- **Additional information:** The lists that were valid during the compilation were used as basis.

- 8.2 Exposure controls

- Personal protective equipment

- General protective and hygienic measures

Keep away from food, beverages and fodder.

Instantly remove any soiled and impregnated garments.

Wash hands during breaks and at the end of the work.

Store protective clothing separately.

Avoid contact with the eyes and skin.

Gases, fumes and aerosols should not be inhaled.

- **Breathing equipment:** Use breathing protection in case of insufficient ventilation.

- **Recommended filter device for short term use:** Filter A

- Protection of hands:

Protective gloves.

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

- Material of gloves

Butyl rubber, BR

Nitrile rubber, NBR

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.

- Penetration time of glove material

Material of gloves is recommended for a short-term single use to protect from splashes. For permanent usage contact manufacturer of gloves.

- **Eye protection:** Tightly sealed safety glasses.

- **Body protection:** Standard protective working clothes

SECTION 9: Physical and chemical properties

- 9.1 Information on basic physical and chemical properties

- General Information

- Appearance:

Form:

Fluid

Colour:

Colourless

- Smell:

Pungent

- pH-value at 20 °C:

3.5 - 4.5

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- Melting point/freezing point:	<-15 °C
- Initial boiling point and boiling range:	~ 97 °C
- Flash point:	66-73 °C
- Ignition temperature:	380 °C (DIN 51 794)
- Explosive properties:	Product is not explosive. However, formation of explosive air/steam mixtures is possible.
- Critical values for explosion:	
Lower:	7 Vol %
Upper:	72 Vol %
- Vapour pressure at 20 °C:	1.3 mbar
- Density at 20 °C	ca. 1.09 g/cm ³ (DIN 51 757)
- Solubility in / Miscibility with Water:	Fully miscible
- Viscosity:	
kinematic:	Not determined.
- 9.2 Other information	Odor threshold for formaldehyde 0.05 to 1 ppm

SECTION 10: Stability and reactivity

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability**
- **Thermal decomposition / conditions to be avoided:**
No decomposition if used and stored according to specifications.
Polymerisation at temperatures < 7 °C.
- **10.3 Possibility of hazardous reactions** Forms explosive gas mixture with air
- **10.4 Conditions to avoid** Avoid all sources of ignition: heat, sparks, open flames.
- **10.5 Incompatible materials:**
strong oxidizing agents
alkalies
- **10.6 Hazardous decomposition products:** In case of fire: see section 5

SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
- **Acute toxicity**
Toxic if swallowed, in contact with skin or if inhaled.

- **LD/LC50 values that are relevant for classification:**

50-00-0 formaldehyde

Oral	LD50	100 mg/kg (rat)
Dermal	LD50	270 mg/kg (rbt)
Inhalative	LC50/4 h	0.203 mg/l (rat)

67-56-1 methanol

Oral	LD50	5900 mg/kg (rat)
Dermal	LD50	20000 mg/kg (rbt)

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- **Primary irritant effect:**
- **Skin corrosion/irritation**
Causes severe skin burns and eye damage.
Danger by skin resorption.
- **Serious eye damage/irritation**
Causes severe skin burns and eye damage.
- **Respiratory or skin sensitisation**
May cause an allergic skin reaction.
Sensitization possible of predisposed persons.
- **Other information (about experimental toxicology):**
The IARC (International Agency for Research on Cancer) recommends a classification in Group 1 (carcinogenic to humans). On the basis of epidemiological studies and animal experiments, one gets a relation between formaldehyde exposure and cancer (especially in the nose and throat), considered to be proven.
- **Additional toxicological information:**
Swallowing: strong corrosive action on mouth and throat. Danger of perforation of esophagus and stomach.
Methanol causes blindness and even to death.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
- **Germ cell mutagenicity**
Suspected of causing genetic defects.
- **Carcinogenicity**
May cause cancer.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

- 12.1 Toxicity

- Aquatic toxicity:

50-00-0 formaldehyde

LC 50 / 96 h	6.7 mg/l (fish)
LC 50 / 48 h	140 mg/l (<i>Lepomis macrochirus</i>) 168 mg/l (<i>Salmo gairdneri</i>)
LC 0 / 48 h	32-43 mg/l (<i>Leuciscus idus</i>)
EC 50 / 48 h	5.8 mg/l (<i>Daphnia pulex</i>) (OECD 202)
EC 50 / 24 h	42 mg/l (<i>Daphnia magna</i>)
EC 50 / 72 h	4.89 mg/l (<i>Scenedesmus subspicatus</i>)
EC 50 / 3 h	12.2 mg/l (activated sludge (method OECD 209)) (OECD 209)
NOEC	≥48 mg/l (<i>Oryzias latipes</i>) (28 d)

67-56-1 methanol

LC 50 / 96 h	15,400 mg/l (<i>Lepomis macrochirus</i>)
EC 50 / 48 h	24,500 mg/l (<i>Daphnia magna</i>) (DIN 38412)
EC 50 / 96 h	22,000 mg/l (<i>Pseudokirchneriella subcapitata</i>) (OECD 201)
NOEC	7,900 mg/l (<i>Oryzias latipes</i>) (200 h)
IC 50 / 3 h	>1,000 mg/l (activated sludge (method OECD 209)) (Atmungshemmung)

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- 12.2 Persistence and degradability

The product is readily biodegradable.

Degree of elimination: > 90 % BOD

- 12.3 Bioaccumulative potential No further relevant information available.**- 12.4 Mobility in soil** No further relevant information available.**- Ecotoxicological effects:** Inhibition of bacterial growth rate: EC50 = 19,6 mg/l (OECD 209 = ISO 8192)**- Behaviour in sewage processing plants:**

In a model sewage treatment plant, the product after 2.5 days is completely eliminated from wastewater.

- Additional ecological information:**- According to recipe contains the following heavy metals and compounds according to EC guideline NO. 76/464 EC:**

The product contains no organic bound halogen.

- General notes:

Water danger class 3 (Assessment by list): extremely hazardous for water.

Do not allow product to reach ground water, water bodies or sewage system, even in small quantities.

Danger to drinking water if even extremely small quantities leak into soil.

- 12.5 Results of PBT and vPvB assessment**- PBT:** Not applicable.**- vPvB:** Not applicable.**- 12.6 Other adverse effects** No further relevant information available.

SECTION 13: Disposal considerations

- 13.1 Waste treatment methods

The following advice is related to new material and not to any processed products. In case of a mixture with other products other disposal methods may become necessary. If in doubt seek advice from product supplier or from local authorities.

- Recommendation

Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

Product should be disposed according to valid legislations.

Must be specially treated under adherence to official regulations (e.g. hazardous waste incinerator facility).

- Waste disposal key number:

Since 01/01/99 the waste code numbers have not only been product-related but are also essentially application-related. The valid waste code number of the application can be obtained from the European waste catalogue.

- Uncleaned packagings: Disposal must be made according to official regulations.**- Recommendation:**

Rented packaging: After optimal emptying, close immediately and return to the supplier without cleaning.

Care should be taken that no other materials get into the packaging.

Handle contaminated packaging in the same way as the substance itself.

SECTION 14: Transport information

- 14.1 UN-Number**- ADR, IMDG, IATA**

UN2209

- 14.2 UN proper shipping name**- ADR****- IMDG, IATA**2209 FORMALDEHYDE SOLUTION
FORMALDEHYDE SOLUTION

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- 14.3 Transport hazard class(es)	
- ADR	
- Class	8 (C9) Corrosive substances. Corrosive substances.
- Label	8
<hr style="border-top: 1px dashed #000;"/>	
- IMDG, IATA	
- Class	8 Corrosive substances.
- Label	8
- 14.4 Packing group	
- ADR, IMDG, IATA	III
- 14.6 Special precautions for user	
- Kemler Number:	80
- EMS Number:	F-A,S-B
- Stowage Category	A
- 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code	
	Not applicable.
- Transport/Additional information:	
<hr style="border-top: 1px dashed #000;"/>	
- ADR	
- Limited quantities (LQ)	5L
- Excepted quantities (EQ)	Code: E1 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml
- Transport category	3
- Tunnel restriction code	E
<hr style="border-top: 1px dashed #000;"/>	
- IMDG	
- Limited quantities (LQ)	5L
- Excepted quantities (EQ)	Código E4 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 1000 ml
- UN "Model Regulation":	UN 2209 FORMALDEHYDE SOLUTION, 8, III

SECTION 15: Regulatory information

- 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
- Labelling according to Regulation (EC) No 1272/2008
The substance is classified and labelled according to the CLP regulation.
- Hazard pictograms



GHS05 GHS06 GHS08

- Signal word Danger

- Hazard statements

H330 - Fatal if inhaled.
H301 + H311 - Toxic if swallowed or in contact with skin.
H314 - Causes severe skin burns and eye damage.
H317 - May cause an allergic skin reaction.

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H350 - May cause cancer.

H341 - Suspected of causing genetic defects.

H371 - May cause damage to organs.

H335 - May cause respiratory irritation.

- Precautionary statements

P271 - Use only outdoors or in a well-ventilated area.

P280 - Wear protective gloves/protective clothing/eye protection/face protection.

P303 - IF ON SKIN (or hair):

P361 - Remove/Take off immediately all contaminated clothing.

P353 - Rinse skin with water [or shower].

P304 - IF INHALED:

P340 - Remove victim to fresh air and keep at rest in a position comfortable for breathing.

P305 - IF IN EYES:

P351 - Rinse cautiously with water for several minutes.

P338 - Remove contact lenses, if present and easy to do. Continue rinsing.

P310 - Immediately call a POISON CENTER or physician.

P405 - Store locked up.

P501 - Dispose of contents and container in accordance with all local, regional, national and international regulations.

- Directive 2012/18/EU**- Qualifying quantity (tonnes) for the application of lower-tier requirements 5 t****- Qualifying quantity (tonnes) for the application of upper-tier requirements 50 t****- REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3, 28, 72****- National regulations****- Additional classification according to Decree on Hazardous Materials, Annex II: Carc. Kat. 3****- Information about limitation of use:***Workers should not be exposed to this hazardous material. Exceptions can be made by the authorities in certain exceptional cases.**Employment restrictions concerning young persons must be observed.***- 15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.**SECTION 16: Other information***These data are based on our present knowledge. However, they shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.***- Relevant phrases**

H225 Highly flammable liquid and vapour.

H226 Flammable liquid and vapour.

H301 Toxic if swallowed.

H311 Toxic in contact with skin.

H314 Causes severe skin burns and eye damage.

H317 May cause an allergic skin reaction.

H331 Toxic if inhaled.

H341 Suspected of causing genetic defects.

H350 May cause cancer.

H370 Causes damage to organs.

- Department issuing data specification sheet:

SAV Liquid Production GmbH

Hochriesstrasse 2

D- 83126 Flintsbach am Inn

Tel.: +49/8034/90980-0

E-Mail: info@sav-lp.de

- Abbreviations and acronyms:

RPE: Respiratory Protective Equipment

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*RCR: Risk Characterisation Ratio (RCR= PEC/PNEC)**ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)**IMDG: International Maritime Code for Dangerous Goods**IATA: International Air Transport Association**GHS: Globally Harmonized System of Classification and Labelling of Chemicals**CLP: Classification, Labelling and Packaging (Regulation (EC) No. 1272/2008)**EINECS: European Inventory of Existing Commercial Chemical Substances**ELINCS: European List of Notified Chemical Substances**CAS: Chemical Abstracts Service (division of the American Chemical Society)**DNEL: Derived No-Effect Level (REACH)**PNEC: Predicted No-Effect Concentration (REACH)**LC50: Lethal concentration, 50 percent**LD50: Lethal dose, 50 percent**vPvB: very Persistent and very Bioaccumulative**Flam. Liq. 2: Flammable liquids – Category 2**Flam. Liq. 3: Flammable liquids – Category 3**Acute Tox. 3: Acute toxicity - oral – Category 3**Skin Corr. 1B: Skin corrosion/irritation – Category 1B**Skin Sens. 1: Skin sensitisation – Category 1**Muta. 2: Germ cell mutagenicity – Category 2**Carc. 1B: Carcinogenicity – Category 1B**STOT SE 1: Specific target organ toxicity (single exposure) – Category 1***- * Data compared to the previous version altered.**