

LCID Example 6b – Introduction

Antifreeze / Coolant for professional and industrial use

1) Purpose of the example

Example is set to demonstrate the following points:

- How to derive safe use information for mixture.
- How to handle cases where some DNELs for relevant component(s) are missing and expert judgement needs to be applied on step H7 when selecting reference values.
- How to apply expert judgment when dealing with cases where the mixture contains substances with differing physical forms, for example solid organic salt in solution.
- How to consolidate safe use information from Exposure Scenarios for lead components.
- What to do when different safe use information, is provided by different suppliers of the same ingredient.
- How to communicate derived safe use information as an annex, using DUCC SUMI format and demonstrate Pros and Cons of such format.

2) Mixture description

a) Information on the mixture

Composition:	Ethylene glycol 90 %, CAS 107-21-1 Sodium 2-ethylhexanoate 3.5 %, CAS 19766-89-3 Methyl-1H-benzotriazole 0.6 %, CAS 29385-43-1
Classification of the mixture:	Acute Tox4; H302, Repr. 2;H361, STOT RE 2;H373,
Use of the mixture:	Use as a functional fluid (Antifreeze/coolant)
Description of use:	<p>The professional end use of the antifreeze concentrate involves the manual transfer of the material from the container to a cooling system, water is then added, the cooling system sealed and the antifreeze / water mixture is circulated. In use the antifreeze / water mixture acts as a functional fluid in a closed system under pressure.</p> <p>At intervals the used antifreeze / water mixture is drained from the cooling system. This is done into open containers and may be carried out with the antifreeze /water mixture at an elevated temperature of around 40°C.</p> <p>Exposure occurs during filling and draining of the cooling system. Exposure by inhalation is limited to vapour only.</p> <p>Industrial use as a coolant may be carried out in non pressurised systems where the coolant is circulated by pump and returns to an open sump. Formation and exposure to aerosol mist is possible</p>

b) Hazardous substances entering in the composition of the mixture

Substance	Available DNEL(s) [worker unless stated] [other limit values]	CLP classification
Ethylene glycol	DNEL inhalation, long-term, local: 35 mg/m ³ DNEL dermal, long-term, systemic: 106 mg/kg bw/day LD50 (oral, cat) = 1600 mg/kg Point estimate (Acute Tox. 4, oral) = 500 mg/kg	Acute Tox. 4;H302, STOT RE 2;H373
Sodium 2-ethylhexanoate	DNEL inhalation, long-term, systemic: 14 mg/m³ DNEL dermal, long-term, systemic: 2 mg/kg bw/day DNEL oral, long-term, systemic: 1 mg/kg bw/day [General population] LD50 (oral, rat) = 2043 mg/kg	Repr. 2;H361
Methyl-1H-benzotriazole	DNEL inhalation, long-term, systemic: 8.8 mg/m ³ DNEL dermal, long-term, systemic: 0.5 mg/kg bw/day LD50 (oral, rat) = 720 mg/kg	Acute Tox. 4;H302, Aquatic Chronic 2;H411

Highlighted values are those used to determine LCI

3) Outcome of the LCID methodology – Professional use

- *As the mixture is not classified as environmentally hazardous, there is no need to apply LCID methodology beyond step 2 for Environment.*
- *There is is/are no priority substance(s) Human Health (HH).*
- *Although present in the formulation, the concentration of Methyl-1H-benzotriazole is below the generic cut-off values for it to be taken into account for classification purposes. Therefore, it is not a relevant component in respect of contributing to the hazards of the mixture.*
- *There is potential for exposure to vapours.*
- *Lead Component(s) HH inhalation, HH dermal, HH oral are identified in the table below.*

Hazard	Identified Lead Component
HH dermal	Sodium 2-ethylhexanoate. Higher LCI compared to Ethylene glycol.
HH inhalation	<p>Ethylene glycol. Conclusion is based on expert judgment.</p> <p>On step H6, it was identified that two relevant components contribute to the systemic hazard of the mixture, i.e. Ethylene glycol and Sodium 2-ethylhexanoate.</p> <p>At step H7 it was noted that there is no DNEL (systemic, long-term, inhalation) for ethylene glycol. Without this value, it is not possible to calculate LCI for ethylene glycol, hence compare values for two relevant components. However, ethylene glycol has EU indicative exposure limit. Therefore it is clear that this component is considered a concern and must be taken into consideration when identifying the Lead Component for the mixture for this route.</p> <p>It is also noted that sodium 2-ethyl hexanoate is a solid, hence exposure to the substance as a vapour is not possible. Therefore, it was concluded that ethylene glycol is the Lead Component for this route of exposure.</p> <p>If there is a possibility of exposure to an aerosol, then dissolved salt should be taken into account when determining the Lead Component for inhalative route of exposure. However, for this use formation of mist/aerosol is unlikely.</p>
HH oral	Not determined - Product is not intended for consumer use. Also noted that no DNEL for this route of exposure has been derived for Ethylene glycol

4) Operation conditions (OC) and risk management measures (RMM) associated to Priority Substances, Lead Components and components driving local effects for the selected use of the mixture

To derive safe use information for this mixture, it is necessary to review, compare and then extract most stringent/relevant OCs and RMMs from Exposure Scenarios covering the above-listed uses for the identified lead components of the mixture, i.e. sodium 2-ethylhexanoate (LC dermal), ethylene glycol (LC inhalation).

For sodium 2-ethylhexanoate, eSDSs were available from three different suppliers. However, one supplier did not include exposure scenarios for use as a functional fluid, neither industrial or professional. Therefore, that document was disregarded.

For ethylene glycol, eSDSs were available from two different suppliers.

Use in Functional Fluids (Professional)

Sodium 2-ethylhexanoate:

Both eSDS specify concentrations covered. Although varying (15% versus 25%) this is not critical as the concentration in the product is significantly lower.

For PROC 8a both eSDSs state *"Avoid carrying out activities involving exposure for more than 1 hour"*.

For PROC 9 both eSDSs state *"Avoid carrying out activities involving exposure for more than 4 hours"*.

Otherwise, both eSDSs cover exposure up to 8 hours / 5 days per week for indoor use.

One eSDS assumes use at not more than 20°C above ambient temperature, the other eSDS does not specify temperature.

Both eSDSs specify requirements for ventilation, although different terminology is used one calling for *"enhanced general ventilation by mechanical means"* the other for *"a good standard of controlled ventilation (5-10 air changes per hour)"*.

Both eSDSs include *"Wear chemically resistant gloves (tested to EN374) in combination with 'basic' employee training."*

Ethylene glycol:

Both eSDSs cover use up to 100%

Both eSDSs cover indoor use and daily exposure up to 8 hours.

One eSDS Assumes activities are at ambient temperature*. The other eSDS does not specify temperature.

Both eSDSs do not include any ventilation requirements apart from PROC 8a where Local Exhaust Ventilation is required. One supplier specifies with an efficiency of 90%, the other specifies an efficiency of 80%. *"In case no suitable local exhaust ventilation is present: Wear a suitable respiratory protection with adequate effectiveness"*.

One eSDS includes *"Additional good practice advice: Use suitable eye protection."*

*Contact with supplier to clarify if this can be modified is recommended, as typical uses do involve

discharging at elevated temperature – an example being service activities on automotives that have recently been driven to facility.

5) Consolidated OC/RMM for inclusion in the mixture safety data sheet

Professional use

For inclusion in sections 7 and/or 8, selecting the most severe from above unless noted differently.

Provide a good standard of controlled ventilation (5 to 10 air changes per hour).

Wear chemically resistant gloves (tested to EN374) in combination with 'basic' employee training. Use suitable eye protection.

Transfer of substance or mixture (charging/discharging) at non dedicated facilities: Provide local extract ventilation to the point where emissions occur. Effectiveness 90%. In case no suitable local exhaust ventilation is present: Wear suitable respiratory protection with adequate effectiveness. Avoid carrying out activities involving exposure for more than 1 hour.

Transfer of substance or mixture (charging/discharging) into small containers (dedicated filling line, including weighing): Avoid carrying out activities involving exposure for more than 4 hours.

Example 6b - Safety Data Sheet content

Extract of relevant safe use information derived by application of the LCID methodology

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

- 1.1. Product identifier
- 1.2. Relevant identified uses of the substance or mixture and uses advised against
Identified uses: Antifreeze / Coolant
- 1.3. Details of the supplier of the safety data sheet
- 1.4. Emergency telephone number

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008 as amended

Health hazards

Acute toxicity, oral	Category 4	H302 – Harmful if swallowed
Reproductive toxicity	Category 2	H361 - Suspected of damaging fertility or the unborn child.
Specific target organ toxicity – repeated exposure	Category 2	H373 - May cause damage to organs (kidney) through prolonged or repeated exposure.

2.2. Label elements



Warning

Hazard statements

H302 Harmful if swallowed
H361 Suspected of damaging fertility or the unborn child.
H373 May cause damage to organs (kidney) through prolonged or repeated exposure.

Precautionary statements

P201 Obtain special instructions before use.
P260 Do not breathe mist/vapours/spray.
P264 Wash thoroughly after handling
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P308 + P313 If exposed or concerned. Get medical advice/attention.
P405 Store locked up.

2.3. Other hazards: This mixture does not contain substances assessed to be vPvB / PBT.

SECTION 3: Composition/information on ingredients**3.2. Mixtures**

Chemical name	%	CAS No./EC No.	REACH registration number	Index No.
Ethylene glycol Acute Tox. 4;H302, STOT RE 2;H373	>80	107-21-1 / 203-473-3	01-2119456816-28-XXXX	-
Sodium 2-ethylhexanoate Repr. 2;H361	1 - 5	19766-89-3 / 243-283-8	01-2119972937-17-XXXX	-

SECTION 4: First aid measures**SECTION 5: Firefighting measures****SECTION 6: Accidental release measures****SECTION 7: Handling and storage**

7.1. Precautions for safe handling Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not breathe mist or vapour. Do not taste or swallow. Avoid prolonged exposure. When using, do not eat, drink or smoke. Should be handled in closed systems, if possible. Provide adequate ventilation. Wash hands thoroughly after handling. Observe good industrial hygiene practices.

7.2. Conditions for safe storage, including any incompatibilities Store locked up. Store in original tightly closed container. Store away from incompatible materials (see section 10 of the SDS).

SECTION 8: Exposure controls/personal protection**8.1. Control parameters**

Occupational exposure limits

Biological limit values

Recommended monitoring procedures

Derived no effect levels (DNELs) Worker

Substance	
Ethylene glycol	DNEL inhalation, long-term, local: 35 mg/m ³ DNEL dermal, long-term, systemic: 106 mg/kg bw/day
Sodium 2-ethylhexanoate	DNEL inhalation, long-term, systemic: 14 mg/m ³ DNEL dermal, long-term, systemic: 2 mg/kg bw/day

Predicted no effect concentrations (PNECs)

Substance	
Ethylene glycol	PNEC marine water: 1 mg/l PNEC freshwater: 10 mg/l PNEC sediment (freshwater): 37 mg/kg PNEC sediment (marine water): 3.7 mg/kg Soil: 1.53 mg/kg STP: 199.5 mg/kg
Sodium 2-ethylhexanoate	PNEC marine water: 0.04 mg/l PNEC freshwater: 0.36 mg/l PNEC intermittent releases: 0.49 mg/l PNEC sediment (freshwater): 0.3 mg/kg PNEC sediment (marine water): 0.03 mg/kg Soil: 0.06 mg/kg STP: 71.7 mg/kg

8.2. Exposure controls

Appropriate engineering controls

Provide a good standard of controlled ventilation (5 to 10 air changes per hour) Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Individual protection measures, such as personal protective equipment

General information Personal protection equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment.

Eye/face protection Risk of splashes: Wear safety glasses with side shields (or goggles). Eye protection should meet standard EN 166.

Skin protection

- **Hand protection** Wear suitable gloves tested to EN374. Full contact: Use gloves classified protection index 6 with breakthrough time of 480 minutes. Minimum glove thickness 0.38 mm. Neoprene, butyl rubber, nitrile or Viton gloves are recommended.
- **Other** Wash hands thoroughly after handling. Use of an impervious apron is recommended.

Respiratory protection In case of inadequate ventilation or risk of inhalation of mist or vapours, use suitable respiratory equipment with combination filter (type A2/P2).

Thermal hazards Wear appropriate thermal protective clothing, when necessary.

Hygiene measures – Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

Environmental exposure controls Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. Fume scrubbers, filters or engineering modifications to the process equipment may be necessary to reduce emissions to acceptable levels.

SECTION 9: Physical and chemical properties

SECTION 10: Stability and reactivity

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity

Product	Species	Test Results
Acute , Oral		1778 mg/kg ATE _{mix}
Components	Species	Test Results
Ethylene glycol (CAS 107-21-1)		
Acute		
Dermal		
LD50	Mouse	> 3500 mg/kg
Inhalation		
LC50	Rat	> 2.5 mg/l, 6 Hours
Oral		
LD50	Cat	1600 mg/kg
Sodium 2-ethylhexanoate (CAS 19766-89-3)		
Acute		
Dermal		
LD50	Rat	> 2000 mg/kg, 24 Hours
Oral		
LD50	Rat	2043 mg/kg

SECTION 12: Ecological information

SECTION 13: Disposal considerations

SECTION 14: Transport information

SECTION 15: Regulatory information

SECTION 16: Other information

Annex to the extended Safety Data Sheet (eSDS)**Table of contents**

1. Safe Use Mixture Information (SU0, PC4, ERC9a, ERC9b)..... Page XX

Safe Use Information for mixture

General description of the process covered

List of use descriptors

Sector(s) of Use

SU0: Other

Product categories [PC]

PC4: Anti-freeze and de-icing products

Name of contributing environmental scenario and corresponding ERC

ERC9a: Widespread use of functional fluid (indoor)

ERC9b: Widespread use of functional fluid (outdoor)

List of names of contributing scenarios and corresponding PROCs

PROC8a: Transfer of substance or mixture (charging/discharging) at non dedicated-facilities

PROC9: Transfer of substance or mixture into small containers (dedicated filling line, including weighing)

PROC20: Use of functional fluids in small devices

Operational conditions

Maximum duration

PROC8a: Avoid carrying out operation for more than 1 hour per day¹

PROC9: Avoid carrying out operation for more than 4 hours per day

PROC20: Covers daily exposures up to 8 hours

Range of application / process conditions

Indoor use, Outdoor use

Air exchange rate

Provide a good standard of controlled ventilation (5 to 10 air changes per hour).

PROC8a: Transfer of substance or mixture (charging/discharging) at non dedicated-facilities:

Provide local extract ventilation to the point where emissions occur. Efficiency of at least 90%

In case no suitable local exhaust ventilation is present: Wear suitable respiratory protection with adequate effectiveness.¹

Risk management measures

Conditions and measures related to personal protection equipment (PPE), hygiene and health evaluation and the environment

Wear chemically resistant gloves (tested to EN374) in combination with specific activity training. Use eye protection. For further specification, refer to section 8 of the SDS.



Environmental measures

As no environmental hazard was identified no environmental-related exposure assessment and risk characterization was performed. For the disposal of product residues and waste please refer to section 13 of the SDS.

¹ If the advice to carry out process for not more than 1 hours per day seems unrealistic, or effectiveness needs to be clarified, then formulator should contact the supplier and pass on this information. This is per requirement outlined in Article 34(b) of the REACH.

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