The technical association of the European lubricants industry

The technical committee of petroleum additive manufacturers in Europe

ATIEL/ATC
Generic Exposure Scenarios

Document 4: Health Boundary Conditions Matrix

This Matrix is designed to be used in conjunction with the ATIEL/ATC GES Process Flow Charts Steps 1 and 4.

Version 2.0

January 2016

Health Boundary Conditions Matrix

Purpose

This Matrix is designed to be used in conjunction with the ATIEL-ATC GES Process Flow Charts Steps 1 and 4.
Rows 1 & 2 of the Matrix are for use with Step 1a of the Flowchart, and are concerned the initial allocation of GES(s) to products for each relevant Use Group. A comparison of the identified criteria with those of your products will determine whether the products fall within the boundary of the GES. If they fall outside the identified criteria, then the GES does not apply and a Health ES specific to that product will need to be compiled.
Rows 3 & 4 of the Matrix are for use with Step 4 of the Flowchart, and are concerned with checking that health-related information received in a raw material extended-Safety Data Sheet is consistent with the Health component of the GES(s) that have been allocated to products that contain the raw material.

Updates

13.01.2016 Matrix updated to reflect the change to CLP - 'R' Phrases replaced by the new 'H' Phrases

HEALTH BOUNDARY CONDITIONS MATRIX
FOR USE WITH STEP1a & STEP 4 OF THE GES PROCESS FLOWCHART

Row Number	Criteria / Boundary Condition	ATIEL/ATC USE GROUPS (GES TITLES)							
		A: Formulation of additive packages, lubricants & greases **A(i) - Industrial**			**B: General use in vehicles or machinery** **B(i) - Industrial** **B(p) - Professional**	**C: Use in open systems** **C(i) - Industrial** **C(p) - Professional**	**D: Use in open high temperature processes** **D(i) - Industrial**	**E: Metal working fluid concentrates** **E(i) - Industrial**	**F: Use in high energy open processes** **F(i) - Industrial** **F(p) - Professional**
		a) A(i) AddPack with Nil or Low sensitiser concentration	**b) A(i) AddPack with High sensitiser concentration**	**c) A(i) Lubes Formulation with Nil or Low sensitiser concentration**					
1	**Product Classification & Labelling (C&L) covered by one or more of the listed R phrases (DPD human health):**	**R43** **R36; R41** **R37** **R38; R21** **R20** **R65; R66; R22** (see Note 1) **Not classified**	**R43** **R36; R41** **R37** **R38; R21** **R20** **R65; R66; R22** (see Note 1) **Not classified**	**R43** **R36; R41** **R37** **R38; R21** **R20** **R65; R66; R22** (see Note 1) **Not classified**	**R43** **R36; R41** **R37** **R38; R21** **R20** **R65; R66; R22** (see Note 1) **Not classified**	**R43** **R36; R41** **R37** **R38; R21** **R20** **R67** **R65; R66; R22** (see Note 1) **Not classified**	**R43** **R36; R41** **R37** **R38; R21** **R20** **R65; R66; R22** (see Note 1) **Not classified**	**R43** **R36, R41** **R37** **R38, R21** **R65; R66; R22** (see Note 1) **Not classified**	**R43** **R36; R41** **R37** **R38; R21** **R65; R66; R22** (see Note 1) **Not classified**
	Classification, Labelling & Packaging (CLP) covered by one or more of the listed H phrases (GHS human health):	H317 (R43) H319 (R36) H318 (R41) H335 (R37) H315 (R38) H304 (R65) EUH066 (R66) H332 (R20) - vapour/aerosol H331 (R20) - vapour H302 (R22) H301 (R22) - LD50 dependant, see Note 4 H312 (R21) H311 (R21) - LD50 dependant, see Note 5 Not classified	H317 (R43) H319 (R36) H318 (R41) H335 (R37) H315 (R38) H304 (R65) EUH066 (R66) H332 (R20) - vapour/aerosol H331 (R20) - vapour H302 (R22) H301 (R22) - LD50 dependant, see Note 4 H312 (R21) H311 (R21) - LD50 dependant, see Note 5 Not classified	H317 (R43) H319 (R36) H318 (R41) H335 (R37) H315 (R38) H304 (R65) EUH066 (R66) H332 (R20) - vapour/aerosol H331 (R20) - vapour H302 (R22) H301 (R22) - LD50 dependant, see Note 4 H312 (R21) H311 (R21) - LD50 dependant, see Note 5 Not classified	H317 (R43) H319 (R36) H318 (R41) H335 (R37) H315 (R38) H304 (R65) EUH066 (R66) H332 (R20) - vapour/aerosol H331 (R20) - vapour H302 (R22) H301 (R22) - LD50 dependant, see Note 4 H312 (R21) H311 (R21) - LD50 dependant, see Note 5 Not classified	H317 (R43) H319 (R36) H318 (R41) H335 (R37) H315 (R38) H304 (R65) EUH066 (R66) H336 (R67) H332 (R20) - vapour/aerosol H331 (R20) - vapour H302 (R22) H301 (R22) - LD50 dependant, see Note 4 H312 (R21) H311 (R21) - LD50 dependant, see Note 5 Not classified	H317 (R43) H319 (R36) H318 (R41) H335 (R37) H315 (R38) H304 (R65) EUH066 (R66) H332 (R20) - vapour/aerosol H331 (R20) - vapour H302 (R22) H301 (R22) - LD50 dependant, see Note 4 H312 (R21) H311 (R21) - LD50 dependant, see Note 5 Not classified	H317 (R43) H319 (R36) H318 (R41) H335 (R37) H315 (R38) H304 (R65) EUH066 (R66) H302 (R22) H301 (R22) - LD50 dependant, see Note 4 H312 (R21) H311 (R21) - LD50 dependant, see Note 5 Not classified	H317 (R43) H319 (R36) H318 (R41) H335 (R37) H315 (R38) H304 (R65) EUH066 (R66) H302 (R22) H301 (R22) - LD50 dependant, see Note 4 H312 (R21) H311 (R21) - LD50 dependant, see Note 5 Not classified
2	**For products classified as R43 (skin sensitiser), sensitising component is within the listed concentration range:**	**Skin sensitiser** (see Note 2) a) **≥ 0.1 - 1%** Strong b) **≥ 1 - 3%** Weak or Moderate	**Skin sensitiser** (see Note 2) a) **>1 - 50%** Strong b) **>3 - 50%** Weak or Moderate	**Skin sensitiser** (see Note 2) a) **≥ 0.1 - 1%** Strong b) **≥ 1 - 3%** Weak or Moderate	**Skin sensitiser** (see Note 2) a) **≥ 0.1 - 1%** Strong b) **≥ 1 - 3%** Weak or Moderate	**Skin sensitiser** (see Note 2) a) **≥ 0.1 - 1%** Strong b) **≥ 1 - 3%** Weak or Moderate	**Skin sensitiser** (see Note 2) a) **≥ 0.1 - 1%** Strong b) **≥ 1 - 3%** Weak or Moderate	**Skin sensitiser** (see Note 2) a) **≥ 0.1 - 1%** Strong b) **≥ 1 - 3%** Weak or Moderate	**Skin sensitiser** (see Note 2) a) **≥ 0.1 - 1%** Strong b) **≥ 1 - 3%** Weak or Moderate
Rows 1 & 2 above apply in Step 1 of the Flowchart									
Rows 3 & 4 below apply in Step 4 of the Flowchart									

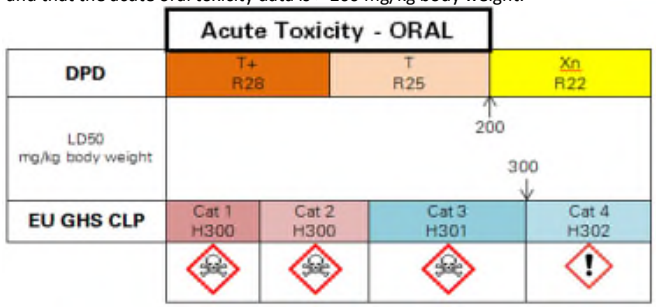
3	**Boundary concentration of health Risk Determining Substance(s) in mixture/formulation**	**Skin sensitisers:** **≤ 1%** of strong sensitiser **≤ 3%** of weak/moderate sensitiser **Other hazardous components except CMRs:** a) **≤ 100%** (industrial) * b) **≤ 100%** (professional) * * Based on generic 'vapour' and 'dermal' RV (see Row 4 (i) and (ii)) c) Other boundary conditions may be valid, if component OCs and RMMs are equal or less stringent than included in the GES. d) GES takes account of potential for aerosol exposure (see Row 4 (iii))	**Skin sensitisers:** **≤ 50%** of strong sensitiser **≤ 50%** of weak/moderate sensitiser **Other hazardous components except CMRs:** a) **≤ 100%** (industrial) * b) **≤ 100%** (professional) * * Based on generic 'vapour' and 'dermal' RV (see Row 4 (i) and (ii)) c) Other boundary conditions may be valid, if component OCs and RMMs are equal or less stringent than included in the GES. d) GES takes account of potential for aerosol exposure (see Row 4 (iii))	**Skin sensitisers:** **≤ 1%** of strong sensitiser **≤ 3%** of weak/moderate sensitiser **Other hazardous components except CMRs:** a) **≤ 100%** (industrial) * b) **≤ 100%** (professional) * * Based on generic 'vapour' and 'dermal' RV (see Row 4 (i) and (ii)) c) Other boundary conditions may be valid, if component OCs and RMMs are equal or less stringent than included in the GES. d) GES takes account of potential for aerosol exposure (see Row 4 (iii))	**Skin sensitisers:** **≤ 1%** of strong sensitiser **≤ 3%** of weak/moderate sensitiser **Other hazardous components except CMRs:** a) **≤ 25%** (industrial) * b) **≤ 5%** (professional) * * Based on generic 'vapour' and 'dermal' RV (see Row 4 (i) and (ii)) c) Other boundary conditions may be valid, if component OCs and RMMs are equal or less stringent than included in the GES.	**Skin sensitisers:** **≤ 1%** of strong sensitiser **≤ 3%** of weak/moderate sensitiser **Other hazardous components except CMRs:** a) **≤ 25%** (industrial) * b) **≤ 5%** (professional) * * Based on generic 'vapour' and 'dermal' RV (see Row 4 (i) and (ii)) c) Other boundary conditions may be valid, if component OCs and RMMs are equal or less stringent than included in the GES. d) GES takes account of potential for aerosol exposure (see Row 4 (iii))	**Skin sensitisers:** **≤ 1%** of strong sensitiser **≤ 3%** of weak/moderate sensitiser **Other hazardous components except CMRs:** a) **≤ 100%** (industrial) Based on generic 'vapour' and 'dermal' RV (see Row 4 (i) and (ii)) b) Other boundary conditions may be valid, if component OCs and RMMs are equal or less stringent than included in the GES. c) GES takes account of potential for aerosol exposure (see Row 4 (iii))	**Skin sensitisers:** **≤ 1%** of strong sensitiser **≤ 3%** of weak/moderate sensitiser **Other hazardous components except CMRs:** a) **≤ 100%** (industrial) Based on generic 'vapour' and 'dermal' RV (see Row 4 (i) and (ii)) b) **≤ 5%** (industrial/ professional) Based on generic 'vapour' and 'dermal' RV (see Row 4 (i) and (iii)) c) Other boundary conditions may be valid, if component OCs and RMMs are equal or less stringent than included in the GES.	**Skin sensitisers:** ≤ 1% of strong sensitiser ≤ 3% of weak/moderate sensitiser **Other hazardous components except CMRs:** a) **≤ 5%** (industrial/ professional) Based on generic 'vapour' and 'dermal' RV (see Row 4 (i) and (ii)) b) Other boundary conditions may be valid, if component OCs and RMMs are equal or less stringent than included in the GES. c) GES takes account of potential for aerosol exposure (see Row 4 (iii))
4	**Boundary Reference Value (RV), long term (8 hour) dermal and inhalation for health Risk Determining Substance(s)**	**(i) RV inhalation vapour:** **≥ 5ppm** OR Vapour Pressure **≤0.01 Pa.** **(ii) RV dermal:** **≥ 0.5** mg/kg bw/day **(iii) RV Aerosol:** **≥ 1.6** mg/m3	**(i) RV inhalation vapour:** **≥ 5ppm** OR Vapour Pressure **≤0.01 Pa**. **(ii) RV dermal:** **≥ 0.5** mg/kg bw/day **(iii) RV Aerosol:** **≥ 1.6** mg/m3	**(i) RV inhalation vapour:** **≥ 5ppm** OR Vapour Pressure **≤0.01 Pa.** **(ii) RV dermal:** **≥ 0.5** mg/kg bw/day **(iii) RV Aerosol:** **≥ 1.6** mg/m3	**(i) RV inhalation vapour:** **≥ 5ppm** OR Vapour Pressure **≤0.01 Pa.** **(ii) RV dermal:** **≥ 0.5** mg/kg bw/day	**(i) RV inhalation vapour:** **≥ 5ppm** OR Vapour Pressure **≤0.01 Pa.** **(ii) RV dermal:** **≥ 0.5** mg/kg bw/day **(iii) RV Aerosol:** **≥ 1.6** mg/m3	**(i) RV inhalation vapour:** **≥ 5ppm** OR Vapour Pressure **≤0.01 Pa.** **(ii) RV dermal:** **≥ 2.5** mg/kg bw/day **(iii) RV Aerosol:** **≥ 1.6** mg/m3	**(i) RV inhalation vapour:** **≥ 5ppm** OR Vapour Pressure **≤0.01Pa.** **(ii) RV dermal:** **≥ 5** mg/kg bw/day (component concentration at ≤100%) **(iii) ≥ 0.5** mg/kg bw/day (component concentration at ≤5%)	**(i) RV inhalation vapour:** **≥ 5ppm** OR Vapour Pressure **≤0.01Pa.** **(ii) RV dermal:** **≥ 0.5** mg/kg bw/day (component concentration at ≤ 5%) **(iii) RV Aerosol:** **≥ 1.6** mg/m3

Note1:
For hazards classified as H304, EH066 and H302, standard Risk Management Measures apply which are general for the product as a whole rather than for a specific Use Group. For these hazards the following recommended phrases are recommended for inclusion within Section 8 of the Safety Data Sheet.

H304 and H302: Do not ingest. If swallowed then seek immediate medical assistance. [E14]
EH066: If repeated and/or prolonged skin exposure to the substance is likely, then wear suitable gloves tested to EN374 and provide employee skin care programmes. [PPE20]

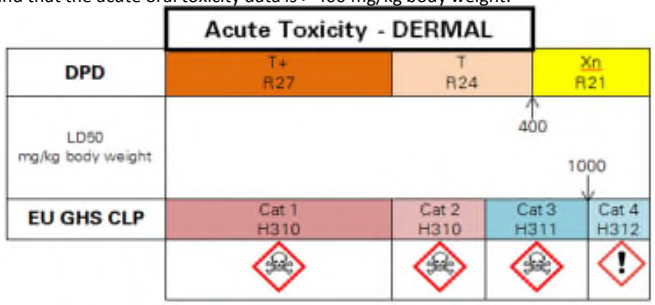
Note 2:
Skin sensitisation upper concentration limit may be over-ridden if test data on the substance/mixture is available to support this.
For R43 substances (sensitisers), 'Strong' means Category 1A and 'Weak/Moderate' means Category 1B, according to CLP. In both cases the hazard phrase H317 'May cause an allergic skin reaction' applies depending on the associated trigger concentration.

Note 3:
The DPD R Phrase 'R22' does not have exact equivalent H Phrase(s) under CLP/GHS. It does cover H302 Acute Tox Cat. 4 but also overlaps into H301 Acute Tox Cat 3. For H301 to be considered in-scope for the GES process, users need to ensure that a review of toxicology information is conducted and that the acute oral toxicity data is > 200 mg/kg body weight.



Cat 3: 50 - 300

Note 4:
The DPD R Phrase 'R21' does not have exact equivalent H Phrase(s) under CLP/GHS. It does cover H312 Acute Tox Cat. 4 but also overlaps into H311 Acute Tox Cat 3. For H311 to be considered in-scope for the GES process, users need to ensure that a review of toxicology information is conducted and that the acute oral toxicity data is > 400 mg/kg body weight.



Cat 3: 200 - 1000