AQUATIC TOXICITY Fatty acids, C8-18 and C18-unsatd., mixed esters with C18-unsatd. fatty acid dimers, decanoic acid, octanoic acid and trimethylolpropane (CASRN: 2411231-33-7)

Within the TMP ester group conclusive data on short-term toxicity to freshwater organisms is available for all three trophic levels (algae, aquatic invertebrates and fish). All tests were conducted according to internationally accepted guidelines. The available data is suitable for hazard and risk assessment of the category.

Studies on the acute toxicity to fish are available for almost all TMP esters and thus the data covers the structural variability and different fatty acid chain length within the TMP ester group. Studies testing the short-term toxicity to fish are available for 2-ethyl-2-[[(1-oxoheptyl)oxy]methyl]propane-1,3-diyl bisheptanoate (CAS 78-16-0), Fatty acids, C6-18, triesters with trimethylolpropane (CAS 91050-88-3), Fatty acids, C8-10, triesters with trimethylolpropane (CAS 91050-89-4), Fatty acids, C8-10 (even), C14-18 (even) and C16-18 (even)-unsatd., triesters with trimethylolpropane (CAS 85186-89-6), Fatty acids, C16-18 (even numbered) and C18-unsatd., branched and linear, di- and triesters with trimethylolpropane (CAS 68002-78-8), 2-ethyl-2-(((1-oxoisooctadecyl)oxy)methyl)-1,3-propanediyl bis (isooctadecanoate) (CAS 68541-50-4), Fatty acids, C8-10 (even numbered), di-and triesters with

propylidynetrimethanol (CAS 11138-60-6) and Fatty acids, C16-18 even numbered and C18-unsatd. Triesters with propylidynetrimethanol (former CAS 57675-44-2, EC 931-461-4). Acute effects on fish within the limit of water solubility of the TMP ester group members were not reported by any of the studies.

A similar outcome was demonstrated by the tests on acute toxicity to aquatic invertebrates available for the group members Fatty acids, C6-18, triesters with trimethylolpropane (CAS 91050-88-3), Fatty acids, C16-18 and C18 unsatd., triesters with trimethylolpropane (CAS 68002-78-8), Fatty acids, C8-10 (even), C14-18 (even) and C16-18 (even)-unsatd., triesters with trimethylolpropane (CAS 85186-89-6 (formerly), 2-ethyl-2-(((1-oxoisooctadecyl)oxy)methyl)-1,3-propanediyl bis (isooctadecanoate) (CAS 68541-50-4), Fatty acids, C8-10 (even numbered), di-and triesters with propylidynetrimethanol (CAS 11138-60-6), Fatty acids, C16-18 (even numbered) and C16-18-unsatd. (even numbered), triesters with trimethylolpropane (CAS 68002-79-9), Fatty acids, C16-18 even numbered and C18-unsatd. Triesters with propylidynetrimethanol (former CAS 57675-44-2), and Trimethylolpropane ester of heptanoic and octanoic acid (CAS 189120-64-7). Existing data gaps for all remaining category members were filled by read-across to TMP ester group members with the highest structural similarity.

Toxic effects of the TMP ester group members were not observed within the limit of water solubility. A trend in toxicity was not demonstrated by the available studies on short-term toxicity to aquatic organisms. Since the data covers the range of fatty acid chain length and degree of esterification it can be concluded that the demonstrated toxicity profile applies to all TMP esters.

Tests on long-term toxicity are available for two TMP ester group members. In a study on Fatty acids, C8-10 (even numbered), di-and triesters with propylidynetrimethanol (CAS 11138-60-6) with fatty acids of chain length C8 and C10 no chronic effect on Daphnia magna (NOELR (15 d) $\geq$ 2570 mg/L) were determined. In a second study conducted with the TMP ester Fatty acids, C16-18 and C18 unsatd., triesters with trimethylolpropane (CAS 68002-78-8) with fatty acids of chain length C16-C18 and C18 a NOELR  $\geq$  0.11 g/L was determined. Generally the two substances reflect the range of fatty acid chain length within the TMP ester group. Therefore a transfer of the results of the two available long-term studies to the other TMP ester group members by read-across is assumed to be suitable. Although chronic toxicity data is available for members within theTMP polyol esters group in accordance with Regulation (EC) No 1907/2006, Annex IX 9.1 Aquatic toxicity, further long-term studies on aquatic invertebrates were proposed for Fatty acids, coco, triester with trimethylolpropane, reaction product of coconut oil fatty acids and trimethylolpropane(CAS 85566-29-6), Fatty acids, C8-10 (even), C14-18 (even) and C16-18 (even)-unsatd., triesters with trimethylolpropane(former CAS 85186-89-6) and Fatty acids, C16-18 (even numbered) and C18-unsatd., branched and linear, di- and triesters with trimethylolpropane(former CAS 85005-23-8) to extend the overall dataset and to cover the medium fatty

acid chain lengths (C12, C14 and C16) and unsaturated fatty acids (C16:1, C18:1).As soon as the studies are available the hazard and chemical safety assessment according to Annex I of Regulation (EC) No. 1907/2006 will be updated.

The toxicity to aquatic algae of the TMP ester group was investigated for 2-ethyl-2-[[(1oxoheptyl)oxy]methyl]propane-1,3-diyl bisheptanoate (CAS 78-16-0), Fatty acids, C6-18, triesters with trimethylolpropane (CAS 91050-88-3), Trimethylolpropane ester of heptanoic and octanoic acid (CAS 189120-64-7), Fatty acids, C16-18 and C18 unsatd., triesters with trimethylolpropane (CAS 68002-78-8), Fatty acids, C16-18 (even numbered) and C16-18-unsatd. (even numbered), triesters with trimethylolpropane (CAS 68002-79-9), 2-ethyl-2-(((1-oxoisooctadecyl)oxy)methyl)-1,3-propanediyl bis (isooctadecanoate) (CAS 68002-79-9), 2-ethyl-2-(((1-oxoisooctadecyl)oxy)methyl)-1,3-propanediyl bis (isooctadecanoate) (CAS 68541-50-4), Fatty acids, C8-10 (even numbered), di-and triesters with propylidynetrimethanol (CAS 11138-60-6) and Fatty acids, C16-18 even numbered and C18-unsatd. Triesters with propylidynetrimethanol (former CAS 57675-44-2). No toxicity was observed up to the limit of water solubility in the available studies. The available studies are covering the variability of fatty acid chain length within the TMP ester group. Thus, the data gaps within the category can be covered by read-across. For each read-across a suitable read-across substance regarding chain length and esterification was chosen.

Data on the toxicity to microorganisms are available for 2-ethyl-2-[[(1-oxoheptyl)oxy]methyl]propane-1,3-diyl bisheptanoate (CAS 78-16-0), Fatty acids, C8-10 (even numbered), di-and triesters with propylidynetrimethanol (CAS 11138-60-6), Fatty acids, C16-18 even numbered and C18-unsatd. Triesters with propylidynetrimethanol (CAS 57675-44-2). Based on the range of fatty acid chain length the studies can be used as read-across for structural similar substances within the TMP ester group. No effects of the substances on respiration or O2 consumption respectively were observed.

In summary no effects on aquatic organisms were observed by the available studies on TMP esters regarding any of the three trophic levels (fish, daphnia, algae). The available studies determined neither acute nor chronic effects up to the limit of water solubility of TMP esters. The data on the TMP ester group is comprehensive and covers the range of fatty acid chain lengths within the group as well as the degrees of esterification and saturation of the fatty acids. Thus a conclusive outline of the ecotoxicity profile of all TMP ester group members is possible. As demonstrated by the available data all the category members exhibit consistent ecotoxicity profiles and the categorisation is therefore approvable.

A detailed reference list is provided in the technical dossier (see IUCLID, section 13) and within CSR.

ID No.	CAS	Short-term toxicity to fish	Long-term toxicity to fish	Short-term toxicity to aquatic invertebrates	Long-term toxicity to aquatic invertebrates	Toxicity to aquatic algae	Toxicity to microorganisms
14	78-16-0	LC50 (96h) >1000 mg/L	Waiving	RA: CAS 11138-60-6 189120-64-7	RA: CAS 11138-60-6	RA: CAS 11138-60-6 189120-64-7	NOEC (14 d) >= 30.4 mg/L
15	91050-88-3	LL50 (96h) > 1000 mg/L	Waiving	EL50 (48h) > 1000 mg/L	RA: CAS 11138-60-6	EL50 (72h) > 1000 mg/L	RA: CAS 11138-60-6 RA: CAS 57675-44-2
16	97281-24-8						

Ecotoxicological parameters for the aquatic toxicity of the TMP ester group

17 18	189120-64-7 11138-60-6	 LL50 (96h)	 Waiving	EL50 (48h) >1000 mg/L (nominal) EL50 (48h) >0.59 mg/L (measured) EL50 (48h)	 NOELR	EL50 >1000 mg/L (nominal) EL50 >0.23 mg/L (measured) EL50 (72h)	 EC50 (3h)
		>10000 mg/L (nom.)		>100 mg/L (nom.)	(15d) <u>&gt;</u> 2570 mg/L (nom.)	>100 mg/L (nom.)	>10000 mg/L (nom.)
19	91050-89-4	LC50 (96h) >10000 mg/L	Waiving	RA: CAS 11138-60-6	RA: CAS 11138-60-6	RA: CAS 11138-60-6	RA: CAS 11138-60-6
20	85566-29-6	RA: CAS 11138-60-6 91050-89-4 85005-23-8 85186-89-6 91050-88-3	Waiving	Waiving RA: CAS 11138-60-6 91050-88-3 85186-89-6	TESTING PROPOSAL RA: CAS 11138-60-6	RA: CAS 11138-60-6 85186-89-6 91050-88-3 68002-79-9	RA: CAS 11138-60-6 85186-89-6
21	(Formerly 85186-89-6)	LL50 (96h) > 10000 mg/L (nom.)	Waiving	EL50 (48h) > 100 mg/L (nom.)	TESTING PROPOSAL RA: CAS 11138-60-6	EL50 (72h) > 100 mg/L (nom.)	EC50 (3h) > 10000 mg/L (nom.)
22	403507-18-6						
23	68002-79-9	RA: CAS 85005-23-8	Waiving	EC50 (48h) >1000 mg/L	RA: CAS 68002-78-8 EC 931-531- 4 (testing proposal)	EL50 (72h) >100 mg/L	RA: CAS 85005-23-8
24	EC# 931- 531-4 (formerly 85005-23-8)	LC50 (96h) > 100 mg/L	Waiving	EL50 (96h) > 100 mg/L (RL3)	TESTING PROPOSAL RA: CAS 68002-78-8	RA: CAS 68002-79-9	EL50 (16h) > 10000 mg/L (nom.)

				RA: CAS 68002-79-9	11138-60-6		
25	91050-90-7						
26	68002-78-8	LL50 (96h) >102 mg/L	Waiving	EL50 (48h) >106 mg/L	NOELR (21d)≥110 mg/L	EL50 (72h) >110 mg/L	RA: EC 931- 461-4
27	EC 931- 461-4 (formerly 57675-44-2)	LC50 (96h) >1000 mg/L RA: CAS 68002 -78 - 8	Waiving	EL50 >100 mg/L RA: CAS 68002-78-8	RA: CAS 68002-78-8 11138-60-6 EC 931-531- 4 (testing proposal)	EL50 (72h) >100 mg/L	EC10 (3h) >10000 mg/L
28	85186-92-1	RA: CAS 57675-44-2 68002-78-8 42222-50-4	Waiving	RA: CAS 57675-44-2 68002-78-8 42222-50-4	RA: CAS 68002-78-8 11138-60-6 42222-50-4 EC 931-531- 4 (testing proposal)	RA: CAS 57675-44-2 68002-78-8 42222-50-4	RA: CAS 57675-44-2
29	68541-50-4	LC50 (96h) >48 mg/L	Waiving	EC50 (48h) >7.6 mg/L	RA: CAS 68002-78-8	EC50 >3.7 mg/L	RA: CAS 57675-44-2

ECHA European Chemicals Agency (2007-2020) Registered substances factsheets. Retrieved from <a href="https://www.echa.europa.eu/registration-dossier/-/registered-dossier/18862/2/1">https://www.echa.europa.eu/registration-dossier/-/registered-dossier/18862/2/1</a>.