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Milliput: toxicological assessment of two-part epoxy adhesive

1. Conclusions

Milliput products are two-part epoxy putties. They are based on a basic formulation for Component A and Component B, with colour variations.

Component A contains the epoxy resin. The main hazard is dermal sensitisation and irritation. There is potential for eye irritation if the product enters the eye. The product is sold in small quantities, so the toxicity to aquatic organisms is mitigated.

Component B contains a polyaminoamide ingredient. The main hazard is dermal sensitisation and irritation. There is potential for eye irritation if the product enters the eye. This ingredient also has the potential to cause respiratory irritation, but inhalation is not foreseen for the viscous product.

Polyaminoamides: this product group has slight irritating effects on skin and mucous membranes compared to other hardeners, but may contain significant quantities of unreacted amine, which causes them to be irritating to skin, eyes and mucous membranes, and may cause dermal sensitisation. [i]

Some colour variations (Superfine White, Silver, and Turquoise-Blue) contain small amounts of BHT which is very toxic to aquatic life and is expected to persists in the environment. These products are considered harmful to aquatic life with long lasting effects. The product is sold in small quantities, so this hazard is mitigated.

2. Component A

Hazard classification of main components

	Ingredient name (EC and CAS numbers)	**Wt%**	**CLP hazard classification**	**Notes**
1	Epoxy resin (500-033-5, 25068-38-6)	34 to 36	Skin Irrit 2, H315; Eye Irrit 2, H319; Skin Sens 1, H317; Aquatic Chronic 2, H411	Annex VI to CLP Regulation and classification and labelling inventory; SCL C ≥ 5, then Skin Irrit 2, Eye Irrit 2
2	Talc (238-877-9, 14807-96-6)	35 to 58	Not classified	REACH registration dossier IARC Group 3 and ACGIH A4 (not classifiable as to its carcinogenicity to humans)
3	Kaolin (310-194-1, 1332-58-7)	5.7 to 6.5	Not classified	Classification and labelling inventory
H315: Causes skin irritation. H317: May cause an allergic skin reaction. H319: Causes serious eye irritation. H411: Toxic to aquatic life with long lasting effects.				

Hazard classification of colorants

	Ingredient name (EC and CAS numbers)	Wt%	CLP hazard classification	Notes
1	Titanium dioxide (236-675-5, 13463-67-7)	1.2 to 22	Not classified	REACH registration dossier Present in Standard, and Superfine White
2	DCC Yellow (228-768-4, 6358-31-2)	0.1 to 0.2	Not classified	REACH registration dossier Present in Standard and Terracotta
3	Iron oxide (215-168-2, 1309-37-1)	0.6	Not classified	REACH registration dossier Present in Terracotta
4	Carbon black (215-609-9, 1333-86-4)	0.45	Not classified	REACH registration dossier Present in Black Carbon black: classified by IARC as Group 2B: possibly carcinogenic to humans; ACGIH TLV-A3: confirmed animal carcinogen with unknown relevance to humans.
5	DCC Blue (201-375-5, 81-77-8)	0.03	Not classified	REACH registration dossier Present in Turquoise-Blue
6	DCC Green (215-524-7, 1328-53-6)	0.18	Not classified	REACH registration dossier Present in Turquoise-Blue

Hazard assessment

Acute toxicity

Based on available data, the classification criteria are not met for the oral route. No ingredients has a hazard classification for the oral, dermal, or inhalation routes.

Epoxy resin: LD_{50} (oral, rat, method OECD 420) > 2000 mg/kg.

Skin corrosion/irritation

Based on available data, the classification criteria are met for Category 2 (causes skin irritation).

Epoxy resin: some evidence that it may cause skin irritation. The irritant potential is increased due to its stickiness, which may lead to prolonged skin contact.

Serious eye damage/irritation

Based on available data, the classification criteria are met for Category 2 (causes serious eye irritation).

Epoxy resin: may cause serious eye irritation.

Respiratory or skin sensitisation

Respiratory sensitisation: no relevant ingredient has been classified for this effect.

Epoxy resin: vapour/spray/dust generated during use may cause respiratory sensitisation or irritation..

Dermal sensitisation: based on available data, the classification criteria are met for Category 1 (may cause an allergic skin reaction).

Epoxy resin: skin contact can result in contact dermatitis, through irritation or sensitisation (allergic) effects. Photodermatitis (light responsive dermatitis) to epoxy resins can also occur. [ii]

Germ cell mutagenicity

Based on available data, the classification criteria are not met.

No relevant ingredient has been classified for this effect.

Carcinogenicity

Based on available data, the classification criteria are not met.

No relevant ingredient has been classified for this effect. There are concerns regarding carcinogenicity following inhalation of 'poorly soluble, low toxicity particles (PSLT)' such as carbon black, titanium dioxide, talc and some inorganic pigments. These concerns are based on high doses in animal studies, and their relevance to human exposures is controversial. [iii] Inhalation exposure to the Milliput products is not considered a relevant route of exposure.

Reproductive toxicity

Based on available data, the classification criteria are not met.

No relevant ingredient has been classified for this effect.

Specific target-organ toxicity (STOT) – single exposure

Based on available data, the classification criteria are not met.

Epoxy resin: vapour/spray/dust generated during use may cause respiratory sensitisation or irritation.

Specific target-organ toxicity (STOT) – repeated exposure

Based on available data, the classification criteria are not met.

No relevant ingredient has been classified for this effect.

Aspiration hazard

Based on available data, the classification criteria are not met.

No relevant ingredient has been classified for this effect.

Information on other hazards

No further hazards have been identified for the ingredients.

Environmental

Based on available data, the classification criteria are met for Aquatic Chronic 2 (toxic to aquatic life with long lasting effects).

Epoxy resin: toxic to aquatic organisms with long lasting effects: EC_{50} (Daphnia, 48 h) 1 mg/L; EC_{50} (algae, 72 h) 9 mg/L.

3. Component B

Hazard classification of main components

	Ingredient name (EC and CAS numbers)	Wt%	CLP hazard classification	Notes
1	Fatty acids, tall-oil, reaction products with tetraethylene-pentamine (Tall oil – TEPA) (273-201-6, 68953-36-6)	15 to 32	Skin Irrit 2, H315; Eye Irrit 2, H319; Skin Sens 1, H317; STOT SE 3, H335	Classification and labelling inventory
2	Tetraethylenepentamine (TEPA) (203-986-2, 112-57-2)	0.2 to 1.5	Acute Tox 4, H302; Acute Tox 4, H312; Skin Corr 1B, H314; Eye Dam 1, H318; Skin Sens 1, H317; Aquatic Chronic 2, H411	Annex VI to CLP Regulation and classification and labelling inventory
3	Talc (238-877-9, 14807-96-6)	44 to 65	Not classified	REACH registration dossier IARC Group 3 and ACGIH A4 (not classifiable as to its carcinogenicity to humans)
H302: Harmful if swallowed. H312: Harmful in contact with skin. H314: Causes severe skin burns and eye damage. H315: Causes skin irritation. H317: May cause an allergic skin reaction. H318: Causes serious eye damage. H319: Causes serious eye irritation. H335: May cause respiratory irritation. H411: Toxic to aquatic life with long lasting effects.				

Hazard classification of colorants and other ingredients

	Ingredient name (EC and CAS numbers)	Wt%	CLP hazard classification	Notes
1	Titanium dioxide (236-675-5, 13463-67-7)	12 to 17	Not classified	REACH registration dossier Present in Superfine White, Silver-Grey, and Turquoise-Blue
2	Kaolin (310-194-1, 1332-58-7)	5.9 to 6.0	Not classified	Classification and labelling inventory Present in Standard, Terracotta, Black, and Superfine White
3	2,6-Di-tert-butyl-p-cresol (BHT) (204-881-4, 128-37-0)	0.2 to 0.3	Aquatic Acute 1, H400; Aquatic Chronic 1, H410 (M = 1) (REACH)	REACH registration dossier Present in Superfine White, Silver, and Turquoise-Blue
5	DCC Blue (201-375-5, 81-77-8)	0.03	Not classified	REACH registration dossier Turquoise-Blue
H400: Very toxic to aquatic life.				

H410: Very toxic to aquatic life with long lasting effects.

Hazard assessment

Acute toxicity

Based on available data, the classification criteria are not met. The amine ingredient TEPA (CAS 112-57-2) has a hazard classification for the oral and dermal routes. Based on default acute toxicity estimates (ATEs) for the ingredient, the Milliput products are not classified as hazardous for acute toxicity by the oral, dermal or inhalation routes.

Skin corrosion/irritation

Based on available data, the classification criteria are met for Category 2 (causes skin irritation).

Tall oil – TEPA: causes skin irritation.

TEPA: Causes severe skin burns.

Serious eye damage/irritation

Based on available data, the classification criteria are met for Category 2 (causes serious eye irritation).

Tall oil – TEPA: causes serious eye irritation.

TEPA: causes serious eye damage.

Respiratory or skin sensitisation

Respiratory sensitisation: no relevant ingredient has been classified for this effect.

Dermal sensitisation: based on available data, the classification criteria are met for Category 1 (may cause an allergic skin reaction).

Tall oil – TEPA and TEPA: may cause an allergic skin reaction.

Germ cell mutagenicity

Based on available data, the classification criteria are not met.

No relevant ingredient has been classified for this effect.

Carcinogenicity

Based on available data, the classification criteria are not met.

No relevant ingredient has been classified for this effect. There are concerns regarding carcinogenicity following inhalation of ‘poorly soluble, low toxicity particles (PSLT)’ such as titanium dioxide, talc and some inorganic pigments. These concerns are based on high doses in animal studies, and their relevance to human exposures is controversial. Inhalation exposure to the Milliput products is not considered a relevant route of exposure.

Reproductive toxicity

Based on available data, the classification criteria are not met.

No relevant ingredient has been classified for this effect.

Specific target-organ toxicity (STOT) – single exposure

Based on available data, the classification criteria are not met.

Tall oil – TEPA: vapour/spray/dust generated during use may cause respiratory irritation.

Specific target-organ toxicity (STOT) – repeated exposure

Based on available data, the classification criteria are not met.

No relevant ingredient has been classified for this effect.

Aspiration hazard

Based on available data, the classification criteria are not met.

No relevant ingredient has been classified for this effect.

Information on other hazards

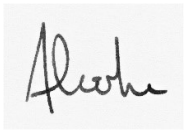
No further hazards have been identified for the ingredients.

Environmental

Based on available data, the classification criteria are met for those product colour variations containing BHT: Superfine White, Silver, and Turquoise-Blue (Aquatic Chronic 3: harmful to aquatic life with long lasting effects).

BHT: very toxic to aquatic organisms with long-lasting effects.

Other coloured products in the range do not meet the criteria for classification for environmental hazards.

Signature	
Date	31 October 2023
Name, position, company	Dr Mel Cooke, Director, Alchemy Compliance Ltd., Nottingham, UK

[i] Epoxy resins and curing agents; Toxicology, Health, Safety and Environmental Aspects; Plastics Europe; August 2017.
[ii] Epoxy Resins Information Sheet; Health and Safety Authority (Ireland); November 2010.
[iii] Carcinogenicity of Poorly Soluble Low Toxicity Particles: Commentary on Epidemiology as a Risk Assessment 'Reality Check'; Kenneth Mundt et al.; Frontiers in Public Health; 12 July 2022.