

Toxicological Assessment of KEEKO STANDARD CRAYONS

Supplier KEEKO KIDS

Assessment of exposure

Product Class	Crayon
Physical form	Wax
Amount of product used per application	10mg per application
Part of body exposed to undiluted product	Hands
Frequency of exposure to undiluted product	Four times a day
Time of exposure to undiluted product	Removed at end of day.

This safety assessment relates to the formulation described below. If the information below is incorrect, please amend and resubmit for reassessment.

Composition of the product

Chemical name	Conc %	%active	Active in Product	CAS No	Einecs No
PARAFFIN	48.3	100.0000	48.3	8002-74-2 64742-51-4 64771-72-8	232-315-6 & 265-154-5 & 265-233-4
STEARIC ACID	48.3	100.0000	48.3	57-11-4	200-313-4
CALCIUM CARBONATE	3.4	100.0000	3.4	471-34-1 / 1317-65-3	207-439-9
MAY CONTAIN +/-					
CI 74260	0.0125	100.0000	.0125	1328-53-6	215-524-7
CI 19140:1 (YELLOW 5 LAKE)	0.00827	100.0000	.00827	12225-21-7	235-428-9
CI 74160	0.0068	100.0000	.0068	147-14-8	205-685-1
CI 15865:2	0.0047	100.0000	.0047	5280-66-0 147-14-8	226-102-7 205-685-1

The chemical names in the above table identify the specific chemicals used to formulate this product and which have been taken into account in the toxicological assessment. Where possible INCI names are used but it must be recognised that INCI is for ingredient declaration and the same chemical can have several different INCI names. Also, the same INCI name can apply to several different chemicals often with different physical and toxicological properties. In order to identify the specific chemicals used, the above chemical names may differ from the names used for labelling purposes. Where possible, the active concentration of the ingredient is used. The assessment takes into account typical manufacturing tolerances/adjustments.

Assessment of toxicity

Overall toxicity rationale

No substances present which are classified as Dangerous on Health criteria.

A typical crayon mix with food grade wax and stearic acid and cosmetic grade colorants. Will comply with part 9,10, 11 of EN71. Should be well received as toys.

The raw materials used to formulate this product are all well known ingredients. They are present at typical concentrations where they are unlikely to cause irritation or allergy.

This formulation is typical of this product type. Products of similar composition have been widely used and well received in the marketplace.

If used as directed, use of this product should be uneventful.

Effects of the product as supplied on the skin

The formulation as supplied may cause only minimal skin irritation even if exposure is prolonged and/or repeated.

Repeated exposure to the formulation as supplied is unlikely to produce allergy by skin contact.

Exposure to this product is unlikely to result in phototoxic effects.

Unlikely to cause damage to internal organs following absorption through the skin.

Effects of the product as supplied on the eye

Accidental exposure of the eye to the formulation as supplied may result in slight eye irritation.

Effects following ingestion of the product as supplied

The formulation as supplied if swallowed may cause slight, transient irritation to the mouth and upper digestive tract.

Effects of inhaling the product

Inhalation is an unlikely route of exposure

Overall product safety statement

This toy is not classified as a Dangerous Preparation as per the health criteria of European Directives 67/548/EEC and 88/379/EEC. Taking into account typical ways children play with toys, the toy is unlikely to cause harm.

Under normal or reasonably foreseeable conditions of use, product made to this formulation is unlikely to produce an abnormally high number of adverse reactions. The product will give consumers the level of safety they can reasonably expect.



Toys Toxicological Safety Assessor

M U Iwobi

M U Iwobi BSc, MSc, PhD, C Biol, MI Biol.

Intertek
Labtest

Product Safety Assessment Ltd., Centre Court, Meridian Business Park, Leicester. LE19 1WD **Date** Jul 13, 2004

KEEKO STANDARD CRAYONS

Information on the raw materials

<i>Chemicals present</i>	<i>% active in product</i>	<i>Tox summary on active</i>	<i>Cosmetic Regulatory control</i>	
Paraffin	48.3	A mineral hydrocarbon wax with minimal skin and eye irritancy potential. High melting point petroleum waxes are not absorbed from the intestine, probably due to the high molecular weight, and in 90 day feeding studies were shown not to accumulate in tissues.		
Stearic Acid	48.3	Low potential to irritate the skin. When added as super fatting agent to soap reduces the skin and eye irritancy potential.		
Calcium carbonate	3.4	Unlikely to cause adverse effects at the typical concentrations used in cosmetics.	Approved colour all products	Controlled E170
May contain +/- CI 74260	.0125	A phthalocyanine colour is unlikely to cause skin or eye irritancy at the typical levels of use in a rinse off product. When used in a chalk unlikely to cause skin or eye irritancy. Is not based on carcinogenic amines.	Approved colour but not close to eyes	IV/1
CI 19140:1 (Yellow 5 lake)	.00827	The insoluble aluminium lake of tartrazine. Although some people and children are particularly sensitive to products containing tartrazine by the oral route, there is no evidence of it causing problems by the dermal route. This insoluble form of tartrazine is even less likely to cause problems.	Approved colour all products	Controlled E102
CI 74160	.0068	An approved cosmetic colour. As supplied reported to lack potential to irritate the skin and minimally irritating to eyes. The acute oral LD50 is in excess of 10g/kg. If used at low concentrations unlikely to cause irritancy or sensitisation.	Approved colour all products	
CI 15865:2	.0047	A lake of a pigment permitted in all cosmetic products. Will not break down to a carcinogenic amine. Unlikely to cause problems in use. An approved cosmetic colour. As supplied reported to lack potential to irritate the skin and minimally irritating to eyes. The acute oral LD50 is in excess of 10g/kg. If used at low concentrations unlikely to cause irritancy or sensitisation.	Approved colour all products Approved colour all products	IV/1