Committee for Risk Assessment

RAC

Annex 1
Background document
to the Opinion proposing harmonised classification and labelling at EU level of

2,2'-[[3-methyl-4-[(4-nitrophenyl)azo]phenyl]imino]bisethanol

EC Number: 221-665-5
CAS Number: 3179-89-3

CLH-O-0000007056-76-01/F

The background document is a compilation of information considered relevant by the dossier submitter or by RAC for the proposed classification. It includes the proposal of the dossier submitter and the conclusion of RAC. It is based on the official CLH report submitted to consultation. RAC has not changed the text of this CLH report but inserted text which is specifically marked as 'RAC evaluation'. Only the RAC text reflects the view of RAC.

Adopted

26 November 2021

CLH report

Proposal for Harmonised Classification and Labelling

Based on Regulation (EC) No 1272/2008 (CLP Regulation), Annex VI, Part 2

International Chemical Identification:

2,2'-[[3-methyl-4-[(4-nitrophenyl)azo]phenyl]imino]bisethanol

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Index Number: -

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Version number: 1.0 **Date:** January 2021

ANNEX 1 - BACKGROUND DOCUMENT TO RAC OPINION ON 2,2'-[[3-METHYL-4-[(4-NITROPHENYL)AZO]PHENYL]IMINO]BISETHANOL

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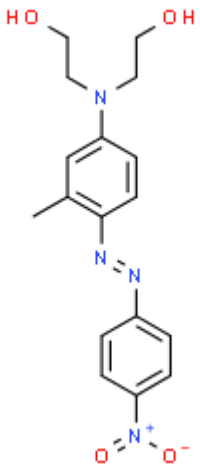
ANNEX 1 - BACKGROUND DOCUMENT TO RAC OPINION ON 2,2'-[[3-METHYL-4-[(4-NITROPHENYL)AZO]PHENYL]IMINO]BISETHANOL

1 IDENTITY OF THE SUBSTANCE

1.1 Name and other identifiers of the substance

Table 1: Substance identity and information related to molecular and structural formula of the substance

Name(s) in the IUPAC nomenclature or other international chemical name(s)	2,2'-[[3-methyl-4-[(E)-(4-nitrophenyl)azo]phenyl]imino]diethanol
Other names (usual name, trade name, abbreviation)	C.I. 11210, Disperse Red 17
ISO common name (if available and appropriate)	
EC number (if available and appropriate)	221-665-5
EC name (if available and appropriate)	2,2'-[[3-methyl-4-[(4-nitrophenyl)azo]phenyl]imino]bisethanol
CAS number (if available)	3179-89-3
Other identity code (if available)	
Molecular formula	$C_{17}H_{20}N_4O_4$
Structural formula	
SMILES notation (if available)	Cc1cc(ccc1N=Nc2ccc(cc2)[N+]([O-])=O)N(CCO)CCO
Molecular weight or molecular weight range	344.37
Information on optical activity and typical ratio of (stereo) isomers (if applicable and appropriate)	-
Description of the manufacturing process and identity of the source (for UVCB substances only)	-
Degree of purity (%) (if relevant for the entry in Annex VI)	-

1.2 Composition of the substance

Table 2: Constituents (non-confidential information)

Constituent (Name and numerical identifier)	Concentration range (% w/w minimum and maximum in multi-constituent substances)	Current CLH in Annex VI Table 3 (CLP)	Current self- classification and labelling (CLP)
2,2'-[[3-methyl-4-[(E)-(4-nitrophenyl)azo]phenyl]imino]diethanol CAS: 3179-89-3 EC: 221-665-5	-	-	Acute Tox. 4; H301 (34) Skin Sens. 1; H317 (3) STOT RE 2; H373 (30) Aquatic Chronic 2; H411 (42)

Table 3: Impurities (non-confidential information) if relevant for the classification of the substance

Impurity (Name and numerical identifier)	Concentration range (% w/w minimum and maximum)	Current CLH in Annex VI Table 3.1 (CLP)	Current self- classification and labelling (CLP)	The impurity contributes to the classification and labelling
-				

Table 4: Additives (non-confidential information) if relevant for the classification of the substance

Additive (Name and numerical identifier)	Function	Concentration range (% w/w minimum and maximum)	Current CLH in Annex VI Table 3.1 (CLP)	Current self-classification and labelling (CLP)	The additive contributes to the classification and labelling
-					

Table 5: Test substances (non-confidential information) (this table is optional)

Identification of test substance	Purity	Impurities and additives (identity, %, classification if available)	Other information	The study(ies) in which the test substance is used
-				

2 PROPOSED HARMONISED CLASSIFICATION AND LABELLING

2.1 Proposed harmonised classification and labelling according to the CLP criteria

Table 6: Proposed harmonised classification and labelling according to the CLP criteria

	Index No	International Chemical Identification	EC No	CAS No	Classification		Labelling			Specific Conc. Limits, M-factors	Notes
					Hazard Class and Category Code(s)	Hazard statement Code(s)	Pictogram, Signal Word Code(s)	Hazard statement Code(s)	Suppl. Hazard statement Code(s)		
Current Annex VI entry	No existing entry in Annex VI of CLP										
Dossier submitters proposal	tba	2,2'-[[3-methyl-4-[(4-nitrophenyl)azo]phenyl]imino]bisethanol	221-665-5	3179-89-3	Skin Sens 1	H317	GHS07 Wng	H317			
Resulting Annex VI entry if agreed by RAC and COM	tba	2,2'-[[3-methyl-4-[(4-nitrophenyl)azo]phenyl]imino]bisethanol	221-665-5	3179-89-3	Skin Sens 1	H317	GHS07 Wng	H317			

Table 7: Reason for not proposing harmonised classification and status under public consultation

Hazard class	Reason for no classification	Within the scope of public consultation
Explosives	Not assessed in this dossier	No
Flammable gases (including chemically unstable gases)		
Oxidising gases		
Gases under pressure		
Flammable liquids		
Flammable solids		
Self-reactive substances		
Pyrophoric liquids		
Pyrophoric solids		
Self-heating substances		
Substances which in contact with water emit flammable gases		
Oxidising liquids		
Oxidising solids		
Organic peroxides		
Corrosive to metals		
Acute toxicity via oral route		
Acute toxicity via dermal route		
Acute toxicity via inhalation route		
Skin corrosion/irritation		
Serious eye damage/eye irritation		
Respiratory sensitisation		
Skin sensitisation	Harmonised classification proposed	Yes
Germ cell mutagenicity	Not assessed in this dossier	No
Carcinogenicity		
Reproductive toxicity		
Specific target organ toxicity-single exposure		
Specific target organ toxicity-repeated exposure		
Aspiration hazard		
Hazardous to the aquatic environment		
Hazardous to the ozone layer		

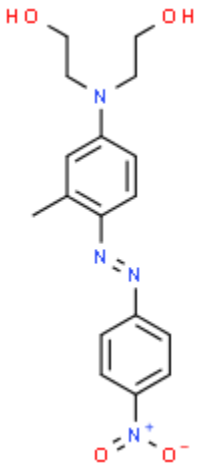
3 HISTORY OF THE PREVIOUS CLASSIFICATION AND LABELLING

Disperse Red 17 is listed as a pre-registered substance under REACH (substances indicated, in 2009, as being intended to be registered by at least one company in the EEA). It does not have a harmonised classification and labelling in Annex VI to the CLP regulation (ECHA, 2020).

Furthermore, Disperse Red 17 is a substance likely to meet the criteria of Annex III to the REACH Regulation, based on an analysis of publicly available databases with experimental data and by using (Q)SAR model results. According to this analysis, Disperse Red 17 is indicated as "suspected carcinogen", "suspected mutagen", "suspected persistent in the environment", and "suspected toxic for reproduction".

RAC general comment

Disperse Red 17 (2,2'-[[3-methyl-4-[(4-nitrophenyl)azo]phenyl]imino]bisethanol) is listed as a pre-registered substance under REACH. Disperse Red 17 does not have an entry in Annex VI of the CLP regulation. The chemical structure of Disperse Red 17 is shown below:



There is evidence from the literature that Disperse Red 17 elicits skin sensitisation in humans as shown in studies from a high number of dermatological clinics. Disperse Red 17 is listed on the restriction proposal for the placing on the market of textile, leather, hide and fur articles containing skin sensitising substances and on the restriction proposal for substances in tattoo inks and permanent make up.

According to the CLH report, Disperse Red 17 is used to dye fabrics made of synthetic fibres such as polyester. These fibres are used in turn to produce garments that are mostly worn directly on the skin. Disperse Red 17 is also an ingredient in haircare products and is suspected to be used as colorant in tattoo inks.

The Dossier Submitter (DS) prepared the CLH-report for Disperse Red 17 using data obtained from the public ECHA dissemination site and from a search of the published literature in bibliographic databases. Information found in the Scientific Committee on Consumer Safety (SCCS) Opinion on Disperse Red 17 was also used to prepare the CLH-report.

4 JUSTIFICATION THAT ACTION IS NEEDED AT COMMUNITY LEVEL

There is evidence from the literature that Disperse Red 17 elicits skin sensitisation in human as shown in studies from a high number of dermatological clinics. Harmonised classification is proposed because there are differences between the self-classifications notified in the classification and labelling (C&L) inventory (ECHA (2014), section 4.1.1). Furthermore, the DS disagrees with most of the current self-classifications. In fact, the vast majority of the notifiers did not self-classify Disperse Red 17 as a skins sensitiser (Table 8). Harmonised classification of Disperse Red 17 would ensure an adequate perception of the skin sensitisation hazard by setting the concentration limit for the classification of mixtures containing Disperse Red 17 to a value of 1 % (Skin Sens. 1). Furthermore, a harmonised classification as Skin Sens. 1 could improve consumer safety in the context of restriction proposals on the use of the substance referring to harmonised classifications as skin sensitiser. In fact, Disperse Red 17 is listed on the restriction proposal for the placing on the market of textile, leather, hide and fur articles containing skin sensitising substances (ECHA, 2019b) and the restriction proposal for substances in tattoo inks and permanent make up (ECHA, 2019a).

Table 8: Notified classification and labelling according to CLP criteria (ECHA, 2020)

Hazard Class and Category Code(s)	**Hazard Statement Code(s)**	**Pictograms, Signal Word Code(s)**	**Number of Notifiers**
Acute Tox. 4	H302	GHS07 Wng	48
STOT RE 2 Aquatic Chronic 2	H373 (blood) H411	GHS09 GHS08 Wng	36
Aquatic Chronic 2	H411	GHS09 Wng	21
Skin Sens. 1	H317	GHS07 Wng	3
Not Classified	-	-	3
Acute Tox. 4 STOT RE 2 Aquatic Chronic 2	H302 H373 (blood) H411	GHS09 GHS08 GHS07 Wng	1

4.1 Identified uses

Based on data from a literature research (sources: cf. section 6), Disperse Red 17 is used to dye fabrics made of synthetic fibres such as polyester fibres (Clauss and Weiss, 1992; Svedman et al., 2019; Varma et al., 1980; Veena et al., 1979). These fibres are used in turn to produce garments that are mostly worn directly on the skin (Hausen and Schulz, 1984; Suter, 1965). Balato and colleagues reported Disperse Red 17 to be among the most frequently isolated dyes in 51 stockings and panty hoses investigated (Balato et al., 1990a). Based on data from newer studies available to the DS, analysing a limited number of textiles from a very large market, Disperse Red 17 was not detected in the analysed fabrics (BVL, 2010; Malinauskiene et al., 2012; Wu et al., 2019; Zhou et al., 2014). However, with respect to the frequency of positive patch test reactions to Disperse Red 17 in humans, as shown in several clinical settings from newer investigations, it cannot be excluded that Disperse Red 17 is still used in dyeing processes for clothes or in other application areas (Foley et al., 2019; Heratizadeh et al., 2017; Isaksson et al., 2015; Ortiz-Salvador et al., 2017; Toholka et al., 2015). The ÖkoTex Standard 100 lists Disperse Red 17 as an allergenic dye, defining a limit value in textiles produced according to this Standard (OEKO-TEX, 2020). For labelling of textiles with the EU Ecolabel, Disperse Red 17 shall not be used for

dyeing polyester, acrylic, polyamide, elasticated or stretchable skin contact garments, or underwear (EU Ecolabel, 2015).

Disperse Red 17 was found as ingredient of haircare products (Katugampola and Statham, 2005). It is used as a non-reactive hair colouring agent in oxidative hair dye formulations (maximum on-head concentration of 2 %, including dispersant) and as a non-reactive hair colouring agent (direct dye) in semi-permanent hair dye formulations (maximum on-head concentration of 0.2 %, including dispersant, SCCS (2013)). Furthermore, Disperse Red 17 sensitisation was identified in patients that had had a temporary "black henna tattoo" (de Groot, 2013; Kind et al., 2012; Le Coz and Tromp, 2002; Moro et al., 2016; Saunders et al., 2004). Disperse Red 17 is suspected to be used as colorant in tattoo inks and it may also be used for dyeing spectacle frames (Walsh and Wilkinson, 2006).

5 DATA SOURCES

Data for Disperse Red 17 were obtained from the public ECHA dissemination site and from a thorough search of the published literature in bibliographic databases (Web of Science, Embase, PubMed, Scopus, Wiley Online library, and Google Scholar). Furthermore, data were taken from the Scientific Committee on Consumer Safety (SCCS) Opinion on Disperse Red 17 (SCCS, 2013).

6 PHYSICOCHEMICAL PROPERTIES

Table 9: Summary of physicochemical properties

Property	Value	Reference	Comment (e.g. measured or estimated)
Physical state at 20°C and 101,3 kPa	No value available		
Melting/freezing point	No value available		
Boiling point	No value available		
Relative density	No value available		
Vapour pressure	No value available		
Surface tension	No value available		
Water solubility	No value available		
Partition coefficient n-octanol/water	No value available		
Flash point	No value available		
Flammability			
Explosive properties			
Self-ignition temperature			
Oxidising properties			
Granulometry	No value available		
Stability in organic solvents and identity of relevant degradation products	No value available		
Dissociation constant	No value available		
Viscosity	No value available		

7 EVALUATION OF PHYSICAL HAZARDS

Not assessed in this dossier

8 TOXICOKINETICS (ABSORPTION, METABOLISM, DISTRIBUTION AND ELIMINATION)

Table 10: Summary table of toxicokinetic studies

Method	Test substance	Results	Reference
OECD TG 428 GLP compliance Reliability 4: Not assignable Adopted from (SCCS, 2013) Human (female) dermatomed abdominal skin (3 different donors, 9 skin preparations) Test item: formulation with 0.2 % (w/w) test substance (non-oxidative conditions), formulation with 2.0 % (w/w) test substance (oxidative conditions); Doses: non-oxidative: 16.0 mg (25 mg/cm²), oxidative: 13.1 mg (20 mg/cm²) Exposure: 60 min Method of Analysis: HPLC	Disperse Red 17 Dye content: 31 % Batch No.: 40T60N4520	Mean total absorption (= amount present in the receptor fluid, receptor compartment wash and the skin, excluding tape strips): 0.41 µg/cm² (0.89 % of the applied dose, non-oxidative conditions), 0.50 µg/cm² (0.11 % of the applied dose, oxidative conditions)	(SCCS, 2013)
In vitro absorption through human and pig epidermis No guideline study GLP: No information Reliability 3: Not reliable Disperse Red 17, applied at a rate of 200 µl/cm² (200 µg/cm²), Prepared suspensions, 1000 µg/ml in TWEEN 80 (0.5 % in distilled water), Epidermis was prepared from whole skin samples of both species and mounted on glass diffusion cells; Absorption was measured under occlusion, Exposure: 55 h Samples from receptor chamber were analysed by HPLC	Disperse Red 17 Purity: No information	Shown are mean absorption rates (n=6) **Time period (h)** / **µg/cm²/hr¹ ± SEM** **Human epidermis** 1-10: 0.07 ± 0.01 4-30: 0.11 ± 0.01 **Pig epidermis** 1-10: 0.16 ± 0.01 31-55: 1.80 ± 0.28 Disperse Red 17 was absorbed by human skin with a mean absorption rate of 0.1 µg/cm²/h	(ZENECA, 1997)

Toxicological data giving adequate information on the absorption, distribution, biotransformation, and excretion of Disperse Red 17 are lacking. However, two studies available to the DS investigated the absorption of Disperse Red 17 through human epidermis. The absorption of Disperse Red 17, showing a dye content of 31 %, was analysed in a study performed according to OECD TG 428 with GLP compliance. This study was not available to the DS, but the study summary was taken from the Scientific Committee and Consumer Safety's opinion on Disperse Red 17 (SCCS, 2013). The authors applied the dye to human dermatomed abdominal skin mounted in flow-through diffusion cells. Disperse Red 17 was tested in two formulations under non-oxidative and oxidative conditions, representing in use-conditions as semi-permanent hair dye. The mean total absorption (amount present in the receptor fluid, receptor compartment wash and the skin, excluding tape

strips) was 0.41 µg/cm² (0.89 % of the applied dose) under non-oxidative conditions and 0.50 µg/cm² (0.11 % of the applied dose) under oxidative conditions.

In a second non-guideline study (ZENECA, 1997), the epidermis was prepared from human whole skin samples and pig whole skin (prepared from the cartilage of pig ears) and mounted in glass diffusion cells. Disperse Red 17 (no information on purity) was applied with a solution of 0.5% TWEEN 80 in distilled water to give a dye concentration of 1 000 µg/mL using an application rate of 200 µL/cm (corresponding to 200 µg/mL). Receptor fluids were taken at certain intervals over an exposure period of 55 hours. Fluids were analysed for dye concentrations using HPLC. Mean absorption rates for Disperse Red 17 were 0.07 ± 0.01 µg/cm^2 per hour analysed from samples taken one to 10 hours after dye application, and 0.11 ± 0.01 µg/cm^2 per hour analysed from samples taken four to 30 hours after dye application. The authors concluded that Disperse Red 17 is absorbed by human skin with a mean absorption rate of 0.1 µg/cm^2/hr, which corresponds to 0.2 % of the applied dose.

8.1 Short summary and overall relevance of the provided toxicokinetic information on the proposed classification(s)

Two studies investigated the absorption of Disperse Red 17 through human skin *in vitro*. Studies were of low reliability or not assignable to the DS. Mean absorption rates of Disperse Red 17 through human skin were between 0.1 % (oxidative conditions) and 0.9 % (non-oxidative conditions) of the applied dose.

9 EVALUATION OF HEALTH HAZARDS

9.1 Acute toxicity - oral route

Not assessed in this dossier

9.2 Acute toxicity - dermal route

Not assessed in this dossier

9.3 Acute toxicity - inhalation route

Not assessed in this dossier

9.4 Skin corrosion/irritation

Not assessed in this dossier

9.5 Serious eye damage/eye irritation

Not assessed in this dossier

9.6 Respiratory sensitisation

Not assessed in this dossier

9.7 Skin sensitisation

9.7.1 Animal data

Table 11: Summary table of animal studies on skin sensitisation

Method, guideline, deviations if any	Species, strain, sex, no/group	Test substance,	Dose levels duration of exposure	Results	Reference
"Sensitive mouse lymph node assay" (SLNA) Non-guideline study No information on GLP Study reliability 3: Not reliable Deviations to OECD TG 429: Intradermal injection: Day 1, adjuvant was used Topical application: Day 6-8, instead of monophasic application; Endpoint analysis: Day 9, instead of two days without treatment; Analysis of lymph node cell number (SI_n) after excision of lymph nodes, using automated cell counter; Determination of ^{3}HTdR incorporation in lymphocytes after 24 h of cell culture (SI_p) was analysed; Individual body weights at start of dosing and at scheduled sacrifice not reported;	Mouse, BALB/c, female n=3/dose	Disperse Red 17 (CI 11210) Purity: No information p-Phenylenediamine (PPD) (CI 76060) Purity: No information; purchased from Wako Pure Chemical Industries, Ltd. (Osaka, Japan)	Intradermal injection: 2 % in saline/Freund's complete adjuvant (FCA) (1:1) Topical application: 10 % in DMF Results of stimulation index (SI), defined by authors: SI_n (Disperse Red 17): 0.9 SI_p (Disperse Red 17): 0.9 SI_{total} (SI_n x SI_p) = total LN response: 0.8 Vehicle control: intradermal injection of vehicle-FCA emulsion, topical application of vehicle alone PPD, intradermal injection: 0.2 % in DMSO/FCA Topical application: 10 % in DMSO SI_n (PPD): 4.1 SI_p (PPD): 7.3 SI_{total} (SI_n x SI_p): 29.6	Negative	(Ikarashi et al., 1996)
GPMT OECD TG 406 GLP-compliant Study reliability 4: Not assignable Cited from secondary reference (SCCS, 2013)	Guinea pig, Dunkin-Hartley, female N=10/ dose N=5/control group	Disperse Red 17, dispersed in water Dye content: 41.2% Batch No.: 928017/02	Intradermal induction (3x): 0.1 mL 5 % (w/v) test substance/FCA[1]; 0.1 mL 50 % FCA; 0.1 mL 5 % (w/v) test substance Day 6, induction of irritation: 10 % sodium lauryl sulphate Day 8, topical induction: 0.5 mL 2.5 % test substance for 48 h (occluded) Two weeks later, challenge: 2.5 % test substance for 24 h (occluded) Excessive staining due to test substance precluded accurate assessment in 6/10 animals	Negative	(Karunaratne, 1995)

Two animal studies investigated the sensitising potential of Disperse Red 17. In a non-guideline "Sensitive

[1] FCA - Freund's Complete Adjuvant

mouse lymph node assay (SLNA)" Disperse Red 17 of unspecified purity was intradermally injected in a 2 % test chemical-FCA emulsion into two sites of the abdominal skin at both sides of the ventral midline. After five days, topical application on the ears followed with 10 % test substance for three consecutive days (day 6 to 8). The following day, excised auricular lymph nodes were pooled for each experimental group. A single cell suspension of a defined number of local lymph node cells was cultured with [^{3}H] methyl thymidine (^{3}HTdR). After 24 hours, ^{3}HTdR incorporation was determined using liquid scintillation counting. The increase in local lymph node cell number and ^{3}HTdR incorporation compared to controls were expressed as stimulation index n (SI_n - calculated from local lymph node cell number after excision), and SI_p (calculated from local lymph node cell proliferation in cell culture), respectively. According to the authors, a chemical was regarded as a sensitiser, if SI_{total} (SI_n x SI_p, which indicates the total lymph node activation induced by the test chemicals) showed a value of 3 or more. SI values for Disperse Red 17 were SI_n= 0.9, SI_p= 0.9, resulting in a SI_{total} of 0.8. The authors concluded that Disperse Red 17 was not a sensitiser in this test. However, each test substance was tested without varying concentrations and concentrations higher than 2 % were not applied, "to prevent systemic toxicity" (Ikarashi et al., 1996). However, there are no further information on which (pre-) study this concentration is based on.

Furthermore, the skin sensitising potential of Disperse Red 17 was investigated in a guinea pig maximisation test according to OECD testing guidelines (OECD TG 406) and in compliance with GLP. This study was not available to the DS, but was already assessed by the Scientific Committee on Consumer Safety (SCCS). According to the SCCS report, a preliminary intradermal study showed that a concentration of 5 % test substance did not induce an irritant response. For induction in the main study, guinea pigs received three intradermal injections of Disperse Red 17 (dye content: 41.2 %), using 5 % test substance in Freund's complete adjuvant (FCA), followed by a single epidermal induction on day 8 using 2.5 % of the test material under occlusive patch for 48 hours. Two weeks after completed induction, animals were challenged by a single application of 2.5 % test substance under occlusive conditions for 24 hours. Skin examination followed 24 and 48 hours after removal of the challenge patches. In its opinion on Disperse Red 17 the SCCS stated, that *"skin staining was observed due to the test substance and was reported to preclude accurate assessment of erythema after the induction and the challenge application in 6/10 animals. No adverse reaction was observed in any of the treated guinea pigs. The author concluded that the test substance was not a sensitiser to guinea pig skin"* (SCCS, 2013).

Altogether, none of the two available animal studies revealed a relevant skin sensitising potential of Disperse Red 17. However, one study is of low reliability due to the insufficient characterisation of the test material and deviations from OECD test guideline procedures, e.g. by not testing a dose series of the test material. A second study comprising a GPMT was performed with Disperse Red 17 of low dye content (41.2 %). This study was not assignable to the DS. According to the SCCS opinion on Disperse Red 17 this GPMT was of low reliability as well, because "excessive staining due to test substance preclude accurate assessment in 6/10 animals".

In conclusion, none of the available animal studies is sufficiently reliable to conclude on the skin sensitising potential of Disperse Red 17.

9.7.2 Human data

Table 12: Summary table of human patch test data and published cases on skin sensitisation[2]

No.	Type of data/report	Relevant information about the study (as applicable)	Observations	Results[3], classification	Reference
	Dermatitis patients (unselected, consecutive)				
1	Retrospective analysis from dermatological departments to identify the most relevant allergens	01/2001 - 12/2010: 5 521 patients presented, of whom 5 281 were generally patch-tested with an extended European standard series and additional allergens or series based on the dermatologist's assessment (806 patients were patch-tested with Disperse Red 17, 1 % in pet.). Patch test data were presented for positive and relevant reactions of test substances in the whole patch test population (N= 5281). This assumed that subjects not patch tested to the allergen would not have tested positive and that the test substance was available for the whole 10-year patch test study. Data were calculated for the most accurate comparison of allergens in the whole patch test population; however, patch test results for substances not tested in all patients are considerably underestimated.	Disperse Red 17: 1.5 % (77/5 281) positive reactions Disperse Red 17: 0.2 % (10/5 281) relevant reactions	**Positive** **Low/moderate frequency of relevant reactions** Previous exposure to Disperse Red 17 not documented, no sub-categorisation possible	(Toholka et al., 2015)
2	Patch tests from dermatological clinic	Consecutive patients with eczema (n = 327) and healthy student volunteers (n = 205, non-patient population, recruited by advertisement; confirmed or suspected textile allergy was neither an inclusion nor an exclusion criterion) were patch-tested with the modified European baseline series and textile dye allergens (incl. Disperse Red 17, 1 % in pet.). No time window reported; self-selected volunteers, sensitisation rate may be over-represented; volunteers aged 20-27 years	Disperse Red 17: Consecutive eczema patients: 0.9 % positive reactions Healthy volunteers: 2.0 % positive reactions	**Positive** **Low/moderate frequency among consecutive eczema patients** Previous exposure to Disperse Red 17 not documented, no sub-categorisation possible	(Li, 2010)
3	Patch tests/consumer tests from two dermatological departments	02 - 12/2005 (first department) and 08/2004 – 11/2005 (second department): 982 dermatitis patients were consecutively patch-tested with baseline patch test series of respective departments, temporarily including a textile dye mix and its eight separate	20/982 positive reactions to textile dye mix Disperse Red 17: 0.3 % (3/982) positive reactions	**Positive** **Low/moderate frequency**	(Ryberg et al., 2009)

[2] Available patch test readings according to International Contact Dermatitis Research Group criteria: (+) weak positive (erythema, infiltration, possibly papules), (++) strong positive (erythema, infiltration, papules, vesicles), (+++) extreme positive reaction (intense erythema, infiltrate, coalescing vesicles) (Johansen et al., 2015).

[3] Frequency and exposure are rated as relatively high or low/moderate in line with Tables 3.2 and 3.3 of the ECHA "Guidance on the Applicability of the CLP criteria", where possible.

No.	Type of data/report	Relevant information about the study (as applicable)	Observations	Results[3], classification	Reference
		components (incl. Disperse Red 17, 0.5 % in pet.); 858 patients answered a questionnaire.	(++) reaction in 1 patient, (+) in 2 patients	Previous exposure to Disperse Red 17 not documented, no sub-categorisation possible	
4	Patch test from two dermatological clinics	286 consecutive patients were patch-tested over a period of one year with the TRUE Test standard series and a textile colour and finish series (incl. Disperse Red 17, 1 % in pet.).	Disperse Red 17: 0.3 % (1/286) positive reactions	**Positive** **Low/moderate frequency** Previous exposure to Disperse Red 17 not documented, no sub-categorisation possible	(Lazarov and Cordoba, 2000)
5	Patch test from dermatological clinic	78 unselected patients were patch-tested with the Portuguese standard series and textile dye mixes. Mixes with three (Disperse Blue 35, Disperse Blue 106, and Disperse Orange 3, each at 1 %), five (Disperse Red 1, Disperse Red 17, Disperse Yellow 3, Disperse Blue 35, and Disperse Blue 124), and eight (five-component mix, plus Disperse Orange 3, Disperse Blue 3, and Disperse Orange 37) textile dye components were tested. Time window not reported.	Two positive reactions with five- and eight-component mixes (5 mix and 8 mix), each gave ++ reactions at 2 and 4 days Disperse Red 17: 1.3 % (1/78) positive reactions	**Positive** **High frequency** Previous exposure to Disperse Red 17 not documented, no sub-categorisation possible	(Sousa-Basto and Azenha, 1994)
6	Patch test from dermatological department	593 cadets (18 to 28 years) without a present or previous history of dermatitis were patch-tested with the modified GIRDCA[4] standard series (time window not reported). The later part of the group, comprising 336 soldiers, was also patch-tested with textile dyes, finishes, and mordant (incl. Disperse Red 17, 1 % in pet.).	In total, 74 subjects (12.5 %) were sensitised. Disperse Red 17: 1.2 % (4/336) positive reactions	**Positive** **High frequency** Previous exposure to Disperse Red 17 not documented, no sub-categorisation possible	(Seidenari et al., 1990)
	Selected dermatitis patients				
7	Patch test from dermatological department	01/2013 - 12/ 2015: Among 753 patients attending for cutaneous allergy testing, 99 subjects presented with anogenital symptoms. Among patients with symptoms, 36 subjects were patch-tested with a textile and leather series (incl. Disperse Red 17, 1 % in pet.).	Disperse Red 17: 0 % (0/36) positive reactions	**Negative**	(Foley et al., 2019)

[4] GIRDCA - Italian Research Group on Contact and Environmental Dermatitis

No.	Type of data/report	Relevant information about the study (as applicable)	Observations	Results[3], classification	Reference
8	Retrospective analysis including 56 dermatological departments (IVDK[5])	2007 - 2014: Among 98 417 patients in total, 3 207 patients with suspected textile allergy (study group) and 95 210 patients as control group were patch-tested with textile and leather dye series. Among subjects of study group, 1 594 patients were patch-tested with Disperse Red 17, 1 % in pet.	Disperse Red 17: 1.1 % (18/1 594) positive reactions (++) reaction in 5 patients, (+) in 13 patients	**Positive** **Low/moderate frequency** Previous exposure to Disperse Red 17 not documented, no sub-categorisation possible	(Heratizadeh et al., 2017)
9	Retrospective study of dermatological department	1996 - 2015: 389 children were patch-tested; reactions of 52 children with dermatitis to the feet exclusively were compared to children with dermatitis of other locations than the feet (n = 337). Patch tests were performed with GEIDAC[6] standard series and specific shoe series (28 patients), with additional series and the child's daily footwear, where indicated (incl. Disperse Red 17, 1 %, no further information).	Disperse Red 17: 1.9 % (1/52) positive reactions Relevance: 100 %, shoes identified as source	**Positive** **Low/moderate frequency** Previous exposure to Disperse Red 17 not documented, no sub-categorisation possible	(Ortiz-Salvador et al., 2017)
10	Outcome of patch tests with textile dye mix (TDM) at nine clinics from nine countries representing ICDRG[7]	03 - 12/2013: 2 493 consecutive dermatitis patients were patch-tested with a TDM, consisting of six disperse dyes (6.6 % in pet.). 83 patients allergic to the TDM were patch-tested with eight separate dyes of the mix (incl. Disperse Red 17, 1 % in pet.). Patch test reactions to single separate dyes are presented for patients allergic to the textile dye mix.	3.6 % (1.3 - 18.2 %; 90/2493) positive reactions to TDM; Patch testing with separate textile dye Disperse Red 17: 16.9 % (14/83) positive reactions	**Positive** **High frequency** Previous exposure to Disperse Red 17 not documented, no sub-categorisation possible	(Isaksson et al., 2015)
11	Retrospective analysis from dermatological departments to identify the most relevant allergens	01/2001 - 12/2010: 5 521 patients presented, of whom 5 281 were generally patch-tested with an extended European standard series and additional allergens or series based on the dermatologist's assessment (806 patients were patch-tested with Disperse Red 17, 1 % in pet.).	Disperse Red 17: 10 % (77/806) positive reactions Disperse Red 17: 1 % (10/806) relevant reactions	**Positive** **Low/moderate frequency of relevant reactions** Previous exposure to Disperse Red 17 not documented, no sub-categorisation possible	(Toholka et al., 2015)

[5] IVDK - Information Network of Departments of Dermatology
[6] GEIDAC - Spanish Group for the Study of Contact Dermatitis and Cutaneous Allergy
[7] ICDRG - International Contact Dermatitis Research Group

No.	Type of data/report	Relevant information about the study (as applicable)	Observations	Results[3], classification	Reference
12	Patch test evaluation of clinical features and epidemiology of textile contact dermatitis	277 selected textile dermatitis patients were patch-tested, including 264 patients that were affected by allergic textile contact dermatitis (time window not reported). The SIDAPA[8] baseline series, textile series, and suspected garment samples, when available, were used for patch testing (incl. Disperse Red 17, 1 % in pet.). Only strong positive reactions (++ and +++) were considered.	154/277 positive reactions to textile allergens, (132 non-occupational and 22 occupational) Disperse Red 17: 3.9 % (6/154) positive reactions	**Positive** **High frequency** Previous exposure to Disperse Red 17 not documented, no sub-categorisation possible	(Lisi et al., 2014)
13	Investigations of the patch testing outcome of 12 EECDRG[9] clinics from nine countries to textile dye mix (TDM).	01 - 06/2011: 2 907 consecutive dermatitis patients were patch-tested to TDM, 6.6 % in pet. (Comprising six disperse dyes, incl. Disperse Red 17, 1% in pet.). Ninety-four mix-positive patients were tested with single dyes.	3.7 % (108/2 907) positive reactions to TDM; Disperse Red 17: 5.3 % (5/94) positive reactions	**Positive** **High frequency** Previous exposure to Disperse Red 17 not documented, no sub-categorisation possible	(Ryberg et al., 2014)
14	Patch test of "Tattoo Clinic" of dermatological department	2009 - 2013: 90 patients with chronic tattoo reactions were patch tested with the European baseline series, series of disperse dyes, and an empirical selection of problematic tattoo ink stock products, which were selected based on observations and experience in the clinic (incl. Disperse Red 17, assumed 1 % in pet.).	Disperse Red 17: 1.4 % (1/74) positive reaction, (+) reaction	**Positive** **Low/moderate frequency** Previous exposure to Disperse Red 17 not documented, no sub-categorisation possible	(Serup and Hutton Carlsen, 2014)
15	Patch test from Department of Dermato-Allergology	01/2010 - 08/2011: 228 patients diagnosed with suspected occupational contact dermatitis were patch-tested with European baseline series supplemented with allergens identified in a stepwise exposure assessment (incl. Disperse Red 17, assumed 1 % in pet.).	Disperse Red 17: 0.4 % (1/228) positive reactions	**Positive** **Low/moderate frequency** Previous exposure to Disperse Red 17 not documented, no sub-categorisation possible	(Friis et al., 2013)
16	Retrospective review of patch tests from department of dermatology	01/2000 - 09/2011: A total of 671 patients with suspected allergic contact dermatitis to textile dyes and resins were patch-tested with the standard series (no further information) and additional textile dye series (containing 42 dyes and resins; 664 patients tested to Disperse Red 17, 1% in pet.).	Disperse Red 17: 5.3 % positive reactions (97.1 % total relevant reactions) 2.3 % irritant reactions	**Positive** **High frequency** Previous exposure to Disperse Red 17 not documented, no sub-categorisation possible	(Wentworth et al., 2012)

[8] SIDAPA - Societa Italiana di Dermatologia Allergologica Professionale e Ambientale

[9] EECDRG - European Environmental Contact Dermatitis Research Group

No.	Type of data/report	Relevant information about the study (as applicable)	Observations	Results[3], classification	Reference
17	Patch tests from general and occupational contact dermatitis clinics at the Skin and Cancer Foundation	1993 - 2006: 2 069 patients with suspected textile allergy were patch-tested with an extended European baseline series and textile series. One hundred and fifty-seven patients reacted to any of the textile-related allergens (incl. Disperse Red 17, 1 % in pet.)	Disperse Red 17: 0.1 % (3/2 069) positive patch test reactions	**Positive** **Low/moderate frequency** Previous exposure to Disperse Red 17 not documented, no sub-categorisation possible	(Slodownik et al., 2011)
18	Patch test analysis from contact sensitisation research network IVDK[10]	2003 - 2006: 3 271 patients were patch-tested with a "textile and leather dye" series of the DKG[11] (3 240 patients tested to Disperse Red 17, 1 % in pet.).	Disperse Red 17: 1.0 % (31/3 240) positive reactions (+) reaction in 25 patients, (++/+++) in 6 patients 0.4 % irritant reactions	**Positive** **Low/moderate frequency** Previous exposure to Disperse Red 17 not documented, no sub-categorisation possible	(Uter et al., 2008)
19	Patch test results from Department of Occupational and Environmental Dermatology and Department of Dermatology	01/1999 - 12/2003: 3 325 patients were consecutively patch-tested with standard series of the departments including a textile dye mix (TDM, incl. Disperse Red 17, 0.5 % in pet). Patients who reacted positively to a patch test with the mix were tested with the eight components separately (47 subjects).	50/3 325 patients patch test reacted positively to TDM Disperse Red 17: 11 % (5/47) positive reactions among TDM-positively tested patients (+) reaction in 4 patients, (++) in 1 patient	**Positive** **High frequency** Previous exposure to Disperse Red 17 not documented, no sub-categorisation possible	(Ryberg et al., 2006)
20	Patch test from BCDS[12] dermatological departments	Over a period of 2 to 6 years, data on footwear allergens from nine dermatology centres were investigated. Patients were patch-tested to BCDS Standard series (Disperse Red 17 tested in one centre, no further information).	Disperse Red 17: 0 % (0/486) reactions	**Negative**	(Katugampola and Statham, 2005)
21	Patch test analysis from 37 IVDK[10] dermatological clinics	1998 - 2002: 696 patients with suspected textile dermatitis were patch-tested with the DKG[11] textile dye series; 680 test subjects were patch-tested with Disperse Red 17 (1 % in pet.).	Disperse Red 17: 1.9 % (13/680) positive reactions (+) reaction in 9 patients, (++) in 3 patients, (+++) in 1 patient	**Positive** **Low/moderate frequency** Previous exposure to Disperse Red 17 not documented, no sub-categorisation possible	(Bauer et al., 2004)
22	Patch test from dermatological clinic	01/1999 - 12/2002: 644 patients with suspected textile allergic contact dermatitis were patch-tested with a standard series (TRUE Tests, no further information), textile colour and finish	Disperse Red 17: 0.6 % (4/644) positive reactions	**Positive** **Low/moderate frequency**	(Lazarov, 2004)

[10] IVDK - Information Network of Departments of Dermatology
[11] DKG - German Contact Allergy Group
[12] BCD - British Contact Dermatitis Society

No.	Type of data/report	Relevant information about the study (as applicable)	Observations	Results[3], classification	Reference
		series (TCFS) and additional series, as well as clothing extracts in 21 cases (incl. Disperse Red 17, 1 % in pet.).		Previous exposure to Disperse Red 17 not documented, no sub-categorisation possible	
23	Patch test analysis from dermatological clinic	128 patients patch-tested positively to PPD, were also patch-tested to textile dyes; the clinical presentation was dermatitis where textiles were suspected as the cause. Patch testing to textile dye allergens (incl. Disperse Red 17, assumed 1 % in pet.) was performed (time window not reported).	Disperse Red 17: 11.5 % (6/61) positive reactions among PPD positively patch-tested patients	**Positive** **High frequency** Previous exposure to Disperse Red 17 not documented, no sub-categorisation possible	(Goon et al., 2003)
24	Patch test analysis of patients with textile dye allergic contact dermatitis from 10 clinics or physicians representing five countries	09/2000: 20 patients with suspected dyed fabric allergic contact dermatitis were identified from reports of 10 clinics. Results of 16 patients, patch-tested with 12 commercial disperse dyes from the Textile Colour & Finishes series (incl. Disperse Red 17, assumed 1 % in pet.) are presented. Disperse dyes in 32 garments submitted by the patients were identified using HPLC and confirmed by LC/MS analysis. 35 different disperse dyes were identified in 22/32 garments. However, Disperse Red 17 was not detected in textiles. Small number of patients investigated	Disperse Red 17: 25 % (4/16) positive reactions	**Positive** **High frequency** Previous exposure to Disperse Red 17 not documented, no sub-categorisation possible	(Hatch et al., 2003)
25	Retrospective analysis from a dermatological department	01/1996 - 12/1999, data of all patients patch-tested with the European standard series and showing positive patch test reactions to para-phenylenediamine (PPD) were included; 154 patients were patch-tested with para compounds and 577 patients were patch-tested with disperse (azo) dyes (incl. Disperse Red 17, assumed 1 % in pet.).	Disperse Red 17: 0.5 % (3/577) positive reactions (0/3 reactions to PPD)	**Positive** **Low/moderate frequency** Previous exposure to Disperse Red 17 not documented, no sub-categorisation possible	(Koopmans and Bruynzeel, 2003)
26	Patch test from dermatological clinic	08/1997 - 04/2001: 203 patients with eyelid dermatitis were patch-tested with a diagnostic “standard” series and cosmetic ingredients (incl. Disperse Red 17, no further information).	Disperse Red 17: 1 % (2/203) positive reactions (++) reaction in 1 patient, (+) in 1 patient	**Positive** **Low/moderate frequency** Previous exposure to Disperse Red 17 not documented, no sub-categorisation possible	(Guin, 2002)
27	Patch test from dermatological clinic	06/1996 - 02/2000: allergic contact dermatitis to textile allergens (disperse dyes), was seen in 28 (1.7 %) of 1 638 patients; 18 patients had been patch-tested to a modified British Contact Dermatitis Group standard series, and a series consisting of 18	Disperse Red 17: 16.7 % (3/18) positive reactions	**Positive** **High frequency**	(Smith and Gawkrodger, 2002a; Smith and

No.	Type of data/report	Relevant information about the study (as applicable)	Observations	Results[3], classification	Reference
		dyes and four textile chemicals (incl. Disperse Red 17, 1% in pet.). Small number of patients		Previous exposure to Disperse Red 17 not documented, no sub-categorisation possible	Gawkrodger, 2002b)
28	Patch test from dermatological clinic	During five years: 18 out of 1 400 patients with suspected contact dermatitis due to textile fibres were patch-tested with the GRDCI[13] standard battery and a battery of textile allergens (incl. Disperse Red 17, assumed 1% in pet.)	Disperse Red 17: 16.7 % (3/18) positive reactions	**Positive** **High frequency** Previous exposure to Disperse Red 17 not documented, no sub-categorisation possible	(Fuentes Cuesta et al., 2000)
29	Patch test analysis from dermatological clinic	During 1998, 103 patients with suspected allergic contact dermatitis to clothing were clinically evaluated and patch-tested with standard series (TRUE Tests) and Textile Colour & Finish series (incl. Disperse Red 17; concentration and vehicle assumed 1 % in pet.)	Disperse Red 17: 1.0 % (1/103) positive reactions Disperse Red 17 evokes development of purpuric allergic contact dermatitis[14]	**Positive** **Low/moderate frequency** Previous exposure to Disperse Red 17 not documented, no sub-categorisation possible	(Lazarov and Cordoba, 2000)
30	A retrospective study on textile dermatitis from three dermatological clinics	Data of 55 patients, patch-tested from 1991 to 1997 and with positive reactions to allergens from the Textile Colours and Finish series in three contact dermatitis clinics were reviewed (incl. Disperse Red 17, 1 % in pet.).	Disperse Red 17: 15 % positive reactions	**Positive** **High frequency** Previous exposure to Disperse Red 17 not documented, no sub-categorisation possible	(Lazarov et al., 2000)
31	Patch test from dermatological clinic	01/1997 - 06/1999: 788 patients with textile dye allergy were patch-tested to standard series (NACDG[15] or European). A textile series was utilised in 271 patients (incl. Disperse Red 17, 1 % pet.) because of suspected textile dermatitis. Forty patients reacted positively to one or more textile dyes.	Disperse Red 17: 3.7 % (10/271) positive reactions (+++) reaction in 3 patients, (++) in 1 patient, (+) in 6 patients	**Positive** **High frequency** Previous exposure to Disperse Red 17 not documented, no sub-categorisation possible	(Pratt and Taraska, 2000)
32	Patch test from dermatological department	1990 - 1995: 6 203 patients were consecutively patch-tested with textile dyes included in standard series (Department of Dermatology in Modena, Italy); 236 were sensitised to at least 1 of 6 azo dyes. Thirty-three patients out of 236 azo-dye-positive subjects were patch-tested with an additional textile	Disperse Red 17: 9.1 % (3/33) positive reactions among azo dye-positive patients	**Positive** **High frequency** Previous exposure to Disperse Red 17 not documented, no	(Seidenari et al., 1997)

[13] GRDCI - Grupo Europeo de Investigación de Dermatitis de Contacto

[14] Purpuric lesions have been described as an uncommon manifestation of allergic contact dermatitis (Lazarov and Cordoba, 2000).

[15] NACDG - North American Contact Dermatitis Group

No.	Type of data/report	Relevant information about the study (as applicable)	Observations	Results[3], classification	Reference
		dye series (Disperse Red 17 included; no further information).		sub-categorisation possible	
33	Patch test from dermatological clinic	04/1992 - 04/1994: 1 236 patients were patch-tested in total, among the test subjects 26 patients were identified with suspected contact dermatitis to textiles. Patch tests were performed with DKG[16] standard series, textile dyes, and finishing substances (incl. Disperse Red 17, 1% in pet.). Small number of patients	Disperse Red 17: 11.5 % (3/26) positive reactions (++) reaction in 1 patient, (+) in 1 patient, one reading not reported	**Positive** **High frequency** Previous exposure to Disperse Red 17 not documented, no sub-categorisation possible	(Maurer et al., 1995)
34	Patch test analysis from dermatological department	1987 - 1991: 3 336 patients were investigated for contact dermatitis and patch-tested with the European standard series; 159 patients were also tested with 15 textile dyes (incl. Disperse Red 17, assumed 1 % in pet.).	Disperse Red 17: 3.8 % (6/159) positive reactions	**Positive** **High frequency** Previous exposure to Disperse Red 17 not documented, no sub-categorisation possible	(Dooms-Goossens, 1992)
35	Patch test from dermatological clinic	1990 - 1991: 32 patients with presumable allergic contact dermatitis and all with a positive patch test reaction to p-aminoazobenzene were additionally patch-tested with a series of textile azo dyes (incl. Disperse Red 17, 1 % in pet.) and one food azo dye. Small number of subjects	Disperse Red 17: 9.4 % (3/32) positive reactions among patients positively patch-tested to p-aminoazobenzene	**Positive** **High frequency** Previous exposure to Disperse Red 17 not documented, no sub-categorisation possible	(Thierbach et al., 1992)
36	Patch test from dermatological department	10/1987 - 04/1990: 100 subjects were found to be sensitised to textile dyes. They were identified from 2 752 consecutive patients patch-tested with the GIRDCA[4] standard series supplemented with disperse dyes and specifically patch testing with textile dyes. Among patients, 98 were also patch-tested with 12 further textile dyes (incl. Disperse Red 17, 1 % in pet.).	Disperse Red 17: 20.4 % (20/98) positive reactions	**Positive** **High frequency** Previous exposure to Disperse Red 17 not documented, no sub-categorisation possible	(Seidenari et al., 1991)
37	Patch test from dermatological clinic	During two years, 145 patients, suspected of having allergic contact dermatitis from textile chemicals, were patch-tested with a textile series (Disperse Red 17, 1 % pet.). In all cases, readings were ++ or +++.	Disperse Red 17: 4.4 % (3/145) positive reactions	**Positive** **High frequency** Previous exposure to Disperse Red 17 not documented, no sub-categorisation possible	(Balato et al., 1990b)
38	Allergological study of selected workers with known exposure	1986 - 1987: 161 subjects with suspected occupational contact dermatitis were examined; 104 subjects were garment industry and 57 textile industry workers. Patch testing was performed	Disperse Red 17: 0.6 % (1/161) positive reactions among	**Positive** **Low/moderate frequency**	(Gasperini et al., 1989)

[16] DKG - German contact allergy group

No.	Type of data/report	Relevant information about the study (as applicable)	Observations	Results[3], classification	Reference
	or dermatitis	using a battery of haptens prepared according to recommendations in the literature and experience using the Rapid Patch Test technique (incl. Disperse Red 17, 1 % in pet.).	workers 1.7 % (1/57) positive reactions among textile industry workers 0 % (0/104) reactions among garment industry workers	Previous exposure to Disperse Red 17 not documented, no sub-categorisation possible	
Case report					
39	Case report	1981 - 1984: Ten patients with suspected textile dye allergy from stockings and other textiles, including black blouse, blue trousers, or grey pantsuit presented. Most subjects reported itching, and erythema at the inner thighs, shortly after wearing fabrics. Patch testing with piece of stockings and textile, dye extracts, and single dye components was performed (incl. Disperse Red 17, 1 % in pet.). Dyes were extracted from 27 commercial stockings of different colours and analysed using preparative thin-layer chromatography and HPLC.	2/7 women reacted positively to Disperse Red 17; (Case 8) Disperse Red 17 patch test re-actions (-/++) and dye extract (-/+) after 24 and 72h; (Case 9) Disperse Red 17 positive patch test reactions (++/+++) after 24 and 72 h, dye extract not tested Disperse Red 17 was identified in extracts from stockings	**Positive** Previous exposure to Disperse Red 17 not documented, no sub-categorisation possible	(Hausen and Schulz, 1984)

There is strong evidence from human data that Disperse Red 17 consistently and repetitively evokes skin sensitisation as indicated in diagnostic patch tests from individual clinics or collated clinic data. Patch test studies considered as reliable (reliable with restriction) and relevant are summarised in Table 12, while studies of low reliability (not reliable or not assignable to the DS) were precluded from further assessment (Chromej et al., 2008; Cunha et al., 2003; Garcia-Bravo et al., 2004; Gee and Powell, 2001; Su et al., 2014; Thomas et al., 2013).

Diagnostic patch tests comprise studies with unselected (consecutive) or selected dermatitis patients analysing the number of patients sensitised to Disperse Red 17 compared to all patients tested in a certain time period. In studies with unselected, consecutive dermatitis patients, patch testing is generally more standardised. In contrast, for selected (specific) groups of patients or workers, usually targeted patch testing with special test series is performed.

Consecutive patients patch-tested with Disperse Red 17 show frequencies between 0.2 % and 1.3 % positive reactions. According to ECHA's Guidance on the application of CLP criteria, most of the studies revealed a relatively low/moderate frequency of positive patch test reactions (4/6 studies, frequency < 1 % for consecutive, unselected dermatitis patients, Section 3.4.2.2.3.1, Table 3.2 (ECHA, 2017)). Less studies revealed a relatively high frequency for Disperse Red 17 positive reactions among consecutive dermatitis patients (2/6 studies, frequency ≥ 1 % for consecutive, unselected dermatitis patients, Section 3.4.2.2.3.1, Table 3.2).

Aimed testing with Disperse Red 17 in selected dermatitis patients identified between 0 % and 25 % positive patch test reactions. The majority of the patch tests identified high frequencies of Disperse Red 17 positively patch-tested patients (17/32 studies, frequency ≥ 2 % for selected dermatitis patients (ECHA, 2017)). A low/moderate frequency of Disperse Red 17 reactions in selected dermatitis patients was seen in numerous publications (13/32 studies, frequency < 2 % for selected dermatitis patients). Two available studies on patch testing in selected dermatitis patients revealed negative results for Disperse Red 17.

Furthermore, a high number of case reports are available, which describe the patients' clinical history with dermatitis due to wearing coloured textiles or contact to hair dyes and report positive patch test results for Disperse Red 17 in these subjects. Hausen and Schulz investigated ten women with suspected textile dye allergy from stockings and other dyed textiles, including a black blouse, blue trousers, or grey pantsuit (Hausen and Schulz, 1984). Most subjects reported itching and erythema on the inner thighs, shortly after wearing fabrics. The authors analysed the dyes of 27 commercial stockings using chromatography, and among other dyes identified Disperse Red 17. Positive patch test reactions to Disperse Red 17 were shown in two patients with dermatitis from stockings. Further case reports with Disperse Red 17 positive patch test reaction were considered not relevant. In these reports, a detection of Disperse Red 17 in the suspected source of dermatitis (e.g. textiles) is missing (Alberta et al., 2005; Ameur et al., 2019; Batchelor and Wilkinson, 2006; Crichlow and Warin, 2004; Dejobert et al., 1995; Fuentes Cuesta et al., 2000; Goldminz and Scheinman, 2018; Hausen, 2006; Hausen, 1993; Kind et al., 2012; Kuuliala et al., 2006; Lisboa et al., 1994; Mohamoud and Andersen, 2017; Mota et al., 2000; Nakagawa et al., 1996; Narganes et al., 2013; Patrizi et al., 1990; Pousa-Martínez et al., 2018; Pousa-Martinez et al., 2016; Pratt and Taraska, 2000; Raffi et al., 2019; Ramírez et al., 2007; Saunders et al., 2004; Seidenari et al., 1995; Shehade and Beck, 1990; Su and Horton, 1998; Warren and Marren, 1997; Wilkinson and Thomson, 2000).

Human data do not give information on previous exposure levels to Disperse Red 17. Furthermore, human induction studies such as a Human Repeated Insult Patch Test (HRIPT) or Human Maximisation Test (HMT) performed with Disperse Red 17 are not available to the DS.

Analytical investigations using thin-layer chromatography revealed that Disperse Red 17 patch test preparations showed not only one main spot, but also one (or two) additional weaker spots in the chromatograms (Foussereau and Dallara, 1986; Ryberg et al., 2008). However, there was no characterisation of the additional spots with regard to cleavage products or impurities. Patch testing with impure preparations may result in false positive test results and complicate the diagnosis of the patients and prevention of contact allergy. Furthermore, analysis revealed that the mean concentrations of several commercial Disperse Red 17 patch test preparations were much lower than labelled (0.35 % (0.3-0.5 %) instead of 1.0 %, 14 preparations (Ryberg et al., 2008)). In such cases an overestimation of the dye concentration causing sensitisation (and therefore, an underestimation of its potency) and/or a smaller than expected number of sensitised subjects may result. However, the

occurrence of positive diagnostic patch test reactions from a large number of dermatological clinics, representing numerous different countries leaves no doubt that Disperse Red 17 elicits skin sensitisation in humans.

9.7.3 Short summary and overall relevance of the provided information on skin sensitisation

Two animal studies investigated the skin sensitising potential of Disperse Red 17, namely a none-guideline "Sensitive mouse lymph node assay" and a GPMT, performed according to OECD testing guideline 406. None of these studies on skin sensitisation obtained any positive test result for Disperse Red 17. However, these studies were considered too unreliable to allow for a conclusion on the skin sensitising properties of Disperse Red 17 (for details cf. section 9.7.1).

There is strong evidence from human data that Disperse Red 17 evokes skin sensitisation in humans (shown in > 200 subjects), indicated by dermatological patch tests and performed in a high number of dermatological clinics from several countries as well as published cases. Patch test data reveal mainly low/moderate frequencies of Disperse Red 17 positive patch test reactions among unselected, consecutive dermatitis patients (< 1 % positive reactions for consecutive, unselected dermatitis patients, Section 3.4.2.2.3.1, Table 3.2 (ECHA, 2017)). Selected dermatitis patients patch-tested with Disperse Red 17 show mainly high frequencies of positive reactions (≥ 2 % positive reactions for selected dermatitis patients (ECHA, 2017)). The available human data do not give information on the previous level of exposure to Disperse Red 17. Human tests on induction thresholds of Disperse Red 17 are not available. In conclusion, data are insufficient to allow for classification into sub-categories.

9.7.4 Comparison with the CLP criteria

Table 13: Comparison of human and animal data for skin sensitisation of Disperse Red 17 with CLP criteria

Reference(s)	**Criteria acc. to CLP regulation, as laid out in (ECHA, 2017)**	**Results**	**Resulting Classification**
Animal data			
No reliable studies available			
Human data			
Dermatitis patients (unselected, consecutive) (Lazarov and Cordoba, 2000; Li, 2010; Ryberg et al., 2009; Seidenari et al., 1990; Sousa-Basto and Azenha, 1994; Toholka et al., 2015)	Skin Sens. 1 Frequency < 1.0 % and relatively low exposure or frequency ≥ 1.0 % and relatively high exposure Skin Sens. 1A Frequency ≥ 1.0 % and relatively low exposure Skin Sens. 1B Frequency < 1.0 % and relatively high exposure	Frequency from "relatively low/moderate" to "relatively high" 4/6 studies revealed a relatively low/moderate frequency Exposure unclear	Skin Sens. 1 (no sub-categorisation possible)
Selected dermatitis patients (aimed testing) (Balato et al., 1990b; Bauer et al., 2004; Dooms-Goossens, 1992; Foley et al., 2019; Friis et al., 2013; Fuentes Cuesta et al., 2000; Gasperini et al., 1989; Goon et al., 2003; Guin, 2002; Hatch et al., 2003; Heratizadeh et al., 2017; Isaksson et al., 2015; Katugampola and Statham, 2005; Knackstedt and Zug, 2015; Lazarov, 2004; Lazarov and Cordoba, 2000; Lazarov et	Skin Sens. 1 Frequency < 2.0 % and relatively low exposure or frequency ≥ 2.0 % and relatively high exposure Skin Sens. 1A Frequency ≥ 2.0 % and relatively low exposure Skin Sens. 1B Frequency < 2.0 % and relatively high exposure	Frequency from negative, "relatively low/moderate" to "relatively high" 17/32 studies with a relatively high frequency 13/32 studies with a relatively low/moderate frequency	Skin Sens. 1 (no sub-categorisation possible)

Reference(s)	Criteria acc. to CLP regulation, as laid out in (ECHA, 2017)	Results	Resulting Classification
al., 2000; Lisi et al., 2014; Maurer et al., 1995; Ortiz-Salvador et al., 2017; Pratt and Taraska, 2000; Ryberg et al., 2014; Ryberg et al., 2006; Seidenari et al., 1997; Seidenari et al., 1991; Serup and Hutton Carlsen, 2014; Slodownik et al., 2011; Smith and Gawkrodger, 2002a; Smith and Gawkrodger, 2002b; Thierbach et al., 1992; Toholka et al., 2015; Uter et al., 2008; Wentworth et al., 2012)		2/32 studies with negative results Exposure unclear	
Number of published cases (Hausen and Schulz, 1984)	Skin Sens. 1 Number of published cases < 100 and relatively low exposure or Number of published cases ≥ 100 and relatively high exposure Skin Sens. 1A Number of published cases ≥ 100 and relatively low exposure Skin Sens. 1B Number of published cases < 100 and relatively high exposure	Low/moderate frequency Two published cases Exposure unclear	Skin Sens. 1 (no sub-categorisation possible)

9.7.4.1 Weight of evidence consideration

According to the CLP regulation "substances shall be classified as skin sensitisers (Category 1) where data are not sufficient for sub-categorisation in accordance with the following criteria:

a) if there is evidence in humans that the substance can lead to sensitisation by skin contact in a substantial number of persons; or

b) if there are positive results from an appropriate animal test" (CLP, Annex I, Table 3.4.2).

Classification into sub-categories is required when data are sufficient. Human evidence for sub-categorisation can include data on the induction threshold and/or exposure level a substance (CLP, Section 3.4.2.2.2.). Furthermore, a skin sensitisation potency from animal studies can be used for sub-categorisation (CLP, Annex I, Table 3.4.3 and 3.4.4)."

There is a large number of human studies, including diagnostic patch tests and case reports performed in multiple dermatological clinics from different countries, which show that Disperse Red 17 elicits skin sensitisation in humans. Frequencies of Disperse Red 17 positive patch test reactions are mainly low/moderate for consecutive, unselected dermatitis patients (< 1.0 % occurrence of skin sensitisation). Selected dermatitis patients reveal mostly high frequencies of positive patch test reactions for Disperse Red 17 (≥ 2 % occurrence of skin sensitisation) and low/moderate frequencies (< 2 % occurrence of skin sensitisation), while a low number of studies show negative results for Disperse Red 17. However, available data do not give information on exposure levels or an induction threshold of Disperse Red 17. Therefore, sub-categorisation is not possible based on the available human data.

The available animal data on skin sensitisation are unreliable and cannot be used for classification.

Altogether, based on the positive data from patch testing, obtained in numerous different dermatology clinics it is warranted to classify Disperse Red 17 as a skin sensitiser. However, available data are not sufficient for sub-categorisation. In conclusion, Disperse Red 17 shall be classified as skin sensitiser in Category 1.

9.7.5 Conclusion on classification and labelling for skin sensitisation

Based on the data in Table 13 the DS proposes to classify Disperse Red 17 as skin sensitiser, **Skin Sens 1 (H317 - May cause an allergic skin reaction)**, without sub-categorisation, and with a GCL of 1 % (w/v).

RAC evaluation of skin sensitisation

Summary of the Dossier Submitter's proposal

Based on human studies, including diagnostic patch tests and case reports performed in multiple dermatological clinics from different countries, the DS proposed classification of Disperse Red 17 as skin sensitiser, Skin Sens. 1 (H317: May cause an allergic skin reaction) with the General Concentration Limit (GCL) of 1 % (w/v).

Comments received during consultation

One Member State Competent Authority supported the DS's classification proposal.

Assessment and comparison with the classification criteria

Animal data

The CLH-report summarised two animal studies, one "sensitive mouse lymph node assay" and one Guinea Pig Maximisation Test (GPMT). The table below summarises both studies.

In a non-guideline compliant "sensitive mouse lymph node assay" Disperse Red 17 of unspecified purity was intradermally injected in a 2 % test chemical-FCA emulsion into two sites on the abdominal skin on both sides of the ventral midline. After five days, topical application on the ears followed with 10 % test substance for three consecutive days (days 6 to 8). The following day, excised auricular lymph nodes were pooled for each experimental group. A single cell suspension consisting of a defined number of local lymph node cells was cultured with [^{3}H] methyl thymidine. After 24 hours, the increase in local lymph node cell number and [^{3}H] methyl thymidine incorporation compared to controls were expressed as a stimulation index, SI. Specifically, SI_n was calculated from the local lymph node cell number after excision; while SI_p was calculated from local lymph node cell proliferation in cell culture. A chemical was regarded as a sensitiser, if SI_{total} ($SI_n \times Si_p$) resulted in a value of 3 or greater. SI values for Disperse Red 17 were SI_n= 0.9 and SI_p= 0.9; this resulted in a SI_{total} of 0.8. SI_{total} for the positive control was 29.6. Thus, the authors and the DS concluded that Disperse Red 17 was not a sensitiser in this test. RAC concurs with this conclusion but notes the limitations of the study; these are: i) this was a non-guideline study performed without observing GLP; ii) there is no information on the systemic toxicity of Disperse Red 17 in treated

animals; iii) insufficient characterisation of the test material; and, iv) concentrations higher than 2 % were not tested.

The skin sensitising potential of Disperse Red 17 was investigated in a GPMT according to OECD testing guidelines (OECD TG 406) and in compliance with GLP. A preliminary intradermal study showed that a concentration of 5 % test substance did not induce an irritant response. For induction in the main study, guinea pigs received three intradermal injections of Disperse Red 17 (41.2 % purity) using 5 % test substance in Freund's complete adjuvant (FCA), followed by a single epidermal induction on day 8 using 2.5 % of the test material under occlusive patch for 48 hours. Two weeks after completed induction, animals were challenged by a single application of 2.5% test substance under occlusive conditions for 24 hours. Skin examination followed 24 and 48 hours after removal of the challenge patches. Skin staining due to the test substance was observed in 6/10 animals and precluded accurate assessment of erythema after the challenge application. No adverse reaction was observed in any of the treated guinea pigs. The DS considered this study as not assignable for reliability.

***Table**: Summary of the animal studies on skin sensitisation with Disperse Red 17.*

Study	Dose level	Results	Reference
Sensitive mouse lymph node assay Non-guideline study No information on GLP Study reliability 3: Not reliable 3 BALB/c females/dose	Disperse Red 17 and positive control (p-phenylene-diamine): unknown purity Intradermal injection (day 1): 2 % in saline/Freund's complete adjuvant (FCA) (1:1) Topical application (days 6-8): 10 % in DMF	<u>Day 9:</u> <u>Disperse Red 17</u> SI_n = 0.9 SIp = 0.9 SI_{total} = 0.8 <u>Positive control:</u> SI_n = 4.1 SI_p = 7.3 SI_{total} = 29.6 **Negative**	Ikarashi *et al*., 1996
GPMT OECD TG 406 GLP-compliant Study reliability 4: Not assignable Dunkin-Hartley female guinea pigs (N=10/ dose, N=5/control)	Disperse Red 17 (purity 41.2 %) dispersed in water Intradermal induction: 0.1 mL 5 % (w/v) test substance/FCA; 0.1 mL 50 % FCA; 0.1 mL 5 % (w/v) test substance Day 6, induction of irritation: 10 % sodium lauryl sulphate Day 8, topical induction: 0.5 mL 2.5 % test substance for 48 h (occluded)	Excessive staining due to the test substance precluded accurate assessment in 6/10 animals No adverse reaction in any of the treated animals **Negative**	Karunaratne, 1995

	Two weeks later, challenge: 2.5 % test substance for 24 h (occluded)	

In conclusion, RAC notes that none of the available animal studies was sufficiently reliable to conclude on the skin sensitising potential of Disperse Red 17.

Human data

The CLH-report compiled published studies corresponding to 6 independent diagnostic patch test with unselected (consecutive) dermatitis patients together with 32 independent studies performed with selected dermatitis patients plus one case report. For details on all these studies see Table 12 of the CLH-report. The CLH-report only summarised those available studies which were considered reliable (or reliable with restrictions) by the DS, while those studies of low reliability (or not reliable) were not considered by the DS. The table below summarises the main features of these studies relevant for classification. The CLH-report does not contain information about previous exposure levels to Disperse Red 17. Furthermore, human induction studies such as a Human Repeated Insult Patch Test (HRIPT) or Human Maximisation Test (HMT) performed with Disperse Red 17 were not available to the DS.

Table**: Summary table of human patch test data and published cases on skin sensitisation caused by Disperse Red 17. See Table 12 in CLH-report for detailed information.

Number of studies	Type of study	Positive reactions	Result Frequency
4	Unselected consecutive dermatitis patients	Lower than 1 % (Range: 0.2-0.9 %)	Positive Low/moderate frequency
2	Unselected consecutive dermatitis patients	Higher than 1 % (1.3 %/1.2 %)	Positive High
12	Selected dermatitis patients	Lower than 2 % (Range: 0.1-1.9 %)	Positive Low/moderate frequency
18	Selected dermatitis patients	Higher than 2 % (Range: 3.6-25 %)	Positive High
2	Selected dermatitis patients	0 %	Negative
1	Case report	2/7 women	Positive

There is strong evidence from human data that Disperse Red 17 consistently and repetitively evokes skin sensitisation, as indicated in diagnostic patch tests from individual clinics or collated clinic data (Table above).

Consecutive patients patch-tested with Disperse Red 17 showed frequencies of positive reactions between 0.2 % and 1.3 % (Table above). Four of six studies showed a low to moderate (lower than 2 %) frequency of positive reactions, while the other two studies revealed a high (higher than 2 %) sensitisation frequency (Table above).

Testing Disperse Red 17 in selected dermatitis patients identified between 0 % and 25 % positive patch test reactions (Table above). The majority of the studies identified high frequencies of patients reacting positively to exposure to Disperse Red 17 (18/32 studies, frequency higher than 2 %). A low/moderate frequency of Disperse Red 17 reactions in selected dermatitis patients was seen in 12/32 studies (frequency lower than 2 %) (Table above). Two additional studies on patch testing in selected dermatitis patients revealed negative results for Disperse Red 17 (Table above).

In one published case-report, ten women with suspected textile dye allergy from stockings and other dyed textiles, including a black blouse, blue trousers, or grey pantsuit were investigated. Most subjects reported itching and erythema on the inner thighs, shortly after wearing these fabrics. Positive patch test reactions to Disperse Red 17 were shown in two patients with dermatitis from stockings.

Overall, RAC concludes that, given the occurrence of positive diagnostic patch test reactions from a large number of dermatological clinics, representing numerous different countries, the capability of Disperse Red 17 to elicit skin sensitisation in humans is well demonstrated.

Comparison with the criteria

None of the two animal studies investigating the skin sensitising potential of Disperse Red 17 gave a positive result (summarised above). However, these studies were considered by RAC to be too unreliable to be given any weight for assessing the capability of Disperse Red 17 to elicit sensitisation of human skin.

There was strong evidence (indicated by dermatological patch tests performed in a high number of dermatological clinics from several countries) that Disperse Red 17 evokes skin sensitisation in humans (Table above).

The table below summarises the criteria considered by the Guidance on the Application of the CLP Criteria for setting classification for skin sensitisation based on human data.

Table**: Criteria for setting classification for skin sensitisation based on dermatitis patients.

	Skin Sens. 1		**Skin Sens. 1A**		**Skin Sens. 1B**	
	Frequency	**Exposure**	**Frequency**	**Exposure**	**Frequency**	**Exposure**
Unselected	≤ 1 %	Low	≥ 1 %	Low	≤ 1 %	High
	≥ 1 %	High	-	-	-	-
Selected	≤ 2 %	Low	≥ 2 %	Low	≤ 2 %	High
	≥ 2 %	High	-	-	-	-

The human database (summarised above) contains 4 studies with unselected consecutive dermatitis patients showing a frequency lower than 1 % (low/moderate

frequency) and 2 studies with unselected consecutive dermatitis patients showing a frequency higher than 1 % (high frequency). Thus, all these six studies warrant classification of Disperse Red 17 as Skin Sens. 1.

The human data also contains 12 studies with selected dermatitis patients showing a frequency lower than 2 % (low/moderate frequency) and 18 studies with selected dermatitis patients showing a frequency higher than 2 % (high frequency). Thus, all these 30 studies indicate that Disperse Red 17 warrants classification of as Skin Sens. 1. RAC does not give weight to the 2 negative studies with selected dermatitis patients given the overwhelming number of studies showing positive results.

The distinction between Skin Sens. 1A and Skin Sens. 1B is based on the frequency of positive results and also on the level of exposure. Establishing the level of exposure (low or high) is based on three different criteria (concentration/dose, repeated exposure and number of exposures). RAC notes that the CLH-report shows information only on the third criterion (number of exposures) but not on the other two. Thus, it is not possible to establish the level of exposure and consequently sub-categorisation based on human data is not possible.

In conclusion, RAC agrees with the DS that **Disperse Red 17 should be classified as Skin Sens. 1 (H317: May cause an allergic skin reaction).**

The available information does not enable a conclusion to be drawn regarding a specific concentration limit.

9.8 Germ cell mutagenicity

Not assessed in this dossier

9.9 Carcinogenicity

Not assessed in this dossier

9.10 Reproductive toxicity

Not assessed in this dossier

9.11 Specific target organ toxicity-single exposure

Not assessed in this dossier

9.12 Specific target organ toxicity-repeated exposure

Not assessed in this dossier

9.13 Aspiration hazard

Not assessed in this dossier

10 EVALUATION OF ENVIRONMENTAL HAZARDS

Not assessed in this dossier

11 EVALUATION OF ADDITIONAL HAZARDS

Not assessed in this dossier

12 ADDITIONAL LABELLING

Not relevant

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