





According to EC Regulations 1907/2006 (REACH), 1272/2008 (CLP) & 453/2010

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY UNDERTAKING

1.1 Product Identifier

Product name: Response Beta Disinfectant Cleaner

CAS No: Not applicable to a mixture EC No: Not applicable to a mixture

1.2 Relevant identified uses of the substance/mixture and uses advised against

Use: High integrity biocidal sanitizer
Uses advised against: Uses other than recommended use

1.3 Details of the supplier of the safety data sheet

Name of supplier: Kays Medical

Address: 3 – 7 Shaw Street, Liverpool, L6 1HH, UK

Tel: +44 (0) 151 482 2830
Fax: +44 (0) 151 207 3384
Email: info@responsebeta.com

1.4 Emergency telephone number:

Tel: +44 (0) 151 482 2830 (UK Office hours only, English)

SECTION 2: HAZARDS IDENTIFICATION

This product is classified as "Hazardous" according to Regulation (EC) No 1272/2008 and its amendments.

2.1 Classification of the substance or mixture

2.1.1 Classification according to Regulation (EC) No 1272/2008 (including amendments):

Eye Irritant Cat 2, H319

Aquatic Chronic Cat 3, H412

EUH208

For the full H-statements mentioned in this section see Section 16.

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008:

Hazard pictograms:

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Signal word: Warning

Hazard statements: H319: Causes serious eye irritation

H412: Harmful to aquatic life with long lasting effects

Precautionary statements

Prevention: P264: Wash hands thoroughly after handling.

P273: Avoid release to the environment.

P280: Wear protective gloves/protective clothing/eye protection/face protection.

Response: P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove

contact lenses, if present and easy to do so. Continue rinsing.

P337 + P313: If eye irritation persists: Get medical advice/attention.

Storage: None

Disposal: P501: Dispose of contents/container in accordance with local/regional/national/international

regulations.

2.3 Other hazards

EUH208: Contains Polyhexammethylenebiguanide. May produce an allergic reaction.

2.4 Additional information

None.

SECTION 3: COMPOSITION.INFORMATION ON INGREDIENTS

3.1 Substances

Not applicable

3.2 Mixtures

Description of mixture: High Integrity Biocidal Sanitizer

EC Number	EC Name	Index number in CLP Annex VI	Weight % Content	Classification according to Regulation (EC) No 1278/2008 (CLP)
200-573-9	Tetrasodium ethylene diamine tetraacetate (EDTA tetrasodium)	607-428-00-2	0.59% w/w	Acute Tox 4, H332 & H302 Eye Dam. 1, H318
201-069-1	Citric acid	Not listed.	0.39% w/w	Eye Irri. 2, H319
230-525-2	Di-n-decyl dimethylammonium chloride	612-131-00-6	0.36% w/w	Acute Tox. 4, H302 Skin Corr. 1B, H314 Aquatic Acute 1, H400 Aquatic Chronic 2, H411
242-354-0	D-gluconic acid, compound with N,N"-bis(4-chlorophenyl)-3,12-diimino-2,4,11,13-tetraazatetradecanediamidine (2:1) (Chlorhexidine digluconate)	Not listed.	0.14% w/w	Eye Dam. 1, H318 Aquatic Acute 1, H400 Aquatic Chronic 1, H410
Not assigned	Polyhexammethylenebiguanide	Not listed.	0.14% w/w	Acute Tox. 4, H302 Skin Sens. 1B, H317 Eye Dam. 1, H318 Carc. 2, H351 STOT RE 1, H372

For the full text of the H-statements, see Section 16.

No REACH registration numbers are provided either because the mixture contains pre-registered phase-in substances and the transition period for their registration according to Article 23 of REACH has not yet expired or because the annual tonnages do not require a REACH registration.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

Ingestion: May cause irritation to mucous membranes. DO NOT INDUCE VOMITING. If irritation or symptoms persist,

seek medical attention.

Skin contact: Remove contaminated clothing. If irritation occurs and symptoms persist, seek medical attention.

Eye contact: May cause irritation to eyes. Rinse immediately with plenty of water for at least 15 minutes holding the

eyelids open. If irritation persists seek medical attention.

Inhalation: May cause irritation to mucous membranes. Remove the exposed person to fresh air. If irritation or

symptoms persist, seek medical attention.

First Aider Protection: Appropriate protective equipment such as protective gloves and glasses should be worn.

4.2 Most important symptoms and effects, both acute and delayed

General advice: Show this safety data sheet to medical personnel.

Ingestion: May cause irritation to mucous membranes. Seek medical attention if symptoms occur.

Skin contact: May cause irritation. Seek medical attention if symptoms occur.

Eye contact: May cause irritation. Seek medical attention if symptoms occur.

Inhalation: May cause irritation to mucous membranes. Seek medical attention if symptoms occur.

4.3 Indication of any immediate medical attention and special treatment needed.

Treatment based on judgement of the doctor in response to symptoms of the patient.

SECTION 5: FIRE FIGHTING MEASURES

5.1 Extinguishing media

Suitable Extinguishing Media: All media suitable – the product is not flammable. Unsuitable Extinguishing Media: None.

5.2 Special hazards arising from the substance or mixture

Combustion produces irritating, toxic and obnoxious fumes.

5.3 Advice for fire-fighters

Wear appropriate protective equipment (gloves, glasses, mask) when fighting fire.

Wear self-contained respirator when necessary.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency measures

6.1.1 For non-emergency personnel

Wear suitable gloves and eye protection.

For details of protective equipment, see Section 8.

6.1.2 For emergency responders

Wear suitable gloves and eye protection.

Ensure adequate ventilation of the working area.

For details of protective equipment, see Section 8.

6.2.1 Environmental precautions

Do not allow product to enter drains. Prevent further spillage, if safe to do so.

6.3 Methods and material for containment and cleaning up

6.3.1 For containment

Absorb with inert, absorbent material.

6.3.2 For cleaning up

Sweep up and transfer to suitable, labelled container/s for disposal via a Licensed Waste Disposal Company in accordance with local and national regulations.

Clean spillage area thoroughly with copious amounts of water.

6.4 Reference to other sections

For personal protection, see Section 8.

For disposal of waste from clean-up operations, see Section 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Do not mix with other chemicals.

Adopt best Manual Handling considerations when handling, carrying and dispensing.

7.2 Conditions for safe storage, including any incompatibilities

Store upright in original closed containers.

Keep containers tightly closed. Keep containers correctly labelled. Keep out of the reach of children. Avoid extremes of temperature.

7.3 Specific end use(s)

None. The material is safe to use as intended.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

8.1.1 Occupational Exposure Limits: None listed for product or components.

8.1.2 Biological Limit Value: No information available.

8.1.3 PNECS and DNELs: No information available for product.

PNECS for EDTA tetrasodium component:

PNEC aqua (freshwater): 2.2 mg/L

PNEC aqua (marine water): 0.22 mg/L

PNEC aqua (intermittent releases): 1.2 mg/L

PNEC STP: 43 mg/L

PNEC soil: 0.72 mg/kg soil dw

PNECS for Citric acid component:

PNEC agua (freshwater): 0.44 mg/L

PNEC aqua (marine water): 0.044 mg/L

PNEC STP: 1000 mg/L

PNEC sediment (freshwater): 34.6 mk/kg sediment dw

PNEC sediment (marine water): 3.46 mg/kg sediment dw

PNEC soil: 33.1 mg/kg soil dw

PNECS for Di-n-decyl dimethylammonium chloride component:

PNEC aqua (freshwater): 2 µg/L

PNEC aqua (marine water): 0.2 µg/L

PNEC aqua (intermittent releases): 0.29 µg/L

PNEC STP: 0.595 mg/L

PNEC sediment (freshwater): 2.82 mg/kg sediment dw

PNEC sediment (marine water): 0.28 mg/kg sediment dw

PNEC soil: 1.4 mg/kg soil dw

PNECS for Chlorhexidine digluconate component:

PNEC aqua (freshwater): 0.002 mg/L

PNEC aqua (marine water): 0.0002 mg/L

PNEC aqua (intermittent releases): 0.002 mg/L

PNEC STP: 0.25 mg/L

PNEC sediment (freshwater): 0.433 mg/kg sediment dw

PNEC sediment (marine water): 0.0433 mg/kg sediment dw

PNEC soil: 5.26 mg/kg soil dw

DNELs for EDTA tetrasodium component:

Workers - long-term exposure - local effects - inhalation: 1.5 mg/m³

Workers - short-term exposure - local effects - inhalation: 3 mg/m³

General population - long-term exposure – local effects – inhalation: 0.6 mg/m³ General population - short-term exposure – local effects – inhalation: 1.2 mg/m³ General population - long-term exposure – systemic effects – oral: 25 mg/kg bw/day

DNELs for Di-n-decyl dimethylammonium chloride component:

Workers - long-term exposure - systemic effects - inhalation: 18.2 mg/m³

Workers - long-term exposure - systemic effects - dermal: 8.6 mg/kg bw/day

DNELs for Chlorhexidine digluconate component:

 $Workers-long-term\ exposure-systemic\ effects-inhalation:\ 0.42\ mg/m3$

Workers - long-term exposure - systemic effects - dermal: 5 mg/kg bw/day

General population – long-term exposure – systemic effects – inhalation: 0.1 mg/m3

General population – long-term exposure – systemic effects – dermal: 3 mg/kg bw/day

General population – short-term exposure – systemic effects – dermal: 5 mg/kg bw/day

 $\label{eq:General population-long-term exposure-systemic effects-oral: 0.03 \ mg/kg \ bw/day}$

General population – short-term exposure – systemic effects – oral: 2 mg/kg bw/day

8.2 Exposure controls

8.2.1 Appropriate engineering controls

Eye and hand-washing facilities should be available near the area of handling.

8.2.2 Individual protection measures, such as personal protective equipment

Personal Protective Equipment is not required during standard use of the product as a sanitiser. In the event of potential exposures to large quantities, the following is recommended:

Respiratory Protection: Respiratory Protection, EN149 as minimum standard.

Eye protection: Safety glasses/goggles with side shields. EN166 as minimum standard.

Skin protection: Protective gloves (EN374 as minimum standard), protective clothing, boots and apron.

Hygiene measures: When using do not eat or drink.

Wash hands thoroughly after handling.

Handle in accordance with good industrial hygiene and safety practice.

8.2.3 Environmental exposure controls

Do not allow to enter drains, sewers or watercourses.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance: Colourless liquid
Odour: Odourless
Odour threshold: None
pH: 4.4 – 4.6

Melting/freezing point: No data available

Initial boiling point and boiling

range: >100°C

Flash point:

Evaporation rate:

Flammability:

No data available
No data available
No data available

Upper/lower flammability or

explosive limits:No data availableVapour pressure:No data availableVapour density:No data availableRelative density:1.0 g/cm³

Solubility:

In water: Soluble

In other solvent:

Partition coefficient (n-octanol/water):

Auto-ignition temperature:

No data available
No data available

Decomposition temperature: No data available

Viscosity:

Explosive properties:

Oxidising properties:

No data available
No data available

9.2 Other information

No data available

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

No data available. Do not mix with other chemicals.

10.2 Chemical stability

Stable under normal conditions of prescribed use.

10.3 Possibility of hazardous reactions

No data available.

10.4 Conditions to avoid

Do not mix with other chemicals.

10.5 Incompatible materials

No data available. It is recommended not to mix with other chemicals.

10.6 Hazardous decomposition products

No data available. Combustion produces irritating, toxic and obnoxious fumes including oxides of carbon and nitrogen.

11.1 Information on toxicological effects

No data is available for the product; data is available for some of the components.

The product is not classified for acute toxicity (oral, dermal and inhalation). Acute toxicity:

EDTA tetrasodium component: Classified as Acute Tox. Category 4 (oral and inhalation. Oral Rat (m/f) LD50: >1780

mg/kg [Standard acute method]

Di-n-decyl dimethylammonium chloride component:

Classified as Acute Tox. Category 4 (oral). Oral rat (m/f) LD50: 800 - 1000 mg/kg bw

[OECD Guideline 401, EU Method B.1]

Dermal rat (m/f) LD50: >1000 mg/kg bw [OECD Guideline 403, EU Method B.3]

Skin corrosion/irritation: The product is not classified.

Di-n-decyl dimethylammonium chloride component:

Classified as Skin Corrosive Category 1B. Rabbit: Corrosive. 4h exposure produced severe erythema and edema up to 72h observation period, skin appeared rough, dry

and scabbed with discolouration. [OECD Guideline 404, EU Method B.4]

Serious eye damage/ irritation: The product classified as Eye Irritant Category 2 on the basis of in vitro derived data. EDTA tetrasodium component:

Classified as Category 1. Rabbit: Irritating. During observation a grease like layer on the eves was observed. [OECD Guideline 405]

Classified as Category 2. Rabbit: Irritating. 30% solution caused well defined to Citric acid component:

moderate conjunctival irritation that was not fully reversible after 14 days. [OECD

Guideline 405].

Chlorhexidine digluconate component: Classified as Eye damage Category 1. Rabbit: Irritating. Severe irritant in non-rinsed

eyes, mildly irritating in rinsed eyes with reversible effects. [OECD Guideline 405]

Respiratory or skin sensitisation:

Respiratory: The product is not classified.

No data is available.

Skin¹ The product is not classified.

Di-n-decyl dimethylammonium chloride component:

Buehler test, guinea pigs: Not sensitising. [OECD Guideline 406, EU Method B.6]

Chlorhexidine digluconate component:

Buehler test, guinea pigs: ambiguous [OECD Guideline 406].

Guinea pig maximisation test: Not sensitising [OECD Guideline 406]

The product is not classified. Germ cell mutagenicity:

Citric acid component: Not a germ cell mutagen. Positive results without metabolic activation (in vitro

chromosome aberration, OECD Guideline 473). Negative results (in vitro Ames assay, in vivo chromosome aberration, OECD Guideline 475, EU method B.22)

Di-n-decyl dimethylammonium chloride component:

Not a germ cell mutagen. Negative results (in vitro Ames assay [OECD Guideline 471, EU Method B13/14], Chromosome aberration [OECD Guideline 473, EU Method B10], Mammalian cell gene mutation test [OECD Guideline 476, EU Method B17] Not a germ cell mutagen. Negative results (in vitro Ames assay [OECD Guideline

Chlorhexidine digluconate component:

471], chromosome aberration [OECD Guideline 473] and mammalian cell gene mutation test [OECD Guideline 476]. In vivo chromosome aberration micronucleus assay [OECD Guideline 474].

Carcinogenicity: The product is not classified.

Di-n-decyl dimethylammonium chloride component:

Not found to be a carcinogen. Oral (feed) rat (m/f) combined chronic

toxicity/carcinogenicity study [OECD Guideline 453]

LOEL (based on pigment-laden in mesenteric lymph nodes, grade II): 8.9 mg a.i./kg Chlorhexidine digluconate component:

bw/day. No evidence for carcinogenetic effects. Oral (feed), rat (m/f), 105w [OECD

Guideline 451].

Reproductive toxicity: The product is not classified.

EDTA tetrasodium component: LOAEL (maternal toxicity): 1374 mg/kg bw/day. NOAEL (developmental

toxicity/teratogenicity/embryotoxicity/fetotoxicity): >= 1374. Diarrhoea, slightly reduced food intake, slightly reduced body weight gain. Oral (gavage) rat.

NOAEL (teratogenicity); >295 mg/kg bw/day (rat); >425 mg/kg bw/day (rabbit); >272 Citric acid component:

mg/kg bw/day (mouse). No indication of adverse effects on nidation, maternal or

fetal survival. Oral (gavage), rat, rabbit and mouse.

Di-n-decyl dimethylammonium chloride component:

NOAEL (maternal toxicity): 4 mg a.i./kg bw/day; NOAEL (teratogenicity): 12 mg a.i./kg bw/day. High dose group showed clear signs of maternal toxicity and resulted in increased number of dead foetuses and post-implantation and a decrease in fetal

body weight. Oral (gavage) rabbit [OECD Guideline 414]

Chlorhexidine digluconate component: NOAEL (maternal toxicity): 10 mg/kg bw/day; NOAEL (embryotoxicity): 30 mg/kg

bw/day; NOAEL (teratogenicity): >100 mg/kg bw/day. No teratogenic properties were noted during external/internal, skeletal and soft tissue examinations. No increase of fetal malformations or variations. At the maternal toxic dose (100 mg/kg bw/day), slight embryotoxic properties were noted (reduced fetal weights, increased

incidences if skeletal retardations).

STOT-single exposure: The product is not classified.

No data available.

The product is not classified. STOT-repeated exposure:

NOAEL 4g/kg bw/day; LOAEL 8 g/kg bw/day. Sedation within 2 hours of 1st Citric acid component:

administration and death of all animals by 3rd administration in the high dose group.

Oral (gavage) rat, 10 day.

Di-n-decyl dimethylammonium chloride component:

LOAEL: 31 mg a.i./kg bw/day. Effects seen on body weight and body weight gain.

Oral (feed), rat (m/f) combined chronic toxicity/carcinogenicity study [OECD

Guideline 453]

NOAEL: 45.5 mg a.i./kg bw/day. No significant toxic effects, although, some

changes in haematology and blood chemistry parameters.

LOAEL: 8.88 mg/kg bw/day. Reactive, non-progressive, reversible histocytosis with Chlorhexidine digluconate component:

histiocyte conglomerates in mesenteric lymph nodes. Oral (drinking water), rat (m/f),

2 yr (chronic study) [OECD Guideline 452]

Aspiration hazard: The product is not classified.

11.2 Other information: None

SECTION 12: ECOLOGICAL INFORMATION

12.1 **Toxicity**

No data is available for the product, however data is available for a number of the components.

Hazards to aquatic environment: The product is classified as Aquatic Chronic Category 3.

No data available for product.

Di-n-decyl dimethylammonium chloride component:

Classified as Aquatic Acute Category 1, Aquatic Chronic Category 2.

96h LC50 (mortality): 0.49 mg/L (Danio rerio) [OECD Guideline 203, EU Method C.1] 48h EC50 (mobility): 0.029 mg/L (Daphnia magna) [OECD Guideline 202, EU Method

C.2]

21d NOEC (reproduction/mortality): 0.021 mg/L (Daphnia magna) [OECD Guideline

Chlorhexidine digluconate component: Classified as Aquatic Acute Category 1, Aquatic Chronic Category 1.

> 96h LC50 (mortality): 2.08 mg a.i./L (Danio rerio) [OECD Guideline 203] 21d NOEC (mortality): 20.6 µg a.i./L (Daphnia magna) [OECD Guideline 211, EU

Method C.20]

12.2 Persistence and degradability

> Persistence/degradability: No data available for product.

Not inherently biodegradable (8% after 28 days) [OECD Guideline 302 B] EDTA tetrasodium component:

Readily biodegradable (97% in 28 days) [OECD Guideline 301 B] (COD removal of Citric acid component:

93%) [OECD Guideline 303 A]

Di-n-decyl dimethylammonium chloride component:

Readily biodegradable (69% in 28 days) [OECD Guideline 301 B & 301 D]

>99.85% in 59 days [OECD Guideline 303A, EU Method C.10]

Chlorhexidine digluconate component: Readily biodegradable (87% in 28 days) [OECD Guideline 301 A, EU Method C4-A]

12.3 **Bioaccumulative potential**

No data available for product. Bio-accumulation:

EDTA tetrasodium component: BCF 1.1 - 1.8 28 day steady state (Lepomis macrochirus)

BCF 3.2 L/kg by calculation (SRC BCFBAF v3.20) Citric acid component:

Chlorhexidine digluconate component: BCF 42 L/kg (Leuciscus idus melanotus)

12.4. Mobility in soil

Mobility in soil: No data available for product

Di-n-decyl dimethylammonium chloride component:

Koc 667 - 24433

Chlorhexidine digluconate component: log Koc >3.9; Koc >7944 [OECD Guideline 122, EU Method C.19]

Results of PBT and vPvB assessment 12.5.

An assessment has not been conducted on the product.

EDTA tetrasodium component: Not PBT/vPvB Citric acid component: Not PBT/vPvB

Di-n-decyl dimethylammonium chloride component:

Not PBT/vPvB

Chlorhexidine digluconate component: Not PBT/vPvB

12.6. Other adverse effects

No data available.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

13.1.1 Residual wastes

Spillages should be absorbed with sand or earth. Dispose of in accordance with local/national regulations via a Licensed Waste Disposal Company.

13.1.2 Contaminated containers and packaging

Containers should be disposed of in accordance with local/national regulations via a Licensed Waste Disposal Company.

13.2 Other information: None

SECTION 14: TRANSPORT INFORMATION

14.1 UN Number: Not applicable

14.2 UN proper shipping name: Not applicable

14.3 Transport hazard class(es): Not applicable

14.4 Packing group: Not applicable

14.5 Environmental hazards: Not applicable

14.6 Special Precautions for user: Not applicable

14.7 Transport in bulk according to

Annex II of Marpol 73/78 and the IBC

Code: Not applicable

SECTION 15: REGULATORY INFORMATION

This safety datasheet complies with the requirements of EC Regulations 1907/2006 (REACH), 1272/2008 (CLP) & 453/2010.

15.1. Safety, health and environmental regulations/legislation specific for the substance

EU regulations

Authorisations: Not applicable Restrictions on use: Not applicable

UK regulations

EH40/2005 Workplace exposure limits. Containing the list of workplace exposure limits for use with the Control of Substances Hazardous to Health Regulations (as amended). Health and Safety Executive, Second edition, published 2011.

The Control of Substances Hazardous to Health Regulations 2002 (as amended).

15.2 Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out for this product.

SECTION 16: OTHER INFORMATION

Full H-statements referred to under Sections 2 and 3

H302: Harmful if swallowed

H314: Causes severe skin burns and eye damage

H317: May cause an allergic skin reaction

H318: Causes serious eye damage

H319: Causes serious eye irritation

H332: Harmful if inhaled

H351: Suspected of causing cancer

H372: Causes damage to organs through prolonged or repeated exposure.

H400: Very toxic to aquatic life

H410: Very toxic to aquatic life with long lasting effects

H411: Toxic to aquatic life with long lasting effects

H412: Harmful to aquatic life with long lasting effects

EUH208: Contains (name of sensitising substance). May produce an allergic reaction.

Methods of evaluation:

The mixture was classified using data available for the neat substances with the application of relevant concentration limits, in accordance with Regulation (EC) No 1272/2008. In addition, an in vitro eye irritation study confirmed the outcome of the calculation method.

References:

ECHA Guidance on the compilation of safety data sheets. Version 3.0. August 2015.

Regulation 1272/2008 on Harmonised Classification and Labelling for Certain Hazardous Substances.

The CLP Regulation. European Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures Disseminated dossiers available on ECHA website.

Abbreviations:

Acute Tox. 4: Acute Toxicant, Category 4

bw: Body weight

Carc. 2: Carcinogen, Category 2 DNEL: Derived no effect level

dw: Dry weight

Eye Dam. 1: Serious Eye Damage, Category 1

Eye Irri. 2: Eye Irritant, Category 2

PBT: Persistent, bioaccumulative and toxic PNEC: Predicted no effect concentration Skin Corr. 1: Skin Corrosive, Category 1 Skin Sens. 1: Skin Sensitiser, Category 1

STOT RE: Specific Target Organ Toxicity Repeated Exposure

vPvB: Very persistent and very bioaccumulative.

Other:

This Safety Data Sheet was issued on 26 January 2016.

The above information is based on the present state of our knowledge at the time of publication. It is given in good faith and no warranty is implied with respect to the quality or specification of the product. This information only relates to the specific material designated and may not be valid for such material used combination with any other materials or in any other process. The user must satisfy himself that the product is entirely suitable his purpose.

DOCUMENT VERSION

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