החלקת שיער. צילום: שאטרסטוק

בת 32 במצב קשה לאחר שעברה 'החלקה הודית' בשיער

חדשות 20
ו' באייר ה'תשפ"א (18 באפריל 2021)

אישה בשנות ה-30 לחייה אושפזה במצב קשה בבית חולים ברזילי לאחר שעברה "החלקה הודית"

במחלקת טיפול נמרץ של המרכז הרפואי ברזילי מאושפזת מטופלת בת 32 שהגיעה למצב של אי ספיקת כליות קשה. פרופ' מיגל גלטשטיין יועץ טוקסיקולוגי למרכז הרפואי, סיפר כי החומר המעורב החשוד הינו אתילן גליקול - נוזל רעיל שמשמש לרוב כמונע קפיאה וכחומר גלם לייצור פולימרים, וכאשר בא במגע עם הגוף הוא מתחמצן ועלול לפגוע במערכת העצבים, בלב או בכליות.

וכאשר בא במגע עם הגוף הוא מתחמצן ועלול לפגוע במערכת העצבים, בלב או בכליות.

ידוע על מקרים נוספים דומים שארעו הן בעבר והן לאחרונה במרכזים רפואיים אחרים, לאחר החלקות שיער בחומרים אסורים לשימוש.

עוד בזמן ביצוע החלקת השיער החלה האישה לחוש ברע. היא הקיאה, בהמשך הועברה למרכז הרפואי ברזילי, וכעת היא מטופלת, בין היתר, בדיאליזה, במחלקת טיפול נמרץ. המקרה דווח למשרד הבריאות.

| e-mail: info@indianoilpro.com | web: indianoilpro.com

INDIANOIL®
It`s All About Oil

בס״ד

18/04/2021

לאור הפרסומים שרצים בכל התקשורת ברצוני להבהיר בפניכם כמה עובדות:

1. אני מאחל רפואה שלמה לאותה אישה שמאושפזת בבית חולים ברזילאי באשקלון.
2. הבחורה לא נמצאת במצב קשה ולזה עדויות משלושה אנשים שונים אשר שמורים אצלי במערכת כולל תמונה, מהיום בשעה 21:45 של אותה בחורה כאשר היא צוחקת עם החברה שלה תודה לאל, ומחוץ למחלקה כשהיא משחקת עם הנייד שלה, וכאשר התקשורת טוענת שהיא במצב קשה, אנוש.
3. מערכת התקשורת החליטה לעשות עליי לינץ' ללא כל סיבה מוצדקת, אני מקווה שהדברים יצאו לאור וינקו את שמנו הטוב.
4. החלקה הודית נרשמה במשרד הבריאות וקבלה רישיון תמרוקים.
5. המוצר עבר את הבדיקות הכי מחמירות בעולם Safety Assessment (הערכת בטיחות) ונמצאה ועברה את כל הבדיקות (בטיחות) בהצלחה רבה.
6. אנחנו מזמינים כ 3000 מספירות בישראל אשר עובדים עם החברה שלנו, לשלוח למעבדות חיצוניות כגון מעבדות סיסטם ולבדוק שאכן החומר אתלין גליקול המסוכן לא נמצא שם, פרטי המעבדה:

   sasi@system-labs.co.il

   טל: 02-5700733
7. <u>אם כמו שטענו בתקשורת כולל ערוץ 12 היו 5 מקרים כבר מזמן משרד הבריאות היה חוקר ומבטל לנו את הרישיונות ומוציא אזהרה כמו שקרה בעבר עם שחקנים אחרים בשוק.</u>

נוכח הפרסומים המטעים בתקשורת ושל פרופ׳ מיגל גלטשטיין מבית חולים ברזילאי שמקשר את ההחלקה הודית למוצר שגרם לה לקריסת מערכות ואינו בכלל נמצא בשום מוצר שלנו וטוען כי החומר המעורב הינו אתילן גליקול.

אנחנו מחברת Indian oil מוסרים לכם כי למוצרים רישיון משרד הבריאות ואין בתכולתם אתילן גליקול כפי שניתן ללמוד מהמסמכים המצורפים בזאת, <u>וזאת אומרת שאין כל קשר לחומר שגרם לקריסת מערכות לבין החלקה הודית.</u>

לשון הרע לא מדבר אליי

בכבוד רב,

יורם וויליאם גדג׳

מנכ״ל ובעלים של Indian Oil

לכבוד:

לכל המעוניין:

אני מייצר את החלקה ההודית Indian oil. ברצוני להבהיר כדלקמן:

1. בניגוד לפרסום אין אתילן גליקול בפורמולה של המוצר שבנדון, מרכיב זה לא הוסף לפורמולה באופן יזום על ידי וגם אינו מהווה חלק מתערובות חומרי הגלם המשמשות לפורמולה.

2. הפורמולה הועברה למערכת בטיחות באירופה, אשר ביצעה את הערכת הבטיחות והסיקה שהמוצר בטוח לשימוש כאשר משתמשים בו למטרה שלשמה הוא יוצר ובהתאם להוראות השימוש.

3. הבקשה הועברה לבדיקת משרד הבריאות לשם קבלת רישיון. לאחר בחינת הבקשה, תוצאות המעבדה ודוח הערכת הבטיחות, ניתן הרישיון ע"י משרד הבריאות.

4. אציין כי ברישיון מופיעה אזהרה שאין להשתמש במוצר אם ידועה רגישות לאחד המרכיבים.

בכבוד רב,

ד"ר רזק

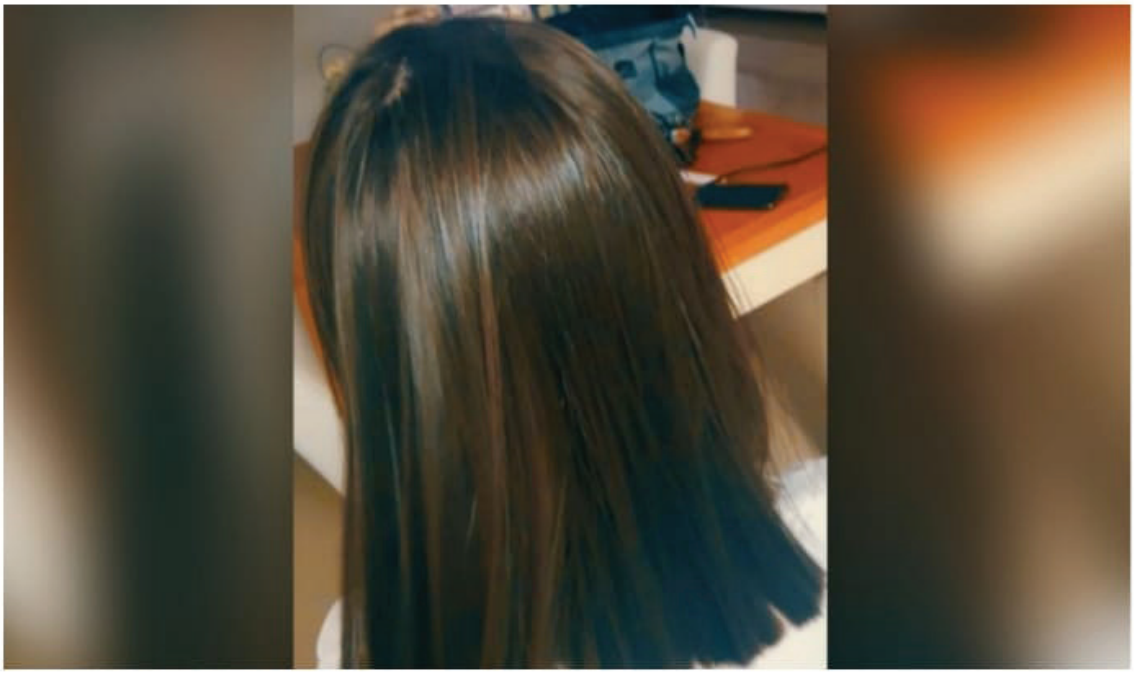
לין ננו טכנולוגיה בע"מ

לין ננו טכנולוגיה בע"מ
ח.פ. 514 334 200

לין ננוטכנולוגיה בע"מ - ייצור ושיווק מוצרי טיפוח
טל. 04-6346724.
leen@leencare.com

ברזילי: אישה במצב קשה לאחר החלקת שיער. משפחתה: אין הוכחה שזה מההחלקה | כאן דרום

www.kan-ashkelon.co.il



ברזילי: אישה במצב קשה לאחר החלקת שיער. משפחתה: אין הוכחה שזה מההחלקה

בת 32 מאשקלון מאושפזת כעת במצב קשה בבית החולים ברזילי. בבית החולים טוענים כי זה קרה בעקבות "החלקה הודית"

מדינת ישראל משרד הבריאות
מחלקה לרישום תמרוקים
MINISTRY OF HEALTH
COSMETIC REGISTRATION DEPARTMENT
STATE OF ISRAEL

רשיון לתמרוק פלוני (רגיל)

עפ"י צו הפיקוח על מצרכים ושרותים (תמרוקים)
התשל"ג - 1973

מספר רשיון : **1/145750/21**

תאריך מתן הרשיון: **24/02/2021**

תוקף הרשיון עד: **28/02/2026**

שם התמרוק בעברית: **החלקה הודית פרו משקמת - לשיער צבוע**

שם התמרוק בלועזית: **INDIAN OIL - HAIR STRAIGHTENING RESTOVATIVE PRO - FOR DYED HAIR**

שם בעל הרשיון: **לין ננו טכנולוגיה בע"מ**
רחוב ובית

כתובתו: **אזור תעשייה ג.ת .ת.ד 70 מיקוד 30091**

שם המפעל המייצר: **לין ננו טכנולוגיה בע"מ**

כתובתו:

משווק יצרן: **לין ננו טכנולוגיה בע"מ**

כתובת מפעל מילוי:

מאפיינים פיזיקוכימיים: **נוזל סמיך לבן**

מטרת התמרוק עפ"י היצרן

*** החלקת שיער**

סוגי אריזות וקיבולן:

שם אריזה	קיבולת	ברקוד אריזה
*** בקבוק,שפופרת,צנצנת (פלסטיק או זכוכית**	**1.00LITER**	.
*** בקבוק,שפופרת,צנצנת (פלסטיק או זכוכית**	**4.00LITER**	.
*** בקבוק,שפופרת,צנצנת (פלסטיק או זכוכית**	**150.00ML**	.
*** בקבוק,שפופרת,צנצנת (פלסטיק או זכוכית**	**500.00ML**	.

ב/ מנהל האגף

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מספר רשיון : **1/145750/21**

שם התמרוק בעברית:

החלקה הודית פרו משקמת - לשיער צבוע

שם התמרוק בלועזית:

INDIAN OIL - HAIR STRAIGHTENING RESTOVATIVE PRO - FOR DYED HAIR

תנאים מיוחדים והגבלות לשיווק

* **בתנאי שכל תמרוק או מיכל המכיל תמרוק יסומן במלים "ברשיון משרד הבריאות".**
* **בתנאי שבתוית יודפסו הוראות ביצוע מבחן רגישות.**
* **בתנאי שעל גבי האריזה יסומנו פירוט כל המרכיבים באותיות לטיניות בסדר כמותי יורד.**
* **בתנאי שעל האריזה יצוינו הוראות השימוש**
* **אין לייחס לתמרוק בכל דרך שהיא מטרות שמוש או סגולות , זולת אלו שאושרו בגוף הרשיון.**
* **במקרה של מגע עם העיניים יש לשטוף במים. אם הגרוי נמשך יש לפנות לרופא.**
* **במקרה של עור קרקפת פגום או חולה יש להמתין עם השימוש עד שהעור יבריא.יש להשתמש בכפפות.**
* **מותר לשמוש מקצועי בלבד ובתנאי שיעבדו במקום מאוורר. יש להמנע ממגע עם העור.**
* **בתנאי שעל גבי התווית יצוינו אזהרות: "להימנע ממגע עם העיניים ובמקרה של מגע כזה יש לשטוף היטב במים".**
* **לשימוש מקצועי בלבד.**
* **בתנאי שעל גבי התוית יצוין: "מומלץ ללבוש כפפות בעת השימוש"**
* **בתנאי שעל גבי התווית ירשם: "לשימוש חיצוני בלבד. להרחיק מילדים."**

המשך ...

ב/ מנהל האגף

מדינת ישראל
משרד הבריאות
מחלקה לרישום תמרוקים
MINISTRY OF HEALTH
COSMETIC REGISTRATION
DEPARTMENT
STATE OF ISRAEL

מספר רשיון : 1/145750/21

שם התמרוק בעברית:

החלקה הודית פרו משקמת - לשיער צבוע

שם התמרוק בלועזית:

INDIAN OIL - HAIR STRAIGHTENING RESTOVATIVE PRO - FOR DYED HAIR

תנאים מיוחדים והגבלות לשיווק

* **בתנאי שעל גבי התווית יצויין האזהרה: "יש להפסיק את השימוש בתמרוק ברגע שמופיעים סימני גירוי".**
* **בתנאי שעל גבי התווית יצוינו האזהרות:יש לבצע מבחן לרגישות על שטח קטן לפני כל שימוש בתמרוק מאחר והרגישות יכולה להתפתח בין שימוש אחר למשנהו.**
* **רשיון התמרוק בתוקף,כל עוד קיים רשיון תמרוקים כללי בתוקף.**
* **בתנאי שעל גבי התמרוק ייכתב:"יש להשתמש בחדר מאוורר היטב"**
* **בתנאי שעל גבי התווית יכתב " יש להקפיד למלא אחר הוראות השימוש "**
* **בתנאי שעל התווית ייכתב: "עלול לגרום לתגובה אלרגית, במקרה של הופעת תגובה אלרגית יש לשטוף במהירות עם הרבה מים ולהפסיק את השימוש"**
* **בתנאי שבתווית ייכתב:"יש לטפטף על השיער בלבד ולא על הקרקפת.יש להמנע ממגע עם העור"**
* **בתנאי שייכתב:"למרוח לאורך השיער בלבד.להימנע ממגע עם השורשים"**
* **בתנאי שעל גבי המוצר ייכתב:"אין להשתמש במוצר אם ידועה רגישות לאחד מהמרכיבים"**
* **בתנאי שעל התווית ייכתב:**
"יש להשתמש בתמרוק רק למטרה שלשמה הוא נועד ובהתאם להוראות השימוש.
אין לבלוע.יש להימנע ממגע בעיניים. להרחיק מילדים."

המשך ...

ב/ מנהל האגף

מספר רשיון : 1/145750/21

שם התמרוק בעברית:

החלקה הודית פרו משקמת - לשיער צבוע

שם התמרוק בלועזית:

INDIAN OIL - HAIR STRAIGHTENING RESTOVATIVE PRO - FOR DYED HAIR

תנאים מיוחדים והגבלות לשיווק

* **בתנאי שעל גבי התווית יופיע הכיתוב:"בטיחות השימוש לא נבדקה בשילוב עם מגהץ,מחליק קרמי וכיו"ב".**
* **בתנאי שעל גבי האריזה ובעלון ייכתב: "אין להשתמש במוצר מתחת לגיל 16"**
* **בתנאי שעל גבי התווית ייכתב:" יש לאחסן במקום קריר ויבש, מתחת ל-30 מעלות".**
* **הרשיון אינו בתוקף ללא התווית המאושרת**
* **בתנאי שבעל הרשיון ידווח מיידית למשרד הבריאות על כל תופעת לוואי שהתקבלה כתוצאה משימוש בתמרוק**
* **בכל מקרה בו נודע לבעל הרישיון על חשש לפגם במוצר עליו להודיע באופן מיידי למשרד הבריאות ולפעול לאיסוף המוצר מן השוק והודעה לציבור.**

ב/ מנהל האגף

מדינת ישראל משרד הבריאות מחלקה לרישום תמרוקים MINISTRY OF HEALTH COSMETIC REGISTRATION DEPARTMENT STATE OF ISRAEL

נספח לרשיון תמרוק מספר: **1/145750/21**

שם התמרוק בעברית:

החלקה הודית פרו משקמת - לשיער צבוע

שם התמרוק בלועזית:

INDIAN OIL - HAIR STRAIGHTENING RESTOVATIVE PRO - FOR DYED HAIR

הרכב התמרוק

WATER
CETEARYL ALCOHOL
GLYOXYLIC ACID
SIMMONDSIA CHINENSIS (JOJOBA) SEED OIL
GLYOXYLOYL CARBOCYSTEINE
GLYOXYLOYL KERATIN AMINO ACIDS
SODIUM HYDROXIDE
BEHENTRIMONIUM CHLORIDE
ISOPROPYL MYRISTATE
CETEARYL ETHYLHEXANOATE
PHENOXYETHANOL
AMODIMETHICONE
CETRIMONIUM CHLORIDE
ETHYLHEXYLGLYCERIN
CYCLOPENTASILOXANE
TRIDECETH-12
DIMETHICONE CROSSPOLYMER
DIMETHICONOL
FRAGRANCE(SUPPLEMENT)
LINALOOL
BUTYLPHENYL METHYLPROPIONAL
HEXYL CINNAMAL

משרד הבריאות נתן רישיון זה בהסתמך על הצהרת בעל הרישיון (היצרן, יבואן) כי מיוצר בתנאי יצור נאותים ובחומרים/מרכיבים המותרים בתעשיית התמרוקים וכי התמרוק איכותי ובטוח לשימוש בהתאם להוראות השימוש.

תאריך : **24/02/2021** **שם:** **שני לרוש** **חתימה:** _____

ב/ מנהל האגף

מדינת ישראל משרד הבריאות מחלקה לרישום תמרוקים MINISTRY OF HEALTH COSMETIC REGISTRATION DEPARTMENT STATE OF ISRAEL

רצ"ב תוית

COSMETIC PRODUCT TOXICOLOGICAL EVALUATION

INDIAN OIL HAIR STRAIGHTENING RESTOVATIVE PRO-FOR DYED HAIR

ISSUE DATE: February 4, 2021

SAFETY ASSESSMENT REFERENCE NO.: 5965

VERSION: I

SAFETY ASSESSOR

Tanja Židan

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Tel: +353.1.4370.955 | Fax: +353.1.6335.088 | info@ceway.eu | CRO Reg. No: 508497 | VAT: IE9837938L

1. QUANTITATIVE AND QUALITATIVE COMPOSITION OF THE COSMETIC PRODUCT

INCI name	CAS	EINECS/ELINCS	Concentration in the final product	Function
AQUA	7732-18-5	231-791-2	71,580	Solvent
CETEARYL ALCOHOL	67762-27-0 / 8005-44-5	267-008-6 / -	6,000	EMOLLIENT, EMULSIFYING, EMULSION STABILISING, FOAM BOOSTING, OPACIFYING, SURFACTANT, VISCOSITY CONTROLLING
GLYOXYLIC ACID	298-12-4	206-058-5	4,800	ANTISTATIC, BUFFERING, HAIR WAVING OR STRAIGHTENING
GLYOXYLOYL KERATIN AMINO ACIDS	Not available	Not available	2,500	ANTISTATIC, HAIR WAVING OR STRAIGHTENING
GLYOXYLOYL CARBOCYSTEINE	1268868-51-4	-	2,500	ANTISTATIC, HAIR WAVING OR STRAIGHTENING
SIMMONDSIA CHINENSIS SEED OIL	90045-98-0	289-964-3	2,500	EMOLLIENT, HAIR CONDITIONING, SKIN CONDITIONING
SODIUM HYDROXIDE	1310-73-2	215-185-5	2,350	Buffering, Denaturant
BEHENTRIMONIUM CHLORIDE	17301-53-0	241-327-0	1,800	ANTISTATIC, HAIR CONDITIONING, PRESERVATIVE
ISOPROPYL MYRISTATE	110-27-0	203-751-4	1,700	BINDING, EMOLLIENT, MASKING, PERFUMING
CETEARYL ETHYLHEXANOATE	90411-68-0	291-445-1	1,500	EMOLLIENT, HAIR CONDITIONING, SKIN CONDITIONING
CETRIMONIUM CHLORIDE	112-02-7	203-928-6	0,500	ANTIMICROBIAL, ANTISTATIC, EMULSIFYING, PRESERVATIVE, SURFACTANT
CYCLOPENTASILOXANE	541-02-6	208-764-9	0,094	EMOLLIENT, HAIR CONDITIONING, SKIN CONDITIONING, SOLVENT
PHENOXYETHANOL	122-99-6	204-589-7	0,880	PRESERVATIVE
AMODIMETHICONE	71750-80-6	Not available	0,700	ANTISTATIC, HAIR CONDITIONING
DIMETHICONOL	31692-79-2 / 70131-67-8	Not available	0,006	ANTIFOAMING, EMOLLIENT, MOISTURISING
ETHYLHEXYLGLYCERIN	70445-33-9	408-080-2	0,120	SKIN CONDITIONING
DIMETHICONE CROSSPOLYMER	Not available	Not available	0,011	EMULSION STABILISING, HAIR FIXING, VISCOSITY CONTROLLING

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TRIDECETH-12	24938-91-8 / 69011-36-5	607-463-3 / 500-241-6	0,060	EMULSIFYING, SURFACTANT
PARFUM	NA	NA	0,400	DEODORANT, MASKING, PERFUMING

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2. PHYSICAL/CHEMICAL CHARACTERISTICS AND STABILITY OF THE COSMETIC PRODUCT

a. PHYSICAL/CHEMICAL CHARACTERISTICS AND STABILITY OF SUBSTANCES OR MIXTURES

Substance (INCI) / Mixture	Chemical NAME	Physical form	Molecular weight (g/mol)	Water Solubility /Solubility	Partition coefficient	Absorption spectra (UV absorbers)
AQUA	Water	Liquid	18.02 g/mol	Soluble in alcohol	Not available	Not applicable
CETEARYL ALCOHOL	Not available	Solid (waxy)	512.93	Soluble in alcohols, oils	Not available	Not applicable
GLYOXYLIC ACID	Glyoxylic acid	colourless to yellowish liquid	74,035 g/mol	Soluble	Not available	Not applicable
GLYOXYLOYL KERATIN AMINO ACIDS	Oxoacetamide Amino Acids	Yellow transparen liquid	Not available	Not available	Not available	Not available
GLYOXYLOYL CARBOCYSTEINE	Oxoacetamide Carbocysteine	Yellow transparen liquid	235.21 g/mol	Not available	LogP=-0,7	Not available
SIMMONDSIA CHINENSIS SEED OIL	Not available	Liquid	Not available	Not soluble	Not available	Not available
SODIUM HYDROXIDE	Sodium hydroxide	Solid	40.00	Miscible at all proportions but solidifies at 20°C if the concentration is higher than 52% (by weight).	Not relevant for ionisable compounds.	Not applicable
BEHENTRIMONIUM CHLORIDE	Docosyltrimethylammonium chloride	Solid	404.16	Partially soluble in water. Solubility in ethanol and isopropanol > 10 g/l.	Not available	Not applicable
ISOPROPYL MYRISTATE	Tetradecanoic acid, isopropyl ester	Liquid	270.45	< 50 µg/L at 20°C (insoluble in water); soluble in acetone, castor oil, chloroform, cottonseed oil, ethanol	log POW = 7.71	Not applicable
CETEARYL ETHYLHEXANOATE	Not applicable	Liquid	Not available	< 0.15 mg/l at 20°C	Not available	Not applicable
PHENOXYETHANOL	2-Phenoxyethanol	Liquid	138.17	26.7 g/l at 20 °C	log Pow = 1.16	Not applicable
AMODIMETHICONE	Not available	Liquid	Not available	Not available	Not available	Not applicable
CETRIMONIUM CHLORIDE	1-Hexadecanaminium, N,N,N-trimethyl-, chloride	Liquid	320.00	Soluble in water; very slightly soluble in ethanol	Not available	Not applicable
PARFUM	Not applicable	Liquid	Not applicable	Not available	Not available	Not applicable
ETHYLHEXYLGLYCERIN	1,2-Propanediol, 3-(2-ethylhexyloxy)	Liquid	204.31	Limited solubility in water (cca. 0.1%); highly soluble in organic solvents, such as alcohols, glycols, and glycol ethers.	log POW = 2.4	Not applicable
CYCLOPENTASILOXANE	Decamethylcyclopentasiloxane	Liquid	370.8	17-20 µg/L	log POW = 5.2	Not applicable
TRIDECETH-12	Not available	Liquid	Not available	Not available	Not available	Not available

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DIMETHICONE CROSSPOLYMER	**Not available**	**Solid (paste)**	**In a product mixture containing dimethicone crosspolymer (12% in cyclomethicone), the crosspolymer has a MW of 15 500 - 1 000 000.**	**Not available**	**Not available**	**Not applicable**
DIMETHICONOL	**Not available**	**Liquid**	**530 000 - 570 000 (Dow Corning®1401 Fluid)**	**Soluble in non-polar solvents (Dow Corning®1401 Fluid)**	**Not available**	**Not applicable**

b. STABILITY OF THE COSMETIC PRODUCT

The physical stability of the finished product is justified on the basis of the stability report document, which is ensuring that no changes in physical state of the finished product occur during transport, storage or handling of the product.

Based on the information available, PAO of 12M has been assigned to the product by the manufacturer.

3. MICROBIOLOGICAL QUALITY

a. MICROBIOLOGICAL QUALITY OF SUBSTANCES AND MIXTURES

Substances and mixtures susceptible to microbial growth (water based mixtures, protein - rich materials, plant or animal raw materials)	Present
Raw materials which do not support microbial growth (organic solvents)	Not present

b. MICROBIOLOGICAL QUALITY OF THE FINISHED COSMETIC PRODUCT

According to the 'Guidelines on Microbiological Quality of the finished product' (SCCS Notes of Guidance), the following limits apply:

Category 1: Products specifically intended for children under 3 years, eye area and mucous membranes.

Category 2: Other cosmetic products.

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Types of microorganism	Products specifically intended for children under three years of age, the eye area or the mucous membranes	Other products
Total Aerobic Mesophilic Microorganisms (Bacteria plus yeast and mould)	**≤ 1 x 10^2 CFU per g or ml [a]**	**≤ 1 x 10^3 CFU per g or ml [b]**
Escherichia coli	Absence in 1 g or 1 ml	Absence in 1 g or 1 ml
Pseudomonas aeruginosa	Absence in 1 g or 1 ml	Absence in 1 g or 1 ml
Staphyloccocus aureus	Absence in 1 g or 1 ml	Absence in 1 g or 1 ml
Candida albicans	Absence in 1 g or 1 ml	Absence in 1 g or 1 ml
Due to inherent variability of the plate count method, according to USP Chapter 61 or EP Chapter 2.6.12, Interpretation of results, results considered out of limit if **a > 200 CFU/g or ml,** **b > 2 000 CFU/g or ml.** NOTE When colonies of bacteria are detected on Sabouraud Dextrose agar, Sabouraud Dextrose agar containing antibiotics may be used.		

(Source: The SCCS Notes of Guidance for testing of cosmetic ingredients and their safety evaluation, SCCS/1602/18, October 2018)

4. IMPURITIES, TRACES, INFORMATION ABOUT THE PACKAGING MATERIAL

a. IMPURITIES AND TRACES

The test stability and compatibility test was performed according to the generally acceptable method.

This product is manufactured according to Good Manufacturing Practice (ISO 22716). Ingredients used throughout must be of a high quality and (where specified) they have to meet purity criteria listed in the Cosmetics legislation. Information provided on ingredient purity and representative certificates of analysis are held in the PIF and are acceptable.

b. THE RELEVANT CHARACTERISTICS OF PACKAGING MATERIAL

The product is packaged in a plastic container. These packaging components are widely used for consumer products. They are non-porous to inks and adhesives and are unlikely to react chemically with this product. They are considered to be safe since there is no evidence of a possible migration of packaging components into the product.

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5. NORMAL AND RESONABLY FORSEEABLE USE

This product is a hair relaxer intended to be used by adults on monthly basis.

Instructions for use written on the label	Wash the hair with the open shampoo before straightening Indian Oil, then dry the hair well and apply the straightener at a distance of half a centimetre from the root of the hair, wait 90 minutes and wash the hair well and before using the straightener.
Precautions for use written on the label	Do not use the product if sensitivity to one of the ingredients is known, use the cosmetic only for the purpose for which it is intended and in accordance with the instructions for use. Do not swallow. Eye contact should be avoided and in case of such contact rinse thoroughly with water. Keep away from children. Store in a cool place, below 30 degrees.

A clear explanation of the normal intended use and the reasonably foreseeable use is provided on the product label and therefore a mistaken use (not a misuse) is not recognisable.

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6. EXPOSURE TO THE COSMETIC PRODUCT

Product Type:	Straightening cream
Targeted Population:	Adults
Estimated daily amount applied (g):	100*
Skin Surface Area of Application/cm2:	1440**
Calculated daily exposure (g/day)	0,1332
Calculated relative daily exposure (mg/kg bw/day):	2,22
Exposure time:	Max 90min**
Frequency of application:	1/month
Part of the body exposed:	Hair and scalp area

**data from the manufacturer, * Hair conditioner, SCCS

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7. EXPOSURE TO THE SUBSTANCES

INCI	Retention factor	POD	SED	MoS
AQUA	0,1	Not available	1,5509	/
CETEARYL ALCOHOL	0,1	300	0,1300	2307,692308
GLYOXYLIC ACID	0,1	200	0,1040	1923,076923
GLYOXYLOYL KERATIN AMINO ACIDS	0,1	Not available	0,0542	/
GLYOXYLOYL CARBOCYSTEINE	0,1	Not available	0,0542	/
SIMMONDSIA CHINENSIS SEED OIL	0,1	Not available	0,0542	/
SODIUM HYDROXIDE	0,1	Not available	0,0509	/
BEHENTRIMONIUM CHLORIDE	0,1	10	0,0390	256,4102564
ISOPROPYL MYRISTATE	0,1	1000	0,0368	27149,32127
CETEARYL ETHYLHEXANOATE	0,1	1000	0,0325	30769,23077
PHENOXYETHANOL	0,1	80	0,0191	4195,804196
AMODIMETHICONE	0,1	Not available	0,0152	/
CETRIMONIUM CHLORIDE	0,1	10	0,0108	923,0769231
PARFUM	0,1	Not available	0,0087	/
ETHYLHEXYLGLYCERIN	0,1	50	0,0026	19230,76923
CYCLOPENTASILOXANE	0,1	1600	0,0020	789798,4369
TRIDECETH-12	0,1	500	0,0013	384615,3846
DIMETHICONE CROSSPOLYMER	0,1	Not available	0,0002	/
DIMETHICONOL	0,1	Not available	0,0001	/

Calculations of Margin of Safety (MoS) have been determined for all ingredients where this is possible from published toxicity information. The method used to do this is:

SED (whole product)*% ingredient = SED (ingredient)

MoS = POD (ingredient)/SED (ingredient).

In every case, the MoS is >100 which is considered to be acceptable. In addition, calculations are also presented to show by how much each ingredient is below the recommendations of industry (CTFA) and those required by European cosmetic legislation. All ingredients fall below any recommended maxima.

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8. TOXICOLOGICAL PROFILE OF THE SUBSTANCES

INCI name	AQUA
Restriction	None
General description	Simply water unlikely to cause irritation, allergy or harm. Used in many cosmetic products as a solvent and necessary to sustain biological life. The source of water should be known, monitored to GMP and either a deionised or high purity grade free from toxins, pollutants and bacteriological contamination should be used in cosmetic products.
Acute toxicity via relevant routes of exposure	Not toxic. The actual or estimated LD50 value: 100000 mg/kg. Oral Rat LD50: >90 mL/kg.
Skin irritation and skin corrosivity	Not irritating
Mucous membrane irritation (eye irritation)	Not irritating
Skin Sensitization	Not sensitizing
Dermal/ percutaneous absorption	Non-permeator by skin
Repeated dose toxicity (normally 28- or 90-day studies)	Not available
Mutagenicity/ genotoxicity	Not available
Carcinogenicity	Not available
Reproduction toxicity	Not available
Toxicokinetics (ADME studies)	Not available
Phototoxicity / Photosensitization	Not available
Nanomaterials	Not applicable
Reference	(1) Dweck A. C. Handbook of Cosmetics Ingredients - their use, safety and toxicology. Third edition, 2012.

INCI name	CETEARYL ALCOHOL
Restriction	None
General description	It is a mixture of mostly cetyl and stearyl alcohols. The safety of Cetearyl Alcohol has been assessed by the CIR Expert Panel. The CIR Expert Panel evaluated the scientific data and concluded that this fatty alcohol is safe for use as cosmetic ingredient in the present practicies of use and concentrations up to 25%.
Acute toxicity via relevant routes of exposure	Oral LD50 (rat): 5000 mg/kg; Oral LD50 (mouse): 3200 mg/kg; Dermal LD50 (rabbit): 2600 mg/kg

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Skin irritation and skin corrosivity	Mild irritation (3.0% in cream, rabbit)
Mucous membrane irritation (eye irritation)	Not irritating (3.0% in cream, rabbit)
Skin Sensitization	No sensitization (3.0% in cream, clinical study)
Dermal/ percutaneous absorption	Not available
Repeated dose toxicity (normally 28- or 90-day studies)	No data available for the ingredient Cetearyl Alcohol. Read accross is made from Alcohols, C10-16 (CAS 67762-41-8) on the basis of similarities in structural, physicochemical, environmental and health parameters (long chain alcohols category according to US EPA). A 28-day oral repeated-dose toxicity study in rats with CAS 67762-41-8 shows decreased body weight gain (10%) in males and liver effects (increased alanine transaminase, alkaline phosphatase and cholesterol) in females at 1000 mg/kg/day. The NOAEL for systemic toxicity is 300 mg/kg/day.
Mutagenicity/ genotoxicity	Not available
Carcinogenicity	Not available
Reproduction toxicity	Not available
Toxicokinetics (ADME studies)	Not available
Phototoxicity / Photosensitization	Not available
Nanomaterials	Not applicable
Reference	(1) US EPA. Hazard Characterization Document, SCREENING-LEVEL HAZARD CHARACTERIZATION, Long Chain Alcohols Category. December, 2009. Retrieved from http://www.epa.gov/hpvis/hazchar/Category_Long%20Chain%20Alcohols_December2009.pdf (NOAEL) (2) CIR Expert Panel. Final Report on the Safety Assessment of Cetearyl Alcohol, Cetyl Alcohol, Isostearyl Alcohol, Myristyl Alcohol, and Behenyl Alcohol. IJT 7(Suppl. 3):359-, 1988. (3) Dweck A. C. Handbook of Cosmetics Ingredients - Their Use, Safety and Toxicology. Third edition, 2012.

INCI name	GLYOXYLIC ACID
Restriction	None

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General description	Glyoxylic acid or oxoacetic acid is an organic compound that is both an aldehyde and a carboxylic acid. Glyoxylic acid is a liquid with a melting Point of -93 degree centigrade and a boiling Point of 111 degree centigrade. It is an intermediate of the glyoxylate cycle, which enables certain organisms to convert fatty acids into carbohydrates. The conjugate base of gloxylic acid is known as glyoxylate. This compound is an intermediate of the glyoxylate cycle, which enables organisms, such as bacteria, fungi and plants to convert fatty acids into carbohydrates. Glyoxylate is the byproduct of the amidation process in biosynthesis of several amidated peptides. The glyoxylate cycle is a metabolic pathway occurring in plants, and several microorganisms, such as E. coli and yeast. Recent research shows that it is present in vertebrates (including humans) and insects. The glyoxylate cycle allows these organisms to use fats for the synthesis of carbohydrates.
Acute toxicity via relevant routes of exposure	The oral LD50 value was calculated to be 2528 mg/kg bw.
Skin irritation and skin corrosivity	In a primary dermal irritation study conducted according to OECD TG 404, six male Albino New Zealand rabbits (per test), weighing about 2.5 kg (+/- 200g) at the beginning of the study were dermally exposed to 0.5 ml of Glyoxalic Acid 50% for 4 hours to a body surface area of 2.5 cm square. Animals then were observed for 3 days. Cutaneous Primary Irritation was scored according to the AFNOR protocol (NF T03 -263). Only one animal (No. 027) showed a slight erythema (barely perceptile) and no other skin irritating effect was observed by all the animals during the whole study period. Based on these results it can be concluded that Glyoxylic Acid 50% is not irritating to the rabbits skin.
Mucous membrane irritation (eye irritation)	In a primary dermal irritation study conducted according to OECD TG 404, six male Albino New Zealand rabbits (per test), weighing about 2.5 kg (+/- 200g) at the beginning of the study were dermally exposed to 0.5 ml of Glyoxalic Acid 50% for 4 hours to a body surface area of 2.5 cm square. Animals then were observed for 3 days. Cutaneous Primary Irritation was scored according to the AFNOR protocol (NF T03 -263).

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	Only one animal (No. 027) showed a slight erythema (barely perceptile) and no other skin irritating effect was observed by all the animals during the whole study period. Based on these results it can be concluded that Glyoxylic Acid 50% is not irritating to the rabbits skin. However, concentartions below 5% do not cause irritation.
Skin Sensitization	In a dermal sensitisation study with Glyoxylic acid in acetone 8 - 12 weeks old female Balb/c mice were tested using a combined Local Lymph Node Assay. The test concentrations were 1.25 , 2.5, 5.0, 10 , 20 or 40 %. The stimulation index was > 3, with a maximal value of 23.9 achieved at the maximum applied concentration of 40 %. Therefore Glyoxylic acid tested positive in the LLNA with an EC3 value of 5.05 %. Significant increases were observed in the B220+ cell population in the draining lymph nodes. No changes were identified in the IgE+B220+ cell population in the draining lymph nodes or total serum IgE levels; this suggests that Glyoxylic acid functions as a T-cell-mediated contact sensitizer.
Dermal/ percutaneous absorption	There is no percutaneous absorption study in vitro available.
Repeated dose toxicity (normally 28- or 90-day studies)	Based on the effects observed in this study a NOAEL of 6000 ppm (200 mg/kg/d) for males due to the statistically significantly reduced cumulative bodyweight gain among males at 18000 ppm and 18000 (730 mg/kg bw/d) for females can be derived.
Mutagenicity/ genotoxicity	Not available
Carcinogenicity	Glyoxylic Acid 50 % did not induce mutations in the mouse lymphoma thymidinekinase locus assay using the L5178Y cell line with or without metabolic activation.
Reproduction toxicity	Not available
Toxicokinetics (ADME studies)	Not available
Phototoxicity / Photosensitization	Not available
Nanomaterials	
Reference	(1) ECHA Information on Chemicals. REACH Registered Substance CAS 298-12-4. Joint Submission. First published 27 Feb 2013, Last modified 24 Dec 2015 (2) SCCS opinion on Glyoxal, June 2005 (3) Dweck A. C. Handbook of Cosmetics Ingredients - Their Use, Safety and Toxicology. Third edition, 2012.

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INCI name	GLYOXYLOYL KERATIN AMINO ACIDS
Restriction	None
General description	Glyoxyloyl Keratin Amino Acids is the product obtained by the reaction of oxoacetamide and Keratin Amino Acids.
Acute toxicity via relevant routes of exposure	Not available
Skin irritation and skin corrosivity	Slightly irritant (in vitro ECVAM test)
Mucous membrane irritation (eye irritation)	Not available
Skin Sensitization	Not available
Dermal/ percutaneous absorption	Not available
Repeated dose toxicity (normally 28- or 90-day studies)	Not available
Mutagenicity/ genotoxicity	No reports to indicate that oxoacetamide carbocysteine itself is carcinogenic/mutagenic.
Carcinogenicity	No reports to indicate that oxoacetamide carbocysteine itself is carcinogenic/mutagenic.
Reproduction toxicity	Not available
Toxicokinetics (ADME studies)	Not available
Phototoxicity / Photosensitization	Not available
Nanomaterials	
Reference	(1) Pro.Liss® 100 MSDS, Aqia

INCI name	GLYOXYLOYL CARBOCYSTEINE
Restriction	None
General description	Oxoacetamide carbocysteine acts as a crosslinker just like formaldehyde. The difference however is that it is a weaker crosslinker than formaldehyde and it is not a gas. The crosslinker has the ability to disrupt the disulfide bonds, the ionic interactions as well as the hydrogen bonds by interacting with the amino acids of the hair. It then acts as a bridge between the hair's protein and the added keratin. Usually the process is heat activated. The low pH (1.5-2) of oxoacetamide carbocysteine helps to disrupt the curls in hair.
Acute toxicity via relevant routes of exposure	Not available
Skin irritation and skin corrosivity	Slightly irritant (in vitro ECVAM test)
Mucous membrane irritation (eye irritation)	Not available
Skin Sensitization	Not available
Dermal/ percutaneous absorption	Not available

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Repeated dose toxicity (normally 28- or 90-day studies)	Not available
Mutagenicity/ genotoxicity	No reports to indicate that oxoacetamide carbocysteine itself is carcinogenic/mutagenic.
Carcinogenicity	No reports to indicate that oxoacetamide carbocysteine itself is carcinogenic/mutagenic.
Reproduction toxicity	Not available
Toxicokinetics (ADME studies)	Not available
Phototoxicity / Photosensitization	Not available
Nanomaterials	
Reference	(1) iCAPIL LISS 100 MSDS, βIOΛLK∑MIΛ

INCI name	SIMMONDSIA CHINENSIS SEED OIL
Restriction	None
General description	Simmondsia Chinensis Seed Oil is the fixed oil expressed or extracted from seeds of the desert shrub, Jojoba, Simmondsia chinensis, Buxaceae. This oil is an enigma, since if one looks at the chemical structure, one would expect it to be a wax. Nature's only liquid wax has some extraordinary properties, since it has the protective power of a wax but with the light emollient softness of oil. It is reported in the literature to alleviate minor skin irritations andto be effective in the treatment of dry and sore skin. The oil also has extensive use in the care of the hair. Jojoba is a good solvent for sebum and is used to control and complement this skin's natural moisturiser. The safety of Simmondsia Chinensis (Jojoba) Seed Oil, Simmondsia Chinensis (Jojoba) Seed Wax, Simmondsia Chinensis (Jojoba) Butter, Hydrogenated Jojoba Oil, Jojoba Esters, Hydrolyzed Jojoba Esters, Isomerized Jojoba Oil, Jojoba Alcohol and Synthetic Jojoba Oil has been assessed by the Cosmetic Ingredient Review (CIR) Expert Panel. The CIR Expert Panel evaluated the scientific data and based on the available information concluded that Jojoba Oil and the related ingredients were safe for use as cosmetic ingredients.
Acute toxicity via relevant routes of exposure	The actual or estimated LD50 value: 40,000 mg/kg body weight.

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Skin irritation and skin corrosivity	The skin irritation potential of refined Simmondsia Chinensis (Jojoba) Seed Oil (100%) was evaluated using 10 male albino guinea pigs (weights = 350 g; strain not stated). Olive oil and light liquid paraffin served as controls. Half of the animals were simultaneously patch tested with Simmondsia Chinensis (Jojoba) Seed Oil (0.5 ml) and each control (0.5 ml) daily for 15 days. Applications were made to shaved skin. The remaining animals were patch tested (same procedure) daily for 30 days. Reactions were scored according to the Draize scale: 0 (no erythema or edema) to 4 (severe erythema to slight eschar formation, and edema). No significant reactions to Simmondsia Chinensis (Jojoba) Seed Oil or olive oil were observed. However, flare reactions to liquid paraffin were observed on the third day of the study. The results of microscopic examinations indicated no edema or cellular infiltration.
Mucous membrane irritation (eye irritation)	The ocular irritation potential of a lip balm product containing 20.0% Simmondsia Chinensis (Jojoba) Seed Oil was evaluated using 6 New Zealand white rabbits. The test substance (0.1 ml) was instilled once into the conjunctival sac of one eye. The untreated eye served as the control. Reactions were scored at 24, 48, and 72 h post-instillation according to the Draize scale. At 24 h post-instillation, the mean ocular irritation score was 0.3 ± 0.8. No reactions were observed at 48 and 72 h. The product was classified as a nonirritant (CTFA 1985c).

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Skin Sensitization	Consumer Product Testing Company (2003) conducted a repeated insult patch test of Simmondsia Chinensis (Jojoba) Seed Oil (100%) on 102 volunteers (males and females). The test material (0.2 ml) was applied to the upper back and covered by an absorbent pad held in place with a clear adhesive dressing (semioccluded). Patches were applied 3 times/week for 3 weeks to the same location. Patches were removed by the volunteers 24 h after application and the test area was examined before each application for reaction. A challenge patch was applied 2 weeks after final induction patch to an area adjacent to the induction area. The patch was removed after 24 h and scored 24 and 72 h after application. All readings were negative throughout the test period. The authors concluded that Simmondsia Chinensis (Jojoba) Seed Oil does not have a potential for dermal irritation or allergic contact sensitization.
Dermal/ percutaneous absorption	Comparison of the weights of feed consumed and the amount of feed in the rats' stomachs showed that the emptying of the animals' stomachs was not affected by Simmondsia Chinensis (Jojoba) Seed Oil ingestion. No ill effects from the consumption of Simmondsia Chinensis (Jojoba) Seed Oil were reported by the authors.
Repeated dose toxicity (normally 28- or 90-day studies)	Not available
Mutagenicity/ genotoxicity	Not available
Carcinogenicity	Not available
Reproduction toxicity	Not available
Toxicokinetics (ADME studies)	Not available
Phototoxicity / Photosensitization	CTFA (1985f) submitted a report where a total of 102 female subjects (18-49 years old) participated in an outdoor use test.

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	Each subject used a sunscreen oil containing 0.5% Simmondsia Chinensis (Jojoba) Seed Oil for 2 h (in sunlight) on 2 consecutive days. The subjects were evaluated at 24 and 48 h post-exposure. Three subjects experienced slight, transient discomfort that was considered to be clinically insignificant.
Nanomaterials	
Reference	(1) CIR Expert Panel. Safety Assessment of Simmondsia Chinensis (Jojoba) Seed Oil, Simmondsia Chinensis (Jojoba) Seed Wax, Hydrogenated Jojoba Oil, Hydrolyzed Jojoba Esters, Isomerized Jojoba Oil, Jojoba Esters, Simmondsia Chinensis (Jojoba) Butter, Jojoba Alcohol, and Synthetic Jojoba Oil. September 2008. (2) Dweck A. C. Handbook of Cosmetics Ingredients - Their Use, Safety and Toxicology. Third edition, 2012.

INCI name	SODIUM HYDROXIDE
Restriction	Annex III/15a
General description	NaOH has been used for a long time and has wide dispersive use and therefore there is information on human exposure and effects. The major human health hazard of sodium hydroxide is local irritation and/or corrosion. In terms of Regulation (EC) No 1272/2008 (CLP) the harmonized classification of NaOH is as follows: Skin Corr. 1A, H314 - Causes severe skin burns and eye damage, with specific concentration limits being Skin Corr. 1B (H314: 2% ≤ C < 5%); Eye Irrit. 2 (H319: 0,5% ≤ C < 2%); Skin Irrit. 2 (H315: 0,5% ≤ C < 2%); Skin Corr. 1A (H314: C ≥ 5%). Sodium hydroxide is restricted for use in cosmetics products - see Annex III of Regulation (EC) No 1223/2009.
Acute toxicity via relevant routes of exposure	The existing animal and human data on acute toxicity show that NaOH has a local effect (corrosive substance) and that systemic effects are not to be expected. There is no need for

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	further acute toxicity testing, as NaOH is a corrosive substance.
Skin irritation and skin corrosivity	Corrosive substance. Causes severe skin burns. Based on human data concentrations of 0.5–4% were irritating for the skin.
Mucous membrane irritation (eye irritation)	Causes serious eye damage.
Skin Sensitization	Based on a negative human skin sensitisation study and the fact that no human cases of skin and respiratory sensitisation have been reported despite the long and widespread use of NaOH, the substance is not considered to be a skin and respiratory sensitiser.
Dermal/ percutaneous absorption	The systemic exposure in all scenarios can be considered to be negligible. It should be noted, that it is unlikely that sodium ions penetrate the skin to a considerable extent. In an extreme worst case assumption dermal absorption of these ions will be 1-10% following recommendations of the TGD. This would lead to a 1 to 2 orders of magnitude lower systemic dose then described above. This amount is negligible compared to the daily dietary intake of sodium ions.
Repeated dose toxicity (normally 28- or 90-day studies)	No valid studies available. Under normal handling and use conditions NaOH is not expected to be systemically available in the body. For this reason additional testing for repeated dose toxicity is considered unnecessary.
Mutagenicity/ genotoxicity	Both the in vitro and the in vivo genotoxicity studies indicated no evidence for a mutagenic activity. Furthermore NaOH is not expected to be systemically available in the body under normal handling and use conditions.
Carcinogenicity	Systemic carcinogenicity is not expected to occur because NaOH is not expected to be systemically available in the body under normal handling and use conditions.
Reproduction toxicity	NaOH is not expected to be systemically available in the body under normal handling and use conditions and for this reason it can be stated that the substance will not reach the foetus nor reach male and female reproductive organs.
Toxicokinetics (ADME studies)	Sodium is a normal constituent of the blood and an excess is excreted in the urine. A significant amount of sodium is taken up via the food because the normal uptake of sodium via food is 3.1-6.0 g per day. Exposure to NaOH could potentially increase the pH of the blood.

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	However, the pH of the blood is regulated between narrow ranges to maintain homeostasis. Via urinary excretion of bicarbonate and via exhalation of carbon dioxide the pH of blood is maintained at the normal physiological pH of 7.4-7.5. Therefore, NaOH is not expected to be systemically available in the body under normal handling and use conditions.
Phototoxicity / Photosensitization	No data
Nanomaterials	Not applicable
Reference	(1) European Commision (EC). Sodium Hydroxide - Summary Risk Assessment Report. 2008. (2) Dweck A. C. Handbook of Cosmetics Ingredients - their use, safety and toxicology. Third edition, 2012. (3) ECHA. Retrieved from http://echa.europa.eu/information-on-chemicals/registered-substances (4) OECD, SIDS Initial Assessment Report, Sodium Hydroxide, 2002.

INCI name	BEHENTRIMONIUM CHLORIDE
Restriction	V/44
General description	Behentrimonium chloride is a toxic compound, and concentrations of 0.1% and higher have been shown to damage the eyes by causing tissue death of the mucous membranes. It's irritating to the skin, however, used at the typical levels in rinse off products its benefits are great and the risk of adverse effects negligible. The safety of Behentrimonium Chloride has been assessed by the CIR Expert Panel. The CIR Expert Panel evaluated the scientific data and concluded that this ingredient is safe for use in cosmetics when formulated to be non-irritating.
Acute toxicity via relevant routes of exposure	Oral LD50 (rat) > 2000 mg/kg
Skin irritation and skin corrosivity	Severely irritating down to concentrations of about 25%. After 3 minutes of skin contact, an 8% dilution of behentrimonium chloride caused some skin irritation and a 3% solution was shown to be non-irritant. 5% behentrimonium chloride

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	in a cosmetic formulation produced some skin irritation (human patch test).
Mucous membrane irritation (eye irritation)	Cause irreversible ocular damage in the rabbit eye when applied at concentrations above 8%. Diluted to 5%, behentrimonium chloride caused persistent conjunctival irritation while a 3% dilution showed some irritating effects to the eye.
Skin Sensitization	Not sensitizing (guinea pig, human)
Dermal/ percutaneous absorption	Not available for the ingredient behentrimonium chloride. For laurtrimonium bromide maximum absorption through the skin = 3.15% (in vivo rat study).
Repeated dose toxicity (normally 28- or 90-day studies)	Not available for the ingredient behentrimonium chloride. For supporting substance (structural analogue) having CAS 112-02-7 a NOAEL of 10 mg/kg/day was determined in a chronic (12 months) oral study in rat.
Mutagenicity/ genotoxicity	Not genotoxic in Ames tests using multiple strains of S. typhimurium
Carcinogenicity	Not available
Reproduction toxicity	Not available
Toxicokinetics (ADME studies)	Not available
Phototoxicity / Photosensitization	Not available
Nanomaterials	Not applicable
Reference	(1) SCCS. OPINION ON ALKYL (C16, C18, C22) TRIMETHYLAMMONIUM CHLORIDE. For other uses than as a preservative. SCCS/1246/09. 2009 (2) Dweck A. C. Handbook of Cosmetics Ingredients - Their Use, Safety and Toxicology. Third edition, 2012.

INCI name	ISOPROPYL MYRISTATE
Restriction	None
General description	Ingredient in not irritating and not acute toxicant.
Acute toxicity via relevant routes of exposure	Oral LD50 (rat) > 2000 mg/kg
Skin irritation and skin corrosivity	Not irritating (undiluted, rabbit)
Mucous membrane irritation (eye irritation)	Not irritating (undiluted, rabbit)
Skin Sensitization	Not sensitizing (5% solution, guinea pigs)
Dermal/ percutaneous absorption	Isopropyl myristate, as a non-polar penetration enhancer, is largely retained in the stratum corneum.
Repeated dose toxicity (normally 28- or 90-day studies)	In a repeated dose 28-day oral toxicity study in rats a NOAEL of >1000 mg/kg/day was found. No

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	adverse effects were observed at any dose administered; 0, 100, 500 and 1000 mg/kg/day.
Mutagenicity/ genotoxicity	Not genotoxic in Ames tests using multiple strains of S. typhimurium and E. Coli
Carcinogenicity	Not available
Reproduction toxicity	Not available
Toxicokinetics (ADME studies)	Not available
Phototoxicity / Photosensitization	Not available
Nanomaterials	Not applicable
Reference	(1) ECHA Information on Chemicals. REACH Registered Substance CAS 110-27-0 . Joint Submission. First published 04 Mar 2011, Last modified 18 May 2015. Accessed July 2015 at http://echa.europa.eu/information-on-chemicals/registered-substances (NOAEL: Exp Key Repeated dose toxicity: oral.001) (2) CIR Expert Panel. Amended Safety Assessment of Alkyl Esters as Used in Cosmetics- Final Report (April 12,2013).

INCI name	CETEARYL ETHYLHEXANOATE
Restriction	None
General description	The safety of Cetearyl Ethylhexanoate has been assessed by the CIR Expert Panel. The CIR Expert Panel evaluated the scientific data and concluded that this fatty alcohol is safe for use as cosmetic ingredient in the present practicies of use and concentrations up to 25%.
Acute toxicity via relevant routes of exposure	CIR: Acute Dermal LD50 (rabbit) > 9.4 ml/kg; Formulations containing 25-30% produced no acute dermal toxicity. Acute Oral LD50 (rats) > 8.0 ml/kg. Formulations containing 2.5% produced no acute oral toxicity. No inhalation toxicity in rats exposed for 1 h to a formulation containing 1.9-2.2%. ECHA: Acute Oral LD50 (rat) > 2000 mg/kg
Skin irritation and skin corrosivity	Generally, formulations did not produce significant irritation (rabbit, human testing)
Mucous membrane irritation (eye irritation)	Not irritating (rabbit)
Skin Sensitization	Not sensitizing (guinea pig, human)
Dermal/ percutaneous absorption	Not available
Repeated dose toxicity (normally 28- or 90-day studies)	Not toxic in rabbits when applied undiluted dermal for up to 90 days. For supporting

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	substance (structural analogue), fatty acid ester (C8-10, C12-18-alkyl), NOAEL > 1000 mg/kg/day was determined in a repeated dose 28-day oral toxicity study in rats. No treatment-related effects were observed up to and including the highest dose level.
Mutagenicity/ genotoxicity	Not available
Carcinogenicity	Not available
Reproduction toxicity	2-ethylhexanoic acid, a possible metabolite, was shown to be a liver and developmental toxicant in animal studies at high dose levels, and it was postulated that the maternal liver toxicity began a cascade of effects that included MT induction, zinc accumulation in the liver due to MT binding, and a resulting zinc deficiency in the developing embryo; the CIR Expert Panel found that results of testing with DEHT and the fact that cetearyl ethylhexanoate would have to pass through the stratum corneum before entering the blood stream precluded the risk of developmental toxicity.
Toxicokinetics (ADME studies)	Although no specific toxicokinetics data were available, comparison to similar long chain fatty acid esters suggests that it would be hydrolyzed in the gastrointestinal tract to 2-ethylhexanoic acid and the corresponding alcohols; these products, in turn, would enter their respective metabolic pathways.
Phototoxicity / Photosensitization	Not phototoxic (guinea pig, human testing)
Nanomaterials	Not applicable
Reference	(1) ECHA. REACH, Registration Dossier, CAS 90411-68-0. Joint Submission (INDUSTRIAL QUIMICA LASEM, S.A.U.,...) First published 25 Jun 2013 , Last modified 13 Apr 2015. (2) CIR Expert Panel. Amended Safety Assessment of Alkyl Ethylhexanoates as Used in Cosmetics. April 12, 2013. (3) Dweck A. C. Handbook of Cosmetics Ingredients - Their Use, Safety and Toxicology. Third edition, 2012.

INCI name	CETRIMONIUM CHLORIDE
Restriction	V/44

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General description	Apart from the fact that quaternary ammonium derivative formulations have the potential to be irritative, especially when combinations of the concerned compounds are used, the SCCS is of the opinion that the use of cetrimonium chloride does not pose a risk to the health of the consumer under the following concentration limits: Rinse-off hair care products up to 2.5%, Leave-on hair care products up to 1.0%.
Acute toxicity via relevant routes of exposure	Oral LD50 (mouse): reported to be between 400 and 600 mg/kg; Dermal = 4300 mg/kg
Skin irritation and skin corrosivity	Concentrated cetrimonium chloride is corrosive to skin. Skin irritant at 25%. Human patch tests with cetrimonium chloride-formulations (from 0.4 to 3.5%): no irritation up to moderate irritation.
Mucous membrane irritation (eye irritation)	Concentrations above 8% caused irreversible ocular damage in the rabbit eye.
Skin Sensitization	Not sensitizing (3%, guinea pig and 0.25%, human)
Dermal/ percutaneous absorption	3.15% absorption value was used by the SCCS for the calculation of MoS
Repeated dose toxicity (normally 28- or 90-day studies)	According to SCCS the NOAEL value of cetrimonium bromide, 10 mg/kg/day, was considered representative for cetrimonium chloride. This NOAEL was found in a chronic (12 months) oral study with cetrimonium bromide in rats. A 28-day oral repeated dose toxicity study revealed cetrimonium chloride to cause significant forestomach and stomach changes caused by its irritative effects. 100 mg/kg bw/day was regarded as the NOEL value for Dehyquart A-CA, corresponding to 24-26 mg cetrimonium chloride/kg bw/day. A 28-day dermal repeated dose toxicity study revealed that the only tested dosage of 10 mg cetrimonium chloride/kg bw/day caused no systemic toxicity, but it did cause a number of local effects on the skin at the only tested dose of 0.5%.
Mutagenicity/ genotoxicity	Not genotoxic in bacterial tests
Carcinogenicity	Not available
Reproduction toxicity	Dermal developmental toxicity studies with cetrimonium chloride in the rabbit and the rat revealed dose-dependent irritative effects, but no

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	increased incidence of foetal malformations nor developmental variations in the treated groups compared to controls were observed. Cetrimonium chloride was found to be non-foetotoxic and non-teratogenic in both species. The NOEL for maternal systemic toxicity and embryo-foetal toxicity appeared to be 40 mg cetrimonium chloride/kg bw/day for the rabbit and 12.5 mg cetrimonium chloride/kg bw/day for the rat.
Toxicokinetics (ADME studies)	Not available
Phototoxicity / Photosensitization	Not available
Nanomaterials	Not applicable
Reference	(1) SCCS. Opinion on alkyl (C16, C18, C22) trimethylammonium chloride, non-preservative uses. SCCS/1246/09. 8 December 2009 (2) CIR Expert Panel. Safety assessment of trimoniums as used in cosmetics. IJT 31(3) 296-341, 2012.

INCI name	CYCLOPENTASILOXANE
Restriction	None
General description	In general siloxanes have a relatively low order of acute toxicity by oral, dermal and inhalatory routes. They are not shown to be irritating to skin or eyes and are also not found sensitizing by skin contact. Silicones such as Cyclopentasiloxane (D5) do not appear to have adverse effects on the human body. The safety of Cyclopentasiloxane has been assessed by the CIR Expert Panel. The CIR Expert Panel evaluated the scientific data and concluded that this ingredient is safe as used in cosmetics at concentrations up to 93%.
Acute toxicity via relevant routes of exposure	Oral LD50 (rat): 4600 and 4800 mg/kg; Dermal LD50 (rabbit): 4640 mg/kg
Skin irritation and skin corrosivity	Not irritating
Mucous membrane irritation (eye irritation)	Not irritating
Skin Sensitization	Not sensitizing
Dermal/ percutaneous absorption	Small percentage of the substance reaches systemic circulation through dermal absorption. In vitro studies using rat and human skin and in vivo studies in rats and humans have shown very low dermal absorption rates of ≤ 0.1% to 0.17%.

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Repeated dose toxicity (normally 28- or 90-day studies)	Dermal application to rats of up to 1600 mg/kg for 28 days did not produce any test material related effects. Oral studies for 14 and 28 days at dose levels up to 1600 mg/kg/day revealed liver weight increases in Sprague Dawley rats, and a LOEL is 100 mg/kg/day. Primary target organ for D5 exposure by inhalation is the lung. D5 has an enzyme induction profile similar to that of D4.
Mutagenicity/ genotoxicity	No signs of genotoxic effects in vitro or in vivo. Negative results obtained in the bacterial reverse mutation test, in vitro chromosomal aberrations in Chinese Hamster V79 cells, and in vivo unscheduled DNA synthesis and micronucleus assays.
Carcinogenicity	Potential carcinogenic effects
Reproduction toxicity	In both, one- and two-generation studies in rats there were no significant effects on any of the parameters examined upon exposure by whole-body vapour inhalation to Cyclopentasiloxane up to 160 ppm (NOAEL).
Toxicokinetics (ADME studies)	Small percentage of the substance reaches systemic circulation through dermal absorption.
Phototoxicity / Photosensitization	Not available
Nanomaterials	Not applicable
Reference	(1) SCCS. OPINION ON Cyclomethicone Octamethylcyclotetrasiloxane (Cyclotetrasiloxane, D4) and Decamethylcyclopentasiloxane (Cyclopentasiloxane, D5). SCCS/1241/10, 2010. (2) Danish Ministry of Environment. Environmental Protection Agency. Siloxanes - Consumption, Toxicity and Alternatives. Environmental Project No. 1031 2005 (3) Dweck A. C. Handbook of Cosmetics Ingredients - Their Use, Safety and Toxicology. Third edition, 2012.

INCI name	PHENOXYETHANOL
Restriction	V/29
General description	European Cosmetics Regulation Annex V (Line 29) lists phenoxyethanol as an approved preservative in the EU at concentrations up to 1%. In terms of Regulation (EC) No 1272/2008 (CLP) the following hazard classes are assigned to this ingredient (EU

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	harmonized classification): Acute Tox. 4, Eye Irrit. 2.
Acute toxicity via relevant routes of exposure	Oral LD50 (rat): 1386 - 4013 mg/kg; Dermal LD50 (rat): 14300 mg/kg
Skin irritation and skin corrosivity	Not skin irritating (humans); slightly irritating (animals)
Mucous membrane irritation (eye irritation)	Irritating (rabbit)
Skin Sensitization	Not sensitizing (human, animal)
Dermal/ percutaneous absorption	Rapidly absorbed through the rat skin.
Repeated dose toxicity (normally 28- or 90-day studies)	The critical impact of phenoxyethanol is assessed to be kidney toxicity if swallowed. A 90 days repeated test with oral exposure of rats with the doses 80, 400 and 2000 mg/kg/day showed no impacts at 80 mg/kg/day (NOAEL value). At 400 mg/kg/day kidney toxicity and changes ingrooming behavior were seen. At a dose of 2000 mg/kg/day toxicity towards red blood corpuscles was seen.
Mutagenicity/ genotoxicity	Nonmutagenic in the Ames test and in the mouse micronucleus test.
Carcinogenicity	Not expected to be carcinogenic.
Reproduction toxicity	Phenoxyethanol has shown damaging impacts on reproduction and developmental toxicity in animal tests with mice. In several reproduction studies with mice the impacts were decreasing body weight on the mice and their progeny as well as increased liver weight at high doses of between 1875 and 4000 mg/kg/day.
Toxicokinetics (ADME studies)	Tests with rats show that more than 75% and up to 99% of the phenoxyethanol after either oral or dermal exposure can be found unchanged in the urine together with small quantities of two substances to which the phenoxyethanol has metabolized. One of the metabolism products is phenoxyacetic acid.
Phototoxicity / Photosensitization	In clinical studies phenoxyethanol was nonphototoxic.
Nanomaterials	Not applicable
Reference	(1) Danish Ministry of Environment, EPA. A survey and health assessment of cosmetic products for children. Survey of Chemical Substances in Consumer Products,No. 88 2007.

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	(2) CIR Expert Panel. Final Report on the Safety Assessment of Phenoxyethanol. JACT 9(2):259-277, 1990.

INCI name	AMODIMETHICONE
Restriction	None
General description	The safety of Amodimethicone has been assessed by the CIR Expert Panel. The CIR Expert Panel evaluated the scientific data and concluded that this ingredient is safe for use in cosmetics at concentrations up to 3%.
Acute toxicity via relevant routes of exposure	The actual or estimated LD50 value: 5000 mg/kg
Skin irritation and skin corrosivity	Not available
Mucous membrane irritation (eye irritation)	Not available
Skin Sensitization	Not available
Dermal/ percutaneous absorption	Not significantly absorbed into the skin due to its large molecular weight.
Repeated dose toxicity (normally 28- or 90-day studies)	Not available
Mutagenicity/ genotoxicity	Not available
Carcinogenicity	Not available
Reproduction toxicity	Not available
Toxicokinetics (ADME studies)	Not available
Phototoxicity / Photosensitization	Not available
Nanomaterials	Not applicable
Reference	(1) Dweck A. C. Handbook of Cosmetics Ingredients - Their Use, Safety and Toxicology. Third edition, 2012. (2) CIR Expert Panel. Final report on the safety assessment of stearoxy dimethicone, dimethicone, methicone, amino bispropyl dimethicone, aminopropyl dimethicone ... IJT 22(2), 11-35, 2003.

INCI name	DIMETHICONOL
Restriction	None

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General description	The US FDA has approved its use as a skin protectant ingredient in OTC drug products. Furthermore, the the safety of dimethiconol has been assessed by the CIR Expert Panel. The CIR Expert Panel evaluated the scientific data and concluded that this ingredient is safe as used in cosmetics at concentrations up to 36%.
Acute toxicity via relevant routes of exposure	The actual or estimated LD50 value: 2000 mg/kg
Skin irritation and skin corrosivity	Not irritating (HRIPT)
Mucous membrane irritation (eye irritation)	Not available
Skin Sensitization	Not sensitizing (HRIPT)
Dermal/ percutaneous absorption	Not expected to be absorbed through the skin due to its high molecular weight.
Repeated dose toxicity (normally 28- or 90-day studies)	Not available
Mutagenicity/ genotoxicity	Not available
Carcinogenicity	Not available
Reproduction toxicity	Not available
Toxicokinetics (ADME studies)	Not expected to be absorbed through the skin and metabolized due to its high molecular weight.
Phototoxicity / Photosensitization	Not available
Nanomaterials	Not applicable
Reference	(1) CIR Expert Panel. Dimethiconol and its Derivitatives as used in Cosmetics. Final Report. December 14, 2010. (2) Dweck A. C. Handbook of Cosmetics Ingredients - Their Use, Safety and Toxicology. Third edition, 2012.

INCI name	ETHYLHEXYLGLYCERIN
Restriction	None
General description	The safety of ethylhexylglycerin has been assessed by the CIR Expert Panel. The CIR Expert Panel evaluated the scientific data and concluded that this ingredient is safe as used in cosmetics at concentrations up to 8%. Although ethylhexylglycerin is generally considered safe, it has been found to be an irritant to the skin in two studies, causing allergic contact dermatitis.
Acute toxicity via relevant routes of exposure	No mortalities or exposure-related toxicological findings were observed in rats dosed orally with undiluted ethylhexylglycerin. Oral LD50 (rat) > 2000 mg/kg

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Skin irritation and skin corrosivity	Non-irritating in HRIPT (up to 1%); mildly to non-irritating (undiluted, rabbit).
Mucous membrane irritation (eye irritation)	Undiluted ethylhexylglycerin was severely irritating, but 5% ethylhexylglycerin was mildly irritating, to the eyes of rabbits.
Skin Sensitization	Not sensitizing (up to 50%, guinea pig and local lymph node assay); not sensitizing (0.4-1%, HRIPT). Positive patch test results were reported for dermatitis patients patch tested with ethylhexylglycerin at concentrations up to 10%. However, results were negative for control group.
Dermal/ percutaneous absorption	Not available
Repeated dose toxicity (normally 28- or 90-day studies)	In rats dosed orally with ethylhexylglycerin at doses up to 1500 mg/kg for 28 days, the 100 mg/kg dose was defined as the NOAEL. Ethylhexylglycerin administered orally to rats, at doses up to 800 mg/kg/day, in a 13-week study, a NOAEL of 50 mg/kg/day (lowest dose) was derived.
Mutagenicity/ genotoxicity	Not genotoxic in Ames tests using multiple strains of S. typhimurium and in the mouse lymphoma assay in vitro. Nonclastogenic in the micronucleus assay in vivo.
Carcinogenicity	Not available
Reproduction toxicity	In a preliminary test, the results of visceral and skeletal examinations in litters of female rats given oral doses of ethylhexylglycerin up to 800 mg/kg/day were negative. The NOAEL for developmental toxicity was considered to be 800 mg/kg/day. In the 1-generation developmental toxicity study in rats, NOEL was 50 mg/kg/day.
Toxicokinetics (ADME studies)	In an acute toxicokinetic study in vivo, the mean absorption of ethylhexylglycerin through the skin of rabbits was 0.02% at approximately 2-hour postapplication, and there were no signs of skin irritation. The amount of ethoxyglycerin in the plasma was below the detection limit at the end of the 4-hour application period. Over a range of 3 concentrations (44.65%, 47.15%, and 54.94%) applied to human skin in vitro, mean penetration rates of 2.38, 8.19, and 20.38 µg/cm2/h were reported.
Phototoxicity / Photosensitization	Not phototoxic of photoallergic (guinea pig).
Nanomaterials	Not applicable
Reference	(1) CIR Expert Panel. Safety assessment of alkyl glyceryl ethers as used in cosmetics. IJT 32(Suppl. 3):5-21, 2013.

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INCI name	DIMETHICONE CROSSPOLYMER
Restriction	None
General description	Siloxanes and silicones, di-Me, crosspolymers with C3-20 alkyl groups. The safety of dimethicone crosspolymer has been assessed by the CIR Expert Panel. The CIR Expert Panel evaluated the scientific data and concluded that this ingredient is safe as used in cosmetics at concentrations up to 25%.
Acute toxicity via relevant routes of exposure	Data for dimethicone crosspolymer (12% in cyclomethicone): Dermal LD50 (rabbit) > 2000 mg/kg; Oral LD50 (rat) > 2000 mg/kg.
Skin irritation and skin corrosivity	Not irritating (at 100%, rabbit and human)
Mucous membrane irritation (eye irritation)	Mild, transient ocular irritation (at 100%, rabbit). Not irritating (12% in cyclomethicone, rabbit).
Skin Sensitization	Not sensitizing (guinea pig, human)
Dermal/ percutaneous absorption	Not available
Repeated dose toxicity (normally 28- or 90-day studies)	Not available
Mutagenicity/ genotoxicity	Not mutagenic to S. typhimurium.
Carcinogenicity	Not available
Reproduction toxicity	Not available
Toxicokinetics (ADME studies)	Not available
Phototoxicity / Photosensitization	Not available
Nanomaterials	Not applicable
Reference	(1) CIR Expert Panel. Safety Assessment of Dimethicone Crosspolymers as Used in Cosmetics. IJT 33(Suppl. 2):65-115, 2014.

INCI name	TRIDECETH-12
Restriction	None
General description	Poly(oxy-1,2-ethanediyl), .alpha.-tridecyl-.omega.-hydroxy; Isotridecanol, ethoxylated. Poly(oxy-1,2-ethanediyl), .alpha.-tridecyl-.omega.-hydroxy; Isotridecanol, ethoxylated. The Food and Drug Administration (FDA) permits the Trideceth ingredients (polyoxyethylated tridecyl alcohol) to be used as indirect food additives. They

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	may be used as defoaming agents in paper and paperboard, and in coatings of paper andpaperboard used for food packaging. The safety of related polyethylene glycol ether compounds has been assessed by the Cosmetic Ingredient Review (CIR) Expert Panel. For example, the CIR Expert Panel concluded that Laureth-4 and Laureth-12, Steareth ingredients and Ceteareth ingredients were safe for use in cosmetics and personal care products.
Acute toxicity via relevant routes of exposure	The actual or estimated LD50 value: 1,000 mg/kg body weight.
Skin irritation and skin corrosivity	Slight to moderate erythema and edema were observed as early as 1 h after removal of the patch. Erythema and edema scores increased until the 72 h reading. At the 48 h reading time point dry skin was seen in 2/3 rabbits. Eschar formation was observed in all animals beginning 6 days after exposure. Beginning scale off of eschar was observed 8 days after exposure. No scoring was performed 8, 10 and 14 days (3/3, 3/3 and 2/3 animals) after exposure. After 14 days no eschar and no erythema and edema were seen in 1/3 rabbits. Findings of the other rabbits comprised of eschar which was not completely scaled off.
Mucous membrane irritation (eye irritation)	highly irritating (R41)
Skin Sensitization	not sensitising (guinea pig)
Dermal/ percutaneous absorption	Not available
Repeated dose toxicity (normally 28- or 90-day studies)	No effects on the general health and behaviour of treated rats were evident. Significant treatment-related effects on body weight, food intake, organ weights, clinical chemistry and haematology were identified in one or both sexes at daily doses of 150 and 500 mg/kg bw/d. Due to the fact that no compound-related gross or histopathological lesions were identified at any dose level, the changes reported are considered minor and not of toxicological significance. Hence, the NOAEL for systemic toxicity was set to greater than 500 mg/kg bw/d.
Mutagenicity/ genotoxicity	Not genotoxic
Carcinogenicity	Not available
Reproduction toxicity	Not available
Toxicokinetics (ADME studies)	Not available
Phototoxicity / Photosensitization	Not available
Nanomaterials	

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Reference	(1) ECHA Information on Chemicals. REACH Registered Substance CAS 69011-36-5. Individual Submission. First publishe 25 Jun 2013, Last modified 18 Mar 2016 (2) Dweck A. C. Handbook of Cosmetics Ingredients - Their Use, Safety and Toxicology. Third edition, 2012.

INCI name	PARFUM
Restriction	Cosing makes the following cosmetic restrictions regarding allergens (Annex III): • Butylphenyl Methylpropional (III/83), Linalool (III/84), Alpha-Isomethyl Ionone (III/90), Citronellol (III/86), Limonene (III/88), Geraniol (III/78), Benzyl Benzoate (III/85), Eugenol (III/71), Farnesol (III/82), Citral (III/70): The presence of the substance must be indicated in the list of ingredients referred to in Article 19(1) g when its concentration exceeds: 0.001% in leave-on products; 0.01% in rinse-off products. • Limonene (Annex III/88): Peroxide value less than 20 mmoles/L. This limit applies to the substance and not to the finished cosmetic product. • Benzyl Alcohol (Annex III/45): For purposes other than inhibiting the development of microorganisms in the product. This purpose has to be apparent from the presentation of the product.
General description	Not available
Acute toxicity via relevant routes of exposure	Not available
Skin irritation and skin corrosivity	Not available
Mucous membrane irritation (eye irritation)	Not available
Skin Sensitization	Not available
Dermal/ percutaneous absorption	Not available
Repeated dose toxicity (normally 28- or 90-day studies)	Not available
Mutagenicity/ genotoxicity	Not available
Carcinogenicity	Not available
Reproduction toxicity	Not available
Toxicokinetics (ADME studies)	Not available
Phototoxicity / Photosensitization	Not available
Nanomaterials	Not applicable
Reference	

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Perfume compliance to IFRA regulations:

No fragrance information has been provided

9. UNDESIRABLE EFFECTS AND SERIOUS UNDESIRABLE EFFECTS

The product is available on the market, no undesirable effects have been reported till now. Rarely, reports of skin and eye irritation may be received on this type of product.

10. INFORMATION ON THE COSMETIC PRODUCT

- The product has not been tested on animals
- The products does (not) contain CMR, nanoparticles...
- Additional testing: /

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PART B - COSMETIC PRODUCT SAFETY ASSESSMENT

1. ASSESSMENT CONCLUSION

The cosmetic product INDIAN OIL HAIR STRAIGHTENING RESTOVATIVE PRO-FOR DYED HAIR can be assessed as **SAFE** based on the toxicological information available for its constructive ingredients.

2. LABELLED WARNINGS AND INSTRUCTIONS FOR USE

The following instructions for use and warnings are written on both, primary and secondary packaging:

Instructions for use written on the label	Wash the hair with the open shampoo before straightening Indian Oil, then dry the hair well and apply the straightener at a distance of half a centimetre from the root of the hair, wait 90 minutes and wash the hair well and before using the straightener.
Precautions for use written on the label	Do not use the product if sensitivity to one of the ingredients is known, use the cosmetic only for the purpose for which it is intended and in accordance with the instructions for use. Do not swallow. Eye contact should be avoided and in case of such contact rinse thoroughly with water. Keep away from children. Store in a cool place, below 30 degrees.

The labelled instructions for use and the general description of the product indicate the explicit use of the finished product as a hair relaxer intended to be used on monthly basis. A reasonably foreseeable mistaken use additional to this use (not a misuse) is not recognisable

3. REASONING

a. SAFETY EVALUATION OF SUBSTANCES AND/OR MIXTURES

The margin of safety, which takes into account all systemic toxicity endpoints, has been calculated for each of the ingredient used in this cosmetic product. All ingredients (where the NOAEL value was available) have a sufficiently large MoS (>100), which is supporting the safety of the finished product. Specific exposure consideration for the targeted consumer group (adults) has been taken into account as documented in the exposure and MoS calculation.

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b. SAFETY EVALUATION OF COSMETIC PRODUCT

Stability data

The stability data (microbiological and physical-chemical stability) of the formula after storage meet the previously specified characteristics. They confirm a sufficient stability of the formula. The shelf life for the final product is above 30 months. The final product is released with PAO 12M. Based on the above mentioned the product is rated as safe.

Packaging

The package consists of a plastic container. The packaging of the product is made to protect the product during shelf life and use and to enable the safe use of the product. No interaction with packaging material is expected as the packaging compatibility with the formulation was confirmed during its stability test. Based on that the packaging is rated to be suitable and safe for this specific product type. This package does not contain hazardous materials that require special markings or labelling on the shippers.

Normal and reasonably foreseeable use

A reasonably foreseeable mistaken use (not a misuse), is not recognizable.

Undesirable effects and serious undesirable effects

From the market launch until today the complaint statistics as documented in the Consumer Response System (CRS) of the manufacturer of this product show no remarkable consumer complaints regarding undesirable effects or serious undesirable effects in general.

Information on the cosmetic product

The product is hair relaxer intended to be used by adults on monthly basis.

The packaging of cosmetic product should include the following information in indelible, easily legible and visible lettering:

- Brand name
- Name of the product
- Function of the cosmetic product (unless it is clear from its presentation)
- Ingredients list
- Particular precautions for use:Do not use the product if sensitivity to one of the ingredients is known, use the cosmetic only for the purpose for which it is intended and in accordance with the

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instructions for use. Do not swallow. Eye contact should be avoided and in case of such contact rinse thoroughly with water. Keep away from children. Store in a cool place, below 30 degrees.

- Instructions for use: Wash the hair with the open shampoo before straightening Indian Oil, then dry the hair well and apply the straightener at a distance of half a centimetre from the root of the hair, wait 90 minutes and wash the hair well and before using the straightener.
- Date of minimum durability (for products with a minimum durability ≤ 30 months) or PAO (for products with a minimum durability > 30 months)
- Nominal quantity (except for packaging containing less than 5 grams or 5 millilitres, free samples and single-application packs)
- Batch number or the reference for identifying the cosmetic product
- Responsible person name and address
- Manufacturer name and address
- Products' country of origin

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SUMMARY

The safety assessment is based on the chemical specification and toxicological profile of the ingredients as supplied at the time of assessment and an assessment of the final cosmetic product.

All statements in this safety assessment were elaborated on the recent level of knowledge. Every change in the formulation or changes and/or additional information of relevant data respectively will require an immediate re-evaluation of this safety assessment.

Concerning the skin tolerance, the final product is expected to be well tolerated and to have a good cosmetic acceptability.

Safety assessor: Tanja židan, MPharm

Signature:

We confirm that the product is **SAFE** based on the toxicological information available for its constructive ingredients.

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