

Regulatory Data Sheet

Copyright, 2017, 3M Company.

All rights reserved. Copying and/or downloading of this information for the purpose of properly utilizing 3M products is allowed provided that: (1) the information is copied in full with no changes unless prior written agreement is obtained from 3M, and (2) neither the copy nor the original is resold or otherwise distributed with the intention of earning a profit thereon.

This Regulatory Data Sheet is provided as a courtesy in response to a customer request.

Document Group:	18-1161-1	Version Number:	1.00
Issue Date:	09/28/17	Supercedes Date:	Initial Issue

ЗМ^{тм} RELYX^{тм} UNICEM^{тм} Aplicap/Maxicap

3M

Oral Care Solutions Division 3M Center, St. Paul, MN 55144-1000, USA 1-888-3M HELPS (1-888-364-3577)

RDSs are available at www.3M.com

This product is a kit or a multipart product which consists of multiple, independently packaged components. An RDS for each of these components is included. Please do not separate the component RDSs from this cover page. The document numbers of the RDSs for components of this product are:

18-0262-8, 17-9608-5

Disclaimers: The information provided in this document related to material content represents 3M's knowledge and belief, which may be based in whole or in part on information provided by suppliers to 3M. This is intended to answer commonly asked questions about 3M products and is not intended to be a comprehensive listing of all substances that may be of interest or that may be regulated in this or other 3M products, nor is it intended to be a comprehensive summary of any and all regulations that may apply to this product. Where substances are listed, their listing does not infer or constitute a judgment as to their safety, environmental or health impacts. Information is supplied upon the condition that the persons receiving the same will make their own determination as to its suitability for their purposes prior to use. Customers are encouraged to consult with legal and regulatory experts to determine applicable regulations in light of intended use of the product.

Limitation of Remedies and Liability: In the event any Product is proven not to conform with the information in this document, then to the extent permitted by law, 3M's entire liability and Buyer's exclusive remedy, will be at 3M's option either: (i) replacement of Product with a conforming product, or (ii) refund of the purchase price paid by Buyer for each non-conforming Product, within a reasonable time after written notification of said non-conformance and return of said Product to 3M. 3M shall not under any circumstances be liable for direct, incidental, special, or consequential damages (including but not limited to loss of profits, revenue, or business) related to or arising out of this certification, including, the use, misuse or inability to use the Product. Unless stated otherwise in writing, the foregoing language cannot be waived, modified, or supplemented in any manner whatsoever.



Regulatory Data Sheet

Copyright, 2017, 3M Company.

All rights reserved. Copying and/or downloading of this information for the purpose of properly utilizing 3M products is allowed provided that: (1) the information is copied in full with no changes unless prior written agreement is obtained from 3M, and (2) neither the copy nor the original is resold or otherwise distributed with the intention of earning a profit thereon.

This Regulatory Data Sheet is provided as a courtesy in response to a customer request.

Document Group:	17-9608-5	Version Number:	2.00
Issue Date:	08/07/17	Supercedes Date:	05/22/16

$\mathbf{3M^{TM}} \, \mathbf{ESPE^{TM}} \, \mathbf{RELYX^{TM}} \, \mathbf{UNICEM^{TM}} \, \mathbf{APLICAP} / \mathbf{MAXICAP} \\ \mathbf{LIQUID}$

3M Oral Care Solutions Division 3M Center, St. Paul, MN 55144-1000, USA 1-888-3M HELPS (1-888-364-3577)

RDSs are available at www.3M.com

Regulations and Industry Standards

SDS (US OSHA)

See Safety Data Sheet (SDS) for hazard and other regulatory data.

US FALCPA

This product complies with the United States Food Allergy Labeling and Consumer Protection Act of 2004, as there is no intentionally added milk, egg, fish, crustacean shellfish, tree nuts, wheat, peanuts, soybeans, and/or proteins thereof. **EU CMR Directive**

This product does not contain an ingredient at $\geq 0.1\%$ that is classified as a Category 1 or 2 carcinogen, mutagen, or reproductive toxicant according to Annex VI (Table 3.2) of European Regulation 1272/2008 on Classification, Labelling, and Packaging of Dangerous Substances and Mixtures or that is classified by 3M or its vendors as an EU Category 1 or 2 carcinogen, mutagen, or reproductive toxicant according to the criteria of European Council Directive 67/548/EEC (the Dangerous Substances Directive).

EU Food Allergens

This product complies with Regulation (EU) 1169/2011 on the provision of food information to consumers, as there is no intentionally added component identified in Annex II of this regulation. Specifically, none of the following are intentionally added: cereals containing gluten, crustaceans, eggs, fish, peanuts, soybeans, milk, nuts, celery, mustard, sesame seeds, sulphur dioxide and sulphites at concentrations of more than 10 mg/kg or 10 mg/L expressed as sulphur dioxide, lupin, mollusks, and/or derivatives thereof.

Halal

This product has not been certified Halal.

Kosher

This product has not been certified Kosher.

California Proposition 65

To the best of the manufacturer's knowledge, this product is in compliance with Proposition 65, and reasonably anticipated

use of this product will not result in exposure to any Proposition 65 chemicals that would require a Proposition 65 warning.

Chemicals and/or Compounds of Interest

Arsenic and (As) Compounds : This chemical or chemical compound is not intentionally added. Beryllium and (Be) Compounds : This chemical or chemical compound is not intentionally added. Bismuth and (Bi) Compounds : This chemical or chemical compound is not intentionally added. **Bisphenol A (BPA)**: This chemical or chemical compound is not intentionally added. Butyl Benzyl Phthalate (BBP) : This chemical or chemical compound is not intentionally added. **Cadmium and (Cd) Compounds** : This chemical or chemical compound is not intentionally added. Chromium and (Cr) Compounds : This chemical or chemical compound is not intentionally added. Colophony (Rosin) : This chemical or chemical compound is not intentionally added. **Dibutyl Phthalate (DBP)**: This chemical or chemical compound is not intentionally added. **Dibutyl Tin Compounds** : This chemical or chemical compound is not intentionally added. Di(2-Ethylhexyl) Phthalate (DEHP) : This chemical or chemical compound is not intentionally added. **Diisodecyl Phthalate (DIDP)**: This chemical or chemical compound is not intentionally added. Diisononyl Phthalate (DINP) : This chemical or chemical compound is not intentionally added. Di-n-Octyl Phthalate (DNOP) : This chemical or chemical compound is not intentionally added. Dyes : This chemical or chemical compound is not intentionally added. Flavorings : This chemical or chemical compound is not intentionally added. Formaldehyde : This chemical or chemical compound is not intentionally added. Hexavalent Chromium and (Cr+6) Compounds : This chemical or chemical compound is not intentionally added. Lead and (Pb) Compounds : This chemical or chemical compound is not intentionally added. Melamine : This chemical or chemical compound is not intentionally added. Mercury and (Hg) Compounds : This chemical or chemical compound is not intentionally added. Natural Rubber Latex : This product is not made with natural rubber latex. Nickel and (Ni) Compounds : This chemical or chemical compound is not intentionally added. Organotin Compounds : This chemical or chemical compound is not intentionally added. Phthalates : This chemical or chemical compound is not intentionally added. Selenium and (Se) Compounds : This chemical or chemical compound is not intentionally added. Tributyl Tin Compounds : This chemical or chemical compound is not intentionally added. Triphenyl Tin Compounds : This chemical or chemical compound is not intentionally added. Zinc and (Zn) Compounds : This chemical or chemical compound is not intentionally added.

Disclaimers: The information provided in this document related to material content represents 3M's knowledge and belief, which may be based in whole or in part on information provided by suppliers to 3M. This is intended to answer commonly asked questions about 3M products and is not intended to be a comprehensive listing of all substances that may be of interest or that may be regulated in this or other 3M products, nor is it intended to be a comprehensive summary of any and all regulations that may apply to this product. Where substances are listed, their listing does not infer or constitute a judgment as to their safety, environmental or health impacts. Information is supplied upon the condition that the persons receiving the same will make their own determination as to its suitability for their purposes prior to use. Customers are encouraged to consult with legal and regulatory experts to determine applicable regulations in light of intended use of the product.

Limitation of Remedies and Liability: In the event any Product is proven not to conform with the information in this document, then to the extent permitted by law, 3M's entire liability and Buyer's exclusive remedy, will be at 3M's option either: (i) replacement of Product with a conforming product, or (ii) refund of the purchase price paid by Buyer for each non-conforming Product, within a reasonable time after written notification of said non-conformance and return of said Product to 3M. 3M shall not under any circumstances be liable for direct, incidental, special, or consequential damages (including but not limited to loss of profits, revenue, or business) related to or arising out of this certification, including, the use, misuse or inability to use the Product. Unless stated otherwise in writing, the foregoing language cannot be waived, modified, or supplemented in any manner whatsoever.



Regulatory Data Sheet

Copyright, 2017, 3M Company.

All rights reserved. Copying and/or downloading of this information for the purpose of properly utilizing 3M products is allowed provided that: (1) the information is copied in full with no changes unless prior written agreement is obtained from 3M, and (2) neither the copy nor the original is resold or otherwise distributed with the intention of earning a profit thereon.

This Regulatory Data Sheet is provided as a courtesy in response to a customer request.

Document Group:	18-0262-8	Version Number:	2.00
Issue Date:	08/07/17	Supercedes Date:	05/22/16

3MTM ESPETM RelyXTM Unicem Aplicap/Maxicap Powder

3M Oral Care Solutions Division 3M Center, St. Paul, MN 55144-1000, USA 1-888-3M HELPS (1-888-364-3577)

RDSs are available at www.3M.com

Regulations and Industry Standards

SDS (US OSHA)

See Safety Data Sheet (SDS) for hazard and other regulatory data.

US FALCPA

This product complies with the United States Food Allergy Labeling and Consumer Protection Act of 2004, as there is no intentionally added milk, egg, fish, crustacean shellfish, tree nuts, wheat, peanuts, soybeans, and/or proteins thereof. **EU CMR Directive**

This product does not contain an ingredient at $\geq 0.1\%$ that is classified as a Category 1 or 2 carcinogen, mutagen, or reproductive toxicant according to Annex VI (Table 3.2) of European Regulation 1272/2008 on Classification, Labelling, and Packaging of Dangerous Substances and Mixtures or that is classified by 3M or its vendors as an EU Category 1 or 2 carcinogen, mutagen, or reproductive toxicant according to the criteria of European Council Directive 67/548/EEC (the Dangerous Substances Directive).

EU Food Allergens

This product complies with Regulation (EU) 1169/2011 on the provision of food information to consumers, as there is no intentionally added component identified in Annex II of this regulation. Specifically, none of the following are intentionally added: cereals containing gluten, crustaceans, eggs, fish, peanuts, soybeans, milk, nuts, celery, mustard, sesame seeds, sulphur dioxide and sulphites at concentrations of more than 10 mg/kg or 10 mg/L expressed as sulphur dioxide, lupin, mollusks, and/or derivatives thereof.

Halal

This product has not been certified Halal.

Kosher

This product has not been certified Kosher.

California Proposition 65

To the best of the manufacturer's knowledge, this product is in compliance with Proposition 65, and reasonably anticipated use of this product will not result in exposure to any Proposition 65 chemicals that would require a Proposition 65 warning.

Chemicals and/or Compounds of Interest

Arsenic and (As) Compounds : This chemical or chemical compound is not intentionally added. Beryllium and (Be) Compounds : This chemical or chemical compound is not intentionally added. Bismuth and (Bi) Compounds : This chemical or chemical compound is not intentionally added. Bisphenol A (BPA) : This chemical or chemical compound is not intentionally added. Butyl Benzyl Phthalate (BBP) : This chemical or chemical compound is not intentionally added. Cadmium and (Cd) Compounds : This chemical or chemical compound is not intentionally added. Chromium and (Cr) Compounds : This chemical or chemical compound is not intentionally added. **Colophony (Rosin)**: This chemical or chemical compound is not intentionally added. Dibutyl Phthalate (DBP) : This chemical or chemical compound is not intentionally added. Dibutyl Tin Compounds : This chemical or chemical compound is not intentionally added. Di(2-Ethylhexyl) Phthalate (DEHP) : This chemical or chemical compound is not intentionally added. **Diisodecyl Phthalate (DIDP)**: This chemical or chemical compound is not intentionally added. Diisononyl Phthalate (DINP) : This chemical or chemical compound is not intentionally added. Di-n-Octyl Phthalate (DNOP) : This chemical or chemical compound is not intentionally added. Dyes : This product is known to contain this chemical or chemical compound. Flavorings : This chemical or chemical compound is not intentionally added. Formaldehyde : This chemical or chemical compound is not intentionally added. Hexavalent Chromium and (Cr+6) Compounds : This chemical or chemical compound is not intentionally added. Lead and (Pb) Compounds : This chemical or chemical compound is not intentionally added. Melamine : This chemical or chemical compound is not intentionally added. Mercury and (Hg) Compounds : This chemical or chemical compound is not intentionally added. Natural Rubber Latex : This product is not made with natural rubber latex. Nickel and (Ni) Compounds : This chemical or chemical compound is not intentionally added. **Organotin Compounds**: This chemical or chemical compound is not intentionally added. **Phthalates** : This chemical or chemical compound is not intentionally added. Selenium and (Se) Compounds : This chemical or chemical compound is not intentionally added. Tributyl Tin Compounds : This chemical or chemical compound is not intentionally added. **Triphenyl Tin Compounds**: This chemical or chemical compound is not intentionally added. Zinc and (Zn) Compounds : This chemical or chemical compound is not intentionally added.

Disclaimers: The information provided in this document related to material content represents 3M's knowledge and belief, which may be based in whole or in part on information provided by suppliers to 3M. This is intended to answer commonly asked questions about 3M products and is not intended to be a comprehensive listing of all substances that may be of interest or that may be regulated in this or other 3M products, nor is it intended to be a comprehensive summary of any and all regulations that may apply to this product. Where substances are listed, their listing does not infer or constitute a judgment as to their safety, environmental or health impacts. Information is supplied upon the condition that the persons receiving the same will make their own determination as to its suitability for their purposes prior to use. Customers are encouraged to consult with legal and regulatory experts to determine applicable regulations in light of intended use of the product.

Limitation of Remedies and Liability: In the event any Product is proven not to conform with the information in this document, then to the extent permitted by law, 3M's entire liability and Buyer's exclusive remedy, will be at 3M's option either: (i) replacement of Product with a conforming product, or (ii) refund of the purchase price paid by Buyer for each non-conforming Product, within a reasonable time after written notification of said non-conformance and return of said Product to 3M. 3M shall not under any circumstances be liable for direct, incidental, special, or consequential damages (including but not limited to loss of profits, revenue, or business) related to or arising out of this certification, including, the use, misuse or inability to use the Product. Unless stated otherwise in writing, the foregoing language cannot be waived, modified, or supplemented in any manner whatsoever.