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PURCHASING SPECIFICATION

DOCUMENT NUMBER: PUR-07-054	
Product Name: Senset Skin Cleansing Foam **Product Reference(s):** 900FM150 / 900FM200 / 900FM300 **Supplier Reference:** L003	**Supplier Name and Address:** LEC Liverpool Ltd. LEC House, Alfred Street, Wavertree, Liverpool, L15 4LH.

Specification Approval

Vernacare Limited

Product Manager:	Procurement Representative:	Quality Assurance Engineer:
Name: E Jamieson	Name: James Catterall	Name: Leanne Redcliffe
Date: 28th Jan 2022	Date: 7th February 2022	Date: 16 Feb 2022
Signature:	Signature:	Signature:

Supplier:

I acknowledge receipt of this purchase specification and, on behalf of the company specified above, hereby provide acceptance of the specification outlined.

All changes to this specification, which are deemed necessary by Vernacare Limited, shall be communicated to the supplier in a timely fashion, and mutual agreement sought.

Changes to the supplier's manufacturing methods, or procurement systems, shall be communicated by the supplier to the relevant Product Manager at Vernacare Limited with sufficient time to conduct any product/quality assurance testing or three months (whichever is greater), before implementation. Failure to comply with this request may result in Vernacare Limited being unable to purchase product from the named supplier.

Name:

Date:

Position Within Company:

Signature:

Version Control

It is the responsibility of the user to verify that are using the current released version.
HARD COPY UNCONTROLLED UNLESS STAMPED, SIGNED AND DATED BY AUTHORISED PERSONEL

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Revision	Date of Revision	Reason for Revision
01	04 December 2019	First issue
02	12 May 2020	Reduction in perfume levels – Change control 2020 - 012
03	12 January 2021	Introduction of EU Responsible person – Change control 2020-047
04	16 June 2021	Product reformulation (replacement of Miranol 2MCA) and removal of temporary product code 900FM150EU) – Change control CC-2021-031
05	26 January 2022	Addition of the UKCA mark on Primary packaging & Secondary labelling content under section 14.0.

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1.0 Product Description

Senset Emollient Skin Cleansing Foam provides a convenient cleansing system for continence care.
Ideal for use with bariatric patients or patients with urinary and / or faecal incontinence, Senset gently lifts soiling, whilst cleansing, restoring and moisturising the skin.

2.0 Finished Product Code

- 900FM150
- 900FM200
- 900FM300

3.0 Pre-Production Samples

Pre-production Samples Received	Yes **X**	No ☐	Not Applicable ☐
Pre-production Samples Approved	Yes **X**	No ☐	Not Applicable ☐

Samples reviewed and approved by NDC Scotland – March 2020

4.0 Product Classification

Medical Device ☐	1 Non sterile ☐	1 ☐ Rule _____	2a ☐ Rule___	2b ☐ Rule ____
Biocide ☐	Cosmetic **X**	Not Applicable ☐		

5.0 Components

900FM150

Component	Description	Component Code	Quantity per case	Appendix Reference
Aluminum Canister	150ml Capacity	AL0401	12	Appendix 2
Valve	Lindal Inverted Mouse Valve 100mm	V00648	12	Not Applicable
Actuator	AQ 0800	A00408	12	Not Applicable
Cap	35mm White Gloss	CP0500	12	Not Applicable
Formulation	Vernacare Foam Formulation	VER-1-***	12 x 150ml	Appendix 9

900FM200

Component	Description	Component Code	Quantity per case	Appendix Reference
Aluminum Canister	200ml Capacity	AL0401	12	Appendix 2
Valve	Lindal Inverted Mouse valve 100mm	V00648	12	Not Applicable
Actuator	AQ 0800	A00408	12	Not Applicable
Cap	35mm White Gloss	CP0500	12	Not Applicable
Formulation	Vernacare Foam Formulation	VER-1-***	12 x 200ml	Appendix 9

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900FM300

Component	Description	Component Code	Quantity per case	Appendix Reference
Aluminum canister	300ml Capacity	AL0401	12	Appendix 2
Valve	Lindal Inverted Mouse valve100mm	V00648	12	Not Applicable
Actuator	AQ 0800	A00408	12	Not Applicable
Cap	35mm White Gloss	CP0500	12	Not Applicable
Formulation	Vernacare Foam formulation	VER-1-***	12 x 300ml	Appendix 9

All components should comply with REACH guidelines, and not be manufactured using natural rubber latex unless otherwise agreed.

6.0 Packaging

900FM150

Layer	Component Code	Construction	GS1 Code	Vernacare Artwork Identifier	Appendix Reference
Primary	Ver-1-150	150ml Aluminum canister preprinted with product branding.	800239060017	PH081 REV01	Appendix 2
Secondary	CT150ML	Shrink wrapped canisters placed with cardboard carton Carton is taped and adhesive case label applied 176 x 143 x 197 mm	08002390600176	PH128 REV01	Appendix 3
Tertiary	PALLET	4 way Pallet: L1200 x W1000 x H1148mm	Not Applicable	Not Applicable	Not Applicable

900FM200

Layer	Component Code	Construction	GS1 Code	Vernacare Artwork Identifier	Appendix Reference
Primary	Ver-1-200	200ml Aluminum canister preprinted with product branding.	0800239060178	PH082 REV01	Appendix 2
Secondary	CT200ML	Shrink wrapped canisters placed with cardboard carton Carton is taped and adhesive case label applied 185 X 142 X 230 mm	08002390601784	PH129 REV01	Appendix 3
Tertiary	PALLET	4-way Pallet: L1200 x W1000 x H1313mm	Not Applicable	Not Applicable	Not Applicable

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900FM300

Layer	Component Code	Construction	GS1 Code	Vernacare Artwork Identifier	Appendix Reference
Primary	Ver-1-300	300ml Aluminum canister preprinted with product branding.	0800239060154	PH083 REV01	Appendix 2
Secondary	CT300ML	Shrink wrapped canisters placed with cardboard carton. Carton is taped and adhesive case label applied 210 X 168 X 250 mm	08002390601548	PH130 REV01	Appendix 3
Tertiary	PALLET	4-way Pallet: L1200 x W1000 x H1413mm	Not Applicable	Not Applicable	Not Applicable

All components should comply with REACH guidelines, and not be manufactured using natural rubber latex unless otherwise agreed.

7.0 Manufacturing Location(s)

LEC Liverpool Ltd
LEC House, Alfred Street, Wavertree, Liverpool, L15 4LH

8.0 Assembly Instructions

The below refers to the process for producing bulk formulation:

1. Mixing Room prepare bulk formulation from manufacturing sheet, recording all batch numbers and following method of manufacture:
    a. Charge the tank with the required quantity of water
    b. Add the Miranol C2M (RL0551), SLS 28U (RL0550), Hexylene Glycol (RL0552),Procetyl AWS (RS0024), Isopropyl myristate (RL1040), Phenyl ethyl alcohol (RL0345),Benzyl Alcohol (RL0176) and Citric Acid (RS0055) to the tank whilst mixing slowly.
    c. Next add the CDE (RL0170), SI1288 (RL0391) and White Oil (RL0595) and continue mixing.
    d. Finally add the fragrance (RP2235) and mix for a further 10 minutes.
2. A sample of bulk formulation is checked in the lab, making sure it conforms to specification. A sample is retained.
3. Once passed send the product to the filling line.
4. Empty cans are filled, then the valve is placed on top and crimped to seal the container.
5. The propellant (Shap 40) is fed through the valve on top of the concentrate.

The below refers to the process for filling each unit:

1. Quality Control confirm that the formulation conforms to specification.
2. Quality Control check all components are correct as listed on job ticket.
3. Engineers check filling line is clean and ready to receive product.
4. Engineers set product & gas weights using correct components.
5. A sample from each filling head of product & gas is taken to the lab for approval.
6. Quality Control check filling weights, barcodes & batch numbers are correct.
7. Upon approval from lab canister filling (Liquid / gas) can commence.
8. Nozzle and cap to be applied securely to the canister.

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9. Apply date / batch code to bottom of canister (See Labelling / LOT numbers for format). Ensure legible and horizontal.
10. Pack 12 into Box (See Packing Configuration and Instructions for next steps).

900FM150 / 900FM200 / 900FM300 Transition

The updated case labels containing the EU RP should only be introduced at the same time as new canister stock, detailed below:

- PH081 REV01
- PH082 REV01
- PH083 REV01

9.0 Packing Configuration and Instructions

Total units per box:	900FM150	900FM200	900FM300
Case Weight:	2.2KG	2.8KG	4.1KG
Total cases per layer:	43	43	31
Total layers per pallet:	5	5	5
Total cases per pallet:	215	215	155
Number of pallet labels per pallet:	2	2	2
Pallet footprint:	1200 X 1000 mm	1200 X 1000 mm	1200 X 1000 mm
Pallet height:	1148 mm	X 1313 mm	X 1413 mm
Pallet weight:	500 kg	630 kg	665 kg

10.0 Standards of Compliance

The final product should be manufactured in accordance with the following standards:

Standard / Document	Description
BS EN ISO 9001:2015	Quality Management Systems
Directive EU 358/2014	EU Cosmetic Directive
Directive 75/324/EEC	Aerosol Dispensers Directive (ADD)

11.0 Sterilisation Type

Ethylene Oxide	Yes ☐	No ☐	Not Applicable **X**
Gamma	Yes ☐	No ☐	Not Applicable **X**
Other:			

12.0 Place of Sterilisation

Not applicable

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13.0 Labelling / LOT Numbers

LOT numbers and expiry dates are clearly displayed on primary and secondary packaging.
LOT numbers and expiry dates should be consistent between pack and case labels.

LOT numbers:

LOT number format: Day of Year (DDD) - last two digits of Year (YY) - Time of Day (HH:MM)
E.g.: LOT number: 22018 16:42

Expiry date:

Expiry Date Format: MMYY
E.g., Expiry Date: 0920

14.0 Labelling Content

Primary (inner):		
• Senset logo, • Product description, • Made in Britain logo, • ML per canister, • Caution statement, • Directions for use, • Ingredients,	• Individual details, • Barcode, • Aluminum logo, • Solvent abuse logo, • Canister capacity, • Manufacturer name & address,	• EU RP (Responsible Person) detail, • UKCA Mark, • Product reference code, • Danger symbol, • Lot number and expiry date, • Artwork 'PH' reference.
Secondary (middle):		
• Product code, • Product description, • Canister size, • Case quantity,	• Manufacturer name & address, • EU RP (Responsible Person) detail, • Barcode,	• LOT no, • Artwork 'PH' reference, • Handle with Care.
Tertiary (outer):		
N/A		

Do not use specification artwork for colour or size. Always print original artwork where supplied.

15.0 Unacceptable Faults

If any unacceptable fault is discovered by Vernacare Limited at any point, we reserve the right to request a refund or a corrective action for the entire production batch. Unacceptable faults may include, but are not limited to:

- Incorrect components,
- Contamination,
- Damaged cases,
- Damaged components,
- Components which do not comply with the requirements of this specification,
- Missing LOT Numbers and / or Expiry Dates,
- Leaking canister,
- Solution dosage outside of specification,
- Canisters packed upside down in the case,
- Cases placed upside down on the pallet.

16.0 Bioburdens

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Microbiological limits testing and positive product release is not a regulatory requirement for aerosol products in the EU, in accordance to Cosmetics Regulation (EC) 1223/2009. As such, microbial limits testing will not be conducted by the supplier.

17.0 Shelf Life

Two (2) years from the date of manufacture.

18.0 Quality Controls

The product and bulk formulation is tested for the following:

Appearance:	Creamy white liquid
Odour:	As fragrance
pH:	6 - 6.5
S.G:	0.990 -1.000
R.I:	5 - 6%

If the product passes the tests it is pumped to the line for filling.
If it fails suitable adjustments are made to the mix which is then retested.

Once the batch is sent to the line a sample of the liquid is withdrawn and tested to ensure the same parameters as above are still correct, i.e., there is no contamination.

A sample filled aerosol and a sample of propellant are also taken to the lab and tested against standard.

In the event of rejection of a batch, the supplier should immediately notify Vernacare Limited in writing. A CAPA plan should then be implemented to prevent this from happening in the future.

19.0 Certificates of Conformity / Analysis / Sterilisation

A certificate as listed below must be provided with each delivery or to raqa.hcs@vernacare.com.

This will include (on supplier headed paper):

- Name of product
- LOT number
- Purchase order number
- Quantity of product
- Confirmation of conformity to Cosmetics Regulation (EC) 1223/2009

Certificate of Conformity	Yes **X**	No ☐	Not Applicable ☐
Certificate of Analysis	Yes ☐	No ☐	Not Applicable **X**
Certificate of Sterilisation*	Yes ☐	No ☐	Not Applicable **X**

**For certificate of sterilisation only, reference to the sterilisation validation reference number; reference to the sterilisation batch number and confirmation the BI results passed must be included.*

20.0 Transportation

- Road transport, single stacked pallets topped with a polythene topper then shrink wrapped to ensure full protection and stability of load.
- Each container should only contain a single batch / lot of product for any product code unless by prior agreement with Vernacare Limited.

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- Product should be packed in a clean sea container.
- Product should be stacked in such a way to aid easy segregation of products at the point of delivery.
- Heavier products should be placed at the bottom of the container to minimise crushing.

21,0 Additional Requirements

No additional requirements.

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Appendix 1 – Pre-production Sample Sign

Sample Photos:

Sample Photo A	Sample Photo B	Sample Photo C
N/A	**N/A**	**N/A**

Are the samples representative of full-scale manufacture?

Yes **X**	No ☐

Has a sample been retained by both Vernacare and Supplier?

Yes **X**	No ☐

Approved by: E Jamieson

Date: 26th May 2021

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Appendix 2 - Primary Artwork.

Note: the expiry date, manufacturing date and lot number will change accordingly for each manufacturing batch as detailed in the main section.

900FM150

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900FM200

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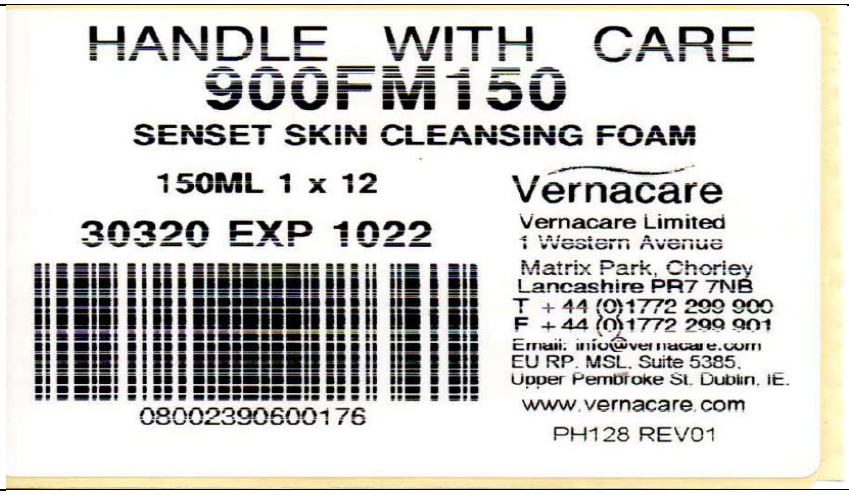
Appendix 3 - Secondary Case Label

Note: The expiry date and lot number will change accordingly for each manufacturing batch as detailed in the main section.

900FM150	
900FM200	
900FM300	

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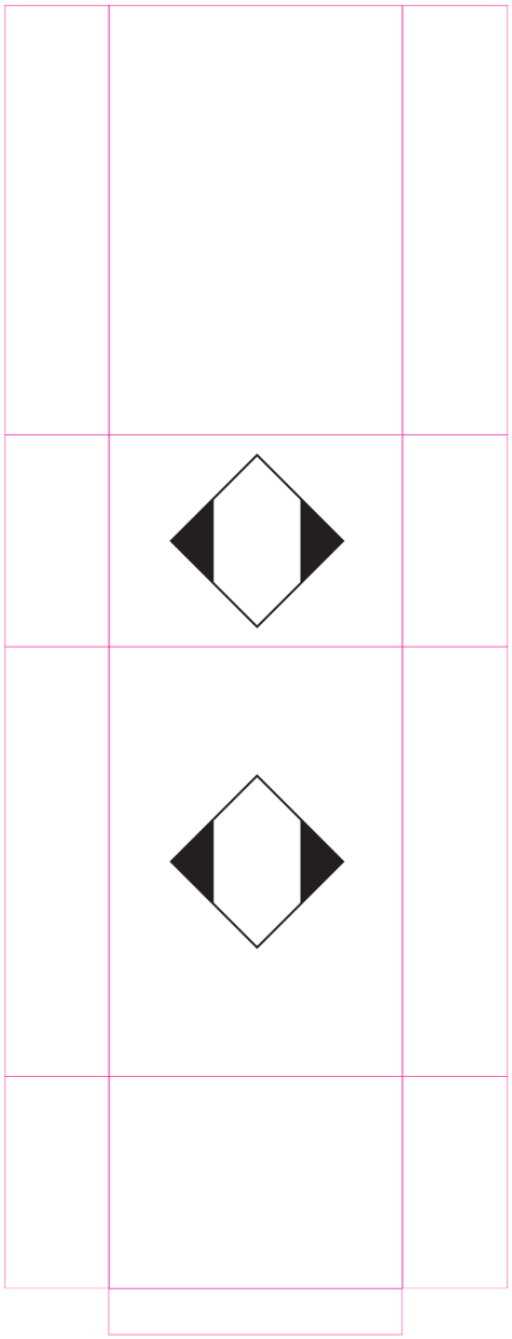
Appendix 4 - Secondary Case Print

Limited Quantities ‘diamond’ symbols (referring to dangerous goods that are shipped in small containers) will be pre-printed on 2 of 4 container sides, leaving room for adhesive labels to be placed on the remaining 2 sides:



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Appendix 5 – Tertiary Case Label

Not applicable

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Appendix 6 – Pallet label

Not applicable

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Appendix 7 - Packing Configuration into Case

The below packing configuration is applicable to all 3 products detailed within this specification:

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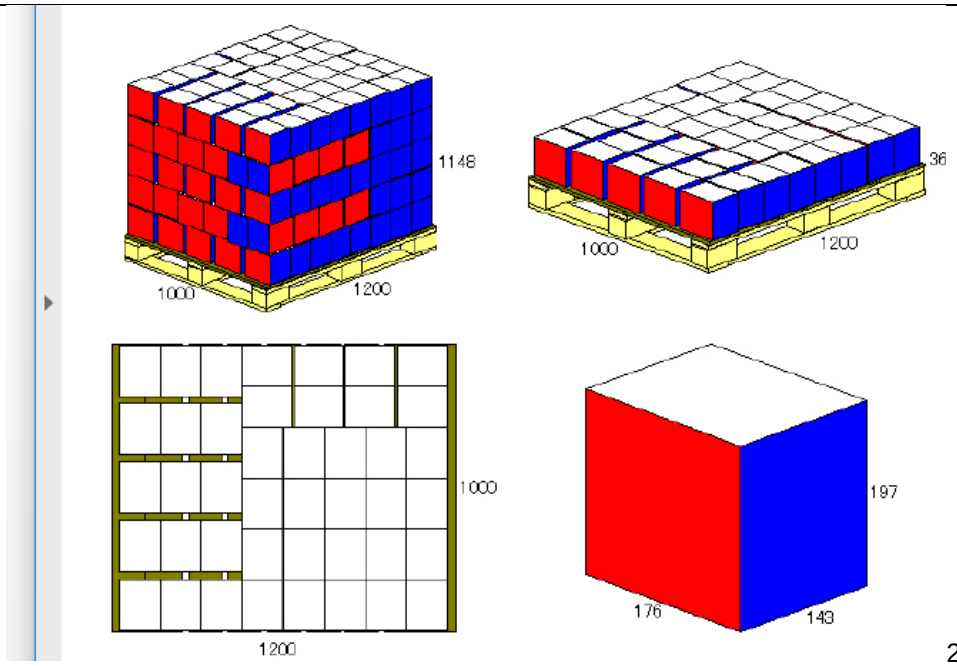
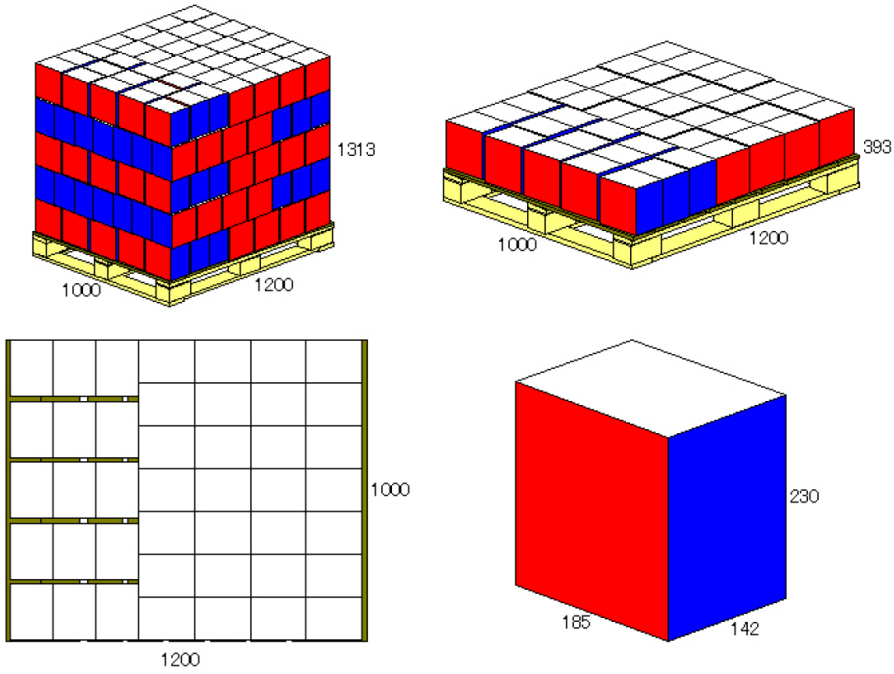
Appendix 8 - Pallet Configuration

900FM150	 215 cases per pallet
900FM200	 215 cases per pallet

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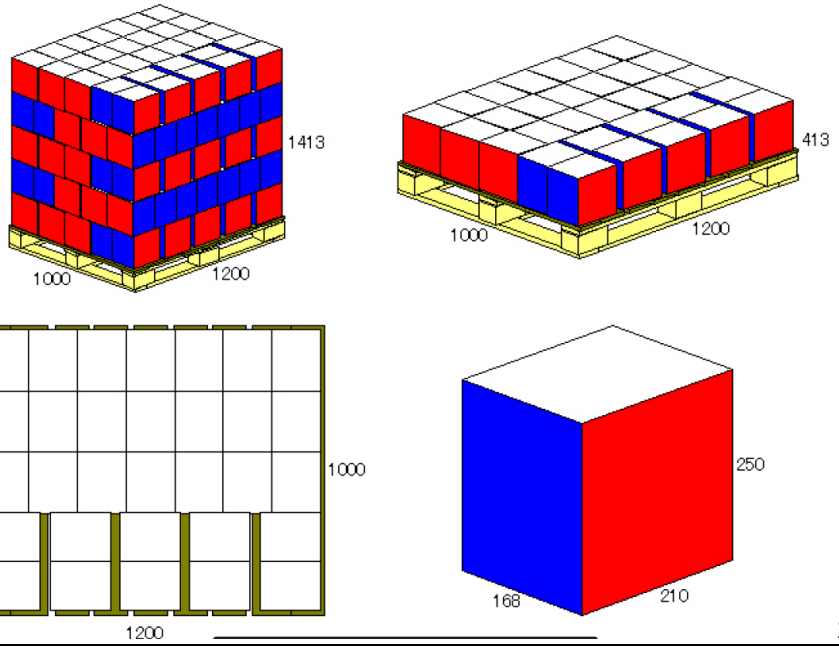
900FM300



155 cases per pallet

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Appendix 9 – Formulation

LEC Product Specification:

LEC Code	Ingredient	% in Can	Formulation
RL0551	Miranol C2M	1.711	1.820
RL0550	SLS 28U	1.711	1.820
RL0552	Hexylene Glycol	0.338	0.360
RL0170	Surfac CDE	1.410	1.500
RS0024	Procetyl AWS / Protachem AWS 100	0.470	0.500
RL0391	SI1288	0.188	0.200
RL0595	White Oil WOM 14	2.820	3.000
RL1040	IPM (Isopropyl Myristate)	0.940	1.000
RL0345	Phenyl Ethyl Alcohol	0.282	0.300
RL0176	Benzyl Alcohol	0.188	0.200
RP2235	Perfume Neptune 102797	0.010	0.011
RS0055	Citric Acid	0.056	0.060
N/A	Water	83.876	89.229
SHAP40	Shap 40	6.000	0.000
N/A	Total	100.000	100.000