

Overview:	Design and Development Outputs Form
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Project:	Coolact HK™-OUP-00
Revision:	00
Implementation Date:	03/05/2025

Outputs define what the organization will produce to meet the design input requirements. design and development must satisfy. A technical package containing the following documents must be included:

Required Documentations	Included	Not Included (Explain)
Manufacturing process and instructions	x	
Analytical methods	x	
Data, data interpretation, and calculations	x	
Raw material(s) and suppliers list	x	
Raw material(s) specifications	x	
Product specifications	x	
Shelf life	x	
Packaging and labeling specifications	x	
Safety precautions	x	
Safety warnings, labels, and reminders	x	
Safety Data Sheets	x	
Certificate of Analysis	x	

Any additional documentation other than what is stated that may be useful in the technical package must be included. All documentation must be attached with the form in written or electronic format with two copies. One copy shall be retained for R&D department and one copy shall be provided to the manufacturing department.

Revision Control

Prepared By - Name/Title Tania Salam	Date Prepared Click or tap to enter a date.
Approved by (CSO or designee) - Name/Title	Date Approved Click or tap to enter a date.
Received by (Operations Manager or designee) - Name/Title	Date Approved Click or tap to enter a date.

Revision	Description of changes	Date of Change	Prepared By
0			

Products	Coolact® HK
Research Project:	Purification of Coolact® HK
Research Time	03/05/2025-04/11/2025
Researcher	Tania Salam

A. Manufacturing Process and Instructions

1. 3595 g of raw material was transferred into a vessel and dissolved in 2 L of heptane at 35°C. Once the solid was completely dissolved, additional heptane was added. The total amount of heptane used for crystallization was four times the weight of the raw material. A cloudy mixture was obtained, containing small white solid particles.
2. The heptane solution was filtered through Whatman 1 filter paper (catalog #1001-185) to obtain a clear solution.
3. The clear solution was transferred into a 20 L vessel, and the temperature was set to -10° C for 18 hours without agitation. After 18 hours, solid crystal product was observed, surrounded by a clear liquid solution.
4. The liquid was drained out from the crystal product.
5. The crystals were melted at 50-55° C, which took approximately 2 hours.
6. Once the crystal product was fully liquefied, a vacuum was applied to remove any residual heptane. The product was dried under high vacuum (1-2 Torr) at 50-55° C for 4-5 hours.
After drying, the product was discharged and collected in plates to form a thin layer of solid. The solid was broken into small pieces and transferred into a container. A total of 2549 g of product was obtained.
7. The solid product was analyzed by GC for purity and residual heptane content. NMR was also collected to confirm the product (not included).

B. Analytical Method

GC Methods and Parameters:

Table 3: Method and Parameters

Column	Restek - Stabilwax (crossbond Carbowax Polyethylene glycol) 30m x 0.25mm x 0.25um (car. #10623)
Method Name	22 min @ 1 min hot
Cleaning Solvent:	Ethyl Acetate, EtOAc
Injection	
Inj. Vol.:	1 ul; Splitless
Inlet	
Liner:	Topaz 4.0 mm ID Cyclo Double Taper Inlet Liner (cat.# 23310)
Inlet Temp.:	300 °C
Inlet Pressure	22.4 psi
Total Flow (He)	639.8mL/min
Mode	Splitless; 635mL/min Purge flow to Split vent @0.5min
Oven	
Maximum Temp:	220 °C
Equilibration min:	3.00 min
Setpoint:	100 °C
Oven Temp.:	100 °C (hold 5 min) to 220°C at 20 °C/min (hold 10 min)
Carrier Gas	He, constant flow
Flow Rate:	1.8 mL/min
Pressure:	22.39 psi
Average Velocity:	42 cm/sec
Detector	Flame Ionization Detector @ 220 °C
Make-up Gas Flow Rate:	45 mL/min
Make-up Gas Type:	He
Hydrogen flow:	40 mL/min
Air flow:	450 mL/min
Lit Offset:	2.0
Data Rate:	10 Hz
Minimum Peak Width:	0.02 min
Instrument	Agilent 6890N GC

C. Raw Materials and Suppliers List

Feedstock	CAS #	Supplier Info.
HK-80	NA	P2Science
n-Heptane	142-82-5	Brand-Nu (catalog # PC2625H-7)

D. Analytical data and interpretation

GC Data:

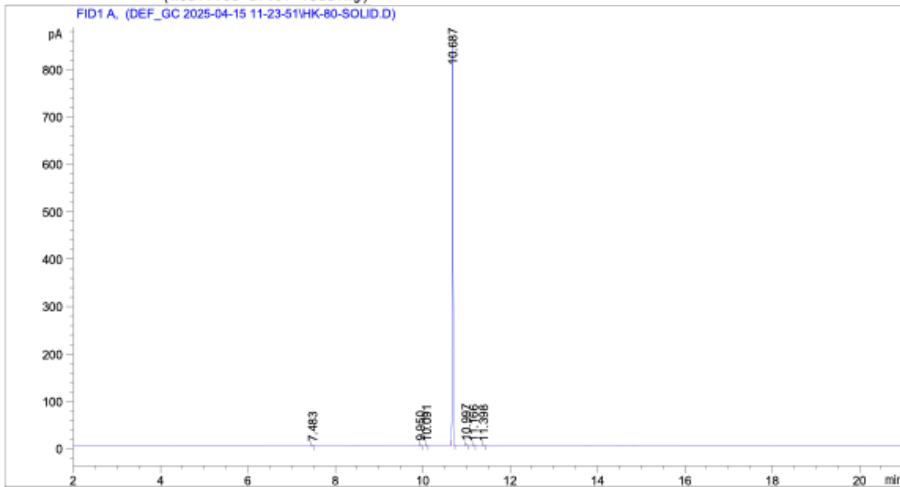
1. Raw material:

Data File C:\CHEM32\1\DATA\DEF_GC 2025-04-15 11-23-51\HK-80-SOLID.D
Sample Name: HK-80-SOLID

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=====
Acq. Operator   : BL                      Seq. Line :    2
Acq. Instrument : Instrument 1             Location  : Vial 2
Injection Date  : 4/15/2025 11:57:27 AM Inj       :    1
                                           Inj Volume: 1 µl
Acq. Method    : C:\CHEM32\1\DATA\DEF_GC 2025-04-15 11-23-51\22 MIN@ 1MIN@ HOT.M
Last changed   : 8/3/2023 3:55:27 PM by BL
Analysis Method: C:\CHEM32\1\METHODS\RESIDUAL SOLVENT.M
Last changed   : 4/14/2025 3:22:32 PM by BL
                (modified after loading)
=====

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Area Percent Report

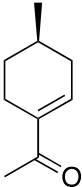
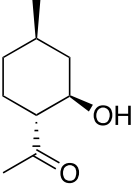
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=====
Sorted By      : Signal
Multiplier     : 1.0000
Dilution       : 1.0000
Use Multiplier & Dilution Factor with ISTDs
=====

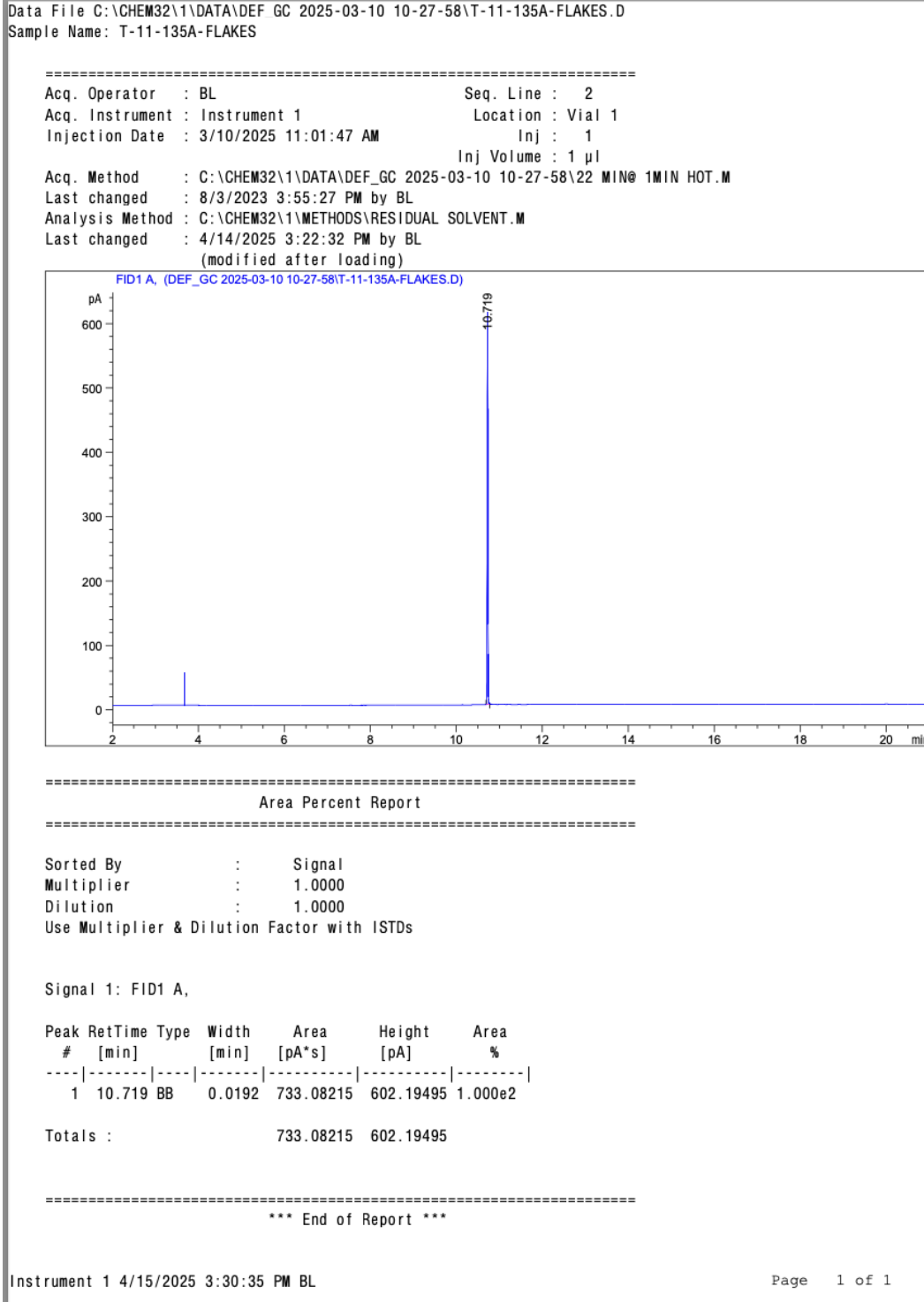
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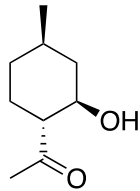
Signal 1: FID1 A,

Peak #	RetTime [min]	Type	Width [min]	Area [pA*s]	Height [pA]	Area %
1	7.483	BB	0.0229	2.04314	1.41175	0.19356
2	9.950	BB	0.0192	2.86291	2.35956	0.27122
3	10.091	BB	0.0193	2.68168	2.19118	0.25405
4	10.687	BB	0.0196	1041.80933	831.22852	98.69756
5	10.997	BB	0.0198	3.23658	2.55971	0.30662
6	11.166	BB	0.0167	1.33634	1.33360	0.12660
7	11.398	BB	0.0207	1.58731	1.18144	0.15038

Retention Time	Name/ Structure	Cas Number	GC- %AREA
7.483	Enone 	36129-14-3	0.18
10.687	OIP-enone 	20549-50-2	98.7

2. Product:



Retention Time	Name/ Structure	Cas Number	GC- %AREA
10.687	 Oxoisopulegol	20549-50-2	100

E. **Product Specification**

Product Specification Sheet: Coolact HK™

Product Names: Coolact HK™

Product Code: 30017

INCI Name: Flavor

Expected Shelf Life: 24 months

Physico-Chemical Properties	Specifications
*Appearance	White crystalline solid
*Odor	Light, Minty
*Purity (%) by GC	> 98
Minor isomer (%) by GC	≤ 0.5
Other single peaks (%) by GC	≤ 0.5
Heptane (ppm)	≤ 200
NMR	Confirms major isomer

*Appears on COA

P2 Science Inc. 4 Research Drive, Woodbridge, CT 06525 USA, Phone: +1 (203) 821-7457

Confidential

QC-LI-1008-2

F. Raw Materials Certificate of Analysis



Certificate of Analysis

Product Name: HK-80
Lot Number: 484003
Manufacture date: 04/27/2022

Physico-Chemical Properties	Recorded Value
Appearance	semi-solid to solid
Odor	Light, minty
Purity (%) by GC	98.7

Reviewed By:

Date: 04/15/2025

Tania Salam
Manager of Quality Control & Analytical Chemistry

The data herein are correct to the best of our knowledge. Note that this specification may not contain all of the constituents of the product. This analysis is not to be constructed as a warranty, expressed, or implied. Purchasers or other recipients of this product are advised to be responsible for performing its own analysis to ensure that the material is suitable for their particular use.

G. Product Certificate of Analysis



Certificate of Analysis

Product Name: Coolact® HK
Product Code: 30017
INCI Name: Flavor
Lot Number: T-11-135A-flakes
Manufacture date: 03/07/2025
Expected Shelf Life: 24 Months

Physico-Chemical Properties	Recorded Value
Appearance	White crystalline solid
Odor	Light, minty
Purity (%) by GC	100

Reviewed By:

Date: 04/15/2025

Tania Salam
Manager of Quality Control & Analytical Chemistry

The data herein are correct to the best of our knowledge. Note that this specification may not contain all of the constituents of the product. This analysis is not to be construed as a warranty, expressed, or implied. Purchasers or other recipients of this product are advised to be responsible for performing its own analysis to ensure that the material is suitable for their particular use.

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www.p2science.com 24-Hour Emergency Assistance: CHEMTREC: +1-800-424-9300

H. Shelf- Life

Product is stable up to 24 months at room temperature

I. Packaging and Labeling Specifications

Packaging: HDPE drums with heavy plastic bag to seal the product is required.

Label:

Product Name
Lot Number
Manufacture Date
Net amount
Expiration Date

J. Certification:

Halal and Kosher certification is required

K. Safety Precaution:

Proper PPE must be worn while handling chemicals. Heptane is highly flammable and should be handled in accordance with the guidelines provided in the Safety Data Sheet (SDS).

L. Safety Warnings, Labels, and Reminders

This product is not a hazardous material, therefore, does not require any packaging or labeling instructions indicating so.

M. Safety Data Sheets

